FDA Guidance of Industy Documents download for new drug discovery,CMC manufacturing, gene therapy and cell therapy

The table below lists all official FDA Guidance Documents and other regulatory guidance.

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Interstitial Cystitis/Bladder Pain Syndrome (IC/BPS): Establishing Effectiveness of Drugs for Treatment Guidance for Industry: Draft Guidance for Industry	PDF (242.07 KB)PDF (242.07 KB) of Interstitial Cystitis/Bladder Pain Syndrome (IC/BPS): Establishing Effectiveness of Drugs for Treatment Guidance for Industry: Draft Guidance for Industry	12/04/2019	Center for Drug Evaluation and Research	Clinical - Medical	Draft	Yes	02/03/2020	2019-D-4656
Adaptive Design Clinical Trials for Drugs and Biologics Guidance for Industry	PDF (306.43 KB)PDF (306.43 KB) of Adaptive Design Clinical Trials for Drugs and Biologics Guidance for Industry	11/29/2019	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Clinical - Medical	Final	Yes	01/01/2020	FDA-2018-D-3124
Clinical Immunogenicity Considerations for Biosimilar and Interchangeable Insulin Products	PDF (165.86 KB)PDF (165.86 KB) of Clinical Immunogenicity Considerations for Biosimilar and Interchangeable Insulin Products	11/27/2019	Center for Drug Evaluation and Research	Biosimilarity	Draft	Yes	01/27/2020	FDA-2019-D-5255
Compliance Policy for Limited Modifications to Certain Marketed Tobacco Products: Guidance for Industry	PDF (283.2 KB)PDF (283.2 KB) of Compliance Policy for Limited Modifications to Certain Marketed Tobacco Products: Guidance for Industry	11/26/2019	Center for Tobacco Products		Final	No		
Certificates of Confidentiality: Draft Guidance for Sponsors, Sponsor-Investigators, Researchers, Industry, and Food and Drug Administration Staff	PDF (293.02 KB)PDF (293.02 KB) of Certificates of Confidentiality: Draft Guidance for Sponsors, Sponsor-Investigators, Researchers, Industry, and Food and Drug Administration Staff	11/22/2019	Office of Policy, Center for Biologics Evaluation and Research, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Tobacco Products, Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine, Office of the Chief Scientist	Research, Good Clinical Practices (GCP)	Draft	Yes	01/08/2020	FDA-2019-D-3592
CVM GFI #256 - Compounding Animal Drugs from Bulk Drug Substances	PDF (302.89 KB)PDF (302.89 KB) of CVM GFI #256 - Compounding Animal Drugs from Bulk Drug Substances	11/20/2019	Center for Veterinary Medicine	Compounding	Draft	Yes	02/18/2020	FDA-2018-D-4533
Transdermal and Topical Delivery Systems - Product Development and Quality Considerations	PDF (355.79 KB)PDF (355.79 KB) of Transdermal and Topical Delivery Systems - Product Development and Quality Considerations	11/20/2019	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Draft	Yes	02/19/2020	FDA-2019-D-4447
Smallpox (Variola Virus) Infection: Developing Drugs for Treatment or Prevention Guidance for Industry	PDF (127.18 KB)PDF (127.18 KB) of Smallpox (Variola Virus) Infection: Developing Drugs for Treatment or Prevention Guidance for Industry	11/15/2019	Center for Drug Evaluation and Research	Clinical - Antimicrobial	Final	No		FDA-2018-D-1835
Process to Request a Review of FDA's Decision Not to Issue Certain Export Certificates for Devices: Guidance for Industry and Food and Drug Administration Staff	PDF (103.16 KB)PDF (103.16 KB) of Process to Request a Review of FDA's Decision Not to Issue Certain Export Certificates for Devices: Guidance for Industry and Food and Drug Administration Staff	11/14/2019	Center for Devices and Radiological Health	Postmarket, Export, Import	Final	No		FDA-2018-D-2310

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Assessing User Fees Under the Generic Drug User Fee Amendments of 2017	PDF (594.35 KB)PDF (594.35 KB) of Assessing User Fees Under the Generic Drug User Fee Amendments of 2017	11/01/2019	Center for Drug Evaluation and Research	User Fees,	Draft	Yes	01/01/2020	FDA-2012-D-0880
Chronic Hepatitis D Virus Infection: Developing Drugs for Treatment Guidance for Industry	PDF (323.63 KB)PDF (323.63 KB) of Chronic Hepatitis D Virus Infection: Developing Drugs for Treatment Guidance for Industry	11/01/2019	Center for Drug Evaluation and Research	Clinical - Antimicrobial	Draft	Yes	01/01/2020	FDA-2019-D-4042
Electronic Submission of IND Safety Reports Technical Conformance Guide : Guidance for Industry	PDF (138.09 KB)PDF (138.09 KB) of Electronic Submission of IND Safety Reports Technical Conformance Guide : Guidance for Industry	10/30/2019	Center for Drug Evaluation and Research		Final	Yes	12/30/2019	
Providing Regulatory Submissions in Electronic Format: IND Safety Reports: Guidance for Industry	PDF (258.08 KB)PDF (258.08 KB) of Providing Regulatory Submissions in Electronic Format: IND Safety Reports: Guidance for Industry	10/30/2019	Center for Drug Evaluation and Research		Draft	Yes	12/30/2019	FDA-2019-D-3953
Type V DMFs for CDER-Led Combination Products Using Device Constituent Parts With Electronics or Software Guidance for Industry	PDF (145.25 KB)PDF (145.25 KB) of Type V DMFs for CDER-Led Combination Products Using Device Constituent Parts With Electronics or Software Guidance for Industry	10/28/2019	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Draft	Yes	12/30/2019	FDA-2019-D-4258
Breast Implants - Certain Labeling Recommendations to Improve Patient Communication: Draft Draft Guidance for Industry and Food and Drug Administration Staff	PDF (723.81 KB)PDF (723.81 KB) of Breast Implants - Certain Labeling Recommendations to Improve Patient Communication: Draft Draft Guidance for Industry and Food and Drug Administration Staff	10/24/2019	Center for Devices and Radiological Health	Labeling, General & Plastic Surgery	Draft	Yes	12/23/2019	FDA-2019-D-4467
Drug Products Labeled as Homeopathic Guidance for FDA Staff and Industry: Draft Revised Draft	PDF (110.33 KB)PDF (110.33 KB) of Drug Products Labeled as Homeopathic Guidance for FDA Staff and Industry: Draft Revised Draft	10/24/2019	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Compliance,	Draft	Yes	01/23/2020	FDA-2017-D-6580
Postmarketing Studies and Clinical Trials—Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act Guidance for Industry	PDF (384.58 KB)PDF (384.58 KB) of Postmarketing Studies and Clinical Trials—Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act Guidance for Industry	10/24/2019	Center for Drug Evaluation and Research	Safety - Issues, Errors, and Problems	Draft	Yes	12/24/2019	2019-23312
Identification of Manufacturing Establishments in Applications Submitted to CBER and CDER Questions and Answers	PDF (108.22 KB)PDF (108.22 KB) of Identification of Manufacturing Establishments in Applications Submitted to CBER and CDER Questions and Answers	10/22/2019	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		
Drug Master Files Guidance for Industry	PDF (195.14 KB)PDF (195.14 KB) of Drug Master Files Guidance for Industry	10/18/2019	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Draft	Yes	12/20/2019	FDA-2019-D-3989
Postmarketing Studies and Clinical Trials — Implementation of Section 505(O)(3) of the Federal Food, Drug, and Cosmetic Act	PDF (276.13 KB)PDF (276.13 KB) of Postmarketing Studies and Clinical Trials — Implementation of Section 505(O)(3) of the Federal Food, Drug, and Cosmetic Act	10/17/2019	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Safety - Issues, Errors, and Problems	Draft	Yes	01/17/2020	FDA-2009-D-0283
Prescription Drug User Fee Act Waivers, Reductions, and Refunds for Drug and Biological Products Guidance for Industry	PDF (514.8 KB)PDF (514.8 KB) of Prescription Drug User Fee Act Waivers, Reductions, and Refunds for Drug and Biological Products Guidance for Industry	10/16/2019	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	User Fees,	Final	No		2019-22690
Submitting Study Datasets for Vaccines to the Office of Vaccines Research and Review: Guidance for Industry; Technical Specifications Document	PDF (241.93 KB)PDF (241.93 KB) of Submitting Study Datasets for Vaccines to the Office of Vaccines Research and Review: Guidance for Industry; Technical Specifications Document	10/15/2019	Center for Biologics Evaluation and Research	Electronic Submissions, Administrative / Procedural	Final	No		FDA-2018-D-1216

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Coronary, Peripheral, and Neurovascular Guidewires - Performance Tests and Recommended Labeling: Guidance for Industry and Food and Drug Administration Staff	PDF (527.16 KB)PDF (527.16 KB) of Coronary, Peripheral, and Neurovascular Guidewires - Performance Tests and Recommended Labeling: Guidance for Industry and Food and Drug Administration Staff	10/10/2019	Center for Devices and Radiological Health	Premarket, 510(k), Neurological, Cardiovascular	Final	No		FDA-2018-D-1775
Intravascular Catheters, Wires, and Delivery Systems with Lubricious Coatings - Labeling Considerations: Guidance for Industry and Food and Drug Administration Staff	PDF (371.46 KB)PDF (371.46 KB) of Intravascular Catheters, Wires, and Delivery Systems with Lubricious Coatings - Labeling Considerations: Guidance for Industry and Food and Drug Administration Staff	10/10/2019	Center for Devices and Radiological Health	510(k), Labeling, Premarket Approval (PMA), Neurological, Cardiovascular	Final	No		FDA-2018-D-1788
Investigational In Vitro Diagnostics in Oncology Trials: Streamlined Submission Process for Study Risk Determination Guidance for Industry	PDF (83.67 KB)PDF (83.67 KB) of Investigational In Vitro Diagnostics in Oncology Trials: Streamlined Submission Process for Study Risk Determination Guidance for Industry	10/09/2019	Center for Drug Evaluation and Research	Administrative / Procedural	Final	No		FDA-2018-D-0944
Further Testing of Donations that are Reactive on a Licensed Donor Screening Test for Antibodies to Hepatitis C Virus: Guidance for Industry	PDF (109.92 KB)PDF (109.92 KB) of Further Testing of Donations that are Reactive on a Licensed Donor Screening Test for Antibodies to Hepatitis C Virus: Guidance for Industry	10/02/2019	Center for Biologics Evaluation and Research	Blood Products	Final	No	12/24/2018	FDA-2018-D-3197
Investigational Enzyme Replacement Therapy Products: Nonclinical Assessment: Guidance for Industry	PDF (95.62 KB)PDF (95.62 KB) of Investigational Enzyme Replacement Therapy Products: Nonclinical Assessment: Guidance for Industry	10/02/2019	Center for Drug Evaluation and Research	Pharm/Tox	Final	Yes	01/02/2020	2019-21507
Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion: Guidance for Industry	PDF (573.73 KB)PDF (573.73 KB) of Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion: Guidance for Industry	09/30/2019	Center for Biologics Evaluation and Research	Blood Products	Final	No		FDA-2014-D-1814
CVM GFI #171 - Demonstrating Bioequivalence for Soluble Powder Oral Dosage Form Products or Type A Medicated Articles Manufactured from Active Pharmaceutical Ingredients Considered to be Soluble in Aqueous Media	PDF (155.64 KB)PDF (155.64 KB) of CVM GFI #171 - Demonstrating Bioequivalence for Soluble Powder Oral Dosage Form Products or Type A Medicated Articles Manufactured from Active Pharmaceutical Ingredients Considered to be Soluble in Aqueous Media	09/30/2019	Center for Veterinary Medicine	Premarket, Aquaculture, New Animal Drug Application (NADA), Generic Animal Drugs, Investigational New Animal Drug (INAD)	Draft	No	11/29/2019	FDA-2019-D-3764
CVM GFI #261 - Eligibility Criteria for Expanded Conditional Approval of New Animal Drugs	PDF (205.7 KB)PDF (205.7 KB) of CVM GFI #261 - Eligibility Criteria for Expanded Conditional Approval of New Animal Drugs	09/30/2019	Center for Veterinary Medicine	Premarket, User Fees, Antimicrobial Resistance, New Animal Drug Application (NADA), Target Animal – Effectiveness	Draft	Yes	01/28/2020	FDA-2019-D-3361
Patient-Focused Drug Development: Methods to Identify What Is Important to Patients Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders	PDF (632.95 KB)PDF (632.95 KB) of Patient-Focused Drug Development: Methods to Identify What Is Important to Patients Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders	09/30/2019	Center for Drug Evaluation and Research	Administrative / Procedural	Draft	Yes	12/30/2019	FDA-2019-D-4247
Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act: Guidance for Industry and Food and Drug Administration Staff	PDF (591.34 KB)PDF (591.34 KB) of Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act: Guidance for Industry and Food and Drug Administration Staff	09/27/2019	Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Postmarket, Premarket, Digital Health	Final	No		FDA-2017-D-6294

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Clinical Decision Support Software: Draft Guidance for Industry and Food and Drug Administration Staff	PDF (612.75 KB)PDF (612.75 KB) of Clinical Decision Support Software: Draft Guidance for Industry and Food and Drug Administration Staff	09/27/2019	Center for Devices and Radiological Health, Center for Biologics Evaluation and Research, Center for Drug Evaluation and Research	Digital Health	Draft	Yes	12/26/2019	FDA-2017-D-6569
General Wellness: Policy for Low Risk Devices: Guidance for Industry and Food and Drug Administration Staff	PDF (364.4 KB)PDF (364.4 KB) of General Wellness: Policy for Low Risk Devices: Guidance for Industry and Food and Drug Administration Staff	09/27/2019	Center for Devices and Radiological Health	Premarket, Digital Health	Final	No		FDA-2014-N-1039
Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices: Guidance for Industry and Food and Drug Administration Staff	PDF (420.95 KB)PDF (420.95 KB) of Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices: Guidance for Industry and Food and Drug Administration Staff	09/27/2019	Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Digital Health	Final	No		FDA-2014-D-0798
Off-The-Shelf Software Use in Medical Devices: Guidance for Industry and Food and Drug Administration Staff	PDF (635.68 KB)PDF (635.68 KB) of Off-The-Shelf Software Use in Medical Devices: Guidance for Industry and Food and Drug Administration Staff	09/27/2019	Center for Devices and Radiological Health	Premarket, Digital Health	Final	No		FDA-2019-D-3598
Policy for Device Software Functions and Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff	PDF (709.16 KB)PDF (709.16 KB) of Policy for Device Software Functions and Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff	09/27/2019	Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Premarket, Digital Health	Final	No		FDA-2011-D-0530
Providing Regulatory Submissions for Medical Devices in Electronic Format - Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act: Draft Guidance for Industry and Food and Drug Administration Staff	PDF (385.46 KB)PDF (385.46 KB) of Providing Regulatory Submissions for Medical Devices in Electronic Format - Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act: Draft Guidance for Industry and Food and Drug Administration Staff	09/26/2019	Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Electronic Submissions,	Draft	No	11/25/2019	FDA-2019-D-3769
CVM GFI #263 Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring Under Veterinary Oversight All Products That Continue to be Available Over-the-Counter	PDF (191.39 KB)PDF (191.39 KB) of CVM GFI #263 Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring Under Veterinary Oversight All Products That Continue to be Available Over-the-Counter	09/25/2019	Center for Veterinary Medicine	Premarket, Antimicrobial Resistance, Labeling, New Animal Drug Application (NADA)	Draft	Yes	12/24/2019	FDA-2019-D-3614
Patient Engagement in the Design and Conduct of Medical Device Clinical Investigations: Draft Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders	PDF (354.51 KB)PDF (354.51 KB) of Patient Engagement in the Design and Conduct of Medical Device Clinical Investigations: Draft Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders	09/24/2019	Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Premarket, Good Clinical Practices (GCP)	Draft	No	11/22/2019	FDA-2019-D-3846
Amyotrophic Lateral Sclerosis: Developing Drugs for Treatment Guidance for Industry: Guidance for Industry	PDF (228.24 KB)PDF (228.24 KB) of Amyotrophic Lateral Sclerosis: Developing Drugs for Treatment Guidance for Industry: Guidance for Industry	09/23/2019	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		FDA-2013-N-0035
The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program: Draft Guidance for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff	PDF (965.67 KB)PDF (965.67 KB) of The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program: Draft Guidance for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff	09/23/2019	Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Premarket,	Draft	Yes	12/23/2019	FDA-2019-D-3805

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Wholesale Distributor Verification Requirement for Saleable Returned Drug Product—Compliance Policy Guidance for Industry	PDF (68.96 KB)PDF (68.96 KB) of Wholesale Distributor Verification Requirement for Saleable Returned Drug Product—Compliance Policy Guidance for Industry	09/23/2019	Center for Drug Evaluation and Research	Administrative / Procedural	Final	No		FDA-2019-D-4212.
Conventional Foley Catheters - Performance Criteria for Safety and Performance Based Pathway: Draft Guidance for Industry and Food and Drug Administration Staff	PDF (420.57 KB)PDF (420.57 KB) of Conventional Foley Catheters - Performance Criteria for Safety and Performance Based Pathway: Draft Guidance for Industry and Food and Drug Administration Staff	09/20/2019	Center for Devices and Radiological Health	Premarket, 510(k), Gastroenterology-Urology	Draft	Yes	12/19/2019	FDA-2019-D-1651
Cutaneous Electrodes for Recording Purposes - Performance Criteria for Safety and Performance Based Pathway: Draft Guidance for Industry and Food and Drug Administration Staff	PDF (326.88 KB)PDF (326.88 KB) of Cutaneous Electrodes for Recording Purposes - Performance Criteria for Safety and Performance Based Pathway: Draft Guidance for Industry and Food and Drug Administration Staff	09/20/2019	Center for Devices and Radiological Health	Premarket, 510(k), Neurological	Draft	Yes	12/19/2019	FDA-2019-D-1649
Interacting with the FDA on Complex Innovative Trial Designs for Drugs and Biological Products: Draft Draft Guidance for Industry	PDF (292.54 KB)PDF (292.54 KB) of Interacting with the FDA on Complex Innovative Trial Designs for Drugs and Biological Products: Draft Draft Guidance for Industry	09/20/2019	Center for Biologics Evaluation and Research, Center for Drug Evaluation and Research	Clinical - Medical	Draft	No		FDA-2019-D-3679
Orthopedic Non-Spinal Metallic Bone Screws and Washers - Performance Criteria for Safety and Performance Based Pathway: Draft Guidance for Industry and Food and Drug Administration Staff	PDF (223.29 KB)PDF (223.29 KB) of Orthopedic Non-Spinal Metallic Bone Screws and Washers - Performance Criteria for Safety and Performance Based Pathway: Draft Guidance for Industry and Food and Drug Administration Staff	09/20/2019	Center for Devices and Radiological Health	Premarket, 510(k), Orthopedic	Draft	Yes	12/19/2019	FDA-2019-D-1652
Safety and Performance Based Pathway: Guidance for Industry and Food and Drug Administration	PDF (358.91 KB)PDF (358.91 KB) of Safety and Performance Based Pathway: Guidance for Industry and Food and Drug Administration	09/20/2019	Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Premarket, 510(k)	Final	No		FDA-2018-D-1387
Spinal Plating Systems - Performance Criteria for Safety and Performance Based Pathway: Draft Guidance for Industry and Food and Drug Administration Staff	PDF (497.6 KB)PDF (497.6 KB) of Spinal Plating Systems - Performance Criteria for Safety and Performance Based Pathway: Draft Guidance for Industry and Food and Drug Administration Staff	09/20/2019	Center for Devices and Radiological Health	Premarket, 510(k), Orthopedic	Draft	Yes	12/19/2019	FDA-2019-D-1647
Safer Technologies Program for Medical Devices: Draft Guidance for Industry and Food and Drug Administration Staff	PDF (592.8 KB)PDF (592.8 KB) of Safer Technologies Program for Medical Devices: Draft Guidance for Industry and Food and Drug Administration Staff	09/19/2019	Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Premarket, 510(k), Premarket Approval (PMA)	Draft	No	11/18/2019	FDA-2019-D-4048
Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act: Guidance for Industry	PDF (202.28 KB)PDF (202.28 KB) of Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act: Guidance for Industry	09/18/2019	Center for Drug Evaluation and Research	Administrative / Procedural	Final	No		FDA-2009-D-0008
Draft Guidance for Industry: Reconditioning of Fish and Fishery Products by Segregation	PDF (247.97 KB)PDF (247.97 KB) of Draft Guidance for Industry: Reconditioning of Fish and Fishery Products by Segregation	09/16/2019	Office of Food Safety	Seafood/Seafood Product	Draft	No	11/18/2019	FDA-2019-D-3324
Format for Traditional and Abbreviated 510(k)s: Guidance for Industry and FDA Staff	PDF (246.92 KB)PDF (246.92 KB) of Format for Traditional and Abbreviated 510(k)s: Guidance for Industry and FDA Staff	09/13/2019	Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Premarket, 510(k)	Final	No		FDA-2019-D-4014
Refuse to Accept Policy for 510(k)s: Guidance for Industry and Food and Drug Administration Staff	PDF (863.46 KB)PDF (863.46 KB) of Refuse to Accept Policy for 510(k)s: Guidance for Industry and Food and Drug Administration Staff	09/13/2019	Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Premarket, 510(k), Administrative / Procedural	Final	No		FDA-2012-D-0523

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
The Abbreviated 510(k) Program: Guidance for Industry and Food and Drug Administration Staff	PDF (282.19 KB)PDF (282.19 KB) of The Abbreviated 510(k) Program: Guidance for Industry and Food and Drug Administration Staff	09/13/2019	Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Premarket, 510(k)	Final	No		FDA-2019-D-4015
The Special 510(k) Program: Guidance for Industry and Food and Drug Administration Staff	PDF (672.44 KB)PDF (672.44 KB) of The Special 510(k) Program: Guidance for Industry and Food and Drug Administration Staff	09/13/2019	Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Premarket, 510(k), Administrative / Procedural	Final	No		FDA-2018-D-3304
Acceptance Review for De Novo Classification Requests: Guidance for Industry and Food and Drug Administration Staff	PDF (319.63 KB)PDF (319.63 KB) of Acceptance Review for De Novo Classification Requests: Guidance for Industry and Food and Drug Administration Staff	09/09/2019	Center for Devices and Radiological Health	Premarket,	Final	No		FDA-2017-D-6069
FDA and Industry Actions on De Novo Classification Requests: Effect on FDA Review Clock and Goals: Guidance for Industry and Food and Drug Administration Staff	PDF (334.78 KB)PDF (334.78 KB) of FDA and Industry Actions on De Novo Classification Requests: Effect on FDA Review Clock and Goals: Guidance for Industry and Food and Drug Administration Staff	09/09/2019	Center for Devices and Radiological Health	Premarket, Administrative / Procedural	Final	No		FDA-2017-D-5712
User Fees and Refunds for De Novo Classification Requests : Guidance for Industry and Food and Drug Administration Staff	PDF (367.02 KB)PDF (367.02 KB) of User Fees and Refunds for De Novo Classification Requests : Guidance for Industry and Food and Drug Administration Staff	09/09/2019	Center for Devices and Radiological Health	Premarket, User Fees, Administrative / Procedural	Final	No		FDA-2017-D-5713
Humanitarian Device Exemption (HDE) Program: Guidance for Industry and Food and Drug Administration Staff	PDF (957.02 KB)PDF (957.02 KB) of Humanitarian Device Exemption (HDE) Program: Guidance for Industry and Food and Drug Administration Staff	09/06/2019	Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Premarket, Good Clinical Practices (GCP), Premarket Approval (PMA), HUD/HDE	Final	No		FDA-2014-D-0223
Drugs for Treatment of Partial Onset Seizures: Full Extrapolation of Efficacy from Adults to Pediatric Patients 2 Years of Age and Older Guidance for Industry	PDF (61.18 KB)PDF (61.18 KB) of Drugs for Treatment of Partial Onset Seizures: Full Extrapolation of Efficacy from Adults to Pediatric Patients 2 Years of Age and Older Guidance for Industry	09/05/2019	Center for Drug Evaluation and Research	Clinical - Medical, Clinical - Pharmacology	Final	No		FDA-2018-D-0178
Humanitarian Use Device (HUD) Designations : Guidance for Industry and Food and Drug Administration Staff	PDF (349.8 KB)PDF (349.8 KB) of Humanitarian Use Device (HUD) Designations : Guidance for Industry and Food and Drug Administration Staff	09/05/2019	Office of Orphan Products Development, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Premarket, Good Clinical Practices (GCP)	Final	No		
Evaluation of Internal Standard Responses During Chromatographic Bioanalysis: Questions and Answers	PDF (117.32 KB)PDF (117.32 KB) of Evaluation of Internal Standard Responses During Chromatographic Bioanalysis: Questions and Answers	09/04/2019	Center for Drug Evaluation and Research	Biopharmaceutics	Final	No		FDA-2009-D-0008
Consideration of Uncertainty in Making Benefit-Risk Determinations in Medical Device Premarket Approvals, De Novo Classifications, and Humanitarian Device Exemptions: Guidance for Industry and Food and Drug Administration Staff	PDF (510.27 KB)PDF (510.27 KB) of Consideration of Uncertainty in Making Benefit-Risk Determinations in Medical Device Premarket Approvals, De Novo Classifications, and Humanitarian Device Exemptions: Guidance for Industry and Food and Drug Administration Staff	08/30/2019	Center for Devices and Radiological Health	Postmarket, Premarket Approval (PMA), HUD/HDE	Final	No		FDA-2018-D-3130
Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications: Guidance for Industry and Food and Drug Administration Staff	PDF (642.92 KB)PDF (642.92 KB) of Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications: Guidance for Industry and Food and Drug Administration Staff	08/30/2019	Center for Devices and Radiological Health	Premarket, Premarket Approval (PMA)	Final	No		FDA-2011-D-0577

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Guidance for Industry: Policy Related to Cranberry Products with Added Flavorings	PDF (291.77 KB)PDF (291.77 KB) of Guidance for Industry: Policy Related to Cranberry Products with Added Flavorings	08/30/2019	Office of Nutrition and Food Labeling	Labeling, Nutrition Label	Final	No		FDA-2018-D-0075
Placebos and Blinding in Randomized Controlled Cancer Clinical Trials for Drug and Biological Products Guidance for Industry	PDF (69.75 KB)PDF (69.75 KB) of Placebos and Blinding in Randomized Controlled Cancer Clinical Trials for Drug and Biological Products Guidance for Industry	08/28/2019	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Clinical - Medical	Final	No		FDA-2018-D-3092
Male Breast Cancer: Developing Drugs for Treatment: Draft Guidance for Industry	PDF (88.86 KB)PDF (88.86 KB) of Male Breast Cancer: Developing Drugs for Treatment: Draft Guidance for Industry	08/27/2019	Oncology Center of Excellence, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Clinical - Medical	Draft	No	10/28/2019	FDA-2019-D-2966
CVM GFI #257 (VICH GL57) Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Species: Marker Residue Depletion Studies to Establish Product Withdrawal Periods in Aquatic Species	PDF (152.79 KB)PDF (152.79 KB) of CVM GFI #257 (VICH GL57) Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Species: Marker Residue Depletion Studies to Establish Product Withdrawal Periods in Aquatic Species	08/19/2019	Center for Veterinary Medicine	Human Food Safety, VICH, Minor Use/ Minor Species (MUMS)	Final	No	09/24/2018	FDA-2018-D-2354
Guidance for Industry: Converting Units of Measure for Folate, Niacin, and Vitamins A, D, and E on the Nutrition and Supplement Facts Labels	PDF (247.1 KB)PDF (247.1 KB) of Guidance for Industry: Converting Units of Measure for Folate, Niacin, and Vitamins A, D, and E on the Nutrition and Supplement Facts Labels	08/15/2019	Office of Nutrition and Food Labeling	Labeling, Nutrition Label	Final	No		FDA-2016-D-4484
Osteoporosis: Nonclinical Evaluation of Drugs Intended for Treatment Guidance for Industry: Guidance for Industry	PDF (94.69 KB)PDF (94.69 KB) of Osteoporosis: Nonclinical Evaluation of Drugs Intended for Treatment Guidance for Industry: Guidance for Industry	08/14/2019	Center for Drug Evaluation and Research	Pharm/Tox	Final	No		FDA-2016-D-1273
Child-Resistant Packaging Statements in Drug Product Labeling Guidance for Industry	PDF (97.52 KB)PDF (97.52 KB) of Child-Resistant Packaging Statements in Drug Product Labeling Guidance for Industry	08/13/2019	Center for Drug Evaluation and Research	Labeling	Final	No		FDA-2017-D-2163
Gastroparesis: Clinical Evaluation of Drugs for Treatment Guidance for Industry	PDF (99.88 KB)PDF (99.88 KB) of Gastroparesis: Clinical Evaluation of Drugs for Treatment Guidance for Industry	08/13/2019	Center for Drug Evaluation and Research	Clinical - Medical	Draft	No	10/14/2019	FDA-2015-D-2479
Fabry Disease: Developing Drugs for Treatment Guidance for Industry	PDF (285.28 KB)PDF (285.28 KB) of Fabry Disease: Developing Drugs for Treatment Guidance for Industry	08/07/2019	Center for Drug Evaluation and Research	Clinical - Medical	Draft	No	11/06/2019	FDA-2019-D-2973
Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment: Draft Guidance for Industry and Food and Drug Administration Staff	PDF (446.2 KB)PDF (446.2 KB) of Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment: Draft Guidance for Industry and Food and Drug Administration Staff	08/02/2019	Center for Devices and Radiological Health	Labeling, Premarket Approval (PMA), X-Ray Products, Radiology	Draft	No	10/31/2019	FDA-2019-D-2837
Oncology Therapeutic Radiopharmaceuticals: Nonclinical Studies and Labeling Recommendations Guidance for Industry	PDF (167.51 KB)PDF (167.51 KB) of Oncology Therapeutic Radiopharmaceuticals: Nonclinical Studies and Labeling Recommendations Guidance for Industry	08/01/2019	Center for Drug Evaluation and Research	Pharm/Tox	Final	No		FDA-2018-D-1772
Bacterial Vaginosis: Developing Drugs for Treatment Guidance for Industry	PDF (269.89 KB)PDF (269.89 KB) of Bacterial Vaginosis: Developing Drugs for Treatment Guidance for Industry	07/31/2019	Center for Drug Evaluation and Research	Clinical - Antimicrobial	Final	No		FDA-2016-D-1659

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
E8(R1) GENERAL CONSIDERATIONS FOR CLINICAL STUDIES	PDF (288.4 KB)PDF (288.4 KB) of E8(R1) GENERAL CONSIDERATIONS FOR CLINICAL STUDIES	07/31/2019	Center for Drug Evaluation and Research	ICH-Efficacy	Draft	No	09/30/2019	FDA-2019-D-3049
General Clinical Pharmacology Considerations for Neonatal Studies for Drugs and Biological Products Guidance for Industry	PDF (220.47 KB)PDF (220.47 KB) of General Clinical Pharmacology Considerations for Neonatal Studies for Drugs and Biological Products Guidance for Industry	07/31/2019	Center for Drug Evaluation and Research	Clinical - Pharmacology	Draft	No	10/30/2019	2019-16375
Pathology Peer Review in Nonclinical Toxicology Studies: Questions and Answers	PDF (57.38 KB)PDF (57.38 KB) of Pathology Peer Review in Nonclinical Toxicology Studies: Questions and Answers	07/31/2019	Center for Drug Evaluation and Research	Pharm/Tox	Draft	No	09/30/2019	2019-16361
Uncomplicated Urinary Tract Infections: Developing Drugs for Treatment Guidance for Industry	PDF (301.3 KB)PDF (301.3 KB) of Uncomplicated Urinary Tract Infections: Developing Drugs for Treatment Guidance for Industry	07/31/2019	Center for Drug Evaluation and Research	Clinical - Antimicrobial	Final	No		FDA-2018-D-1562
Vulvovaginal Candidiasis: Developing Drugs for Treatment	PDF (91.37 KB)PDF (91.37 KB) of Vulvovaginal Candidiasis: Developing Drugs for Treatment	07/31/2019	Center for Drug Evaluation and Research	Clinical - Antimicrobial	Final	No		FDA-2016-D-1662
Rare Pediatric Disease Priority Review Vouchers: Draft Guidance for Industry	PDF (306.41 KB)PDF (306.41 KB) of Rare Pediatric Disease Priority Review Vouchers: Draft Guidance for Industry	07/30/2019	Office of Orphan Products Development, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Administrative / Procedural	Draft	No	09/28/2019	FDA-2014-D-1461
Delayed Graft Function in Kidney Transplantation: Developing Drugs for Prevention Guidance for Industry	PDF (277.36 KB)PDF (277.36 KB) of Delayed Graft Function in Kidney Transplantation: Developing Drugs for Prevention Guidance for Industry	07/26/2019	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		FDA-2017-D-0198
Metal Expandable Biliary Stents - Premarket Notification (510(k)) Submissions: Guidance for Industry and Food and Drug Administration Staff	PDF (369.7 KB)PDF (369.7 KB) of Metal Expandable Biliary Stents - Premarket Notification (510(k)) Submissions: Guidance for Industry and Food and Drug Administration Staff	07/26/2019	Center for Devices and Radiological Health	Premarket, 510(k), Gastroenterology-Urology	Final	No		FDA-2018-D-1771
CVM GFI #181 Blue Bird Medicated Feed Labels	PDF (146.78 KB)PDF (146.78 KB) of CVM GFI #181 Blue Bird Medicated Feed Labels	07/23/2019	Center for Veterinary Medicine	Labeling, Animal Feed	Final	No		FDA-2008-D-0165
Providing Regulatory Submissions in Electronic Format--Submission of Manufacturing Establishment Information Guidance for Industry		07/23/2019	Center for Drug Evaluation and Research		Draft	No		
Postmarketing Safety Reporting for Combination Products: Guidance for Industry and FDA Staff	PDF (379.36 KB)PDF (379.36 KB) of Postmarketing Safety Reporting for Combination Products: Guidance for Industry and FDA Staff	07/22/2019	Office of Combination Products, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Combination Products	Final	No	06/19/2018	FDA-2008-N-0424
Submitting Next Generation Sequencing Data to the Division of Antiviral Products Guidance for Industry Technical Specifications Document	PDF (250.51 KB)PDF (250.51 KB) of Submitting Next Generation Sequencing Data to the Division of Antiviral Products Guidance for Industry Technical Specifications Document	07/18/2019	Center for Drug Evaluation and Research	Clinical - Antimicrobial	Final	No		FDA-2017-D-6821
Advanced Prostate Cancer: Developing Gonadotropin-Releasing Hormone Analogues Guidance for Industry: Draft Clinical/Medical	PDF (128.73 KB)PDF (128.73 KB) of Advanced Prostate Cancer: Developing Gonadotropin-Releasing Hormone Analogues Guidance for Industry: Draft Clinical/Medical	07/17/2019	Center for Drug Evaluation and Research	Clinical - Medical	Draft	No	09/17/2019	FDA-2019-D-2808

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications Guidance for Industry	PDF (171.87 KB)PDF (171.87 KB) of Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications Guidance for Industry	07/16/2019	Center for Drug Evaluation and Research		Draft	No	09/16/2019	2019-15103
Establishing Effectiveness and Safety for Hormonal Drug Products Intended to Prevent Pregnancy Guidance for Industry	PDF (133.02 KB)PDF (133.02 KB) of Establishing Effectiveness and Safety for Hormonal Drug Products Intended to Prevent Pregnancy Guidance for Industry	07/11/2019	Center for Drug Evaluation and Research	Clinical - Medical	Draft	No	09/11/2019	FDA-2019-D-2153
Live Case Presentations During Investigational Device Exemption (IDE) Clinical Trials: Guidance for Institutional Review Boards, Industry, Clinical Investigators, and Food and Drug Administration Staff	PDF (345.35 KB)PDF (345.35 KB) of Live Case Presentations During Investigational Device Exemption (IDE) Clinical Trials: Guidance for Institutional Review Boards, Industry, Clinical Investigators, and Food and Drug Administration Staff	07/11/2019	Center for Devices and Radiological Health	Premarket, Good Clinical Practices (GCP), Device Exception (IDE)	Final	No		FDA-2014-D-0331
Population Pharmacokinetics	PDF (344.38 KB)PDF (344.38 KB) of Population Pharmacokinetics	07/11/2019	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Clinical - Pharmacology	Draft	No	09/11/2019	FDA-2019-D-2398
Harmonizing Compendial Standards With Drug Application Approval Using the USP Pending Monograph Process Guidance for Industry	PDF (176.07 KB)PDF (176.07 KB) of Harmonizing Compendial Standards With Drug Application Approval Using the USP Pending Monograph Process Guidance for Industry	07/10/2019	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Draft	No	09/10/2019	FDA-2019-D-1768
Using the Inactive Ingredient Database Guidance for Industry	PDF (121.68 KB)PDF (121.68 KB) of Using the Inactive Ingredient Database Guidance for Industry	07/10/2019	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Draft	No	10/09/2019	FDA-2019-D-2397
Risk Evaluation and Mitigation Strategies: Modifications and Revisions Guidance for Industry	PDF (354.55 KB)PDF (354.55 KB) of Risk Evaluation and Mitigation Strategies: Modifications and Revisions Guidance for Industry	07/09/2019	Center for Drug Evaluation and Research	Device & Drug Safety	Final	No		FDA-2014-D-1747
Compliance Policy for Certain Compounding of Oral Oxitriptan (5-HTP) Drug Products for Patients With Tetrahydrobiopterin (BH4) Deficiency Immediately in Effect Guidance for Industry	PDF (77.61 KB)PDF (77.61 KB) of Compliance Policy for Certain Compounding of Oral Oxitriptan (5-HTP) Drug Products for Patients With Tetrahydrobiopterin (BH4) Deficiency Immediately in Effect Guidance for Industry	07/05/2019	Center for Drug Evaluation and Research	Compounding	Final	No		FDA-2019-D-2733
Center for Devices and Radiological Health (CDRH) Appeals Processes: Guidance for Industry and Food and Drug Administration Staff	PDF (605.64 KB)PDF (605.64 KB) of Center for Devices and Radiological Health (CDRH) Appeals Processes: Guidance for Industry and Food and Drug Administration Staff	07/02/2019	Center for Devices and Radiological Health	510(k), Premarket Approval (PMA)	Final	No		FDA-2011-D-0893
Center for Devices and Radiological Health (CDRH) Appeals Processes: Questions and Answers About 517A: Guidance for Industry and Food and Drug Administration Staff	PDF (86.02 KB)PDF (86.02 KB) of Center for Devices and Radiological Health (CDRH) Appeals Processes: Questions and Answers About 517A: Guidance for Industry and Food and Drug Administration Staff	07/02/2019	Center for Devices and Radiological Health	510(k), Premarket Approval (PMA)	Final	No		FDA-2013-D-0501
Drug Abuse and Dependence Section of Labeling for Human Prescription Drug and Biological Products — Content and Format Guidance for Industry	PDF (130.14 KB)PDF (130.14 KB) of Drug Abuse and Dependence Section of Labeling for Human Prescription Drug and Biological Products — Content and Format Guidance for Industry	07/01/2019	Center for Drug Evaluation and Research	Labeling	Draft	No	09/02/2019	FDA-2019-D-1917

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Instructions for Use — Patient Labeling for Human Prescription Drug and Biological Products and Drug-Device and Biologic-Device Combination Products — Content and Format Guidance for Industry	PDF (154.06 KB)PDF (154.06 KB) of Instructions for Use — Patient Labeling for Human Prescription Drug and Biological Products and Drug-Device and Biologic-Device Combination Products — Content and Format Guidance for Industry	07/01/2019	Center for Drug Evaluation and Research	Labeling	Draft	No	09/02/2019	FDA-2019-D-1615
Epidermolysis Bullosa: Developing Drugs for Treatment of Cutaneous Manifestations; Guidance for Industry	PDF (259.75 KB)PDF (259.75 KB) of Epidermolysis Bullosa: Developing Drugs for Treatment of Cutaneous Manifestations; Guidance for Industry	06/28/2019	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Clinical - Medical	Final	No		FDA-2018-D-2016
Marketing Clearance of Diagnostic Ultrasound Systems and Transducers : Guidance for Industry and Food and Drug Administration Staff	PDF (418.97 KB)PDF (418.97 KB) of Marketing Clearance of Diagnostic Ultrasound Systems and Transducers : Guidance for Industry and Food and Drug Administration Staff	06/27/2019	Center for Devices and Radiological Health	Premarket, 510(k), Radiological Health, Radiology	Final	No		FDA-2017-D-5372
Treatment for Heart Failure: Endpoints for Drug Development Guidance for Industry	PDF (86.02 KB)PDF (86.02 KB) of Treatment for Heart Failure: Endpoints for Drug Development Guidance for Industry	06/27/2019	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Clinical - Medical	Draft	No	08/27/2019	FDA-2019-D-2314
Clinical Investigations for Prostate Tissue Ablation Devices: Draft Guidance for Industry and Food and Drug Administration Staff	PDF (352.13 KB)PDF (352.13 KB) of Clinical Investigations for Prostate Tissue Ablation Devices: Draft Guidance for Industry and Food and Drug Administration Staff	06/26/2019	Center for Devices and Radiological Health	Premarket, 510(k), Good Clinical Practices (GCP), Device Exception (IDE), Gastroenterology-Urology	Draft	No	08/26/2019	FDA-2019-D-2223
E19 OPTIMISATION OF SAFETY DATA COLLECTION	PDF (188.94 KB)PDF (188.94 KB) of E19 OPTIMISATION OF SAFETY DATA COLLECTION	06/26/2019	Center for Drug Evaluation and Research	ICH-Efficacy	Draft	No	08/26/2019	FDA-2019-D-1828
M10 BIOANALYTICAL METHOD VALIDATION	PDF (620.74 KB)PDF (620.74 KB) of M10 BIOANALYTICAL METHOD VALIDATION	06/26/2019	Center for Drug Evaluation and Research	ICH-Multidisciplinary	Draft	No	08/26/2019	FDA-2019-D-1469
Draft Guidance for Industry: Reducing Microbial Food Safety Hazards in the Production of Seed for Sprouting	PDF (71.24 KB)PDF (71.24 KB) of Draft Guidance for Industry: Reducing Microbial Food Safety Hazards in the Production of Seed for Sprouting	06/24/2019	Center for Food Safety and Applied Nutrition	Produce	Draft	No	08/26/2019	FDA-2018-D-4534
Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs	PDF (265.57 KB)PDF (265.57 KB) of Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs	06/21/2019	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Electronic Submissions,	Final	No		FDA-2015-D-1163
Opioid Analgesic Drugs: Considerations for Benefit-Risk Assessment Framework Guidance for Industry	PDF (280.65 KB)PDF (280.65 KB) of Opioid Analgesic Drugs: Considerations for Benefit-Risk Assessment Framework Guidance for Industry	06/20/2019	Center for Drug Evaluation and Research	Clinical - Medical	Draft	No	08/20/2019	FDA-2019-D-1536
Guidance for Industry: Determining the Number of Employees for Purposes of the “Small Business” Definition in Parts 117 and 507	PDF (163.46 KB)PDF (163.46 KB) of Guidance for Industry: Determining the Number of Employees for Purposes of the “Small Business” Definition in Parts 117 and 507	06/19/2019	Office of Foods and Veterinary Medicine, Office of Food Safety, Center for Veterinary Medicine		Final	No		FDA-2018-D-0671
Guidance for Industry: Declaration of Added Sugars on Honey, Maple Syrup, Other Single-Ingredient Sugars and Syrups, and Certain Cranberry Products	PDF (408.53 KB)PDF (408.53 KB) of Guidance for Industry: Declaration of Added Sugars on Honey, Maple Syrup, Other Single-Ingredient Sugars and Syrups, and Certain Cranberry Products	06/18/2019	Office of Nutrition and Food Labeling	Labeling	Final	No		FDA-2018-D-0075

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Mouse Embryo Assay for Assisted Reproduction Technology Devices	PDF (347.27 KB)PDF (347.27 KB) of Mouse Embryo Assay for Assisted Reproduction Technology Devices	06/13/2019	Center for Devices and Radiological Health	Premarket, 510(k), Premarket Approval (PMA), Device Exception (IDE), Obstetrical & Gynecological	Draft	No	08/12/2019	FDA-2019-D-2105
Testing for Biotin Interference in In Vitro Diagnostic Devices: Draft Draft Guidance for Industry	PDF (122.64 KB)PDF (122.64 KB) of Testing for Biotin Interference in In Vitro Diagnostic Devices: Draft Draft Guidance for Industry	06/13/2019	Center for Biologics Evaluation and Research, Center for Devices and Radiological Health	Blood Products, IVDs (In Vitro Diagnostic Devices)	Draft	No		FDA-2019-D-1876
ANDA Submissions — Content and Format of Abbreviated New Drug Applications: Guidance for Industry	PDF (308.01 KB)PDF (308.01 KB) of ANDA Submissions — Content and Format of Abbreviated New Drug Applications: Guidance for Industry	06/12/2019	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	User Fees, Generic Drugs	Final	No		FDA-2014-D-0725
Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS): Guidance for Industry		06/11/2019	Center for Tobacco Products		Final	No		
Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry	PDF (152.64 KB)PDF (152.64 KB) of Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry	06/06/2019	Center for Drug Evaluation and Research	Clinical - Medical	Draft	No	08/06/2019	FDA-2019-D-1264
Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry	PDF (152.64 KB)PDF (152.64 KB) of Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry	06/06/2019	Center for Drug Evaluation and Research	Clinical - Medical	Draft	No	08/06/2019	FDA-2019-D-1264
Nonalcoholic Steatohepatitis with Compensated Cirrhosis: Developing Drugs for Treatment Guidance for Industry	PDF (230.62 KB)PDF (230.62 KB) of Nonalcoholic Steatohepatitis with Compensated Cirrhosis: Developing Drugs for Treatment Guidance for Industry	06/06/2019	Center for Drug Evaluation and Research	Clinical - Medical	Draft	No	08/06/2019	FDA-2019-D-1516
Draft Guidance for Industry: Evaluating Alternate Curricula for the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	PDF (398.38 KB)PDF (398.38 KB) of Draft Guidance for Industry: Evaluating Alternate Curricula for the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	06/03/2019	Center for Food Safety and Applied Nutrition		Draft	No	10/02/2019	FDA-2019-D-2131
CPG Sec. 651.100 Ethylenediamine Dihydroiodide (EDDI)	PDF (43.63 KB)PDF (43.63 KB) of CPG Sec. 651.100 Ethylenediamine Dihydroiodide (EDDI)	06/01/2019	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Animal Drugs	Final	No		
Formal Dispute Resolution: Sponsor Appeals Above the Division Level Guidance for Industry and Review Staff	PDF (288.1 KB)PDF (288.1 KB) of Formal Dispute Resolution: Sponsor Appeals Above the Division Level Guidance for Industry and Review Staff	05/30/2019	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Administrative / Procedural	Final	No		
Section 503A Bulks List Final Rule Questions and Answers; Small Entity Compliance Guide;: Guidance for Industry	PDF (68.34 KB)PDF (68.34 KB) of Section 503A Bulks List Final Rule Questions and Answers; Small Entity Compliance Guide;: Guidance for Industry	05/24/2019	Center for Drug Evaluation and Research	Compounding	Final	No		FDA-2019-D-2011
Development of Therapeutic Protein Biosimilars: Comparative Analytical Assessment and Other Quality-Related Considerations Guidance for Industry	PDF (847.82 KB)PDF (847.82 KB) of Development of Therapeutic Protein Biosimilars: Comparative Analytical Assessment and Other Quality-Related Considerations Guidance for Industry	05/21/2019	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Biosimilarity	Draft	No		FDA-2019-D-2102
Draft Guidance for Industry: The Use of an Alternate Name for Potassium Chloride in Food Labeling	PDF (85.31 KB)PDF (85.31 KB) of Draft Guidance for Industry: The Use of an Alternate Name for Potassium Chloride in Food Labeling	05/17/2019	Office of Nutrition and Food Labeling	Labeling	Draft	No	09/17/2019	FDA-2019-D-0892

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Considerations in Demonstrating Interchangeability With a Reference Product Guidance for Industry	PDF (448.98 KB)PDF (448.98 KB) of Considerations in Demonstrating Interchangeability With a Reference Product Guidance for Industry	05/09/2019	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Biosimilarity	Final	No		FDA-2017-D-0154
Determining Whether to Submit an ANDA or a 505(b)(2) Application	PDF (149.99 KB)PDF (149.99 KB) of Determining Whether to Submit an ANDA or a 505(b)(2) Application	05/09/2019	Center for Drug Evaluation and Research	Generic Drugs	Final	No		2019-09662
Maximal Usage Trials for Topically Applied Active Ingredients Being Considered for Inclusion in an Over-The -Counter Monograph: Study Elements and Considerations	PDF (156 KB)PDF (156 KB) of Maximal Usage Trials for Topically Applied Active Ingredients Being Considered for Inclusion in an Over-The -Counter Monograph: Study Elements and Considerations	05/09/2019	Center for Drug Evaluation and Research	Clinical - Pharmacology, Over-the-Counter Drugs	Final	No		2019-09692
Oncology Pharmaceuticals: Reproductive Toxicity Testing and Labeling Recommendations Guidance for Industry: Guidance for Industry	PDF (118.32 KB)PDF (118.32 KB) of Oncology Pharmaceuticals: Reproductive Toxicity Testing and Labeling Recommendations Guidance for Industry: Guidance for Industry	05/09/2019	Center for Drug Evaluation and Research	Pharm/Tox	Final	No		FDA-2017-D-2165
Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis: Guidance for Industry	PDF (205.83 KB)PDF (205.83 KB) of Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis: Guidance for Industry	05/09/2019	Center for Biologics Evaluation and Research	Blood Products	Final	No		FDA-2018-D-2478
Classification and Requirements for Laser Illuminated Projectors (LIPs) (Laser Notice No. 57): Guidance for Industry and Food and Drug Administration	PDF (368.73 KB)PDF (368.73 KB) of Classification and Requirements for Laser Illuminated Projectors (LIPs) (Laser Notice No. 57): Guidance for Industry and Food and Drug Administration	05/08/2019	Center for Devices and Radiological Health	Radiological Health	Final	No		FDA-2014-D-2245
Clinical Lactation Studies: Considerations for Study Design	PDF (329.81 KB)PDF (329.81 KB) of Clinical Lactation Studies: Considerations for Study Design	05/08/2019	Center for Drug Evaluation and Research	Clinical - Medical, Clinical - Pharmacology	Draft	No		FDA-2018-D-4525.
Guidance for Industry: Preparation of Food Contact Notifications for Food Contact Substances in Contact with Infant Formula and/or Human Milk	PDF (281.59 KB)PDF (281.59 KB) of Guidance for Industry: Preparation of Food Contact Notifications for Food Contact Substances in Contact with Infant Formula and/or Human Milk	05/08/2019	Office of Food Additive Safety	Food & Color Additives, Infant Formula & Foods, Milk/Milk Product	Final	No		FDA-2016-D-1814
Laser Products - Conformance with IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1 (Laser Notice No. 56): Guidance for Industry and Food and Drug Administration Staff	PDF (83.04 KB)PDF (83.04 KB) of Laser Products - Conformance with IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1 (Laser Notice No. 56): Guidance for Industry and Food and Drug Administration Staff	05/08/2019	Center for Devices and Radiological Health	Export, Import, Radiological Health, Radiology	Final	No		FDA-2017-D-7011
Medical X-Ray Imaging Devices Conformance with IEC Standards: Guidance for Industry and Food and Drug Administration Staff	PDF (539.57 KB)PDF (539.57 KB) of Medical X-Ray Imaging Devices Conformance with IEC Standards: Guidance for Industry and Food and Drug Administration Staff	05/08/2019	Center for Devices and Radiological Health	Premarket, 510(k), Radiological Health, Radiology	Final	No		FDA-2016-D-2049
Policy Clarification for Certain Fluoroscopic Equipment Requirements: Guidance for Industry and Food and Drug Administration Staff	PDF (336.85 KB)PDF (336.85 KB) of Policy Clarification for Certain Fluoroscopic Equipment Requirements: Guidance for Industry and Food and Drug Administration Staff	05/08/2019	Center for Devices and Radiological Health	Radiological Health	Final	No		FDA-2014-D-1344
Postapproval Pregnancy Safety Studies Guidance for Industry	PDF (403.33 KB)PDF (403.33 KB) of Postapproval Pregnancy Safety Studies Guidance for Industry	05/08/2019	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research		Draft	No	07/08/2019	2019-09527

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Submitting Documents Using Real-World Data and Real-World Evidence to FDA for Drugs and Biologics Guidance for Industry	PDF (87.79 KB)PDF (87.79 KB) of Submitting Documents Using Real-World Data and Real-World Evidence to FDA for Drugs and Biologics Guidance for Industry	05/08/2019	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Administrative / Procedural	Draft	No		2019-09529
Utilizing Animal Studies to Evaluate Organ Preservation Devices: Guidance for Industry and Food and Drug Administration Staff	PDF (175.89 KB)PDF (175.89 KB) of Utilizing Animal Studies to Evaluate Organ Preservation Devices: Guidance for Industry and Food and Drug Administration Staff	05/08/2019	Center for Devices and Radiological Health	Premarket, 510(k), Gastroenterology-Urology	Final	No		FDA-2017-D-4886
Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program: Guidance for Industry and Food and Drug Administration Staff	PDF (261.66 KB)PDF (261.66 KB) of Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program: Guidance for Industry and Food and Drug Administration Staff	05/07/2019	Center for Devices and Radiological Health	510(k), Administrative / Procedural, CLIA (Clinical Laboratory Improvement Amendments), Premarket Approval (PMA), Device Exception (IDE), HUD/HDE	Final	No		FDA-2018-D-1774
Attention Deficit Hyperactivity Disorder: Developing Stimulant Drugs for Treatment Guidance for Industry	PDF (247.83 KB)PDF (247.83 KB) of Attention Deficit Hyperactivity Disorder: Developing Stimulant Drugs for Treatment Guidance for Industry	05/03/2019	Center for Drug Evaluation and Research	Clinical - Medical, Over-the-Counter Drugs	Draft	No	07/03/2019	2019-09193
Characterization of Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic Devices: Guidance for Industry and Food and Drug Administration Staff	PDF (519.76 KB)PDF (519.76 KB) of Characterization of Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic Devices: Guidance for Industry and Food and Drug Administration Staff	04/26/2019	Center for Devices and Radiological Health	510(k), Premarket Approval (PMA), Device Exception (IDE), Orthopedic	Final	No	05/12/2016	FDA-2016-D-0363
Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions: Guidance for Industry and Food and Drug Administration Staff	PDF (376.39 KB)PDF (376.39 KB) of Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions: Guidance for Industry and Food and Drug Administration Staff	04/26/2019	Center for Devices and Radiological Health	Premarket,	Final	No		FDA-2018-D-1329
Unique Device Identification: Convenience Kits : Guidance for Industry and Food and Drug Administration Staff	PDF (364.59 KB)PDF (364.59 KB) of Unique Device Identification: Convenience Kits : Guidance for Industry and Food and Drug Administration Staff	04/26/2019	Center for Devices and Radiological Health	Labeling	Final	No	04/05/2016	FDA-2015-D-4048
Adjusting for Covariates in Randomized Clinical Trials for Drugs and Biologics with Continuous Outcomes Guidance for Industry	PDF (66.87 KB)PDF (66.87 KB) of Adjusting for Covariates in Randomized Clinical Trials for Drugs and Biologics with Continuous Outcomes Guidance for Industry	04/24/2019	Center for Drug Evaluation and Research		Draft	No	06/24/2019	FDA-2019-D-0934
Extending Expiration Dates of Doxycycline Tablets and Capsules in Strategic Stockpiles : Guidance for Government Public Health and Emergency Response Stakeholders	PDF (209.17 KB)PDF (209.17 KB) of Extending Expiration Dates of Doxycycline Tablets and Capsules in Strategic Stockpiles : Guidance for Government Public Health and Emergency Response Stakeholders	04/24/2019	Center for Drug Evaluation and Research	Administrative / Procedural	Final	No		2019-08349
Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C Guidance for Industry and FDA Staff	PDF (85.01 KB)PDF (85.01 KB) of Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C Guidance for Industry and FDA Staff	04/24/2019	Office of the Associate Commissioner for Regulatory Affairs	Recalls,	Draft	No	06/24/2019	FDA-2018-D-2074
Surgical Staplers and Staples for Internal Use - Labeling Recommendations: Draft Guidance for Industry and Food and Drug Administration Staff	PDF (175.15 KB)PDF (175.15 KB) of Surgical Staplers and Staples for Internal Use - Labeling Recommendations: Draft Guidance for Industry and Food and Drug Administration Staff	04/24/2019	Center for Devices and Radiological Health	Device & Drug Safety, Labeling, General & Plastic Surgery , Device & Drug Safety	Draft	No	06/23/2019	FDA-2019-D-1262

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Compliance Policy for Combination Product Postmarketing Safety Reporting: Immediately in Effect Guidance for Industry and Food and Drug Administration Staff	PDF (57.6 KB)PDF (57.6 KB) of Compliance Policy for Combination Product Postmarketing Safety Reporting: Immediately in Effect Guidance for Industry and Food and Drug Administration Staff	04/20/2019	Office of Combination Products, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Combination Products	Final	No		FDA-2008-N-0424
Technical Considerations for Non-Clinical Assessment of Medical Devices Containing Nitinol: Draft Guidance for Industry and Food and Drug Administration Staff	PDF (624.89 KB)PDF (624.89 KB) of Technical Considerations for Non-Clinical Assessment of Medical Devices Containing Nitinol: Draft Guidance for Industry and Food and Drug Administration Staff	04/19/2019	Center for Devices and Radiological Health	Premarket, Animal Cell-Based Products	Draft	No	06/18/2019	FDA-2019-D-1261
Technical Performance Assessment of Quantitative Imaging in Device Premarket Submissions: Draft Guidance for Industry and Food and Drug Administration Staff	PDF (450.84 KB)PDF (450.84 KB) of Technical Performance Assessment of Quantitative Imaging in Device Premarket Submissions: Draft Guidance for Industry and Food and Drug Administration Staff	04/19/2019	Center for Devices and Radiological Health	510(k), Digital Health, Radiology	Draft	No	06/18/2019	FDA-2019-D-1470
Bispecific Antibody Development Programs Guidance for Industry	PDF (90.17 KB)PDF (90.17 KB) of Bispecific Antibody Development Programs Guidance for Industry	04/18/2019	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Draft	No	06/18/2019	FDA-2019-D-0621
Draft Guidance for Industry: The Declaration of Allulose and Calories from Allulose on Nutrition and Supplement Facts Labels	PDF (88.33 KB)PDF (88.33 KB) of Draft Guidance for Industry: The Declaration of Allulose and Calories from Allulose on Nutrition and Supplement Facts Labels	04/17/2019	Office of Nutrition and Food Labeling	Labeling, Nutrition Label	Draft	No	06/17/2019	FDA-2019-D-0725
REMS: FDA's Application of Statutory Factors in Determining When a REMS Is Necessary Guidance for Industry		04/04/2019	Center for Drug Evaluation and Research		Final	No		2019-06663
FDA's Application of Statutory Factors in Determining When a REMS Is Necessary	PDF (110.01 KB)PDF (110.01 KB) of FDA's Application of Statutory Factors in Determining When a REMS Is Necessary	04/04/2019	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Safety - Issues, Errors, and Problems	Final	No		FDA-2016-D-2730
Class II Special Controls Guideline: In Vitro Diagnostic Devices for Bacillus spp. Detection: Guideline for Industry and Food and Drug Administration Staff	PDF (200.5 KB)PDF (200.5 KB) of Class II Special Controls Guideline: In Vitro Diagnostic Devices for Bacillus spp. Detection: Guideline for Industry and Food and Drug Administration Staff	04/01/2019	Center for Devices and Radiological Health	Microbiology, IVDs (In Vitro Diagnostic Devices), Laboratory Tests	Final	No	02/15/2016	FDA-2011-N-0103
Review and Update of Device Establishment Inspection Processes and Standards: Draft Guidance for Industry	PDF (80.56 KB)PDF (80.56 KB) of Review and Update of Device Establishment Inspection Processes and Standards: Draft Guidance for Industry	03/29/2019	Office of Regulatory Affairs, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Investigation & Enforcement, Good Clinical Practices (GCP)	Draft	No	05/28/2019	FDA-2019-D-0914
CVM GFI #120 Veterinary Feed Directive Regulation Questions and Answers	PDF (637.33 KB)PDF (637.33 KB) of CVM GFI #120 Veterinary Feed Directive Regulation Questions and Answers	03/28/2019	Center for Veterinary Medicine	Animal Feed	Draft	No	05/28/2019	FDA-2010-N-0155
Guidance for Industry: Enforcement Policy for Entities Growing, Harvesting, Packing, or Holding Hops, Wine Grapes, Pulse Crops, and Almonds	PDF (95.49 KB)PDF (95.49 KB) of Guidance for Industry: Enforcement Policy for Entities Growing, Harvesting, Packing, or Holding Hops, Wine Grapes, Pulse Crops, and Almonds	03/27/2019	Center for Food Safety and Applied Nutrition		Final	No		FDA-2019-D-1266
Pediatric Information Incorporated Into Human Prescription Drug and Biological Products Labeling Good Review Practice	PDF (315.2 KB)PDF (315.2 KB) of Pediatric Information Incorporated Into Human Prescription Drug and Biological Products Labeling Good Review Practice	03/27/2019	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Labeling	Final	No		

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Rare Diseases: Natural History Studies for Drug Development: Draft Guidance for Industry	PDF (354.85 KB)PDF (354.85 KB) of Rare Diseases: Natural History Studies for Drug Development: Draft Guidance for Industry	03/25/2019	Office of Orphan Products Development, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research		Draft	No	05/24/2019	FDA-2019-D-0481
Standards Development and the Use of Standards in Regulatory Submissions Reviewed in the Center for Biologics Evaluation and Research: Guidance for Industry	PDF (132.78 KB)PDF (132.78 KB) of Standards Development and the Use of Standards in Regulatory Submissions Reviewed in the Center for Biologics Evaluation and Research: Guidance for Industry	03/25/2019	Center for Biologics Evaluation and Research	Compliance, Administrative / Procedural	Final	No		FDA-2017-D-6535
Interpretation of and Compliance Policy for Certain Label Requirement; Applicability of Certain Federal Food, Drug, and Cosmetic Act Requirements to Vape Shops: Guidance for Industry		03/22/2019	Center for Tobacco Products		Final	No		FDA-2017-D-0120
Pediatric HIV Infection: Drug Development for Treatment	PDF (70.68 KB)PDF (70.68 KB) of Pediatric HIV Infection: Drug Development for Treatment	03/19/2019	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Clinical - Medical	Final	No		
Human Immunodeficiency Virus-1 Infection: Developing Systemic Drug Products for Pre-Exposure Prophylaxis	PDF (90.91 KB)PDF (90.91 KB) of Human Immunodeficiency Virus-1 Infection: Developing Systemic Drug Products for Pre-Exposure Prophylaxis	03/18/2019	Center for Drug Evaluation and Research	Clinical - Antimicrobial	Final	No		FDA-2018-D-1918
A Risk-Based Approach to Monitoring of Clinical Investigations Questions and Answers: Draft Guidance for Industry	PDF (117.55 KB)PDF (117.55 KB) of A Risk-Based Approach to Monitoring of Clinical Investigations Questions and Answers: Draft Guidance for Industry	03/15/2019	Office of Regulatory Affairs, Office of Good Clinical Practice, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Administrative / Procedural, Good Clinical Practices (GCP)	Draft	No	05/14/2019	FDA-2019-D-0362
Enrichment Strategies for Clinical Trials to Support Approval of Human Drugs and Biological Products: Guidance for Industry	PDF (576.03 KB)PDF (576.03 KB) of Enrichment Strategies for Clinical Trials to Support Approval of Human Drugs and Biological Products: Guidance for Industry	03/15/2019	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Clinical - Medical, Good Clinical Practices (GCP)	Final	No		FDA-2012-D-1145
Medical Devices Containing Materials Derived from Animal Sources (Except for In Vitro Diagnostic Devices): Guidance for Industry and Food and Drug Administration Staff	PDF (602.81 KB)PDF (602.81 KB) of Medical Devices Containing Materials Derived from Animal Sources (Except for In Vitro Diagnostic Devices): Guidance for Industry and Food and Drug Administration Staff	03/15/2019	Center for Devices and Radiological Health	Premarket, Laboratory Tests	Final	No		FDA-2013-D-1574
Severely Debilitating or Life-Threatening Hematologic Disorders: Nonclinical Development of Pharmaceuticals Guidance for Industry	PDF (121.8 KB)PDF (121.8 KB) of Severely Debilitating or Life-Threatening Hematologic Disorders: Nonclinical Development of Pharmaceuticals Guidance for Industry	03/15/2019	Center for Drug Evaluation and Research	Pharm/Tox	Final	No		
Cancer Clinical Trial Eligibility Criteria: Brain Metastases		03/13/2019	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Clinical - Medical	Draft	No	05/13/2019	FDA-2019-D-0357

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Cancer Clinical Trial Eligibility Criteria: Minimum Age for Pediatric Patients		03/13/2019	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, Office of the Commissioner	Clinical - Medical	Draft	No	05/13/2019	FDA-2019-D-0358
Cancer Clinical Trial Eligibility Criteria: Patients with HIV, Hepatitis B Virus, or Hepatitis C Virus Infections	PDF (312.57 KB)PDF (312.57 KB) of Cancer Clinical Trial Eligibility Criteria: Patients with HIV, Hepatitis B Virus, or Hepatitis C Virus Infections	03/13/2019	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, Office of the Commissioner	Clinical - Medical	Draft	No	05/13/2019	FDA-2019-D-0363
Cancer Clinical Trial Eligibility Criteria: Patients with Organ Dysfunction or Prior or Concurrent Malignancies	PDF (280.99 KB)PDF (280.99 KB) of Cancer Clinical Trial Eligibility Criteria: Patients with Organ Dysfunction or Prior or Concurrent Malignancies	03/13/2019	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Clinical - Medical	Draft	No	05/13/2019	FDA-2019-D-0359
Considerations for the Inclusion of Adolescent Patients in Adult Oncology Clinical Trials	PDF (87.34 KB)PDF (87.34 KB) of Considerations for the Inclusion of Adolescent Patients in Adult Oncology Clinical Trials	03/13/2019	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, Office of the Commissioner	Clinical - Medical	Draft	No	08/01/2018	FDA-2018-D-1540
Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act	PDF (323.4 KB)PDF (323.4 KB) of Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act	03/13/2019	Center for Drug Evaluation and Research	Compounding	Final	No		FDA-2018-D-1067
Modifications to Compliance Policy for Certain Deemed Tobacco Products: Draft Guidance for Industry	PDF (144.11 KB)PDF (144.11 KB) of Modifications to Compliance Policy for Certain Deemed Tobacco Products: Draft Guidance for Industry	03/13/2019	Center for Tobacco Products		Draft	No	04/15/2019	FDA-2019-D-0661
Draft Guidance for Industry: Voluntary Labeling Indicating Whether Food Has or Has Not Been Derived From Genetically Engineered Atlantic Salmon	PDF (102.78 KB)PDF (102.78 KB) of Draft Guidance for Industry: Voluntary Labeling Indicating Whether Food Has or Has Not Been Derived From Genetically Engineered Atlantic Salmon	03/11/2019	Office of Nutrition and Food Labeling, Office of the Director	Labeling, Bioengineering / GMOs	Draft	No	01/25/2016	FDA-2015-D-4272
Guidance for Industry: FDA's Voluntary Qualified Importer Program	PDF (143.61 KB)PDF (143.61 KB) of Guidance for Industry: FDA's Voluntary Qualified Importer Program	03/11/2019	Center for Food Safety and Applied Nutrition	Import	Final	No		FDA-2011-N-0144
Guidance for Industry: FDA's Voluntary Qualified Importer Program	PDF (224.32 KB)PDF (224.32 KB) of Guidance for Industry: FDA's Voluntary Qualified Importer Program	03/11/2019	Center for Food Safety and Applied Nutrition	Import	Final	No		FDA-2011-N-0144
Guidance for Industry: FDA's Voluntary Qualified Importer Program	PDF (415.94 KB)PDF (415.94 KB) of Guidance for Industry: FDA's Voluntary Qualified Importer Program	03/11/2019	Center for Food Safety and Applied Nutrition	Import	Final	No		FDA-2011-N-0144
Guidance for Industry: FDA's Voluntary Qualified Importer Program	PDF (511.73 KB)PDF (511.73 KB) of Guidance for Industry: FDA's Voluntary Qualified Importer Program	03/11/2019	Center for Food Safety and Applied Nutrition	Import	Final	No		FDA-2011-N-0144
Guidance for Industry: FDA's Voluntary Qualified Importer Program	PDF (289.64 KB)PDF (289.64 KB) of Guidance for Industry: FDA's Voluntary Qualified Importer Program	03/11/2019	Center for Food Safety and Applied Nutrition	Import	Final	No		FDA-2011-N-0144
Guidance for Industry: FDA's Voluntary Qualified Importer Program	PDF (189.72 KB)PDF (189.72 KB) of Guidance for Industry: FDA's Voluntary Qualified Importer Program	03/11/2019	Center for Food Safety and Applied Nutrition	Import	Final	No		FDA-2011-N-0144

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Guidance for Industry: FDA's Voluntary Qualified Importer Program	PDF (380.26 KB)PDF (380.26 KB) of Guidance for Industry: FDA's Voluntary Qualified Importer Program	03/11/2019	Center for Food Safety and Applied Nutrition	Import	Final	No		FDA-2011-N-0144
Guidance for Industry: FDA's Voluntary Qualified Importer Program	PDF (194.42 KB)PDF (194.42 KB) of Guidance for Industry: FDA's Voluntary Qualified Importer Program	03/11/2019	Center for Food Safety and Applied Nutrition	Import	Final	No		FDA-2011-N-0144
Guidance for Industry: FDA's Voluntary Qualified Importer Program	PDF (183.77 KB)PDF (183.77 KB) of Guidance for Industry: FDA's Voluntary Qualified Importer Program	03/11/2019	Center for Food Safety and Applied Nutrition	Import	Final	No		FDA-2011-N-0144
Guidance for Industry: FDA's Voluntary Qualified Importer Program	PDF (338.72 KB)PDF (338.72 KB) of Guidance for Industry: FDA's Voluntary Qualified Importer Program	03/11/2019	Center for Food Safety and Applied Nutrition	Import	Final	No		FDA-2011-N-0144
Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants	PDF (137.72 KB)PDF (137.72 KB) of Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants	03/11/2019	Office of Nutrition and Food Labeling	Labeling, Bioengineering / GMOs	Final	No		FDA-2000-D-0075
Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule: Guidance for Industry		03/08/2019	Center for Tobacco Products		Final	No		
FDA Deems Certain Tobacco Products Subject to FDA Authority, Sales and Distribution Restrictions, and Health Warning Requirements for Packages and Advertisements: Guidance for Industry		03/08/2019	Center for Tobacco Products		Final	No		
Nonproprietary Naming of Biological Products: Update Guidance for Industry	PDF (322.39 KB)PDF (322.39 KB) of Nonproprietary Naming of Biological Products: Update Guidance for Industry	03/08/2019	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Labeling	Draft	No	05/07/2019	FDA-2013-D-1543
Withdrawn CDER Product Specific Guidances	PDF (81.62 KB)PDF (81.62 KB) of Withdrawn CDER Product Specific Guidances	03/07/2019	Center for Drug Evaluation and Research	Generic Drugs	Final	No		
Draft Guidance for Industry: Mitigation Strategies to Protect Food Against Intentional Adulteration	PDF (995.91 KB)PDF (995.91 KB) of Draft Guidance for Industry: Mitigation Strategies to Protect Food Against Intentional Adulteration	03/06/2019	Center for Food Safety and Applied Nutrition		Draft	No	07/05/2019	FDA-2018-D-1398
CPG Sec. 608.200 Prescription Use of Certain Injectable Animal Drugs	PDF (24.7 KB)PDF (24.7 KB) of CPG Sec. 608.200 Prescription Use of Certain Injectable Animal Drugs	03/01/2019	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Animal Drugs	Final	No		
CPG Sec. 635.100 Large Volume Parenterals (LVPs) for Animal Use	PDF (29.64 KB)PDF (29.64 KB) of CPG Sec. 635.100 Large Volume Parenterals (LVPs) for Animal Use	03/01/2019	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Animal Drugs	Final	No		
CPG Sec. 653.100 Animal Grooming Aids	PDF (23.15 KB)PDF (23.15 KB) of CPG Sec. 653.100 Animal Grooming Aids	03/01/2019	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement,	Final	No		
CPG Sec. 665.300 Use of Type A Medicated Article Proprietary Names in the Names of Medicated Feeds	PDF (47.62 KB)PDF (47.62 KB) of CPG Sec. 665.300 Use of Type A Medicated Article Proprietary Names in the Names of Medicated Feeds	03/01/2019	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Labeling, Medicated Feed	Final	No		
CPG Sec. 666.100 Alternate Feeding of Different Medicated Feeds	PDF (22.87 KB)PDF (22.87 KB) of CPG Sec. 666.100 Alternate Feeding of Different Medicated Feeds	03/01/2019	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Medicated Feed	Final	No		
CPG Sec. 683.100 Action Levels for Aflatoxins in Animal Feeds	PDF (38.81 KB)PDF (38.81 KB) of CPG Sec. 683.100 Action Levels for Aflatoxins in Animal Feeds	03/01/2019	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Animal Feed	Final	No		

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IOM Index	PDF (297.16 KB)PDF (297.16 KB) of IOM Index	03/01/2019	Office of the Associate Commissioner for Regulatory Affairs	Compliance, Inspection,	Final	Yes	03/01/2020	
Release of ORA Laboratory Analytical Results to the Responsible Party: Guidance for Food and Drug Administration Staff	PDF (69.02 KB)PDF (69.02 KB) of Release of ORA Laboratory Analytical Results to the Responsible Party: Guidance for Food and Drug Administration Staff	03/01/2019	Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine, Office of Regulatory Affairs, Center for Tobacco Products, Center for Devices and Radiological Health	Investigation & Enforcement, Administrative / Procedural	Final	No		FDA-2019-D-1163
Enforcement Policy for Certain Marketed Tobacco Products: Draft Guidance for Industry	PDF (74.91 KB)PDF (74.91 KB) of Enforcement Policy for Certain Marketed Tobacco Products: Draft Guidance for Industry	02/28/2019	Center for Tobacco Products		Draft	No	04/30/2019	FDA-2018-D-3244
Quality Considerations for Continuous Manufacturing	PDF (197.29 KB)PDF (197.29 KB) of Quality Considerations for Continuous Manufacturing	02/27/2019	Center for Drug Evaluation and Research	Current Good Manufacturing Practices (CGMP), Pharmaceutical Quality	Draft	No	05/28/2019	FDA-2019-D-0298
Assessing the Effects of Food on Drugs in INDs and NDAs – Clinical Pharmacology Considerations	PDF (153.26 KB)PDF (153.26 KB) of Assessing the Effects of Food on Drugs in INDs and NDAs – Clinical Pharmacology Considerations	02/26/2019	Center for Drug Evaluation and Research	Clinical - Pharmacology	Draft	No	04/29/2019	FDA-2018-D-4368
Bioavailability Studies Submitted in NDAs or INDs – General Considerations	PDF (254.25 KB)PDF (254.25 KB) of Bioavailability Studies Submitted in NDAs or INDs – General Considerations	02/26/2019	Center for Drug Evaluation and Research	Clinical - Pharmacology	Draft	No	05/28/2019	FDA-2018-D-4367
Implanted Brain-Computer Interface (BCI) Devices for Patients with Paralysis or Amputation - Non-clinical Testing and Clinical Considerations: Draft Guidance for Industry and Food and Drug Administration Staff	PDF (691.76 KB)PDF (691.76 KB) of Implanted Brain-Computer Interface (BCI) Devices for Patients with Paralysis or Amputation - Non-clinical Testing and Clinical Considerations: Draft Guidance for Industry and Food and Drug Administration Staff	02/25/2019	Center for Devices and Radiological Health	Premarket, Device Exception (IDE), Neurological	Draft	No	04/26/2019	FDA-2014-N-1130
Providing Lot Release Protocol Submissions to the Center for Biologics Evaluation and Research (CBER) in Electronic Format: Guidance for Industry	PDF (220.05 KB)PDF (220.05 KB) of Providing Lot Release Protocol Submissions to the Center for Biologics Evaluation and Research (CBER) in Electronic Format: Guidance for Industry	02/22/2019	Center for Biologics Evaluation and Research	Premarket, Administrative / Procedural	Final	No		1998D-0315
Smoking Cessation and Related Indications: Developing Nicotine Replacement Therapy Drug Products	PDF (316.3 KB)PDF (316.3 KB) of Smoking Cessation and Related Indications: Developing Nicotine Replacement Therapy Drug Products	02/22/2019	Center for Drug Evaluation and Research	Clinical - Medical	Draft	No	04/23/2019	FDA-2019-D-0297
Acceptance and Filing Reviews for Premarket Approval Applications (PMAs): Guidance for Industry and Food and Drug Administration Staff	PDF (582.58 KB)PDF (582.58 KB) of Acceptance and Filing Reviews for Premarket Approval Applications (PMAs): Guidance for Industry and Food and Drug Administration Staff	02/21/2019	Center for Devices and Radiological Health	Premarket, Premarket Approval (PMA)	Final	No		FDA- 2012-D-0524
Use of Investigational Tobacco Products: Draft Guidance for Industry and Investigators		02/20/2019	Center for Tobacco Products		Draft	No	04/21/2019	FDA-2014-D-1939
Competitive Generic Therapies	PDF (185.74 KB)PDF (185.74 KB) of Competitive Generic Therapies	02/19/2019	Center for Drug Evaluation and Research	Generic Drugs	Draft	No	04/22/2019	FDA-2019-D-0065
Nonbinding Feedback After Certain Food and Drug Administration Inspections of Device Establishments: Draft Guidance for Industry and Food and Drug Administration Staff	PDF (402.45 KB)PDF (402.45 KB) of Nonbinding Feedback After Certain Food and Drug Administration Inspections of Device Establishments: Draft Guidance for Industry and Food and Drug Administration Staff	02/19/2019	Center for Devices and Radiological Health		Draft	No	04/20/2019	FDA-2018-D-4711

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Evaluation of Devices Used with Regenerative Medicine Advanced Therapies: Guidance for Industry	PDF (193.57 KB)PDF (193.57 KB) of Evaluation of Devices Used with Regenerative Medicine Advanced Therapies: Guidance for Industry	02/15/2019	Center for Biologics Evaluation and Research, Center for Devices and Radiological Health, Office of Combination Products	Combination Products, Gene Therapy	Final	No	02/15/2018	FDA-2017-D-6154
Expedited Programs for Regenerative Medicine Therapies for Serious Conditions: Guidance for Industry	PDF (219.2 KB)PDF (219.2 KB) of Expedited Programs for Regenerative Medicine Therapies for Serious Conditions: Guidance for Industry	02/15/2019	Center for Biologics Evaluation and Research	Cellular & Gene Therapy, Gene Therapy	Final	No	02/15/2018	FDA-2017-D-6159
CDER's Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality	PDF (98.62 KB)PDF (98.62 KB) of CDER's Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality	02/14/2019	Center for Drug Evaluation and Research	Administrative / Procedural	Draft	No	04/15/2019	FDA-2018-D-4417
Intent to Exempt Certain Unclassified Medical Devices from Premarket Notification Requirements: Guidance for Industry and Food and Drug Administration Staff	PDF (240.59 KB)PDF (240.59 KB) of Intent to Exempt Certain Unclassified Medical Devices from Premarket Notification Requirements: Guidance for Industry and Food and Drug Administration Staff	02/08/2019	Center for Devices and Radiological Health	Premarket, 510(k), Anesthesiology , Physical Medicine, Orthopedic, Ophthalmic, Obstetrical & Gynecological, Neurological, Cardiovascular , General Hospital & Personal Use , General & Plastic Surgery , Gastroenterology-Urology , Ear, Nose & Throat , Dental	Final	No		FDA-2014-D-0967
Public Warning-Notification of Recalls Under 21 CFR Part 7, Subpart C	PDF (441.33 KB)PDF (441.33 KB) of Public Warning-Notification of Recalls Under 21 CFR Part 7, Subpart C	02/08/2019	Office of Regulatory Affairs	Recalls,	Final	Yes	02/08/2020	FDA-2016-D-3548
Opioid Use Disorder: Developing Depot Buprenorphine Products for Treatment		02/07/2019	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		FDA-2018-D-1334
Eosinophilic Esophagitis: Developing Drugs for Treatment Guidance for Industry	PDF (279.29 KB)PDF (279.29 KB) of Eosinophilic Esophagitis: Developing Drugs for Treatment Guidance for Industry	02/06/2019	Center for Drug Evaluation and Research	Clinical - Medical	Draft	No	04/08/2019	FDA-2019-D-0177
Principles of Premarket Pathways for Combination Products: Draft Guidance for Industry and FDA Staff	PDF (226.35 KB)PDF (226.35 KB) of Principles of Premarket Pathways for Combination Products: Draft Guidance for Industry and FDA Staff	02/06/2019	Office of Combination Products, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Combination Products	Draft	No	05/07/2019	FDA-2019-D-0078
The Least Burdensome Provisions: Concept and Principles: Guidance for Industry and FDA Staff	PDF (483.29 KB)PDF (483.29 KB) of The Least Burdensome Provisions: Concept and Principles: Guidance for Industry and FDA Staff	02/05/2019	Center for Devices and Radiological Health	Premarket,	Final	No		FDA-2017-D-6702
Coordinated Development of Antimicrobial Drugs and Antimicrobial Susceptibility Test Devices: Guidance for Industry and Food and Drug Administration Staff	PDF (580.43 KB)PDF (580.43 KB) of Coordinated Development of Antimicrobial Drugs and Antimicrobial Susceptibility Test Devices: Guidance for Industry and Food and Drug Administration Staff	02/01/2019	Center for Devices and Radiological Health	IVDs (In Vitro Diagnostic Devices), Premarket Approval (PMA), Testing	Final	No		FDA-2016-D-2561
Rare Diseases: Common Issues in Drug Development Guidance for Industry: Draft Guidance for Industry	PDF (393.74 KB)PDF (393.74 KB) of Rare Diseases: Common Issues in Drug Development Guidance for Industry: Draft Guidance for Industry	02/01/2019	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research		Draft	No	04/02/2019	FDA-2015-D-2818
Marketing Status Notifications Under Section 506I of the Federal Food, Drug, and Cosmetic Act	PDF (86.98 KB)PDF (86.98 KB) of Marketing Status Notifications Under Section 506I of the Federal Food, Drug, and Cosmetic Act	01/31/2019	Center for Drug Evaluation and Research	Administrative / Procedural	Draft	No	04/01/2019	FDA-2018-D-4615

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Rare Diseases: Common Issues in Drug Development Guidance for Industry	PDF (210.79 KB)PDF (210.79 KB) of Rare Diseases: Common Issues in Drug Development Guidance for Industry	01/31/2019	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research		Draft	No		
Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications: Guidance for Industry	PDF (121.22 KB)PDF (121.22 KB) of Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications: Guidance for Industry	01/29/2019	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Electronic Submissions, Good Clinical Practices (GCP)	Final	No		
REMS Assessment: Planning and Reporting	PDF (590.24 KB)PDF (590.24 KB) of REMS Assessment: Planning and Reporting	01/24/2019	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Administrative / Procedural	Draft	No	04/02/2019	FDA-2018-D-4628
Survey Methodologies to Assess REMS Goals That Relate to Knowledge	PDF (462.82 KB)PDF (462.82 KB) of Survey Methodologies to Assess REMS Goals That Relate to Knowledge	01/24/2019	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Administrative / Procedural	Draft	No		FDA-2018-D-4629
Immunogenicity Testing of Therapeutic Protein Products — Developing and Validating Assays for Anti-Drug Antibody Detection	PDF (371.72 KB)PDF (371.72 KB) of Immunogenicity Testing of Therapeutic Protein Products — Developing and Validating Assays for Anti-Drug Antibody Detection	01/23/2019	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		FDA-2009-D-0539
Labeling for Human Prescription Drug and Biological Products Approved Under the Accelerated Approval Regulatory Pathway	PDF (84.95 KB)PDF (84.95 KB) of Labeling for Human Prescription Drug and Biological Products Approved Under the Accelerated Approval Regulatory Pathway	01/22/2019	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Labeling	Final	No		FDA-2014-D-0250
S11 Nonclinical Safety Testing in Support of Development of Paediatric Medicines	PDF (1.37 MB)PDF (1.37 MB) of S11 Nonclinical Safety Testing in Support of Development of Paediatric Medicines	01/22/2019	Center for Drug Evaluation and Research	ICH-Safety	Draft	No	04/02/2019	FDA-2018-D-4524
ANDA Submissions – Amendments and Requests for Final Approval to Tentatively Approved ANDAs	PDF (135.39 KB)PDF (135.39 KB) of ANDA Submissions – Amendments and Requests for Final Approval to Tentatively Approved ANDAs	01/16/2019	Center for Drug Evaluation and Research	Generic Drugs	Draft	No	04/02/2019	FDA-2018-D-4726
CVM GFI #259 (VICH GL58) Stability Testing of New Veterinary Drug Substances and Medicinal Products in Climatic Zones III and IV	PDF (200.75 KB)PDF (200.75 KB) of CVM GFI #259 (VICH GL58) Stability Testing of New Veterinary Drug Substances and Medicinal Products in Climatic Zones III and IV	12/28/2018	Center for Veterinary Medicine	Chemistry, Manufacturing, and Controls (CMC), VICH	Draft	No	02/26/2019	FDA-2018-D-4662
Developing and Submitting Proposed Draft Guidance Relating to Patient Experience Data	PDF (137.82 KB)PDF (137.82 KB) of Developing and Submitting Proposed Draft Guidance Relating to Patient Experience Data	12/21/2018	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Administrative / Procedural	Draft	No	03/21/2019	FDA-2018-D-4455
Labeling of Red Blood Cell Units with Historical Antigen Typing Results: Guidance for Industry	PDF (135.21 KB)PDF (135.21 KB) of Labeling of Red Blood Cell Units with Historical Antigen Typing Results: Guidance for Industry	12/20/2018	Center for Biologics Evaluation and Research	Blood Products	Final	No		FDA-2016-D-4308
Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics: Guidance for Industry	PDF (145.97 KB)PDF (145.97 KB) of Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics: Guidance for Industry	12/19/2018	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, Oncology Center of Excellence	Clinical - Medical	Final	No		

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Breakthrough Devices Program: Guidance for Industry and Food and Drug Administration Staff	PDF (585.94 KB)PDF (585.94 KB) of Breakthrough Devices Program: Guidance for Industry and Food and Drug Administration Staff	12/18/2018	Center for Devices and Radiological Health	Premarket, 510(k), Administrative / Procedural, Premarket Approval (PMA), Device Exception (IDE), HUD/HDE	Final	No	12/24/2017	FDA-2017-D-5966
Clarification of Radiation Control Regulations For Manufacturers of Diagnostic X-Ray Equipment: Draft Guidance for Industry and Food and Drug Administration Staff	PDF (637.72 KB)PDF (637.72 KB) of Clarification of Radiation Control Regulations For Manufacturers of Diagnostic X-Ray Equipment: Draft Guidance for Industry and Food and Drug Administration Staff	12/17/2018	Office of In Vitro Diagnostics and Radiological Health	Export, Import, Labeling, Radiology	Draft	No		
Manufacturing Site Change Supplements: Content and Submission: Guidance for Industry and Food and Drug Administration Staff	PDF (185.12 KB)PDF (185.12 KB) of Manufacturing Site Change Supplements: Content and Submission: Guidance for Industry and Food and Drug Administration Staff	12/17/2018	Center for Devices and Radiological Health	Postmarket, Premarket Approval (PMA)	Final	No		FDA-2015-N-3454
Data Integrity and Compliance With Drug CGMP Questions and Answers Guidance for Industry: Guidance for Industry	PDF (127.11 KB)PDF (127.11 KB) of Data Integrity and Compliance With Drug CGMP Questions and Answers Guidance for Industry: Guidance for Industry	12/12/2018	Center for Veterinary Medicine, Office of Regulatory Policy, Center for Biologics Evaluation and Research	Current Good Manufacturing Practices (CGMP), Pharmaceutical Quality	Final	No		FDA-2018-D-3984
User Fees and Refunds for Premarket Approval Applications and Device Biologics License Applications : Guidance for Industry and Food and Drug Administration Staff	PDF (151.8 KB)PDF (151.8 KB) of User Fees and Refunds for Premarket Approval Applications and Device Biologics License Applications : Guidance for Industry and Food and Drug Administration Staff	12/12/2018	Center for Devices and Radiological Health	Premarket, User Fees,	Final	No		FDA-2009-D-0051
Biomarker Qualification: Evidentiary Framework: Draft Guidance for Industry and FDA Staff	PDF (346.05 KB)PDF (346.05 KB) of Biomarker Qualification: Evidentiary Framework: Draft Guidance for Industry and FDA Staff	12/11/2018	Center for Drug Evaluation and Research	Drug Development Tools	Draft	No	02/11/2019	2018-26900
Interpretation of the “Deemed to be a License” Provision of the Biologics Price Competition and Innovation Act of 2009 : Guidance for Industry	PDF (410.32 KB)PDF (410.32 KB) of Interpretation of the “Deemed to be a License” Provision of the Biologics Price Competition and Innovation Act of 2009 : Guidance for Industry	12/11/2018	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Administrative / Procedural	Final	No		FDA-2015-D-4750
New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 2): Draft New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 2).”	PDF (679.16 KB)PDF (679.16 KB) of New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 2): Draft New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 2).”	12/11/2018	Center for Drug Evaluation and Research	Biosimilarity	Draft	No	02/11/2019	FDA-2011-D-0611
Questions and Answers on Biosimilar Development and the BPCI Act Guidance for Industry: Guidance for Industry	PDF (342.59 KB)PDF (342.59 KB) of Questions and Answers on Biosimilar Development and the BPCI Act Guidance for Industry: Guidance for Industry	12/11/2018	Center for Drug Evaluation and Research	Biosimilarity	Final	No	02/11/2019	FDA-2011-D-0611
The “Deemed to be a License” Provision of the BPCI Act: Questions and Answers : Draft Guidance for Industry	PDF (446.48 KB)PDF (446.48 KB) of The “Deemed to be a License” Provision of the BPCI Act: Questions and Answers : Draft Guidance for Industry	12/11/2018	Office of Regulatory Policy, Center for Biologics Evaluation and Research	Administrative / Procedural	Draft	No	02/11/2019	2018-26855
Current Good Manufacturing Practice—Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act Guidance for Industry: Draft Guidance for Industry	PDF (476.16 KB)PDF (476.16 KB) of Current Good Manufacturing Practice—Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act Guidance for Industry: Draft Guidance for Industry	12/10/2018	Center for Drug Evaluation and Research	Compounding, Current Good Manufacturing Practices (CGMP), Pharmaceutical Quality	Draft	No	02/11/2019	2018-26724

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Developing and Labeling In vitro Companion Diagnostic Devices for a Specific Group or Class of Oncology Therapeutic Products: Draft Guidance for Industry	PDF (103.56 KB)PDF (103.56 KB) of Developing and Labeling In vitro Companion Diagnostic Devices for a Specific Group or Class of Oncology Therapeutic Products: Draft Guidance for Industry	12/07/2018	Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research, Oncology Center of Excellence	Premarket, Labeling	Draft	No	02/05/2019	FDA-2018-D-3380
Noncirrhotic Nonalcoholic Steatohepatitis With Liver Fibrosis: Developing Drugs for Treatment	PDF (97.63 KB)PDF (97.63 KB) of Noncirrhotic Nonalcoholic Steatohepatitis With Liver Fibrosis: Developing Drugs for Treatment	12/04/2018	Center for Drug Evaluation and Research	Clinical - Medical	Draft	No	02/04/2019	FDA-2018-D-3632
Post-Complete Response Letter Meetings Between the Food and Drug Administration and Abbreviated New Drug Application Applicants Under Generic Drug User Fee Amendments	PDF (100.84 KB)PDF (100.84 KB) of Post-Complete Response Letter Meetings Between the Food and Drug Administration and Abbreviated New Drug Application Applicants Under Generic Drug User Fee Amendments	12/04/2018	Center for Drug Evaluation and Research	User Fees, Generic Drugs	Final	No		FDA-2017-D-5928
Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use: Draft Guidance for Industry and Food and Drug Administration Staff	PDF (365.34 KB)PDF (365.34 KB) of Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use: Draft Guidance for Industry and Food and Drug Administration Staff	11/30/2018	Center for Devices and Radiological Health	510(k), CLIA (Clinical Laboratory Improvement Amendments), General Hospital & Personal Use , Clinical Chemistry & Clinical Toxicology	Draft	No	02/28/2019	FDA-2013-D-1445
Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use: Draft Guidance for Industry and Food and Drug Administration Staff	PDF (328.21 KB)PDF (328.21 KB) of Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use: Draft Guidance for Industry and Food and Drug Administration Staff	11/30/2018	Center for Devices and Radiological Health	510(k), CLIA (Clinical Laboratory Improvement Amendments), IVDs (In Vitro Diagnostic Devices), General Hospital & Personal Use , Clinical Chemistry & Clinical Toxicology	Draft	No	02/28/2019	FDA-2013-D-1446
Recommendations for Dual 510(k) and CLIA Waiver by Application Studies: Draft Guidance for Industry and Food and Drug Administration Staff	PDF (205.59 KB)PDF (205.59 KB) of Recommendations for Dual 510(k) and CLIA Waiver by Application Studies: Draft Guidance for Industry and Food and Drug Administration Staff	11/29/2018	Center for Devices and Radiological Health	510(k), CLIA (Clinical Laboratory Improvement Amendments)	Draft	No	02/27/2019	FDA-2017-D-5625
Select Updates for Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices: Draft Guidance for Industry and Food and Drug Administration Staff	PDF (458.5 KB)PDF (458.5 KB) of Select Updates for Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices: Draft Guidance for Industry and Food and Drug Administration Staff	11/29/2018	Center for Devices and Radiological Health	CLIA (Clinical Laboratory Improvement Amendments)	Draft	No	02/28/2019	FDA-2017-D-5570
Guidance for Industry and FDA: Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/Processors with Interest in Exporting to Chile	PDF (64.85 KB)PDF (64.85 KB) of Guidance for Industry and FDA: Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/Processors with Interest in Exporting to Chile	11/27/2018	Office of Food Safety	Export, Import	Final	No		FDA-2006-N-0183
Guidance for Industry: Establishing and Maintaining a List of U.S. Milk and Milk Product, Seafood, Infant Formula, and Formula for Young Children Manufacturers/Processors with Interest in Exporting to China	PDF (52.84 KB)PDF (52.84 KB) of Guidance for Industry: Establishing and Maintaining a List of U.S. Milk and Milk Product, Seafood, Infant Formula, and Formula for Young Children Manufacturers/Processors with Interest in Exporting to China	11/27/2018	Office of Food Safety	Export	Final	No		

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
CVM GFI #243 (VICH GL56) Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Species: Study Design Recommendations for Residue Studies in Honey for Establishing Maximum Residue Limits and Withdrawal Periods	PDF (202.44 KB)PDF (202.44 KB) of CVM GFI #243 (VICH GL56) Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Species: Study Design Recommendations for Residue Studies in Honey for Establishing Maximum Residue Limits and Withdrawal Periods	11/14/2018	Center for Veterinary Medicine	Human Food Safety, VICH	Final	No	03/06/2017	FDA-2016-D-4461
Nonmetastatic, Castration-Resistant Prostate Cancer: Considerations for Metastasis-Free Survival Endpoint in Clinical Trials	PDF (72.48 KB)PDF (72.48 KB) of Nonmetastatic, Castration-Resistant Prostate Cancer: Considerations for Metastasis-Free Survival Endpoint in Clinical Trials	11/14/2018	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Clinical - Medical	Draft	No	01/14/2019	FDA-2018-D-3931
Hypertension: Developing Fixed-Dose Combination Drugs for Treatment	PDF (95.73 KB)PDF (95.73 KB) of Hypertension: Developing Fixed-Dose Combination Drugs for Treatment	11/07/2018	Center for Drug Evaluation and Research	Clinical - Medical	Final	No	01/26/2019	FDA-2018-D-3860
Meta-Analyses of Randomized Controlled Clinical Trials to Evaluate the Safety of Human Drugs or Biological Products	PDF (227.44 KB)PDF (227.44 KB) of Meta-Analyses of Randomized Controlled Clinical Trials to Evaluate the Safety of Human Drugs or Biological Products	11/07/2018	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Device & Drug Safety	Draft	No	01/07/2019	FDA-2018-D-3710
Guidance for Industry and FDA Staff: Questions and Answers Regarding Mandatory Food Recalls	PDF (113.13 KB)PDF (113.13 KB) of Guidance for Industry and FDA Staff: Questions and Answers Regarding Mandatory Food Recalls	11/06/2018	Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine, Office of Regulatory Affairs	Recalls,	Final	No	07/06/2015	FDA-2015-D-0138
Listing of Ingredients in Tobacco Products: Guidance for Industry		11/06/2018	Center for Tobacco Products		Final	No	12/01/2009	
Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marking: Immediately in Effect Guidance for Industry and Food and Drug Administration Staff	PDF (374.14 KB)PDF (374.14 KB) of Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marking: Immediately in Effect Guidance for Industry and Food and Drug Administration Staff	11/05/2018	Center for Devices and Radiological Health	Investigation & Enforcement, Labeling, Safety - Issues, Errors, and Problems	Final	No		FDA-2017-D-6841
Chronic Hepatitis B Virus Infection: Developing Drugs for Treatment	PDF (506.95 KB)PDF (506.95 KB) of Chronic Hepatitis B Virus Infection: Developing Drugs for Treatment	11/02/2018	Center for Drug Evaluation and Research	Clinical - Antimicrobial	Final	No	01/02/2019	FDA-2018-D-3903
Draft Guidance for Industry: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion, Reference Amounts Customarily Consumed, Serving Size-Related Issues, Dual-Column Labeling, and Miscellaneous Topics	PDF (326.61 KB)PDF (326.61 KB) of Draft Guidance for Industry: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion, Reference Amounts Customarily Consumed, Serving Size-Related Issues, Dual-Column Labeling, and Miscellaneous Topics	11/02/2018	Office of Nutrition and Food Labeling	Labeling, Nutrition Label	Draft	No	01/04/2019	FDA-2018-D-1459
Guidance for Industry: Nutrition and Supplement Facts Labels Questions and Answers Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals	PDF (226.13 KB)PDF (226.13 KB) of Guidance for Industry: Nutrition and Supplement Facts Labels Questions and Answers Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals	11/02/2018	Office of Nutrition and Food Labeling	Labeling, Nutrition Label	Final	No		FDA-2016-D-4414
Considerations for the Development of Dried Plasma Products Intended for Transfusion: Draft Draft Guidance for Industry	PDF (103.74 KB)PDF (103.74 KB) of Considerations for the Development of Dried Plasma Products Intended for Transfusion: Draft Draft Guidance for Industry	10/29/2018	Center for Biologics Evaluation and Research	Blood Products	Draft	No	01/28/2019	FDA-2018-D-3759

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M9 Biopharmaceutics Classification System-Based Biowaivers	PDF (460.2 KB)PDF (460.2 KB) of M9 Biopharmaceutics Classification System-Based Biowaivers	10/26/2018	Center for Drug Evaluation and Research	ICH-Multidisciplinary	Draft	No	01/24/2019	FDA-2018-D-3614
Testicular Toxicity: Evaluation During Drug Development	PDF (180.41 KB)PDF (180.41 KB) of Testicular Toxicity: Evaluation During Drug Development	10/25/2018	Center for Drug Evaluation and Research	Clinical - Medical, Pharm/Tox	Final	No		FDA-2015-D-2306
Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs: Draft Guidance for Industry	PDF (356.73 KB)PDF (356.73 KB) of Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs: Draft Guidance for Industry	10/25/2018	Office of Regulatory Policy, Center for Biologics Evaluation and Research	Administrative / Procedural	Draft	No	12/24/2018	FDA-2018-D-3462
Draft Guidance for Industry: Guide to Minimize Food Safety Hazards of Fresh-cut Produce	PDF (446.91 KB)PDF (446.91 KB) of Draft Guidance for Industry: Guide to Minimize Food Safety Hazards of Fresh-cut Produce	10/22/2018	Center for Food Safety and Applied Nutrition	Fruit/Fruit Product , Vegetable Products	Draft	No	04/22/2019	FDA-2018-D-3583
Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	PDF (1.72 MB)PDF (1.72 MB) of Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	10/22/2018	Office of Food Safety	Fruit/Fruit Product , Vegetable Products	Draft	No	04/22/2019	FDA-2018-D-3631
Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	PDF (144.64 KB)PDF (144.64 KB) of Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	10/22/2018	Office of Food Safety	Fruit/Fruit Product , Vegetable Products	Draft	No	04/22/2019	FDA-2018-D-3631
Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	PDF (91.61 KB)PDF (91.61 KB) of Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	10/22/2018	Office of Food Safety	Fruit/Fruit Product , Vegetable Products	Draft	No	04/22/2019	FDA-2018-D-3631
Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	PDF (77.74 KB)PDF (77.74 KB) of Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	10/22/2018	Office of Food Safety	Fruit/Fruit Product , Vegetable Products	Draft	No	04/22/2019	FDA-2018-D-3631
Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	PDF (67.71 KB)PDF (67.71 KB) of Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	10/22/2018	Office of Food Safety	Fruit/Fruit Product , Vegetable Products	Draft	No	04/22/2019	FDA-2018-D-3631
Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	PDF (77.94 KB)PDF (77.94 KB) of Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	10/22/2018	Office of Food Safety	Fruit/Fruit Product , Vegetable Products	Draft	No	04/22/2019	FDA-2018-D-3631
Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	PDF (72.42 KB)PDF (72.42 KB) of Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	10/22/2018	Office of Food Safety	Fruit/Fruit Product , Vegetable Products	Draft	No	04/22/2019	FDA-2018-D-3631
Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	PDF (112.25 KB)PDF (112.25 KB) of Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	10/22/2018	Office of Food Safety	Fruit/Fruit Product , Vegetable Products	Draft	No	04/22/2019	FDA-2018-D-3631

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Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	PDF (54.14 KB)PDF (54.14 KB) of Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	10/22/2018	Office of Food Safety	Fruit/Fruit Product , Vegetable Products	Draft	No	04/22/2019	FDA-2018-D-3631
Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	PDF (60.07 KB)PDF (60.07 KB) of Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	10/22/2018	Office of Food Safety	Fruit/Fruit Product , Vegetable Products	Draft	No	04/22/2019	FDA-2018-D-3631
Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	PDF (51.45 KB)PDF (51.45 KB) of Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	10/22/2018	Office of Food Safety	Fruit/Fruit Product , Vegetable Products	Draft	No	04/22/2019	FDA-2018-D-3631
Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	PDF (62.25 KB)PDF (62.25 KB) of Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	10/22/2018	Office of Food Safety	Fruit/Fruit Product , Vegetable Products	Draft	No	04/22/2019	FDA-2018-D-3631
Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	ZIP (823.11 KB)ZIP (823.11 KB) of Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	10/22/2018	Office of Food Safety	Fruit/Fruit Product , Vegetable Products	Draft	No	04/22/2019	FDA-2018-D-3631
Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	PDF (98.74 KB)PDF (98.74 KB) of Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	10/22/2018	Office of Food Safety	Fruit/Fruit Product , Vegetable Products	Draft	No	04/22/2019	FDA-2018-D-3631
Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	PDF (94.67 KB)PDF (94.67 KB) of Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	10/22/2018	Office of Food Safety	Fruit/Fruit Product , Vegetable Products	Draft	No	04/22/2019	FDA-2018-D-3631
Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	PDF (83.97 KB)PDF (83.97 KB) of Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	10/22/2018	Office of Food Safety	Fruit/Fruit Product , Vegetable Products	Draft	No	04/22/2019	FDA-2018-D-3631
Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	PDF (86.64 KB)PDF (86.64 KB) of Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	10/22/2018	Office of Food Safety	Fruit/Fruit Product , Vegetable Products	Draft	No	04/22/2019	FDA-2018-D-3631
Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	PDF (86.64 KB)PDF (86.64 KB) of Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	10/22/2018	Office of Food Safety	Fruit/Fruit Product , Vegetable Products	Draft	No	04/22/2019	FDA-2018-D-3631
Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	PDF (87.15 KB)PDF (87.15 KB) of Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	10/22/2018	Office of Food Safety	Fruit/Fruit Product , Vegetable Products	Draft	No	04/22/2019	FDA-2018-D-3631

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	PDF (119.03 KB)PDF (119.03 KB) of Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	10/22/2018	Office of Food Safety	Fruit/Fruit Product , Vegetable Products	Draft	No	04/22/2019	FDA-2018-D-3631
Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	PDF (90.34 KB)PDF (90.34 KB) of Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	10/22/2018	Office of Food Safety	Fruit/Fruit Product , Vegetable Products	Draft	No	04/22/2019	FDA-2018-D-3631
Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	PDF (70.23 KB)PDF (70.23 KB) of Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	10/22/2018	Office of Food Safety	Fruit/Fruit Product , Vegetable Products	Draft	No	04/22/2019	FDA-2018-D-3631
Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	PDF (68.66 KB)PDF (68.66 KB) of Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	10/22/2018	Office of Food Safety	Fruit/Fruit Product , Vegetable Products	Draft	No	04/22/2019	FDA-2018-D-3631
Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	PDF (54.45 KB)PDF (54.45 KB) of Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	10/22/2018	Office of Food Safety	Fruit/Fruit Product , Vegetable Products	Draft	No	04/22/2019	FDA-2018-D-3631
Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	PDF (129.37 KB)PDF (129.37 KB) of Draft Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	10/22/2018	Office of Food Safety	Fruit/Fruit Product , Vegetable Products	Draft	No	04/22/2019	FDA-2018-D-3631
Content of Premarket Submissions for Management of Cybersecurity in Medical Devices: Draft Guidance for Industry and Food and Drug Administration Staff	PDF (603.86 KB)PDF (603.86 KB) of Content of Premarket Submissions for Management of Cybersecurity in Medical Devices: Draft Guidance for Industry and Food and Drug Administration Staff	10/18/2018	Center for Devices and Radiological Health	510(k), Premarket Approval (PMA), Digital Health	Draft	No	03/17/2019	FDA-2018-D-3443
Developing Targeted Therapies in Low-Frequency Molecular Subsets of a Disease	PDF (90.9 KB)PDF (90.9 KB) of Developing Targeted Therapies in Low-Frequency Molecular Subsets of a Disease	10/16/2018	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research		Final	No		FDA-2017-D-6617
Hematologic Malignancies: Regulatory Considerations for Use of Minimal Residual Disease in Development of Drug and Biological Products for Treatment: Draft Guidance for Industry	PDF (160.75 KB)PDF (160.75 KB) of Hematologic Malignancies: Regulatory Considerations for Use of Minimal Residual Disease in Development of Drug and Biological Products for Treatment: Draft Guidance for Industry	10/16/2018	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Clinical - Medical	Draft	No	12/17/2018	FDA-2018-D-3090
Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer Promotional Labeling and Advertisements: Draft Guidance for Industry	PDF (161.08 KB)PDF (161.08 KB) of Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer Promotional Labeling and Advertisements: Draft Guidance for Industry	10/16/2018	Center for Veterinary Medicine, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research		Draft	No	12/17/2018	FDA-2018-D-2613
Rare Diseases: Early Drug Development and the Role of Pre-IND Meetings : Draft Guidance for Industry	PDF (131.81 KB)PDF (131.81 KB) of Rare Diseases: Early Drug Development and the Role of Pre-IND Meetings : Draft Guidance for Industry	10/16/2018	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research		Draft	No	12/17/2018	FDA-2018-D-3268

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Impact of Certain Provisions of the Revised Common Rule on FDA-Regulated Clinical Investigations: Guidance for Sponsors, Investigators, and Institutional Review Boards	PDF (135.4 KB)PDF (135.4 KB) of Impact of Certain Provisions of the Revised Common Rule on FDA-Regulated Clinical Investigations: Guidance for Sponsors, Investigators, and Institutional Review Boards	10/11/2018	Office of Good Clinical Practice	Good Clinical Practices (GCP)	Final	No		FDA-2018-D-3551
Assessing the Irritation and Sensitization Potential of Transdermal and Topical Delivery Systems for ANDAs: Draft Guidance for Industry	PDF (235.12 KB)PDF (235.12 KB) of Assessing the Irritation and Sensitization Potential of Transdermal and Topical Delivery Systems for ANDAs: Draft Guidance for Industry	10/10/2018	Center for Drug Evaluation and Research	Generic Drugs	Draft	No	12/10/2018	FDA-2018-D-3546
Assessing Adhesion with Transdermal Delivery Systems and Topical Patches for ANDAs Draft Guidance for Industry	PDF (186.56 KB)PDF (186.56 KB) of Assessing Adhesion with Transdermal Delivery Systems and Topical Patches for ANDAs Draft Guidance for Industry	10/09/2018	Center for Drug Evaluation and Research	Generic Drugs	Draft	No	07/31/2016	
Atopic Dermatitis: Timing of Pediatric Studies During Development of Systemic Drugs	PDF (70.95 KB)PDF (70.95 KB) of Atopic Dermatitis: Timing of Pediatric Studies During Development of Systemic Drugs	10/03/2018	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Clinical - Medical	Final	No		FDA-2018-D-1175
Selection of the Appropriate Package Type Terms and Recommendations for Labeling Injectable Medical Products Packaged in Multiple-Dose, Single-Dose, and Single-Patient-Use Containers for Human Use: Guidance for Industry	PDF (166.88 KB)PDF (166.88 KB) of Selection of the Appropriate Package Type Terms and Recommendations for Labeling Injectable Medical Products Packaged in Multiple-Dose, Single-Dose, and Single-Patient-Use Containers for Human Use: Guidance for Industry	10/03/2018	Office of Combination Products, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Combination Products, Pharmaceutical Quality	Final	No		FDA-2015-D-3438
Master Protocols: Efficient Clinical Trial Design Strategies To Expedite Development of Oncology Drugs and Biologics: Draft Guidance for Industry	PDF (479.44 KB)PDF (479.44 KB) of Master Protocols: Efficient Clinical Trial Design Strategies To Expedite Development of Oncology Drugs and Biologics: Draft Guidance for Industry	10/01/2018	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, Oncology Center of Excellence	Administrative / Procedural	Draft	No	11/30/2018	FDA-2018-D-3292
Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act	PDF (138.48 KB)PDF (138.48 KB) of Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act	09/28/2018	Center for Drug Evaluation and Research	Compounding, Safety - Issues, Errors, and Problems	Final	No	05/17/2015	
Contents of a Complete Submission for Threshold Analyses and Human Factors Submissions to Drug and Biologic Applications	PDF (457.33 KB)PDF (457.33 KB) of Contents of a Complete Submission for Threshold Analyses and Human Factors Submissions to Drug and Biologic Applications	09/28/2018	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Administrative / Procedural	Draft	No		FDA-2018-D-3275
Public Availability of Lists of Retail Consignees to Effectuate Certain Human and Animal Food Recalls	PDF (59.87 KB)PDF (59.87 KB) of Public Availability of Lists of Retail Consignees to Effectuate Certain Human and Animal Food Recalls	09/26/2018	Office of Regulatory Affairs	Recalls, Retail Food Protection	Draft	No	11/26/2018	
Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications (510(k)) with Different Technological Characteristics: Guidance for Industry and Food and Drug Administration Staff	PDF (537.58 KB)PDF (537.58 KB) of Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications (510(k)) with Different Technological Characteristics: Guidance for Industry and Food and Drug Administration Staff	09/25/2018	Center for Devices and Radiological Health	510(k)	Final	No		FDA-2014-D-0900
Compounding and Repackaging of Radiopharmaceuticals By Outsourcing Facilities Guidance for Industry	PDF (324.37 KB)PDF (324.37 KB) of Compounding and Repackaging of Radiopharmaceuticals By Outsourcing Facilities Guidance for Industry	09/25/2018	Center for Drug Evaluation and Research	Compounding	Final	No		

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies and Federal Facilities Guidance for Industry	PDF (306.64 KB)PDF (306.64 KB) of Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies and Federal Facilities Guidance for Industry	09/25/2018	Center for Drug Evaluation and Research	Compounding	Final	No		FDA-2016-D-4318
Insanitary Conditions at Compounding Facilities Guidance for Industry	PDF (342.63 KB)PDF (342.63 KB) of Insanitary Conditions at Compounding Facilities Guidance for Industry	09/25/2018	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Administrative / Procedural, Compounding	Draft	No		
Good Review Management Principles and Practices for New Drug Applications and Biologics License Applications: Draft Guidance for Industry and Review Staff	PDF (98.25 KB)PDF (98.25 KB) of Good Review Management Principles and Practices for New Drug Applications and Biologics License Applications: Draft Guidance for Industry and Review Staff	09/24/2018	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Administrative / Procedural	Draft	No	11/23/2018	
Heparin-Containing Medical Devices and Combination Products: Recommendations for Labeling and Safety Testing: Guidance for Industry and Food and Drug Administration Staff	PDF (345.46 KB)PDF (345.46 KB) of Heparin-Containing Medical Devices and Combination Products: Recommendations for Labeling and Safety Testing: Guidance for Industry and Food and Drug Administration Staff	09/20/2018	Center for Devices and Radiological Health	Premarket, 510(k), Combination Products, Premarket Approval (PMA), HUD/HDE	Final	No		FDA-2015-D-2167
Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank: Draft Guidance for FDA Staff, Responsible Parties, and Submitters of Certain Applications and Submissions to FDA	PDF (78.75 KB)PDF (78.75 KB) of Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank: Draft Guidance for FDA Staff, Responsible Parties, and Submitters of Certain Applications and Submissions to FDA	09/19/2018	Office of Regulatory Affairs, Office of Good Clinical Practice, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Good Clinical Practices (GCP)	Draft	No	11/19/2018	FDA-2018-D-0787
Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier	PDF (319.01 KB)PDF (319.01 KB) of Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier	09/19/2018	Center for Drug Evaluation and Research	Administrative / Procedural	Final	No		
Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act: Questions and Answers	PDF (119.41 KB)PDF (119.41 KB) of Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act: Questions and Answers	09/19/2018	Center for Drug Evaluation and Research	Over-the-Counter Drugs	Final	No		
Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy Guidance for Industry	PDF (249.15 KB)PDF (249.15 KB) of Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy Guidance for Industry	09/19/2018	Center for Drug Evaluation and Research	Administrative / Procedural	Final	No		
Product Identifiers under the Drug Supply Chain Security Act - Questions and Answers	PDF (363.18 KB)PDF (363.18 KB) of Product Identifiers under the Drug Supply Chain Security Act - Questions and Answers	09/19/2018	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Labeling	Draft	No	11/19/2018	FDA-2018-D-3175
Guidance for Industry: Determination of Status as a Qualified Facility	PDF (236.61 KB)PDF (236.61 KB) of Guidance for Industry: Determination of Status as a Qualified Facility	09/17/2018	Office of Compliance, Office of Surveillance and Compliance		Final	No		FDA-2016-D-1164

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
510(k) Third Party Review Program: Draft Guidance for Industry, Food and Drug Administration Staff, and Third Party Review Organizations	PDF (781.11 KB)PDF (781.11 KB) of 510(k) Third Party Review Program: Draft Guidance for Industry, Food and Drug Administration Staff, and Third Party Review Organizations	09/14/2018	Center for Devices and Radiological Health	Premarket, 510(k), Administrative / Procedural	Draft	No	12/13/2018	FDA-2016-D-2565
Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices: Guidance for Industry and Food and Drug Administration Staff	PDF (400.61 KB)PDF (400.61 KB) of Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices: Guidance for Industry and Food and Drug Administration Staff	09/14/2018	Center for Devices and Radiological Health	Postmarket, Premarket, Administrative / Procedural	Final	No		FDA-2014-D-0456
Recognition and Withdrawal of Voluntary Consensus Standards: Draft Guidance for Industry and Food and Drug Administration Staff	PDF (515.36 KB)PDF (515.36 KB) of Recognition and Withdrawal of Voluntary Consensus Standards: Draft Guidance for Industry and Food and Drug Administration Staff	09/14/2018	Center for Devices and Radiological Health	Premarket, Administrative / Procedural	Draft	No	11/13/2018	FDA-2018-D-2936
Draft Guidance for Industry: Policy Regarding Quantitative Labeling of Dietary Supplements Containing Live Microbials	PDF (116.62 KB)PDF (116.62 KB) of Draft Guidance for Industry: Policy Regarding Quantitative Labeling of Dietary Supplements Containing Live Microbials	09/07/2018	Office of Dietary Supplement Programs		Draft	No	11/06/2018	FDA-2011-D-0376
Allergic Rhinitis: Developing Drug Products for Treatment Guidance for Industry	PDF (120.43 KB)PDF (120.43 KB) of Allergic Rhinitis: Developing Drug Products for Treatment Guidance for Industry	09/05/2018	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		
Nonallergic Rhinitis: Developing Drug Products for Treatment	PDF (75.16 KB)PDF (75.16 KB) of Nonallergic Rhinitis: Developing Drug Products for Treatment	09/05/2018	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		
Physiologically Based Pharmacokinetic Analyses — Format and Content Guidance for Industry	PDF (87.1 KB)PDF (87.1 KB) of Physiologically Based Pharmacokinetic Analyses — Format and Content Guidance for Industry	09/04/2018	Center for Drug Evaluation and Research	Clinical - Pharmacology	Final	No		FDA-2016-D-3969
Recommendations for Requalification of Blood Donors Deferred Because of Reactive Test Results for Antibodies to Human T-Lymphotropic Virus Types I and II (anti-HTLV-I/II): Draft Draft Guidance for Industry	PDF (434.49 KB)PDF (434.49 KB) of Recommendations for Requalification of Blood Donors Deferred Because of Reactive Test Results for Antibodies to Human T-Lymphotropic Virus Types I and II (anti-HTLV-I/II): Draft Draft Guidance for Industry	09/01/2018	Center for Biologics Evaluation and Research	Blood Products	Draft	No	12/24/2018	FDA-2018-D-3324
Osteoarthritis: Structural Endpoints for the Development of Drugs	PDF (59.55 KB)PDF (59.55 KB) of Osteoarthritis: Structural Endpoints for the Development of Drugs	08/22/2018	Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Clinical - Medical	Draft	No	11/22/2018	FDA-2018-D-2896
Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Seventh Edition)	PDF (463.59 KB)PDF (463.59 KB) of Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Seventh Edition)	08/20/2018	Office of Foods and Veterinary Medicine, Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine, Office of Regulatory Affairs	Food & Beverage Safety, Food & Beverage Safety	Final	No		FDA-2012-D-1002
Microdose Radiopharmaceutical Diagnostic Drugs: Nonclinical Study Recommendations: Guidance for Industry	PDF (83.23 KB)PDF (83.23 KB) of Microdose Radiopharmaceutical Diagnostic Drugs: Nonclinical Study Recommendations: Guidance for Industry	08/20/2018	Center for Drug Evaluation and Research	Pharm/Tox	Final	No		

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Quality Attribute Considerations for Chewable Tablets Guidance for Industry	PDF (169.2 KB)PDF (169.2 KB) of Quality Attribute Considerations for Chewable Tablets Guidance for Industry	08/20/2018	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		
Expansion Cohorts: Use in First-In-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics Guidance for Industry	PDF (145.25 KB)PDF (145.25 KB) of Expansion Cohorts: Use in First-In-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics Guidance for Industry	08/10/2018	Center for Drug Evaluation and Research	Administrative / Procedural	Draft	No	11/09/2018	
Compliance Policy for Certain Labeling and Warning Statement Requirements for Cigars and Pipe Tobacco: Guidance for Industry		08/09/2018	Center for Tobacco Products		Final	No		
Compliance Policy for Required Warning Statements on Small-Packaged Cigars: Guidance for Industry		08/09/2018	Center for Tobacco Products		Final	No		
Submission of Warning Plans for Cigars: Guidance for Industry		08/09/2018	Center for Tobacco Products		Final	No		
Tobacco Retailer Training Programs: Guidance for Industry		08/09/2018	Center for Tobacco Products		Final	No	09/04/2013	
Dissolution Testing and Acceptance Criteria for Immediate-Release Solid Oral Dosage Form Drug Products Containing High Solubility Drug Substances Guidance for Industry	PDF (103.25 KB)PDF (103.25 KB) of Dissolution Testing and Acceptance Criteria for Immediate-Release Solid Oral Dosage Form Drug Products Containing High Solubility Drug Substances Guidance for Industry	08/08/2018	Center for Drug Evaluation and Research	Biopharmaceutics	Final	No		FDA-2018-D-2614
Elemental Impurities in Drug Products Guidance for Industry	PDF (91.65 KB)PDF (91.65 KB) of Elemental Impurities in Drug Products Guidance for Industry	08/07/2018	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		
Opioid Use Disorder: Endpoints for Demonstrating Effectiveness of Drugs for Medication-Assisted Treatment Guidance for Industry	PDF (67.11 KB)PDF (67.11 KB) of Opioid Use Disorder: Endpoints for Demonstrating Effectiveness of Drugs for Medication-Assisted Treatment Guidance for Industry	08/06/2018	Center for Drug Evaluation and Research	Clinical - Medical	Draft	No	11/06/2018	
Nonclinical Testing of Orally Inhaled Nicotine-Containing Drug Products Guidance for Industry	PDF (115.22 KB)PDF (115.22 KB) of Nonclinical Testing of Orally Inhaled Nicotine-Containing Drug Products Guidance for Industry	08/03/2018	Center for Drug Evaluation and Research	Pharm/Tox	Draft	No	11/02/2018	FDA-2018-D-2583
Medical Device User Fee Small Business Qualification and Certification: Guidance for Industry, Food and Drug Administration Staff and Foreign Governments	PDF (223.07 KB)PDF (223.07 KB) of Medical Device User Fee Small Business Qualification and Certification: Guidance for Industry, Food and Drug Administration Staff and Foreign Governments	08/01/2018	Center for Devices and Radiological Health	User Fees, Administrative / Procedural, Laser Notice	Final	No		FDA-2017-N-0007
Draft Guidance for Industry: Supplemental Questions and Answers Regarding Food Facility Registration	PDF (65.8 KB)PDF (65.8 KB) of Draft Guidance for Industry: Supplemental Questions and Answers Regarding Food Facility Registration	07/31/2018	Office of Foods and Veterinary Medicine, Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine, Office of Regulatory Affairs		Draft	No	08/20/2018	FDA-2012-D-1002
Peripheral Vascular Atherectomy Devices - Premarket Notification [510(k)] Submissions: Draft Guidance for Industry and Food and Drug Administration Staff	PDF (400.01 KB)PDF (400.01 KB) of Peripheral Vascular Atherectomy Devices - Premarket Notification [510(k)] Submissions: Draft Guidance for Industry and Food and Drug Administration Staff	07/27/2018	Center for Devices and Radiological Health	Premarket, 510(k), Labeling, Cardiovascular	Draft	No	09/25/2018	FDA-2018-D-2494

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Slowly Progressive, Low-Prevalence Rare Diseases with Substrate Deposition That Results from Single Enzyme Defects: Providing Evidence of Effectiveness for Replacement or Corrective Therapies Guidance for Industry: Draft Guidance for Industry	PDF (111.03 KB)PDF (111.03 KB) of Slowly Progressive, Low-Prevalence Rare Diseases with Substrate Deposition That Results from Single Enzyme Defects: Providing Evidence of Effectiveness for Replacement or Corrective Therapies Guidance for Industry: Draft Guidance for Industry	07/26/2018	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research		Draft	No	10/26/2018	
Use of Liquids and/or Soft Foods as Vehicles for Drug Administration: General Considerations for Selection and In Vitro Methods for Product Quality Assessments	PDF (410.15 KB)PDF (410.15 KB) of Use of Liquids and/or Soft Foods as Vehicles for Drug Administration: General Considerations for Selection and In Vitro Methods for Product Quality Assessments	07/24/2018	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Draft	No	10/24/2018	FDA-2018-D-2544
Inborn Errors of Metabolism That Use Dietary Management: Considerations for Optimizing and Standardizing Diet in Clinical Trials for Drug Product Development: Guidance for Industry	PDF (83.71 KB)PDF (83.71 KB) of Inborn Errors of Metabolism That Use Dietary Management: Considerations for Optimizing and Standardizing Diet in Clinical Trials for Drug Product Development: Guidance for Industry	07/23/2018	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Clinical - Medical	Draft	No		FDA-2018-15777
Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs): Draft Draft Guidance for Industry	PDF (577.76 KB)PDF (577.76 KB) of Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs): Draft Draft Guidance for Industry	07/20/2018	Center for Biologics Evaluation and Research	Cellular & Gene Therapy, Gene Therapy	Draft	No	10/10/2018	2008-D-0205
E17 General Principles for Planning and Design of Multi-Regional Clinical Trials	PDF (403.56 KB)PDF (403.56 KB) of E17 General Principles for Planning and Design of Multi-Regional Clinical Trials	07/18/2018	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Efficacy	Final	No	11/08/2016	2018-15395
Field Alert Report Submission: Questions and Answers Guidance for Industry: Draft Guidance for Industry	PDF (123.2 KB)PDF (123.2 KB) of Field Alert Report Submission: Questions and Answers Guidance for Industry: Draft Guidance for Industry	07/18/2018	Office of Regulatory Affairs, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Current Good Manufacturing Practices (CGMP), Pharmaceutical Quality	Draft	No	10/18/2018	2018-15389
Labeling for Biosimilar Products Guidance for Industry	PDF (284.71 KB)PDF (284.71 KB) of Labeling for Biosimilar Products Guidance for Industry	07/18/2018	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Labeling	Final	No	10/18/2018	FDA-2016-D-0643
Real World Data / Real World Evidence RWD/RWE		07/18/2018	Center for Drug Evaluation and Research		Final	No		
Use of Electronic Health Record Data in Clinical Investigations Guidance for Industry	PDF (327.2 KB)PDF (327.2 KB) of Use of Electronic Health Record Data in Clinical Investigations Guidance for Industry	07/18/2018	Center for Drug Evaluation and Research	Administrative / Procedural	Final	No		FDA-2016-D-1224
Innovative Approaches for Nonprescription Drug Products	PDF (246.74 KB)PDF (246.74 KB) of Innovative Approaches for Nonprescription Drug Products	07/17/2018	Center for Drug Evaluation and Research	Over-the-Counter Drugs	Draft	No	10/17/2018	FDA-2018-D-2281
Hypertension: Conducting Studies of Drugs to Treat Patients on a Background of Multiple Antihypertensive Drugs Guidance for Industry	PDF (56.96 KB)PDF (56.96 KB) of Hypertension: Conducting Studies of Drugs to Treat Patients on a Background of Multiple Antihypertensive Drugs Guidance for Industry	07/13/2018	Center for Drug Evaluation and Research	Clinical - Medical	Draft	No	10/12/2018	FDA-2018-D-2515
Q3D(R1) ELEMENTAL IMPURITIES	PDF (177.13 KB)PDF (177.13 KB) of Q3D(R1) ELEMENTAL IMPURITIES	07/13/2018	Center for Drug Evaluation and Research	ICH-Quality	Draft	No		

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Human Gene Therapy for Hemophilia: Draft Draft Guidance for Industry	PDF (371.12 KB)PDF (371.12 KB) of Human Gene Therapy for Hemophilia: Draft Draft Guidance for Industry	07/11/2018	Center for Biologics Evaluation and Research	Cellular & Gene Therapy, Gene Therapy	Draft	No	10/18/2018	FDA 2018-D-2238
Human Gene Therapy for Rare Diseases: Draft Draft Guidance for Industry	PDF (136.08 KB)PDF (136.08 KB) of Human Gene Therapy for Rare Diseases: Draft Draft Guidance for Industry	07/11/2018	Center for Biologics Evaluation and Research	Cellular & Gene Therapy, Gene Therapy	Draft	No	10/10/2018	FDA-2018-D-2258
Human Gene Therapy for Retinal Disorders: Draft Draft Guidance for Industry	PDF (172.14 KB)PDF (172.14 KB) of Human Gene Therapy for Retinal Disorders: Draft Draft Guidance for Industry	07/11/2018	Center for Biologics Evaluation and Research	Cellular & Gene Therapy, Gene Therapy	Draft	No	10/10/2018	FDA-2018-D-2236
Long Term Follow-up After Administration of Human Gene Therapy Products: Draft Draft Guidance for Industry	PDF (293.75 KB)PDF (293.75 KB) of Long Term Follow-up After Administration of Human Gene Therapy Products: Draft Draft Guidance for Industry	07/11/2018	Center for Biologics Evaluation and Research	Cellular & Gene Therapy,	Draft	No	10/10/2018	FDA-2018-D-2173
Testing of Retroviral Vector-Based Human Gene Therapy Products for Replication Competent Retrovirus During Product Manufacture and Patient Follow-up: Draft Draft Guidance for Industry	PDF (128.43 KB)PDF (128.43 KB) of Testing of Retroviral Vector-Based Human Gene Therapy Products for Replication Competent Retrovirus During Product Manufacture and Patient Follow-up: Draft Draft Guidance for Industry	07/11/2018	Center for Biologics Evaluation and Research	Cellular & Gene Therapy, Gene Therapy	Draft	No	10/10/2018	FDA-1999-D-0081
Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components: Guidance for Industry	PDF (222.25 KB)PDF (222.25 KB) of Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components: Guidance for Industry	07/09/2018	Center for Biologics Evaluation and Research	Blood Products	Final	No		FDA-2016-D-0545
Indications and Usage Section of Labeling for Human Prescription Drug and Biological Products — Content and Format Guidance for Industry	PDF (480.52 KB)PDF (480.52 KB) of Indications and Usage Section of Labeling for Human Prescription Drug and Biological Products — Content and Format Guidance for Industry	07/06/2018	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Labeling	Draft	No	10/05/2018	FDA-2018-D-1895
ANDA Submissions — Amendments to Abbreviated New Drug Applications Under GDUFA: Guidance for Industry	PDF (219.25 KB)PDF (219.25 KB) of ANDA Submissions — Amendments to Abbreviated New Drug Applications Under GDUFA: Guidance for Industry	07/03/2018	Center for Drug Evaluation and Research	User Fees, Generic Drugs	Final	No		
Redbook 2000: IV.C.1.a. Bacterial Reverse Mutation Test		07/01/2018	Office of Food Additive Safety	Food & Color Additives	Final	No		
CVM GFI #252 Small Entity Compliance Guide Antimicrobial Animal Drug Sales and Distribution Reporting	PDF (34.08 KB)PDF (34.08 KB) of CVM GFI #252 Small Entity Compliance Guide Antimicrobial Animal Drug Sales and Distribution Reporting	06/29/2018	Center for Veterinary Medicine	Administrative / Procedural, Antimicrobial Resistance	Final	No		FDA-2012-N-0447
Assessing User Fees Under the Biosimilar User Fee Amendments of 2017 Guidance for Industry: Guidance for Industry	PDF (447.28 KB)PDF (447.28 KB) of Assessing User Fees Under the Biosimilar User Fee Amendments of 2017 Guidance for Industry: Guidance for Industry	06/28/2018	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	User Fees,	Final	No	02/15/2018	FDA-2017-D-6209
Major Depressive Disorder: Developing Drugs for Treatment	PDF (291.28 KB)PDF (291.28 KB) of Major Depressive Disorder: Developing Drugs for Treatment	06/20/2018	Center for Drug Evaluation and Research	Clinical - Medical	Draft	No	09/20/2018	FDA-2018-D-1919
CVM GFI #246 Hazard Analysis and Risk-Based Preventive Controls for Food for Animals: Supply-Chain Program	PDF (301.2 KB)PDF (301.2 KB) of CVM GFI #246 Hazard Analysis and Risk-Based Preventive Controls for Food for Animals: Supply-Chain Program	06/15/2018	Center for Veterinary Medicine	Administrative / Procedural, Animal Feed	Draft	No	12/12/2018	FDA-2018-D-1861

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Guidance for Industry: The Declaration of Certain Isolated or Synthetic Non-Digestible Carbohydrates as Dietary Fiber on Nutrition and Supplement Facts Labels	PDF (94.84 KB)PDF (94.84 KB) of Guidance for Industry: The Declaration of Certain Isolated or Synthetic Non-Digestible Carbohydrates as Dietary Fiber on Nutrition and Supplement Facts Labels	06/15/2018	Office of Nutrition and Food Labeling	Nutrition Label	Final	No		FDA-2018-D-1323
Logical Observation Identifiers Names and Codes for In Vitro Diagnostic Tests : Guidance for Industry and Food and Drug Administration Staff	PDF (322.78 KB)PDF (322.78 KB) of Logical Observation Identifiers Names and Codes for In Vitro Diagnostic Tests : Guidance for Industry and Food and Drug Administration Staff	06/15/2018	Center for Devices and Radiological Health	IVDs (In Vitro Diagnostic Devices), Labeling, Laboratory Tests, Digital Health	Final	No		FDA-2017-D-6982
S9 Nonclinical Evaluation for Anticancer Pharmaceuticals--Questions and Answers	PDF (536.49 KB)PDF (536.49 KB) of S9 Nonclinical Evaluation for Anticancer Pharmaceuticals--Questions and Answers	06/15/2018	Center for Drug Evaluation and Research	ICH-Safety	Final	No	11/16/2016	FDA-2009-D-0006
CVM GFI #3 General Principles for Evaluating the Human Food Safety of New Animal Drugs Used In Food-Producing Animals	PDF (390.46 KB)PDF (390.46 KB) of CVM GFI #3 General Principles for Evaluating the Human Food Safety of New Animal Drugs Used In Food-Producing Animals	06/12/2018	Center for Veterinary Medicine	Human Food Safety	Final	No	09/19/2016	FDA-2005-D-0155
Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities – Questions and Answers: Guidance for Industry and Review Staff	PDF (523.72 KB)PDF (523.72 KB) of Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities – Questions and Answers: Guidance for Industry and Review Staff	06/12/2018	Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research, Office of the Commissioner	Administrative / Procedural	Final	No		
Limited Population Pathway for Antibacterial and Antifungal Drugs Guidance for Industry	PDF (128.09 KB)PDF (128.09 KB) of Limited Population Pathway for Antibacterial and Antifungal Drugs Guidance for Industry	06/12/2018	Center for Drug Evaluation and Research	Administrative / Procedural	Draft	No	09/12/2018	FDA-2018-D-2032
Medical Product Communications That Are Consistent With the FDA-Required Labeling — Questions and Answers : Guidance for Industry	PDF (458.3 KB)PDF (458.3 KB) of Medical Product Communications That Are Consistent With the FDA-Required Labeling — Questions and Answers : Guidance for Industry	06/12/2018	Center for Veterinary Medicine, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research, Office of the Commissioner	Administrative / Procedural	Final	No		
Patient-Focused Drug Development: Collecting Comprehensive and Representative Input	PDF (545.36 KB)PDF (545.36 KB) of Patient-Focused Drug Development: Collecting Comprehensive and Representative Input	06/12/2018	Center for Drug Evaluation and Research	Administrative / Procedural	Draft	No	09/12/2018	FDA-2018-D-1893
Prescription Drug User Fee Act Waivers for Fixed-Combination Antiretroviral Drugs for the President's Emergency Plan for AIDS Relief: Draft Guidance for Industry	PDF (331.85 KB)PDF (331.85 KB) of Prescription Drug User Fee Act Waivers for Fixed-Combination Antiretroviral Drugs for the President's Emergency Plan for AIDS Relief: Draft Guidance for Industry	06/06/2018	Center for Drug Evaluation and Research	User Fees,	Draft	No	08/06/2018	FDA-2018-D-1635
Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products Guidance for Industry	PDF (183.5 KB)PDF (183.5 KB) of Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products Guidance for Industry	06/04/2018	Center for Drug Evaluation and Research	Administrative / Procedural, Biosimilarity	Draft	No	08/03/2018	FDA-2018-D-1922
Complicated Urinary Tract Infections: Developing Drugs for Treatment	PDF (380.96 KB)PDF (380.96 KB) of Complicated Urinary Tract Infections: Developing Drugs for Treatment	06/01/2018	Center for Drug Evaluation and Research	Clinical - Antimicrobial	Final	No		

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Development of a Shared System REMS Guidance for Industry	PDF (98.62 KB)PDF (98.62 KB) of Development of a Shared System REMS Guidance for Industry	05/31/2018	Center for Drug Evaluation and Research	Safety - Issues, Errors, and Problems	Draft	No	07/31/2018	
Waivers of the Single, Shared System REMS Requirement; Draft Guidance for Industry	PDF (91.3 KB)PDF (91.3 KB) of Waivers of the Single, Shared System REMS Requirement; Draft Guidance for Industry	05/31/2018	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Safety - Issues, Errors, and Problems	Draft	No	07/31/2018	FDA-2018 - D-1043
Assessment of Pressor Effects of Drugs Guidance for Industry	PDF (105.56 KB)PDF (105.56 KB) of Assessment of Pressor Effects of Drugs Guidance for Industry	05/30/2018	Center for Drug Evaluation and Research	Clinical - Medical	Draft	No	07/30/2018	FDA-2018-D-1636
Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management Annex	PDF (223.29 KB)PDF (223.29 KB) of Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management Annex	05/30/2018	Center for Drug Evaluation and Research	ICH-Quality	Draft	No	07/30/2018	FDA-2018-D-1609
Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management Core Guideline Guidance for Industry	PDF (450.61 KB)PDF (450.61 KB) of Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management Core Guideline Guidance for Industry	05/30/2018	Center for Drug Evaluation and Research	ICH-Quality	Draft	No	07/30/2018	FDA-2018-D-1609
Complicated Intra-Abdominal Infections: Developing Drugs for Treatment	PDF (129.97 KB)PDF (129.97 KB) of Complicated Intra-Abdominal Infections: Developing Drugs for Treatment	05/29/2018	Center for Drug Evaluation and Research	Clinical - Antimicrobial	Final	No		
Small Entity Compliance Guide: Registration of Food Facilities	PDF (361.57 KB)PDF (361.57 KB) of Small Entity Compliance Guide: Registration of Food Facilities	05/29/2018	Office of Compliance, Office of Surveillance and Compliance	Defense & Security	Final	No		FDA-2012-D-1003
Anthrax: Developing Drugs for Prophylaxis of Inhalational Anthrax Guidance for Industry	PDF (116.35 KB)PDF (116.35 KB) of Anthrax: Developing Drugs for Prophylaxis of Inhalational Anthrax Guidance for Industry	05/23/2018	Center for Drug Evaluation and Research	Clinical - Antimicrobial	Final	No		
CVM GFI #132 Administrative Applications and the Phased Review Process	PDF (85.62 KB)PDF (85.62 KB) of CVM GFI #132 Administrative Applications and the Phased Review Process	05/23/2018	Center for Veterinary Medicine	New Animal Drug Application (NADA)	Final	No		FDA-2002-D-0147
CVM GFI #108 Registering with CVM's Electronic Submission System	PDF (220.28 KB)PDF (220.28 KB) of CVM GFI #108 Registering with CVM's Electronic Submission System	05/22/2018	Center for Veterinary Medicine	Electronic Submissions,	Final	No		FDA-1992-S-0039
Enforcement Policy -- OTC Sunscreen Drug Products Marketed Without an Approved Application	PDF (163.48 KB)PDF (163.48 KB) of Enforcement Policy -- OTC Sunscreen Drug Products Marketed Without an Approved Application	05/22/2018	Center for Drug Evaluation and Research	Compliance,	Final	No		
Acne Vulgaris: Establishing Effectiveness of Drugs Intended for Treatment	PDF (84.75 KB)PDF (84.75 KB) of Acne Vulgaris: Establishing Effectiveness of Drugs Intended for Treatment	05/21/2018	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		
Bioanalytical Method Validation Guidance for Industry	PDF (385.62 KB)PDF (385.62 KB) of Bioanalytical Method Validation Guidance for Industry	05/21/2018	Center for Drug Evaluation and Research	Biopharmaceutics	Final	No		FDA-2013-D-1020
CVM GFI #197 Documenting Electronic Data Files and Statistical Analysis Programs	PDF (110.43 KB)PDF (110.43 KB) of CVM GFI #197 Documenting Electronic Data Files and Statistical Analysis Programs	05/21/2018	Center for Veterinary Medicine	Target Animal – Effectiveness, Target Animal – Safety, Investigational New Animal Drug (INAD)	Draft	No	07/20/2018	FDA-2009-D-0052
Cytomegalovirus in Transplantation: Developing Drugs to Treat or Prevent Disease	PDF (457.27 KB)PDF (457.27 KB) of Cytomegalovirus in Transplantation: Developing Drugs to Treat or Prevent Disease	05/18/2018	Center for Drug Evaluation and Research	Clinical - Antimicrobial	Draft	No	07/17/2018	

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Establishing Effectiveness for Drugs Intended to Treat Male Hypogonadotropic Hypogonadism Attributed to Nonstructural Disorders Guidance for Industry	PDF (65.97 KB)PDF (65.97 KB) of Establishing Effectiveness for Drugs Intended to Treat Male Hypogonadotropic Hypogonadism Attributed to Nonstructural Disorders Guidance for Industry	05/18/2018		Clinical - Medical	Final	No		
Institutional Review Board (IRB) Written Procedures: Guidance for Institutions and IRBs	PDF (346.16 KB)PDF (346.16 KB) of Institutional Review Board (IRB) Written Procedures: Guidance for Institutions and IRBs	05/17/2018	Office of Regulatory Affairs, Office of Good Clinical Practice, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Good Clinical Practices (GCP)	Final	No	09/30/2016	FDA-2016-D-1605
Small Entity Compliance Guide: Extension and Clarification of Compliance Dates for Certain Provisions of Four Implementing Rules of the FDA Food Safety Modernization Act	PDF (36.51 KB)PDF (36.51 KB) of Small Entity Compliance Guide: Extension and Clarification of Compliance Dates for Certain Provisions of Four Implementing Rules of the FDA Food Safety Modernization Act	05/14/2018	Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine		Final	No		FDA-2018-D-1378
Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act	PDF (86.66 KB)PDF (86.66 KB) of Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act	05/10/2018	Center for Drug Evaluation and Research	Compounding	Final	No		
S3A Guidance: Note for Guidance on Toxicokinetics: The Assessment of Systemic Exposure in Toxicity Studies: Focus on Microsampling	PDF (148.76 KB)PDF (148.76 KB) of S3A Guidance: Note for Guidance on Toxicokinetics: The Assessment of Systemic Exposure in Toxicity Studies: Focus on Microsampling	05/09/2018	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Safety	Final	No		
Waivers, Exceptions, and Exemptions from the Requirements of Section 582 of the Federal Food, Drug, and Cosmetic Act Guidance for Industry	PDF (117.04 KB)PDF (117.04 KB) of Waivers, Exceptions, and Exemptions from the Requirements of Section 582 of the Federal Food, Drug, and Cosmetic Act Guidance for Industry	05/08/2018	Center for Drug Evaluation and Research	Administrative / Procedural	Draft	No		
Guidance for Industry: Menu Labeling Supplemental Guidance	PDF (3.62 MB)PDF (3.62 MB) of Guidance for Industry: Menu Labeling Supplemental Guidance	05/05/2018	Office of Nutrition and Food Labeling	Nutrition Label	Final	No		FDA-2011-F-0172
Assessing User Fees Under the Prescription Drug User Fee Amendments of 2017 Guidance for Industry: Guidance for Industry	PDF (145.45 KB)PDF (145.45 KB) of Assessing User Fees Under the Prescription Drug User Fee Amendments of 2017 Guidance for Industry: Guidance for Industry	05/02/2018	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	User Fees,	Final	No	12/12/2017	FDA-2017-D-5913
Donor Screening Recommendations to Reduce the Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue-Based Products: Guidance for Industry	PDF (85.9 KB)PDF (85.9 KB) of Donor Screening Recommendations to Reduce the Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue-Based Products: Guidance for Industry	05/02/2018	Center for Biologics Evaluation and Research	Tissue	Final	No		FDA-2016-D-0768
Guidance for Industry: Preparing a Color Additive Petition for Submission to the Center for Food Safety and Applied Nutrition for Color Additives Used in or on Contact Lenses		05/01/2018	Office of Food Additive Safety	Electronic Submissions Gateway (ESG), Food & Color Additives	Final	No		FDA-1998-N-0050-0007
CVM GFI #210 The Index of Legally Marketed Unapproved New Animal Drugs for Minor Species	PDF (239.29 KB)PDF (239.29 KB) of CVM GFI #210 The Index of Legally Marketed Unapproved New Animal Drugs for Minor Species	04/27/2018	Center for Veterinary Medicine	Aquaculture, Minor Use/ Minor Species (MUMS)	Final	No	11/14/2017	FDA-2017-D-2462

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Multiple Function Device Products: Policy and Considerations: Draft Guidance for Industry and Food and Drug Administration	PDF (472.46 KB)PDF (472.46 KB) of Multiple Function Device Products: Policy and Considerations: Draft Guidance for Industry and Food and Drug Administration	04/27/2018	Center for Devices and Radiological Health	Postmarket, Premarket, Digital Health	Draft	No	06/26/2018	FDA-2018-D-1339
Clinical Trial Imaging Endpoint Process Standards Guidance for Industry	PDF (186.17 KB)PDF (186.17 KB) of Clinical Trial Imaging Endpoint Process Standards Guidance for Industry	04/26/2018	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Clinical - Medical	Final	No		
Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients Questions and Answers Guidance for Industry	PDF (218.22 KB)PDF (218.22 KB) of Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients Questions and Answers Guidance for Industry	04/19/2018	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Quality	Final	No		FDA-2018-D-1176
Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products--Quality Considerations	PDF (449.28 KB)PDF (449.28 KB) of Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products--Quality Considerations	04/18/2018	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Draft	No		FDA-2018-D-1098
Guidance for Industry: Highly Concentrated Caffeine in Dietary Supplements	PDF (132.05 KB)PDF (132.05 KB) of Guidance for Industry: Highly Concentrated Caffeine in Dietary Supplements	04/16/2018	Office of Dietary Supplement Programs	Caffeine , Food & Beverage Safety, Ingredient Level, Nutrition, Food & Beverage Safety	Final	No		FDA-2015-P-0059
Policy Clarification and Premarket Notification [510(k)] Submissions for Ultrasonic Diathermy Devices: Guidance for Industry and Food and Drug Administration Staff	PDF (458.21 KB)PDF (458.21 KB) of Policy Clarification and Premarket Notification [510(k)] Submissions for Ultrasonic Diathermy Devices: Guidance for Industry and Food and Drug Administration Staff	04/16/2018	Center for Devices and Radiological Health	Premarket, 510(k), Physical Medicine	Final	No	10/30/2017	FDA-2017-D-4764
Considerations for Design, Development, and Analytical Validation of Next Generation Sequencing (NGS) - Based In Vitro Diagnostics (IVDs) Intended to Aid in the Diagnosis of Suspected Germline Diseases: Guidance for Stakeholders and Food and Drug Administration Staff	PDF (868.7 KB)PDF (868.7 KB) of Considerations for Design, Development, and Analytical Validation of Next Generation Sequencing (NGS) - Based In Vitro Diagnostics (IVDs) Intended to Aid in the Diagnosis of Suspected Germline Diseases: Guidance for Stakeholders and Food and Drug Administration Staff	04/13/2018	Center for Devices and Radiological Health		Final	No		FDA-2016-D-1233
Use of Public Human Genetic Variant Databases to Support Clinical Validity for Genetic and Genomic-Based In Vitro Diagnostics : Guidance for Stakeholders and Food and Drug Administration Staff	PDF (443.57 KB)PDF (443.57 KB) of Use of Public Human Genetic Variant Databases to Support Clinical Validity for Genetic and Genomic-Based In Vitro Diagnostics : Guidance for Stakeholders and Food and Drug Administration Staff	04/13/2018	Center for Devices and Radiological Health	Premarket, IVDs (In Vitro Diagnostic Devices), Laboratory Tests, Molecular and Clinical Genetics	Final	No		FDA-2016-D-1233
Special Protocol Assessment Guidance for Industry	PDF (181.98 KB)PDF (181.98 KB) of Special Protocol Assessment Guidance for Industry	04/12/2018	Center for Drug Evaluation and Research	Administrative / Procedural	Final	No		
Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic	PDF (289.89 KB)PDF (289.89 KB) of Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic	04/11/2018	Center for Food Safety and Applied Nutrition, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Safety - Issues, Errors, and Problems	Final	No		

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
E11(R1) Addendum: Clinical Investigation of Medicinal Products in the Pediatric Population	PDF (354.33 KB)PDF (354.33 KB) of E11(R1) Addendum: Clinical Investigation of Medicinal Products in the Pediatric Population	04/10/2018	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Efficacy	Final	No		
Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials	PDF (116.6 KB)PDF (116.6 KB) of Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials	04/06/2018	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Clinical - Medical	Draft	No		FDA-2018-D-1201
Liposome Drug Products: Chemistry, Manufacturing, and Controls; Human Pharmacokinetics and Bioavailability; and Labeling Documentation	PDF (120.36 KB)PDF (120.36 KB) of Liposome Drug Products: Chemistry, Manufacturing, and Controls; Human Pharmacokinetics and Bioavailability; and Labeling Documentation	04/04/2018	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		
CVM GFI #255 Elemental Impurities in Animal Drug Products Questions and Answers	PDF (191.77 KB)PDF (191.77 KB) of CVM GFI #255 Elemental Impurities in Animal Drug Products Questions and Answers	03/27/2018	Center for Veterinary Medicine	Chemistry, Manufacturing, and Controls (CMC)	Draft	No	05/29/2018	FDA-2018-D-0943
Chronic Obstructive Pulmonary Disease: Use of the St. George's Respiratory Questionnaire as a PRO Assessment Tool Guidance for Industry	PDF (69.43 KB)PDF (69.43 KB) of Chronic Obstructive Pulmonary Disease: Use of the St. George's Respiratory Questionnaire as a PRO Assessment Tool Guidance for Industry	03/26/2018	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		
Guidance for Industry: Application of the Foreign Supplier Verification Program Regulation to the Importation of Live Animals	PDF (69.36 KB)PDF (69.36 KB) of Guidance for Industry: Application of the Foreign Supplier Verification Program Regulation to the Importation of Live Animals	03/22/2018	Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine, Office of Regulatory Affairs	Import	Final	No		FDA-2018-D-0721
M7(R1) Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals To Limit Potential Carcinogenic Risk	PDF (1.37 MB)PDF (1.37 MB) of M7(R1) Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals To Limit Potential Carcinogenic Risk	03/13/2018	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Multidisciplinary	Final	No		
CVM GFI #240 Proprietary Names for New Animal Drugs	PDF (164.46 KB)PDF (164.46 KB) of CVM GFI #240 Proprietary Names for New Animal Drugs	03/12/2018	Center for Veterinary Medicine	Administrative / Procedural, Advertising, Labeling, New Animal Drug Application (NADA)	Draft	No	05/11/2018	FDA-2018-D-0626
E18 Genomic Sampling and Management of Genomic Data Guidance for Industry	PDF (97.94 KB)PDF (97.94 KB) of E18 Genomic Sampling and Management of Genomic Data Guidance for Industry	03/01/2018	Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	ICH-Efficacy	Final	No		
Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act Guidance for Industry	PDF (282.6 KB)PDF (282.6 KB) of Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act Guidance for Industry	02/28/2018		Administrative / Procedural	Draft	No	04/30/2018	2018-04181
E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1)	PDF (483.52 KB)PDF (483.52 KB) of E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1)	02/28/2018	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Efficacy	Final	No		FDA-2018-D-0719
Standardization of Data and Documentation Practices for Product Tracing Guidance for Industry	PDF (170.08 KB)PDF (170.08 KB) of Standardization of Data and Documentation Practices for Product Tracing Guidance for Industry	02/28/2018	Center for Drug Evaluation and Research	Administrative / Procedural	Draft	No	05/01/2018	FDA-2018-D-0688

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Guidance for Industry: Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints	PDF (762.08 KB)PDF (762.08 KB) of Guidance for Industry: Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints	02/27/2018	Office of Nutrition and Food Labeling	Labeling	Final	No		FDA-2004-N-0258
Guidance for Industry: Proper Labeling of Honey and Honey Products	PDF (70.21 KB)PDF (70.21 KB) of Guidance for Industry: Proper Labeling of Honey and Honey Products	02/27/2018	Office of Nutrition and Food Labeling	Labeling	Final	No		FDA-2006-P-0207
Guidance for Industry: Reference Amounts Customarily Consumed: List of Products for Each Product Category	PDF (289.34 KB)PDF (289.34 KB) of Guidance for Industry: Reference Amounts Customarily Consumed: List of Products for Each Product Category	02/27/2018	Office of Nutrition and Food Labeling	Labeling, Nutrition	Final	No		FDA-2016-D-4098
Guidance for Industry: Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates Submitted as a Citizen Petition (21 CFR 10.30)	PDF (283.85 KB)PDF (283.85 KB) of Guidance for Industry: Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates Submitted as a Citizen Petition (21 CFR 10.30)	02/27/2018	Office of Nutrition and Food Labeling	Labeling	Final	No		FDA-2016-D-3401
Q11 Development and Manufacture of Drug Substances--Questions and Answers (Chemical Entities and Biotechnological/Biological Entities)	PDF (843.18 KB)PDF (843.18 KB) of Q11 Development and Manufacture of Drug Substances--Questions and Answers (Chemical Entities and Biotechnological/Biological Entities)	02/23/2018	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Quality	Final	No		
Acceptance of Clinical Data to Support Medical Device Applications and Submissions: Frequently Asked Questions: Guidance for Industry and Food and Drug Administration Staff	PDF (484.51 KB)PDF (484.51 KB) of Acceptance of Clinical Data to Support Medical Device Applications and Submissions: Frequently Asked Questions: Guidance for Industry and Food and Drug Administration Staff	02/21/2018	Center for Devices and Radiological Health	Premarket, Good Clinical Practices (GCP)	Final	No		FDA-2013-N-0080
BIORESEARCH MONITORING TECHNICAL CONFORMANCE GUIDE	PDF (697.26 KB)PDF (697.26 KB) of BIORESEARCH MONITORING TECHNICAL CONFORMANCE GUIDE	02/21/2018	Center for Drug Evaluation and Research	Electronic Submissions,	Draft	No		
Standardized Format for Electronic Submission of NDA and BLA Content for the Planning of Bioresearch Monitoring (BIMO) Inspections for CDER Submissions Guidance for Industry	PDF (109.92 KB)PDF (109.92 KB) of Standardized Format for Electronic Submission of NDA and BLA Content for the Planning of Bioresearch Monitoring (BIMO) Inspections for CDER Submissions Guidance for Industry	02/21/2018	Center for Drug Evaluation and Research	Electronic Submissions,	Draft	No		FDA-2018-D-0481
Alzheimer’s Disease: Developing Drugs for Treatment Guidance for Industy	PDF (61.06 KB)PDF (61.06 KB) of Alzheimer’s Disease: Developing Drugs for Treatment Guidance for Industy	02/15/2018	Center for Drug Evaluation and Research	Clinical - Medical	Draft	No		
Duchenne Muscular Dystrophy and Related Dystrophinopathies: Developing Drugs for Treatment Guidance for Industry	PDF (118.81 KB)PDF (118.81 KB) of Duchenne Muscular Dystrophy and Related Dystrophinopathies: Developing Drugs for Treatment Guidance for Industry	02/15/2018	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		
Migraine: Developing Drugs for Acute Treatment	PDF (115.42 KB)PDF (115.42 KB) of Migraine: Developing Drugs for Acute Treatment	02/15/2018	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
How to Prepare a Pre-Request for Designation (Pre-RFD): Guidance for Industry	PDF (342.72 KB)PDF (342.72 KB) of How to Prepare a Pre-Request for Designation (Pre-RFD): Guidance for Industry	02/14/2018	Office of Combination Products	Combination Products	Final	No	04/13/2017	FDA-2017-D-0040
Regulatory Classification of Pharmaceutical Co-Crystals	PDF (86.7 KB)PDF (86.7 KB) of Regulatory Classification of Pharmaceutical Co-Crystals	02/14/2018	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		FDA-2011-D-0800
Bacillus Calmette-Guérin-Unresponsive Nonmuscle Invasive Bladder Cancer: Developing Drugs and Biologics for Treatment Guidance for Industry	PDF (95.94 KB)PDF (95.94 KB) of Bacillus Calmette-Guérin-Unresponsive Nonmuscle Invasive Bladder Cancer: Developing Drugs and Biologics for Treatment Guidance for Industry	02/12/2018	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Clinical - Medical	Final	No		FDA-2018-D-0342
Microbiological Data for Systemic Antibacterial Drug Products — Development, Analysis, and Presentation	PDF (162.12 KB)PDF (162.12 KB) of Microbiological Data for Systemic Antibacterial Drug Products — Development, Analysis, and Presentation	02/07/2018	Center for Drug Evaluation and Research	Clinical - Antimicrobial	Final	No		
Payment and Reimbursement to Research Subjects: Guidance for Institutional Review Boards and Clinical Investigators		01/29/2018	Office of Good Clinical Practice	Good Clinical Practices (GCP)	Final	No		
Qualified Infectious Disease Product Designation Questions and Answers	PDF (390.03 KB)PDF (390.03 KB) of Qualified Infectious Disease Product Designation Questions and Answers	01/29/2018	Center for Drug Evaluation and Research	Administrative / Procedural	Draft	No		
Draft Guidance for Industry: Considerations for Determining Whether a Measure Provides the Same Level of Public Health Protection as the Corresponding Requirement in 21 CFR part 112 or the Preventive Controls Requirements in part 117 or 507	PDF (112.96 KB)PDF (112.96 KB) of Draft Guidance for Industry: Considerations for Determining Whether a Measure Provides the Same Level of Public Health Protection as the Corresponding Requirement in 21 CFR part 112 or the Preventive Controls Requirements in part 117 or 507	01/25/2018	Office of Foods and Veterinary Medicine		Draft	No	05/25/2018	FDA-2017-D-0397
Guidance for Industry: Application of the Foreign Supplier Verification Program Regulation to Importers of Grain Raw Agricultural Commodities	PDF (72.31 KB)PDF (72.31 KB) of Guidance for Industry: Application of the Foreign Supplier Verification Program Regulation to Importers of Grain Raw Agricultural Commodities	01/25/2018	Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine, Office of Regulatory Affairs	Import	Final	No		FDA-2017-D-6592
Small Entity Compliance Guide: Foreign Supplier Verification Programs for Importers of Food for Humans and Animals	PDF (142.45 KB)PDF (142.45 KB) of Small Entity Compliance Guide: Foreign Supplier Verification Programs for Importers of Food for Humans and Animals	01/25/2018	Center for Food Safety and Applied Nutrition	Import	Final	No		FDA-2011-N-0143
CVM GFI #245 Hazard Analysis and Risk-Based Preventive Controls for Food for Animals	PDF (1.17 MB)PDF (1.17 MB) of CVM GFI #245 Hazard Analysis and Risk-Based Preventive Controls for Food for Animals	01/23/2018	Center for Veterinary Medicine	Animal Feed	Draft	No	07/23/2018	FDA-2018-D-0388
Draft Guidance for Industry: Foreign Supplier Verification Programs for Importers of Food for Humans and Animals	PDF (638.06 KB)PDF (638.06 KB) of Draft Guidance for Industry: Foreign Supplier Verification Programs for Importers of Food for Humans and Animals	01/22/2018	Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine, Office of Regulatory Affairs	Import	Draft	No	05/25/2018	FDA-2017-D-5225
Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food	PDF (2.38 MB)PDF (2.38 MB) of Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food	01/22/2018	Center for Food Safety and Applied Nutrition		Draft	No	04/04/2018	FDA-2016-D-2343
Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food	PDF (118 KB)PDF (118 KB) of Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food	01/22/2018	Center for Food Safety and Applied Nutrition		Draft	No	04/04/2018	FDA-2016-D-2343

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Material Threat Medical Countermeasure Priority Review Vouchers - Draft Guidance for Industry: Draft Guidance for Industry	PDF (148.16 KB)PDF (148.16 KB) of Material Threat Medical Countermeasure Priority Review Vouchers - Draft Guidance for Industry: Draft Guidance for Industry	01/19/2018	Office of Counterterrorism and Emerging Threats	Emergencies,	Draft	No	03/20/2018	FDA-2017-D-6880
Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry	PDF (552.95 KB)PDF (552.95 KB) of Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry	01/18/2018	Center for Drug Evaluation and Research	Compounding	Final	No		
Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act Guidance for Industry	PDF (468.33 KB)PDF (468.33 KB) of Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act Guidance for Industry	01/18/2018	Center for Drug Evaluation and Research	Compounding	Final	No		
Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application: Guidance for Industry	PDF (555.69 KB)PDF (555.69 KB) of Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application: Guidance for Industry	01/18/2018	Center for Drug Evaluation and Research	Compounding, Current Good Manufacturing Practices (CGMP), Pharmaceutical Quality	Final	No	03/13/2017	
Product Title and Initial U.S. Approval in the Highlights of Prescribing Information for Human Prescription Drug and Biological Products — Content and Format Guidance for Industry	PDF (679.86 KB)PDF (679.86 KB) of Product Title and Initial U.S. Approval in the Highlights of Prescribing Information for Human Prescription Drug and Biological Products — Content and Format Guidance for Industry	01/18/2018	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Labeling	Draft	No	03/19/2018	FDA-2017-D-6969
Guidance for Industry: Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs	PDF (228.05 KB)PDF (228.05 KB) of Guidance for Industry: Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs	01/05/2018	Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine		Final	No		FDA-2017-N-6908
Good ANDA Submission Practices Guidance for Industry	PDF (249.56 KB)PDF (249.56 KB) of Good ANDA Submission Practices Guidance for Industry	01/03/2018	Center for Drug Evaluation and Research	Generic Drugs	Draft	No	03/02/2018	FDA-2017-D-6854
Labeling for Combined Hormonal Contraceptives Guidance for Industry	PDF (436.92 KB)PDF (436.92 KB) of Labeling for Combined Hormonal Contraceptives Guidance for Industry	12/29/2017	Center for Drug Evaluation and Research	Labeling	Draft	No	02/28/2018	
Best Practices for Communication Between IND Sponsors and FDA During Drug Development	PDF (191.28 KB)PDF (191.28 KB) of Best Practices for Communication Between IND Sponsors and FDA During Drug Development	12/28/2017	Center for Drug Evaluation and Research	Administrative / Procedural	Final	No		
Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products Guidance for Industry	PDF (156.17 KB)PDF (156.17 KB) of Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products Guidance for Industry	12/28/2017	Center for Drug Evaluation and Research	Administrative / Procedural	Draft	No	02/28/2018	FDA-2017-D-6530
Nucleic Acid Testing (NAT) for Human Immunodeficiency Virus Type 1 (HIV-1) and Hepatitis C Virus (HCV): Testing, Product Disposition, and Donor Deferral and Reentry: Guidance for Industry	PDF (219.18 KB)PDF (219.18 KB) of Nucleic Acid Testing (NAT) for Human Immunodeficiency Virus Type 1 (HIV-1) and Hepatitis C Virus (HCV): Testing, Product Disposition, and Donor Deferral and Reentry: Guidance for Industry	12/28/2017	Center for Biologics Evaluation and Research	Blood Products	Final	No		FDA-2005-D-0140

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Implementation of Pathogen Reduction Technology in the Manufacture of Blood Components in Blood Establishments: Questions and Answers: Draft Draft Guidance for Industry	PDF (138.71 KB)PDF (138.71 KB) of Implementation of Pathogen Reduction Technology in the Manufacture of Blood Components in Blood Establishments: Questions and Answers: Draft Draft Guidance for Industry	12/26/2017	Center for Biologics Evaluation and Research	Blood Products	Draft	No	03/27/2018	FDA-2017-D-6784
Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System. Guidance for Industry	PDF (160.6 KB)PDF (160.6 KB) of Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System. Guidance for Industry	12/22/2017	Center for Drug Evaluation and Research	Biopharmaceutics	Final	No		FDA-2015-D-1245
Amendment to "Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Products; Guidance for Industry": Draft Draft Guidance for Industry	PDF (155.24 KB)PDF (155.24 KB) of Amendment to "Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Products; Guidance for Industry": Draft Draft Guidance for Industry	12/21/2017	Center for Biologics Evaluation and Research	Blood Products	Draft	No	03/22/2018	FDA-2012-D-0307
Chemistry, Manufacturing, and Controls Changes to an Approved Application: Certain Biological Products; Draft Guidance for Industry	PDF (252.19 KB)PDF (252.19 KB) of Chemistry, Manufacturing, and Controls Changes to an Approved Application: Certain Biological Products; Draft Guidance for Industry	12/21/2017			Draft	No		
Medical Device Accessories - Describing Accessories and Classification Pathways: Guidance for Industry and FDA Staff	PDF (449.3 KB)PDF (449.3 KB) of Medical Device Accessories - Describing Accessories and Classification Pathways: Guidance for Industry and FDA Staff	12/20/2017	Center for Devices and Radiological Health	Premarket, Administrative / Procedural, Laser Notice, Digital Health	Final	No	04/10/2015	FDA-2015-D-0025
Clarification of Orphan Designation of Drugs and Biologics for Pediatric Subpopulations of Common Diseases: Guidance for Industry	PDF (81.03 KB)PDF (81.03 KB) of Clarification of Orphan Designation of Drugs and Biologics for Pediatric Subpopulations of Common Diseases: Guidance for Industry	12/19/2017	Office of Orphan Products Development	Premarket,	Final	No	07/27/2018	FDA-2017-D-6380.
Replacement Reagent and Instrument Family Policy for In Vitro Diagnostic Devices: Draft Guidance for Industry and Food and Drug Administration Staff	PDF (614.86 KB)PDF (614.86 KB) of Replacement Reagent and Instrument Family Policy for In Vitro Diagnostic Devices: Draft Guidance for Industry and Food and Drug Administration Staff	12/19/2017	Center for Devices and Radiological Health	Premarket, 510(k), Device Exception (IDE)	Draft	No	03/18/2018	
Investigational IVDs Used in Clinical Investigations of Therapeutic Products: Draft Guidance for Industry, Food and Drug Administration Staff, Sponsors, and Institutional Review Boards	PDF (730.53 KB)PDF (730.53 KB) of Investigational IVDs Used in Clinical Investigations of Therapeutic Products: Draft Guidance for Industry, Food and Drug Administration Staff, Sponsors, and Institutional Review Boards	12/18/2017	Center for Devices and Radiological Health	Good Clinical Practices (GCP), Investigational New Drug Application (INDA), IVDs (In Vitro Diagnostic Devices), Labeling, Device Exception (IDE), Laboratory Tests	Draft	No	03/19/2018	
Drug Products, Including Biological Products, that Contain Nanomaterials - Guidance for Industry	PDF (234.64 KB)PDF (234.64 KB) of Drug Products, Including Biological Products, that Contain Nanomaterials - Guidance for Industry	12/15/2017	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Draft	No	03/13/2018	
Information Requests and Discipline Review Letters Under the Generic Drug User Fee Amendments; Draft Guidance for Industry: Draft Guidance for Industry	PDF (80.59 KB)PDF (80.59 KB) of Information Requests and Discipline Review Letters Under the Generic Drug User Fee Amendments; Draft Guidance for Industry: Draft Guidance for Industry	12/15/2017	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	User Fees, Generic Drugs	Draft	No	03/15/2018	

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
An Acceptable Circular of Information for the Use of Human Blood and Blood Components: Guidance for Industry	PDF (70.15 KB)PDF (70.15 KB) of An Acceptable Circular of Information for the Use of Human Blood and Blood Components: Guidance for Industry	12/14/2017	Center for Biologics Evaluation and Research	Blood Products	Final	No		2002D-0428
Systemic Antibacterial and Antifungal Drugs: Susceptibility Test Interpretive Criteria Labeling for NDAs and ANDAs	PDF (92 KB)PDF (92 KB) of Systemic Antibacterial and Antifungal Drugs: Susceptibility Test Interpretive Criteria Labeling for NDAs and ANDAs	12/13/2017	Center for Drug Evaluation and Research	Labeling	Final	No		
Draft Guidance for Industry: Refusal of Inspection by a Foreign Food Establishment or Foreign Government	PDF (84.36 KB)PDF (84.36 KB) of Draft Guidance for Industry: Refusal of Inspection by a Foreign Food Establishment or Foreign Government	12/12/2017	Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine, Office of Regulatory Affairs		Draft	No	02/26/2018	FDA-2017-D-6528
Gluten in Drug Products and Associated Labeling Recommendations; Draft Guidance for Industry	PDF (135.93 KB)PDF (135.93 KB) of Gluten in Drug Products and Associated Labeling Recommendations; Draft Guidance for Industry	12/12/2017	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Labeling	Draft	No	03/12/2018	FDA-2017-D-6352
Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling-Final	PDF (114.58 KB)PDF (114.58 KB) of Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling-Final	12/12/2017	Center for Veterinary Medicine, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Advertising	Final	No		FDA-1999-D-4079
Refuse to File: NDA and BLA Submissions to CDER Guidance for Industry	PDF (109.48 KB)PDF (109.48 KB) of Refuse to File: NDA and BLA Submissions to CDER Guidance for Industry	12/12/2017	Center for Drug Evaluation and Research	Administrative / Procedural	Draft	No	03/12/2018	
Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use: Guidance for Industry and Food and Drug Administration Staff	PDF (198.42 KB)PDF (198.42 KB) of Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use: Guidance for Industry and Food and Drug Administration Staff	12/12/2017	Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Cellular & Gene Therapy, Tissue	Final	No		FDA-2017-D-6146
Software as a Medical Device (SAMD): Clinical Evaluation - Guidance for Industry and Food and Drug Administration Staff	PDF (1.23 MB)PDF (1.23 MB) of Software as a Medical Device (SAMD): Clinical Evaluation - Guidance for Industry and Food and Drug Administration Staff	12/08/2017	Center for Devices and Radiological Health	Premarket, International,	Final	No		FDA-2016-D-2483
Pediatric Rare Diseases--A Collaborative Approach for Drug Development Using Gaucher Disease as a Model; Draft Guidance for Industry: Draft Guidance for Industry	PDF (262.2 KB)PDF (262.2 KB) of Pediatric Rare Diseases--A Collaborative Approach for Drug Development Using Gaucher Disease as a Model; Draft Guidance for Industry: Draft Guidance for Industry	12/06/2017	Center for Drug Evaluation and Research		Draft	No	03/06/2018	
Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments: Guidance for Industry		12/06/2017	Center for Tobacco Products		Final	No	04/07/2014	
FDA Categorization of Investigational Device Exemption (IDE) Devices to Assist the Centers for Medicare and Medicaid Services (CMS) with Coverage Decisions: Guidance for Sponsors, Clinical Investigators, Industry, Institutional Review Boards, and Food and Drug Administration Staff	PDF (572.88 KB)PDF (572.88 KB) of FDA Categorization of Investigational Device Exemption (IDE) Devices to Assist the Centers for Medicare and Medicaid Services (CMS) with Coverage Decisions: Guidance for Sponsors, Clinical Investigators, Industry, Institutional Review Boards, and Food and Drug Administration Staff	12/05/2017	Center for Devices and Radiological Health	Device Exception (IDE)	Final	No		FDA-2016-D-1159

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Technical Considerations for Additive Manufactured Medical Devices - Guidance for Industry and Food and Drug Administration Staff	PDF (802.88 KB)PDF (802.88 KB) of Technical Considerations for Additive Manufactured Medical Devices - Guidance for Industry and Food and Drug Administration Staff	12/05/2017	Center for Devices and Radiological Health	Premarket, Biotechnology, 510(k), Premarket Approval (PMA), Device Exception (IDE), HUD/HDE, Orthopedic	Final	No	08/08/2016	FDA-2016-D-1210
Use of Serological Tests to Reduce the Risk of Transmission of Trypanosoma cruzi Infection in Blood and Blood Components: Guidance for Industry	PDF (151.46 KB)PDF (151.46 KB) of Use of Serological Tests to Reduce the Risk of Transmission of Trypanosoma cruzi Infection in Blood and Blood Components: Guidance for Industry	12/05/2017	Center for Biologics Evaluation and Research	Blood Products	Final	No	12/06/2017	FDA-2009-D-0137
CPG Sec. 645.100 Biological Drugs for Animal Use	PDF (67.74 KB)PDF (67.74 KB) of CPG Sec. 645.100 Biological Drugs for Animal Use	12/01/2017	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Biopharmaceutics, Animal Drugs	Final	No		
Pediatric Information for X-ray Imaging Device Premarket Notifications: Guidance for Industry and Food and Drug Administration Staff	PDF (671.92 KB)PDF (671.92 KB) of Pediatric Information for X-ray Imaging Device Premarket Notifications: Guidance for Industry and Food and Drug Administration Staff	11/28/2017	Center for Devices and Radiological Health	Premarket, 510(k), Radiology	Final	No		FDA-2012-D-0384
Small Entity Compliance Guide: Sanitary Transportation of Human and Animal Food: What You Need to Know About the FDA Regulation	PDF (131.42 KB)PDF (131.42 KB) of Small Entity Compliance Guide: Sanitary Transportation of Human and Animal Food: What You Need to Know About the FDA Regulation	11/22/2017	Center for Food Safety and Applied Nutrition		Final	No		FDA-2013-N-0013
General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products Guidance for Industry	PDF (520.34 KB)PDF (520.34 KB) of General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products Guidance for Industry	11/21/2017	Center for Drug Evaluation and Research	Generic Drugs	Final	No		FDA-2016-D-0785
Unique Device Identification: Direct Marking of Devices : Guidance for Industry and Food and Drug Administration Staff	PDF (586.68 KB)PDF (586.68 KB) of Unique Device Identification: Direct Marking of Devices : Guidance for Industry and Food and Drug Administration Staff	11/17/2017	Center for Devices and Radiological Health	Labeling, Laser Notice	Final	No	09/24/2015	FDA-2015-D-2245
Draft Guidance for Industry: Best Practices for Convening a GRAS Panel	PDF (188.86 KB)PDF (188.86 KB) of Draft Guidance for Industry: Best Practices for Convening a GRAS Panel	11/16/2017	Office of Food Additive Safety	GRAS	Draft	No	05/15/2018	FDA-2017-D-0085
Same Surgical Procedure Exception under 21 CFR 1271.15(b): Questions and Answers Regarding the Scope of the Exception	PDF (79.29 KB)PDF (79.29 KB) of Same Surgical Procedure Exception under 21 CFR 1271.15(b): Questions and Answers Regarding the Scope of the Exception	11/16/2017	Center for Biologics Evaluation and Research	Cellular & Gene Therapy, Tissue	Final	No		FDA-2014-D-1584
Guidance for Industry: Use of the Terms “Brown King Crab” and “Golden King Crab” in the Labeling of Human Food Products	PDF (34.76 KB)PDF (34.76 KB) of Guidance for Industry: Use of the Terms “Brown King Crab” and “Golden King Crab” in the Labeling of Human Food Products	11/15/2017	Office of Food Safety	Food & Beverage Safety, Labeling, Seafood/Seafood Product, Food & Beverage Safety	Final	No		
S5(R3) Detection of Toxicity to Reproduction	PDF (1.35 MB)PDF (1.35 MB) of S5(R3) Detection of Toxicity to Reproduction	11/09/2017	Center for Drug Evaluation and Research	ICH-Safety	Draft	No	02/09/2018	FDA-2017-D-5138
Use of a Drug Master File for Shared System Risk Evaluation and Mitigation Strategy Submissions	PDF (13.66 KB)PDF (13.66 KB) of Use of a Drug Master File for Shared System Risk Evaluation and Mitigation Strategy Submissions	11/09/2017	Center for Drug Evaluation and Research	Administrative / Procedural	Final	No	01/08/2018	FDA-2017-D-6231
Evaluating Drug Effects on the Ability to Operate a Motor Vehicle	PDF (104.38 KB)PDF (104.38 KB) of Evaluating Drug Effects on the Ability to Operate a Motor Vehicle	11/08/2017	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		
Use of a Drug Master File for Shared System REMS Submissions Guidance for Industry	PDF (102.63 KB)PDF (102.63 KB) of Use of a Drug Master File for Shared System REMS Submissions Guidance for Industry	11/08/2017	Center for Drug Evaluation and Research	Administrative / Procedural	Draft	No		

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Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Drugs for Treatment Guidance for Industry	PDF (257.59 KB)PDF (257.59 KB) of Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Drugs for Treatment Guidance for Industry	11/06/2017	Center for Drug Evaluation and Research	Clinical - Antimicrobial	Final	No		
Guidance for Industry: Supply-Chain Program Requirements and Co-Manufacturer Supplier Approval and Verification for Human Food and Animal Food	PDF (84.49 KB)PDF (84.49 KB) of Guidance for Industry: Supply-Chain Program Requirements and Co-Manufacturer Supplier Approval and Verification for Human Food and Animal Food	11/06/2017	Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine		Final	No		FDA-2017-D-5996
Recommended Statement for Over-the-Counter Aspirin-Containing Drug Products Labeled With Cardiovascular Related Imagery Guidance for Industry	PDF (192.74 KB)PDF (192.74 KB) of Recommended Statement for Over-the-Counter Aspirin-Containing Drug Products Labeled With Cardiovascular Related Imagery Guidance for Industry	11/06/2017	Center for Drug Evaluation and Research	Compliance,	Final	No		
Recurrent Herpes Labialis: Developing Drugs for Treatment and Prevention	PDF (153.47 KB)PDF (153.47 KB) of Recurrent Herpes Labialis: Developing Drugs for Treatment and Prevention	11/06/2017	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		
ANDAs: Pre-Submission of Facility Information Related to Prioritized Generic Drug Applications (Pre-Submission Facility Correspondence) Guidance for Industry	PDF (151.29 KB)PDF (151.29 KB) of ANDAs: Pre-Submission of Facility Information Related to Prioritized Generic Drug Applications (Pre-Submission Facility Correspondence) Guidance for Industry	11/03/2017	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Generic Drugs, Pharmaceutical Quality	Draft	No	02/02/2018	
Guidance for Industry: Supply-Chain Program Requirements and Co-Manufacturer Supplier Approval and Verification for Human Food and Animal Food PDF	PDF (84.49 KB)PDF (84.49 KB) of Guidance for Industry: Supply-Chain Program Requirements and Co-Manufacturer Supplier Approval and Verification for Human Food and Animal Food PDF	11/03/2017	Center for Food Safety and Applied Nutrition		Final	No		FDA-2017-D-5996
Controlled Correspondence Related to Generic Drug Development Draft Guidance for Industry: Draft Guidance for Industry	PDF (170.66 KB)PDF (170.66 KB) of Controlled Correspondence Related to Generic Drug Development Draft Guidance for Industry: Draft Guidance for Industry	11/02/2017	Center for Drug Evaluation and Research	User Fees, Generic Drugs	Draft	No		
Guidance for Industry: Regulatory Framework for Substances Intended for Use in Human Food or Animal Food on the Basis of the Generally Recognized as Safe (GRAS) Provision of the Federal Food, Drug, and Cosmetic Act	PDF (176.65 KB)PDF (176.65 KB) of Guidance for Industry: Regulatory Framework for Substances Intended for Use in Human Food or Animal Food on the Basis of the Generally Recognized as Safe (GRAS) Provision of the Federal Food, Drug, and Cosmetic Act	11/01/2017	Office of Food Additive Safety, Office of Surveillance and Compliance	GRAS	Final	No		FDA-2016-D-4484
De Novo Classification Process (Evaluation of Automatic Class III Designation): Guidance for Industry and Food and Drug Administration Staff	PDF (182.93 KB)PDF (182.93 KB) of De Novo Classification Process (Evaluation of Automatic Class III Designation): Guidance for Industry and Food and Drug Administration Staff	10/30/2017	Center for Devices and Radiological Health	Premarket, Administrative / Procedural	Final	No		FDA-2011-D-0689
E9(R1) Statistical Principles for Clinical Trials: Addendum: Estimands and Sensitivity Analysis in Clinical Trials	PDF (221.9 KB)PDF (221.9 KB) of E9(R1) Statistical Principles for Clinical Trials: Addendum: Estimands and Sensitivity Analysis in Clinical Trials	10/30/2017	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Efficacy	Draft	No	04/30/2018	FDA-2017-D-6113
Manufacturers Sharing Patient-Specific Information from Medical Devices with Patients Upon Request: Guidance for Industry and Food and Drug Administration Staff	PDF (268.93 KB)PDF (268.93 KB) of Manufacturers Sharing Patient-Specific Information from Medical Devices with Patients Upon Request: Guidance for Industry and Food and Drug Administration Staff	10/30/2017	Center for Devices and Radiological Health	Postmarket,	Final	No	08/09/2016	FDA-2016-D-1264

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Product Labeling for Certain Ultrasonic Surgical Aspirator Devices: Guidance for Industry and Food and Drug Administration Staff	PDF (273 KB)PDF (273 KB) of Product Labeling for Certain Ultrasonic Surgical Aspirator Devices: Guidance for Industry and Food and Drug Administration Staff	10/30/2017	Center for Devices and Radiological Health	Premarket, 510(k), Labeling, Safety - Issues, Errors, and Problems, Obstetrical & Gynecological, General & Plastic Surgery	Final	No	01/09/2017	FDA-2016-D-3275
Assessing User Fees Under the Generic Drug User Fee Amendments of 2017 Guidance for Industry	PDF (707.75 KB)PDF (707.75 KB) of Assessing User Fees Under the Generic Drug User Fee Amendments of 2017 Guidance for Industry	10/27/2017	Center for Drug Evaluation and Research	User Fees,	Draft	No	01/26/2018	
Pediatric Gastroesophageal Reflux Disease: Developing Drugs for Treatment Guidance for Industry	PDF (310.68 KB)PDF (310.68 KB) of Pediatric Gastroesophageal Reflux Disease: Developing Drugs for Treatment Guidance for Industry	10/26/2017	Center for Drug Evaluation and Research	Clinical - Medical	Draft	No	01/26/2018	FDA-2017-D-5912
Clinical Drug Interaction Studies — Study Design, Data Analysis, and Clinical Implications Guidance for Industry	PDF (224.08 KB)PDF (224.08 KB) of Clinical Drug Interaction Studies — Study Design, Data Analysis, and Clinical Implications Guidance for Industry	10/25/2017	Center for Drug Evaluation and Research	Clinical - Pharmacology	Draft	No	12/25/2017	
Deciding When to Submit a 510(k) for a Change to an Existing Device: Guidance for Industry and Food and Drug Administration Staff	PDF (1.04 MB)PDF (1.04 MB) of Deciding When to Submit a 510(k) for a Change to an Existing Device: Guidance for Industry and Food and Drug Administration Staff	10/25/2017	Center for Devices and Radiological Health	Premarket, 510(k), IVDs (In Vitro Diagnostic Devices), Labeling, Laboratory Tests	Final	No	11/06/2016	FDA-2016-D-2021
Deciding When to Submit a 510(k) for a Software Change to an Existing Device: Guidance for Industry and Food and Drug Administration Staff	PDF (585.18 KB)PDF (585.18 KB) of Deciding When to Submit a 510(k) for a Software Change to an Existing Device: Guidance for Industry and Food and Drug Administration Staff	10/25/2017	Center for Devices and Radiological Health	Premarket, 510(k), IVDs (In Vitro Diagnostic Devices), Labeling, Laboratory Tests, Digital Health	Final	No	11/06/2016	FDA-2011-D-0453
In Vitro Metabolism- and Transporter- Mediated Drug-Drug Interaction Studies Guidance for Industry	PDF (396.04 KB)PDF (396.04 KB) of In Vitro Metabolism- and Transporter- Mediated Drug-Drug Interaction Studies Guidance for Industry	10/25/2017	Center for Drug Evaluation and Research	Clinical - Pharmacology	Draft	No	12/25/2017	
CVM GFI #235 Current Good Manufacturing Practice Requirements for Food for Animals	PDF (361.86 KB)PDF (361.86 KB) of CVM GFI #235 Current Good Manufacturing Practice Requirements for Food for Animals	10/20/2017	Center for Veterinary Medicine	Current Good Manufacturing Practices (CGMP), Animal Feed	Final	No	11/23/2016	FDA-2016-D-1229
Draft Guidance for Industry: Application of the "Solely Engaged" Exemptions in Parts 117 and 507 PDF	PDF (97.61 KB)PDF (97.61 KB) of Draft Guidance for Industry: Application of the "Solely Engaged" Exemptions in Parts 117 and 507 PDF	10/20/2017			Draft	No		2017-D-6333
Draft Guidance for Industry: Application of the “Solely Engaged” Exemptions in Parts 117 and 507	PDF (97.61 KB)PDF (97.61 KB) of Draft Guidance for Industry: Application of the “Solely Engaged” Exemptions in Parts 117 and 507	10/20/2017	Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine		Draft	No	04/18/2018	FDA-2017-D-6133
Tobacco Health Document Submission: Guidance for Industry		10/18/2017	Center for Tobacco Products		Final	No	04/20/2010	
Chapter 5 - Establishment Inspections	PDF (4.47 MB)PDF (4.47 MB) of Chapter 5 - Establishment Inspections	10/16/2017		Inspection, Compliance,	Final	No		
Chapter 6 - Imports	PDF (1.32 MB)PDF (1.32 MB) of Chapter 6 - Imports	10/16/2017		Inspection, Compliance,	Final	No		
Format and Content of a REMS Document Guidance for Industry	PDF (240.04 KB)PDF (240.04 KB) of Format and Content of a REMS Document Guidance for Industry	10/11/2017	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Safety - Issues, Errors, and Problems	Draft	No	12/11/2017	
Requests for Reconsideration at the Division Level Under GDUFA Guidance for Industry	PDF (98.54 KB)PDF (98.54 KB) of Requests for Reconsideration at the Division Level Under GDUFA Guidance for Industry	10/11/2017	Center for Drug Evaluation and Research	User Fees, Generic Drugs	Draft	No	12/11/2017	FDA-2017-D-5868

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Respiratory Syncytial Virus Infection: Developing Antiviral Drugs for Prophylaxis and Treatment Guidance for Industry	PDF (179.49 KB)PDF (179.49 KB) of Respiratory Syncytial Virus Infection: Developing Antiviral Drugs for Prophylaxis and Treatment Guidance for Industry	10/11/2017	Center for Drug Evaluation and Research	Clinical - Antimicrobial	Draft	No	12/11/2017	
Prohibition of Distributing Free Samples of Tobacco Products: Guidance for Industry		10/10/2017	Center for Tobacco Products		Final	No		
CVM GFI #236 Clarification of FDA and EPA Jurisdiction Over Mosquito-Related Products	PDF (85.08 KB)PDF (85.08 KB) of CVM GFI #236 Clarification of FDA and EPA Jurisdiction Over Mosquito-Related Products	10/05/2017	Center for Veterinary Medicine	New Animal Drug Application (NADA)	Final	No	02/21/2017	FDA-2016-D-4482
ANDA Submissions – Prior Approval Supplements Under GDUFA: Guidance for Industry	PDF (147.26 KB)PDF (147.26 KB) of ANDA Submissions – Prior Approval Supplements Under GDUFA: Guidance for Industry	10/04/2017	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	User Fees, Generic Drugs	Final	No		
Completeness Assessments for Type II API DMFs Under GDUFA Guidance for Industry: Guidance for Industry	PDF (379.2 KB)PDF (379.2 KB) of Completeness Assessments for Type II API DMFs Under GDUFA Guidance for Industry: Guidance for Industry	10/04/2017	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	User Fees, Chemistry, Manufacturing, and Controls (CMC), Generic Drugs, Pharmaceutical Quality	Final	No		
Expanded Access to Investigational Drugs for Treatment Use - Questions and Answers: Guidance for Industry	PDF (253.12 KB)PDF (253.12 KB) of Expanded Access to Investigational Drugs for Treatment Use - Questions and Answers: Guidance for Industry	10/03/2017	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Administrative / Procedural, Good Clinical Practices (GCP)	Final	No		
Individual Patient Expanded Access Applications: Form FDA 3926	PDF (356.32 KB)PDF (356.32 KB) of Individual Patient Expanded Access Applications: Form FDA 3926	10/03/2017		Administrative / Procedural	Final	No		
M4 Organization of the Common Technical Document for the Registration of Pharmaceuticals for Human Use Guidance for Industry	PDF (269.33 KB)PDF (269.33 KB) of M4 Organization of the Common Technical Document for the Registration of Pharmaceuticals for Human Use Guidance for Industry	10/03/2017	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Multidisciplinary	Final	No		
Waiver of IRB Requirements for Drug and Biological Product Studies: Guidance For Sponsors, Clinical Investigators, and IRBs	PDF (87.28 KB)PDF (87.28 KB) of Waiver of IRB Requirements for Drug and Biological Product Studies: Guidance For Sponsors, Clinical Investigators, and IRBs	10/03/2017	Office of Good Clinical Practice	Good Clinical Practices (GCP)	Final	No		
Administrative Procedures for CLIA Categorization: Guidance for Industry and Food and Drug Administration Staff	PDF (124.22 KB)PDF (124.22 KB) of Administrative Procedures for CLIA Categorization: Guidance for Industry and Food and Drug Administration Staff	10/02/2017	Center for Devices and Radiological Health	User Fees, Administrative / Procedural, CLIA (Clinical Laboratory Improvement Amendments)	Final	No		
ANDA Submissions - Refuse-to-Receive Standards: Questions and Answers Guidance for Industry	PDF (153.07 KB)PDF (153.07 KB) of ANDA Submissions - Refuse-to-Receive Standards: Questions and Answers Guidance for Industry	10/02/2017	Center for Drug Evaluation and Research	User Fees, Generic Drugs	Draft	No	01/02/2018	FDA-2017-D-5846
ANDAs for Certain Highly Purified Synthetic Peptide Drug Products That Refer to Listed Drugs of rDNA Origin Guidance for Industry	PDF (104.95 KB)PDF (104.95 KB) of ANDAs for Certain Highly Purified Synthetic Peptide Drug Products That Refer to Listed Drugs of rDNA Origin Guidance for Industry	10/02/2017	Center for Drug Evaluation and Research	User Fees, Generic Drugs	Draft	No	01/02/2018	
Display Devices for Diagnostic Radiology: Guidance for Industry and Food and Drug Administration Staff	PDF (445.95 KB)PDF (445.95 KB) of Display Devices for Diagnostic Radiology: Guidance for Industry and Food and Drug Administration Staff	10/02/2017	Center for Devices and Radiological Health	Premarket, 510(k), Labeling, Radiological Health, Radiology	Final	No		FDA-2016-D-0270

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
FDA and Industry Actions on Premarket Approval Applications (PMAs): Effect on FDA Review Clock and Goals: Guidance for Industry and Food and Drug Administration Staff	PDF (594.44 KB)PDF (594.44 KB) of FDA and Industry Actions on Premarket Approval Applications (PMAs): Effect on FDA Review Clock and Goals: Guidance for Industry and Food and Drug Administration Staff	10/02/2017	Center for Devices and Radiological Health	Premarket, Premarket Approval (PMA)	Final	No		
FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals: Guidance for Industry and Food and Drug Administration Staff	PDF (484.98 KB)PDF (484.98 KB) of FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals: Guidance for Industry and Food and Drug Administration Staff	10/02/2017	Center for Devices and Radiological Health	Premarket, 510(k)	Final	No		
Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA Guidance for Industry	PDF (154.38 KB)PDF (154.38 KB) of Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA Guidance for Industry	10/02/2017	Center for Drug Evaluation and Research	User Fees, Generic Drugs	Draft	No	01/02/2018	FDA-2017-D-6530
User Fees and Refunds for Premarket Notification Submissions (510(k)s) : Guidance for Industry and Food and Drug Administration Staff	PDF (117.91 KB)PDF (117.91 KB) of User Fees and Refunds for Premarket Notification Submissions (510(k)s) : Guidance for Industry and Food and Drug Administration Staff	10/02/2017	Center for Devices and Radiological Health	Premarket, User Fees, 510(k)	Final	No		
User Fees for 513(g) Requests for Information: Guidance for Industry and Food and Drug Administration Staff	PDF (82.67 KB)PDF (82.67 KB) of User Fees for 513(g) Requests for Information: Guidance for Industry and Food and Drug Administration Staff	10/02/2017	Center for Devices and Radiological Health	Premarket, User Fees,	Final	No		
Assessing User Fees Under the Generic Drug User Fee Amendments of 2017 Guidance for Industry	PDF (316.1 KB)PDF (316.1 KB) of Assessing User Fees Under the Generic Drug User Fee Amendments of 2017 Guidance for Industry	10/01/2017	Center for Drug Evaluation and Research	User Fees, Generic Drugs	Draft	No		
Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions: Guidance for Industry and Food and Drug Administration Staff	PDF (439.74 KB)PDF (439.74 KB) of Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions: Guidance for Industry and Food and Drug Administration Staff	09/29/2017	Center for Devices and Radiological Health	Premarket, Premarket Approval (PMA)	Final	No		
Advancement of Emerging Technology Applications for Pharmaceutical Innovation and Modernization Guidance for Industry	PDF (71.22 KB)PDF (71.22 KB) of Advancement of Emerging Technology Applications for Pharmaceutical Innovation and Modernization Guidance for Industry	09/28/2017	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		FDA-2015-D-4644
Classification of Products as Drugs and Devices and Additional Product Classification Issues: Guidance for Industry and FDA Staff	PDF (86.73 KB)PDF (86.73 KB) of Classification of Products as Drugs and Devices and Additional Product Classification Issues: Guidance for Industry and FDA Staff	09/25/2017	Office of Combination Products	Combination Products	Final	No	09/01/2011	
Minutes of Institutional Review Board (IRB) Meetings: Guidance for Institutions and IRBs	PDF (117.59 KB)PDF (117.59 KB) of Minutes of Institutional Review Board (IRB) Meetings: Guidance for Institutions and IRBs	09/25/2017	Office of Regulatory Affairs, Office of Good Clinical Practice, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Good Clinical Practices (GCP)	Final	No	01/04/2016	FDA-2015-D-3638
Expedited Programs for Serious Conditions—Drugs and Biologics	PDF (159.79 KB)PDF (159.79 KB) of Expedited Programs for Serious Conditions—Drugs and Biologics	09/22/2017	Center for Drug Evaluation and Research	Administrative / Procedural	Final	No		

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Q4B Annex 10: Polyacrylamide Gel Electrophoresis General Chapter	PDF (57.26 KB)PDF (57.26 KB) of Q4B Annex 10: Polyacrylamide Gel Electrophoresis General Chapter	09/18/2017	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Quality	Final	No		
Q4B Annex 2: Test for Extractable Volume of Parenteral Preparations General Chapter	PDF (69.05 KB)PDF (69.05 KB) of Q4B Annex 2: Test for Extractable Volume of Parenteral Preparations General Chapter	09/18/2017	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Quality	Final	No		
Q4B Annex 3: Test for Particulate Contamination: Subvisible Particles General Chapter	PDF (992.85 KB)PDF (992.85 KB) of Q4B Annex 3: Test for Particulate Contamination: Subvisible Particles General Chapter	09/18/2017	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Quality	Final	No		
Q4B Annex 4A: Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests General Chapter	PDF (68.81 KB)PDF (68.81 KB) of Q4B Annex 4A: Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests General Chapter	09/18/2017	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Quality	Final	No		
Q4B Annex 4B: Microbiological Examination of Non-Sterile Products: Tests for Specified Micro-organisms General Chapter	PDF (69.05 KB)PDF (69.05 KB) of Q4B Annex 4B: Microbiological Examination of Non-Sterile Products: Tests for Specified Micro-organisms General Chapter	09/18/2017	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Quality	Final	No		
Q4B Annex 4C: Microbiological Examination of Non-Sterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use General Chapter	PDF (57.38 KB)PDF (57.38 KB) of Q4B Annex 4C: Microbiological Examination of Non-Sterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use General Chapter	09/18/2017	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Quality	Final	No		
Q4B Annex 5: Disintegration Test General Chapter	PDF (68.62 KB)PDF (68.62 KB) of Q4B Annex 5: Disintegration Test General Chapter	09/18/2017	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Quality	Final	No		
Q4B Annex 8: Sterility Test General Chapter	PDF (68.49 KB)PDF (68.49 KB) of Q4B Annex 8: Sterility Test General Chapter	09/18/2017	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Quality	Final	No		
Q4B Annex 9: Tablet Friability General Chapter	PDF (67.76 KB)PDF (67.76 KB) of Q4B Annex 9: Tablet Friability General Chapter	09/18/2017	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Quality	Final	No		
Q4B Annex I: Residue on Ignition/Sulphated Ash General Chapter	PDF (58.33 KB)PDF (58.33 KB) of Q4B Annex I: Residue on Ignition/Sulphated Ash General Chapter	09/18/2017	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Quality	Final	No		
Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Human Papillomaviruses: Guidance for Industry and Food and Drug Administration Staff	PDF (785.66 KB)PDF (785.66 KB) of Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Human Papillomaviruses: Guidance for Industry and Food and Drug Administration Staff	09/15/2017	Center for Devices and Radiological Health	Premarket, Microbiology, IVDs (In Vitro Diagnostic Devices), Premarket Approval (PMA), Laboratory Tests	Final	No	11/12/2015	FDA-2009-D-0386
Regulatory Considerations for Microneedling Devices: Draft Guidance for Industry and Food and Drug Administration Staff	PDF (440.57 KB)PDF (440.57 KB) of Regulatory Considerations for Microneedling Devices: Draft Guidance for Industry and Food and Drug Administration Staff	09/15/2017	Center for Devices and Radiological Health	Premarket, General & Plastic Surgery	Draft	No	11/14/2017	FDA-2017-D-4792

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Evaluation and Reporting of Age-, Race-, and Ethnicity-Specific Data in Medical Device Clinical Studies: Guidance for Industry and Food and Drug Administration Staff	PDF (1.1 MB)PDF (1.1 MB) of Evaluation and Reporting of Age-, Race-, and Ethnicity-Specific Data in Medical Device Clinical Studies: Guidance for Industry and Food and Drug Administration Staff	09/12/2017	Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Premarket, 510(k), Clinical - Medical, Good Clinical Practices (GCP), IVDs (In Vitro Diagnostic Devices), Labeling, Premarket Approval (PMA), Radiological Health, Device Exception (IDE), HUD/HDE, Laboratory Tests, Physical Medicine, Orthopedic, Ophthalmic, Obstetrical & Gynecological, Neurological, Molecular and Clinical Genetics, Immunology & Microbiology , Cardiovascular , Hematology & Pathology , General Hospital & Personal Use , General & Plastic Surgery , Gastroenterology-Urology , Ear, Nose & Throat , Dental , Clinical Chemistry & Clinical Toxicology , Radiology	Final	No	09/18/2016	FDA-2016-D-0734
Guidance Agenda: Guidances CDER is Planning...	PDF (45.69 KB)PDF (45.69 KB) of Guidance Agenda: Guidances CDER is Planning...	09/12/2017	Center for Drug Evaluation and Research		Final	No		
Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices: Guidance for Industry and Food and Drug Administration Staff	PDF (421.33 KB)PDF (421.33 KB) of Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices: Guidance for Industry and Food and Drug Administration Staff	09/06/2017	Center for Devices and Radiological Health	510(k), Radiological Health, Anesthesiology , Neurological, Cardiovascular , General Hospital & Personal Use , Digital Health, Dental	Final	No	04/28/2016	FDA-2015-D-4852
Deviation Reporting for Human Cells, Tissues, and Cellular and Tissue-Based Products Regulated Solely Under Section 361 of the Public Health Service Act and 21 CFR Part 1271: Guidance for Industry	PDF (157.07 KB)PDF (157.07 KB) of Deviation Reporting for Human Cells, Tissues, and Cellular and Tissue-Based Products Regulated Solely Under Section 361 of the Public Health Service Act and 21 CFR Part 1271: Guidance for Industry	09/06/2017	Center for Biologics Evaluation and Research	Cellular & Gene Therapy, Tissue	Final	No		FDA-2015-D-4386
Small Entity Compliance Guide: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	PDF (244.17 KB)PDF (244.17 KB) of Small Entity Compliance Guide: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	09/06/2017	Office of Food Safety	Produce	Final	No		FDA-2011-N-0921
Procedures for Meetings of the Medical Devices Advisory Committee: Guidance for Industry and Food and Drug Administration Staff	PDF (443.17 KB)PDF (443.17 KB) of Procedures for Meetings of the Medical Devices Advisory Committee: Guidance for Industry and Food and Drug Administration Staff	09/01/2017	Center for Devices and Radiological Health	Premarket, Advisory Committees, 510(k), Administrative / Procedural, IVDs (In Vitro Diagnostic Devices), Labeling, Laser Notice, Premarket Approval (PMA), Safety - Issues, Errors, and Problems, Anesthesiology , HUD/HDE, Laboratory Tests, Physical Medicine, Orthopedic, Ophthalmic, Obstetrical & Gynecological, Neurological, Molecular and Clinical Genetics, Immunology & Microbiology , Cardiovascular , Hematology & Pathology , General Hospital & Personal Use , General & Plastic Surgery , Gastroenterology-Urology , Ear, Nose & Throat , Dental , Clinical Chemistry & Clinical Toxicology , Radiology	Final	No	05/29/2015	FDA-2015-D-0838
Providing Regulatory Submissions in Electronic Format -- Content of the Risk Evaluation and Mitigation Strategies Document Using Structured Product Labeling	PDF (75.92 KB)PDF (75.92 KB) of Providing Regulatory Submissions in Electronic Format --Content of the Risk Evaluation and Mitigation Strategies Document Using Structured Product Labeling	09/01/2017	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Electronic Submissions,	Draft	No	12/03/2017	

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Requalification of Donors Previously Deferred for a History of Viral Hepatitis after the 11th Birthday: Guidance for Industry	PDF (77.49 KB)PDF (77.49 KB) of Requalification of Donors Previously Deferred for a History of Viral Hepatitis after the 11th Birthday: Guidance for Industry	09/01/2017	Center for Biologics Evaluation and Research	Blood Products	Final	No		FDA-2017-D-5152
Guidance for Industry: Juice HACCP and the FDA Food Safety Modernization Act	PDF (132.49 KB)PDF (132.49 KB) of Guidance for Industry: Juice HACCP and the FDA Food Safety Modernization Act	08/31/2017	Center for Food Safety and Applied Nutrition	HACCP, Juice	Final	No		FDA-2017-D-3716
Guidance for Industry: Low-Acid Foods Packaged in Hermetically Sealed Containers (LACF) Regulation and the FDA Food Safety Modernization Act	PDF (119.69 KB)PDF (119.69 KB) of Guidance for Industry: Low-Acid Foods Packaged in Hermetically Sealed Containers (LACF) Regulation and the FDA Food Safety Modernization Act	08/31/2017	Center for Food Safety and Applied Nutrition	Canned Foods	Final	No		FDA-2017-D-3176
Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices : Guidance for Industry and Food and Drug Administration Staff	PDF (537.22 KB)PDF (537.22 KB) of Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices : Guidance for Industry and Food and Drug Administration Staff	08/31/2017	Center for Devices and Radiological Health	Postmarket, Biostatistics, Adverse Event Reporting System (FAERS), Adverse Event Reporting, Antimicrobial Resistance, Anesthesiology , Physical Medicine, Orthopedic, Ophthalmic, Obstetrical & Gynecological, Neurological, Molecular and Clinical Genetics, Immunology & Microbiology , Cardiovascular , Hematology & Pathology , General Hospital & Personal Use , General & Plastic Surgery , Gastroenterology-Urology , Ear, Nose & Throat , Dental , Radiology	Final	No	10/25/2016	FDA-2016-D-2153
Small Entity Compliance Guide: Mitigation Strategies to Protect Food Against Intentional Adulteration	PDF (128.82 KB)PDF (128.82 KB) of Small Entity Compliance Guide: Mitigation Strategies to Protect Food Against Intentional Adulteration	08/25/2017	Center for Food Safety and Applied Nutrition		Final	No		FDA-2013-N-1425
CVM GFI #232 (VICH GL54) Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish an Acute Reference Dose (ARfD)	PDF (99.89 KB)PDF (99.89 KB) of CVM GFI #232 (VICH GL54) Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish an Acute Reference Dose (ARfD)	08/23/2017	Center for Veterinary Medicine	Human Food Safety, VICH	Final	No	07/31/2015	FDA-2015-D-1804
CVM GFI #237 Oncology Drugs for Companion Animals	PDF (198.25 KB)PDF (198.25 KB) of CVM GFI #237 Oncology Drugs for Companion Animals	08/23/2017	Center for Veterinary Medicine	Investigational New Animal Drug (INAD)	Final	No	08/09/2016	FDA-2016-D-1248
Identifying Trading Partners Under the Drug Supply Chain Security Act Guidance for Industry	PDF (180.61 KB)PDF (180.61 KB) of Identifying Trading Partners Under the Drug Supply Chain Security Act Guidance for Industry	08/18/2017		Administrative / Procedural	Draft	No	10/18/2017	
Guidance for Industry: Ultrafiltered Milk in the Production of Standardized Cheeses and Related Cheese Products	PDF (38.08 KB)PDF (38.08 KB) of Guidance for Industry: Ultrafiltered Milk in the Production of Standardized Cheeses and Related Cheese Products	08/14/2017	Office of Nutrition and Food Labeling	Cheese/Cheese Product	Final	No		FDA-2017-D-4713
Qualification of Medical Device Development Tools: Guidance for Industry, Tool Developers, and Food and Drug Administration Staff	PDF (174.12 KB)PDF (174.12 KB) of Qualification of Medical Device Development Tools: Guidance for Industry, Tool Developers, and Food and Drug Administration Staff	08/10/2017	Center for Devices and Radiological Health	Premarket,	Final	No		FDA-2013-D-1279
CMC Postapproval Manufacturing Changes for Specified Biological Products To Be Documented in Annual Reports	PDF (93.47 KB)PDF (93.47 KB) of CMC Postapproval Manufacturing Changes for Specified Biological Products To Be Documented in Annual Reports	08/08/2017	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Draft	No		

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Expiration Dating of Unit-Dose Repackaged Solid Oral Dosage Form Drug Products: Draft Guidance for Industry	PDF (71.74 KB)PDF (71.74 KB) of Expiration Dating of Unit-Dose Repackaged Solid Oral Dosage Form Drug Products: Draft Guidance for Industry	08/08/2017	Center for Drug Evaluation and Research	Current Good Manufacturing Practices (CGMP), Pharmaceutical Quality	Draft	No	11/08/2017	
Antibacterial Therapies for Patients With an Unmet Medical Need for the Treatment of Serious Bacterial Diseases	PDF (148.81 KB)PDF (148.81 KB) of Antibacterial Therapies for Patients With an Unmet Medical Need for the Treatment of Serious Bacterial Diseases	08/01/2017	Center for Drug Evaluation and Research	Clinical - Antimicrobial	Final	No		
Guidance for Industry: Clarification on Food Establishment Waiver from Requirements of the Sanitary Transportation of Human and Animal Food Rule	PDF (37.42 KB)PDF (37.42 KB) of Guidance for Industry: Clarification on Food Establishment Waiver from Requirements of the Sanitary Transportation of Human and Animal Food Rule	07/31/2017	Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine	Sanitation, Transportation	Final	No		FDA-2013-N-0013
Guidance for Industry: Seafood HACCP and the FDA Food Safety Modernization Act	PDF (126.17 KB)PDF (126.17 KB) of Guidance for Industry: Seafood HACCP and the FDA Food Safety Modernization Act	07/31/2017	Center for Food Safety and Applied Nutrition	HACCP, Seafood/Seafood Product	Final	No		FDA-2017-D-3176
Consumer Antiseptic Wash Final Rule Questions and Answers: Guidance for Industry	PDF (91.76 KB)PDF (91.76 KB) of Consumer Antiseptic Wash Final Rule Questions and Answers: Guidance for Industry	07/25/2017	Center for Drug Evaluation and Research	Over-the-Counter Drugs	Final	No		
CVM GFI #170 Animal Drug User Fees and Fee Waivers and Reductions	PDF (171.65 KB)PDF (171.65 KB) of CVM GFI #170 Animal Drug User Fees and Fee Waivers and Reductions	07/25/2017	Center for Veterinary Medicine	User Fees,	Final	No	01/03/2017	FDA-2004-D-0369
M4E(R2): The CTD – Efficacy	PDF (470.31 KB)PDF (470.31 KB) of M4E(R2): The CTD – Efficacy	07/24/2017	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Multidisciplinary	Final	No		
PDEs for Triethylamine and for Methylisobutylketone	PDF (129.02 KB)PDF (129.02 KB) of PDEs for Triethylamine and for Methylisobutylketone	07/24/2017		ICH-Efficacy	Final	No		
Q3C Maintenance Procedures	PDF (94.02 KB)PDF (94.02 KB) of Q3C Maintenance Procedures	07/24/2017		ICH-Quality	Final	No		
Q3C Tables and List Rev. 3	PDF (185.22 KB)PDF (185.22 KB) of Q3C Tables and List Rev. 3	07/24/2017	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Quality	Final	No		
ICH Q3C Maintenance Procedures for the Guidance for Industry Q3C Impurities: Residual Solvents		07/23/2017	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Quality	Final	No		
IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects: Guidance for Sponsors, Investigators, and Institutional Review Boards	PDF (237 KB)PDF (237 KB) of IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects: Guidance for Sponsors, Investigators, and Institutional Review Boards	07/13/2017	Office of Good Clinical Practice, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Good Clinical Practices (GCP)	Final	No		
Current Good Manufacturing Practice for Medical Gases: Draft Guidance for Industry	PDF (218.85 KB)PDF (218.85 KB) of Current Good Manufacturing Practice for Medical Gases: Draft Guidance for Industry	06/28/2017	Center for Drug Evaluation and Research	Current Good Manufacturing Practices (CGMP), Pharmaceutical Quality	Draft	No	09/28/2017	
Considerations for the Design of Early-Phase Clinical Trials of Cellular and Gene Therapy Products: Guidance for Industry	PDF (312.74 KB)PDF (312.74 KB) of Considerations for the Design of Early-Phase Clinical Trials of Cellular and Gene Therapy Products: Guidance for Industry	06/27/2017	Center for Biologics Evaluation and Research	Gene Therapy	Final	No		FDA-2013-D-0576

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11 –	PDF (239.81 KB)PDF (239.81 KB) of Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11 –	06/20/2017		Administrative / Procedural	Draft	No		
E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs Questions and Answers (R3) Guidance for Industry	PDF (117.17 KB)PDF (117.17 KB) of E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs Questions and Answers (R3) Guidance for Industry	06/13/2017	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Efficacy	Final	No		
Form FDA 3674 - Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions: Guidance for Sponsors, Industry, Researchers, Investigators, and Food and Drug Administration Staff	PDF (51.64 KB)PDF (51.64 KB) of Form FDA 3674 - Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions: Guidance for Sponsors, Industry, Researchers, Investigators, and Food and Drug Administration Staff	06/07/2017	Office of Good Clinical Practice	Premarket,	Final	No		
Guidance for Industry: Recognition of Acceptable Unique Facility Identifier (UFI) for the Foreign Supplier Verification Programs Regulation	PDF (81.38 KB)PDF (81.38 KB) of Guidance for Industry: Recognition of Acceptable Unique Facility Identifier (UFI) for the Foreign Supplier Verification Programs Regulation	03/31/2017	Office of Compliance, Office of Surveillance and Compliance		Final	No		FDA-2011-N-0143
Guidance for Industry: Compliance with Providing an Acceptable Unique Facility Identifier for the Foreign Supplier Verification Programs Regulation	PDF (80.79 KB)PDF (80.79 KB) of Guidance for Industry: Compliance with Providing an Acceptable Unique Facility Identifier for the Foreign Supplier Verification Programs Regulation	03/01/2017	Office of Compliance, Office of Surveillance and Compliance	Food & Beverage Safety, Food & Beverage Safety	Final	No		FDA-2011-N-0143
Requirements for Transactions with First Responders under Section 582 of the Federal Food, Drug, and Cosmetic Act— Compliance Policy Guidance for Industry	PDF (88.52 KB)PDF (88.52 KB) of Requirements for Transactions with First Responders under Section 582 of the Federal Food, Drug, and Cosmetic Act— Compliance Policy Guidance for Industry	02/16/2017		Administrative / Procedural	Final	No		
Dear Health Care Provider Letters: Improving Communication of Important Safety Information	PDF (127.59 KB)PDF (127.59 KB) of Dear Health Care Provider Letters: Improving Communication of Important Safety Information	02/08/2017	Center for Drug Evaluation and Research	Administrative / Procedural	Final	No		
Withdrawn Guidances (Biologics)		01/27/2017	Center for Biologics Evaluation and Research		Final	No		
Draft Guidance for Industry: Compliance with and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations	PDF (1 MB)PDF (1 MB) of Draft Guidance for Industry: Compliance with and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations	01/23/2017	Office of Food Safety	Produce	Draft	No	07/24/2017	FDA-2017-D-0175
CVM GFI #187 Regulation of Intentionally Altered Genomic DNA in Animals	PDF (200.02 KB)PDF (200.02 KB) of CVM GFI #187 Regulation of Intentionally Altered Genomic DNA in Animals	01/19/2017	Center for Veterinary Medicine	Biotechnology,	Draft	No	04/19/2017	FDA-2008-D-0394
2016 Medical Gas Container-Closure Rule Questions and Answers Guidance for Industry: Guidance for Industry	PDF (81.54 KB)PDF (81.54 KB) of 2016 Medical Gas Container-Closure Rule Questions and Answers Guidance for Industry: Guidance for Industry	01/17/2017	Center for Drug Evaluation and Research	Current Good Manufacturing Practices (CGMP), Labeling	Final	No		
Assessment of Abuse Potential of Drugs	PDF (285.09 KB)PDF (285.09 KB) of Assessment of Abuse Potential of Drugs	01/17/2017	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		FDA-2010-D-0026

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA: Draft Guidance for Industry	PDF (199.81 KB)PDF (199.81 KB) of Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA: Draft Guidance for Industry	01/13/2017	Center for Drug Evaluation and Research	Generic Drugs	Draft	No	03/13/2017	FDA-2016-D-4412
Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders	PDF (287.5 KB)PDF (287.5 KB) of Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders	01/13/2017	Office of Counterterrorism and Emerging Threats	Premarket, Emergencies,	Final	No	06/04/2016	FDA-2016-D-1025
Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions: Guidance for Investigational Device Exemption Sponsors, Sponsor-Investigators and Food and Drug Administration Staff	PDF (748.9 KB)PDF (748.9 KB) of Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions: Guidance for Investigational Device Exemption Sponsors, Sponsor-Investigators and Food and Drug Administration Staff	01/13/2017	Center for Devices and Radiological Health	Premarket, Clinical - Medical, Device Exception (IDE)	Final	No	09/16/2015	FDA-2015-D-1777
Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry	PDF (133.73 KB)PDF (133.73 KB) of Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry	01/13/2017	Center for Drug Evaluation and Research	Administrative / Procedural, Compounding	Final	No		
Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act	PDF (111.64 KB)PDF (111.64 KB) of Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act	01/13/2017	Center for Drug Evaluation and Research	Administrative / Procedural, Compounding	Final	No		
Referencing Approved Drug Products in ANDA Submissions Guidance for Industry	PDF (154.58 KB)PDF (154.58 KB) of Referencing Approved Drug Products in ANDA Submissions Guidance for Industry	01/13/2017	Center for Drug Evaluation and Research	Generic Drugs	Draft	No	03/13/2017	
Guidance for Industry 180-Day Exclusivity: Questions and Answers	PDF (239.52 KB)PDF (239.52 KB) of Guidance for Industry 180-Day Exclusivity: Questions and Answers	01/12/2017	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Generic Drugs	Draft	No	03/12/2017	FDA-2016-D-4645
Multiple Endpoints in Clinical Trials Guidance for Industry	PDF (687.5 KB)PDF (687.5 KB) of Multiple Endpoints in Clinical Trials Guidance for Industry	01/12/2017	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Clinical - Medical	Draft	No	03/13/2017	
Nonproprietary Naming of Biological Products Guidance for Industry	PDF (114.73 KB)PDF (114.73 KB) of Nonproprietary Naming of Biological Products Guidance for Industry	01/12/2017	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Labeling	Final	No		FDA-2013-D-1543
Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities: Guidance for Industry	PDF (645.92 KB)PDF (645.92 KB) of Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities: Guidance for Industry	01/12/2017	Center for Drug Evaluation and Research	Compliance, Compounding, Current Good Manufacturing Practices (CGMP), Pharmaceutical Quality	Final	No		
Recommended Warning for Over-the-Counter Acetaminophen-Containing Drug Products and Labeling Statements Regarding Serious Skin Reactions	PDF (89.49 KB)PDF (89.49 KB) of Recommended Warning for Over-the-Counter Acetaminophen-Containing Drug Products and Labeling Statements Regarding Serious Skin Reactions	01/11/2017	Center for Drug Evaluation and Research	Compliance, Current Good Manufacturing Practices (CGMP), Over-the-Counter Drugs	Final	No		

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Recommendations for Assessment of Blood Donor Eligibility, Donor Deferral and Blood Product Management in Response to Ebola Virus: Guidance for Industry	PDF (99.42 KB)PDF (99.42 KB) of Recommendations for Assessment of Blood Donor Eligibility, Donor Deferral and Blood Product Management in Response to Ebola Virus: Guidance for Industry	01/10/2017	Center for Biologics Evaluation and Research	Blood Products	Final	No		FDA-2014-D-2175
Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers: Questions and Answers Guidance for Industry	PDF (111.44 KB)PDF (111.44 KB) of Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers: Questions and Answers Guidance for Industry	01/09/2017		Administrative / Procedural	Draft	No		
Current Good Manufacturing Practice Requirements for Combination Products: Guidance for Industry and FDA Staff	PDF (555.16 KB)PDF (555.16 KB) of Current Good Manufacturing Practice Requirements for Combination Products: Guidance for Industry and FDA Staff	01/09/2017	Office of Regulatory Affairs, Office of Combination Products, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Compounding, Current Good Manufacturing Practices (CGMP), Pharmaceutical Quality	Final	No	03/30/2015	FDA-2015-D-0198
Draft Guidance for Industry: Control of Listeria monocytogenes in Ready-To-Eat Foods	PDF (852.17 KB)PDF (852.17 KB) of Draft Guidance for Industry: Control of Listeria monocytogenes in Ready-To-Eat Foods	01/05/2017	Office of Food Safety	Food & Beverage Safety, Potential Foodborne Illness, Potential Foodborne Illness, Food & Beverage Safety	Draft	No	07/26/2017	FDA-2008-D-0096
CVM GFI #242 In-Use Stability Studies and Associated Labeling Statements for Multiple-Dose Injectable Animal Drug Products	PDF (111.34 KB)PDF (111.34 KB) of CVM GFI #242 In-Use Stability Studies and Associated Labeling Statements for Multiple-Dose Injectable Animal Drug Products	01/04/2017	Center for Veterinary Medicine	Chemistry, Manufacturing, and Controls (CMC), New Animal Drug Application (NADA), Investigational New Animal Drug (INAD)	Draft	No	03/06/2017	FDA-2016-D-4437
Premarket Notification (510(k)) Submissions for Bone Anchors: Draft Guidance for Industry and Food and Drug Administration Staff	PDF (493.48 KB)PDF (493.48 KB) of Premarket Notification (510(k)) Submissions for Bone Anchors: Draft Guidance for Industry and Food and Drug Administration Staff	01/03/2017	Center for Devices and Radiological Health	Premarket, 510(k), Orthopedic	Draft	No	03/04/2017	FDA-2016-D-4436
Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act.”	PDF (190.66 KB)PDF (190.66 KB) of Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act.”	12/30/2016	Center for Drug Evaluation and Research	Administrative / Procedural, Compounding	Final	No		
Botanical Drug Development: Guidance for Industry	PDF (221.35 KB)PDF (221.35 KB) of Botanical Drug Development: Guidance for Industry	12/28/2016	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		
Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product	PDF (149.89 KB)PDF (149.89 KB) of Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product	12/28/2016	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Biosimilarity	Final	No		FDA-2014-D-0234
Postmarket Management of Cybersecurity in Medical Devices: Guidance for Industry and Food and Drug Administration Staff	PDF (1.23 MB)PDF (1.23 MB) of Postmarket Management of Cybersecurity in Medical Devices: Guidance for Industry and Food and Drug Administration Staff	12/28/2016	Center for Devices and Radiological Health	Postmarket, Premarket, 510(k), Labeling, Premarket Approval (PMA), Safety - Issues, Errors, and Problems, Digital Health	Final	No		FDA-2015-D-5105
Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry	PDF (348.92 KB)PDF (348.92 KB) of Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry	12/28/2016	Center for Drug Evaluation and Research	Compounding	Final	No		

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Factors to Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions: Guidance for Industry and Food and Drug Administration Staff	PDF (870.11 KB)PDF (870.11 KB) of Factors to Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions: Guidance for Industry and Food and Drug Administration Staff	12/27/2016	Center for Devices and Radiological Health	Postmarket, Recalls, Adverse Event Reporting System (FAERS), 510(k), Adverse Event Reporting, Combination Products, Laser Notice, Premarket Approval (PMA), Safety - Issues, Errors, and Problems, Device Exception (IDE), HUD/HDE	Final	No	09/14/2016	FDA-2016-D-1495
Draft Guidance for Industry: Lead in Cosmetic Lip Products and Externally Applied Cosmetics: Recommended Maximum Level	PDF (115.52 KB)PDF (115.52 KB) of Draft Guidance for Industry: Lead in Cosmetic Lip Products and Externally Applied Cosmetics: Recommended Maximum Level	12/22/2016	Office of Cosmetics and Colors	Contaminants, Potential Metal or Chemical Contaminant, Potential Metal or Chemical Contaminant	Draft	No	02/21/2010	FDA-2014-D-2275
ANDA Submissions -- Refuse-to-Receive Standards Rev.2	PDF (198.75 KB)PDF (198.75 KB) of ANDA Submissions -- Refuse-to-Receive Standards Rev.2	12/21/2016	Center for Drug Evaluation and Research	User Fees, Generic Drugs	Final	No		
CVM GFI #234 Question-Based Review for the Chemistry, Manufacturing, and Controls Technical Section of Animal Drug Applications	PDF (614.22 KB)PDF (614.22 KB) of CVM GFI #234 Question-Based Review for the Chemistry, Manufacturing, and Controls Technical Section of Animal Drug Applications	12/20/2016	Center for Veterinary Medicine	Chemistry, Manufacturing, and Controls (CMC)	Final	No	05/17/2016	FDA-2016-D-0620
CVM GFI #224 (VICH GL52) Bioequivalence: Blood Level Bioequivalence Study	PDF (282.71 KB)PDF (282.71 KB) of CVM GFI #224 (VICH GL52) Bioequivalence: Blood Level Bioequivalence Study	12/16/2016	Center for Veterinary Medicine	Generic Drugs, New Animal Drug Application (NADA), VICH, Generic Animal Drugs	Final	No	11/24/2014	FDA-2014-D-1352
Gifts to FDA: Evaluation and Acceptance: Guidance for the Public and FDA Staff	PDF (95.02 KB)PDF (95.02 KB) of Gifts to FDA: Evaluation and Acceptance: Guidance for the Public and FDA Staff	12/16/2016	Office of Policy		Final	No	09/12/2016	FDA-2015-D-4361
Civil Money Penalties and No-Tobacco-Sale Orders For Tobacco Retailers (*Revised): Guidance for Industry		12/14/2016	Center for Tobacco Products		Final	No		
Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers Responses to Frequently Asked Questions (*Revised): Guidance for Industry		12/14/2016	Center for Tobacco Products		Final	No		
Public Notification of Emerging Postmarket Medical Device Signals ("Emerging Signals"): Guidance for Industry and Food and Drug Administration Staff	PDF (127.96 KB)PDF (127.96 KB) of Public Notification of Emerging Postmarket Medical Device Signals ("Emerging Signals"): Guidance for Industry and Food and Drug Administration Staff	12/14/2016	Center for Devices and Radiological Health	Postmarket, Safety - Issues, Errors, and Problems	Final	No		FDA-2015-D-4803
Use of Electronic Informed Consent in Clinical Investigations – Questions and Answers: Guidance for Institutional Review Boards, Investigators, and Sponsors	PDF (230.82 KB)PDF (230.82 KB) of Use of Electronic Informed Consent in Clinical Investigations – Questions and Answers: Guidance for Institutional Review Boards, Investigators, and Sponsors	12/14/2016	Office of Good Clinical Practice, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Administrative / Procedural, Good Clinical Practices (GCP)	Final	No		
Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans: Guidance for Industry	PDF (294.51 KB)PDF (294.51 KB) of Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans: Guidance for Industry	12/13/2016	Center for Biologics Evaluation and Research	Xenotransplantation	Final	No		00D-1662
Immediately in Effect Guidance Document: Conditions for Sale for Air-Conduction Hearing Aids: Guidance for Industry and Food and Drug Administration Staff	PDF (402.27 KB)PDF (402.27 KB) of Immediately in Effect Guidance Document: Conditions for Sale for Air-Conduction Hearing Aids: Guidance for Industry and Food and Drug Administration Staff	12/12/2016	Center for Devices and Radiological Health	Postmarket, Ear, Nose & Throat	Final	No		FDA-2016-D-3466
Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions: Guidance for Industry		12/11/2016	Center for Tobacco Products		Final	No		

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification Guidance for Industry	PDF (145.54 KB)PDF (145.54 KB) of Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification Guidance for Industry	12/08/2016		Administrative / Procedural	Final	No		
Guidance for Industry and FDA Staff: Model Accreditation Standards for Third-Party Certification Body Accreditation for Food Safety Audits	PDF (118.21 KB)PDF (118.21 KB) of Guidance for Industry and FDA Staff: Model Accreditation Standards for Third-Party Certification Body Accreditation for Food Safety Audits	12/07/2016	Office of Foods and Veterinary Medicine	Export	Final	No		FDA-2011-N-0146
Clinical Pharmacology Labeling for Human Prescription Drug and Biological Products — Content and Format	PDF (143.76 KB)PDF (143.76 KB) of Clinical Pharmacology Labeling for Human Prescription Drug and Biological Products — Content and Format	12/02/2016	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Labeling	Final	No		
CPG Sec 615.115 Extralabel Use of Medicated Feeds for Minor Species	PDF (101.75 KB)PDF (101.75 KB) of CPG Sec 615.115 Extralabel Use of Medicated Feeds for Minor Species	12/01/2016	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Medicated Feed, Minor Use/ Minor Species (MUMS)	Final	No		
Mitigating the Risk of Cross-Contamination from Valves and Accessories Used for Irrigation Through Flexible Gastrointestinal Endoscopes: Guidance for Industry and Food and Drug Administration Staff	PDF (445.11 KB)PDF (445.11 KB) of Mitigating the Risk of Cross-Contamination from Valves and Accessories Used for Irrigation Through Flexible Gastrointestinal Endoscopes: Guidance for Industry and Food and Drug Administration Staff	11/29/2016	Center for Devices and Radiological Health	Premarket, Gastroenterology-Urology	Final	No		FDA-2014-D-2153
Providing Postmarket Periodic Safety Reports in the ICH E2C(R2) Format (Periodic Benefit-Risk Evaluation Report)	PDF (115.79 KB)PDF (115.79 KB) of Providing Postmarket Periodic Safety Reports in the ICH E2C(R2) Format (Periodic Benefit-Risk Evaluation Report)	11/28/2016	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Safety - Issues, Errors, and Problems	Final	No		
Submission of Quality Metrics Data Guidance for Industry	PDF (339.64 KB)PDF (339.64 KB) of Submission of Quality Metrics Data Guidance for Industry	11/23/2016	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Current Good Manufacturing Practices (CGMP), Pharmaceutical Quality	Draft	No	01/23/2017	
Contract Manufacturing Arrangements for Drugs: Quality Agreements Guidance for Industry: Guidance for Industry	PDF (122.79 KB)PDF (122.79 KB) of Contract Manufacturing Arrangements for Drugs: Quality Agreements Guidance for Industry: Guidance for Industry	11/22/2016	Center for Veterinary Medicine, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Compliance, Current Good Manufacturing Practices (CGMP), Pharmaceutical Quality	Final	No		
Nonprescription Sunscreen Drug Products – Format and Content of Data Submissions	PDF (116.77 KB)PDF (116.77 KB) of Nonprescription Sunscreen Drug Products – Format and Content of Data Submissions	11/22/2016	Center for Drug Evaluation and Research	Over-the-Counter Drugs	Final	No		
Nonprescription Sunscreen Drug Products – Safety and Effectiveness Data	PDF (140.4 KB)PDF (140.4 KB) of Nonprescription Sunscreen Drug Products – Safety and Effectiveness Data	11/22/2016	Center for Drug Evaluation and Research	Over-the-Counter Drugs	Final	No		
Safety Testing of Drug Metabolites	PDF (184.56 KB)PDF (184.56 KB) of Safety Testing of Drug Metabolites	11/22/2016		Pharm/Tox	Final	No		
Generic Drug User Fee Amendments of 2012: Questions and Answers Related to User Fee Assessments: Guidance for Industry	PDF (221.68 KB)PDF (221.68 KB) of Generic Drug User Fee Amendments of 2012: Questions and Answers Related to User Fee Assessments: Guidance for Industry	11/21/2016	Center for Drug Evaluation and Research	User Fees, Generic Drugs	Final	No		

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices: Guidance for Industry and Food and Drug Administration Staff	PDF (465.54 KB)PDF (465.54 KB) of Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices: Guidance for Industry and Food and Drug Administration Staff	11/18/2016	Center for Devices and Radiological Health	Premarket, 510(k), Radiological Health, Radiology	Final	No	10/12/2015	FDA-2015-D-2148
Medical Device Reporting for Manufacturers : Guidance for Industry and Food and Drug Administration Staff	PDF (366.22 KB)PDF (366.22 KB) of Medical Device Reporting for Manufacturers : Guidance for Industry and Food and Drug Administration Staff	11/08/2016	Center for Devices and Radiological Health	Postmarket, Adverse Event Reporting System (FAERS), Adverse Event Reporting	Final	No		FDA-2013-D-0743
Clinical Considerations for Investigational Device Exemptions (IDEs) for Neurological Devices Targeting Disease Progression and Clinical Outcomes: Guidance for Industry and Food and Drug Administration Staff	PDF (176.87 KB)PDF (176.87 KB) of Clinical Considerations for Investigational Device Exemptions (IDEs) for Neurological Devices Targeting Disease Progression and Clinical Outcomes: Guidance for Industry and Food and Drug Administration Staff	11/07/2016	Center for Devices and Radiological Health	Premarket, Advisory Committees, 510(k), Clinical - Medical, Good Clinical Practices (GCP), Labeling, Laser Notice, Premarket Approval (PMA), Safety - Issues, Errors, and Problems, HUD/HDE, Neurological	Final	No	06/05/2016	FDA-2016-D-0539
Non-Inferiority Clinical Trials	PDF (473.9 KB)PDF (473.9 KB) of Non-Inferiority Clinical Trials	11/07/2016	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Clinical - Medical	Final	No		
CVM GFI #241 Small Entity Compliance Guide – What You Need to Know About the FDA Regulation: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals (21 CFR Part 507)	PDF (237.57 KB)PDF (237.57 KB) of CVM GFI #241 Small Entity Compliance Guide – What You Need to Know About the FDA Regulation: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals (21 CFR Part 507)	11/01/2016	Center for Veterinary Medicine	Animal Feed	Final	No		FDA-2011-N-0922
Revised Recommendations for Determining Eligibility of Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products Who Have Received Human-Derived Clotting Factor Concentrates: Guidance for Industry	PDF (55.24 KB)PDF (55.24 KB) of Revised Recommendations for Determining Eligibility of Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products Who Have Received Human-Derived Clotting Factor Concentrates: Guidance for Industry	11/01/2016	Center for Biologics Evaluation and Research	Tissue	Final	No		FDA-2016-D-3750
Small Entity Compliance Guide: What You Need to Know About Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food	PDF (313.99 KB)PDF (313.99 KB) of Small Entity Compliance Guide: What You Need to Know About Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food	11/01/2016	Center for Food Safety and Applied Nutrition		Final	No		FDA-2011-N-0920
Draft Guidance for Industry: Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing FSMA	PDF (60.3 KB)PDF (60.3 KB) of Draft Guidance for Industry: Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing FSMA	10/31/2016	Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine, Office of Policy		Draft	No	05/01/2017	FDA-2016-D-2841
Labeling for Permanent Hysteroscopically-Placed Tubal Implants Intended for Sterilization: Guidance for Industry and Food and Drug Administration Staff	PDF (384.46 KB)PDF (384.46 KB) of Labeling for Permanent Hysteroscopically-Placed Tubal Implants Intended for Sterilization: Guidance for Industry and Food and Drug Administration Staff	10/31/2016	Center for Devices and Radiological Health	Postmarket, Biostatistics, Adverse Event Reporting System (FAERS), 510(k), Adverse Event Reporting, Labeling, Gastroenterology-Urology	Final	No	04/29/2016	FDA-2016-D-0435

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Collection of Race and Ethnicity Data in Clinical Trials: Guidance for Industry and Food and Drug Administration Staff	PDF (896.11 KB)PDF (896.11 KB) of Collection of Race and Ethnicity Data in Clinical Trials: Guidance for Industry and Food and Drug Administration Staff	10/26/2016	Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research, Office of Minority Health, Office of Women's Health	Clinical - Medical, Good Clinical Practices (GCP)	Final	No		FDA-2016-D-3561
Low Sexual Interest, Desire, and/or Arousal in Women: Developing Drugs for Treatment Guidance for Industry	PDF (298.14 KB)PDF (298.14 KB) of Low Sexual Interest, Desire, and/or Arousal in Women: Developing Drugs for Treatment Guidance for Industry	10/25/2016	Center for Drug Evaluation and Research	Clinical - Medical	Draft	No	12/25/2016	
FDA Considerations for Recommending Charges for Causing the Introduction of Violative Products into Interstate Commerce	PDF (27.22 KB)PDF (27.22 KB) of FDA Considerations for Recommending Charges for Causing the Introduction of Violative Products into Interstate Commerce	10/17/2016		Investigation & Enforcement,	Final	No		
Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use: Guidance for Industry and Food and Drug Administration Staff	PDF (805.19 KB)PDF (805.19 KB) of Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use: Guidance for Industry and Food and Drug Administration Staff	10/11/2016	Office of In Vitro Diagnostics and Radiological Health	Premarket, 510(k), CLIA (Clinical Laboratory Improvement Amendments), IVDs (In Vitro Diagnostic Devices), Laboratory Tests, Clinical Chemistry & Clinical Toxicology	Final	No		FDA-2013-D-1445
Investigational Use of Deemed, Finished Tobacco Products That Were on the U.S. Market on August 8, 2016 During the Deeming Compliance Periods: Guidance for Industry		10/11/2016	Center for Tobacco Products		Final	No		
Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use: Guidance for Industry and Food and Drug Administration Staff	PDF (806.31 KB)PDF (806.31 KB) of Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use: Guidance for Industry and Food and Drug Administration Staff	10/11/2016	Center for Devices and Radiological Health	Premarket, 510(k), IVDs (In Vitro Diagnostic Devices), Over-the-Counter Drugs, Laboratory Tests, Clinical Chemistry & Clinical Toxicology	Final	No		FDA-2013-D-1446
Sunscreen Innovation Act: Section 586C(c) Advisory Committee Process	PDF (102.97 KB)PDF (102.97 KB) of Sunscreen Innovation Act: Section 586C(c) Advisory Committee Process	10/07/2016	Center for Drug Evaluation and Research	Over-the-Counter Drugs	Final	No		
Sunscreen Innovation Act: Withdrawal of a 586A Request or Pending Request Guidance for Industry	PDF (105.1 KB)PDF (105.1 KB) of Sunscreen Innovation Act: Withdrawal of a 586A Request or Pending Request Guidance for Industry	10/07/2016	Center for Drug Evaluation and Research	Over-the-Counter Drugs	Final	No		
Head Lice Infestation: Developing Drugs for Topical Treatment Guidance for Industry	PDF (232.93 KB)PDF (232.93 KB) of Head Lice Infestation: Developing Drugs for Topical Treatment Guidance for Industry	10/05/2016	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		
Tropical Disease Priority Review Vouchers	PDF (278.88 KB)PDF (278.88 KB) of Tropical Disease Priority Review Vouchers	10/05/2016	Center for Drug Evaluation and Research	Administrative / Procedural	Final	No		
Draft Guidance for Industry: New Dietary Ingredient Notifications and Related Issues	PDF (927.77 KB)PDF (927.77 KB) of Draft Guidance for Industry: New Dietary Ingredient Notifications and Related Issues	10/04/2016	Office of Dietary Supplement Programs		Draft	No	12/12/2016	FDA-2011-D-0376
Guidance for Industry: Frequently Asked Questions About GRAS for Substances Intended for Use in Human or Animal Food	PDF (117.29 KB)PDF (117.29 KB) of Guidance for Industry: Frequently Asked Questions About GRAS for Substances Intended for Use in Human or Animal Food	09/30/2016	Office of Food Additive Safety, Office of Surveillance and Compliance	Food & Color Additives	Final	No		FDA-2013-S-0610
Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients Guidance for Industry	PDF (253.13 KB)PDF (253.13 KB) of Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients Guidance for Industry	09/30/2016	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Quality	Final	No		

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Guidance for Industry: Use of the Term “Healthy” in the Labeling of Human Food Products	PDF (41.23 KB)PDF (41.23 KB) of Guidance for Industry: Use of the Term “Healthy” in the Labeling of Human Food Products	09/28/2016	Office of Nutrition and Food Labeling	Labeling	Final	No		FDA-2016-D-2335
CVM GFI #233 Veterinary Feed Directive Common Format Questions and Answers	PDF (834.27 KB)PDF (834.27 KB) of CVM GFI #233 Veterinary Feed Directive Common Format Questions and Answers	09/22/2016	Center for Veterinary Medicine	Antimicrobial Resistance, Labeling, New Animal Drug Application (NADA)	Final	No	02/01/2016	FDA-2010-N-0155
Self-Identification of Generic Drug Facilities, Sites, and Organizations; Guidance for Industry	PDF (268.36 KB)PDF (268.36 KB) of Self-Identification of Generic Drug Facilities, Sites, and Organizations; Guidance for Industry	09/22/2016	Center for Drug Evaluation and Research	User Fees, Generic Drugs	Final	No		
Reporting of Computational Modeling Studies in Medical Device Submissions: Guidance for Industry and Food and Drug Administration Staff	PDF (771.67 KB)PDF (771.67 KB) of Reporting of Computational Modeling Studies in Medical Device Submissions: Guidance for Industry and Food and Drug Administration Staff	09/21/2016	Center for Devices and Radiological Health	Premarket, 510(k), Premarket Approval (PMA), Device Exception (IDE)	Final	No		FDA-2013-D-1530
Recommendations for Microbial Vectors Used for Gene Therapy: Guidance for Industry	PDF (161.34 KB)PDF (161.34 KB) of Recommendations for Microbial Vectors Used for Gene Therapy: Guidance for Industry	09/16/2016	Center for Biologics Evaluation and Research	Cellular & Gene Therapy, Gene Therapy	Final	No		FDA-2015-D-3399
Qualification of Biomarker Total Kidney Volume in Studies for Treatment of Autosomal Dominant Polycystic Kidney Disease Draft Guidance for Industry	PDF (32.23 KB)PDF (32.23 KB) of Qualification of Biomarker Total Kidney Volume in Studies for Treatment of Autosomal Dominant Polycystic Kidney Disease Draft Guidance for Industry	09/15/2016	Center for Drug Evaluation and Research	Drug Development Tools	Final	No		
Qualification of Biomarker Plasma Fibrinogen in Studies Examining Exacerbations and/or All-Cause Mortality in Patients With Chronic Obstructive Pulmonary Disease Guidance for Industry	PDF (38.52 KB)PDF (38.52 KB) of Qualification of Biomarker Plasma Fibrinogen in Studies Examining Exacerbations and/or All-Cause Mortality in Patients With Chronic Obstructive Pulmonary Disease Guidance for Industry	09/14/2016	Center for Drug Evaluation and Research	Drug Development Tools	Final	No		FDA-2015-D-2244
Draft Guidance for Industry: Substantiation for Structure/Function Claims Made in Infant Formula Labels and Labeling	PDF (130.07 KB)PDF (130.07 KB) of Draft Guidance for Industry: Substantiation for Structure/Function Claims Made in Infant Formula Labels and Labeling	09/09/2016	Office of Nutrition and Food Labeling	Infant Formula & Foods	Draft	No	02/21/2017	FDA-2016-D-2241
Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Living Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps): Guidance for Industry	PDF (101.63 KB)PDF (101.63 KB) of Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Living Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps): Guidance for Industry	09/08/2016	Center for Biologics Evaluation and Research	Policy Making, Tissue	Final	No		FDA-2013-D-1143
Guidance for Industry: Necessity of the Use of Food Product Categories in Food Facility Registrations and Updates to Food Product Categories (2016 Edition)	PDF (92.38 KB)PDF (92.38 KB) of Guidance for Industry: Necessity of the Use of Food Product Categories in Food Facility Registrations and Updates to Food Product Categories (2016 Edition)	09/01/2016	Office of Compliance	Defense & Security	Final	No		FDA-2012-D-0585
Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices: Guidance for Industry and Food and Drug Administration Staff	PDF (388.18 KB)PDF (388.18 KB) of Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices: Guidance for Industry and Food and Drug Administration Staff	09/01/2016	Center for Devices and Radiological Health	Premarket, 510(k), Radiological Health, Radiology	Final	No		FDA-1997-N-0389
“Harmful and Potentially Harmful Constituents” in Tobacco Products as Used in Section 904(e) of the Federal Food, Drug, and Cosmetic Act: Guidance for Industry and FDA Staff		08/31/2016	Center for Tobacco Products		Final	No	01/31/2011	

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Enforcement Policy on National Health Related Item Code and National Drug Code Numbers Assigned to Devices: Guidance for Industry and Food and Drug Administration Staff	PDF (286.18 KB)PDF (286.18 KB) of Enforcement Policy on National Health Related Item Code and National Drug Code Numbers Assigned to Devices: Guidance for Industry and Food and Drug Administration Staff	08/30/2016	Center for Devices and Radiological Health	Postmarket, Premarket, Recalls, Clinical - Medical, Combination Products, Safety - Issues, Errors, and Problems, Physical Medicine, Orthopedic, Ophthalmic, Obstetrical & Gynecological, Neurological, General Hospital & Personal Use , General & Plastic Surgery , Gastroenterology-Urology , Ear, Nose & Throat , Radiology	Final	No		FDA-2016-D-0199
CVM GFI #239 Human Food By-Products For Use As Animal Food	PDF (145.58 KB)PDF (145.58 KB) of CVM GFI #239 Human Food By-Products For Use As Animal Food	08/25/2016	Center for Veterinary Medicine	Current Good Manufacturing Practices (CGMP), Animal Feed	Draft	No	11/23/2016	FDA-2016-D-1220
Draft Guidance for Industry: Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities	PDF (256.75 KB)PDF (256.75 KB) of Draft Guidance for Industry: Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities	08/25/2016	Center for Food Safety and Applied Nutrition		Draft	No	02/21/2017	FDA-2016-D-2373
ANDA Submissions — Refuse to Receive for Lack of Justification of Impurity Limits: Guidance for Industry	PDF (325.96 KB)PDF (325.96 KB) of ANDA Submissions — Refuse to Receive for Lack of Justification of Impurity Limits: Guidance for Industry	08/24/2016	Center for Drug Evaluation and Research	User Fees, Generic Drugs	Final	No		
Patient Preference Information - Voluntary Submission, Review in Premarket Approval Applications, Humanitarian Device Exemption Applications, and De Novo Requests, and Inclusion in Decision Summaries and Device Labeling: Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders	PDF (765.74 KB)PDF (765.74 KB) of Patient Preference Information - Voluntary Submission, Review in Premarket Approval Applications, Humanitarian Device Exemption Applications, and De Novo Requests, and Inclusion in Decision Summaries and Device Labeling: Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders	08/24/2016	Center for Devices and Radiological Health		Final	No		
Draft Guidance for Industry: Calorie Labeling of Articles of Food in Vending Machines	PDF (109.07 KB)PDF (109.07 KB) of Draft Guidance for Industry: Calorie Labeling of Articles of Food in Vending Machines	08/16/2016	Office of Nutrition and Food Labeling	Food & Color Additives, Labeling, Nutrition Label	Draft	No	09/30/2016	FDA-2011-F-0171
Small Entity Compliance Guide: Calorie Labeling of Articles of Food in Vending Machines	PDF (447.85 KB)PDF (447.85 KB) of Small Entity Compliance Guide: Calorie Labeling of Articles of Food in Vending Machines	08/16/2016	Office of Nutrition and Food Labeling	Labeling, Nutrition Label	Final	No		FDA-2011-F-0171
Premarket Notification (510(k)) Submissions for Bipolar Electrosurgical Vessel Sealers for General Surgery: Guidance for Industry and Food and Drug Administration Staff	PDF (450.4 KB)PDF (450.4 KB) of Premarket Notification (510(k)) Submissions for Bipolar Electrosurgical Vessel Sealers for General Surgery: Guidance for Industry and Food and Drug Administration Staff	08/15/2016	Center for Devices and Radiological Health	Premarket, 510(k), Clinical - Medical, Good Clinical Practices (GCP), Labeling, Laser Notice, General & Plastic Surgery	Final	No		
Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery: Guidance for Industry and Food and Drug Administration Staff	PDF (508.28 KB)PDF (508.28 KB) of Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery: Guidance for Industry and Food and Drug Administration Staff	08/15/2016	Center for Devices and Radiological Health	Premarket, 510(k), Clinical - Medical, Good Clinical Practices (GCP), Labeling, Laser Notice, General & Plastic Surgery	Final	No		
Calorie Labeling of Articles of Food in Vending Machines: Guidance for Industry; Draft Guidance	PDF (109.07 KB)PDF (109.07 KB) of Calorie Labeling of Articles of Food in Vending Machines: Guidance for Industry; Draft Guidance	08/12/2016			Draft	No		FDA-2011-F-0171
Calorie Labeling of Articles of Food in Vending Machines: Guidance for Industry; Small Entity Compliance Guide	PDF (447.85 KB)PDF (447.85 KB) of Calorie Labeling of Articles of Food in Vending Machines: Guidance for Industry; Small Entity Compliance Guide	08/12/2016		Nutrition Label	Final	No		FDA-2011-F-0171

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Ulcerative Colitis: Clinical Trial Endpoints Guidance for Industry	PDF (564.66 KB)PDF (564.66 KB) of Ulcerative Colitis: Clinical Trial Endpoints Guidance for Industry	08/05/2016	Center for Drug Evaluation and Research	Clinical - Medical	Draft	No		FDA-2016-D-2319
Substantiation for Structure/Function Claims Made in Infant Formula Labels and Labeling	PDF (130.07 KB)PDF (130.07 KB) of Substantiation for Structure/Function Claims Made in Infant Formula Labels and Labeling	08/02/2016		Infant Formula & Foods	Final	No		
Determining Donor Eligibility for Autologous Donors of Blood and Blood Components Intended Solely for Autologous Use - Compliance Policy: Guidance for Industry	PDF (85.63 KB)PDF (85.63 KB) of Determining Donor Eligibility for Autologous Donors of Blood and Blood Components Intended Solely for Autologous Use - Compliance Policy: Guidance for Industry	08/01/2016	Center for Biologics Evaluation and Research	Blood Products	Final	No		FDA-2016-D-2071
Use of Nucleic Acid Tests to Reduce the Risk of Transmission of Hepatitis B Virus from Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products: Guidance for Industry	PDF (66.85 KB)PDF (66.85 KB) of Use of Nucleic Acid Tests to Reduce the Risk of Transmission of Hepatitis B Virus from Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products: Guidance for Industry	08/01/2016	Center for Biologics Evaluation and Research	Tissue	Final	No		FDA-2015-D-5073
Guidance for Industry: Labeling of Infant Formula	PDF (146.17 KB)PDF (146.17 KB) of Guidance for Industry: Labeling of Infant Formula	07/31/2016	Office of Nutrition and Food Labeling	Infant Formula & Foods, Labeling	Final	No		
Adaptive Designs for Medical Device Clinical Studies: Guidance for Industry and Food and Drug Administration Staff	PDF (587.38 KB)PDF (587.38 KB) of Adaptive Designs for Medical Device Clinical Studies: Guidance for Industry and Food and Drug Administration Staff	07/27/2016	Center for Devices and Radiological Health	Premarket, Good Clinical Practices (GCP), Premarket Approval (PMA), Device Exception (IDE), HUD/HDE	Final	No		FDA-2015-D-1439
Implementation of Acceptable Full-Length and Abbreviated Donor History Questionnaires and Accompanying Materials for Use in Screening Donors of Source Plasma: Guidance for Industry	PDF (361.01 KB)PDF (361.01 KB) of Implementation of Acceptable Full-Length and Abbreviated Donor History Questionnaires and Accompanying Materials for Use in Screening Donors of Source Plasma: Guidance for Industry	07/27/2016	Center for Biologics Evaluation and Research	Blood Products	Final	No		FDA-2011-D-0722
Unique Device Identification System: Form and Content of the Unique Device Identifier (UDI): Draft Guidance for Industry and Food and Drug Administration Staff	PDF (384.12 KB)PDF (384.12 KB) of Unique Device Identification System: Form and Content of the Unique Device Identifier (UDI): Draft Guidance for Industry and Food and Drug Administration Staff	07/26/2016	Center for Devices and Radiological Health		Draft	No	09/24/2016	FDA-2016-D-1853
E2C(R2) Periodic Benefit-Risk Evaluation Report (PBRER)	PDF (461.54 KB)PDF (461.54 KB) of E2C(R2) Periodic Benefit-Risk Evaluation Report (PBRER)	07/18/2016	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Efficacy	Final	No		
E2C(R2) Periodic Benefit-Risk Evaluation Report – Questions and Answers	PDF (153.4 KB)PDF (153.4 KB) of E2C(R2) Periodic Benefit-Risk Evaluation Report – Questions and Answers	07/18/2016	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Efficacy	Final	No		
Principles for Codevelopment of an In Vitro Companion Diagnostic Device with a Therapeutic Product: Draft Guidance for Industry and Food and Drug Administration Staff	PDF (1.1 MB)PDF (1.1 MB) of Principles for Codevelopment of an In Vitro Companion Diagnostic Device with a Therapeutic Product: Draft Guidance for Industry and Food and Drug Administration Staff	07/15/2016	Center for Devices and Radiological Health	Premarket, 510(k), IVDs (In Vitro Diagnostic Devices), Premarket Approval (PMA), Laboratory Tests	Draft	No	10/13/2016	FDA-2016-D-1703
Meetings with Industry and Investigators on the Research and Development of Tobacco Products: Guidance for Industry and Investigators		07/14/2016	Center for Tobacco Products		Final	No	05/24/2012	

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Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices: Guidance for Industry and Food and Drug Administration Staff	PDF (295.55 KB)PDF (295.55 KB) of Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices: Guidance for Industry and Food and Drug Administration Staff	07/11/2016	Center for Devices and Radiological Health	Premarket, Biotechnology, 510(k), IVDs (In Vitro Diagnostic Devices), Radiological Health, Safety - Issues, Errors, and Problems, Device Exception (IDE), Anesthesiology , HUD/HDE, Laboratory Tests, Physical Medicine, Orthopedic, Ophthalmic, Neurological, Cardiovascular , Ear, Nose & Throat , Radiology	Final	No		FDA-2015-D-3787
Updating ANDA Labeling After the Marketing Application for the Reference Listed Drug Has Been Withdrawn Guidance for Industry	PDF (94.11 KB)PDF (94.11 KB) of Updating ANDA Labeling After the Marketing Application for the Reference Listed Drug Has Been Withdrawn Guidance for Industry	07/08/2016	Center for Drug Evaluation and Research	Generic Drugs	Draft	No		FDA-2016-D-1673
Early Clinical Trials With Live Biotherapeutic Products: Chemistry, Manufacturing, and Control Information; Guidance for Industry	PDF (174.31 KB)PDF (174.31 KB) of Early Clinical Trials With Live Biotherapeutic Products: Chemistry, Manufacturing, and Control Information; Guidance for Industry	06/30/2016		Good Clinical Practices (GCP)	Final	No		
Procedures for Evaluating Appearance Issues and Granting Authorizations for Participation in FDA Advisory Committees: Draft Guidance for the Public, FDA Advisory Committee Members, and FDA Staff	PDF (946.76 KB)PDF (946.76 KB) of Procedures for Evaluating Appearance Issues and Granting Authorizations for Participation in FDA Advisory Committees: Draft Guidance for the Public, FDA Advisory Committee Members, and FDA Staff	06/29/2016	Center for Food Safety and Applied Nutrition, Center for Tobacco Products, Office of Special Medical Programs, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research, NCTR (National Center for Toxicological Research)	Advisory Committees,	Draft	No	11/26/2016	FDA-2016-D-1399
FDA Regional Implementation Specifications for ICH E2B(R3) Reporting to the FDA Adverse Event Reporting System (FAERS)	PDF (202.33 KB)PDF (202.33 KB) of FDA Regional Implementation Specifications for ICH E2B(R3) Reporting to the FDA Adverse Event Reporting System (FAERS)	06/22/2016		ICH-Efficacy	Final	No		
Leveraging Existing Clinical Data for Extrapolation to Pediatric Uses of Medical Devices: Guidance for Industry and Food and Drug Administration Staff	PDF (367.42 KB)PDF (367.42 KB) of Leveraging Existing Clinical Data for Extrapolation to Pediatric Uses of Medical Devices: Guidance for Industry and Food and Drug Administration Staff	06/21/2016	Center for Devices and Radiological Health	Premarket, Good Clinical Practices (GCP), Premarket Approval (PMA), HUD/HDE	Final	No	09/19/2016	FDA-2015-D-1376
CVM GFI #238 Modified Release Veterinary Parenteral Dosage Forms: Development, Evaluation, and Establishment of Specifications	PDF (164.17 KB)PDF (164.17 KB) of CVM GFI #238 Modified Release Veterinary Parenteral Dosage Forms: Development, Evaluation, and Establishment of Specifications	06/17/2016	Center for Veterinary Medicine	Chemistry, Manufacturing, and Controls (CMC)	Final	No	03/21/2016	FDA-2015-N-4563
Guidance for Industry: Prior Notice of Imported Food Questions and Answers (Edition 3)	PDF (237.56 KB)PDF (237.56 KB) of Guidance for Industry: Prior Notice of Imported Food Questions and Answers (Edition 3)	06/16/2016	Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine, Office of Regulatory Affairs	Defense & Security, Import	Final	No		FDA-2011-N-0179
Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" : Guidance for Industry and Food and Drug Administration Staff	PDF (1.2 MB)PDF (1.2 MB) of Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" : Guidance for Industry and Food and Drug Administration Staff	06/16/2016	Center for Devices and Radiological Health	Premarket, 510(k), Premarket Approval (PMA), Safety - Issues, Errors, and Problems, Device Exception (IDE), HUD/HDE	Final	No	09/14/2016	FDA-2013-D-0350

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance	PDF (84.64 KB)PDF (84.64 KB) of Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance	06/09/2016	Center for Drug Evaluation and Research	Administrative / Procedural, Compounding	Final	No		
Charging for Investigational Drugs Under an IND - Questions and Answers: Guidance for Industry	PDF (86.76 KB)PDF (86.76 KB) of Charging for Investigational Drugs Under an IND - Questions and Answers: Guidance for Industry	06/02/2016	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Administrative / Procedural, Good Clinical Practices (GCP)	Final	No		
Draft Guidance for Industry: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods for Voluntary Sodium Reduction Goals	PDF (313.7 KB)PDF (313.7 KB) of Draft Guidance for Industry: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods for Voluntary Sodium Reduction Goals	06/02/2016	Office of Nutrition and Food Labeling		Draft	No	12/02/2016	FDA-2014-D-0055
Implementation of Acceptable Full-Length and Abbreviated Donor History Questionnaires and Accompanying Materials for Use in Screening Donors of Blood and Blood Components: Guidance for Industry	PDF (85.05 KB)PDF (85.05 KB) of Implementation of Acceptable Full-Length and Abbreviated Donor History Questionnaires and Accompanying Materials for Use in Screening Donors of Blood and Blood Components: Guidance for Industry	05/27/2016	Center for Biologics Evaluation and Research	Blood Products	Final	No		FDA-2011-D-0722
Guidance for Industry: Ingredients Declared as Evaporated Cane Juice	PDF (102.88 KB)PDF (102.88 KB) of Guidance for Industry: Ingredients Declared as Evaporated Cane Juice	05/26/2016	Office of Nutrition and Food Labeling	Juice, Labeling	Final	No		FDA-2009-D-0430
Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act: Guidance for Industry and Food and Drug Administration Staff	PDF (527.64 KB)PDF (527.64 KB) of Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act: Guidance for Industry and Food and Drug Administration Staff	05/16/2016	Center for Devices and Radiological Health	Postmarket, Premarket, Adverse Event Reporting System (FAERS), Adverse Event Reporting, Combination Products, Anesthesiology , Physical Medicine, Orthopedic, Ophthalmic, Obstetrical & Gynecological, Neurological, Immunology & Microbiology , Cardiovascular , Hematology & Pathology , General Hospital & Personal Use , General & Plastic Surgery , Ear, Nose & Throat , Dental , Radiology	Final	No		FDA-2011-D-0514
Considerations for Use of Histopathology and Its Associated Methodologies to Support Biomarker Qualification Guidance for Industry	PDF (125.91 KB)PDF (125.91 KB) of Considerations for Use of Histopathology and Its Associated Methodologies to Support Biomarker Qualification Guidance for Industry	05/13/2016	Center for Drug Evaluation and Research	Administrative / Procedural	Final	No		
Infectious Disease Next Generation Sequencing Based Diagnostic Devices: Microbial Identification and Detection of Antimicrobial Resistance and Virulence Markers: Draft Guidance for Industry and Food and Drug Administration Staff	PDF (1.44 MB)PDF (1.44 MB) of Infectious Disease Next Generation Sequencing Based Diagnostic Devices: Microbial Identification and Detection of Antimicrobial Resistance and Virulence Markers: Draft Guidance for Industry and Food and Drug Administration Staff	05/13/2016	Center for Devices and Radiological Health	Premarket, Microbiology, 510(k), IVDs (In Vitro Diagnostic Devices), Labeling, Premarket Approval (PMA), Laboratory Tests	Draft	No	08/11/2016	FDA-2016-D-0971
Small Entity Compliance Guide: Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products: Guidance for Industry		05/04/2016	Center for Tobacco Products		Final	No		
Tobacco Product Master Files: Guidance for Industry		05/04/2016	Center for Tobacco Products		Final	No		

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Compliance Policy Guide Sec 540.275 Crabmeat – Fresh and Frozen – Adulteration with Filth, Involving the Presence of Escherichia coli	PDF (19.11 KB)PDF (19.11 KB) of Compliance Policy Guide Sec 540.275 Crabmeat – Fresh and Frozen – Adulteration with Filth, Involving the Presence of Escherichia coli	04/30/2016		Investigation & Enforcement,	Final	No		
Assay Development and Validation for Immunogenicity Testing of Therapeutic Protein Products	PDF (230.21 KB)PDF (230.21 KB) of Assay Development and Validation for Immunogenicity Testing of Therapeutic Protein Products	04/22/2016	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Draft	No		
CVM GFI #231 Distributor Labeling for New Animal Drugs	PDF (84.76 KB)PDF (84.76 KB) of CVM GFI #231 Distributor Labeling for New Animal Drugs	04/20/2016	Center for Veterinary Medicine	Administrative / Procedural, Advertising, Labeling, New Animal Drug Application (NADA)	Final	No	11/09/2015	FDA-2015-D-3056
Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices : Guidance for Industry and Food and Drug Administration Staff	PDF (579.46 KB)PDF (579.46 KB) of Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices : Guidance for Industry and Food and Drug Administration Staff	04/20/2016	Center for Devices and Radiological Health	Premarket, 510(k), IVDs (In Vitro Diagnostic Devices), Labeling, Laboratory Tests	Final	No		FDA-2015-D-0230
Comparability Protocols for Human Drugs and Biologics: Chemistry, Manufacturing, and Controls Information Guidance for Industry	PDF (200.31 KB)PDF (200.31 KB) of Comparability Protocols for Human Drugs and Biologics: Chemistry, Manufacturing, and Controls Information Guidance for Industry	04/19/2016	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Draft	No		
Radiation Biodosimetry Medical Countermeasure Devices: Guidance for Industry and Food and Drug Administration Staff	PDF (514.01 KB)PDF (514.01 KB) of Radiation Biodosimetry Medical Countermeasure Devices: Guidance for Industry and Food and Drug Administration Staff	04/18/2016	Center for Devices and Radiological Health	Premarket, Emergencies, IVDs (In Vitro Diagnostic Devices), Radiological Health, Laboratory Tests	Final	No	03/30/2015	FDA-2014-D-2065
Guidance for Industry: Exempt Infant Formula Production	PDF (255.08 KB)PDF (255.08 KB) of Guidance for Industry: Exempt Infant Formula Production	04/15/2016	Office of Nutrition and Food Labeling	Food & Beverage Safety, Infant Formula & Foods, Records, Food & Beverage Safety	Final	No		FDA-2014-D-0044
Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act Guidance for Industry	PDF (81.23 KB)PDF (81.23 KB) of Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act Guidance for Industry	04/15/2016	Center for Drug Evaluation and Research	Compounding	Draft	No		
Safety Considerations for Product Design to Minimize Medication Errors Guidance for Industry	PDF (211.98 KB)PDF (211.98 KB) of Safety Considerations for Product Design to Minimize Medication Errors Guidance for Industry	04/11/2016	Center for Drug Evaluation and Research	Safety - Issues, Errors, and Problems	Final	No		
Draft Guidance for Industry: Action Level for Inorganic Arsenic in Rice Cereals for Infants	PDF (153.36 KB)PDF (153.36 KB) of Draft Guidance for Industry: Action Level for Inorganic Arsenic in Rice Cereals for Infants	04/06/2016	Center for Food Safety and Applied Nutrition	Infant Formula & Foods	Draft	No	07/05/2016	FDA-2016-D-1099
Contents of a Complete Submission for the Evaluation of Proprietary Names	PDF (146.01 KB)PDF (146.01 KB) of Contents of a Complete Submission for the Evaluation of Proprietary Names	04/05/2016	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Labeling	Final	No		
CVM GFI #156 Comparability Protocols - Chemistry, Manufacturing, and Controls Information for New Animal Drugs	PDF (110.64 KB)PDF (110.64 KB) of CVM GFI #156 Comparability Protocols - Chemistry, Manufacturing, and Controls Information for New Animal Drugs	04/04/2016	Center for Veterinary Medicine	Chemistry, Manufacturing, and Controls (CMC)	Final	No		FDA-2016-D-0938
CPG Sec. 690.150 Labeling and Marketing of Dog and Cat Food Diets Intended to Diagnose, Cure, Mitigate, Treat, or Prevent Diseases	PDF (91.21 KB)PDF (91.21 KB) of CPG Sec. 690.150 Labeling and Marketing of Dog and Cat Food Diets Intended to Diagnose, Cure, Mitigate, Treat, or Prevent Diseases	04/01/2016	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Labeling, Pet Food	Final	No	11/09/2012	FDA-2012-D-0755

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices: Guidance for Industry and Food and Drug Administration Staff	PDF (393.81 KB)PDF (393.81 KB) of Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices: Guidance for Industry and Food and Drug Administration Staff	03/22/2016	Center for Devices and Radiological Health	Premarket, 510(k), Labeling, Premarket Approval (PMA), Safety - Issues, Errors, and Problems, Device Exception (IDE), Anesthesiology , Physical Medicine, Orthopedic, Ophthalmic, Obstetrical & Gynecological, Neurological, Cardiovascular , General Hospital & Personal Use , General & Plastic Surgery , Gastroenterology-Urology , Ear, Nose & Throat , Dental , Radiology	Final	No	08/28/2015	FDA-2015-D-2104
CVM GFI #158 Use of Material from Deer and Elk in Animal Feed	PDF (24.46 KB)PDF (24.46 KB) of CVM GFI #158 Use of Material from Deer and Elk in Animal Feed	03/16/2016	Center for Veterinary Medicine	Animal Feed	Final	No		FDA-2003-D-0432
Guidance for Industry: Acrylamide in Foods	PDF (1.28 MB)PDF (1.28 MB) of Guidance for Industry: Acrylamide in Foods	03/11/2016	Office of Food Safety	Contaminants, Food & Beverage Safety, Food & Beverage Safety	Final	No		FDA-2013-D-0715
CVM GFI #203 Ensuring Safety of Animal Feed Maintained and Fed On-Farm	PDF (107.8 KB)PDF (107.8 KB) of CVM GFI #203 Ensuring Safety of Animal Feed Maintained and Fed On-Farm	03/09/2016	Center for Veterinary Medicine	Animal Feed	Final	No	06/03/2015	FDA-2014-D-1180
Investigating and Reporting Adverse Reactions Related to Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) Regulated Solely under Section 361 of the Public Health Service Act and 21 CFR Part 1271: Guidance for Industry	PDF (391.84 KB)PDF (391.84 KB) of Investigating and Reporting Adverse Reactions Related to Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) Regulated Solely under Section 361 of the Public Health Service Act and 21 CFR Part 1271: Guidance for Industry	03/08/2016	Center for Biologics Evaluation and Research	Tissue	Final	No		FDA-2015-D-0309
Pediatric Study Plans: Content of and Process for Submitting Initial Pediatric Study Plans and Amended Pediatric Study Plans	PDF (407.99 KB)PDF (407.99 KB) of Pediatric Study Plans: Content of and Process for Submitting Initial Pediatric Study Plans and Amended Pediatric Study Plans	03/08/2016	Center for Drug Evaluation and Research	Administrative / Procedural	Draft	No		
Medical Devices and Clinical Trial Design for the Treatment or Improvement in the Appearance of Fungally-Infected Nails: Guidance for Industry and Food and Drug Administration Staff	PDF (215.75 KB)PDF (215.75 KB) of Medical Devices and Clinical Trial Design for the Treatment or Improvement in the Appearance of Fungally-Infected Nails: Guidance for Industry and Food and Drug Administration Staff	03/07/2016	Center for Devices and Radiological Health	Premarket, 510(k), Good Clinical Practices (GCP), Labeling, Premarket Approval (PMA), Device Exception (IDE), HUD/HDE, General & Plastic Surgery	Final	No		FDA-2014-D-1849
Environmental Assessment: Questions and Answers Regarding Drugs With Estrogenic, Androgenic, or Thyroid Activity	PDF (68.67 KB)PDF (68.67 KB) of Environmental Assessment: Questions and Answers Regarding Drugs With Estrogenic, Androgenic, or Thyroid Activity	03/04/2016	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		
Enforcement Policy Regarding Investigational New Drug Requirements for Use of Fecal Microbiota for Transplantation to Treat Clostridium difficile Infection Not Responsive to Standard Therapies: Draft Draft Guidance for Industry	PDF (54.91 KB)PDF (54.91 KB) of Enforcement Policy Regarding Investigational New Drug Requirements for Use of Fecal Microbiota for Transplantation to Treat Clostridium difficile Infection Not Responsive to Standard Therapies: Draft Draft Guidance for Industry	03/01/2016	Center for Biologics Evaluation and Research	Vaccines	Draft	No		FDA-2013-D-0811
Evaluating Respiratory Symptoms in Chronic Obstructive Pulmonary Disease, a Patient-Reported Outcome Instrument for the Measurement of Severity of Respiratory Symptoms in Stable Chronic Obstructive Pulmonary Disease: Qualification for Exploratory Use	PDF (50.04 KB)PDF (50.04 KB) of Evaluating Respiratory Symptoms in Chronic Obstructive Pulmonary Disease, a Patient-Reported Outcome Instrument for the Measurement of Severity of Respiratory Symptoms in Stable Chronic Obstructive Pulmonary Disease: Qualification for Exploratory Use	03/01/2016	Center for Drug Evaluation and Research	Clinical - Medical	Draft	No		

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Small Entity Compliance Guide: Alpha-Linolenic Acid, Eicosapentaenoic Acid, and Docosahexaenoic Acid Omega-3 Fatty Acids Nutrient Content Claims	PDF (134.8 KB)PDF (134.8 KB) of Small Entity Compliance Guide: Alpha-Linolenic Acid, Eicosapentaenoic Acid, and Docosahexaenoic Acid Omega-3 Fatty Acids Nutrient Content Claims	02/23/2016	Office of Nutrition and Food Labeling	Labeling	Final	No		FDA-2016-N-0585
Determining the Extent of Safety Data Collection Needed in Late Stage Premarket and Postapproval Clinical Investigations	PDF (140.43 KB)PDF (140.43 KB) of Determining the Extent of Safety Data Collection Needed in Late Stage Premarket and Postapproval Clinical Investigations	02/18/2016	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Clinical - Medical	Final	No		
Immunogenicity-Related Considerations for Low Molecular Weight Heparin Guidance for Industry	PDF (136.19 KB)PDF (136.19 KB) of Immunogenicity-Related Considerations for Low Molecular Weight Heparin Guidance for Industry	02/18/2016	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		
Recommendations for Premarket Notifications for Lamotrigine and Zonisamide Assays: Guidance for Industry and Food and Drug Administration Staff	PDF (130.13 KB)PDF (130.13 KB) of Recommendations for Premarket Notifications for Lamotrigine and Zonisamide Assays: Guidance for Industry and Food and Drug Administration Staff	02/09/2016	Center for Devices and Radiological Health	Premarket, 510(k)	Final	No		FDA-2010-D-0395
Applying Human Factors and Usability Engineering to Medical Devices: Guidance for Industry and Food and Drug Administration Staff	PDF (918.39 KB)PDF (918.39 KB) of Applying Human Factors and Usability Engineering to Medical Devices: Guidance for Industry and Food and Drug Administration Staff	02/03/2016	Center for Devices and Radiological Health	Postmarket, Premarket, 510(k), IVDs (In Vitro Diagnostic Devices), Labeling, Premarket Approval (PMA), Safety - Issues, Errors, and Problems, Anesthesiology , Laboratory Tests, Physical Medicine, Orthopedic, Ophthalmic, Obstetrical & Gynecological, Neurological, Molecular and Clinical Genetics, Immunology & Microbiology , Cardiovascular , Hematology & Pathology , General Hospital & Personal Use , General & Plastic Surgery , Gastroenterology-Urology , Ear, Nose & Throat , Digital Health, Dental , Clinical Chemistry & Clinical Toxicology , Radiology	Final	No	04/03/2016	FDA-2011-D-0469
Human Factors Studies and Related Clinical Study Considerations in Combination Product Design and Development: Draft Guidance for Industry and FDA Staff	PDF (336.22 KB)PDF (336.22 KB) of Human Factors Studies and Related Clinical Study Considerations in Combination Product Design and Development: Draft Guidance for Industry and FDA Staff	02/03/2016	Office of Combination Products, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Combination Products	Draft	No	05/03/2016	FDA-2015-D-4848
List of Highest Priority Devices for Human Factors Review: Draft Guidance for Industry and Food and Drug Administration Staff	PDF (359.16 KB)PDF (359.16 KB) of List of Highest Priority Devices for Human Factors Review: Draft Guidance for Industry and Food and Drug Administration Staff	02/03/2016	Center for Devices and Radiological Health	Postmarket, Premarket, Labeling, Premarket Approval (PMA), Safety - Issues, Errors, and Problems, Device Exception (IDE)	Draft	No	04/03/2016	FDA-2015-D-4599
CVM GFI #226 Target Animal Safety Data Presentation and Statistical Analysis	PDF (560.62 KB)PDF (560.62 KB) of CVM GFI #226 Target Animal Safety Data Presentation and Statistical Analysis	01/21/2016	Center for Veterinary Medicine	Target Animal – Safety, Investigational New Animal Drug (INAD)	Final	No	06/01/2015	FDA-2015-D-0839
Implanted Blood Access Devices for Hemodialysis: Guidance for Industry and Food and Drug Administration Staff	PDF (709.54 KB)PDF (709.54 KB) of Implanted Blood Access Devices for Hemodialysis: Guidance for Industry and Food and Drug Administration Staff	01/21/2016	Center for Devices and Radiological Health		Final	No		FDA-2013-D-0749

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile: Guidance for Industry and Food and Drug Administration Staff	PDF (385.58 KB)PDF (385.58 KB) of Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile: Guidance for Industry and Food and Drug Administration Staff	01/21/2016	Center for Devices and Radiological Health	Premarket, 510(k)	Final	No		FDA-2008-D-0611
Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Products: Guidance for Industry	PDF (271.18 KB)PDF (271.18 KB) of Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Products: Guidance for Industry	01/14/2016	Center for Biologics Evaluation and Research	Blood Products	Final	No		FDA-2012-D-0307
Electroconvulsive Therapy (ECT) Devices for Class II Intended Uses: Draft Guidance for Industry, Clinicians and Food and Drug Administration Staff	PDF (314.78 KB)PDF (314.78 KB) of Electroconvulsive Therapy (ECT) Devices for Class II Intended Uses: Draft Guidance for Industry, Clinicians and Food and Drug Administration Staff	12/29/2015	Center for Devices and Radiological Health	Premarket, 510(k), Labeling, Premarket Approval (PMA), Neurological	Draft	No	03/28/2016	FDA-2014-D-1318
Safety Assessment for IND Safety Reporting Guidance for Industry	PDF (410.54 KB)PDF (410.54 KB) of Safety Assessment for IND Safety Reporting Guidance for Industry	12/16/2015	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Safety - Issues, Errors, and Problems	Draft	No		
Premarket Studies of Implantable Minimally Invasive Glaucoma Surgical (MIGS) Devices: Guidance for Industry and Food and Drug Administration Staff	PDF (609.04 KB)PDF (609.04 KB) of Premarket Studies of Implantable Minimally Invasive Glaucoma Surgical (MIGS) Devices: Guidance for Industry and Food and Drug Administration Staff	12/15/2015	Center for Devices and Radiological Health	Premarket, Premarket Approval (PMA), Ophthalmic	Final	No	05/12/2015	
Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products: Guidance for Industry	PDF (153.44 KB)PDF (153.44 KB) of Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products: Guidance for Industry	12/15/2015	Center for Biologics Evaluation and Research	Blood Products	Final	No		FDA-2015-D-1211
Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings: Guidance for Industry and Food and Drug Administration Staff	PDF (318.85 KB)PDF (318.85 KB) of Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings: Guidance for Industry and Food and Drug Administration Staff	12/09/2015	Center for Devices and Radiological Health		Final	No	08/29/2015	FDA-2015-D-2261
eCopy Program for Medical Device Submissions: Guidance for Industry and Food and Drug Administration Staff	PDF (524.74 KB)PDF (524.74 KB) of eCopy Program for Medical Device Submissions: Guidance for Industry and Food and Drug Administration Staff	12/03/2015	Center for Devices and Radiological Health	Premarket,	Final	No		
CVM GFI #204 Active Controls in Studies to Demonstrate Effectiveness of a New Animal Drug for use in Companion Animals	PDF (180.96 KB)PDF (180.96 KB) of CVM GFI #204 Active Controls in Studies to Demonstrate Effectiveness of a New Animal Drug for use in Companion Animals	12/01/2015	Center for Veterinary Medicine	Target Animal – Effectiveness	Final	No		FDA-2012-D-0419
Certification Process of Designated Medical Gases	PDF (279.43 KB)PDF (279.43 KB) of Certification Process of Designated Medical Gases	11/24/2015	Center for Drug Evaluation and Research	Administrative / Procedural	Draft	No		
Organ-Specific Warnings: Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use —: Guidance for Industry	PDF (173.4 KB)PDF (173.4 KB) of Organ-Specific Warnings: Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use —: Guidance for Industry	11/16/2015	Center for Drug Evaluation and Research	Compliance, Current Good Manufacturing Practices (CGMP), Over-the-Counter Drugs, Pharmaceutical Quality	Final	No		
Qualification of Biomarker — Galactomannan in studies of treatments of invasive	PDF (162.39 KB)PDF (162.39 KB) of Qualification of Biomarker — Galactomannan in studies of treatments of invasive	11/13/2015	Center for Drug Evaluation and Research	Drug Development Tools	Draft	No		

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Guidance for Industry: Questions and Answers on FDA's Fortification Policy	PDF (127.24 KB)PDF (127.24 KB) of Guidance for Industry: Questions and Answers on FDA's Fortification Policy	11/05/2015	Office of Nutrition and Food Labeling		Final	No		
Class II Special Controls Guideline: Gastrointestinal Microorganism Multiplex Nucleic Acid-Based Assays for Detection and Identification of Microorganisms and Toxin Genes from Human Stool Specimens: Guideline for Industry and Food and Drug Administration	PDF (717.88 KB)PDF (717.88 KB) of Class II Special Controls Guideline: Gastrointestinal Microorganism Multiplex Nucleic Acid-Based Assays for Detection and Identification of Microorganisms and Toxin Genes from Human Stool Specimens: Guideline for Industry and Food and Drug Administration	11/02/2015	Office of Medical Products and Tobacco	Laboratory Tests	Final	No		FDA-2015-N-3392
Human Immunodeficiency Virus-1 Infection: Developing Antiretroviral Drugs for Treatment	PDF (609.36 KB)PDF (609.36 KB) of Human Immunodeficiency Virus-1 Infection: Developing Antiretroviral Drugs for Treatment	11/02/2015	Center for Drug Evaluation and Research	Clinical - Antimicrobial	Final	No		
DSCSA Implementation: Product Tracing Requirements for Dispensers — Compliance Policy (Revised) Guidance for Industry	PDF (54.76 KB)PDF (54.76 KB) of DSCSA Implementation: Product Tracing Requirements for Dispensers — Compliance Policy (Revised) Guidance for Industry	10/28/2015		Administrative / Procedural	Final	No		
Nonclinical Safety Evaluation of Reformulated Drug Products and Products Intended for Administration by an Alternate Route	PDF (153.48 KB)PDF (153.48 KB) of Nonclinical Safety Evaluation of Reformulated Drug Products and Products Intended for Administration by an Alternate Route	10/27/2015		Pharm/Tox	Final	No		
Product Development Under the Animal Rule	PDF (573.6 KB)PDF (573.6 KB) of Product Development Under the Animal Rule	10/27/2015	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Animal Rule	Final	No		FDA-2009-D-0007
National Environmental Policy Act; Environmental Assessments for Tobacco Products; Categorical Exclusions – Small Entity Compliance Guide: Guidance for Industry		10/25/2015	Center for Tobacco Products		Final	No		
CVM GFI #229 Evaluating the Effectiveness of New Animal Drugs for the Reduction of Pathogenic Shiga Toxin-Producing E. coli in Cattle	PDF (128.2 KB)PDF (128.2 KB) of CVM GFI #229 Evaluating the Effectiveness of New Animal Drugs for the Reduction of Pathogenic Shiga Toxin-Producing E. coli in Cattle	10/19/2015	Center for Veterinary Medicine	Target Animal – Effectiveness	Final	No	04/27/2015	FDA-2015-D-0235
General Considerations for Animal Studies for Medical Devices: Draft Guidance for Industry and Food and Drug Administration Staff	PDF (417.53 KB)PDF (417.53 KB) of General Considerations for Animal Studies for Medical Devices: Draft Guidance for Industry and Food and Drug Administration Staff	10/14/2015	Center for Devices and Radiological Health	Premarket, 510(k), Premarket Approval (PMA), Device Exception (IDE)	Draft	No	01/12/2016	FDA-2015-D-3419
Guidance for Industry: Submitting Forms for Food Canning Establishment Registration and Food Process Filing to FDA in Electronic or Paper Format	PDF (122.72 KB)PDF (122.72 KB) of Guidance for Industry: Submitting Forms for Food Canning Establishment Registration and Food Process Filing to FDA in Electronic or Paper Format	10/08/2015	Office of Food Safety		Final	No		FDA-2013-D-1622
Integrated Summary of Effectiveness	PDF (274.45 KB)PDF (274.45 KB) of Integrated Summary of Effectiveness	10/07/2015	Center for Drug Evaluation and Research	Administrative / Procedural	Final	No		
Acceptability of Draft Labeling to Support Abbreviated New Drug Application Approval; Guidance for Industry	PDF (52.58 KB)PDF (52.58 KB) of Acceptability of Draft Labeling to Support Abbreviated New Drug Application Approval; Guidance for Industry	10/05/2015	Center for Drug Evaluation and Research	Generic Drugs	Draft	No		FDA-2015-D-3378

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Controlled Correspondence Related to Generic Drug Development: Guidance for Industry	PDF (379.11 KB)PDF (379.11 KB) of Controlled Correspondence Related to Generic Drug Development: Guidance for Industry	09/28/2015	Center for Drug Evaluation and Research	User Fees, Generic Drugs	Final	No		
M7(R1) Addendum to ICH M7: Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk; Application of the Principles of the ICH M7 Guidance to Calculation of Compound-Specific Acceptable Intakes	PDF (728.66 KB)PDF (728.66 KB) of M7(R1) Addendum to ICH M7: Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk; Application of the Principles of the ICH M7 Guidance to Calculation of Compound-Specific Acceptable Intakes	09/25/2015		ICH-Multidisciplinary	Draft	No		
Enforcement Policy for Certain (Provisional) Tobacco Products that FDA Finds Not Substantially Equivalent: Guidance for Industry and Tobacco Retailers		09/10/2015	Center for Tobacco Products		Final	No	02/25/2014	
Q3D Elemental Impurities	PDF (685.24 KB)PDF (685.24 KB) of Q3D Elemental Impurities	09/09/2015	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Quality	Final	No		
Use of Donor Screening Tests to Test Donors of Human Cells, Tissues and Cellular and Tissue-Based Products for Infection with Treponema pallidum (Syphilis): Guidance for Industry	PDF (175.47 KB)PDF (175.47 KB) of Use of Donor Screening Tests to Test Donors of Human Cells, Tissues and Cellular and Tissue-Based Products for Infection with Treponema pallidum (Syphilis): Guidance for Industry	09/09/2015	Center for Biologics Evaluation and Research	Tissue	Final	No		FDA-2013-D-1213
Nonclinical Evaluation of Endocrine-Related Drug Toxicity	PDF (129.18 KB)PDF (129.18 KB) of Nonclinical Evaluation of Endocrine-Related Drug Toxicity	09/08/2015		Pharm/Tox	Final	No		
CVM GFI #225 (VICH GL53) Electronic Exchange of Documents: File Format Recommendations	PDF (113.45 KB)PDF (113.45 KB) of CVM GFI #225 (VICH GL53) Electronic Exchange of Documents: File Format Recommendations	09/01/2015	Center for Veterinary Medicine	Electronic Submissions, New Animal Drug Application (NADA), VICH	Final	No	10/27/2014	FDA-2014-D-1177
CVM GFI #227 Two-Phased Chemistry, Manufacturing, and Controls (CMC) Technical Sections	PDF (104.53 KB)PDF (104.53 KB) of CVM GFI #227 Two-Phased Chemistry, Manufacturing, and Controls (CMC) Technical Sections	09/01/2015	Center for Veterinary Medicine	Chemistry, Manufacturing, and Controls (CMC)	Final	No	02/17/2015	FDA-2014-D-1492
Guidance for Industry: Colored Sea Salt	PDF (173.3 KB)PDF (173.3 KB) of Guidance for Industry: Colored Sea Salt	09/01/2015	Office of Food Additive Safety	Food & Color Additives	Final	No		
Class II Special Controls Guideline Document: Toxin Gene Amplification Assays for the Detection of Clostridium difficile: Guideline for Industry and Food and Drug Administration Staff	PDF (740.04 KB)PDF (740.04 KB) of Class II Special Controls Guideline Document: Toxin Gene Amplification Assays for the Detection of Clostridium difficile: Guideline for Industry and Food and Drug Administration Staff	08/27/2015	Center for Devices and Radiological Health	Premarket, Microbiology, 510(k)	Final	No		FDA-2015-N-2963
Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products: Guidance for Industry	PDF (120.35 KB)PDF (120.35 KB) of Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products: Guidance for Industry	08/27/2015	Center for Biologics Evaluation and Research	Cellular & Gene Therapy, Gene Therapy	Final	No		FDA-2014-D-0852
Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance With an Order: Guidance for Tobacco Retailers		08/27/2015	Center for Tobacco Products		Final	No		
Providing Submissions in Electronic Format — Postmarketing Safety Reports for Vaccines: Guidance for Industry	PDF (77.06 KB)PDF (77.06 KB) of Providing Submissions in Electronic Format — Postmarketing Safety Reports for Vaccines: Guidance for Industry	08/18/2015	Center for Biologics Evaluation and Research	Postmarket, Electronic Submissions, Safety - Issues, Errors, and Problems, Vaccines	Final	No		FDA-2014-D-0903

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Select Updates for Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems: Guidance for Industry and Food and Drug Administration Staff	PDF (410.18 KB)PDF (410.18 KB) of Select Updates for Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems: Guidance for Industry and Food and Drug Administration Staff	08/18/2015	Center for Devices and Radiological Health	Premarket,	Final	No		FDA-2013-D-0920
Endotoxin Testing Recommendations for Single-Use Intraocular Ophthalmic Devices	PDF (418.97 KB)PDF (418.97 KB) of Endotoxin Testing Recommendations for Single-Use Intraocular Ophthalmic Devices	08/17/2015	Center for Devices and Radiological Health	Premarket, Ophthalmic	Final	No		FDA-2014-D-0332
Uncomplicated Gonorrhea: Developing Drugs for Treatment	PDF (222.06 KB)PDF (222.06 KB) of Uncomplicated Gonorrhea: Developing Drugs for Treatment	08/17/2015	Center for Drug Evaluation and Research	Clinical - Antimicrobial	Final	No		
Global Unique Device Identification Database (GUDID): Data Submission Compliance Date of September 24, 2015: Guidance for Industry and FDA Staff	PDF (198.69 KB)PDF (198.69 KB) of Global Unique Device Identification Database (GUDID): Data Submission Compliance Date of September 24, 2015: Guidance for Industry and FDA Staff	08/14/2015	Center for Devices and Radiological Health		Final	No		
Guidance For Entities Considering Whether to Register As Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act	PDF (74.03 KB)PDF (74.03 KB) of Guidance For Entities Considering Whether to Register As Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act	08/11/2015	Center for Drug Evaluation and Research	Administrative / Procedural, Compounding	Final	No	05/17/2015	
Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription Drugs	PDF (303.33 KB)PDF (303.33 KB) of Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription Drugs	08/06/2015	Center for Veterinary Medicine, Office of Regulatory Policy, Center for Biologics Evaluation and Research	Advertising	Draft	No	10/05/2015	FDA-2004-D-0500
CVM GFI #220 Use of Nanomaterials in Food for Animals	PDF (86.3 KB)PDF (86.3 KB) of CVM GFI #220 Use of Nanomaterials in Food for Animals	08/05/2015	Center for Veterinary Medicine	Nanotechnology, Animal Food Additives	Final	No	09/10/2014	FDA-2013-D-1009
Class II Special Controls Guideline: Nucleic Acid Amplification Assays for the Detection of Trichomonas vaginalis: Guideline for Industry and Food and Drug Administration Staff	PDF (534.32 KB)PDF (534.32 KB) of Class II Special Controls Guideline: Nucleic Acid Amplification Assays for the Detection of Trichomonas vaginalis: Guideline for Industry and Food and Drug Administration Staff	08/04/2015	Center for Devices and Radiological Health	Premarket, Microbiology, 510(k), IVDs (In Vitro Diagnostic Devices), Laboratory Tests	Final	No		
Over-the-Counter Pediatric Oral Liquid Drug Products Containing Acetaminophen	PDF (81.71 KB)PDF (81.71 KB) of Over-the-Counter Pediatric Oral Liquid Drug Products Containing Acetaminophen	08/04/2015	Center for Drug Evaluation and Research	Over-the-Counter Drugs, Safety - Issues, Errors, and Problems	Final	No		
Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the FD&C Act	PDF (118.74 KB)PDF (118.74 KB) of Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the FD&C Act	08/03/2015	Center for Drug Evaluation and Research	User Fees, Administrative / Procedural, Compounding	Final	No		FDA-2015-N-0007
CVM GFI #198 (VICH GL45) Bracketing and Matrixing Designs For Stability Testing of New Veterinary Drug Substances and Medicinal Products	PDF (141.6 KB)PDF (141.6 KB) of CVM GFI #198 (VICH GL45) Bracketing and Matrixing Designs For Stability Testing of New Veterinary Drug Substances and Medicinal Products	07/31/2015	Center for Veterinary Medicine	VICH	Final	No		FDA-2009-D-0309

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Recommendations for Premarket Notification (510(k)) Submissions for Nucleic Acid-Based Human Leukocyte Antigen (HLA) Test Kits Used for Matching of Donors and Recipients in Transfusion and Transplantation: Guidance for Industry	PDF (75.4 KB)PDF (75.4 KB) of Recommendations for Premarket Notification (510(k)) Submissions for Nucleic Acid-Based Human Leukocyte Antigen (HLA) Test Kits Used for Matching of Donors and Recipients in Transfusion and Transplantation: Guidance for Industry	07/31/2015	Center for Biologics Evaluation and Research	Premarket, Blood Products	Final	No		
Analytical Procedures and Methods Validation for Drugs and Biologics	PDF (133.79 KB)PDF (133.79 KB) of Analytical Procedures and Methods Validation for Drugs and Biologics	07/24/2015	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		
Gastroparesis: Clinical Evaluation of Drugs for Treatment	PDF (196.66 KB)PDF (196.66 KB) of Gastroparesis: Clinical Evaluation of Drugs for Treatment	07/22/2015	Center for Drug Evaluation and Research	Clinical - Medical	Draft	No		
Meetings with the Office of Orphan Products Development: Guidance for Industry, Researchers, Patient Groups, and Food and Drug Administration Staff	PDF (134.31 KB)PDF (134.31 KB) of Meetings with the Office of Orphan Products Development: Guidance for Industry, Researchers, Patient Groups, and Food and Drug Administration Staff	07/09/2015	Office of Orphan Products Development	Administrative / Procedural	Final	No		
Guidance for Industry: FDA's Policy on Declaring Small Amounts of Nutrients and Dietary Ingredients on Nutrition Labels	PDF (99.12 KB)PDF (99.12 KB) of Guidance for Industry: FDA's Policy on Declaring Small Amounts of Nutrients and Dietary Ingredients on Nutrition Labels	07/01/2015	Office of Nutrition and Food Labeling	Labeling, Nutrition	Final	No		FDA-2015-D-1839
Guidance for Industry: Questions and Answers Regarding the Final Rule, Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation	PDF (297.17 KB)PDF (297.17 KB) of Guidance for Industry: Questions and Answers Regarding the Final Rule, Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation	07/01/2015	Office of Food Safety	Egg/Egg Product, Transportation	Final	No		FDA-2011-D-0398
Allowable Excess Volume and Labeled Vial Fill Size in Injectable Drug and Biological Products	PDF (76.58 KB)PDF (76.58 KB) of Allowable Excess Volume and Labeled Vial Fill Size in Injectable Drug and Biological Products	06/24/2015	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		
Size, Shape, and Other Physical Attributes of Generic Tablets and Capsules	PDF (89.4 KB)PDF (89.4 KB) of Size, Shape, and Other Physical Attributes of Generic Tablets and Capsules	06/18/2015	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		
Content and Format for Abbreviated 510(k)s for Early Growth Response 1 (EGR1) Gene Fluorescence In-Situ Hybridization (FISH) Test System for Specimen Characterization Devices: Guidance for Industry and Food and Drug Administration Staff	PDF (330.31 KB)PDF (330.31 KB) of Content and Format for Abbreviated 510(k)s for Early Growth Response 1 (EGR1) Gene Fluorescence In-Situ Hybridization (FISH) Test System for Specimen Characterization Devices: Guidance for Industry and Food and Drug Administration Staff	06/17/2015	Center for Devices and Radiological Health	Premarket, 510(k), IVDs (In Vitro Diagnostic Devices), Labeling, Laboratory Tests, Molecular and Clinical Genetics, Immunology & Microbiology	Final	No		FDA-2014-D-1242
Naming of Drug Products Containing Salt Drug Substances	PDF (209.94 KB)PDF (209.94 KB) of Naming of Drug Products Containing Salt Drug Substances	06/16/2015	Center for Drug Evaluation and Research	Labeling	Final	No		
CVM GFI #218 Cell-Based Products for Animal Use	PDF (161.91 KB)PDF (161.91 KB) of CVM GFI #218 Cell-Based Products for Animal Use	06/12/2015	Center for Veterinary Medicine	Cellular & Gene Therapy, Investigational New Animal Drug (INAD)	Final	No	09/30/2014	FDA-2014-D-0634
CVM GFI #221 Recommendations for Preparation and Submission of Animal Food Additive Petitions	PDF (121.79 KB)PDF (121.79 KB) of CVM GFI #221 Recommendations for Preparation and Submission of Animal Food Additive Petitions	06/12/2015	Center for Veterinary Medicine	Animal Food Additives	Final	No		FDA-2013-D-0928

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Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products — Content and Format Guidance for Industry (Small Entity Compliance Guide)	PDF (164.53 KB)PDF (164.53 KB) of Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products — Content and Format Guidance for Industry (Small Entity Compliance Guide)	06/10/2015	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Labeling	Final	No		
5-10 FORM FDA 482c NOTICE OF INSPECTION - REQUEST FOR RECORDS	PDF (831.88 KB)PDF (831.88 KB) of 5-10 FORM FDA 482c NOTICE OF INSPECTION - REQUEST FOR RECORDS	05/30/2015		Inspection, Compliance,	Final	No		
Class II Special Controls Guideline: Multiplex Nucleic Acid Assay for Identification of Microorganisms and Resistance Markers from Positive Blood Cultures: Guideline for Industry and Food and Drug Administration Staff	PDF (695.4 KB)PDF (695.4 KB) of Class II Special Controls Guideline: Multiplex Nucleic Acid Assay for Identification of Microorganisms and Resistance Markers from Positive Blood Cultures: Guideline for Industry and Food and Drug Administration Staff	05/27/2015	Center for Devices and Radiological Health	Premarket, 510(k), Antimicrobial Resistance, IVDs (In Vitro Diagnostic Devices), Labeling, Laboratory Tests, Immunology & Microbiology	Final	No		FDA-2015-N-1072
Investigational New Drug Applications Prepared and Submitted by Sponsor-Investigators	PDF (430.73 KB)PDF (430.73 KB) of Investigational New Drug Applications Prepared and Submitted by Sponsor-Investigators	05/14/2015		Administrative / Procedural	Draft	No		
CVM GFI #116 (VICH GL23) Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Genotoxicity Testing	PDF (222.19 KB)PDF (222.19 KB) of CVM GFI #116 (VICH GL23) Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Genotoxicity Testing	05/13/2015	Center for Veterinary Medicine	Human Food Safety, VICH	Final	No		FDA-2000-D-0598
CVM GFI #191 Changes to Approved NADAs - New NADAs vs. Category II Supplemental NADAs	PDF (183.11 KB)PDF (183.11 KB) of CVM GFI #191 Changes to Approved NADAs - New NADAs vs. Category II Supplemental NADAs	05/07/2015	Center for Veterinary Medicine	New Animal Drug Application (NADA)	Final	No		FDA-2008-D-0614
Guidance for Industry: A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods - Part II	PDF (349.16 KB)PDF (349.16 KB) of Guidance for Industry: A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods - Part II	05/05/2015	Office of Nutrition and Food Labeling	Labeling	Final	No		FDA-2011-F-0172
1-1 Allowable Expenses Chart	PDF (57.21 KB)PDF (57.21 KB) of 1-1 Allowable Expenses Chart	04/30/2015		Compliance, Inspection,	Final	No		
2-1 INTERROGATION: ADVICE OF RIGHTS	PDF (34.94 KB)PDF (34.94 KB) of 2-1 INTERROGATION: ADVICE OF RIGHTS	04/30/2015		Compliance, Inspection,	Final	No		
2-2 FORM FDA 2289	PDF (1.38 MB)PDF (1.38 MB) of 2-2 FORM FDA 2289	04/30/2015		Compliance, Inspection,	Final	No		
2-3 DETENTION TAG	PDF (172.8 KB)PDF (172.8 KB) of 2-3 DETENTION TAG	04/30/2015		Compliance, Inspection,	Final	No		
2-4 FORM FDA 2291	PDF (49.04 KB)PDF (49.04 KB) of 2-4 FORM FDA 2291	04/30/2015		Compliance, Inspection,	Final	No		
3-1 FDA/USDA JURISDICTIONAL CHART	PDF (38.82 KB)PDF (38.82 KB) of 3-1 FDA/USDA JURISDICTIONAL CHART	04/30/2015		Compliance, Inspection,	Final	No		
3-2 HISTORY OF MENU ITEMS	PDF (26.9 KB)PDF (26.9 KB) of 3-2 HISTORY OF MENU ITEMS	04/30/2015		Compliance, Inspection,	Final	No		
3-3 ADDRESS INFORMATION REQUEST	PDF (47.55 KB)PDF (47.55 KB) of 3-3 ADDRESS INFORMATION REQUEST	04/30/2015		Compliance, Inspection,	Final	No		
4-1 FACTS SAMPLE COLLECTION SCREEN (5 pgs)	PDF (514.5 KB)PDF (514.5 KB) of 4-1 FACTS SAMPLE COLLECTION SCREEN (5 pgs)	04/30/2015		Compliance, Inspection,	Final	No		
4-10 AFFIDAVIT - FDA 463a	PDF (63.58 KB)PDF (63.58 KB) of 4-10 AFFIDAVIT - FDA 463a	04/30/2015		Compliance, Inspection,	Final	No		

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4-11 AFFIDAVIT - FDA 463a	PDF (45.55 KB)PDF (45.55 KB) of 4-11 AFFIDAVIT - FDA 463a	04/30/2015		Compliance, Inspection,	Final	No		
4-12 AFFIDAVIT - (Dealer/Warehouseman) - FDA 1664	PDF (81.7 KB)PDF (81.7 KB) of 4-12 AFFIDAVIT - (Dealer/Warehouseman) - FDA 1664	04/30/2015		Compliance, Inspection,	Final	No		
4-13 AFFIDAVIT - FDA 463a	PDF (66.79 KB)PDF (66.79 KB) of 4-13 AFFIDAVIT - FDA 463a	04/30/2015		Compliance, Inspection,	Final	No		
4-14 AFFIDAVIT - (Jobber) - FDA 1664a	PDF (53.48 KB)PDF (53.48 KB) of 4-14 AFFIDAVIT - (Jobber) - FDA 1664a	04/30/2015		Compliance, Inspection,	Final	No		
4-15 FACTS SAMPLE COLLECTION SCREEN		04/30/2015		Compliance, Inspection,	Final	No		
4-16 FACTS SAMPLE COLLECTION SCREEN (2 Pgs)		04/30/2015		Compliance, Inspection,	Final	No		
4-17 OFFICIAL SEAL - FDA 415a	PDF (165.47 KB)PDF (165.47 KB) of 4-17 OFFICIAL SEAL - FDA 415a	04/30/2015		Compliance, Inspection,	Final	No		
4-18 DECLARATION FOR DANGEROUS GOODS	PDF (80.93 KB)PDF (80.93 KB) of 4-18 DECLARATION FOR DANGEROUS GOODS	04/30/2015		Compliance, Inspection,	Final	No		
4-19 DRY ICE STICKER	PDF (147.04 KB)PDF (147.04 KB) of 4-19 DRY ICE STICKER	04/30/2015		Compliance, Inspection,	Final	No		
4-2 FACTS SAMPLE COLLECTION SCREEN	PDF (67.6 KB)PDF (67.6 KB) of 4-2 FACTS SAMPLE COLLECTION SCREEN	04/30/2015		Compliance, Inspection,	Final	No		
4-20 ENVIRONMENTAL SAMPLING FOR THE DETECTION OF LISTERIA MONOCYTOGENES	PDF (50.09 KB)PDF (50.09 KB) of 4-20 ENVIRONMENTAL SAMPLING FOR THE DETECTION OF LISTERIA MONOCYTOGENES	04/30/2015		Compliance, Inspection,	Final	No		
4-3 AFFIDAVIT (IN-TRANSIT) - FDA 1664b	PDF (66.88 KB)PDF (66.88 KB) of 4-3 AFFIDAVIT (IN-TRANSIT) - FDA 1664b	04/30/2015		Compliance, Inspection,	Final	No		
4-5 RECEIPT FOR SAMPLES - FDA 484	PDF (90.87 KB)PDF (90.87 KB) of 4-5 RECEIPT FOR SAMPLES - FDA 484	04/30/2015		Compliance, Inspection,	Final	No		
4-6 FIELD WEIGHT SHEET - FDA 485	PDF (34.38 KB)PDF (34.38 KB) of 4-6 FIELD WEIGHT SHEET - FDA 485	04/30/2015		Compliance, Inspection,	Final	No		
4-7 AFFIDAVIT - "301(k) Sample" - FDA 463a	PDF (64.93 KB)PDF (64.93 KB) of 4-7 AFFIDAVIT - "301(k) Sample" - FDA 463a	04/30/2015		Compliance, Inspection,	Final	No		
4-8 COPY OF INVOICE/SHIPPING RECORD - FD 1662	PDF (55.49 KB)PDF (55.49 KB) of 4-8 COPY OF INVOICE/SHIPPING RECORD - FD 1662	04/30/2015		Compliance, Inspection,	Final	No		
4-9 AFFIDAVIT (PARCEL POST) - FDA 463	PDF (75.22 KB)PDF (75.22 KB) of 4-9 AFFIDAVIT (PARCEL POST) - FDA 463	04/30/2015		Compliance, Inspection,	Final	No		
5-11 FOOD ADDITIVES NOMOGRAPHS	PDF (319.67 KB)PDF (319.67 KB) of 5-11 FOOD ADDITIVES NOMOGRAPHS	04/30/2015		Compliance, Inspection,	Final	No		
5-12 SUMMARY OF REGISTRATION AND LISTING HUMAN PHARMACEUTICALS	PDF (87.53 KB)PDF (87.53 KB) of 5-12 SUMMARY OF REGISTRATION AND LISTING HUMAN PHARMACEUTICALS	04/30/2015		Compliance, Inspection,	Final	No		
5-14 FACTS PROFILE - COMSTAT	PDF (177.5 KB)PDF (177.5 KB) of 5-14 FACTS PROFILE - COMSTAT	04/30/2015		Compliance, Inspection,	Final	No		
5-15 COMPLIANCE ACHIEVEMENT REPORT	PDF (253.47 KB)PDF (253.47 KB) of 5-15 COMPLIANCE ACHIEVEMENT REPORT	04/30/2015		Compliance, Inspection,	Final	No		
5-16 FACTS EI RECORD	PDF (60.73 KB)PDF (60.73 KB) of 5-16 FACTS EI RECORD	04/30/2015		Compliance, Inspection,	Final	No		
5-17 MEMO FOR RECORDS	PDF (319.13 KB)PDF (319.13 KB) of 5-17 MEMO FOR RECORDS	04/30/2015		Compliance, Inspection,	Final	No		

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5-18 FACTS REIMBURSABLE CHECK BOX	PDF (74.01 KB)PDF (74.01 KB) of 5-18 FACTS REIMBURSABLE CHECK BOX	04/30/2015		Compliance, Inspection,	Final	No		
5-2 FORM FDA 482a	PDF (272.76 KB)PDF (272.76 KB) of 5-2 FORM FDA 482a	04/30/2015		Inspection, Compliance,	Final	No		
5-3 FORM FDA 482b	PDF (172.59 KB)PDF (172.59 KB) of 5-3 FORM FDA 482b	04/30/2015		Inspection, Compliance,	Final	No		
5-4 MODIFIED FDA 482	PDF (46.84 KB)PDF (46.84 KB) of 5-4 MODIFIED FDA 482	04/30/2015		Inspection, Compliance,	Final	No		
5-5 FORM FDA 483	PDF (191.24 KB)PDF (191.24 KB) of 5-5 FORM FDA 483	04/30/2015		Compliance, Inspection,	Final	No		
5-6 INSERTING DIGITAL PHOTOS INTO TURBO EIR (RESIZE PHOTO)	PDF (61.4 KB)PDF (61.4 KB) of 5-6 INSERTING DIGITAL PHOTOS INTO TURBO EIR (RESIZE PHOTO)	04/30/2015		Compliance, Inspection,	Final	No		
5-7 INSERTING DIGITAL PHOTOS INTO TURBO EIR (INSERT PHOTO)	PDF (72.37 KB)PDF (72.37 KB) of 5-7 INSERTING DIGITAL PHOTOS INTO TURBO EIR (INSERT PHOTO)	04/30/2015		Inspection, Compliance,	Final	No		
5-8 INSERTING DIGITAL PHOTOS INTO TURBO EIR (RESIZE USING MS OFFICE PICTURE MANAGER)	PDF (581.73 KB)PDF (581.73 KB) of 5-8 INSERTING DIGITAL PHOTOS INTO TURBO EIR (RESIZE USING MS OFFICE PICTURE MANAGER)	04/30/2015		Compliance, Inspection,	Final	No		
6-1 NOTICE OF FDA ACTION	PDF (51.99 KB)PDF (51.99 KB) of 6-1 NOTICE OF FDA ACTION	04/30/2015		Compliance, Inspection,	Final	No		
6-2 FORM FDA 766	PDF (514.63 KB)PDF (514.63 KB) of 6-2 FORM FDA 766	04/30/2015		Compliance, Inspection,	Final	No		
6-3 CHARGES FOR SUPERVISION FORM FDA 790	PDF (299.46 KB)PDF (299.46 KB) of 6-3 CHARGES FOR SUPERVISION FORM FDA 790	04/30/2015		Compliance, Inspection,	Final	No		
6-4 CHARGES FOR SUPERVISION FORM FDA 790	PDF (413.94 KB)PDF (413.94 KB) of 6-4 CHARGES FOR SUPERVISION FORM FDA 790	04/30/2015		Compliance, Inspection,	Final	No		
6-5 IMPORT INVESTIGATION AFFIDAVIT	PDF (245.53 KB)PDF (245.53 KB) of 6-5 IMPORT INVESTIGATION AFFIDAVIT	04/30/2015		Compliance, Inspection,	Final	No		
7-1 RECALL COMMUNICATIONS - EXAMPLE	PDF (36.47 KB)PDF (36.47 KB) of 7-1 RECALL COMMUNICATIONS - EXAMPLE	04/30/2015		Compliance, Inspection,	Final	No		
7-2 FORM FDA-3177 RECALL AUDIT CHECK REPORT	PDF (703.49 KB)PDF (703.49 KB) of 7-2 FORM FDA-3177 RECALL AUDIT CHECK REPORT	04/30/2015		Compliance, Inspection,	Final	No		
8-1 FACTS ADVERSE EVENT QUESTIONNAIRE	PDF (28.16 KB)PDF (28.16 KB) of 8-1 FACTS ADVERSE EVENT QUESTIONNAIRE	04/30/2015		Compliance, Inspection,	Final	No		
8-10 MEDWATCH FORM	PDF (403.77 KB)PDF (403.77 KB) of 8-10 MEDWATCH FORM	04/30/2015		Inspection, Compliance,	Final	No		
8-11 VACCINE ADVERSE EVENT REPORT SYSTEM	PDF (1.31 MB)PDF (1.31 MB) of 8-11 VACCINE ADVERSE EVENT REPORT SYSTEM	04/30/2015		Inspection, Compliance,	Final	No		
8-12 NATURAL DISASTER REPORT	PDF (37.75 KB)PDF (37.75 KB) of 8-12 NATURAL DISASTER REPORT	04/30/2015		Inspection, Compliance,	Final	No		
8-13 FORM FDA-457	PDF (63.29 KB)PDF (63.29 KB) of 8-13 FORM FDA-457	04/30/2015		Inspection, Compliance,	Final	No		
8-14 FEDERAL ANTI-TAMPERING ACT	PDF (45.53 KB)PDF (45.53 KB) of 8-14 FEDERAL ANTI-TAMPERING ACT	04/30/2015		Inspection, Compliance,	Final	No		
8-2 FACTS CONSUMER COMPLAINT REPORT	PDF (45.18 KB)PDF (45.18 KB) of 8-2 FACTS CONSUMER COMPLAINT REPORT	04/30/2015		Compliance, Inspection,	Final	No		

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8-3 FACTS CONSUMER COMPLAINT FOLLOW-UP REPORT	PDF (28.82 KB)PDF (28.82 KB) of 8-3 FACTS CONSUMER COMPLAINT FOLLOW-UP REPORT	04/30/2015		Compliance, Inspection,	Final	No		
8-4 FACTS COSMETIC ADVERSE EVENT	PDF (36.61 KB)PDF (36.61 KB) of 8-4 FACTS COSMETIC ADVERSE EVENT	04/30/2015		Compliance, Inspection,	Final	No		
8-5 FORM FDA-461	PDF (55.01 KB)PDF (55.01 KB) of 8-5 FORM FDA-461	04/30/2015		Compliance, Inspection,	Final	No		
8-6 CLASSIFICATION OF ILLNESS ATTRIBUTED TO FOODS	PDF (124.56 KB)PDF (124.56 KB) of 8-6 CLASSIFICATION OF ILLNESS ATTRIBUTED TO FOODS	04/30/2015		Compliance, Inspection,	Final	No		
8-8 ATTACK RATE TABLE	PDF (45.24 KB)PDF (45.24 KB) of 8-8 ATTACK RATE TABLE	04/30/2015		Compliance, Inspection,	Final	No		
8-9 EPIDEMIC CURVE	PDF (16.93 KB)PDF (16.93 KB) of 8-9 EPIDEMIC CURVE	04/30/2015		Compliance, Inspection,	Final	No		
Appendix B Calendars	PDF (44.39 KB)PDF (44.39 KB) of Appendix B Calendars	04/30/2015		Inspection, Compliance,	Final	No		
Appendix C Blood Values	PDF (16.87 KB)PDF (16.87 KB) of Appendix C Blood Values	04/30/2015		Inspection, Compliance,	Final	No		
Appendix D Conversion Factors	PDF (44.67 KB)PDF (44.67 KB) of Appendix D Conversion Factors	04/30/2015		Inspection, Compliance,	Final	No		
Chapter 1 - Administration	PDF (491.11 KB)PDF (491.11 KB) of Chapter 1 - Administration	04/30/2015		Inspection, Compliance,	Final	No		
Chapter 2 - Regulatory	PDF (1.04 MB)PDF (1.04 MB) of Chapter 2 - Regulatory	04/30/2015		Inspection, Compliance,	Final	No		
Chapter 3 - Federal and State Cooperation	PDF (355.13 KB)PDF (355.13 KB) of Chapter 3 - Federal and State Cooperation	04/30/2015		Inspection, Compliance,	Final	No		
Chapter 4 - Sampling	PDF (2.12 MB)PDF (2.12 MB) of Chapter 4 - Sampling	04/30/2015		Inspection, Compliance,	Final	No		
Chapter 7 - Recall Activities	PDF (279.64 KB)PDF (279.64 KB) of Chapter 7 - Recall Activities	04/30/2015		Inspection, Compliance,	Final	No		
Chapter 8 - Investigations	PDF (2.43 MB)PDF (2.43 MB) of Chapter 8 - Investigations	04/30/2015		Inspection, Compliance,	Final	No		
CSFAN Guidance - Environmental Sampling for Detection of Salmonellae	PDF (48.69 KB)PDF (48.69 KB) of CSFAN Guidance - Environmental Sampling for Detection of Salmonellae	04/30/2015		Compliance, Inspection,	Final	No		
Investigations Operations Manual - Table of Contents	PDF (41.13 KB)PDF (41.13 KB) of Investigations Operations Manual - Table of Contents	04/30/2015		Inspection, Compliance,	Final	No		
IOM Appendix	PDF (6.52 MB)PDF (6.52 MB) of IOM Appendix	04/30/2015		Inspection, Compliance,	Final	No		
IOM Foreword	PDF (539.69 KB)PDF (539.69 KB) of IOM Foreword	04/30/2015	Office of Regulatory Affairs	Compliance, Inspection,	Final	No		
IOM Sample Schedules		04/30/2015		Inspection, Compliance,	Final	No		
ORA Directory	PDF (605.13 KB)PDF (605.13 KB) of ORA Directory	04/30/2015		Inspection, Compliance,	Final	No		
Vision / Mission / Values	PDF (298.52 KB)PDF (298.52 KB) of Vision / Mission / Values	04/30/2015		Inspection, Compliance,	Final	No		
Scientific Considerations in Demonstrating Biosimilarity to a Reference Product	PDF (169.02 KB)PDF (169.02 KB) of Scientific Considerations in Demonstrating Biosimilarity to a Reference Product	04/28/2015	Center for Drug Evaluation and Research	Biosimilarity	Final	No		FDA-2011-D-0605
Clinical Trial Endpoints for the Approval of Non-Small Cell Lung Cancer Drugs and Biologics	PDF (343 KB)PDF (343 KB) of Clinical Trial Endpoints for the Approval of Non-Small Cell Lung Cancer Drugs and Biologics	04/21/2015	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Clinical - Medical	Final	No		

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M8 Electronic Common Technical Document (eCTD) v4.0 DRAFT Implementation Guide v2.0; and eCTD Implementation Package DRAFT Specification for Submission Formats v2.0		04/21/2015		ICH-Multidisciplinary	Final	No		
Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval: Guidance for Industry and Food and Drug Administration Staff	PDF (500.14 KB)PDF (500.14 KB) of Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval: Guidance for Industry and Food and Drug Administration Staff	04/13/2015	Center for Devices and Radiological Health	Postmarket, Premarket, Premarket Approval (PMA)	Final	No		FDA-2014-D-0090
Risk Evaluation and Mitigation Strategies: Modifications and Revisions Guidance for Industry		04/06/2015	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Safety - Issues, Errors, and Problems	Draft	No		
CVM GFI #211 Residual Solvents in Animal Drug Products Questions and Answers	PDF (75.83 KB)PDF (75.83 KB) of CVM GFI #211 Residual Solvents in Animal Drug Products Questions and Answers	04/03/2015	Center for Veterinary Medicine	Chemistry, Manufacturing, and Controls (CMC)	Final	No		FDA-2010-D-0566
Abuse-Deterrent Opioids-Evaluation and Labeling	PDF (226.28 KB)PDF (226.28 KB) of Abuse-Deterrent Opioids-Evaluation and Labeling	04/01/2015	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		
Critical Path Innovation Meetings	PDF (68.37 KB)PDF (68.37 KB) of Critical Path Innovation Meetings	03/30/2015		Administrative / Procedural	Final	No		
Development and Submission of Near Infrared Analytical Procedures	PDF (175.93 KB)PDF (175.93 KB) of Development and Submission of Near Infrared Analytical Procedures	03/30/2015	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Draft	No		
Electronic Submission of Lot Distribution Reports: Guidance for Industry	PDF (64.97 KB)PDF (64.97 KB) of Electronic Submission of Lot Distribution Reports: Guidance for Industry	03/20/2015	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Electronic Submissions,	Final	No		
Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling : Guidance for Industry and Food and Drug Administration Staff	PDF (804.72 KB)PDF (804.72 KB) of Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling : Guidance for Industry and Food and Drug Administration Staff	03/17/2015	Center for Devices and Radiological Health	Premarket, 510(k), Premarket Approval (PMA), Device Exception (IDE)	Final	No		
Small Entity Compliance Guide: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments	PDF (282.72 KB)PDF (282.72 KB) of Small Entity Compliance Guide: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments	03/13/2015	Office of Nutrition and Food Labeling	Labeling, Nutrition Label, Nutrition	Final	No		FDA-2011-F-0172
CVM GFI #207 (VICH GL48) Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs In Food-Producing Animals: Marker Residue Depletion Studies to Establish Product Withdrawal Periods	PDF (303.03 KB)PDF (303.03 KB) of CVM GFI #207 (VICH GL48) Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs In Food-Producing Animals: Marker Residue Depletion Studies to Establish Product Withdrawal Periods	03/09/2015	Center for Veterinary Medicine	Human Food Safety, VICH	Final	No		FDA-2010-D-0166
CVM GFI #208 (VICH GL49) Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Validation of Analytical Methods Used in Residue Depletion Studies	PDF (290.89 KB)PDF (290.89 KB) of CVM GFI #208 (VICH GL49) Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Validation of Analytical Methods Used in Residue Depletion Studies	03/09/2015	Center for Veterinary Medicine	Human Food Safety, VICH	Final	No		FDA-2010-D-0165

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Determining the Need for and Content of Environmental Assessments for Gene Therapies, Vectored Vaccines, and Related Recombinant Viral or Microbial Products: Guidance for Industry	PDF (103.71 KB)PDF (103.71 KB) of Determining the Need for and Content of Environmental Assessments for Gene Therapies, Vectored Vaccines, and Related Recombinant Viral or Microbial Products: Guidance for Industry	03/01/2015	Center for Biologics Evaluation and Research	Gene Therapy	Final	No		FDA-2014-D-0663
Alcoholism: Developing Drugs for Treatment	PDF (350.4 KB)PDF (350.4 KB) of Alcoholism: Developing Drugs for Treatment	02/11/2015	Center for Drug Evaluation and Research	Clinical - Medical	Draft	No		FDA-2015-D-0152
Safety Considerations to Mitigate the Risks of Misconnections with Small-bore Connectors Intended for Enteral Applications: Guidance for Industry and Food and Drug Administration Staff	PDF (141.95 KB)PDF (141.95 KB) of Safety Considerations to Mitigate the Risks of Misconnections with Small-bore Connectors Intended for Enteral Applications: Guidance for Industry and Food and Drug Administration Staff	02/11/2015	Center for Devices and Radiological Health	Premarket, 510(k)	Final	No		FDA-2012-D-0630
S10 Photosafety Evaluation of Pharmaceuticals	PDF (255.89 KB)PDF (255.89 KB) of S10 Photosafety Evaluation of Pharmaceuticals	01/26/2015	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Safety	Final	No		
User Fee Waivers, Reductions, and Refunds for Drug and Biological Products	PDF (152.59 KB)PDF (152.59 KB) of User Fee Waivers, Reductions, and Refunds for Drug and Biological Products	01/06/2015	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	User Fees,	Final	No		FDA-2011-D-0108
DSCSA Implementation: Product Tracing Requirements — Compliance Policy	PDF (55.76 KB)PDF (55.76 KB) of DSCSA Implementation: Product Tracing Requirements — Compliance Policy	12/23/2014		Administrative / Procedural	Final	No		
Guidance for Industry: Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration	PDF (183.03 KB)PDF (183.03 KB) of Guidance for Industry: Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration	12/23/2014	Office of Nutrition and Food Labeling	Labeling	Final	No	10/16/2009	FDA-2009-D-0268
Transfer of a Premarket Notification (510(k)) Clearance – Questions and Answers: Draft Guidance for Industry and Food and Drug Administration Staff	PDF (356.57 KB)PDF (356.57 KB) of Transfer of a Premarket Notification (510(k)) Clearance – Questions and Answers: Draft Guidance for Industry and Food and Drug Administration Staff	12/22/2014	Center for Devices and Radiological Health	Postmarket, 510(k)	Draft	No		
Minimizing Risk for Children's Toy Laser Products: Guidance for Industry and Food and Drug Administration Staff	PDF (58.93 KB)PDF (58.93 KB) of Minimizing Risk for Children's Toy Laser Products: Guidance for Industry and Food and Drug Administration Staff	12/19/2014	Center for Devices and Radiological Health	Radiological Health	Final	No		
Providing Regulatory Submissions in Electronic Format -- Standardized Study Data	PDF (131.69 KB)PDF (131.69 KB) of Providing Regulatory Submissions in Electronic Format -- Standardized Study Data	12/17/2014	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Electronic Submissions,	Final	No		
Providing Regulatory Submissions in Electronic Format — Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act	PDF (81.47 KB)PDF (81.47 KB) of Providing Regulatory Submissions in Electronic Format — Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act	12/17/2014	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Electronic Submissions,	Final	No		
Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment: Guidance for Industry and Food and Drug Administration Staff	PDF (223.98 KB)PDF (223.98 KB) of Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment: Guidance for Industry and Food and Drug Administration Staff	12/11/2014	Center for Devices and Radiological Health	Premarket,	Final	No		

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
CVM GFI #214 (VICH GL35) Pharmacovigilance of Veterinary Medicinal Products Electronic Standards for Transfer of Data	PDF (1.53 MB)PDF (1.53 MB) of CVM GFI #214 (VICH GL35) Pharmacovigilance of Veterinary Medicinal Products Electronic Standards for Transfer of Data	12/10/2014	Center for Veterinary Medicine	Adverse Event Reporting, VICH	Final	No		FDA-2011-D-0588
Patient Counseling Information Section of Labeling for Human Prescription Drug and Biological Products — Content and Format	PDF (91.12 KB)PDF (91.12 KB) of Patient Counseling Information Section of Labeling for Human Prescription Drug and Biological Products — Content and Format	12/09/2014	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Labeling	Final	No		
DSCSA Implementation: Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers	PDF (94.17 KB)PDF (94.17 KB) of DSCSA Implementation: Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers	12/08/2014		Administrative / Procedural	Draft	No		
General Clinical Pharmacology Considerations for Pediatric Studies for Drugs and Biological Products	PDF (375.17 KB)PDF (375.17 KB) of General Clinical Pharmacology Considerations for Pediatric Studies for Drugs and Biological Products	12/08/2014	Center for Drug Evaluation and Research	Clinical - Pharmacology	Draft	No		
How to Obtain a Letter from FDA Stating that Bioequivalence Study Protocols Contain Safety Protections Comparable to Applicable REMS for RLD: Draft Guidance for Industry	PDF (71.88 KB)PDF (71.88 KB) of How to Obtain a Letter from FDA Stating that Bioequivalence Study Protocols Contain Safety Protections Comparable to Applicable REMS for RLD: Draft Guidance for Industry	12/04/2014	Center for Drug Evaluation and Research	User Fees, Generic Drugs	Draft	No		
Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products-Content and Format: Draft Guidance for Industry	PDF (208.1 KB)PDF (208.1 KB) of Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products-Content and Format: Draft Guidance for Industry	12/03/2014	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Labeling	Draft	No		
Infusion Pumps Total Product Life Cycle: Guidance for Industry and FDA Staff	PDF (474.39 KB)PDF (474.39 KB) of Infusion Pumps Total Product Life Cycle: Guidance for Industry and FDA Staff	12/02/2014	Center for Devices and Radiological Health	Premarket, 510(k)	Final	No		FDA-2010-D-0194
Recommendations for Labeling Medical Products to Inform Users that the Product or Product Container is not Made with Natural Rubber Latex: Guidance for Industry and Food and Drug Administration Staff	PDF (75.67 KB)PDF (75.67 KB) of Recommendations for Labeling Medical Products to Inform Users that the Product or Product Container is not Made with Natural Rubber Latex: Guidance for Industry and Food and Drug Administration Staff	12/02/2014	Center for Devices and Radiological Health	Premarket,	Final	No		FDA-2013-D-0168
Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture: Final Guidance	PDF (390.87 KB)PDF (390.87 KB) of Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture: Final Guidance	12/01/2014	Center for Biologics Evaluation and Research	Blood Products	Final	No		FDA-1999-D-3528
SUPAC: Manufacturing Equipment Addendum	PDF (212.88 KB)PDF (212.88 KB) of SUPAC: Manufacturing Equipment Addendum	12/01/2014	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Draft	No		
DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information	PDF (85.02 KB)PDF (85.02 KB) of DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information	11/26/2014		Administrative / Procedural	Draft	No		

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Immediately in Effect Guidance Document: Product Labeling for Laparoscopic Power Morcellators: Guidance for Industry and Food and Drug Administration Staff	PDF (2.18 MB)PDF (2.18 MB) of Immediately in Effect Guidance Document: Product Labeling for Laparoscopic Power Morcellators: Guidance for Industry and Food and Drug Administration Staff	11/25/2014	Center for Devices and Radiological Health	Postmarket, Premarket, 510(k), Labeling, Safety - Issues, Errors, and Problems, Obstetrical & Gynecological, General & Plastic Surgery	Final	No	01/23/2015	FDA-2014-D-1804
Design Considerations for Devices Intended for Home Use: Guidance for Industry and Food and Drug Administration Staff	PDF (522.91 KB)PDF (522.91 KB) of Design Considerations for Devices Intended for Home Use: Guidance for Industry and Food and Drug Administration Staff	11/24/2014	Center for Devices and Radiological Health	Premarket,	Final	No		FDA-2012-D-1161
Registration for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act	PDF (71.02 KB)PDF (71.02 KB) of Registration for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act	11/21/2014	Center for Drug Evaluation and Research	Administrative / Procedural, Compounding	Final	No		
Vaginal Microbicides:Development for the Prevention of HIV Infection PDF	PDF (352.3 KB)PDF (352.3 KB) of Vaginal Microbicides:Development for the Prevention of HIV Infection PDF	11/18/2014	Center for Drug Evaluation and Research	Clinical - Antimicrobial	Final	No		
Molecular Diagnostic Instruments with Combined Functions: Guidance for Industry and Food and Drug Administration Staff	PDF (424.7 KB)PDF (424.7 KB) of Molecular Diagnostic Instruments with Combined Functions: Guidance for Industry and Food and Drug Administration Staff	11/12/2014	Center for Devices and Radiological Health	Premarket,	Final	No		
Specification of the Unique Facility Identifier (UFI) System for Drug Establishment	PDF (61.12 KB)PDF (61.12 KB) of Specification of the Unique Facility Identifier (UFI) System for Drug Establishment	11/05/2014		Administrative / Procedural	Final	No		
4-4 CARRIER'S RECEIPT FOR SAMPLE - FDA 472	PDF (23.39 KB)PDF (23.39 KB) of 4-4 CARRIER'S RECEIPT FOR SAMPLE - FDA 472	10/29/2014		Compliance, Inspection,	Final	No		
5-1 FORM FDA 482 NOTICE OF INSPECTION	PDF (1.69 MB)PDF (1.69 MB) of 5-1 FORM FDA 482 NOTICE OF INSPECTION	10/29/2014		Compliance, Inspection,	Final	No		
5-9 FACTS CREATE ASSIGNMENT SCREEN	PDF (77.59 KB)PDF (77.59 KB) of 5-9 FACTS CREATE ASSIGNMENT SCREEN	10/29/2014		Compliance, Inspection,	Final	No		
Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection: Guidance for Industry	PDF (106.06 KB)PDF (106.06 KB) of Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection: Guidance for Industry	10/21/2014	Center for Veterinary Medicine, Office of Regulatory Affairs, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Postmarket,	Final	No	09/01/2013	
Distinguishing Medical Device Recalls from Medical Device Enhancements: Guidance for Industry and Food and Drug Administration Staff	PDF (359.71 KB)PDF (359.71 KB) of Distinguishing Medical Device Recalls from Medical Device Enhancements: Guidance for Industry and Food and Drug Administration Staff	10/15/2014	Center for Devices and Radiological Health	Postmarket,	Final	No		FDA-2013-D-0114
New Chemical Entity Exclusivity Determinations for Certain Fixed-Combination Drug Products	PDF (351.45 KB)PDF (351.45 KB) of New Chemical Entity Exclusivity Determinations for Certain Fixed-Combination Drug Products	10/10/2014		Administrative / Procedural	Final	No		
CVM GFI #143 (VICH GL30) Pharmacovigilance of Veterinary Medicinal Products: Controlled List of Terms	PDF (149.17 KB)PDF (149.17 KB) of CVM GFI #143 (VICH GL30) Pharmacovigilance of Veterinary Medicinal Products: Controlled List of Terms	10/09/2014	Center for Veterinary Medicine	Adverse Event Reporting, VICH	Final	No		FDA-2002-D-0268

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
CVM GFI #188 Data Elements for Submission of Veterinary Adverse Event Reports to the Center for Veterinary Medicine	PDF (254.61 KB)PDF (254.61 KB) of CVM GFI #188 Data Elements for Submission of Veterinary Adverse Event Reports to the Center for Veterinary Medicine	10/09/2014	Center for Veterinary Medicine	Adverse Event Reporting	Final	No		FDA-2010-D-0241
FDA's guidance on uniform national policy (Section 585 of the FD&C Act)	PDF (154.89 KB)PDF (154.89 KB) of FDA's guidance on uniform national policy (Section 585 of the FD&C Act)	10/07/2014		Administrative / Procedural	Draft	No		
Pathologic Complete Response in Neoadjuvant Treatment of High-Risk Early-Stage Breast Cancer: Use as an Endpoint to Support Accelerated Approval	PDF (286.94 KB)PDF (286.94 KB) of Pathologic Complete Response in Neoadjuvant Treatment of High-Risk Early-Stage Breast Cancer: Use as an Endpoint to Support Accelerated Approval	10/06/2014	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		
FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs): Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories	PDF (565.34 KB)PDF (565.34 KB) of FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs): Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories	10/03/2014	Center for Devices and Radiological Health	Premarket, Clinical - Medical, Premarket Approval (PMA)	Draft	No	02/04/2015	FDA-2011-D-0357
Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs): Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories	PDF (312.49 KB)PDF (312.49 KB) of Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs): Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories	10/03/2014	Center for Devices and Radiological Health	Premarket, Clinical - Medical, Premarket Approval (PMA)	Draft	No	02/04/2015	FDA-2011-D-0360
Content of Premarket Submissions for Management of Cybersecurity in Medical Devices : Guidance for Industry and Food and Drug Administration Staff	PDF (323.98 KB)PDF (323.98 KB) of Content of Premarket Submissions for Management of Cybersecurity in Medical Devices : Guidance for Industry and Food and Drug Administration Staff	10/02/2014	Center for Devices and Radiological Health	Premarket, Digital Health	Final	No		FDA-2013-D-0616-0001
Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007: Guidance for Industry		09/28/2014	Center for Tobacco Products		Final	No		
Custom Device Exemption: Guidance for Industry and Food and Drug Administration Staff	PDF (596.2 KB)PDF (596.2 KB) of Custom Device Exemption: Guidance for Industry and Food and Drug Administration Staff	09/24/2014	Center for Devices and Radiological Health	Premarket,	Final	No		FDA-2013-D-1601
CVM GFI #224 (Supplement to VICH GL52) Supplemental Examples For Illustrating Statistical Concepts Described in the VICH In Vivo Bioequivalence Guidance GL52	PDF (131.25 KB)PDF (131.25 KB) of CVM GFI #224 (Supplement to VICH GL52) Supplemental Examples For Illustrating Statistical Concepts Described in the VICH In Vivo Bioequivalence Guidance GL52	09/24/2014	Center for Veterinary Medicine	Generic Drugs, New Animal Drug Application (NADA), VICH, Generic Animal Drugs	Final	No	11/24/2014	FDA-2014-D-1352
Class II Special Controls Guideline: Tryptase Test System as an Aid in the Diagnosis of Systemic Mastocytosis: Guideline for Industry and Food and Drug Administration Staff	PDF (142.18 KB)PDF (142.18 KB) of Class II Special Controls Guideline: Tryptase Test System as an Aid in the Diagnosis of Systemic Mastocytosis: Guideline for Industry and Food and Drug Administration Staff	09/18/2014	Center for Devices and Radiological Health	IVDs (In Vitro Diagnostic Devices)	Final	No		FDA-2014-N-1251
Class II Special Controls Guideline: Dengue Virus Nucleic Acid Amplification Test Reagents: Guideline for Industry and Food and Drug Administration Staff	PDF (199.07 KB)PDF (199.07 KB) of Class II Special Controls Guideline: Dengue Virus Nucleic Acid Amplification Test Reagents: Guideline for Industry and Food and Drug Administration Staff	09/10/2014	Center for Devices and Radiological Health	Microbiology,	Final	No		FDA-2014-N-1166

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Recommendations for Screening, Testing, and Management of Blood Donors and Blood and Blood Components Based on Screening Tests for Syphilis: Guidance for Industry	PDF (114.38 KB)PDF (114.38 KB) of Recommendations for Screening, Testing, and Management of Blood Donors and Blood and Blood Components Based on Screening Tests for Syphilis: Guidance for Industry	09/01/2014	Center for Biologics Evaluation and Research	Blood Products	Final	No		FDA-2003-D-0128
Highly Multiplexed Microbiological/Medical Countermeasure In Vitro Nucleic Acid Based Diagnostic Devices: Guidance for Industry and Food and Drug Administration Staff	PDF (798.55 KB)PDF (798.55 KB) of Highly Multiplexed Microbiological/Medical Countermeasure In Vitro Nucleic Acid Based Diagnostic Devices: Guidance for Industry and Food and Drug Administration Staff	08/27/2014	Center for Devices and Radiological Health	IVDs (In Vitro Diagnostic Devices), Laboratory Tests	Final	No		
Evaluation of Sex-Specific Data in Medical Device Clinical Studies - Guidance for Industry and Food and Drug Administration Staff	PDF (940.93 KB)PDF (940.93 KB) of Evaluation of Sex-Specific Data in Medical Device Clinical Studies - Guidance for Industry and Food and Drug Administration Staff	08/22/2014	Center for Devices and Radiological Health	Premarket, Good Clinical Practices (GCP)	Final	No		
Unique Device Identifier System: Frequently Asked Questions, Vol. 1 : Guidance for Industry and Food and Drug Administration Staff	PDF (462.01 KB)PDF (462.01 KB) of Unique Device Identifier System: Frequently Asked Questions, Vol. 1 : Guidance for Industry and Food and Drug Administration Staff	08/20/2014	Center for Devices and Radiological Health	Labeling, Laser Notice	Final	No		
FDA Decisions for Investigational Device Exemption Clinical Investigations: Guidance for Sponsors, Clinical Investigators, Institutional Review Boards, and Food and Drug Administration Staff	PDF (630.79 KB)PDF (630.79 KB) of FDA Decisions for Investigational Device Exemption Clinical Investigations: Guidance for Sponsors, Clinical Investigators, Institutional Review Boards, and Food and Drug Administration Staff	08/19/2014	Center for Devices and Radiological Health	Premarket, Device Exception (IDE)	Final	No		
Immunogenicity Assessment for Therapeutic Protein Products	PDF (241.55 KB)PDF (241.55 KB) of Immunogenicity Assessment for Therapeutic Protein Products	08/13/2014	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Clinical - Medical, Pharmaceutical Quality	Final	No		
Unique Device Identification System: Small Entity Compliance Guide: Guidance for Industry and Food and Drug Administration Staff	PDF (419.86 KB)PDF (419.86 KB) of Unique Device Identification System: Small Entity Compliance Guide: Guidance for Industry and Food and Drug Administration Staff	08/13/2014	Center for Devices and Radiological Health	Labeling, Laser Notice	Final	No		
In Vitro Companion Diagnostic Devices: Guidance for Industry and Food and Drug Administration Staff	PDF (159.23 KB)PDF (159.23 KB) of In Vitro Companion Diagnostic Devices: Guidance for Industry and Food and Drug Administration Staff	08/06/2014	Center for Devices and Radiological Health	Premarket,	Final	No		
Upper Facial Lines: Developing Botulinum Toxin Drug Products	PDF (239.54 KB)PDF (239.54 KB) of Upper Facial Lines: Developing Botulinum Toxin Drug Products	08/05/2014	Center for Drug Evaluation and Research	Clinical - Medical	Draft	No		FDA-2014-D-0968
Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the PHS Act	PDF (99.35 KB)PDF (99.35 KB) of Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the PHS Act	08/04/2014	Center for Drug Evaluation and Research	Administrative / Procedural, Biosimilarity	Draft	No		FDA-2013-D-1165
Recommendations for Donor Questioning, Deferral, Reentry and Product Management to Reduce the Risk of Transfusion-Transmitted Malaria: Guidance for Industry	PDF (188.81 KB)PDF (188.81 KB) of Recommendations for Donor Questioning, Deferral, Reentry and Product Management to Reduce the Risk of Transfusion-Transmitted Malaria: Guidance for Industry	08/01/2014	Center for Biologics Evaluation and Research	Laboratory Methods, Blood Products	Final	No		FDA-2000-D-0187
CVM GFI #200 SECG for Designation of New Animal Drugs for Minor Uses or Minor Species	PDF (71.19 KB)PDF (71.19 KB) of CVM GFI #200 SECG for Designation of New Animal Drugs for Minor Uses or Minor Species	07/29/2014	Center for Veterinary Medicine	Minor Use/ Minor Species (MUMS)	Final	No		FDA-2010-D-0432

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
CVM GFI #201 SECG for The Index of Legally Marketed Unapproved New Animal Drugs for Minor Species	PDF (72.54 KB)PDF (72.54 KB) of CVM GFI #201 SECG for The Index of Legally Marketed Unapproved New Animal Drugs for Minor Species	07/29/2014	Center for Veterinary Medicine	Minor Use/ Minor Species (MUMS)	Final	No		FDA-2010-D-0435
The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]: Guidance for Industry and Food and Drug Administration Staff	PDF (843.9 KB)PDF (843.9 KB) of The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]: Guidance for Industry and Food and Drug Administration Staff	07/28/2014	Center for Devices and Radiological Health	Premarket, 510(k), Administrative / Procedural	Final	No		FDA-2011-D-0652
Exhibits		07/21/2014		Compliance, Inspection,	Final	No		
Informed Consent: Draft Guidance for IRBs, Clinical Investigators, and Sponsors	PDF (294.89 KB)PDF (294.89 KB) of Informed Consent: Draft Guidance for IRBs, Clinical Investigators, and Sponsors	07/14/2014	Office of Good Clinical Practice, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Good Clinical Practices (GCP)	Draft	No	09/15/2014	
Substantial Equivalence Reports: Manufacturer Requests for Extensions or to Change the Predicate Tobacco Product: Draft Draft Guidance for Industry		07/14/2014	Center for Tobacco Products		Draft	No		
Reporting Drug Sample Information Under Section 6004 of the Affordable Care Act	PDF (113.9 KB)PDF (113.9 KB) of Reporting Drug Sample Information Under Section 6004 of the Affordable Care Act	07/10/2014	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Electronic Submissions,	Draft	No		
Neglected Tropical Diseases of the Developing World: Developing Drugs for Treatment or Prevention	PDF (364.01 KB)PDF (364.01 KB) of Neglected Tropical Diseases of the Developing World: Developing Drugs for Treatment or Prevention	07/03/2014	Center for Drug Evaluation and Research	Clinical - Antimicrobial	Final	No		
Global Unique Device Identification Database (GUDID): Guidance for Industry and Food and Drug Administration Staff	PDF (2.78 MB)PDF (2.78 MB) of Global Unique Device Identification Database (GUDID): Guidance for Industry and Food and Drug Administration Staff	06/27/2014	Center for Devices and Radiological Health	Postmarket,	Final	No		FDA-2013-D-0117
Small Entity Compliance Guide: Gluten-Free Labeling of Foods	PDF (78.21 KB)PDF (78.21 KB) of Small Entity Compliance Guide: Gluten-Free Labeling of Foods	06/26/2014	Office of Nutrition and Food Labeling	Allergens, Food & Beverage Safety, Labeling, Food & Beverage Safety	Final	No		FDA-2005-N-0404
Guidance for Industry: Safety of Nanomaterials in Cosmetic Products	PDF (130.65 KB)PDF (130.65 KB) of Guidance for Industry: Safety of Nanomaterials in Cosmetic Products	06/24/2014	Office of Cosmetics and Colors		Final	No		FDA-2011-D-0489
Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology: Guidance for Industry	PDF (111.45 KB)PDF (111.45 KB) of Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology: Guidance for Industry	06/23/2014	Office of Policy	Premarket, Food & Color Additives, Records	Final	No		FDA-2010-D-0530
Criteria for Significant Risk Investigations of Magnetic Resonance Diagnostic Devices - Guidance for Industry and Food and Drug Administration Staff		06/19/2014	Center for Devices and Radiological Health	Premarket,	Final	No		
Guidance for Industry: Food Allergen Labeling Exemption Petitions and Notifications	PDF (524.85 KB)PDF (524.85 KB) of Guidance for Industry: Food Allergen Labeling Exemption Petitions and Notifications	06/19/2014	Office of Nutrition and Food Labeling	Allergens, Labeling	Final	No		FDA-2014-D-0052
Internet/Social Media Platforms with Character Space Limitations— Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices		06/18/2014	Center for Veterinary Medicine, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Advertising	Draft	No		FDA-2014-D-0397

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices	PDF (135.8 KB)PDF (135.8 KB) of Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices	06/18/2014	Center for Veterinary Medicine, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Advertising	Draft	No		FDA-2014-D-0447
Q4B Annex 6: Uniformity of Dosage Units General Chapter	PDF (53.18 KB)PDF (53.18 KB) of Q4B Annex 6: Uniformity of Dosage Units General Chapter	06/13/2014	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Quality	Final	No		
Guidance for Industry: Demonstration of the Quality Factor Requirements Under 21 CFR 106.96(i) for "Eligible" Infant Formulas	PDF (135.65 KB)PDF (135.65 KB) of Guidance for Industry: Demonstration of the Quality Factor Requirements Under 21 CFR 106.96(i) for "Eligible" Infant Formulas	06/10/2014	Office of Food Safety	Food & Beverage Safety, Infant Formula & Foods, Food & Beverage Safety	Final	No		FDA-2014-D-0033
Providing Submissions in Electronic Format — Postmarketing Safety Reports	PDF (124.03 KB)PDF (124.03 KB) of Providing Submissions in Electronic Format — Postmarketing Safety Reports	06/09/2014	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Electronic Submissions,	Draft	No		
Distributing Scientific and Medical Publications on Risk Information for Approved Prescription Drugs and Biological Products—Recommended Practices	PDF (94.88 KB)PDF (94.88 KB) of Distributing Scientific and Medical Publications on Risk Information for Approved Prescription Drugs and Biological Products—Recommended Practices	06/06/2014		Administrative / Procedural	Draft	No		
Recognition and Use of a Standard for Uniform Blood and Blood Component Container Labels: Guidance for Industry	PDF (73.9 KB)PDF (73.9 KB) of Recognition and Use of a Standard for Uniform Blood and Blood Component Container Labels: Guidance for Industry	06/01/2014	Center for Biologics Evaluation and Research	Blood Products	Final	No		FDA-1998-D-0067
United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using ISBT 128	PDF (1.33 MB)PDF (1.33 MB) of United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using ISBT 128	06/01/2014	Center for Biologics Evaluation and Research	Blood Products	Final	No		98D-0965
Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that Are Color Additives	PDF (201.31 KB)PDF (201.31 KB) of Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that Are Color Additives	05/31/2014	Office of Food Additive Safety	Food & Beverage Safety, Food & Color Additives, Food & Beverage Safety	Final	No		FDA-2011-D-0490
Class II Special Controls Guideline: Nucleic Acid-Based In Vitro Diagnostic Devices for the Detection of Mycobacterium tuberculosis Complex and Genetic Mutations Associated with Mycobacterium tuberculosis Complex Antibiotic Resistance in Respiratory Spec: Guideline for Industry and Food and Drug Administration Staff	PDF (265.85 KB)PDF (265.85 KB) of Class II Special Controls Guideline: Nucleic Acid-Based In Vitro Diagnostic Devices for the Detection of Mycobacterium tuberculosis Complex and Genetic Mutations Associated with Mycobacterium tuberculosis Complex Antibiotic Resistance in Respiratory Spec: Guideline for Industry and Food and Drug Administration Staff	05/30/2014	Center for Devices and Radiological Health	IVDs (In Vitro Diagnostic Devices)	Final	No		
Class II Special Controls Guideline: Dengue Virus Serological Reagents - Guideline for Industry and Food and Drug Administration Staff		05/29/2014	Center for Devices and Radiological Health	Laboratory Tests	Final	No		FDA-2014-N-0429

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Class II Special Controls Guideline: Nucleic Acid-Based In Vitro Diagnostic Devices for the Detection of Mycobacterium tuberculosis Complex in Respiratory Specimens - Guideline for Industry and Food and Drug Administration Staff		05/29/2014	Center for Devices and Radiological Health	Laboratory Tests	Final	No		FDA-2013-N-0544
CVM GFI #79 Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by CVM	PDF (139.26 KB)PDF (139.26 KB) of CVM GFI #79 Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by CVM	05/29/2014	Center for Veterinary Medicine	Administrative / Procedural	Final	No		FDA-2003-D-0307
Best Practices in Developing Proprietary Names for Drugs	PDF (279 KB)PDF (279 KB) of Best Practices in Developing Proprietary Names for Drugs	05/28/2014	Center for Drug Evaluation and Research	Safety - Issues, Errors, and Problems	Draft	No		
ANDAs: Stability Testing of Drug Substances and Products, Questions and Answers	PDF (124.21 KB)PDF (124.21 KB) of ANDAs: Stability Testing of Drug Substances and Products, Questions and Answers	05/14/2014	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		
CVM GFI #219 (VICH GL51) Statistical Evaluation of Stability Data	PDF (221.15 KB)PDF (221.15 KB) of CVM GFI #219 (VICH GL51) Statistical Evaluation of Stability Data	05/13/2014	Center for Veterinary Medicine	VICH	Draft	No		FDA-2012-D-0288
Hospital-Acquired Bacterial Pneumonia and Ventilator-Associated Bacterial Pneumonia: Developing Drugs for Treatment	PDF (377.21 KB)PDF (377.21 KB) of Hospital-Acquired Bacterial Pneumonia and Ventilator-Associated Bacterial Pneumonia: Developing Drugs for Treatment	05/06/2014	Center for Drug Evaluation and Research	Clinical - Antimicrobial	Draft	No		
Surveying, Leveling, or Alignment Laser Products: Draft Guidance for Industry and Food and Drug Administration Staff		05/04/2014	Center for Devices and Radiological Health		Draft	No	08/04/2014	FDA-2014-D-0435
Considerations When Transferring Clinical Investigation Oversight to Another IRB: Guidance for IRBs, Clinical Investigators, and Sponsors	PDF (157.26 KB)PDF (157.26 KB) of Considerations When Transferring Clinical Investigation Oversight to Another IRB: Guidance for IRBs, Clinical Investigators, and Sponsors	05/01/2014	Office of Good Clinical Practice, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Good Clinical Practices (GCP)	Final	No		FDA-2011-D-0835
Providing Information about Pediatric Uses of Medical Devices: Guidance for Industry and FDA Staff	PDF (176.69 KB)PDF (176.69 KB) of Providing Information about Pediatric Uses of Medical Devices: Guidance for Industry and FDA Staff	05/01/2014	Center for Devices and Radiological Health	Premarket,	Final	No		
Guidance for Industry: FDA Records Access Authority Under Sections 414 and 704 of the Federal Food, Drug, & Cosmetic Act	PDF (82.97 KB)PDF (82.97 KB) of Guidance for Industry: FDA Records Access Authority Under Sections 414 and 704 of the Federal Food, Drug, & Cosmetic Act	04/04/2014	Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine, Office of Regulatory Affairs	Administrative / Procedural, Defense & Security, Food & Beverage Safety, Laser Notice, Records, Food & Beverage Safety	Final	No	05/23/2012	FDA-2011-D-0674
Small Entity Compliance Guide: What You Need to Know About Establishment and Maintenance of Records	PDF (90.59 KB)PDF (90.59 KB) of Small Entity Compliance Guide: What You Need to Know About Establishment and Maintenance of Records	04/04/2014	Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine, Office of Regulatory Affairs	Defense & Security, Food & Beverage Safety, Records, Food & Beverage Safety	Final	No		FDA-2013-N-1421
Types of Communication During the Review of Medical Device Submissions: Guidance for Industry and FDA Staff	PDF (133.87 KB)PDF (133.87 KB) of Types of Communication During the Review of Medical Device Submissions: Guidance for Industry and FDA Staff	04/04/2014	Center for Devices and Radiological Health	Premarket,	Final	No		
Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations	PDF (88.18 KB)PDF (88.18 KB) of Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations	04/01/2014	Center for Biologics Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		FDA-1999-D-0178

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
The Meaning of "Spouse" and "Family" in FDA's Regulations after the Supreme Court's Ruling in United States v. Windsor: Questions and Answers: Guidance for Industry, Consumers, and FDA Staff	PDF (37.72 KB)PDF (37.72 KB) of The Meaning of "Spouse" and "Family" in FDA's Regulations after the Supreme Court's Ruling in United States v. Windsor: Questions and Answers: Guidance for Industry, Consumers, and FDA Staff	03/31/2014	Office of Policy	Administrative / Procedural, Food & Color Additives	Final	No		FDA-2014-D-0261
Medical Device Tracking : Guidance for Industry and FDA Staff	PDF (291.45 KB)PDF (291.45 KB) of Medical Device Tracking : Guidance for Industry and FDA Staff	03/27/2014	Center for Devices and Radiological Health		Final	No		
Premarket Assessment of Pediatric Medical Devices: Guidance for Industry and FDA Staff	PDF (161.96 KB)PDF (161.96 KB) of Premarket Assessment of Pediatric Medical Devices: Guidance for Industry and FDA Staff	03/24/2014	Center for Devices and Radiological Health	Premarket,	Final	No		
Bioavailability and Bioequivalence Studies Submitted in NDAs or INDs — General Considerations	PDF (804.84 KB)PDF (804.84 KB) of Bioavailability and Bioequivalence Studies Submitted in NDAs or INDs — General Considerations	03/17/2014	Center for Drug Evaluation and Research	Biopharmaceutics	Draft	No		FDA-2014-D-0204
Chronic Fatigue Syndrome/Myalgic Encephalomyelitis: Developing Drug Products for Treatment	PDF (337.45 KB)PDF (337.45 KB) of Chronic Fatigue Syndrome/Myalgic Encephalomyelitis: Developing Drug Products for Treatment	03/10/2014	Center for Drug Evaluation and Research	Clinical - Medical	Draft	No		
CMC Postapproval Manufacturing Changes To Be Documented in Annual Reports	PDF (105.98 KB)PDF (105.98 KB) of CMC Postapproval Manufacturing Changes To Be Documented in Annual Reports	03/04/2014	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		FDA-2010-D-0283
BLA for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic and Immunologic Reconstitution in Patients with Disorders Affecting the Hematopoietic System: Guidance for Industry	PDF (378.54 KB)PDF (378.54 KB) of BLA for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic and Immunologic Reconstitution in Patients with Disorders Affecting the Hematopoietic System: Guidance for Industry	03/01/2014	Center for Biologics Evaluation and Research	Cellular & Gene Therapy, Gene Therapy	Final	No		FDA-2006-D-0157
Clinical Investigator Administrative Actions - Disqualification: Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors	PDF (81.38 KB)PDF (81.38 KB) of Clinical Investigator Administrative Actions - Disqualification: Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors	03/01/2014	Office of Good Clinical Practice	Good Clinical Practices (GCP)	Final	No		
IND Applications for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic and Immunologic Reconstitution in Patients with Disorders Affecting the Hematopoietic System: Guidance for Industry and FDA Staff	PDF (119.68 KB)PDF (119.68 KB) of IND Applications for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic and Immunologic Reconstitution in Patients with Disorders Affecting the Hematopoietic System: Guidance for Industry and FDA Staff	03/01/2014	Center for Biologics Evaluation and Research	Cellular & Gene Therapy, Gene Therapy	Final	No		FDA-2009-D-0490
Distributing Scientific and Medical Publications on Unapproved New Uses — Recommended Practices - Revised Guidance	PDF (150.09 KB)PDF (150.09 KB) of Distributing Scientific and Medical Publications on Unapproved New Uses — Recommended Practices - Revised Guidance	02/28/2014		Administrative / Procedural	Draft	No		

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Public Availability of Advisory Committee Members' Financial Interest Information and Waivers: Guidance for the Public, FDA Advisory Committee Members, and FDA Staff	PDF (93.78 KB)PDF (93.78 KB) of Public Availability of Advisory Committee Members' Financial Interest Information and Waivers: Guidance for the Public, FDA Advisory Committee Members, and FDA Staff	02/28/2014	Office of Special Medical Programs	Advisory Committees, Food & Color Additives	Final	No		
Antiviral Product Development — Conducting and Submitting Virology Studies to the Agency: Guidance for Submitting HIV-1 Resistance Data: Attachment to the Guidance: Draft Draft Guidance: This draft guidance updates the final guidance posted 6/2/06	PDF (166.83 KB)PDF (166.83 KB) of Antiviral Product Development — Conducting and Submitting Virology Studies to the Agency: Guidance for Submitting HIV-1 Resistance Data: Attachment to the Guidance: Draft Draft Guidance: This draft guidance updates the final guidance posted 6/2/06	02/27/2014	Center for Drug Evaluation and Research	Clinical - Antimicrobial	Draft	No		
E2B(R3) Electronic Transmission of Individual Case Safety Reports Implementation Guide — Data Elements and Message Specification; and Appendix to the Implementation Guide — Backwards and Forwards Compatibility		02/20/2014	Center for Drug Evaluation and Research	ICH-Efficacy	Final	No		
Questions and Answers about eMDR - Electronic Medical Device Reporting - Guidance for Industry, User Facilities and FDA Staff		02/13/2014	Center for Devices and Radiological Health	Adverse Event Reporting System (FAERS), Adverse Event Reporting	Final	No		
Annual Reports for Approved Premarket Approval Applications (PMA) : Guidance for Industry and Food and Drug Administration Staff	PDF (94.81 KB)PDF (94.81 KB) of Annual Reports for Approved Premarket Approval Applications (PMA) : Guidance for Industry and Food and Drug Administration Staff	02/10/2014	Center for Devices and Radiological Health	Premarket, Premarket Approval (PMA)	Final	No		
Providing Regulatory Submissions in Electronic Format--Receipt Date	PDF (218.46 KB)PDF (218.46 KB) of Providing Regulatory Submissions in Electronic Format--Receipt Date	02/10/2014	Office of Medical Products and Tobacco	Electronic Submissions,	Final	No		
Class II Special Controls Guideline: John Cunningham Virus Serological Reagents - Guideline for Industry and Food and Drug Administration Staff		01/23/2014	Center for Devices and Radiological Health	Premarket,	Final	No		
Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics	PDF (117.65 KB)PDF (117.65 KB) of Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics	01/14/2014	Center for Veterinary Medicine, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Antimicrobial Resistance	Draft	No		FDA-2013-N-1430
Guidance for Industry: Considerations Regarding Substances Added to Foods, Including Beverages and Dietary Supplements	PDF (108.06 KB)PDF (108.06 KB) of Guidance for Industry: Considerations Regarding Substances Added to Foods, Including Beverages and Dietary Supplements	01/14/2014	Office of Food Additive Safety	Food & Beverage Safety, Ingredients, Food & Beverage Safety	Final	No		FDA-2009-D-0542
Guidance for Industry: Distinguishing Liquid Dietary Supplements from Beverages	PDF (202.31 KB)PDF (202.31 KB) of Guidance for Industry: Distinguishing Liquid Dietary Supplements from Beverages	01/14/2014	Office of Dietary Supplement Programs		Final	No		FDA-2009-D-0542
Community-Acquired Pneumonia — Developing Antimicrobial Drugs for Treatment	PDF (491.58 KB)PDF (491.58 KB) of Community-Acquired Pneumonia — Developing Antimicrobial Drugs for Treatment	01/09/2014	Center for Drug Evaluation and Research	Clinical - Antimicrobial	Draft	No		
Qualification Process for Drug Development Tools		01/06/2014	Center for Drug Evaluation and Research	Administrative / Procedural, Clinical - Medical	Draft	No		

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Attachement - Qualification Process for Drug Development Tools: Qualification of Exacerbations of Chronic Pulmonary Disease Tool for Measurement of Symptoms of Acute Bacterial Exacerbation of Chronic Bronchitis in Patients With Chronic Obstructive Pulmonary Disease	PDF (79.89 KB)PDF (79.89 KB) of Attachement - Qualification Process for Drug Development Tools: Qualification of Exacerbations of Chronic Pulmonary Disease Tool for Measurement of Symptoms of Acute Bacterial Exacerbation of Chronic Bronchitis in Patients With Chronic Obstructive Pulmonary Disease	01/01/2014	Center for Drug Evaluation and Research	Clinical - Medical	Draft	No		
Guidance for Industry: Dear Manufacturer Letter Regarding Changes to FDA's Administration of Process Filings (Forms FDA 2541a and FDA 2541c) for Acidified Foods and Low-Acid Canned Foods	PDF (104.95 KB)PDF (104.95 KB) of Guidance for Industry: Dear Manufacturer Letter Regarding Changes to FDA's Administration of Process Filings (Forms FDA 2541a and FDA 2541c) for Acidified Foods and Low-Acid Canned Foods	12/31/2013	Office of Food Safety		Final	No		
Class II Special Controls Guideline: Temporary Mandibular Condyle Reconstruction Plate - Guideline for Industry and Food and Drug Administration Staff		12/29/2013	Center for Devices and Radiological Health	Premarket,	Final	No		
CVM GFI #213 New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209	PDF (115.35 KB)PDF (115.35 KB) of CVM GFI #213 New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209	12/12/2013	Center for Veterinary Medicine	Antimicrobial Resistance, New Animal Drug Application (NADA)	Final	No		FDA-2011-D-0889
FDA's Strategy on Antimicrobial Resistance - Questions and Answers		12/10/2013	Center for Veterinary Medicine	Antimicrobial Resistance	Final	No		FDA-2010-D-0094
Bioequivalence Studies With Pharmacokinetic Endpoints for Drugs Submitted Under an Abbreviated New Drug Application	PDF (127.87 KB)PDF (127.87 KB) of Bioequivalence Studies With Pharmacokinetic Endpoints for Drugs Submitted Under an Abbreviated New Drug Application	12/04/2013	Center for Drug Evaluation and Research	Biopharmaceutics	Draft	No		FDA-2013-D-1464
CPG Sec. 460.200 Pharmacy Compounding (Withdrawn December 4, 2013)		12/03/2013		Investigation & Enforcement,	Final	No		
Draft Guidance for Industry: Regulatory Submissions to OFAS, Part III Electronic Format		12/01/2013	Office of Food Additive Safety	Food & Color Additives	Draft	No		
Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only: Guidance for Industry and FDA Staff	PDF (195.23 KB)PDF (195.23 KB) of Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only: Guidance for Industry and FDA Staff	11/25/2013	Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Premarket, Good Clinical Practices (GCP), IVDs (In Vitro Diagnostic Devices), Device Exception (IDE), Laboratory Tests	Final	No		
Guidance for Industry: Purchasing Reef Fish Species Associated with the Hazard of Ciguatera Fish Poisoning	PDF (163.61 KB)PDF (163.61 KB) of Guidance for Industry: Purchasing Reef Fish Species Associated with the Hazard of Ciguatera Fish Poisoning	11/22/2013	Office of Food Safety	Seafood/Seafood Product	Final	No		FDA-2013-D-0269
Design Considerations for Pivotal Clinical Investigations for Medical Devices: Guidance for Industry, Clinical Investigators, Institutional Review Boards and FDA Staff	PDF (402.07 KB)PDF (402.07 KB) of Design Considerations for Pivotal Clinical Investigations for Medical Devices: Guidance for Industry, Clinical Investigators, Institutional Review Boards and FDA Staff	11/07/2013	Center for Devices and Radiological Health	Premarket, Good Clinical Practices (GCP)	Final	No		
Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products - Draft Guidance for Industry and Food and Drug Administration Staff		11/06/2013	Center for Devices and Radiological Health		Final	No		

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Pulmonary Tuberculosis: Developing Drugs for Treatment	PDF (526.51 KB)PDF (526.51 KB) of Pulmonary Tuberculosis: Developing Drugs for Treatment	11/05/2013	Center for Drug Evaluation and Research	Clinical - Antimicrobial	Final	No		
Preclinical Assessment of Investigational Cellular and Gene Therapy Products: Guidance for Industry	PDF (165.31 KB)PDF (165.31 KB) of Preclinical Assessment of Investigational Cellular and Gene Therapy Products: Guidance for Industry	11/01/2013	Center for Biologics Evaluation and Research	Cellular & Gene Therapy, Gene Therapy	Final	No		FDA-2012-D-1038
Redbook 2000: IV.C.1.c Mouse Lymphoma Thymidine Kinase Gene Mutation Assay		11/01/2013	Office of Food Additive Safety	Food & Color Additives	Final	No		
Acute Bacterial Skin and Skin Structure Infections: Developing Drugs for Treatment	PDF (266.74 KB)PDF (266.74 KB) of Acute Bacterial Skin and Skin Structure Infections: Developing Drugs for Treatment	10/16/2013	Center for Drug Evaluation and Research	Clinical - Antimicrobial	Final	No		FDA-2013-D-1181
Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions: Annex 14: Bacterial Endotoxins Test General Chapter	PDF (96.23 KB)PDF (96.23 KB) of Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions: Annex 14: Bacterial Endotoxins Test General Chapter	10/15/2013	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Quality	Final	No		
Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies: Guidance for Industry and Food and Drug Administration Staff	PDF (1.34 MB)PDF (1.34 MB) of Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies: Guidance for Industry and Food and Drug Administration Staff	10/01/2013	Center for Devices and Radiological Health	Premarket, Good Clinical Practices (GCP), Device Exception (IDE)	Final	No		
CVM GFI #223 Small Entity Compliance Guide Declaring Color Additives in Animal Foods	PDF (47.67 KB)PDF (47.67 KB) of CVM GFI #223 Small Entity Compliance Guide Declaring Color Additives in Animal Foods	09/27/2013	Center for Veterinary Medicine	Animal Feed	Final	No		FDA-2013-D-1088
Electronic Source Data in Clinical Investigations: Guidance for Industry	PDF (190.31 KB)PDF (190.31 KB) of Electronic Source Data in Clinical Investigations: Guidance for Industry	09/17/2013	Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Administrative / Procedural, Good Clinical Practices (GCP)	Final	No		
Investigational New Drug Applications (INDs) - Determining Whether Human Research Studies Can Be Conducted Without an IND: Guidance for Clinical Investigators, Sponsors, and IRBs	PDF (305.09 KB)PDF (305.09 KB) of Investigational New Drug Applications (INDs) - Determining Whether Human Research Studies Can Be Conducted Without an IND: Guidance for Clinical Investigators, Sponsors, and IRBs	09/10/2013	Center for Food Safety and Applied Nutrition, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Clinical - Medical, Good Clinical Practices (GCP)	Final	No		
Specification of the Unique Facility Identifier (UFI) System for Drug Establishment Registration	PDF (182.56 KB)PDF (182.56 KB) of Specification of the Unique Facility Identifier (UFI) System for Drug Establishment Registration	09/04/2013		Administrative / Procedural	Draft	No		
IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is Needed: Guidance for IRBs, Clinical Investigators, and Sponsors	PDF (47.44 KB)PDF (47.44 KB) of IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is Needed: Guidance for IRBs, Clinical Investigators, and Sponsors	08/27/2013	Office of Good Clinical Practice, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Administrative / Procedural, Good Clinical Practices (GCP)	Final	No		
Compliance with Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents: Guidance for Industry		08/20/2013	Center for Tobacco Products		Final	No	08/21/2013	

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Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and FDA Staff	PDF (138.76 KB)PDF (138.76 KB) of Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and FDA Staff	08/14/2013	Center for Devices and Radiological Health	Premarket, Digital Health	Final	No		
Oversight of Clinical Investigations — A Risk-Based Approach to Monitoring: Guidance for Industry	PDF (162.82 KB)PDF (162.82 KB) of Oversight of Clinical Investigations — A Risk-Based Approach to Monitoring: Guidance for Industry	08/06/2013	Office of Regulatory Affairs, Office of Good Clinical Practice, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Administrative / Procedural, Good Clinical Practices (GCP)	Final	No		
Safety Labeling Changes -- Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act	PDF (117.89 KB)PDF (117.89 KB) of Safety Labeling Changes -- Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act	07/30/2013	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Safety - Issues, Errors, and Problems	Final	No		
Draft Guidance for Industry: Questions and Answers Regarding the Final Rule, Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation (Layers with Outdoor Access)	PDF (241.69 KB)PDF (241.69 KB) of Draft Guidance for Industry: Questions and Answers Regarding the Final Rule, Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation (Layers with Outdoor Access)	07/24/2013	Office of Food Safety	Egg/Egg Product, Transportation	Draft	No	09/23/2013	FDA-2000-N-0190
Pre-Launch Activities Importation Requests (PLAIR)	PDF (180.08 KB)PDF (180.08 KB) of Pre-Launch Activities Importation Requests (PLAIR)	07/24/2013		Administrative / Procedural	Draft	No		
Providing Submissions in Electronic Format – Postmarket Non-Expedited ICSRs Technical Questions and Answers	PDF (103.51 KB)PDF (103.51 KB) of Providing Submissions in Electronic Format – Postmarket Non-Expedited ICSRs Technical Questions and Answers	07/24/2013	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Electronic Submissions,	Final	No		
Compliance Policy Guide Sec 690 800 Salmonella in Food for Animals Final	PDF (44.83 KB)PDF (44.83 KB) of Compliance Policy Guide Sec 690 800 Salmonella in Food for Animals Final	07/16/2013		Investigation & Enforcement, Laser Notice	Final	No	12/31/2010	FDA 2010-D-0378
Draft Guidance for Industry: Action Level for Arsenic in Apple Juice	PDF (188.04 KB)PDF (188.04 KB) of Draft Guidance for Industry: Action Level for Arsenic in Apple Juice	07/15/2013	Office of Food Safety	Contaminants, Food & Beverage Safety, Juice, Food & Beverage Safety	Draft	No	09/13/2013	FDA-2012-D-0322
CPG Sec 690.800 Compliance Policy Guide Salmonella in Food for Animals	PDF (42.07 KB)PDF (42.07 KB) of CPG Sec 690.800 Compliance Policy Guide Salmonella in Food for Animals	07/01/2013	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Animal Feed	Final	No		
Enforcement Policy Regarding Investigational New Drug Requirements for Use of Fecal Microbiota for Transplantation to Treat Clostridium difficile Infection Not Responsive to Standard Therapies: Guidance for Industry	PDF (41.8 KB)PDF (41.8 KB) of Enforcement Policy Regarding Investigational New Drug Requirements for Use of Fecal Microbiota for Transplantation to Treat Clostridium difficile Infection Not Responsive to Standard Therapies: Guidance for Industry	07/01/2013	Center for Biologics Evaluation and Research	Vaccines	Final	No		FDA-2013-D-0811
Heparin for Drug and Medical Device Use: Monitoring Crude Heparin for Quality: Guidance for Industry	PDF (60.37 KB)PDF (60.37 KB) of Heparin for Drug and Medical Device Use: Monitoring Crude Heparin for Quality: Guidance for Industry	06/25/2013	Center for Veterinary Medicine, Center for Drug Evaluation and Research, Center for Devices and Radiological Health	Current Good Manufacturing Practices (CGMP), Pharmaceutical Quality	Final	No		
ANDAs: Stability Testing of Drug Substances and Products	PDF (30.34 KB)PDF (30.34 KB) of ANDAs: Stability Testing of Drug Substances and Products	06/18/2013	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		

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Codevelopment of Two or More New Investigational Drugs for Use in Combination	PDF (91.31 KB)PDF (91.31 KB) of Codevelopment of Two or More New Investigational Drugs for Use in Combination	06/14/2013	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		
Technical Considerations for Pen, Jet, and Related Injectors Intended for Use with Drugs and Biological Products: Guidance for Industry and FDA Staff	PDF (152.84 KB)PDF (152.84 KB) of Technical Considerations for Pen, Jet, and Related Injectors Intended for Use with Drugs and Biological Products: Guidance for Industry and FDA Staff	06/06/2013	Office of Combination Products, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Administrative / Procedural, Combination Products	Final	No		FDA-2009-D-0179
Human Immunodeficiency Virus-1 Infection: Developing Antiretroviral Drugs for Treatment (html)		06/03/2013			Final	No		
M2: eCTD Specification Questions & Answers and Change Requests Companion Document		06/02/2013	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Multidisciplinary	Final	No		
Draft Guidance for Industry: Cosmetic Good Manufacturing Practices	PDF (77.92 KB)PDF (77.92 KB) of Draft Guidance for Industry: Cosmetic Good Manufacturing Practices	06/01/2013	Office of Cosmetics and Colors	Current Good Manufacturing Practices (CGMP)	Draft	No		
Rheumatoid Arthritis: Developing Drug Products for Treatment	PDF (176.46 KB)PDF (176.46 KB) of Rheumatoid Arthritis: Developing Drug Products for Treatment	05/30/2013	Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Clinical - Medical	Draft	No		FDA-2013-D-0571
Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Annex 13: Bulk Density and Tapped Density of Powders General Chapter	PDF (93.51 KB)PDF (93.51 KB) of Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Annex 13: Bulk Density and Tapped Density of Powders General Chapter	05/24/2013		ICH-Quality	Final	No		
Annex 13 Bulk Density and Tapped Density of Powders General Chapter	PDF (93.51 KB)PDF (93.51 KB) of Annex 13 Bulk Density and Tapped Density of Powders General Chapter	05/23/2013	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research		Final	No		
The Open Public Hearing at FDA Advisory Committee Meetings: Guidance for the Public, FDA Advisory Committee Members, and FDA Staff	PDF (68.71 KB)PDF (68.71 KB) of The Open Public Hearing at FDA Advisory Committee Meetings: Guidance for the Public, FDA Advisory Committee Members, and FDA Staff	05/15/2013	Office of the Commissioner	Advisory Committees, Food & Color Additives	Final	No		
Best Practices for Conducting and Reporting Pharmacoepidemiologic Safety Studies Using Electronic Healthcare Data Sets	PDF (501.28 KB)PDF (501.28 KB) of Best Practices for Conducting and Reporting Pharmacoepidemiologic Safety Studies Using Electronic Healthcare Data Sets	05/14/2013	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Safety - Issues, Errors, and Problems	Final	No		FDA-2011-D-0057
Assay Migration Studies for In Vitro Diagnostic Devices: Guidance for Industry and FDA Staff	PDF (1.21 MB)PDF (1.21 MB) of Assay Migration Studies for In Vitro Diagnostic Devices: Guidance for Industry and FDA Staff	04/25/2013	Center for Devices and Radiological Health	Premarket, IVDs (In Vitro Diagnostic Devices), Laboratory Tests	Final	No		
Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors	PDF (608.23 KB)PDF (608.23 KB) of Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors	04/23/2013	Center for Drug Evaluation and Research	Safety - Issues, Errors, and Problems	Draft	No		

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Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Non-Penicillin Beta-Lactam Drugs: A CGMP Framework for Preventing Cross-Contamination: Guidance for Industry	PDF (70.18 KB)PDF (70.18 KB) of Non-Penicillin Beta-Lactam Drugs: A CGMP Framework for Preventing Cross-Contamination: Guidance for Industry	04/17/2013	Center for Drug Evaluation and Research	Current Good Manufacturing Practices (CGMP), Pharmaceutical Quality	Final	No		
Medical Device Classification Product Codes - Guidance for Industry and Food and Drug Administration Staff		04/10/2013	Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Premarket,	Final	No		
Self-Selection Studies for Nonprescription Drug Products	PDF (159.78 KB)PDF (159.78 KB) of Self-Selection Studies for Nonprescription Drug Products	04/10/2013	Center for Drug Evaluation and Research	Over-the-Counter Drugs	Final	No		
CPG Sec.100.250 Food Facility Registration- Human and Animal Food	PDF (98.12 KB)PDF (98.12 KB) of CPG Sec.100.250 Food Facility Registration- Human and Animal Food	04/04/2013		Investigation & Enforcement,	Final	No		
Blood Establishment Computer System Validation in the User's Facility: Guidance for Industry	PDF (65.58 KB)PDF (65.58 KB) of Blood Establishment Computer System Validation in the User's Facility: Guidance for Industry	04/01/2013	Center for Biologics Evaluation and Research	Blood Products	Final	No		FDA-2007-D-0069
Exception from Informed Consent Requirements for Emergency Research: Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors	PDF (340.91 KB)PDF (340.91 KB) of Exception from Informed Consent Requirements for Emergency Research: Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors	04/01/2013	Office of Good Clinical Practice, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Good Clinical Practices (GCP)	Final	No		
Glass Syringes for Delivering Drug and Biological Products: Technical Information to Supplement International Organization for Standardization (ISO) Standard 11040-4: Draft Guidance for Industry and FDA Staff	PDF (98.17 KB)PDF (98.17 KB) of Glass Syringes for Delivering Drug and Biological Products: Technical Information to Supplement International Organization for Standardization (ISO) Standard 11040-4: Draft Guidance for Industry and FDA Staff	03/31/2013	Office of Combination Products, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Combination Products	Draft	No	07/01/2013	
Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection of Antibodies to Borrelia burgdorferi - Guidance for Industry and FDA Staff		03/27/2013	Center for Devices and Radiological Health	Premarket, Laboratory Tests	Final	No		
Tablet Scoring:Nomenclature, Labeling, and Data for Evaluation	PDF (55.61 KB)PDF (55.61 KB) of Tablet Scoring:Nomenclature, Labeling, and Data for Evaluation	03/13/2013	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		
Small Entity Compliance Guide: What You Need To Know About Administrative Detention of Foods	PDF (80.88 KB)PDF (80.88 KB) of Small Entity Compliance Guide: What You Need To Know About Administrative Detention of Foods	03/08/2013	Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine, Office of Regulatory Affairs	Export	Final	No		FDA-2011-D-0643
Investigational Device Exemption (IDE) Guidance for Retinal Prostheses: Guidance for Industry and FDA Staff	PDF (168.79 KB)PDF (168.79 KB) of Investigational Device Exemption (IDE) Guidance for Retinal Prostheses: Guidance for Industry and FDA Staff	03/06/2013	Center for Devices and Radiological Health		Final	No		
CVM GFI #159 (VICH GL36) Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish a Microbiological ADI	PDF (533.01 KB)PDF (533.01 KB) of CVM GFI #159 (VICH GL36) Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish a Microbiological ADI	03/05/2013	Center for Veterinary Medicine	Human Food Safety, VICH	Final	No		FDA-2003-D-0433
Investigational Device Exemption (IDE) Guidance for Retinal Prostheses - Guidance for Industry and Food and Drug Administration Staff		03/05/2013	Center for Devices and Radiological Health	Premarket, Device Exception (IDE)	Final	No		

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Pulse Oximeters - Premarket Notification Submissions [510(k)s]: Guidance for Industry and Food and Drug Administration Staff		03/03/2013	Center for Devices and Radiological Health	Premarket,	Final	No		
Ch. 5 - Administrative Actions	PDF (1.02 MB)PDF (1.02 MB) of Ch. 5 - Administrative Actions	03/01/2013		Investigation & Enforcement, Food & Color Additives	Final	No		
M3(R2)Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals: Questions and Answers	PDF (311.38 KB)PDF (311.38 KB) of M3(R2)Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals: Questions and Answers	02/25/2013	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Multidisciplinary	Final	No		
Antiviral Product Development — Conducting and Submitting Virology Studies to the Agency Guidance for Submitting HCV Resistance Data -Attachment to Guidance	PDF (391.28 KB)PDF (391.28 KB) of Antiviral Product Development — Conducting and Submitting Virology Studies to the Agency Guidance for Submitting HCV Resistance Data -Attachment to Guidance	02/22/2013	Center for Drug Evaluation and Research	Clinical - Antimicrobial	Draft	No		
Labeling for Human Prescription Drug and Biological Products - Implementing the PLR Content and Format Requirements	PDF (526.69 KB)PDF (526.69 KB) of Labeling for Human Prescription Drug and Biological Products - Implementing the PLR Content and Format Requirements	02/22/2013	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Labeling	Final	No		
Clinical Study Designs for Surgical Ablation Devices for Treatment of Atrial Fibrillation - Guidance for Industry and Food and Drug Administration Staff		02/14/2013	Center for Devices and Radiological Health	Premarket,	Final	No		
CPG Sec. 390.225 Early Defects or Noncompliance - 21 CFR 1004.6		02/03/2013		Investigation & Enforcement,	Final	No		
Financial Disclosure by Clinical Investigators: Guidance for Clinical Investigators, Industry,and FDA Staff	PDF (165.38 KB)PDF (165.38 KB) of Financial Disclosure by Clinical Investigators: Guidance for Clinical Investigators, Industry,and FDA Staff	02/01/2013	Office of Good Clinical Practice, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Good Clinical Practices (GCP)	Final	No		
Clinical Pharmacogenomics: Premarket Evaluation in Early-Phase Clinical Studies and Recommendations for Labeling	PDF (130.55 KB)PDF (130.55 KB) of Clinical Pharmacogenomics: Premarket Evaluation in Early-Phase Clinical Studies and Recommendations for Labeling	01/29/2013	Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Clinical - Pharmacology	Final	No		
E3 Structure and Content of Clinical Study Reports - Questions and Answers (R1)	PDF (141.13 KB)PDF (141.13 KB) of E3 Structure and Content of Clinical Study Reports - Questions and Answers (R1)	01/25/2013	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Efficacy	Final	No		
Submissions for Postapproval Modifications to a Combination Product Approved Under a BLA, NDA, or PMA: Draft Guidance for Industry and FDA Staff	PDF (101.18 KB)PDF (101.18 KB) of Submissions for Postapproval Modifications to a Combination Product Approved Under a BLA, NDA, or PMA: Draft Guidance for Industry and FDA Staff	01/18/2013	Office of Combination Products	Combination Products	Draft	No	04/01/2013	
Guidance for Industry: Food Labeling Guide		01/01/2013	Office of Nutrition and Food Labeling	Labeling, Nutrition	Final	No		
Safety Reporting Requirements for INDs (Investigational New Drug Applications) and BA/BE (Bioavailability/Bioequivalence) Studies: Guidance for Industry and Investigators	PDF (227.49 KB)PDF (227.49 KB) of Safety Reporting Requirements for INDs (Investigational New Drug Applications) and BA/BE (Bioavailability/Bioequivalence) Studies: Guidance for Industry and Investigators	12/19/2012	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Good Clinical Practices (GCP), Safety - Issues, Errors, and Problems	Final	No		

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Safety Reporting Requirements for INDs and BA/BE Studies: Guidance for Industry and Investigators	PDF (35.12 KB)PDF (35.12 KB) of Safety Reporting Requirements for INDs and BA/BE Studies: Guidance for Industry and Investigators	12/19/2012	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Good Clinical Practices (GCP), Safety - Issues, Errors, and Problems	Final	No		
Labeling and Effectiveness Testing: Sunscreen Drug Products for Over-The-Counter Human Use — Small Entity Compliance Guide: Guidance for Industry		12/04/2012	Center for Drug Evaluation and Research	Over-the-Counter Drugs	Final	No		
Limiting the Use of Certain Phthalates as Excipients in CDER-Regulated Products: Guidance for Industry		12/04/2012	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		
FDA Oversight of PET Drug Products -- Questions and Answers	PDF (498.96 KB)PDF (498.96 KB) of FDA Oversight of PET Drug Products -- Questions and Answers	12/03/2012	Center for Drug Evaluation and Research	Administrative / Procedural	Final	No		
Investigational New Drug Applications for Positron Emission Tomography (PET) Drugs	PDF (368.85 KB)PDF (368.85 KB) of Investigational New Drug Applications for Positron Emission Tomography (PET) Drugs	12/03/2012	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		
CVM GFI #217 Evaluating the Effectiveness of Anticoccidial Drugs in Food-Producing Animals	PDF (180.91 KB)PDF (180.91 KB) of CVM GFI #217 Evaluating the Effectiveness of Anticoccidial Drugs in Food-Producing Animals	11/20/2012	Center for Veterinary Medicine	Target Animal – Effectiveness	Final	No		FDA-2011-D-0784
Q11 Development and Manufacture of Drug Substances	PDF (708.32 KB)PDF (708.32 KB) of Q11 Development and Manufacture of Drug Substances	11/19/2012	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Quality	Final	No		
Labeling for Bronchodilators: Cold, Cough, Allergy, Bronchodilator, And Antiasthmatic Drug Products for Over-the-Counter Human Use (Small Entity Compliance Guide): Guidance for Industry		11/13/2012	Center for Drug Evaluation and Research	Over-the-Counter Drugs	Final	No		
The Content of Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications for Artificial Pancreas Device Systems: Guidance for Industry and Food and Drug Administration Staff	PDF (847.07 KB)PDF (847.07 KB) of The Content of Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications for Artificial Pancreas Device Systems: Guidance for Industry and Food and Drug Administration Staff	11/09/2012	Center for Devices and Radiological Health	Premarket, Premarket Approval (PMA), Device Exception (IDE)	Final	No		
E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs - Questions and Answers (R1)		10/11/2012		ICH-Efficacy	Final	No		
Acute Bacterial Sinusitis — Developing Antimicrobial Drugs for Treatment	PDF (479.82 KB)PDF (479.82 KB) of Acute Bacterial Sinusitis — Developing Antimicrobial Drugs for Treatment	10/05/2012		Clinical - Antimicrobial	Final	No		
Guidance for Industry Acute Bacterial Sinusitis: Developing Drugs for Treatment	PDF (479.82 KB)PDF (479.82 KB) of Guidance for Industry Acute Bacterial Sinusitis: Developing Drugs for Treatment	10/04/2012	Center for Drug Evaluation and Research	Clinical - Antimicrobial	Final	No		
Use of Nucleic Acid Tests on Pooled and Individual Samples From Donors of Whole Blood and Blood Components, Including Source Plasma, to Reduce the Risk of Transmission of Hepatitis B Virus: Final Guidance for Industry	PDF (187.47 KB)PDF (187.47 KB) of Use of Nucleic Acid Tests on Pooled and Individual Samples From Donors of Whole Blood and Blood Components, Including Source Plasma, to Reduce the Risk of Transmission of Hepatitis B Virus: Final Guidance for Industry	10/01/2012	Center for Biologics Evaluation and Research	Blood Products	Final	No		FDA-2011-D-0799
Guidance for Industry: Acute Bacterial Otitis Media: Developing Drugs for Treatment	PDF (116.59 KB)PDF (116.59 KB) of Guidance for Industry: Acute Bacterial Otitis Media: Developing Drugs for Treatment	09/30/2012	Center for Drug Evaluation and Research		Final	No		

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Acute Bacterial Exacerbations of Chronic Bronchitis in Patients with Chronic Obstructive Pulmonary Disease: Developing Antimicrobial Drugs for Treatment	PDF (143.52 KB)PDF (143.52 KB) of Acute Bacterial Exacerbations of Chronic Bronchitis in Patients with Chronic Obstructive Pulmonary Disease: Developing Antimicrobial Drugs for Treatment	09/28/2012		Clinical - Antimicrobial	Final	No		
Acute Bacterial Exacerbations of Chronic Bronchitis in Patients With Chronic Obstructive Pulmonary Disease: Acute Bacterial Exacerbations of Chronic Bronchitis in Patients		09/27/2012	Center for Drug Evaluation and Research	Clinical - Antimicrobial	Final	No		FDA-2008-D-0419
Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion: Final Guidance for Industry	PDF (226.54 KB)PDF (226.54 KB) of Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion: Final Guidance for Industry	09/01/2012	Center for Biologics Evaluation and Research	Blood Products	Final	No		FDA-2001-D-0254
Guidance for Industry: Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials	PDF (421.53 KB)PDF (421.53 KB) of Guidance for Industry: Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials	08/13/2012	Center for Drug Evaluation and Research	Clinical - Medical	Draft	No		
Q8, Q9, & Q10 Questions and Answers -- Appendix: Q&As from Training Sessions (Q8, Q9, & Q10 Points to Consider)	PDF (262.52 KB)PDF (262.52 KB) of Q8, Q9, & Q10 Questions and Answers -- Appendix: Q&As from Training Sessions (Q8, Q9, & Q10 Points to Consider)	07/24/2012	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Quality	Final	No		
Clinical Performance Assessment: Considerations for Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data - Premarket Approval (PMA) and Premarket Notification [510(k)] Submissions - Guidance for Industry and FDA Staff		07/02/2012	Office of Medical Products and Tobacco	Premarket,	Final	No		
Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data - Premarket Notification [510(k)] Submissions - Guidance for Industry and Food and Drug Administration Staff		07/02/2012	Center for Devices and Radiological Health	Premarket, Radiology	Final	No		
Ch. 2 - FDA Authority	PDF (608.73 KB)PDF (608.73 KB) of Ch. 2 - FDA Authority	07/01/2012		Food & Color Additives	Final	No		
Pyrogen and Endotoxins Testing: Questions and Answers	PDF (173.71 KB)PDF (173.71 KB) of Pyrogen and Endotoxins Testing: Questions and Answers	06/28/2012	Center for Veterinary Medicine, Office of Regulatory Affairs, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Current Good Manufacturing Practices (CGMP), Pharmaceutical Quality	Final	No		
Guidance for Industry: Pyrogen and Endotoxins Testing: Questions and Answers		06/27/2012		Pharmaceutical Quality	Final	No		
"Toll-Free Number Labeling and Related Requirements for Over-the-Counter and Prescription Drugs Marketed With Approved Applications"	PDF (118.75 KB)PDF (118.75 KB) of "Toll-Free Number Labeling and Related Requirements for Over-the-Counter and Prescription Drugs Marketed With Approved Applications"	06/14/2012	Center for Drug Evaluation and Research	Administrative / Procedural	Final	No		
S2(R1) Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use	PDF (427.35 KB)PDF (427.35 KB) of S2(R1) Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use	06/06/2012	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Safety	Final	No		
Irritable Bowel Syndrome -- Clinical Evaluation of Products for Treatment	PDF (317.13 KB)PDF (317.13 KB) of Irritable Bowel Syndrome -- Clinical Evaluation of Products for Treatment	05/30/2012	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		

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S6(R1) Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals		05/16/2012	Center for Drug Evaluation and Research	ICH-Safety	Final	No		
Size of Beads in Drug Products Labeled for Sprinkle Rev.1: Guidance for Industry	PDF (147.91 KB)PDF (147.91 KB) of Size of Beads in Drug Products Labeled for Sprinkle Rev.1: Guidance for Industry	05/02/2012	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		
Small Entity Compliance Guide: Establishing an Allowable Level for di(2-ethylhexyl)phthalate in Bottled Water	PDF (60.41 KB)PDF (60.41 KB) of Small Entity Compliance Guide: Establishing an Allowable Level for di(2-ethylhexyl)phthalate in Bottled Water	05/01/2012	Office of Food Safety	Bottled Water , Carbonated Soft Drinks	Final	No		FDA-2012-D-0316
CVM GFI #209 The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals	PDF (256.08 KB)PDF (256.08 KB) of CVM GFI #209 The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals	04/13/2012	Center for Veterinary Medicine	Antimicrobial Resistance	Final	No		FDA-2010-D-0094
Media Fills for Validation of Aseptic Preparations for Positron Emission Tomography	PDF (155.82 KB)PDF (155.82 KB) of Media Fills for Validation of Aseptic Preparations for Positron Emission Tomography	04/10/2012	Center for Drug Evaluation and Research	Current Good Manufacturing Practices (CGMP), Pharmaceutical Quality	Final	No		
FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act: Guidance for Industry and Food and Drug Administration Staff	PDF (358.04 KB)PDF (358.04 KB) of FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act: Guidance for Industry and Food and Drug Administration Staff	04/06/2012	Center for Devices and Radiological Health	Premarket,	Final	No		
Further Amendments to General Regulations of the Food and Drug Administration to Incorporate Tobacco Products - Small Entity Compliance Guide: Guidance for Industry		03/29/2012	Center for Tobacco Products		Final	No	03/30/2012	
Class II Special Controls Guidance Document: Full Field Digital Mammography System - Guidance for Industry and FDA Staff		03/26/2012	Center for Devices and Radiological Health	Premarket,	Final	No		
Direct-to-Consumer Television Advertisements: FDAAA DTC Television Ad Pre-Dissemination Review Program	PDF (313.76 KB)PDF (313.76 KB) of Direct-to-Consumer Television Advertisements: FDAAA DTC Television Ad Pre-Dissemination Review Program	03/13/2012	Office of Regulatory Policy, Center for Biologics Evaluation and Research	Advertising	Draft	No		FDA-2012-D-0022
Class II Special Controls Guidance Document: Norovirus Serological Reagents - Guidance for Industry and Food and Drug Administration Staff		03/08/2012	Center for Devices and Radiological Health	Premarket,	Final	No		
Classifying Significant Posmarketing Drug Safety Issues	PDF (287.79 KB)PDF (287.79 KB) of Classifying Significant Posmarketing Drug Safety Issues	03/08/2012	Center for Drug Evaluation and Research	Safety - Issues, Errors, and Problems	Draft	No		
CVM GFI #216 Chemistry, Manufacturing, and Controls (CMC) Information - Fermentation-Derived Intermediates, Drug Substances, and Related Drug Products for Veterinary Medicinal Use	PDF (78.44 KB)PDF (78.44 KB) of CVM GFI #216 Chemistry, Manufacturing, and Controls (CMC) Information - Fermentation-Derived Intermediates, Drug Substances, and Related Drug Products for Veterinary Medicinal Use	03/08/2012	Center for Veterinary Medicine	Chemistry, Manufacturing, and Controls (CMC)	Final	No		FDA-2011-D-0112
Drug Safety Information -- FDA's Communication to the Public	PDF (448.71 KB)PDF (448.71 KB) of Drug Safety Information -- FDA's Communication to the Public	03/08/2012		Safety - Issues, Errors, and Problems	Final	No		
Guidance for Industry: Testing for Salmonella Species in Human Foods and Direct-Human-Contact Animal Foods	PDF (75.56 KB)PDF (75.56 KB) of Guidance for Industry: Testing for Salmonella Species in Human Foods and Direct-Human-Contact Animal Foods	03/08/2012	Office of Food Safety, Office of Surveillance and Compliance	Food & Beverage Safety, Potential Foodborne Illness, Salmonella, Potential Foodborne Illness, Salmonella, Food & Beverage Safety	Final	No		FDA-2011-D-0091
Modified Risk Tobacco Product Applications: Draft Draft Guidance for Industry		03/03/2012	Center for Tobacco Products		Draft	No		

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FDA Acceptance of Foreign Clinical Studies Not Conducted Under an IND: Frequently Asked Questions: Guidance for Industry and FDA Staff	PDF (108.02 KB)PDF (108.02 KB) of FDA Acceptance of Foreign Clinical Studies Not Conducted Under an IND: Frequently Asked Questions: Guidance for Industry and FDA Staff	03/01/2012	Office of Good Clinical Practice, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Clinical - Medical, Good Clinical Practices (GCP)	Final	No		
Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under Section 904(a)(3) of the Federal Food, Drug, and Cosmetic Act: Draft Draft Guidance for Industry		03/01/2012	Center for Tobacco Products		Draft	No	04/03/2012	
E7 Studies in Support of Special Populations; Geriatrics; Questions and Answers	PDF (84.94 KB)PDF (84.94 KB) of E7 Studies in Support of Special Populations; Geriatrics; Questions and Answers	02/17/2012	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Efficacy	Final	No		
IRB Continuing Review After Clinical Investigation Approval: Guidance for IRBs, Clinical Investigators, and Sponsors	PDF (144.99 KB)PDF (144.99 KB) of IRB Continuing Review After Clinical Investigation Approval: Guidance for IRBs, Clinical Investigators, and Sponsors	02/01/2012	Office of Good Clinical Practice, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Administrative / Procedural, Good Clinical Practices (GCP)	Final	No		
Questions and Answers on Informed Consent Elements, 21 CFR § 50.25(c): Guidance for Sponsors, Investigators, and Institutional Review Boards	PDF (56.28 KB)PDF (56.28 KB) of Questions and Answers on Informed Consent Elements, 21 CFR § 50.25(c): Guidance for Sponsors, Investigators, and Institutional Review Boards	02/01/2012	Office of Good Clinical Practice, Office of Policy	Good Clinical Practices (GCP)	Final	No		
CPG Sec. 400.210, Radiofrequency Identification Feasibility Studies and Pilot Programs for Drugs		01/31/2012		Investigation & Enforcement,	Final	No		
Guidance for Industry: Questions and Answers Regarding Establishment and Maintenance of Records By Persons Who Manufacture, Process, Pack, Transport, Distribute, Receive, Hold, or Import Food (Edition 5)	PDF (334.4 KB)PDF (334.4 KB) of Guidance for Industry: Questions and Answers Regarding Establishment and Maintenance of Records By Persons Who Manufacture, Process, Pack, Transport, Distribute, Receive, Hold, or Import Food (Edition 5)	01/31/2012	Center for Food Safety and Applied Nutrition	Export, Food & Beverage Safety, Import, Packaging, Records, Transportation, Food & Beverage Safety	Final	No		FDA-2011-D-0598
Guidance for Industry: Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation	PDF (853.05 KB)PDF (853.05 KB) of Guidance for Industry: Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation	12/28/2011	Office of Food Safety	Egg/Egg Product, Sanitation, Transportation	Final	No		FDA-2010-D-0313
Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices	PDF (302.29 KB)PDF (302.29 KB) of Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices	12/27/2011		Administrative / Procedural	Draft	No		
Enforcement Policy for Premarket Notification Requirements for Certain In Vitro Diagnostic and Radiology Devices - Guidance for Industry and Food and Drug Administration Staff		12/19/2011	Center for Devices and Radiological Health	Investigation & Enforcement, FDA Activities, Laboratory Tests	Final	No		
General Principles for the Development of Vaccines to Protect Against Global Infectious Diseases: Guidance for Industry	PDF (57.63 KB)PDF (57.63 KB) of General Principles for the Development of Vaccines to Protect Against Global Infectious Diseases: Guidance for Industry	12/01/2011	Center for Biologics Evaluation and Research	Vaccines	Final	No		FDA-2011-D-0855
Current Good Tissue Practice (CGTP) and Additional Requirements for Manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).: Guidance for Industry	PDF (267.16 KB)PDF (267.16 KB) of Current Good Tissue Practice (CGTP) and Additional Requirements for Manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).: Guidance for Industry	12/01/2011	Center for Biologics Evaluation and Research	Tissue	Final	No		FDA–2008–D–0659

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Preparation of IDEs and INDs for Products Intended to Repair or Replace Knee Cartilage: Guidance for Industry	PDF (156.52 KB)PDF (156.52 KB) of Preparation of IDEs and INDs for Products Intended to Repair or Replace Knee Cartilage: Guidance for Industry	12/01/2011	Center for Biologics Evaluation and Research	Cellular & Gene Therapy, Gene Therapy	Final	No		FDA-2007-D-0020
Nonclinical Evaluation of Late Radiation Toxicity of Therapeutic Radiopharmaceuticals	PDF (137.2 KB)PDF (137.2 KB) of Nonclinical Evaluation of Late Radiation Toxicity of Therapeutic Radiopharmaceuticals	11/25/2011		Pharm/Tox	Final	No		
Medication Guides — Distribution Requirements and Inclusion in Risk Evaluation and Mitigation Strategies (REMS)	PDF (91.2 KB)PDF (91.2 KB) of Medication Guides — Distribution Requirements and Inclusion in Risk Evaluation and Mitigation Strategies (REMS)	11/17/2011	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Safety - Issues, Errors, and Problems	Final	No		
Class II Special Controls Guidance Document: In Vitro Diagnostic Devices for Yersinia spp. Detection - Draft Guidance for Industry and Food and Drug Administration Staff	PDF (1.17 MB)PDF (1.17 MB) of Class II Special Controls Guidance Document: In Vitro Diagnostic Devices for Yersinia spp. Detection - Draft Guidance for Industry and Food and Drug Administration Staff	11/06/2011	Center for Devices and Radiological Health	Premarket, Laboratory Tests	Draft	No		
CVM GFI #100 (VICH GL18) Residual Solvents in New Veterinary Medicinal Products	PDF (163.86 KB)PDF (163.86 KB) of CVM GFI #100 (VICH GL18) Residual Solvents in New Veterinary Medicinal Products	11/02/2011	Center for Veterinary Medicine	Chemistry, Manufacturing, and Controls (CMC), VICH	Final	No		FDA-1999-D-2955
CPG Sec. 230.150 Blood Donor Classification Statement, Paid or Volunteer Donor	PDF (86.08 KB)PDF (86.08 KB) of CPG Sec. 230.150 Blood Donor Classification Statement, Paid or Volunteer Donor	11/01/2011		Investigation & Enforcement, Blood Products	Final	No		
Q8, Q9, and Q10 Questions and Answers	PDF (184.96 KB)PDF (184.96 KB) of Q8, Q9, and Q10 Questions and Answers	11/01/2011	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Quality	Final	No		
Requalification Method for Reentry of Donors Who Test Hepatitis B Surface Antigen (HBsAg) Positive Following a Recent Vaccination against Hepatitis B Virus Infection: Guidance for Industry	PDF (44.45 KB)PDF (44.45 KB) of Requalification Method for Reentry of Donors Who Test Hepatitis B Surface Antigen (HBsAg) Positive Following a Recent Vaccination against Hepatitis B Virus Infection: Guidance for Industry	11/01/2011	Center for Biologics Evaluation and Research	Blood Products	Final	No		FDA-2008-D-0263
Guidance for Industry: Letter to Firms that Grow, Harvest, Sort, Pack, Process, or Ship Fresh Cantaloupe	PDF (1.43 MB)PDF (1.43 MB) of Guidance for Industry: Letter to Firms that Grow, Harvest, Sort, Pack, Process, or Ship Fresh Cantaloupe	10/31/2011	Office of Food Safety	Fruit/Fruit Product , Produce	Final	No		
Guidance for Industry: Evaluating the Safety of Flood-affected Food Crops for Human Consumption		10/24/2011	Office of Food Safety	Emergencies, Fruit/Fruit Product , Produce, Vegetable Products	Final	No		FDA-2011-D-0733
Incorporation of Physical-Chemical Identifiers into Solid Oral Dosage Form Drug Products for Anticounterfeiting: Guidance for Industry	PDF (73.65 KB)PDF (73.65 KB) of Incorporation of Physical-Chemical Identifiers into Solid Oral Dosage Form Drug Products for Anticounterfeiting: Guidance for Industry	10/11/2011	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		
Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products — Content and Format	PDF (101.67 KB)PDF (101.67 KB) of Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products — Content and Format	10/11/2011	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Labeling	Final	No		FDA-2011-D-0694
Guidance for Industry: Implementation of the Fee Provisions of Section 107 of the FDA Food Safety Modernization Act		10/06/2011	Office of Regulatory Affairs	User Fees, Laser Notice	Final	No		FDA-2011-D-0721

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Clinical Considerations for Therapeutic Cancer Vaccines: Guidance for Industry	PDF (75.13 KB)PDF (75.13 KB) of Clinical Considerations for Therapeutic Cancer Vaccines: Guidance for Industry	10/01/2011	Center for Biologics Evaluation and Research	Cellular & Gene Therapy, Gene Therapy, Good Clinical Practices (GCP), Vaccines	Final	No		FDA-2009-D-0427
CVM GFI #215 Target Animal Safety & Effectiveness Protocol Development & Submission	PDF (62.96 KB)PDF (62.96 KB) of CVM GFI #215 Target Animal Safety & Effectiveness Protocol Development & Submission	09/29/2011	Center for Veterinary Medicine	Target Animal – Effectiveness, Target Animal – Safety	Final	No		FDA-2011-D-0023
Time and Extent Applications for Nonprescription Drug Products	PDF (241.46 KB)PDF (241.46 KB) of Time and Extent Applications for Nonprescription Drug Products	09/28/2011	Center for Drug Evaluation and Research	Over-the-Counter Drugs	Final	No		
Applications for Premarket Review of New Tobacco Products		09/27/2011	Center for Tobacco Products		Draft	No	09/27/2011	
Reproductive and Developmental Toxicities -- Integrating Study Results to Assess Concerns	PDF (391.57 KB)PDF (391.57 KB) of Reproductive and Developmental Toxicities -- Integrating Study Results to Assess Concerns	09/22/2011		Pharm/Tox	Final	No		
CPG Sec. 440.100 Marketed New Drugs Without Approved NDAs and ANDAs	PDF (177.42 KB)PDF (177.42 KB) of CPG Sec. 440.100 Marketed New Drugs Without Approved NDAs and ANDAs	09/19/2011		Investigation & Enforcement,	Final	No		
Marketed Unapproved Drugs -- Compliance Policy Guide	PDF (164.25 KB)PDF (164.25 KB) of Marketed Unapproved Drugs -- Compliance Policy Guide	09/19/2011	Center for Drug Evaluation and Research	Compliance, Current Good Manufacturing Practices (CGMP)	Final	No		
CVM GFI #205 (VICH GL46) Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Metabolism Study to Determine the Quantity and Identify the Nature of Residues (MRK)	PDF (209.51 KB)PDF (209.51 KB) of CVM GFI #205 (VICH GL46) Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Metabolism Study to Determine the Quantity and Identify the Nature of Residues (MRK)	09/15/2011	Center for Veterinary Medicine	Human Food Safety, VICH	Final	No		FDA-2010-D-8228
CVM GFI #206 (VICH GL47) Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Comparative Metabolism Studies in Laboratory Animals	PDF (137.74 KB)PDF (137.74 KB) of CVM GFI #206 (VICH GL47) Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Comparative Metabolism Studies in Laboratory Animals	09/15/2011	Center for Veterinary Medicine	Human Food Safety, VICH	Final	No		FDA-2010-D-8229
Submission of Warning Plans for Cigarettes and Smokeless Tobacco Products: Draft Draft Guidance for Industry		09/08/2011	Center for Tobacco Products		Draft	No	09/09/2011	
Guidance for Industry: Measures to Address the Risk for Contamination by Salmonella Species in Food Containing a Pistachio-Derived Product as an Ingredient	PDF (89 KB)PDF (89 KB) of Guidance for Industry: Measures to Address the Risk for Contamination by Salmonella Species in Food Containing a Pistachio-Derived Product as an Ingredient	08/31/2011	Office of Food Safety	Contaminants, Nuts & Nut Products, Contaminants	Final	No		FDA-2009-D-0271
PET Drug Applications - Content and Format for NDAs and ANDAs: Attachment I: Sample formats for chemistry, manufacturing, and controls (CMC) sections_2011	PDF (614.24 KB)PDF (614.24 KB) of PET Drug Applications - Content and Format for NDAs and ANDAs: Attachment I: Sample formats for chemistry, manufacturing, and controls (CMC) sections_2011	08/31/2011	Center for Drug Evaluation and Research	Administrative / Procedural	Final	No		
PET Drug Applications - Content and Format for NDAs and ANDAs_2011	PDF (429.23 KB)PDF (429.23 KB) of PET Drug Applications - Content and Format for NDAs and ANDAs_2011	08/31/2011	Center for Drug Evaluation and Research	Administrative / Procedural	Final	No		
E2F Development Safety Update Report	PDF (272.25 KB)PDF (272.25 KB) of E2F Development Safety Update Report	08/22/2011	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Efficacy	Final	No		

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Exculpatory Language in Informed Consent	PDF (112.4 KB)PDF (112.4 KB) of Exculpatory Language in Informed Consent	08/19/2011	Office of Good Clinical Practice	Good Clinical Practices (GCP)	Draft	No	11/01/2011	
Residual Drug in Transdermal and Related Drug Delivery Systems: Guidance for Industry	PDF (43.68 KB)PDF (43.68 KB) of Residual Drug in Transdermal and Related Drug Delivery Systems: Guidance for Industry	08/16/2011	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		
What You Need to Know About Prior Notice of Imported Food Shipments		08/15/2011	Office of Enforcement and Import Operations	Export, Import	Final	No		
E16 Biomarkers Related to Drug or Biotechnology Product Development: Context, Structure, and Format of Qualification Submissions	PDF (111.49 KB)PDF (111.49 KB) of E16 Biomarkers Related to Drug or Biotechnology Product Development: Context, Structure, and Format of Qualification Submissions	08/10/2011	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Efficacy	Final	No		
Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays: Guidance for Industry and FDA Staff	PDF (102.37 KB)PDF (102.37 KB) of Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays: Guidance for Industry and FDA Staff	08/09/2011	Center for Devices and Radiological Health	Premarket,	Final	No		
PET Drugs--Current Good Manufacturing Practice (CGMP); Small Entity Compliance Guide	PDF (228.68 KB)PDF (228.68 KB) of PET Drugs--Current Good Manufacturing Practice (CGMP); Small Entity Compliance Guide	08/04/2011	Center for Drug Evaluation and Research	Current Good Manufacturing Practices (CGMP), Pharmaceutical Quality	Final	No		
Availability of FDA's eSubmitter Program for Regulatory Submissions from Licensed Blood Establishments: Guidance for Industry	PDF (29.04 KB)PDF (29.04 KB) of Availability of FDA's eSubmitter Program for Regulatory Submissions from Licensed Blood Establishments: Guidance for Industry	08/01/2011	Center for Biologics Evaluation and Research	Blood Products	Final	No		FDA-2011-D-0579
Class II Special Controls Guidance Document: Repetitive Transcranial Magnetic Stimulation (rTMS) Systems - Guidance for Industry and FDA Staff		07/25/2011	Center for Devices and Radiological Health	Premarket,	Final	No		
Class II Special Controls Guidance Document: Electrocardiograph Electrodes - Guidance for Industry and Food and Drug Administration Staff		07/20/2011	Center for Devices and Radiological Health	Premarket,	Final	No		
Class II Special Controls Guidance Document: Focused Ultrasound Stimulator System for Aesthetic Use - Guidance for Industry and FDA Staff		07/19/2011	Center for Devices and Radiological Health	Premarket,	Final	No		
Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Influenza Viruses - Guidance for Industry and FDA Staff		07/14/2011	Center for Devices and Radiological Health		Final	No		
Q4B Annex 7 (R2): Dissolution Test General Chapter	PDF (101.62 KB)PDF (101.62 KB) of Q4B Annex 7 (R2): Dissolution Test General Chapter	06/23/2011	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Quality	Final	No		
Topical Acne Drug Products for Over-the-Counter Human Use--Revision of Labeling and Classification of Benzoyl Peroxide as Safe and Effective: Guidance for Industry	PDF (122.51 KB)PDF (122.51 KB) of Topical Acne Drug Products for Over-the-Counter Human Use--Revision of Labeling and Classification of Benzoyl Peroxide as Safe and Effective: Guidance for Industry	06/21/2011	Center for Drug Evaluation and Research	Labeling, Over-the-Counter Drugs	Final	No		FDA-2011-D-0404
Donors of Blood and Blood Components: Notification of Donor Deferral, Small Entity Compliance Guide: Guidance for Industry	PDF (44.98 KB)PDF (44.98 KB) of Donors of Blood and Blood Components: Notification of Donor Deferral, Small Entity Compliance Guide: Guidance for Industry	06/01/2011	Center for Biologics Evaluation and Research	Blood Products	Final	No		FDA-1998-N-1016
Guidance for Industry: Enforcement Policy Concerning Certain Prior Notice Requirements		06/01/2011	Office of Compliance	Export, Import	Final	No		
Guidance for Industry and Food and Drug Administration Staff - Assembler's Guide to Diagnostic X-Ray Equipment		05/16/2011			Final	No		

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Submission of Summary Bioequivalence Data for Abbreviated New Drug Applications	PDF (137.06 KB)PDF (137.06 KB) of Submission of Summary Bioequivalence Data for Abbreviated New Drug Applications	05/05/2011	Center for Drug Evaluation and Research	Generic Drugs	Final	No		
Dosage Delivery Devices for Orally Ingested OTC Liquid Drug Products	PDF (594.59 KB)PDF (594.59 KB) of Dosage Delivery Devices for Orally Ingested OTC Liquid Drug Products	05/04/2011	Center for Drug Evaluation and Research	Compliance,	Final	No		FDA-2009-D-0322
Class II Special Controls Guidance Document: Topical Oxygen Chamber for Extremities - Guidance for Industry and FDA Staff		04/24/2011	Center for Devices and Radiological Health	Premarket,	Final	No		
How to Write a Request for Designation (RFD): Guidance for Industry	PDF (89.81 KB)PDF (89.81 KB) of How to Write a Request for Designation (RFD): Guidance for Industry	04/14/2011	Office of Combination Products	Combination Products	Final	No		
30-Day Notices, 135-Day Premarket Approval (PMA) Supplements and 75-Day Humanitarian Device Exemption (HDE) Supplements for Manufacturing Method or Process Changes: Guidance for Industry and FDA Staff	PDF (80.03 KB)PDF (80.03 KB) of 30-Day Notices, 135-Day Premarket Approval (PMA) Supplements and 75-Day Humanitarian Device Exemption (HDE) Supplements for Manufacturing Method or Process Changes: Guidance for Industry and FDA Staff	04/13/2011	Center for Devices and Radiological Health	Premarket, Premarket Approval (PMA), HUD/HDE	Final	No		
Class II Special Controls Guidance Document: Low Level Laser System for Aesthetic Use - Guidance for Industry and FDA Staff		04/13/2011	Center for Devices and Radiological Health	Premarket,	Final	No		
Influenza: Developing Drugs for Treatment and/or Prophylaxis	PDF (417.45 KB)PDF (417.45 KB) of Influenza: Developing Drugs for Treatment and/or Prophylaxis	04/12/2011	Center for Drug Evaluation and Research	Clinical - Antimicrobial	Final	No		FDA-2009-D-0044
"Computer Crossmatch" (Computerized Analysis of the Compatibility between the Donor's Cell Type and the Recipient's Serum or Plasma Type); : Guidance for Industry	PDF (77.86 KB)PDF (77.86 KB) of "Computer Crossmatch" (Computerized Analysis of the Compatibility between the Donor's Cell Type and the Recipient's Serum or Plasma Type); : Guidance for Industry	04/01/2011	Center for Biologics Evaluation and Research	Blood Products	Final	No		FDA-2007-D-0019
Guidance for Industry Postmarketing Studies and Clinical Trials — Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act		04/01/2011	Center for Drug Evaluation and Research		Final	No		FDA-2009-D-0283
Guidance for Industry: Questions and Answers About the Food Additive or Color Additive Petition Process		03/31/2011	Office of Food Additive Safety	Food & Beverage Safety, Food & Color Additives, Food & Beverage Safety	Final	No		FDA-2013-S-0610
Class II Special Controls Guidance Document: Ovarian Adnexal Mass Assessment Score Test System - Guidance for Industry and FDA Staff		03/22/2011	Center for Devices and Radiological Health	Premarket,	Final	No		
Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products	PDF (159.06 KB)PDF (159.06 KB) of Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products	03/15/2011	Center for Drug Evaluation and Research	Administrative / Procedural	Draft	Yes	05/31/2020	FDA-2009-D-0568
Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims	PDF (143.6 KB)PDF (143.6 KB) of Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims	03/14/2011	Center for Drug Evaluation and Research	Labeling	Final	No		
Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products		03/14/2011		Administrative / Procedural	Final	No		
Clinical Investigations of Devices Indicated for the Treatment of Urinary Incontinence - Guidance for Industry and FDA Staff		03/07/2011	Center for Devices and Radiological Health	Premarket,	Final	No		

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Class II Special Controls Guidance Document: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle: Guidance for Industry and FDA Staff	PDF (98.71 KB)PDF (98.71 KB) of Class II Special Controls Guidance Document: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle: Guidance for Industry and FDA Staff	03/01/2011	Center for Biologics Evaluation and Research	Blood Products	Final	No		2005D-0019
Class II Special Controls Guidance Document: Cord Blood Processing System and Storage Container: Guidance for Industry	PDF (141.33 KB)PDF (141.33 KB) of Class II Special Controls Guidance Document: Cord Blood Processing System and Storage Container: Guidance for Industry	03/01/2011	Center for Biologics Evaluation and Research	Blood Products, Tissue	Final	No		2007D–0025;FDA–2011–N–0148]
Class II Special Controls Guidance Document: In Vitro HIV Drug Resistance Genotype Assay: Guidance for Industry	PDF (166.81 KB)PDF (166.81 KB) of Class II Special Controls Guidance Document: In Vitro HIV Drug Resistance Genotype Assay: Guidance for Industry	03/01/2011	Center for Biologics Evaluation and Research	Blood Products	Final	No		2001D-0286
Class II Special Controls Guidance Document: Intervertebral Body Fusion Device: Guidance for Industry and FDA Staff	PDF (185.67 KB)PDF (185.67 KB) of Class II Special Controls Guidance Document: Intervertebral Body Fusion Device: Guidance for Industry and FDA Staff	03/01/2011	Center for Biologics Evaluation and Research	Premarket,	Final	No		2005D-0019
Guidance for Industry: Letter to Firms that Grow, Harvest, Sort, Pack, or Ship Fresh Cilantro		03/01/2011	Office of Food Safety	Produce, Vegetable Products	Final	No		
Class II Special Controls Guidance Document: Contact Cooling System for Aesthetic Use - Guidance for Industry and FDA Staff		02/06/2011	Center for Devices and Radiological Health	Premarket,	Final	No		
Sample formats for Form FDA 356h_2011	PDF (601.16 KB)PDF (601.16 KB) of Sample formats for Form FDA 356h_2011	02/02/2011	Center for Drug Evaluation and Research	Administrative / Procedural	Draft	No		
Process Validation: General Principles and Practices: Guidance for Industry	PDF (371.9 KB)PDF (371.9 KB) of Process Validation: General Principles and Practices: Guidance for Industry	01/24/2011	Center for Veterinary Medicine, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Current Good Manufacturing Practices (CGMP), Pharmaceutical Quality	Final	No		
Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products: Guidance for Industry and Food and Drug Administration Staff		01/04/2011	Center for Tobacco Products		Final	No	01/05/2011	
Potency Tests for Cellular and Gene Therapy Products: Final Guidance for Industry:	PDF (121.48 KB)PDF (121.48 KB) of Potency Tests for Cellular and Gene Therapy Products: Final Guidance for Industry:	01/01/2011	Center for Biologics Evaluation and Research	Cellular & Gene Therapy, Gene Therapy	Final	No		FDA-2008-D-0520
CPG Sec. 160.900 Prescription Drug Marketing Act -- Pedigree Requirements under 21 CFR Part 203		12/22/2010		Investigation & Enforcement, Records	Final	No	07/14/2006	1992N-0297, 1988N-0258
Small Entity Compliance Guide: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements		12/16/2010	Office of Dietary Supplement Programs	Labeling, Packaging	Final	No		FDA-2010-D-0605
CPG Sec. 390.500 Definition of "High-Voltage Vacuum Switch" - 21 CFR 1002.61(a)(3) and (b)(2) - withdrawn on 12/07/10		12/07/2010		Investigation & Enforcement, Administrative / Procedural	Final	No		
CPG Sec. 527.300 Microbial Contaminants & Alkaline Phosphatase Activity	PDF (103.81 KB)PDF (103.81 KB) of CPG Sec. 527.300 Microbial Contaminants & Alkaline Phosphatase Activity	12/01/2010		Investigation & Enforcement,	Final	No	02/21/2010	FDAâ€“2009â€“Dâ€“0466
“Lookback” for Hepatitis C Virus (HCV): Product Quarantine, Consignee Notification, Further Testing, Product Disposition, and Notification of Transfusion Recipients Based on Donor Test Results Indicating Infection with HCV: Guidance for Industry	PDF (182.57 KB)PDF (182.57 KB) of “Lookback” for Hepatitis C Virus (HCV): Product Quarantine, Consignee Notification, Further Testing, Product Disposition, and Notification of Transfusion Recipients Based on Donor Test Results Indicating Infection with HCV: Guidance for Industry	12/01/2010	Center for Biologics Evaluation and Research	Blood Products	Final	No		1999D-1878

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Blood Lancet Labeling - Guidance for Industry and Food and Drug Administration Staff		11/28/2010	Center for Devices and Radiological Health	Premarket,	Final	No		
ANDAs: Impurities in Drug Products: Guidance for Industry	PDF (154.52 KB)PDF (154.52 KB) of ANDAs: Impurities in Drug Products: Guidance for Industry	11/26/2010	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		
Antibacterial Drug Products: Use of Noninferiority Studies to Support Approval	PDF (82.6 KB)PDF (82.6 KB) of Antibacterial Drug Products: Use of Noninferiority Studies to Support Approval	11/26/2010	Center for Drug Evaluation and Research	Clinical - Antimicrobial	Final	No		
Guidance for Industry: Safety of Imported Traditional Pottery Intended for Use with Food and the Use of the Term "Lead Free" in the Labeling of Pottery/Proper Identification of Ornamental and Decorative Ceramicware		11/22/2010	Office of Food Safety	Contaminants, Import, Food & Beverage Safety	Final	No		FDA-2010-D-0571
The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #13: Guidance for Industry, MQSA Inspectors and FDA Staff	PDF (424.29 KB)PDF (424.29 KB) of The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #13: Guidance for Industry, MQSA Inspectors and FDA Staff	11/16/2010	Center for Devices and Radiological Health	Radiological Health, Radiology	Final	No		
Class II Special Controls Guidance Document: Non-powered Suction Apparatus Device Intended for Negative Pressure Wound Therapy (NPWT) - Guidance for Industry and FDA Staff		11/09/2010	Center for Devices and Radiological Health	Premarket,	Final	No		
Class II Special Controls Guidance Document: Tissue Adhesive with Adjunct Wound Closure Device Intended for the Topical Approximation of Skin - Guidance for Industry and FDA Staff		11/09/2010	Center for Devices and Radiological Health	Premarket,	Final	No		
Recommendations for Blood Establishments: Training of Back-Up Personnel, Assessment of Blood Donor Suitability and Reporting Certain Changes to an Approved Application: Guidance for Industry	PDF (41.82 KB)PDF (41.82 KB) of Recommendations for Blood Establishments: Training of Back-Up Personnel, Assessment of Blood Donor Suitability and Reporting Certain Changes to an Approved Application: Guidance for Industry	11/01/2010	Center for Biologics Evaluation and Research	Blood Products	Final	No		FDA-2009-D-0533
Cellular Therapy for Cardiac Disease: Guidance for Industry	PDF (199.9 KB)PDF (199.9 KB) of Cellular Therapy for Cardiac Disease: Guidance for Industry	10/01/2010	Center for Biologics Evaluation and Research	Cellular & Gene Therapy, Gene Therapy	Final	No		FDA-2009-D-0132
Guidance for Industry: Food Additive Petition Expedited Review		09/30/2010	Office of Food Additive Safety	Food & Beverage Safety, Food & Color Additives, Food & Beverage Safety	Final	No		FDA-2013-S-0610
Addition of URLs to Electronic Product Labeling: Guidance for Industry and FDA Staff		09/29/2010	Center for Devices and Radiological Health	Postmarket, Labeling	Final	No		
Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters		09/07/2010	Center for Devices and Radiological Health		Final	No		
Impact-Resistant Lenses: Questions and Answers: Guidance for Industry and FDA Staff	PDF (135.12 KB)PDF (135.12 KB) of Impact-Resistant Lenses: Questions and Answers: Guidance for Industry and FDA Staff	09/02/2010	Center for Devices and Radiological Health		Final	No		
Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions Annex 11: Capillary Electrophoresis General Chapter	PDF (92.92 KB)PDF (92.92 KB) of Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions Annex 11: Capillary Electrophoresis General Chapter	09/02/2010	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Quality	Final	No		

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Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions Annex 12: Analytical Sieving General Chapter	PDF (87.38 KB)PDF (87.38 KB) of Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions Annex 12: Analytical Sieving General Chapter	09/01/2010	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Quality	Final	No		
Guidance for the Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH) : Guidance for Industry and Food and Drug Administration Staff	PDF (441.58 KB)PDF (441.58 KB) of Guidance for the Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH) : Guidance for Industry and Food and Drug Administration Staff	08/17/2010	Center for Devices and Radiological Health	Premarket, Good Clinical Practices (GCP)	Final	No		
Organ-Specific Warnings: Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use — Small Entity Compliance Guide	PDF (176.31 KB)PDF (176.31 KB) of Organ-Specific Warnings: Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use — Small Entity Compliance Guide	08/17/2010	Center for Drug Evaluation and Research	Over-the-Counter Drugs	Final	No		
Contact Lens Care Products Labeling - Guidance for Industry and Food and Drug Administration Staff		08/14/2010	Center for Devices and Radiological Health	Premarket,	Final	No		
CVM GFI #169 Drug Substance Chemistry, Manufacturing, and Controls Information	PDF (362.59 KB)PDF (362.59 KB) of CVM GFI #169 Drug Substance Chemistry, Manufacturing, and Controls Information	08/06/2010	Center for Veterinary Medicine	Chemistry, Manufacturing, and Controls (CMC)	Final	No		FDA-2003-D-0243
Label Comprehension Studies for Nonprescription Drug Products	PDF (147.74 KB)PDF (147.74 KB) of Label Comprehension Studies for Nonprescription Drug Products	08/03/2010	Center for Drug Evaluation and Research	Over-the-Counter Drugs	Final	No		
General Considerations for Animal Studies for Cardiovascular Devices - Guidance for Industry and FDA Staff		07/28/2010	Center for Devices and Radiological Health	Premarket, Cardiovascular	Final	No		
Guidance for Industry and FDA: Advisory Levels for Deoxynivalenol (DON) in Finished Wheat Products for Human Consumption and Grains and Grain By-Products used for Animal Feed		07/07/2010	Office of Food Safety, Office of Surveillance and Compliance	Grain/Grain Product, Animal Feed	Final	No		
Guidance for Industry: Recommendations for Submission of Chemical and Technological Data for Food Additive Petitions and GRAS Notices for Enzyme Preparations	PDF (100.85 KB)PDF (100.85 KB) of Guidance for Industry: Recommendations for Submission of Chemical and Technological Data for Food Additive Petitions and GRAS Notices for Enzyme Preparations	06/30/2010	Office of Food Additive Safety	Food & Color Additives	Final	No		
In Vitro Diagnostic (IVD) Device Studies - Frequently Asked Questions: Guidance for Industry and FDA Staff	PDF (352.1 KB)PDF (352.1 KB) of In Vitro Diagnostic (IVD) Device Studies - Frequently Asked Questions: Guidance for Industry and FDA Staff	06/25/2010	Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Premarket, Good Clinical Practices (GCP), IVDs (In Vitro Diagnostic Devices), Laboratory Tests	Final	No		
Systemic Lupus Erythematosus --Developing Drugs for Treatment	PDF (167.92 KB)PDF (167.92 KB) of Systemic Lupus Erythematosus --Developing Drugs for Treatment	06/21/2010	Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Clinical - Medical	Final	No		
Individual Product Bioequivalence Recommendations for Specific Products	PDF (80 KB)PDF (80 KB) of Individual Product Bioequivalence Recommendations for Specific Products	06/10/2010	Center for Drug Evaluation and Research	Generic Drugs	Final	No		
Use of “Light,” “Mild,” “Low,” or Similar Descriptors in the Label, Labeling, or Advertising of Tobacco Products: Guidance for Industry and FDA Staff		06/09/2010	Center for Tobacco Products	Labeling	Final	No	06/10/2010	

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FDA Inspections of Clinical Investigators: Guidance For IRBs, Clinical Investigators, and Sponsors	PDF (58.54 KB)PDF (58.54 KB) of FDA Inspections of Clinical Investigators: Guidance For IRBs, Clinical Investigators, and Sponsors	06/01/2010	Office of Good Clinical Practice	Administrative / Procedural, Good Clinical Practices (GCP)	Final	No		
Draft Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007 (Edition 2)	PDF (171.3 KB)PDF (171.3 KB) of Draft Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007 (Edition 2)	05/25/2010	Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine	Electronic Submissions,	Draft	No	07/26/2010	FDA-2009-D-0260
Guide pour l'industrie : Questions et réponses concernant le Registre de denrées alimentaires à signaler (« Reportable Food Registry » (RFR)) tel qu'établi par le « Food and Drug Administration Amendments Act » de 2007 (FDAAA) (2ème édition)		05/23/2010	Office of Analytics and Outreach		Draft	No	07/26/2010	FDA-2009-D-0260
Orientación preliminar de la industria: Preguntas y respuestas sobre el Registro de productos sanitarios en productos agroalimentarios, según establecido por la Ley de Enmiendas a la Alimentación y Medicamentos (FDA), 2007 (Edición 2)		05/23/2010	Office of Analytics and Outreach		Draft	No	07/26/2010	FDA-2009-D-0260
行业指南草案：关于美国食品药品管理局2007年修正法案规定的应通报食品注册的问答 (第2版)		05/23/2010	Office of Analytics and Outreach		Draft	No	07/26/2010	FDA-2009-D-0260
Guidance for Industry: Use of Water by Food Manufacturers in Areas Subject to a Boil-Water Advisory		05/13/2010	Office of Food Safety	Emergencies, Carbonated Soft Drinks, Sanitation, Transportation	Final	No		FDA-2010-D-0236
Enforcement Policy Concerning Certain Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco: Guidance for Industry and FDA Staff		05/06/2010	Center for Tobacco Products		Final	No	05/07/2011	
Frequently Asked Questions – Statement of Investigator (Form FDA 1572): Guidance for Sponsors, Clinical Investigators, and IRBs	PDF (105.19 KB)PDF (105.19 KB) of Frequently Asked Questions – Statement of Investigator (Form FDA 1572): Guidance for Sponsors, Clinical Investigators, and IRBs	05/01/2010	Office of Good Clinical Practice, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Administrative / Procedural, Good Clinical Practices (GCP)	Final	No		
Requalification Method for Reentry of Blood Donors Deferred Because of Reactive Test Results for Antibody to Hepatitis B Core Antigen (Anti-HBc): Guidance for Industry	PDF (86.38 KB)PDF (86.38 KB) of Requalification Method for Reentry of Blood Donors Deferred Because of Reactive Test Results for Antibody to Hepatitis B Core Antigen (Anti-HBc): Guidance for Industry	05/01/2010	Center for Biologics Evaluation and Research	Blood Products	Final	No		FDA-2008-D-0263
Guidance for Industry: Sanitary Transportation of Food		04/29/2010	Office of Food Safety	Sanitation, Transportation	Final	No		FDA-2013-S-0610
Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems - Guidance for Industry and FDA Staff		04/17/2010	Center for Devices and Radiological Health	Premarket,	Final	No		
Small Entity Compliance Guide: Prevention of Salmonella Enteritidis in Shell Eggs During Production, Transportation, and Storage		04/13/2010	Office of Food Safety	Egg/Egg Product, Food & Beverage Safety, Transportation, Food & Beverage Safety	Final	No		FDA-2010-D-0183
Small Entity Compliance Guide: Bottled Water and Total Coliform and E. coli		03/26/2010	Office of Food Safety	Bottled Water	Final	No		FDA-2010-D-0141
CVM GFI #192 Anesthetics for Companion Animals	PDF (176.54 KB)PDF (176.54 KB) of CVM GFI #192 Anesthetics for Companion Animals	03/25/2010	Center for Veterinary Medicine	Target Animal – Safety	Final	No		FDA-2008-D-0623
Guidance for Industry: Submitting a Report for Multiple Facilities to the Reportable Food Electronic Portal as Established by the Food and Drug Administration Amendments Act of 2007		03/25/2010	Office of Analytics and Outreach	Electronic Submissions,	Final	No		FDA-2009-D-0260
Guide pour l'industrie: Soumission d'un rapport concernant plusieurs usines auprès du portail électronique d'enregistrement des denrées alimentaires à signaler tel qu'établi par le "Food and Drug Administration Amendments Act of 2007"		03/25/2010	Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine	Electronic Submissions,	Final	No		FDA-2009-D-0260

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Orientación para la industria: Presentación de Informe para múltiples instalaciones al Portal electrónico de incidentes sanitarios según lo establece la Ley de Enmiendas de la Administración de Medicamentos y Alimentos de 2007		03/25/2010	Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine	Electronic Submissions,	Final	No		FDA-2009-D-0260
Content and Format of the Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products	PDF (162.88 KB)PDF (162.88 KB) of Content and Format of the Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products	03/22/2010	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Labeling	Final	No		FDA-2007-D-0201
Pharmacokinetics in Patients with Impaired Renal Function — Study Design, Data Analysis, and Impact on Dosing and Labeling	PDF (318.8 KB)PDF (318.8 KB) of Pharmacokinetics in Patients with Impaired Renal Function — Study Design, Data Analysis, and Impact on Dosing and Labeling	03/22/2010	Center for Drug Evaluation and Research	Clinical - Pharmacology	Draft	No		FDA-2010-D-0133
CPG Sec. 540.375 Canned Salmon - Adulteration Involving Decomposition (Withdrawn 3/22/2010)		03/21/2010		Investigation & Enforcement,	Final	No		
Guidance for Industry and FDA Staff: Acceptable Media for Electronic Product User Manuals		03/17/2010			Final	No		
S9 Nonclinical Evaluation for Anticancer Pharmaceuticals	PDF (169.33 KB)PDF (169.33 KB) of S9 Nonclinical Evaluation for Anticancer Pharmaceuticals	03/05/2010	Center for Drug Evaluation and Research	ICH-Safety	Final	No		
Draft Guidance for Industry: Providing Regulatory Submissions in Electronic or Paper Format to the Office of Food Additive Safety Part IV - Food or Color Additive Submissions		03/01/2010	Office of Food Additive Safety	Food & Color Additives	Draft	No		
Draft Guidance for Industry: Providing Regulatory Submissions to the Office of Food Additive Safety	PDF (622.69 KB)PDF (622.69 KB) of Draft Guidance for Industry: Providing Regulatory Submissions to the Office of Food Additive Safety	03/01/2010	Office of Food Additive Safety	Food & Color Additives	Draft	No		
Draft Guidance for Industry: Regulatory Submissions to OFAS, Part X Appendices		03/01/2010	Office of Food Additive Safety	Food & Color Additives	Draft	No		
Draft Guidance for Industry: Regulatory Submissions to OFAS, Part II Common Elements		03/01/2010	Office of Food Additive Safety	Food & Color Additives	Draft	No		
Draft Guidance for Industry: Regulatory Submissions to OFAS, Part IX FDA References		03/01/2010	Office of Food Additive Safety	Food & Color Additives	Draft	No		
Draft Guidance for Industry: Regulatory Submissions to OFAS, Part V Food Contact Substance Submissions		03/01/2010	Office of Food Additive Safety	Food & Color Additives	Draft	No		
Draft Guidance for Industry: Regulatory Submissions to OFAS, Part VI GRAS Notices		03/01/2010	Office of Food Additive Safety	Food & Color Additives	Draft	No		
Draft Guidance for Industry: Regulatory Submissions to OFAS, Part VII Biotechnology Final Consultations		03/01/2010	Office of Food Additive Safety	Food & Color Additives	Draft	No		
Draft Guidance for Industry: Regulatory Submissions to OFAS, Part VIII New Protein Consultations		03/01/2010	Office of Food Additive Safety	Food & Color Additives	Draft	No		
Draft Guidance for Industry: Regulatory Submissions to OFAS, Quick Links		03/01/2010	Office of Food Additive Safety	Food & Color Additives	Draft	No		
Standards for Securing the Drug Supply Chain - Standardized Numerical Identification for Prescription Drug Packages: Guidance for Industry	PDF (60.67 KB)PDF (60.67 KB) of Standards for Securing the Drug Supply Chain - Standardized Numerical Identification for Prescription Drug Packages: Guidance for Industry	02/28/2010	Office of Regulatory Affairs, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, Office of the Commissioner	Labeling	Final	No		
行业指南：向美国食品药品管理局2007年修正法案规定的应通报食品门户网提交多个机构的报告		02/28/2010	Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine	Electronic Submissions,	Final	No		FDA-2009-D-0260

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Submission of Documentation in Applications for Parametric Release of Human and Veterinary Drug Products Terminally Sterilized by Moist Heat Processes: Guidance for Industry	PDF (72.71 KB)PDF (72.71 KB) of Submission of Documentation in Applications for Parametric Release of Human and Veterinary Drug Products Terminally Sterilized by Moist Heat Processes: Guidance for Industry	02/25/2010	Center for Veterinary Medicine, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Microbiology, Pharmaceutical Quality	Final	No		
Guidance for the Use of Bayesian Statistics in Medical Device Clinical Trials (PDF Version)	PDF (341.52 KB)PDF (341.52 KB) of Guidance for the Use of Bayesian Statistics in Medical Device Clinical Trials (PDF Version)	02/05/2010	Center for Devices and Radiological Health	Premarket,	Final	No		
Guidance for the Use of Bayesian Statistics in Medical Device Clinical Trials		02/04/2010	Office of Medical Products and Tobacco	Biostatistics,	Final	No		
Characterization and Qualification of Cell Substrates and Other Biological Materials Used in the Production of Viral Vaccines for Infectious Disease Indications: Guidance for Industry	PDF (311.98 KB)PDF (311.98 KB) of Characterization and Qualification of Cell Substrates and Other Biological Materials Used in the Production of Viral Vaccines for Infectious Disease Indications: Guidance for Industry	02/01/2010	Center for Biologics Evaluation and Research	Vaccines	Final	No		FDA-2006-D-0223
The Use of Mechanical Calibration of Dissolution Apparatus 1 and 2 – Current Good Manufacturing Practice (CGMP): Guidance for Industry	PDF (127.37 KB)PDF (127.37 KB) of The Use of Mechanical Calibration of Dissolution Apparatus 1 and 2 – Current Good Manufacturing Practice (CGMP): Guidance for Industry	01/26/2010	Center for Drug Evaluation and Research	Current Good Manufacturing Practices (CGMP), Pharmaceutical Quality	Final	No		
M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals	PDF (325.22 KB)PDF (325.22 KB) of M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals	01/20/2010	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Multidisciplinary	Final	No		FDA-2008-D-0470
New Contrast Imaging Indication Considerations for Devices and Approved Drug and Biological Products: Guidance for Industry	PDF (159.33 KB)PDF (159.33 KB) of New Contrast Imaging Indication Considerations for Devices and Approved Drug and Biological Products: Guidance for Industry	12/31/2009	Office of Combination Products, Center for Drug Evaluation and Research, Center for Devices and Radiological Health	Combination Products	Final	No		FDA-2008-D-0525
General Questions and Answers on the Ban of Cigarettes that Contain Certain Characterizing Flavors (Edition 2): Guidance to Industry and FDA Staff		12/22/2009	Center for Tobacco Products		Final	No		
S6 (R1) Addendum: Preclinical Safety Evaluation of Biotechnology - Derived Pharmaceuticals	PDF (181.06 KB)PDF (181.06 KB) of S6 (R1) Addendum: Preclinical Safety Evaluation of Biotechnology - Derived Pharmaceuticals	12/16/2009		ICH-Safety	Final	No		
PET Drug Products - Current Good Manufacturing Practice (CGMP)	PDF (399.04 KB)PDF (399.04 KB) of PET Drug Products - Current Good Manufacturing Practice (CGMP)	12/09/2009	Center for Drug Evaluation and Research	Current Good Manufacturing Practices (CGMP), Pharmaceutical Quality	Final	No		
Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims: Guidance for Industry	PDF (295 KB)PDF (295 KB) of Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims: Guidance for Industry	12/08/2009	Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Clinical - Medical, Good Clinical Practices (GCP)	Final	No		FDA-2006-D-0362
Draft Guidance for Industry: Factors that Distinguish Liquid Dietary Supplements from Beverages, Considerations Regarding Novel Ingredients, and Labeling for Beverages and Other Conventional Foods		12/04/2009	Office of Dietary Supplement Programs	Labeling	Draft	No	02/02/2010	FDA-2009-D-0542
Residual Solvents in Drug Products Marketed in the United States: Guidance for Industry	PDF (51.82 KB)PDF (51.82 KB) of Residual Solvents in Drug Products Marketed in the United States: Guidance for Industry	11/24/2009	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		

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Q8(R2) Pharmaceutical Development	PDF (401.81 KB)PDF (401.81 KB) of Q8(R2) Pharmaceutical Development	11/20/2009	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Quality	Final	No		
Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Donors of Whole Blood and Blood Components Intended for Transfusion: Guidance for Industry	PDF (52.46 KB)PDF (52.46 KB) of Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Donors of Whole Blood and Blood Components Intended for Transfusion: Guidance for Industry	11/06/2009	Center for Biologics Evaluation and Research	Blood Products	Final	No		FDA-2008-D-0263
Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects: Guidance for Industry	PDF (163.4 KB)PDF (163.4 KB) of Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects: Guidance for Industry	10/23/2009	Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Administrative / Procedural, Good Clinical Practices (GCP)	Final	No		
Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data - Premarket Notification [510(k)] Submissions: Guidance for Industry and Food and Drug Administration Staff	PDF (272.23 KB)PDF (272.23 KB) of Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data - Premarket Notification [510(k)] Submissions: Guidance for Industry and Food and Drug Administration Staff	10/21/2009	Center for Devices and Radiological Health		Final	No		
Guidance for Industry: Letter Regarding Point of Purchase Food Labeling		10/21/2009	Office of Nutrition and Food Labeling	Labeling	Final	No		FDA-2013-S-0610
Class II Special Controls Guidance Document: Cardiac Allograft Gene Expression Profiling Test Systems - Guidance for Industry and FDA Staff		10/20/2009	Center for Devices and Radiological Health	Premarket,	Final	No		
Labeling for Human Prescription Drug and Biological Products — Determining Established Pharmacologic Class for Use in the Highlights of Prescribing Information	PDF (65.5 KB)PDF (65.5 KB) of Labeling for Human Prescription Drug and Biological Products — Determining Established Pharmacologic Class for Use in the Highlights of Prescribing Information	10/16/2009	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Labeling	Final	No		FDA-2007-D-0302
Class II Special Controls Guidance Document: Wound Dressing with Poly(diallyl dimethyl ammonium chloride) (pDADMAC) Additive - Guidance for Industry and FDA Staff		10/15/2009	Center for Devices and Radiological Health	Premarket,	Final	No		
Class II Special Controls Guidance Document: Respiratory Viral Panel Multiplex Nucleic Acid Assay - Guidance for Industry and FDA Staff		10/08/2009	Center for Devices and Radiological Health	Premarket,	Final	No		
Class II Special Controls Guidance Document: Testing for Detection and Differentiation of Influenza A Virus Subtypes Using Multiplex Assays - Guidance for Industry and FDA Staff		10/08/2009	Center for Devices and Radiological Health	Premarket,	Final	No		
Class II Special Controls Guidance Document: Testing for Human Metapneumovirus (hMPV) Using Nucleic Acid Assays - Guidance for Industry and FDA Staff		10/08/2009	Center for Devices and Radiological Health	Premarket,	Final	No		
Helicobacter pylori-Associated Duodenal Ulcer Disease in Adults: Developing Drugs for Treatment	PDF (147.7 KB)PDF (147.7 KB) of Helicobacter pylori-Associated Duodenal Ulcer Disease in Adults: Developing Drugs for Treatment	10/05/2009	Center for Drug Evaluation and Research	Clinical - Antimicrobial	Draft	No		FDA-2009-D-0447
SPL Standard for Content of Labeling Technical Qs & As	PDF (57.92 KB)PDF (57.92 KB) of SPL Standard for Content of Labeling Technical Qs & As	10/01/2009	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Electronic Submissions,	Draft	No		

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The Scope of the Prohibition Against Marketing a Tobacco Product in Combination with Another Article or Product Regulated under the Federal Food, Drug, and Cosmetic Act: Guidance for Manufacturers, Retailers, Importers and FDA Staff		09/29/2009	Center for Tobacco Products		Final	No	09/30/2009	
End-of-Phase 2A Meetings	PDF (163.2 KB)PDF (163.2 KB) of End-of-Phase 2A Meetings	09/18/2009	Center for Drug Evaluation and Research	Administrative / Procedural	Final	No		FDA-2008-D-0514
Document d'orientation Questions: Réponses Relatives au Registre des aliments à signaler instauré par le Food and Drug Administration Amendments Act de 2007		09/09/2009	Office of Analytics and Outreach	Electronic Submissions Gateway (ESG),	Final	No		FDA-2009-D-0260
Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007		09/09/2009	Office of Analytics and Outreach	Electronic Submissions, Food & Beverage Safety, Reportable Food Registry, Food & Beverage Safety	Final	No		FDA-2009-D-0260
Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Adminstration Amendments Act of 2007 - Appendix		09/09/2009	Center for Food Safety and Applied Nutrition	Food & Beverage Safety, Food & Beverage Safety	Final	No		FDA-2009-D-0260
Preguntas y respuestas sobre el Registro de incidentes sanitarios en productos agroalimentarios, según lo establecido por la Ley de Enmiendas de la Administración de Medicamentos y Alimentos (FDA) de 2007		09/09/2009	Office of Analytics and Outreach	Electronic Submissions,	Final	No		FDA-2009-D-0260
行业指南：关于美国食品药品管理局2007年修正法案规定的应通报食品注册的问答		09/09/2009	Office of Analytics and Outreach	Electronic Submissions,	Final	No		FDA-2009-D-0260
Considerations for Allogeneic Pancreatic Islet Cell Products: Guidance for Industry	PDF (143.76 KB)PDF (143.76 KB) of Considerations for Allogeneic Pancreatic Islet Cell Products: Guidance for Industry	09/01/2009	Center for Biologics Evaluation and Research	Cellular & Gene Therapy, Gene Therapy	Final	No		FDA-2008-D-0293
Guidance for Industry: Questions and Answers Regarding the Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act		09/01/2009	Office of Dietary Supplement Programs		Final	No		FDA-2007-D-0209
Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems		08/27/2009	Center for Devices and Radiological Health	Premarket, Antimicrobial Resistance	Final	No		
Inspection by Accredited Persons Under The Medical Device User Fee and Modernization Act of 2002 and the FDA Amendments Act of 2007; Accreditation Criteria: Guidance for Industry, FDA Staff, and Third Parties	PDF (361.78 KB)PDF (361.78 KB) of Inspection by Accredited Persons Under The Medical Device User Fee and Modernization Act of 2002 and the FDA Amendments Act of 2007; Accreditation Criteria: Guidance for Industry, FDA Staff, and Third Parties	08/06/2009	Center for Devices and Radiological Health	Premarket, User Fees,	Final	No		
Pharmaceutical Components at Risk for Melamine Contamination: Guidance for Industry	PDF (136.64 KB)PDF (136.64 KB) of Pharmaceutical Components at Risk for Melamine Contamination: Guidance for Industry	08/06/2009	Center for Veterinary Medicine, Center for Drug Evaluation and Research	Current Good Manufacturing Practices (CGMP), Pharmaceutical Quality	Final	No		
Recommendations for Management of Donors at Increased Risk for Human Immunodeficiency Virus Type 1 (HIV-1) Group O Infection	PDF (88.74 KB)PDF (88.74 KB) of Recommendations for Management of Donors at Increased Risk for Human Immunodeficiency Virus Type 1 (HIV-1) Group O Infection	08/01/2009	Center for Biologics Evaluation and Research	Blood Products	Final	No		FDA-1997-N-0501
Drug-Induced Liver Injury: Premarketing Clinical Evaluation	PDF (205.82 KB)PDF (205.82 KB) of Drug-Induced Liver Injury: Premarketing Clinical Evaluation	07/29/2009	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Safety - Issues, Errors, and Problems	Final	No		FDA-2008-D-0128
Nucleic Acid Testing to Reduce the Possible Risk of Parvovirus B19 Transmission by Plasma-Derived Products: Guidance for Industry	PDF (57.38 KB)PDF (57.38 KB) of Nucleic Acid Testing to Reduce the Possible Risk of Parvovirus B19 Transmission by Plasma-Derived Products: Guidance for Industry	07/28/2009	Center for Biologics Evaluation and Research	Blood Products	Final	No		FDA-2008-D-0379

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Class II Special Controls Guidance Document: Dental Amalgam, Mercury, and Amalgam Alloy - Guidance for Industry and FDA Staff		07/27/2009	Center for Devices and Radiological Health	Premarket,	Final	No		
ANDAs: Impurities in Drug Substances: Guidance for Industry	PDF (135.79 KB)PDF (135.79 KB) of ANDAs: Impurities in Drug Substances: Guidance for Industry	07/15/2009	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		
CVM GFI #70 Small Entities Compliance Guide for Feeders of Ruminant Animals Without On-Farm Feed Mixing Operations	PDF (58.73 KB)PDF (58.73 KB) of CVM GFI #70 Small Entities Compliance Guide for Feeders of Ruminant Animals Without On-Farm Feed Mixing Operations	07/13/2009	Center for Veterinary Medicine	Current Good Manufacturing Practices (CGMP), Animal Feed	Final	No		
Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application	PDF (297.82 KB)PDF (297.82 KB) of Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application	07/13/2009	Center for Drug Evaluation and Research	Over-the-Counter Drugs	Final	No		FDA-2007-D-0434
Frequently Asked Questions - IRB Registration: Guidance for Institutional Review Boards (IRBs)	PDF (48.34 KB)PDF (48.34 KB) of Frequently Asked Questions - IRB Registration: Guidance for Institutional Review Boards (IRBs)	07/09/2009	Office of Good Clinical Practice	Good Clinical Practices (GCP)	Final	No		
Guidance for Industry: Color Additive Petitions - FDA Recommendations for Submission of Chemical and Technological Data on Color Additives for Food, Drugs, Cosmetics, or Medical Devices		07/01/2009	Office of Food Additive Safety	Electronic Submissions Gateway (ESG), Food & Color Additives	Final	No		OFAS
Draft Guidance for Industry: Measures to Address the Risk for Contamination by Salmonella Species in Food Containing a Pistachio-Derived Product as an Ingredient		06/29/2009	Office of Food Safety	Food & Beverage Safety, Nuts & Nut Products, Ingredients, Foodborne Illness, Food & Beverage Safety	Draft	No	08/28/2009	FDA-2009-D-0271
Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices (final)	PDF (255.44 KB)PDF (255.44 KB) of Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices (final)	06/26/2009	Center for Devices and Radiological Health	Labeling	Final	No		
Procedures for Handling Post-Approval Studies Imposed by PMA Order		06/15/2009	Center for Devices and Radiological Health	Postmarket,	Final	No		1561
Medication Guides — Adding a Toll-Free Number for Reporting Adverse Events	PDF (66.81 KB)PDF (66.81 KB) of Medication Guides — Adding a Toll-Free Number for Reporting Adverse Events	06/08/2009	Center for Drug Evaluation and Research	Administrative / Procedural, Safety - Issues, Errors, and Problems	Final	No		
Radioactive Drug Research Committee: Human Research Without An Investigational New Drug Application	PDF (6.76 MB)PDF (6.76 MB) of Radioactive Drug Research Committee: Human Research Without An Investigational New Drug Application	06/03/2009	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Clinical - Medical	Final	No		FDA-2009-D-0125
Small Entity Compliance Guide: Bottled Water and Residual Disinfectants and Disinfection Byproducts		06/01/2009	Office of Food Safety	Bottled Water	Final	No		FDA-2009-D-0224
Guidance for Industry: Questions and Answers Regarding Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act	PDF (192.6 KB)PDF (192.6 KB) of Guidance for Industry: Questions and Answers Regarding Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act	05/31/2009	Office of Dietary Supplement Programs	Adverse Event Reporting System (FAERS), Adverse Event Reporting	Final	No		FDA-2007-D-0372
Providing Regulatory Submissions in Electronic Format – Drug Establishment Registration and Drug Listing	PDF (103.33 KB)PDF (103.33 KB) of Providing Regulatory Submissions in Electronic Format – Drug Establishment Registration and Drug Listing	05/28/2009	Center for Drug Evaluation and Research	Electronic Submissions,	Final	No		FDA-2005-N-0464

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Presenting Risk Information in Prescription Drug and Medical Device Promotion	PDF (932.59 KB)PDF (932.59 KB) of Presenting Risk Information in Prescription Drug and Medical Device Promotion	05/27/2009	Center for Veterinary Medicine, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Advertising	Draft	No		FDA-2008-D-0253
Small Entity Compliance Guide: Health Claims on Calcium and Osteoporosis; and Calcium, Vitamin D, and Osteoporosis		05/15/2009	Office of Nutrition and Food Labeling	Labeling	Final	No		FDA-2009-D-0209
CVM GFI #199 Animal Generic Drug User Fees and Fee Waivers and Reductions	PDF (87.45 KB)PDF (87.45 KB) of CVM GFI #199 Animal Generic Drug User Fees and Fee Waivers and Reductions	05/13/2009	Center for Veterinary Medicine	User Fees,	Final	No		FDA-2009-D-0189
Labeling OTC Human Drug Products; Small Entity Compliance Guide: Guidance for Industry	PDF (269.87 KB)PDF (269.87 KB) of Labeling OTC Human Drug Products; Small Entity Compliance Guide: Guidance for Industry	05/12/2009	Center for Drug Evaluation and Research	Compliance, Over-the-Counter Drugs	Final	No		FDA-2004-D-0122
Compliance Policy Guide: Sec. 110.310 Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002		05/06/2009	Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Import	Final	No		FDA-2007-D-0487
CVM GFI #195 Small Entities Compliance Guide For Renderers—Substances Prohibited From Use In Animal Food Or Feed	PDF (250.9 KB)PDF (250.9 KB) of CVM GFI #195 Small Entities Compliance Guide For Renderers—Substances Prohibited From Use In Animal Food Or Feed	05/06/2009	Center for Veterinary Medicine		Final	No		FDA-2008-D-0597
Small Entity Compliance Guide: Bottled Water and Arsenic;		04/30/2009	Office of Food Safety	Bottled Water	Final	No		FDA-2009-D-0196
Small Entity Compliance Guide: Bottled Water and Uranium		04/30/2009	Office of Food Safety	Bottled Water	Final	No		FDA-2009-D-0195
Small Entity Compliance Guide: Declaration by Name on the Label of All Foods and Cosmetic Products That Contain Cochineal Extract and Carmine		04/30/2009	Office of Food Additive Safety	Food & Color Additives, Labeling	Final	No		FDA-2009-D-0198
CVM GFI #185 (VICH GL43) Target Animal Safety for Veterinary Pharmaceutical Products	PDF (395.36 KB)PDF (395.36 KB) of CVM GFI #185 (VICH GL43) Target Animal Safety for Veterinary Pharmaceutical Products	04/24/2009	Center for Veterinary Medicine	Target Animal – Safety, VICH	Final	No		FDA-2007-D-0430
Chapter 5 - Establishment Inspections	PDF (4.47 MB)PDF (4.47 MB) of Chapter 5 - Establishment Inspections	04/22/2009		Compliance, Inspection,	Final	No		
Integrated Summaries of Effectiveness and Safety: Location Within the Common Technical Document	PDF (97.96 KB)PDF (97.96 KB) of Integrated Summaries of Effectiveness and Safety: Location Within the Common Technical Document	04/20/2009	Center for Drug Evaluation and Research	Administrative / Procedural	Final	No		
Q10 Pharmaceutical Quality System	PDF (273.92 KB)PDF (273.92 KB) of Q10 Pharmaceutical Quality System	04/07/2009	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Quality	Final	No		FDA-2007-D-0370
Guidance for Industry: Recommendations for Submission of Chemical and Technological Data for Direct Food Additive Petitions		03/22/2009	Office of Food Additive Safety	Food & Color Additives	Final	No		FDA-2013-S-0610
CVM GFI #149 (VICH GL33) Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Testing	PDF (171.13 KB)PDF (171.13 KB) of CVM GFI #149 (VICH GL33) Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Testing	03/17/2009	Center for Veterinary Medicine	Human Food Safety, VICH	Final	No		FDA-2002-D-0186

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Guidance for Industry: Measures to Address the Risk for Contamination by Salmonella Species in Food Containing a Peanut-Derived Product as an Ingredient		03/11/2009	Office of Food Safety	Food & Beverage Safety, Nuts & Nut Products, Ingredients, Foodborne Illness, Food & Beverage Safety	Final	No		FDA-2009-D-0060
Guidance for Industry: The Seafood List		03/06/2009	Office of Food Safety	Seafood/Seafood Product	Final	No		FDA-1994-D-0221
Manufacturer's Notification of the Intent to Use an Accredited Person under the Accredited Persons Inspection Program Authorized by Section 228 of the Food and Drug Administration Amendments Act of 2007 (FDAAA): Guidance for Industry, FDA Staff, and FDA	PDF (202.95 KB)PDF (202.95 KB) of Manufacturer's Notification of the Intent to Use an Accredited Person under the Accredited Persons Inspection Program Authorized by Section 228 of the Food and Drug Administration Amendments Act of 2007 (FDAAA): Guidance for Industry, FDA Staff, and FDA	03/02/2009	Center for Devices and Radiological Health		Final	No		
Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products: Guidance for Industry and FDA Staff	PDF (42.37 KB)PDF (42.37 KB) of Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products: Guidance for Industry and FDA Staff	02/25/2009	Center for Devices and Radiological Health	Premarket,	Final	No		
Guidance for Industry: 1991 Letter to Seafood Manufacturers Regarding the Fraudulent Practice of Including Glaze (ice) as Part of the Weight of Frozen Seafood		02/18/2009	Office of Food Safety	Seafood/Seafood Product	Final	No		FDA-2013-S-0610
Guidance for Industry: Referral Program from the Food and Drug Administration to the National Oceanic and Atmospheric Administration Seafood Inspection Program for the Certification of Fish and Fishery Products for Export to the European Union and the European Free Trade Association		02/11/2009	Office of Foods and Veterinary Medicine	Export, Seafood/Seafood Product	Final	No		FDA-2004-D-0043
CPG Sec. 540.370 Fish and Fishery Products - Decomposition	PDF (21.62 KB)PDF (21.62 KB) of CPG Sec. 540.370 Fish and Fishery Products - Decomposition	02/10/2009		Investigation & Enforcement,	Final	No		
Animal Models — Essential Elements to Address Efficacy Under the Animal Rule_09	PDF (28.2 KB)PDF (28.2 KB) of Animal Models — Essential Elements to Address Efficacy Under the Animal Rule_09	02/05/2009		Pharm/Tox	Final	No		
Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims		01/16/2009	Office of Nutrition and Food Labeling	Labeling	Final	No		FDA-2007-D-0371
Adverse Event Reporting to IRBs — Improving Human Subject Protection: Guidance for Clinical Investigators, Sponsors, and IRBs	PDF (56.53 KB)PDF (56.53 KB) of Adverse Event Reporting to IRBs — Improving Human Subject Protection: Guidance for Clinical Investigators, Sponsors, and IRBs	01/14/2009	Office of Good Clinical Practice, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Administrative / Procedural, Good Clinical Practices (GCP)	Final	No		
Designation of Special Controls for Male Condoms Made of Natural Rubber Latex (21 CFR 884.5300); Small Entity Compliance Guide: Guidance for Industry	PDF (45.64 KB)PDF (45.64 KB) of Designation of Special Controls for Male Condoms Made of Natural Rubber Latex (21 CFR 884.5300); Small Entity Compliance Guide: Guidance for Industry	01/05/2009	Center for Devices and Radiological Health	Premarket,	Final	No		
Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r) (6) of the Federal Food, Drug, and Cosmetic Act		01/05/2009	Office of Dietary Supplement Programs	Labeling	Final	No		FDA-2004-D-0303
Labeling OTC Human Drug Products -- Questions and Answers	PDF (598.82 KB)PDF (598.82 KB) of Labeling OTC Human Drug Products -- Questions and Answers	01/02/2009	Center for Drug Evaluation and Research	Over-the-Counter Drugs	Final	No		
Class II Special Controls Guidance Document: Nucleic Acid Amplification Assay for the Detection of Enterovirus RNA		01/01/2009	Center for Devices and Radiological Health	Premarket,	Final	No		

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Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices: Guidance for Industry		12/31/2008	Office of Policy	Administrative / Procedural	Final	No		
Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms Classified Under 21 CFR 884.5300		12/23/2008	Center for Devices and Radiological Health	Premarket,	Final	No		
Radiation Safety Considerations for X-Ray Equipment Designed for Hand-Held Use		12/23/2008		Postmarket,	Final	No		
Diabetes Mellitus -- Evaluating Cardiovascular Risk in New Antidiabetic Therapies to Treat Type 2 Diabetes	PDF (47.26 KB)PDF (47.26 KB) of Diabetes Mellitus -- Evaluating Cardiovascular Risk in New Antidiabetic Therapies to Treat Type 2 Diabetes	12/17/2008	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		
Orally Disintegrating Tablets: Guidance for Industry	PDF (51.6 KB)PDF (51.6 KB) of Orally Disintegrating Tablets: Guidance for Industry	12/17/2008	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		
Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process: Guidance for Industry and FDA Staff	PDF (199.99 KB)PDF (199.99 KB) of Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process: Guidance for Industry and FDA Staff	12/11/2008	Center for Devices and Radiological Health	Premarket, Premarket Approval (PMA)	Final	No		
CVM GFI #5 Drug Stability Guidelines	PDF (384.72 KB)PDF (384.72 KB) of CVM GFI #5 Drug Stability Guidelines	12/09/2008	Center for Veterinary Medicine	Chemistry, Manufacturing, and Controls (CMC)	Final	No		
Guidance for Industry: Dear Manufacturer Letter Regarding Front-of-Package Symbols		12/01/2008	Office of Nutrition and Food Labeling	Food & Beverage Safety, Labeling, Food & Beverage Safety	Final	No		FDA-2013-S-0610
CPG Sec. 540.700 Processed and/or Blended Seafood Products		11/01/2008		Investigation & Enforcement,	Final	No		
Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics	PDF (84.87 KB)PDF (84.87 KB) of Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics	11/01/2008		Administrative / Procedural	Final	No		
PDUFA Pilot Project: Proprietary Name Review - Concept Paper	PDF (186.4 KB)PDF (186.4 KB) of PDUFA Pilot Project: Proprietary Name Review - Concept Paper	10/07/2008	Center for Drug Evaluation and Research		Final	No		
Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials: Guidance for Sponsors, Clinical Investigators, and IRBs	PDF (74.79 KB)PDF (74.79 KB) of Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials: Guidance for Sponsors, Clinical Investigators, and IRBs	10/01/2008	Office of Good Clinical Practice	Good Clinical Practices (GCP)	Final	No		
S1C(R2) Dose Selection for Carcinogenicity Studies of Pharmaceuticals	PDF (184.53 KB)PDF (184.53 KB) of S1C(R2) Dose Selection for Carcinogenicity Studies of Pharmaceuticals	09/17/2008	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Safety	Final	No		
Animal Models — Essential Elements to Address Efficacy Under the Animal Rule - Concept Paper	PDF (28.21 KB)PDF (28.21 KB) of Animal Models — Essential Elements to Address Efficacy Under the Animal Rule - Concept Paper	09/09/2008			Final	No		
Clinical Study Designs for Catheter Ablation Devices for Treatment of Atrial Flutter: Guidance for Industry and FDA Staff	PDF (86.12 KB)PDF (86.12 KB) of Clinical Study Designs for Catheter Ablation Devices for Treatment of Atrial Flutter: Guidance for Industry and FDA Staff	08/05/2008	Center for Devices and Radiological Health	Premarket, Good Clinical Practices (GCP)	Final	No		1678
Preparation and Public Availability of Information Given to Advisory Committee Members: Guidance for Industry	PDF (169.24 KB)PDF (169.24 KB) of Preparation and Public Availability of Information Given to Advisory Committee Members: Guidance for Industry	08/01/2008	Office of Special Medical Programs	Advisory Committees, Food & Color Additives	Final	No		

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Voting Procedures for Advisory Committee Meetings: Guidance for FDA Advisory Committee Members and FDA Staff	PDF (36.7 KB)PDF (36.7 KB) of Voting Procedures for Advisory Committee Meetings: Guidance for FDA Advisory Committee Members and FDA Staff	08/01/2008	Office of Special Medical Programs	Advisory Committees, Food & Color Additives	Final	No		
CPG Sec. 540.575 Fish - Fresh and Frozen - Adulteration Involving Decomposition (Withdrawn 7/18/2008)		07/18/2008		Investigation & Enforcement,	Final	No		
Small Entity Compliance Guide: Nutrient Content Claims Definition for “High Potency” and Definition for “Antioxidant” for Use in Nutrient Content Claims for Dietary Supplements and Conventional Foods		07/18/2008	Office of Dietary Supplement Programs	Labeling	Final	No		FDA-2013-S-0610
Small Entity Compliance Guide: Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk		07/17/2008	Office of Dietary Supplement Programs		Final	No		FDA-1995-N-0054
Class II Special Controls Guidance Document: Bone Sonometers - Guidance for Industry and FDA Staff		07/16/2008	Center for Devices and Radiological Health		Final	No		
Small Entity Compliance Guide: Standard of Identity for White Chocolate		07/16/2008	Office of Nutrition and Food Labeling	Chocolate/Cocoa Product	Final	No		FDA-2008-N-0361
Current Good Manufacturing Practice for Phase 1 Investigational Drugs: Guidance for Industry	PDF (91.58 KB)PDF (91.58 KB) of Current Good Manufacturing Practice for Phase 1 Investigational Drugs: Guidance for Industry	07/14/2008	Office of Regulatory Affairs, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Current Good Manufacturing Practices (CGMP), Good Clinical Practices (GCP), Pharmaceutical Quality	Final	No		
Intravascular Administration Sets Premarket Notification Submissions [510(k)]: Guidance for Industry and FDA Staff	PDF (317.03 KB)PDF (317.03 KB) of Intravascular Administration Sets Premarket Notification Submissions [510(k)]: Guidance for Industry and FDA Staff	07/11/2008	Center for Devices and Radiological Health	Premarket, 510(k)	Final	No		
Surveillance and Detention Without Physical Examination of Condoms: Guidance for Industry and FDA Staff	PDF (81.04 KB)PDF (81.04 KB) of Surveillance and Detention Without Physical Examination of Condoms: Guidance for Industry and FDA Staff	07/11/2008	Center for Devices and Radiological Health	Postmarket,	Final	No		00D-1139
Surveillance and Detention Without Physical Examination of Surgeons' and/or Patient Examination Gloves: Guidance for Industry and FDA Staff	PDF (79.52 KB)PDF (79.52 KB) of Surveillance and Detention Without Physical Examination of Surgeons' and/or Patient Examination Gloves: Guidance for Industry and FDA Staff	07/11/2008	Center for Devices and Radiological Health	Postmarket,	Final	No		
CPG Sec. 560.700 - Processing of Imported Frozen Products of Multiple Sizes (e.g., Shrimp, Prawns, Etc.) (Withdrawn 6/6/2008)		06/06/2008		Investigation & Enforcement,	Final	No		
Q3A(R) Impurities in New Drug Substances	PDF (54.73 KB)PDF (54.73 KB) of Q3A(R) Impurities in New Drug Substances	06/06/2008	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Quality	Final	No		
Indexing Structured Product Labeling	PDF (51.21 KB)PDF (51.21 KB) of Indexing Structured Product Labeling	06/02/2008	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Electronic Submissions,	Final	No		FDA-2007-D-0364
Safety, Efficacy, and Pharmacokinetic Studies to Support Marketing of Immune Globulin Intravenous (Human) as Replacement Therapy for Primary Humoral Immunodeficiency: Guidance for Industry	PDF (75.91 KB)PDF (75.91 KB) of Safety, Efficacy, and Pharmacokinetic Studies to Support Marketing of Immune Globulin Intravenous (Human) as Replacement Therapy for Primary Humoral Immunodeficiency: Guidance for Industry	06/01/2008	Center for Biologics Evaluation and Research	Blood Products	Final	No		2005D-0438

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Guidance for Industry: Microbiological Considerations for Antimicrobial Food Additive Submissions	PDF (92.1 KB)PDF (92.1 KB) of Guidance for Industry: Microbiological Considerations for Antimicrobial Food Additive Submissions	05/31/2008	Office of Food Additive Safety	Food & Color Additives	Final	No		FDA-2007-D-0207
Class II Special Controls Guidance Document: Tissue Adhesive for the Topical Approximation of Skin - Guidance for Industry and FDA Staff		05/29/2008	Center for Devices and Radiological Health	Premarket,	Final	No		
CVM GFI #61 FDA Approval of New Animal Drugs for MUMS	PDF (507.45 KB)PDF (507.45 KB) of CVM GFI #61 FDA Approval of New Animal Drugs for MUMS	05/29/2008	Center for Veterinary Medicine	New Animal Drug Application (NADA), Minor Use/ Minor Species (MUMS)	Final	No		
Class II Special Controls Guidance Document: Plasmodium Species Antigen Detection Assays		05/19/2008	Center for Devices and Radiological Health	Premarket,	Final	No		
Hemodialysis Blood Tubing Sets - Premarket Notification [510(k)] Submissions: Guidance for Industry and FDA Staff	PDF (110.19 KB)PDF (110.19 KB) of Hemodialysis Blood Tubing Sets - Premarket Notification [510(k)] Submissions: Guidance for Industry and FDA Staff	04/23/2008	Center for Devices and Radiological Health	510(k)	Final	No		
Certain Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) Recovered from Donors Who Were Tested for Communicable Diseases Using Pooled Specimens or Diagnostic Tests: Guidance for Industry	PDF (62.69 KB)PDF (62.69 KB) of Certain Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) Recovered from Donors Who Were Tested for Communicable Diseases Using Pooled Specimens or Diagnostic Tests: Guidance for Industry	04/16/2008	Center for Biologics Evaluation and Research	Tissue	Final	No		2007D-0017
Investigational Device Exemptions (IDEs) for Devices Indicated for Nocturnal Home Hemodialysis: Guidance for Industry and FDA Staff	PDF (141.88 KB)PDF (141.88 KB) of Investigational Device Exemptions (IDEs) for Devices Indicated for Nocturnal Home Hemodialysis: Guidance for Industry and FDA Staff	04/15/2008	Center for Devices and Radiological Health	Premarket, Device Exception (IDE)	Final	No		
Preparation and Review of Investigational Device Exemption Applications (IDEs) for Total Artificial Discs: Guidance for Industry and FDA Staff	PDF (241.1 KB)PDF (241.1 KB) of Preparation and Review of Investigational Device Exemption Applications (IDEs) for Total Artificial Discs: Guidance for Industry and FDA Staff	04/11/2008	Center for Devices and Radiological Health	Premarket, Device Exception (IDE), Orthopedic	Final	No		
Coronary Drug-Eluting Stents — Nonclinical and Clinical Studies -Companion Document	PDF (1.28 MB)PDF (1.28 MB) of Coronary Drug-Eluting Stents — Nonclinical and Clinical Studies - Companion Document	04/07/2008	Center for Drug Evaluation and Research, Center for Devices and Radiological Health	Combination Products, Cardiovascular	Draft	No		
E15 Pharmacogenomics Definitions and Sample Coding	PDF (53.27 KB)PDF (53.27 KB) of E15 Pharmacogenomics Definitions and Sample Coding	04/07/2008	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Efficacy	Final	No		FDA-2008-D-0199
Content and Review of Chemistry, Manufacturing, and Control (CMC) Information for Human Somatic Cell Therapy Investigational New Drug Applications (INDs): Guidance for FDA Reviewers and Sponsors	PDF (160.29 KB)PDF (160.29 KB) of Content and Review of Chemistry, Manufacturing, and Control (CMC) Information for Human Somatic Cell Therapy Investigational New Drug Applications (INDs): Guidance for FDA Reviewers and Sponsors	04/01/2008	Center for Biologics Evaluation and Research	Cellular & Gene Therapy, Gene Therapy	Final	No		FDA-2008-D-0206
Content and Review of Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs): Guidance for FDA Reviewers and Sponsors	PDF (166.31 KB)PDF (166.31 KB) of Content and Review of Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs): Guidance for FDA Reviewers and Sponsors	04/01/2008	Center for Biologics Evaluation and Research	Cellular & Gene Therapy, Gene Therapy	Final	No		FDA-2008-D-0206

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Guidance for Industry: A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods - Part I		03/31/2008	Office of Nutrition and Food Labeling	Labeling, Retail Food Protection	Final	No		
Coronary Drug-Eluting Stents-Nonclinical and Clinical Studies	PDF (1.75 MB)PDF (1.75 MB) of Coronary Drug-Eluting Stents-Nonclinical and Clinical Studies	03/26/2008	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Combination Products, Cardiovascular	Draft	No		
CPG Sec. 500.500 Guidance Levels for 3-MCPD(3-chloro-1,2-propanediol) in Acid-Hydrolyzed Protein and Asian-Style Sauces	PDF (25.9 KB)PDF (25.9 KB) of CPG Sec. 500.500 Guidance Levels for 3-MCPD(3-chloro-1,2-propanediol) in Acid-Hydrolyzed Protein and Asian-Style Sauces	03/14/2008		Investigation & Enforcement,	Final	No		
Diabetes Mellitus: Developing Drugs and Therapeutic Biologics for Treatment and Prevention	PDF (264.64 KB)PDF (264.64 KB) of Diabetes Mellitus: Developing Drugs and Therapeutic Biologics for Treatment and Prevention	03/03/2008	Center for Drug Evaluation and Research	Clinical - Medical	Draft	No		
Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables		02/25/2008	Office of Food Safety	Fruit/Fruit Product , Produce, Sanitation, Vegetable Products	Final	No		FDA-2008-D-0108
Container and Closure System Integrity Testing in Lieu of Sterility Testing as a Component of the Stability Protocol for Sterile Products: Guidance for Industry	PDF (64.2 KB)PDF (64.2 KB) of Container and Closure System Integrity Testing in Lieu of Sterility Testing as a Component of the Stability Protocol for Sterile Products: Guidance for Industry	02/22/2008	Center for Veterinary Medicine, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Postmarket, Administrative / Procedural	Final	No		
Coronary and Carotid Embolic Protection Devices - Premarket Notification [510(k)] Submissions : Guidance for Industry and FDA Staff	PDF (155.34 KB)PDF (155.34 KB) of Coronary and Carotid Embolic Protection Devices - Premarket Notification [510(k)] Submissions : Guidance for Industry and FDA Staff	02/15/2008	Center for Devices and Radiological Health	Premarket, 510(k)	Final	No		
Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices - Guidance for Industry and Food and Drug Administration Staff		01/29/2008	Center for Devices and Radiological Health	Premarket, CLIA (Clinical Laboratory Improvement Amendments), Laboratory Tests	Final	No		
Medical Glove Guidance Manual: Guidance for Industry and FDA Staff	PDF (770.76 KB)PDF (770.76 KB) of Medical Glove Guidance Manual: Guidance for Industry and FDA Staff	01/22/2008	Center for Devices and Radiological Health	Premarket, 510(k)	Final	No		
CVM GFI #179 Use of Animal Clones and Clone Progeny for Human Food and Animal Feed	PDF (51.58 KB)PDF (51.58 KB) of CVM GFI #179 Use of Animal Clones and Clone Progeny for Human Food and Animal Feed	01/15/2008	Center for Veterinary Medicine	Biotechnology,	Final	No		FDA-2008-N-0033
The Review and Inspection of Premarket Approval Application Manufacturing Information and Operations: Guidance for Industry and FDA Staff	PDF (158.84 KB)PDF (158.84 KB) of The Review and Inspection of Premarket Approval Application Manufacturing Information and Operations: Guidance for Industry and FDA Staff	01/08/2008	Center for Devices and Radiological Health	Premarket,	Final	No		
Collection of Platelets by Automated Methods: Guidance for Industry and FDA Review Staff	PDF (153.01 KB)PDF (153.01 KB) of Collection of Platelets by Automated Methods: Guidance for Industry and FDA Review Staff	12/01/2007	Center for Biologics Evaluation and Research	Blood Products	Final	No		2005D-0330
Guidance for Industry: Preparation of Premarket Submissions for Food Contact Substances (Chemistry Recommendations)		12/01/2007	Office of Food Additive Safety	Food & Beverage Safety, Food & Color Additives, Ingredients, Food & Beverage Safety	Final	No		FDA-2013-S-0610
CVM GFI #92 (VICH GL10(R)) Impurities In New Veterinary Drug Substances	PDF (149.87 KB)PDF (149.87 KB) of CVM GFI #92 (VICH GL10(R)) Impurities In New Veterinary Drug Substances	11/26/2007	Center for Veterinary Medicine	Chemistry, Manufacturing, and Controls (CMC), VICH	Final	No		FDA-1999-D-0064

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Adequate and Appropriate Donor Screening Tests for Hepatitis B; Hepatitis B Surface Antigen (HBsAg) Assays Used to Test Donors of Whole Blood and Blood Components, Including Source Plasma and Source Leukocytes: Guidance for Industry	PDF (27.28 KB)PDF (27.28 KB) of Adequate and Appropriate Donor Screening Tests for Hepatitis B; Hepatitis B Surface Antigen (HBsAg) Assays Used to Test Donors of Whole Blood and Blood Components, Including Source Plasma and Source Leukocytes: Guidance for Industry	11/21/2007	Center for Biologics Evaluation and Research	Blood Products	Final	No		2002D-0081
CVM GFI #73 (VICH GL3(R)) Stability Testing of New Veterinary Drug Substances	PDF (227.8 KB)PDF (227.8 KB) of CVM GFI #73 (VICH GL3(R)) Stability Testing of New Veterinary Drug Substances	11/21/2007	Center for Veterinary Medicine	Chemistry, Manufacturing, and Controls (CMC), VICH	Final	No		FDA-2006-D-0299
CVM GFI #93 (VICH GL11(R)) Impurities in New Veterinary Medicinal Products	PDF (133.55 KB)PDF (133.55 KB) of CVM GFI #93 (VICH GL11(R)) Impurities in New Veterinary Medicinal Products	11/21/2007	Center for Veterinary Medicine	Chemistry, Manufacturing, and Controls (CMC), VICH	Final	No		FDA-1999-D-0048
Considerations for Plasmid DNA Vaccines for Infectious Disease Indications: Guidance for Industry	PDF (87.65 KB)PDF (87.65 KB) of Considerations for Plasmid DNA Vaccines for Infectious Disease Indications: Guidance for Industry	11/01/2007	Center for Biologics Evaluation and Research	Vaccines	Final	No		2005D-0047
Guidance for Industry: Providing Regulatory Submissions to the Center for Biologics Evaluation and Research (CBER) in Electronic Format - Lot Release Protocols	PDF (52.52 KB)PDF (52.52 KB) of Guidance for Industry: Providing Regulatory Submissions to the Center for Biologics Evaluation and Research (CBER) in Electronic Format - Lot Release Protocols	11/01/2007	Center for Biologics Evaluation and Research		Final	No		
Inspection and Field Testing of Radiation-Emitting Electronic Products: Attachment A		10/30/2007		Postmarket,	Final	No		
Inspection and Field Testing of Radiation-Emitting Electronic Products: Attachment C: Specific Instructions for Sunlamp Product Inspections and Tests		10/30/2007			Final	No		
Role of HIV Drug Resistance Testing in Antiretroviral Drug Development	PDF (238.03 KB)PDF (238.03 KB) of Role of HIV Drug Resistance Testing in Antiretroviral Drug Development	10/30/2007	Center for Drug Evaluation and Research	Clinical - Antimicrobial	Final	No		
Class II Special Controls Guidance Document: Remote Medication Management System - Guidance for Industry and FDA Staff		10/18/2007	Center for Devices and Radiological Health	Premarket,	Final	No		
Biological Indicator (BI) Premarket Notification [510(k)] Submissions : Guidance for Industry and FDA Staff	PDF (189.01 KB)PDF (189.01 KB) of Biological Indicator (BI) Premarket Notification [510(k)] Submissions : Guidance for Industry and FDA Staff	10/04/2007	Center for Devices and Radiological Health	Premarket, 510(k)	Final	No		
CVM GFI #178 Recommended Design and Evaluation of Effectiveness Studies for Swine Respiratory Disease Claims	PDF (139.98 KB)PDF (139.98 KB) of CVM GFI #178 Recommended Design and Evaluation of Effectiveness Studies for Swine Respiratory Disease Claims	10/01/2007	Center for Veterinary Medicine	Animal Feed	Final	No		FDA-2006-D-0479
Guidance for Industry: Food Security Preventive Measures Guidance for Retail Food Stores and Food Service Establishments		10/01/2007	Center for Food Safety and Applied Nutrition	Food & Beverage Safety, Retail Food Protection, Food & Beverage Safety	Final	No		FDA-2013-S-0610
Guidance for Industry: Food Security Preventive Measures Guidance for Dairy Farms, Bulk Milk Transporters, Bulk Milk Transfer Stations and Fluid Milk Processors		10/01/2007	Center for Food Safety and Applied Nutrition	Sanitation	Final	No		FDA-2013-S-0610
Guidance for Industry: Cosmetics Processors and Transporters of Cosmetics Security Preventive Measures Guidance		09/30/2007	Center for Food Safety and Applied Nutrition	Food & Beverage Safety, Transportation, Food & Beverage Safety	Final	No		FDA-2013-S-0610
Guidance for Industry: Food Security Preventive Measures for Importers and Filers		09/30/2007	Center for Food Safety and Applied Nutrition	Export	Final	No		FDA-2013-S-0610
Guidance for Industry: Food Security Preventive Measures Guidance for Food Producers, Processors, and Transporters		09/30/2007	Center for Food Safety and Applied Nutrition	Transportation, Food & Beverage Safety	Final	No		FDA-2013-S-0610

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Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials: Guidance for Industry	PDF (114.01 KB)PDF (114.01 KB) of Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials: Guidance for Industry	09/27/2007	Center for Biologics Evaluation and Research	Vaccines	Final	No		2005D-0155
Procedures for Renewal and Amendment of Certain Laser Light Show Variances (Laser Notice 55)		09/24/2007			Final	No		
Compliance Guide for Cabinet X-Ray Systems		09/18/2007			Final	No		
CDRH Standard Operating Procedures for the Identification and Evaluation of Candidate Consensus Standards for Recognition: Guidance for Industry and FDA Staff	PDF (212.52 KB)PDF (212.52 KB) of CDRH Standard Operating Procedures for the Identification and Evaluation of Candidate Consensus Standards for Recognition: Guidance for Industry and FDA Staff	09/17/2007	Center for Devices and Radiological Health		Final	No		
Non-clinical Information for Femoral Stem Prostheses: Guidance for Industry and FDA Staff	PDF (156.85 KB)PDF (156.85 KB) of Non-clinical Information for Femoral Stem Prostheses: Guidance for Industry and FDA Staff	09/17/2007	Center for Devices and Radiological Health	Premarket,	Final	No		
CDRH Standard Operating Procedures for the Identification and Evaluation of Candidate Consensus Standards for Recognition		09/16/2007	Center for Devices and Radiological Health	Postmarket, Premarket,	Final	No		
Commercially Distributed Analyte Specific Reagents (ASRs): Frequently Asked Questions: Guidance for Industry and FDA Staff	PDF (138.61 KB)PDF (138.61 KB) of Commercially Distributed Analyte Specific Reagents (ASRs): Frequently Asked Questions: Guidance for Industry and FDA Staff	09/13/2007	Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Premarket, Good Clinical Practices (GCP)	Final	No		
Guidance for Industry and FDA: Dear Manufacturer Letter Regarding Sugar Free Claims		09/03/2007	Office of Nutrition and Food Labeling	Labeling	Final	No		FDA-2013-S-0610
Guidance for Industry: Manufacturing Biological Intermediates and Biological Drug Substances Using Spore-Forming Microorganisms	PDF (156.61 KB)PDF (156.61 KB) of Guidance for Industry: Manufacturing Biological Intermediates and Biological Drug Substances Using Spore-Forming Microorganisms	09/01/2007		Administrative / Procedural	Final	No		
Pharmacogenomic Data Submissions — Companion Guidance	PDF (211.18 KB)PDF (211.18 KB) of Pharmacogenomic Data Submissions — Companion Guidance	08/28/2007	Center for Drug Evaluation and Research	Administrative / Procedural	Draft	No		
Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) - Small Entity Compliance Guide: Guidance for Industry	PDF (91.24 KB)PDF (91.24 KB) of Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) - Small Entity Compliance Guide: Guidance for Industry	08/24/2007	Center for Biologics Evaluation and Research	Tissue	Final	No		FDA-1998-N-1016
Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products: Guidance for Industry	PDF (502.42 KB)PDF (502.42 KB) of Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products: Guidance for Industry	08/08/2007	Center for Biologics Evaluation and Research	Cellular & Gene Therapy, Gene Therapy	Final	No		2004D-0193
Class II Special Controls Guidance Document: Absorbable Poly(hydroxybutyrate) Surgical Suture Produced by Recombinant DNA Technology - Guidance for Industry and FDA Staff		08/02/2007	Center for Devices and Radiological Health	Premarket,	Final	No		
In Vitro Diagnostic Multivariate Index Assays - Draft Guidance for Industry, Clinical Laboratories, and FDA Staff		07/25/2007	Center for Devices and Radiological Health	Premarket, Laboratory Tests	Draft	No		

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Exports Under the FDA Export Reform and Enhancement Act of 1996		07/23/2007	Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research		Final	No		
Writing Dear Doctor Letters for Recalls of Implantable Cardioverter Defibrillators (ICDs): Guidance for Industry and FDA Staff	PDF (144.9 KB)PDF (144.9 KB) of Writing Dear Doctor Letters for Recalls of Implantable Cardioverter Defibrillators (ICDs): Guidance for Industry and FDA Staff	07/19/2007	Center for Devices and Radiological Health	Postmarket, Radiological Health	Final	No		
ANDAs:Pharmaceutical Solid Polymorphism: Chemistry, Manufacturing, and Controls Information: Guidance for Industry	PDF (109.51 KB)PDF (109.51 KB) of ANDAs:Pharmaceutical Solid Polymorphism: Chemistry, Manufacturing, and Controls Information: Guidance for Industry	07/06/2007	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		
Class II Special Controls Guidance Document: Filtering Facepiece Respirator for Use by the General Public in Public Health Medical Emergencies - Guidance for Industry and FDA Staff		07/02/2007	Center for Devices and Radiological Health	Premarket,	Final	No		
Guidance for Industry and Other Stakeholders: Toxicological Principles for the Safety Assessment of Food Ingredients (Redbook 2000)		07/02/2007	Office of Food Additive Safety	Food & Color Additives	Final	No		
Devices Used to Process Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps): Guidance for Industry and FDA Staff		07/01/2007	Office of Combination Products	Combination Products	Final	No		
Redbook 2000: I Introduction		07/01/2007	Office of Food Additive Safety	Food & Color Additives	Final	No		
Redbook 2000: III Recommended Toxicity Studies		07/01/2007		Food & Color Additives	Final	No		
Redbook 2000: IV.C.1. Short-Term Tests for Genetic Toxicity		07/01/2007	Office of Food Additive Safety	Food & Color Additives	Final	No		
Redbook 2000: IV.C.10. Neurotoxicity Studies		07/01/2007	Office of Food Additive Safety	Food & Color Additives	Final	No		
Redbook 2000: IV.C.5.a. Chronic Toxicity Studies with Rodents		07/01/2007	Office of Food Additive Safety	Food & Color Additives	Final	No		
Redbook 2000: IV.C.7. Combined Chronic Toxicity/Carcinogenicity Studies with Rodents		07/01/2007	Office of Food Additive Safety	Food & Color Additives	Final	No		
Redbook 2000: IV.C.8. In-Utero Exposure Phase for Addition to Carcinogenicity Studies or Chronic Toxicity Studies with Rodents		07/01/2007	Office of Food Additive Safety	Food & Color Additives	Final	No		
Redbook 2000: IV.C.9.a. Guidelines for Reproduction Studies		07/01/2007	Office of Food Additive Safety	Food & Color Additives	Final	No		
Guidance for Industry and Other Stakeholders: Toxicological Principles for the Safety Assessment of Food Ingredients (Redbook)		06/30/2007	Center for Food Safety and Applied Nutrition	Food & Color Additives	Final	No		
Laser Products - Conformance with IEC 60825-1 and IEC 60601-2-22; (Laser Notice No. 50)		06/24/2007	Center for Devices and Radiological Health	Postmarket, Laser Notice, Laser Notice	Final	No		
Bundling Multiple Devices or Multiple Indications in a Single Submission: Guidance for Industry and FDA Staff	PDF (439.01 KB)PDF (439.01 KB) of Bundling Multiple Devices or Multiple Indications in a Single Submission: Guidance for Industry and FDA Staff	06/22/2007	Center for Devices and Radiological Health	Premarket,	Final	No		
Pre-Clinical and Clinical Studies for Neurothrombectomy Devices: Guidance for Industry and FDA Staff	PDF (118.87 KB)PDF (118.87 KB) of Pre-Clinical and Clinical Studies for Neurothrombectomy Devices: Guidance for Industry and FDA Staff	06/18/2007	Center for Devices and Radiological Health	Premarket, Good Clinical Practices (GCP)	Final	No		

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Performance Standard for Diagnostic X-Ray Systems and Their Major Components (21CFR 1020.30, 1020.31, 1020.32, 1020.33); Small Entity Compliance Guide		06/06/2007	Center for Devices and Radiological Health	Radiology	Final	No		
Guidance for Industry: Refrigerated Carrot Juice and Other Refrigerated Low-Acid Juices		06/05/2007	Office of Food Safety	Juice	Final	No		FDA-2013-S-0610
CPG Sec. 130.300 FDA Access to Results of Quality Assurance Program Audits and Inspections		06/01/2007		Investigation & Enforcement, Food & Color Additives	Final	No		
Informed Consent Recommendations for Source Plasma Donors Participating in Plasmapheresis and Immunization Programs: Guidance for Industry	PDF (56.11 KB)PDF (56.11 KB) of Informed Consent Recommendations for Source Plasma Donors Participating in Plasmapheresis and Immunization Programs: Guidance for Industry	06/01/2007	Center for Biologics Evaluation and Research	Blood Products	Final	No		2006D-0108
Redbook 2000: IV.B.4. Statistical Considerations in Toxicity Studies		06/01/2007	Office of Food Additive Safety	Food & Color Additives	Final	No	07/01/2007	
Clinical Data Needed to Support the Licensure of Pandemic Influenza Vaccines: Guidance for Industry	PDF (187.68 KB)PDF (187.68 KB) of Clinical Data Needed to Support the Licensure of Pandemic Influenza Vaccines: Guidance for Industry	05/31/2007	Center for Biologics Evaluation and Research	Vaccines	Final	No		2006D-0088
Clinical Data Needed to Support the Licensure of Seasonal Inactivated Influenza Vaccines: Guidance for Industry	PDF (165.68 KB)PDF (165.68 KB) of Clinical Data Needed to Support the Licensure of Seasonal Inactivated Influenza Vaccines: Guidance for Industry	05/31/2007	Center for Biologics Evaluation and Research	Vaccines	Final	No		2006D-0083
CVM GFI #83 Chemistry, Manufacturing and Controls Changes to Approved NADA/ANADA	PDF (162.29 KB)PDF (162.29 KB) of CVM GFI #83 Chemistry, Manufacturing and Controls Changes to Approved NADA/ANADA	05/30/2007	Center for Veterinary Medicine	Chemistry, Manufacturing, and Controls (CMC), New Animal Drug Application (NADA)	Final	No		FDA-1999-D-0011
Guidance for Industry: Frequently Asked Questions About Medical Foods - Second Edition	PDF (245.28 KB)PDF (245.28 KB) of Guidance for Industry: Frequently Asked Questions About Medical Foods - Second Edition	05/13/2007	Office of Nutrition and Food Labeling	Medical Food/Beverage	Final	No		FDA-2013-D-0880
Computerized Systems Used in Clinical Investigations: Guidance for Industry	PDF (52.72 KB)PDF (52.72 KB) of Computerized Systems Used in Clinical Investigations: Guidance for Industry	05/10/2007	Center for Food Safety and Applied Nutrition, Office of Good Clinical Practice, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Compliance, Current Good Manufacturing Practices (CGMP), Good Clinical Practices (GCP)	Final	No		
Class II Special Controls Guidance Document: Gene Expression Profiling Test System for Breast Cancer Prognosis - Guidance for Industry and FDA Staff		05/08/2007	Center for Devices and Radiological Health	Premarket,	Final	No		
CVM GFI #137 Analytical Methods Description for Type C Medicated Feeds	PDF (94.14 KB)PDF (94.14 KB) of CVM GFI #137 Analytical Methods Description for Type C Medicated Feeds	05/08/2007	Center for Veterinary Medicine	Chemistry, Manufacturing, and Controls (CMC), Animal Feed	Final	No		FDA-2006-D-0231
Small Business Nutrition Labeling Exemption Guidance		05/07/2007	Office of Nutrition and Food Labeling	Labeling	Final	No		
Dental Handpieces - Premarket Notification [510(k)] Submissions: Guidance for Industry and FDA Staff	PDF (115.81 KB)PDF (115.81 KB) of Dental Handpieces - Premarket Notification [510(k)] Submissions: Guidance for Industry and FDA Staff	05/02/2007	Center for Devices and Radiological Health	Premarket,	Final	No		
Testing of Glycerin for Diethylene Glycol: Guidance for Industry	PDF (36.13 KB)PDF (36.13 KB) of Testing of Glycerin for Diethylene Glycol: Guidance for Industry	05/01/2007	Center for Drug Evaluation and Research	Current Good Manufacturing Practices (CGMP), Pharmaceutical Quality	Final	No		
Redbook 2000: IV. A. Introduction to Guidelines for Toxicity Studies		04/29/2007	Office of Food Additive Safety	Food & Color Additives	Final	No		

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Redbook 2000: IV.B.1. General Guidelines for Designing and Conducting Toxicity Studies		04/29/2007	Office of Food Additive Safety	Food & Color Additives	Final	No		
Redbook 2000: IV.B.2 Guidelines for Reporting the Results of Toxicity Studies		04/29/2007	Office of Food Additive Safety	Food & Color Additives	Final	No		
Redbook 2000: IV.B.3. Pathology Considerations in Toxicity Studies		04/29/2007	Office of Food Additive Safety	Food & Color Additives	Final	No		
CVM GFI #136 Protocols for the Conduct of Method Transfer Studies for Type C Medicated Feed Assay Methods	PDF (105.42 KB)PDF (105.42 KB) of CVM GFI #136 Protocols for the Conduct of Method Transfer Studies for Type C Medicated Feed Assay Methods	04/26/2007	Center for Veterinary Medicine	Chemistry, Manufacturing, and Controls (CMC)	Final	No		FDA-2006-D-0230
Redbook 2000: VII Glossary. Acronyms and Definitions		04/25/2007	Office of Food Additive Safety	Food & Color Additives	Final	No		
CVM GFI #150 Concerns Related to the use of Clove Oil as an Anesthetic for Fish	PDF (40.75 KB)PDF (40.75 KB) of CVM GFI #150 Concerns Related to the use of Clove Oil as an Anesthetic for Fish	04/24/2007	Center for Veterinary Medicine	Aquaculture	Final	No		
Class II Special Controls Guidance Document: Computerized Labor Monitoring Systems - Guidance for Industry and FDA Staff		04/23/2007	Center for Devices and Radiological Health	Premarket,	Final	No		
Target Product Profile -- A Strategic Development Process Tool	PDF (453.95 KB)PDF (453.95 KB) of Target Product Profile -- A Strategic Development Process Tool	03/30/2007	Center for Drug Evaluation and Research	Administrative / Procedural	Draft	No		
Approval of Alternate Means of Labeling for Laser Products (Laser Notice 53)		03/22/2007			Final	No		
Statistical Guidance on Reporting Results from Studies Evaluating Diagnostic Tests - Guidance for Industry and FDA Staff		03/12/2007	Center for Devices and Radiological Health	Biostatistics,	Final	No		
CVM GFI #183 Animal Drug User Fees: Fees Exceed Costs Waiver/Reduction	PDF (117.49 KB)PDF (117.49 KB) of CVM GFI #183 Animal Drug User Fees: Fees Exceed Costs Waiver/Reduction	03/09/2007	Center for Veterinary Medicine	User Fees,	Final	No		FDA-2006-D-0361
Orally Inhaled and Intranasal Corticosteroids: Evaluation of the Effects on Growth in Children	PDF (82.43 KB)PDF (82.43 KB) of Orally Inhaled and Intranasal Corticosteroids: Evaluation of the Effects on Growth in Children	03/05/2007	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		
Drug Safety Information - FDA's Communication to the Public	PDF (87.05 KB)PDF (87.05 KB) of Drug Safety Information - FDA's Communication to the Public	03/02/2007		Safety - Issues, Errors, and Problems	Final	No		
Guidance for Industry and FDA: Letter to Industry, State and Local Food Regulators and Inspectors Regarding Web-based ALERT Training		02/22/2007	Office of Analytics and Outreach		Final	No		FDA-2013-S-0610
Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions	PDF (54.51 KB)PDF (54.51 KB) of Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions	02/20/2007	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Quality	Final	No		
Developing Products for Weight Management Revision 1	PDF (91.45 KB)PDF (91.45 KB) of Developing Products for Weight Management Revision 1	02/15/2007	Center for Drug Evaluation and Research	Clinical - Medical	Draft	No		
User Fee Waivers for FDC and Co-Packaged HIV Drugs for PEPFAR	PDF (45.96 KB)PDF (45.96 KB) of User Fee Waivers for FDC and Co-Packaged HIV Drugs for PEPFAR	02/07/2007	Center for Drug Evaluation and Research	User Fees,	Final	No		FDA-2018-D-1635
CPG Sec. 540.600 Fish, Shellfish, Crustaceans and other Aquatic Animals - Fresh, Frozen or Processed - Methyl Mercury		02/06/2007		Investigation & Enforcement,	Final	No		
The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #12		02/01/2007		Investigation & Enforcement, FDA Activities,	Final	No		

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Class II Special Controls Guidance Document: Quality Control Material for Cystic Fibrosis Nucleic Acid Assays: Guidance for Industry and FDA Staff	PDF (116.1 KB)PDF (116.1 KB) of Class II Special Controls Guidance Document: Quality Control Material for Cystic Fibrosis Nucleic Acid Assays: Guidance for Industry and FDA Staff	01/10/2007	Center for Devices and Radiological Health	Premarket,	Final	No		
Guidance for Industry and FDA: Dear Manufacturer Letter Regarding Food Labeling		01/01/2007	Office of Nutrition and Food Labeling	Food & Beverage Safety, Labeling, Food & Beverage Safety	Final	No		FDA-2013-S-0610
Complementary and Alternative Medicine Products and their Regulation by the Food and Drug Administration: Draft Guidance for Industry	PDF (123.98 KB)PDF (123.98 KB) of Complementary and Alternative Medicine Products and their Regulation by the Food and Drug Administration: Draft Guidance for Industry	12/01/2006	Center for Food Safety and Applied Nutrition, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Premarket, Administrative / Procedural, Food & Color Additives	Draft	No	03/01/2006	FDA-2006-D-0102
Process for Handling Referrals to FDA Under 21 CFR 50.54 - Additional Safeguards for Children in Clinical Investigations: Guidance for Clinical Investigators, Institutional Review Boards and Sponsors	PDF (115.95 KB)PDF (115.95 KB) of Process for Handling Referrals to FDA Under 21 CFR 50.54 - Additional Safeguards for Children in Clinical Investigations: Guidance for Clinical Investigators, Institutional Review Boards and Sponsors	12/01/2006	Office of Policy	Good Clinical Practices (GCP)	Final	No		
Decorative, Non-corrective Contact Lenses: Guidance for Industry, FDA Staff, Eye Care Professionals, and Consumers	PDF (55.32 KB)PDF (55.32 KB) of Decorative, Non-corrective Contact Lenses: Guidance for Industry, FDA Staff, Eye Care Professionals, and Consumers	11/24/2006	Center for Devices and Radiological Health		Final	No		
Saline, Silicone Gel, and Alternative Breast Implants: Guidance for Industry and FDA Staff	PDF (592.77 KB)PDF (592.77 KB) of Saline, Silicone Gel, and Alternative Breast Implants: Guidance for Industry and FDA Staff	11/17/2006	Center for Devices and Radiological Health	Premarket,	Final	No		
Prescription Drug Marketing Act (PDMA) Requirements- Questions and Answers	PDF (111.75 KB)PDF (111.75 KB) of Prescription Drug Marketing Act (PDMA) Requirements- Questions and Answers	11/13/2006	Center for Devices and Radiological Health	Compliance, Current Good Manufacturing Practices (CGMP)	Final	No		
CVM GFI #35 Bioequivalence Guidance	PDF (181.84 KB)PDF (181.84 KB) of CVM GFI #35 Bioequivalence Guidance	11/08/2006	Center for Veterinary Medicine	Generic Drugs, Generic Animal Drugs	Final	No		FDA-1994-D-0317
Guidance for Industry: Questions and Answers Regarding Food Allergens (Edition 4)	PDF (506.27 KB)PDF (506.27 KB) of Guidance for Industry: Questions and Answers Regarding Food Allergens (Edition 4)	11/02/2006	Office of Nutrition and Food Labeling	Allergens, Food & Beverage Safety, Labeling	Final	No		FDA-2013-S-0610
Gene Therapy Clinical Trials - Observing Subjects for Delayed Adverse Events: Guidance for Industry	PDF (253.23 KB)PDF (253.23 KB) of Gene Therapy Clinical Trials - Observing Subjects for Delayed Adverse Events: Guidance for Industry	11/01/2006	Center for Biologics Evaluation and Research	Cellular & Gene Therapy, Gene Therapy	Final	No		2005D-0310
Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical Trials Using Retroviral Vectors: Guidance for Industry	PDF (69.18 KB)PDF (69.18 KB) of Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical Trials Using Retroviral Vectors: Guidance for Industry	11/01/2006	Center for Biologics Evaluation and Research	Cellular & Gene Therapy, Gene Therapy	Final	No		99D-4114
Guidance for Industry: Lead in Candy Likely To Be Consumed Frequently by Small Children		10/31/2006	Office of Food Safety	Candy/Gum (without chocolate), Contaminants, Food & Beverage Safety, Potential Metal or Chemical Contaminant, Potential Metal or Chemical Contaminant, Food & Beverage Safety	Final	No		FDA-2013-S-0610

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Exemption from Certain Reporting and Recordkeeping Requirements for Television Receivers and Computer Monitors with Cathode Ray Tubes		10/19/2006			Final	No		
Provision for Alternate Measure of the Computed Tomography Dose Index (CTDI) to Assure Compliance with the Dose Information Requirements of the Federal Performance Standard for Computed Tomography		10/19/2006	Center for Devices and Radiological Health	Postmarket, Radiology	Final	No		1609
Biological Product Deviation Reporting for Blood and Plasma Establishments: Guidance for Industry	PDF (132.07 KB)PDF (132.07 KB) of Biological Product Deviation Reporting for Blood and Plasma Establishments: Guidance for Industry	10/18/2006	Center for Biologics Evaluation and Research	Blood Products	Final	No		2001D-0220
Fixed Dose Combinations, Co-Packaged Drug Products, and Single-Entity Versions of Previously Approved Antiretrovirals for the Treatment of HIV	PDF (342.57 KB)PDF (342.57 KB) of Fixed Dose Combinations, Co-Packaged Drug Products, and Single-Entity Versions of Previously Approved Antiretrovirals for the Treatment of HIV	10/17/2006	Center for Drug Evaluation and Research	Administrative / Procedural	Final	No		
Investigating Out-of-Specification Test Results for Pharmaceutical Production: Guidance for Industry	PDF (85.62 KB)PDF (85.62 KB) of Investigating Out-of-Specification Test Results for Pharmaceutical Production: Guidance for Industry	10/11/2006	Center for Drug Evaluation and Research	Current Good Manufacturing Practices (CGMP), Pharmaceutical Quality	Final	No		
CPG Sec. 100.550 Status and Responsibilities of Contract Sterilizers Engaged in the Sterilization of Drugs and Devices		10/02/2006		Investigation & Enforcement,	Final	No		
Biological Product Deviation Reporting for Licensed Manufacturers of Biological Products Other than Blood and Blood Components	PDF (115.19 KB)PDF (115.19 KB) of Biological Product Deviation Reporting for Licensed Manufacturers of Biological Products Other than Blood and Blood Components	10/01/2006			Final	No		
Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations	PDF (362.89 KB)PDF (362.89 KB) of Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations	09/27/2006	Center for Veterinary Medicine, Office of Regulatory Affairs, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Current Good Manufacturing Practices (CGMP), Pharmaceutical Quality	Final	No		
Public Availability of Labeling Changes in "Changes Being Effected" Supplements	PDF (25.91 KB)PDF (25.91 KB) of Public Availability of Labeling Changes in "Changes Being Effected" Supplements	09/20/2006	Center for Drug Evaluation and Research	Labeling	Final	No		
Keratome and Replacement Keratome Blades Premarket Notification [510(k)] Submissions: Guidance for Industry and FDA Staff	PDF (113.6 KB)PDF (113.6 KB) of Keratome and Replacement Keratome Blades Premarket Notification [510(k)] Submissions: Guidance for Industry and FDA Staff	09/18/2006	Center for Devices and Radiological Health	Premarket, 510(k)	Final	No		
Compliance with 21 CFR Part 1271.150(c)(1) – Manufacturing Arrangements: Guidance for Industry	PDF (45.62 KB)PDF (45.62 KB) of Compliance with 21 CFR Part 1271.150(c)(1) – Manufacturing Arrangements: Guidance for Industry	09/08/2006	Center for Biologics Evaluation and Research	Compliance, Tissue	Final	No		
Early Development Considerations for Innovative Combination Products: Guidance for Industry and FDA Staff	PDF (129.58 KB)PDF (129.58 KB) of Early Development Considerations for Innovative Combination Products: Guidance for Industry and FDA Staff	09/01/2006	Office of Combination Products	Combination Products	Final	No		
Implementing a Collection Program for Source Plasma Containing Disease-Associated and Other Immunoglobulin (IgG) Antibodies: Guidance for Industry	PDF (42.09 KB)PDF (42.09 KB) of Implementing a Collection Program for Source Plasma Containing Disease-Associated and Other Immunoglobulin (IgG) Antibodies: Guidance for Industry	08/08/2006	Center for Biologics Evaluation and Research	Blood Products	Final	No		2005D-0362

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Guidance for Industry: Use of Recycled Plastics in Food Packaging (Chemistry Considerations)		08/07/2006	Office of Food Additive Safety	Contaminants, Food & Beverage Safety, Food & Color Additives, Ingredients, Potential Metal or Chemical Contaminant	Final	No		
Q3B(R) Impurities in New Drug Products (Revision 2)	PDF (171.44 KB)PDF (171.44 KB) of Q3B(R) Impurities in New Drug Products (Revision 2)	08/04/2006	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Quality	Final	No		
Guidance for Industry: Estimating Dietary Intake of Substances in Food		08/01/2006	Office of Food Additive Safety	Food & Color Additives, Ingredients	Final	No		
Class II Special Controls Guidance Document: Fecal Calprotectin Immunological Test Systems	PDF (103.29 KB)PDF (103.29 KB) of Class II Special Controls Guidance Document: Fecal Calprotectin Immunological Test Systems	07/27/2006		Premarket,	Final	No		
CVM GFI #115 (VICH GL22) Safety Studies for Veterinary Drug Residues in Human Food: Reproduction Toxicity Testing	PDF (103.59 KB)PDF (103.59 KB) of CVM GFI #115 (VICH GL22) Safety Studies for Veterinary Drug Residues in Human Food: Reproduction Toxicity Testing	07/27/2006	Center for Veterinary Medicine	Human Food Safety, VICH	Final	No		FDA-2000-D-0784
CVM GFI #141 (VICH GL28) Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Carcinogenicity Testing	PDF (82.76 KB)PDF (82.76 KB) of CVM GFI #141 (VICH GL28) Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Carcinogenicity Testing	07/27/2006	Center for Veterinary Medicine	Human Food Safety, VICH	Final	No		FDA-2001-D-0101
CVM GFI #147 (VICH GL31) Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Repeat-Dose (90 Day) Toxicity Testing	PDF (102.13 KB)PDF (102.13 KB) of CVM GFI #147 (VICH GL31) Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Repeat-Dose (90 Day) Toxicity Testing	07/27/2006	Center for Veterinary Medicine	Human Food Safety, VICH	Final	No		FDA-2002-D-0091
CVM GFI #148 (VICH GL32) Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Developmental Toxicity Testing	PDF (52.06 KB)PDF (52.06 KB) of CVM GFI #148 (VICH GL32) Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Developmental Toxicity Testing	07/27/2006	Center for Veterinary Medicine	Human Food Safety, VICH	Final	No		FDA-2002-D-0090
CVM GFI #160 (VICH GL37) Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Repeat-Dose (Chronic) Toxicity Testing	PDF (75.3 KB)PDF (75.3 KB) of CVM GFI #160 (VICH GL37) Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Repeat-Dose (Chronic) Toxicity Testing	07/27/2006	Center for Veterinary Medicine	Human Food Safety, VICH	Final	No		FDA-2003-D-0372
Class II Special Controls Guidance Document: Fecal Calprotectin Immunological Test Systems - Guidance for Industry and FDA Staff		07/26/2006	Center for Devices and Radiological Health	Premarket,	Final	No		
Useful Written Consumer Medication Information (CMI)	PDF (278.35 KB)PDF (278.35 KB) of Useful Written Consumer Medication Information (CMI)	07/17/2006		Administrative / Procedural	Final	No		
CPG Sec. 608.100 Human-Labeled Drugs Distributed and Used in Animal Medicine (Withdrawn 7/7/2006)		07/07/2006	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement,	Final	No		
CPG Sec. 616.100 Streptomycin Residues in Cattle Tissues (Withdrawn 7/7/2006)		07/06/2006	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Human Food Safety, Animal Drugs	Final	No		
Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use		06/19/2006	Office of Food Additive Safety	Biotechnology, Food & Beverage Safety, Bioengineering / GMOs, Food & Beverage Safety	Final	No		FDA-2013-S-0610

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CVM GFI #176 (VICH GL39) Specifications: Test Procedures and Acceptance Criteria for New Veterinary Drug Substances and New Medicinal Products: Chemical Substances	PDF (277.27 KB)PDF (277.27 KB) of CVM GFI #176 (VICH GL39) Specifications: Test Procedures and Acceptance Criteria for New Veterinary Drug Substances and New Medicinal Products: Chemical Substances	06/14/2006	Center for Veterinary Medicine	Chemistry, Manufacturing, and Controls (CMC), VICH	Final	No		FDA-2005-D-0336
CVM GFI #177 (VICH GL40) Test Procedures/Acceptance Criteria for New Biotechnological/Biological Veterinary Medicinal Products	PDF (286.03 KB)PDF (286.03 KB) of CVM GFI #177 (VICH GL40) Test Procedures/Acceptance Criteria for New Biotechnological/Biological Veterinary Medicinal Products	06/14/2006	Center for Veterinary Medicine	VICH	Final	No		FDA-2005-D-0028
Class II Special Controls Guidance Document: Olfactory Test Device - Guidance for Industry and FDA Staff		06/06/2006	Center for Devices and Radiological Health	Premarket,	Final	No		
Antiviral Product Development--Conducting and Submitting Virology Studies to the Agency	PDF (100.47 KB)PDF (100.47 KB) of Antiviral Product Development--Conducting and Submitting Virology Studies to the Agency	06/02/2006	Center for Drug Evaluation and Research	Clinical - Antimicrobial	Final	No		
Antiviral Product Development--Conducting and Submitting Virology Studies to the Agency : Guidance for Submitting Influenza Resistance Data	PDF (107.75 KB)PDF (107.75 KB) of Antiviral Product Development--Conducting and Submitting Virology Studies to the Agency : Guidance for Submitting Influenza Resistance Data	06/02/2006	Center for Drug Evaluation and Research	Clinical - Antimicrobial	Final	No		
Antiviral Product Development--Conducting and Submitting Virology Studies to the Agency: Guidance for Submitting HCV Resistance Data	PDF (128.2 KB)PDF (128.2 KB) of Antiviral Product Development--Conducting and Submitting Virology Studies to the Agency: Guidance for Submitting HCV Resistance Data	06/02/2006	Center for Drug Evaluation and Research	Clinical - Antimicrobial	Final	No		
Antiviral Product Development--Conducting and Submitting Virology Studies to the Agency: Guidance for Submitting HBV Resistance Data	PDF (84.75 KB)PDF (84.75 KB) of Antiviral Product Development--Conducting and Submitting Virology Studies to the Agency: Guidance for Submitting HBV Resistance Data	06/02/2006	Center for Drug Evaluation and Research	Clinical - Antimicrobial	Final	No		
Antiviral Product Development--Conducting and Submitting Virology Studies to the Agency: Guidance for Submitting HIV Resistance Data	PDF (116.53 KB)PDF (116.53 KB) of Antiviral Product Development--Conducting and Submitting Virology Studies to the Agency: Guidance for Submitting HIV Resistance Data	06/02/2006	Center for Drug Evaluation and Research	Clinical - Antimicrobial	Final	No		
Chronic Cutaneous Ulcer and Burn Wounds -- Developing Products for Treatment	PDF (105.62 KB)PDF (105.62 KB) of Chronic Cutaneous Ulcer and Burn Wounds -- Developing Products for Treatment	06/01/2006	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		FDA-2000-D-0037
CVM GFI #126 BACPAC I-Intermediates in Drug Substance Synthesis Bulk Actives Postapproval Changes: Chemistry, Manufacturing, and Controls Documentation	PDF (134.14 KB)PDF (134.14 KB) of CVM GFI #126 BACPAC I-Intermediates in Drug Substance Synthesis Bulk Actives Postapproval Changes: Chemistry, Manufacturing, and Controls Documentation	06/01/2006	Center for Veterinary Medicine	Chemistry, Manufacturing, and Controls (CMC)	Final	No		
Guidance for Industry: Summary Table of Recommended Toxicological Testing for Additives Used in Food		06/01/2006	Office of Food Additive Safety	Food & Color Additives	Final	No		FDA-2013-S-0610
Q9 Quality Risk Management	PDF (112.63 KB)PDF (112.63 KB) of Q9 Quality Risk Management	06/01/2006	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Quality	Final	No		
Guidance for Industry: Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to CFSAN		05/16/2006	Office of Food Additive Safety	Electronic Submissions Gateway (ESG), Environmental Safety, Food & Color Additives	Final	No		FDA-2013-S-0610

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Guidance for Industry: Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to CFSAN - Appendix C		05/16/2006	Office of Food Additive Safety	Food & Color Additives	Final	No		
Guidance for Industry: Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to CFSAN - Appendix D		05/16/2006	Office of Food Additive Safety	Food & Color Additives	Final	No		
Guidance for Industry: Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to CFSAN - Appendix E (40 CFR 1508.27)		05/16/2006	Office of Food Additive Safety	Food & Color Additives	Final	No		
Guidance for Industry: Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to CFSAN - Attachment 1		05/16/2006	Office of Food Additive Safety	Food & Color Additives	Final	No		
Guidance for Industry: Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to CFSAN - Attachment 2		05/16/2006	Office of Food Additive Safety	Food & Color Additives	Final	No		
Guidance for Industry: FDA's Implementation of Qualified Health Claims		05/12/2006	Office of Nutrition and Food Labeling	Labeling	Final	No		FDA-1998-N-0050
Development of Preventive HIV Vaccines for Use in Pediatric Populations: Guidance for Industry	PDF (63.27 KB)PDF (63.27 KB) of Development of Preventive HIV Vaccines for Use in Pediatric Populations: Guidance for Industry	05/04/2006	Center for Biologics Evaluation and Research	Vaccines	Final	No		
Compliance with Section 301 of the Medical Device User Fee and Modernization Act of 2002, as amended – Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices: Guidance for Industry and FDA Staff	PDF (250 KB)PDF (250 KB) of Compliance with Section 301 of the Medical Device User Fee and Modernization Act of 2002, as amended – Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices: Guidance for Industry and FDA Staff	05/01/2006	Center for Devices and Radiological Health	Postmarket, User Fees, Labeling	Final	No		
CVM GFI #117 (VICH GL24) Management of Adverse Event Reports (AER's)	PDF (121.27 KB)PDF (121.27 KB) of CVM GFI #117 (VICH GL24) Management of Adverse Event Reports (AER's)	05/01/2006	Center for Veterinary Medicine	Adverse Event Reporting, VICH	Draft	No		FDA-2000-D-0136
Guidance for Industry: Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to CFSAN - Appendix A		05/01/2006	Office of Food Additive Safety	Food & Color Additives	Final	No		
Guidance for Industry: Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to CFSAN - Appendix B		05/01/2006	Office of Food Additive Safety	Food & Color Additives	Final	No		
Real-Time Premarket Approval Application (PMA) Supplements: Guidance for Industry and FDA Staff	PDF (81.81 KB)PDF (81.81 KB) of Real-Time Premarket Approval Application (PMA) Supplements: Guidance for Industry and FDA Staff	04/28/2006	Center for Devices and Radiological Health	Premarket, Premarket Approval (PMA)	Final	No		
Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable : Guidance for Sponsors, Institutional Review Boards, and Food and Drug Administration Staff	PDF (368.81 KB)PDF (368.81 KB) of Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable : Guidance for Sponsors, Institutional Review Boards, and Food and Drug Administration Staff	04/25/2006	Center for Devices and Radiological Health, Office of Blood Research and Review	Premarket, Good Clinical Practices (GCP)	Final	No		
Exocrine Pancreatic Insufficiency Drug Products--Submitting New Drug Applications	PDF (69.67 KB)PDF (69.67 KB) of Exocrine Pancreatic Insufficiency Drug Products--Submitting New Drug Applications	04/13/2006	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		
S8 Immunotoxicity Studies for Human Pharmaceuticals	PDF (72.49 KB)PDF (72.49 KB) of S8 Immunotoxicity Studies for Human Pharmaceuticals	04/12/2006	Center for Drug Evaluation and Research	ICH-Safety	Final	No		
Dental Curing Lights - Premarket Notification [510(k)]: Guidance for Industry and FDA Staff	PDF (193.97 KB)PDF (193.97 KB) of Dental Curing Lights - Premarket Notification [510(k)]: Guidance for Industry and FDA Staff	03/27/2006	Center for Devices and Radiological Health	Premarket, 510(k), Dental	Final	No		

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Tonometers - Premarket Notification [510(k)] Submissions : Guidance for Industry and FDA Staff	PDF (232.63 KB)PDF (232.63 KB) of Tonometers - Premarket Notification [510(k)] Submissions : Guidance for Industry and FDA Staff	03/27/2006	Center for Devices and Radiological Health	Premarket, 510(k)	Final	No		
Class II Special Controls Guidance Document: Reagents for Detection of Specific Novel Influenza A Viruses - Guidance for Industry and FDA Staff		03/21/2006	Center for Devices and Radiological Health	Premarket,	Final	No		
Nonclinical Safety Evaluation of Drug or Biologic Combinations	PDF (99.71 KB)PDF (99.71 KB) of Nonclinical Safety Evaluation of Drug or Biologic Combinations	03/15/2006	Center for Drug Evaluation and Research	Pharm/Tox	Final	No		2005D-0004
Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment: Guidance for Industry and FDA Staff	PDF (978.13 KB)PDF (978.13 KB) of Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment: Guidance for Industry and FDA Staff	03/10/2006	Center for Devices and Radiological Health	Postmarket,	Final	No		
Establishment and Operation of Clinical Trial Data Monitoring Committees: Guidance for Clinical Trial Sponsors	PDF (204.31 KB)PDF (204.31 KB) of Establishment and Operation of Clinical Trial Data Monitoring Committees: Guidance for Clinical Trial Sponsors	03/01/2006	Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Clinical - Medical, Good Clinical Practices (GCP)	Final	No		
Guidance for Industry: Frequently Asked Questions about FDA's Regulation of Infant Formula		03/01/2006	Office of Food Safety	Infant Formula & Foods	Final	No		FDA-2013-S-0610
Internal Radioactive Contamination —Development of Decorporation Agents	PDF (176.7 KB)PDF (176.7 KB) of Internal Radioactive Contamination —Development of Decorporation Agents	03/01/2006	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		
Prescription Drug Marketing Act — Donation of Prescription Drug Samples to Free Clinics	PDF (37.79 KB)PDF (37.79 KB) of Prescription Drug Marketing Act — Donation of Prescription Drug Samples to Free Clinics	03/01/2006	Center for Drug Evaluation and Research	Compliance, Current Good Manufacturing Practices (CGMP)	Final	No		
Using a Centralized IRB Review Process in Multicenter Clinical Trials: Guidance for Industry	PDF (734.96 KB)PDF (734.96 KB) of Using a Centralized IRB Review Process in Multicenter Clinical Trials: Guidance for Industry	02/28/2006	Office of Regulatory Affairs, Office of Good Clinical Practice, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Administrative / Procedural, Good Clinical Practices (GCP)	Final	No		
Using Electronic Means to Distribute Certain Product Information: Guidance for Industry		02/28/2006	Office of Policy	Administrative / Procedural, Food & Color Additives	Final	No		
Draft Guidance for Industry and FDA Staff: Whole Grain Label Statements		02/17/2006	Office of Nutrition and Food Labeling	Food & Beverage Safety, Labeling, Food & Beverage Safety	Draft	No	04/18/2006	FDA-2006-D-0298
Nonclinical Safety Evaluation of Pediatric Drug Products	PDF (478.84 KB)PDF (478.84 KB) of Nonclinical Safety Evaluation of Pediatric Drug Products	02/15/2006	Center for Drug Evaluation and Research	Pharm/Tox	Final	No		2003D-0001
Reports on the Status of Postmarketing Study Commitments — Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997	PDF (455.98 KB)PDF (455.98 KB) of Reports on the Status of Postmarketing Study Commitments — Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997	02/15/2006	Center for Drug Evaluation and Research	Administrative / Procedural	Final	No		
Class II Special Controls Guidance Document: Implantable Intra-Aneurysm Pressure Measurement System - Guidance for Industry and FDA Staff		02/14/2006	Center for Devices and Radiological Health	Premarket,	Final	No		
Pharmacogenetic Tests and Genetic Tests for Heritable Markers: Guidance for Industry and FDA Staff	PDF (66.47 KB)PDF (66.47 KB) of Pharmacogenetic Tests and Genetic Tests for Heritable Markers: Guidance for Industry and FDA Staff	02/09/2006	Center for Devices and Radiological Health	Premarket,	Final	No		

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Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Hepatitis A Virus Serological Assays		02/08/2006	Center for Devices and Radiological Health	Premarket,	Final	No		
Considerations for Developmental Toxicity Studies for Preventive and Therapeutic Vaccines for Infectious Disease Indications: Guidance for Industry	PDF (53.02 KB)PDF (53.02 KB) of Considerations for Developmental Toxicity Studies for Preventive and Therapeutic Vaccines for Infectious Disease Indications: Guidance for Industry	02/01/2006	Center for Biologics Evaluation and Research	Vaccines	Final	No		2000D-1400
Providing Regulatory Submissions in Electronic Format Orphan-Drug and Humanitarian Use Device Designation Requests and Related Submissions: Draft Draft Guidance for Industry	PDF (128.17 KB)PDF (128.17 KB) of Providing Regulatory Submissions in Electronic Format Orphan-Drug and Humanitarian Use Device Designation Requests and Related Submissions: Draft Draft Guidance for Industry	02/01/2006	Office of Orphan Products Development	Administrative / Procedural	Draft	No		
Adverse Reactions Section of Labeling for Human Prescription Drug and Biological Products — Content and Format	PDF (51.79 KB)PDF (51.79 KB) of Adverse Reactions Section of Labeling for Human Prescription Drug and Biological Products — Content and Format	01/18/2006	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Labeling	Final	No		
Clinical Studies Section of Labeling for Human Prescription Drug and Biological Products — Content and Format: Guidance for Industry	PDF (126.9 KB)PDF (126.9 KB) of Clinical Studies Section of Labeling for Human Prescription Drug and Biological Products — Content and Format: Guidance for Industry	01/18/2006	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Good Clinical Practices (GCP), Labeling	Final	No		
Exploratory IND Studies: Guidance for Industry, Investigators, and Reviewers	PDF (219.74 KB)PDF (219.74 KB) of Exploratory IND Studies: Guidance for Industry, Investigators, and Reviewers	01/12/2006	Center for Drug Evaluation and Research	Good Clinical Practices (GCP), Pharm/Tox	Final	No		
Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical CGMP_PRA	PDF (249.28 KB)PDF (249.28 KB) of Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical CGMP_PRA	01/11/2006	Center for Veterinary Medicine, Office of Regulatory Affairs, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Current Good Manufacturing Practices (CGMP), Pharmaceutical Quality	Final	No		
CVM GFI #166 (VICH GL38) Environmental Impact Assessments (EIA's) for Veterinary Medicinal Products (VMP's) - Phase II	PDF (427.09 KB)PDF (427.09 KB) of CVM GFI #166 (VICH GL38) Environmental Impact Assessments (EIA's) for Veterinary Medicinal Products (VMP's) - Phase II	01/09/2006	Center for Veterinary Medicine	Environmental Safety, VICH	Final	No		FDA-2004-D-0273
CVM GFI #123 Development of Data Supporting Approval of NSAIDS for Use in Animals	PDF (52.46 KB)PDF (52.46 KB) of CVM GFI #123 Development of Data Supporting Approval of NSAIDS for Use in Animals	01/05/2006	Center for Veterinary Medicine	Target Animal – Effectiveness, Target Animal – Safety	Final	No		FDA-2004-D-0372
Exemption from Reporting and Recordkeeping Requirements for Low Power Laser Products (Laser Notice 54)		01/05/2006			Final	No		
Recommended Approaches to Integration of Genetic Toxicology Study Results	PDF (189.87 KB)PDF (189.87 KB) of Recommended Approaches to Integration of Genetic Toxicology Study Results	01/03/2006		Pharm/Tox	Final	No		
FDA Institutional Review Board Inspections: Guidance For IRBs, Clinical Investigators, and Sponsors	PDF (37.77 KB)PDF (37.77 KB) of FDA Institutional Review Board Inspections: Guidance For IRBs, Clinical Investigators, and Sponsors	01/01/2006	Office of Good Clinical Practice	Administrative / Procedural, Good Clinical Practices (GCP)	Final	No		

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Frequently Asked Questions About Medical Devices: Guidance For IRBs, Clinical Investigators, and Sponsors	PDF (266.36 KB)PDF (266.36 KB) of Frequently Asked Questions About Medical Devices: Guidance For IRBs, Clinical Investigators, and Sponsors	01/01/2006	Office of Good Clinical Practice, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Good Clinical Practices (GCP)	Final	No		
Redbook 2000: IV.C.6. Carcinogenicity Studies with Rodents		01/01/2006	Office of Food Additive Safety	Food & Color Additives	Final	No		
Significant Risk and Nonsignificant Risk Medical Device Studies: Guidance For IRBs, Clinical Investigators, and Sponsors	PDF (210.91 KB)PDF (210.91 KB) of Significant Risk and Nonsignificant Risk Medical Device Studies: Guidance For IRBs, Clinical Investigators, and Sponsors	01/01/2006	Office of Good Clinical Practice, Center for Devices and Radiological Health	Good Clinical Practices (GCP)	Final	No		
Guidance for Industry and FDA Staff: Guidance for Records Access Authority Provided in Title III, Subtitle A, of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002		11/30/2005	Center for Food Safety and Applied Nutrition, Office of Regulatory Affairs	Records	Final	No		FDA-2013-S-0610
CPG Sec. 500.200 Food Additives -"GRAS"		11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 500.425 Use of Color Additives in Paper and Paperboard Intended for Use with Food		11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 500.450 Volatile N-Nitrosamines in Rubber Baby Bottle Nipples		11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 505.100 Bakery Products, Candy - "Catch-All" or "Shotgun" Ingredients Declaration		11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 510.400 Dealcoholized Wine and Malt Beverages - Labeling		11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 510.500 Green Coffee Beans - Adulteration with Insects; Mold	PDF (12.51 KB)PDF (12.51 KB) of CPG Sec. 510.500 Green Coffee Beans - Adulteration with Insects; Mold	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 510.600 Dimethylnitrosamine in Malt Beverages		11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 515.750 Cocoa Beans - Adulteration by Mold, Insect Infestation, and Mammalian Excreta	PDF (10.63 KB)PDF (10.63 KB) of CPG Sec. 515.750 Cocoa Beans - Adulteration by Mold, Insect Infestation, and Mammalian Excreta	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 515.775 Cocoa Powder, Press Cake - Adulteration with Insect and Rodent Filth	PDF (10.63 KB)PDF (10.63 KB) of CPG Sec. 515.775 Cocoa Powder, Press Cake - Adulteration with Insect and Rodent Filth	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 525.150 Bay (Laurel) Leaves - Adulteration by Insect Filth; Mold; Mammalian Excreta	PDF (10.25 KB)PDF (10.25 KB) of CPG Sec. 525.150 Bay (Laurel) Leaves - Adulteration by Insect Filth; Mold; Mammalian Excreta	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 525.200 Capsicum Pods, Ground Capsicums Excluding Paprika, Ground Paprika - Adulteration with Insect and Rodent Filth, Mold, Mammalian Excreta	PDF (11.41 KB)PDF (11.41 KB) of CPG Sec. 525.200 Capsicum Pods, Ground Capsicums Excluding Paprika, Ground Paprika - Adulteration with Insect and Rodent Filth, Mold, Mammalian Excreta	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 525.250 Cloves - Adulteration with Stems	PDF (8.82 KB)PDF (8.82 KB) of CPG Sec. 525.250 Cloves - Adulteration with Stems	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 525.300 Condimental Seeds Other than Fennel Seeds and Sesame Seeds - Adulteration by Mammalian Excreta	PDF (9.13 KB)PDF (9.13 KB) of CPG Sec. 525.300 Condimental Seeds Other than Fennel Seeds and Sesame Seeds - Adulteration by Mammalian Excreta	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 525.325 Cumin Seed - Adulteration with Sand and Grit	PDF (8.88 KB)PDF (8.88 KB) of CPG Sec. 525.325 Cumin Seed - Adulteration with Sand and Grit	11/29/2005		Investigation & Enforcement,	Final	No		

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CPG Sec. 525.330 Curry Powder - Adulteration by Insect and Rodent Filth	PDF (9.43 KB)PDF (9.43 KB) of CPG Sec. 525.330 Curry Powder - Adulteration by Insect and Rodent Filth	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 525.350 Fennel Seed - Adulteration by Mammalian Excreta; Insects	PDF (9.67 KB)PDF (9.67 KB) of CPG Sec. 525.350 Fennel Seed - Adulteration by Mammalian Excreta; Insects	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 525.375 Whole Ginger - Adulteration with Insect Filth; Mold; Mammalian Excreta	PDF (9.75 KB)PDF (9.75 KB) of CPG Sec. 525.375 Whole Ginger - Adulteration with Insect Filth; Mold; Mammalian Excreta	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 525.500 Leafy Spices, Other than Bay Leaves - Whole Oregano Leaves, Whole Marjoram, Whole Sage Leaves and Whole Thyme Leaves - Adulteration with Insect Filth; Mold; Mammalian Excreta	PDF (10.7 KB)PDF (10.7 KB) of CPG Sec. 525.500 Leafy Spices, Other than Bay Leaves - Whole Oregano Leaves, Whole Marjoram, Whole Sage Leaves and Whole Thyme Leaves - Adulteration with Insect Filth; Mold; Mammalian Excreta	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 525.550 Mace - Adulteration with Insect Filth; Mold; Foreign Matter; Mammalian Excreta	PDF (10.35 KB)PDF (10.35 KB) of CPG Sec. 525.550 Mace - Adulteration with Insect Filth; Mold; Foreign Matter; Mammalian Excreta	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 525.600 Whole and Ground Nutmeg - Adulteration with Insect Filth; Mold; Rodent Filth	PDF (10.27 KB)PDF (10.27 KB) of CPG Sec. 525.600 Whole and Ground Nutmeg - Adulteration with Insect Filth; Mold; Rodent Filth	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 525.625 Whole and Ground Pepper - Adulteration with Insect & Rodent Filth; Mold; Mammalian Excreta; Foreign Matter	PDF (11.26 KB)PDF (11.26 KB) of CPG Sec. 525.625 Whole and Ground Pepper - Adulteration with Insect & Rodent Filth; Mold; Mammalian Excreta; Foreign Matter	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 525.700 Sesame Seeds - Adulteration with Insect Filth; Decomposition; Mammalian Excreta; Foreign Matter	PDF (10.59 KB)PDF (10.59 KB) of CPG Sec. 525.700 Sesame Seeds - Adulteration with Insect Filth; Decomposition; Mammalian Excreta; Foreign Matter	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 525.850 Whole Plant (Unprocessed) Oregano, Crushed Oregano & Ground Oregano - Adulteration by Insect & Rodent Filth; Mold; Mammalian Excreta	PDF (11.82 KB)PDF (11.82 KB) of CPG Sec. 525.850 Whole Plant (Unprocessed) Oregano, Crushed Oregano & Ground Oregano - Adulteration by Insect & Rodent Filth; Mold; Mammalian Excreta	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 525.900 Whole Plant (Unprocessed) Marjoram, Unground (Processed) Marjoram & Ground Marjoram - Adulteration by Insect & Rodent Filth; Mold; Mammalian Excreta	PDF (12.13 KB)PDF (12.13 KB) of CPG Sec. 525.900 Whole Plant (Unprocessed) Marjoram, Unground (Processed) Marjoram & Ground Marjoram - Adulteration by Insect & Rodent Filth; Mold; Mammalian Excreta	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 525.925 Whole Plant (Unprocessed) Thyme, Unground (Processed) Thyme & Ground Thyme - Adulteration by Insect & Rodent Filth; Mold; Mammalian Excreta	PDF (12.21 KB)PDF (12.21 KB) of CPG Sec. 525.925 Whole Plant (Unprocessed) Thyme, Unground (Processed) Thyme & Ground Thyme - Adulteration by Insect & Rodent Filth; Mold; Mammalian Excreta	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 525.950 Whole Plant (Unprocessed) Sage, and Ground Sage - Adulteration by Insect and Rodent Filth; Mold; Mammalian Excreta	PDF (11.59 KB)PDF (11.59 KB) of CPG Sec. 525.950 Whole Plant (Unprocessed) Sage, and Ground Sage - Adulteration by Insect and Rodent Filth; Mold; Mammalian Excreta	11/29/2005		Investigation & Enforcement,	Final	No		

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CPG Sec. 527.100 Butter - Adulteration Involving Insufficient Fat Content	PDF (15.26 KB)PDF (15.26 KB) of CPG Sec. 527.100 Butter - Adulteration Involving Insufficient Fat Content	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 527.225 Cheese - Misbranding Due to Moisture and Fat	PDF (11.48 KB)PDF (11.48 KB) of CPG Sec. 527.225 Cheese - Misbranding Due to Moisture and Fat	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 535.100 Oleomargarine - Misbranding Due to Insufficient Fat	PDF (9.88 KB)PDF (9.88 KB) of CPG Sec. 535.100 Oleomargarine - Misbranding Due to Insufficient Fat	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 537.100 Eggs and Egg Products - Frozen - Adulteration Involving Decomposition	PDF (10.26 KB)PDF (10.26 KB) of CPG Sec. 537.100 Eggs and Egg Products - Frozen - Adulteration Involving Decomposition	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 540.420 Raw Breaded Shrimp - Microbiological Criteria for Evaluating Compliance with Current Good Manufacturing Practice Regulations		11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 540.500 Tuna, Sable, Salmon, Shad-Smoked Cured, Adulteration Involving Food Additives, Sodium Nitrite		11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 540.525 Decomposition and Histamine Raw, Frozen Tuna and Mahi-Mahi; Canned Tuna; and Related Species		11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 540.590 Fish - Fresh and Frozen, as Listed - Adulteration by Parasites	PDF (11.85 KB)PDF (11.85 KB) of CPG Sec. 540.590 Fish - Fresh and Frozen, as Listed - Adulteration by Parasites	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 540.650 Uneviscerated Fish Products that are Salt-cured, Dried, or Smoked (Revised)		11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 545.300 Foods, Rail Car Sanitation - Adulteration	PDF (12.92 KB)PDF (12.92 KB) of CPG Sec. 545.300 Foods, Rail Car Sanitation - Adulteration	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 545.400 Pottery (Ceramics); Import and Domestic - Cadmium Contamination	PDF (14.65 KB)PDF (14.65 KB) of CPG Sec. 545.400 Pottery (Ceramics); Import and Domestic - Cadmium Contamination	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 545.450 Pottery (Ceramics); Import and Domestic - Lead Contamination	PDF (17.67 KB)PDF (17.67 KB) of CPG Sec. 545.450 Pottery (Ceramics); Import and Domestic - Lead Contamination	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 545.500 Silver-Plated Hollowware - Lead Contamination	PDF (14.47 KB)PDF (14.47 KB) of CPG Sec. 545.500 Silver-Plated Hollowware - Lead Contamination	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 545.600 Cinnamon-Flavored Toothpicks	PDF (8.93 KB)PDF (8.93 KB) of CPG Sec. 545.600 Cinnamon-Flavored Toothpicks	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 550.100 Apple Butter - Adulteration with Mold; Rodent Filth, Insect	PDF (10.52 KB)PDF (10.52 KB) of CPG Sec. 550.100 Apple Butter - Adulteration with Mold; Rodent Filth, Insect	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 550.150 Apricots - Canned - Adulteration with Insects	PDF (9.54 KB)PDF (9.54 KB) of CPG Sec. 550.150 Apricots - Canned - Adulteration with Insects	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 550.155 Apricot, Peach and Pear Nectars and Purees - Adulteration with Mold	PDF (11.59 KB)PDF (11.59 KB) of CPG Sec. 550.155 Apricot, Peach and Pear Nectars and Purees - Adulteration with Mold	11/29/2005		Investigation & Enforcement,	Final	No		

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CPG Sec. 550.200 Drupelet Berries (Blackberries, Raspberries, Etc.) - Common or Usual Names of Varieties; Canned and Frozen - Adulteration with Rot and Insects	PDF (15.51 KB)PDF (15.51 KB) of CPG Sec. 550.200 Drupelet Berries (Blackberries, Raspberries, Etc.) - Common or Usual Names of Varieties; Canned and Frozen - Adulteration with Rot and Insects	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 550.225 Cherries Brined, Fresh, Canned and Frozen - Adulteration Involving Rot and Insect	PDF (9.65 KB)PDF (9.65 KB) of CPG Sec. 550.225 Cherries Brined, Fresh, Canned and Frozen - Adulteration Involving Rot and Insect	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 550.230 Cherries, Canned - Misbranding Involving Food Standards	PDF (12.42 KB)PDF (12.42 KB) of CPG Sec. 550.230 Cherries, Canned - Misbranding Involving Food Standards	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 550.300 Dates and Date Material; Imported and Domestic - Adulteration Involving Mold, Insect Excreta, Sour, Dirty, Worthless and Pits	PDF (22.01 KB)PDF (22.01 KB) of CPG Sec. 550.300 Dates and Date Material; Imported and Domestic - Adulteration Involving Mold, Insect Excreta, Sour, Dirty, Worthless and Pits	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 550.350 Figs; Fig Paste - Adulteration Involving Insect Infestation; Mold, Dirt	PDF (10.24 KB)PDF (10.24 KB) of CPG Sec. 550.350 Figs; Fig Paste - Adulteration Involving Insect Infestation; Mold, Dirt	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 550.500 Lingon Berries, Canned - Adulteration by Insects	PDF (9.45 KB)PDF (9.45 KB) of CPG Sec. 550.500 Lingon Berries, Canned - Adulteration by Insects	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 550.600 Olives - Adulteration Involving Pits; Rot; Insect Infestation	PDF (14.61 KB)PDF (14.61 KB) of CPG Sec. 550.600 Olives - Adulteration Involving Pits; Rot; Insect Infestation	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 550.655 Peaches, Canned - Misbranding Involving Food Standards	PDF (13.61 KB)PDF (13.61 KB) of CPG Sec. 550.655 Peaches, Canned - Misbranding Involving Food Standards	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 550.685 Pineapple, Canned; Imported and Domestic - Misbranding Involving Food Standards	PDF (16.26 KB)PDF (16.26 KB) of CPG Sec. 550.685 Pineapple, Canned; Imported and Domestic - Misbranding Involving Food Standards	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 550.690 Plums, Canned - Adulteration with Rot	PDF (9.43 KB)PDF (9.43 KB) of CPG Sec. 550.690 Plums, Canned - Adulteration with Rot	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 550.700 Dried Prunes, Dehydrated Low Moisture Prunes, and Pitted Prunes - Adulteration Involving Insects; Decomposition; Dirt; Pits; and Pit Fragments	PDF (11.29 KB)PDF (11.29 KB) of CPG Sec. 550.700 Dried Prunes, Dehydrated Low Moisture Prunes, and Pitted Prunes - Adulteration Involving Insects; Decomposition; Dirt; Pits; and Pit Fragments	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 550.750 Raisins - Adulteration Involving Mold, Sand, Grit, & Insects	PDF (9.93 KB)PDF (9.93 KB) of CPG Sec. 550.750 Raisins - Adulteration Involving Mold, Sand, Grit, & Insects	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 550.800 Standardized Canned Fruit - Misbranding Involving Improper Declaration of Packing Medium	PDF (10.36 KB)PDF (10.36 KB) of CPG Sec. 550.800 Standardized Canned Fruit - Misbranding Involving Improper Declaration of Packing Medium	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 550.850 Strawberries; Frozen, Whole, or Sliced - Adulteration with Sand, Mold	PDF (10.12 KB)PDF (10.12 KB) of CPG Sec. 550.850 Strawberries; Frozen, Whole, or Sliced - Adulteration with Sand, Mold	11/29/2005		Investigation & Enforcement,	Final	No		

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CPG Sec. 560.200 Country of Origin Labeling	PDF (13.81 KB)PDF (13.81 KB) of CPG Sec. 560.200 Country of Origin Labeling	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 560.600 Clams, Mussels, Oysters; Fresh or Frozen - Adulteration by Bacteriological Contamination		11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 560.750 Radionuclides in Imported Foods - Levels of Concern	PDF (22.83 KB)PDF (22.83 KB) of CPG Sec. 560.750 Radionuclides in Imported Foods - Levels of Concern	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 562.200 Foods - FPLA Compliance		11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 562.550 Safety and Labeling of Waxed (Coated) Fruits and Vegetables		11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 565.100 FDA Jurisdiction Over Meat and Poultry Products		11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 570.200 Brazil Nuts - Adulteration with Aflatoxin	PDF (10.49 KB)PDF (10.49 KB) of CPG Sec. 570.200 Brazil Nuts - Adulteration with Aflatoxin	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 570.300 Peanut Butter - Adulteration with Filth; Grit	PDF (12.54 KB)PDF (12.54 KB) of CPG Sec. 570.300 Peanut Butter - Adulteration with Filth; Grit	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 570.350 Peanuts, Shelled and Unshelled - Adulteration with Filth and Reject Nuts	PDF (11.77 KB)PDF (11.77 KB) of CPG Sec. 570.350 Peanuts, Shelled and Unshelled - Adulteration with Filth and Reject Nuts	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 570.375 Aflatoxin in Peanuts and Peanut Products	PDF (13.85 KB)PDF (13.85 KB) of CPG Sec. 570.375 Aflatoxin in Peanuts and Peanut Products	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 570.425 Tree Nuts - Adulteration Involving Rejects (Insect Infestation, Moldy, Rancid, Otherwise Decomposed, Blanks, and Shriveled)	PDF (17.86 KB)PDF (17.86 KB) of CPG Sec. 570.425 Tree Nuts - Adulteration Involving Rejects (Insect Infestation, Moldy, Rancid, Otherwise Decomposed, Blanks, and Shriveled)	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 570.450 Tree Nuts - Adulteration with Filth, Involving the Presence of the Organism Escherichia coli	PDF (13.08 KB)PDF (13.08 KB) of CPG Sec. 570.450 Tree Nuts - Adulteration with Filth, Involving the Presence of the Organism Escherichia coli	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 570.500 Pistachio Nuts - Aflatoxin Adulteration	PDF (11.1 KB)PDF (11.1 KB) of CPG Sec. 570.500 Pistachio Nuts - Aflatoxin Adulteration	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 570.700 Mixed Nuts - Misbranding Involving Food Standards		11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 580.100 Food Storage and Warehousing-Adulteration-Filth (Domestic and Import)	PDF (27.04 KB)PDF (27.04 KB) of CPG Sec. 580.100 Food Storage and Warehousing-Adulteration-Filth (Domestic and Import)	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 585.200 Beets, Canned - Adulteration with Rot	PDF (8.87 KB)PDF (8.87 KB) of CPG Sec. 585.200 Beets, Canned - Adulteration with Rot	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 585.275 Brussels Sprouts, Frozen - Adulteration by Insects	PDF (9.37 KB)PDF (9.37 KB) of CPG Sec. 585.275 Brussels Sprouts, Frozen - Adulteration by Insects	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 585.300 Corn, Sweet; Canned - Adulteration by Corn Ear Worms, Corn Borers	PDF (9.91 KB)PDF (9.91 KB) of CPG Sec. 585.300 Corn, Sweet; Canned - Adulteration by Corn Ear Worms, Corn Borers	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 585.400 Cowpeas (Black-Eyed Peas); Canned (Succulent Peas) - Adulteration by Insects	PDF (9.81 KB)PDF (9.81 KB) of CPG Sec. 585.400 Cowpeas (Black-Eyed Peas); Canned (Succulent Peas) - Adulteration by Insects	11/29/2005		Investigation & Enforcement,	Final	No		

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CPG Sec. 585.575 Peas and Beans; Dried - Adulteration Involving Storage, Insect Damage, Rocks	PDF (14.46 KB)PDF (14.46 KB) of CPG Sec. 585.575 Peas and Beans; Dried - Adulteration Involving Storage, Insect Damage, Rocks	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 585.775 Spinach, Canned or Frozen - Adulteration Involving Insects, Decomposition	PDF (11.95 KB)PDF (11.95 KB) of CPG Sec. 585.775 Spinach, Canned or Frozen - Adulteration Involving Insects, Decomposition	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 585.825 Sweet Potatoes - Dyeing of Yellow and Red Varieties	PDF (13.53 KB)PDF (13.53 KB) of CPG Sec. 585.825 Sweet Potatoes - Dyeing of Yellow and Red Varieties	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 587.100 Label Declaration of Certification-Exempt Color Additives		11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 587.300 Color Additives	PDF (9.33 KB)PDF (9.33 KB) of CPG Sec. 587.300 Color Additives	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 590.300 Direct Reference Authority for Pseudomonas Contamination of Cosmetics Used in the Eye Area	PDF (9.57 KB)PDF (9.57 KB) of CPG Sec. 590.300 Direct Reference Authority for Pseudomonas Contamination of Cosmetics Used in the Eye Area	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 590.400 Natural Bristle Brushes (i.e., Hair Brushes, Shaving Brushes) - Nit Contamination	PDF (9.28 KB)PDF (9.28 KB) of CPG Sec. 590.400 Natural Bristle Brushes (i.e., Hair Brushes, Shaving Brushes) - Nit Contamination	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 590.500 Packaging Technologies and Tamper-Resistant Packaging Requirements for Cosmetic Products		11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec.510.150 Apple Juice, Apple Juice Concentrates, and Apple Juice Products - Adulteration with Patulin		11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec.585.475 Canned Green Beans and Canned Wax Beans - Misbranding Involving Food Standards	PDF (16.69 KB)PDF (16.69 KB) of CPG Sec.585.475 Canned Green Beans and Canned Wax Beans - Misbranding Involving Food Standards	11/29/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 160.100 Regulatory Actions and Small Business		11/28/2005		Investigation & Enforcement, Food & Color Additives	Final	No		
CPG Sec. 520.300 Acidified Low-Acid Canned Foods - Adulteration Due to High pH		11/28/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 525.100 Whole & Ground Allspice - Adulteration by Mold; Insect & Rodent Filth		11/28/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 525.575 Prepared Mustard - Composition		11/28/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 525.800 Tomato Sauce or Tomato Hot Sauce Labeling		11/28/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 527.250 Cheese & Cheese Products - Misbranding Involving Net Contents		11/28/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 527.350 Eggnog; Egg Nog Flavored Milk - Common or Usual Names		11/28/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 527.400 Whole Milk, Lowfat Milk, Skim Milk - Aflatoxin M1		11/28/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 530.500 Wheat Germ Containing Non-Wheat Germ Tissue		11/28/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 540.200 Chubs, Hot Process Smoked with Added Nitrite - Adulteration Involving Food Additives, Sodium Nitrite		11/28/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 540.250 Clams, Mussels, Oysters, Fresh, Frozen or Canned - Paralytic Shellfish Poison		11/28/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 540.410 Shrimp - Frozen, Raw, Breaded or Lightly Breaded, Misbranding Involving Non-Compliance with Standards		11/28/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 550.475 Jellies, Nonstandardized		11/28/2005		Investigation & Enforcement,	Final	No		

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CPG Sec. 550.605 Olives Stuffed with Minced Pimentos - Labeling		11/28/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 550.650 Peaches, Canned, Frozen - Adulteration Due to Insects and Mold		11/28/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 555.400 Foods - Adulteration with Aflatoxin		11/28/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 578.500 Dimethylnitrosamine (DMNA) in Barley Malt		11/28/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 585.325 Corn on the Cob, Canned - Quantity of Contents Declaration		11/28/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 585.500 Mushrooms, Canned or Dried (Freeze-Dried or Dehydrated) - Adulteration Involving Maggots, Mites, Decomposition		11/28/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 585.750 Sauerkraut - Definition; Adulteration by Thrips		11/28/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 585.875 Tomatoes - Canned - Misbranding Involving Food Standards (Peel)	PDF (10.64 KB)PDF (10.64 KB) of CPG Sec. 585.875 Tomatoes - Canned - Misbranding Involving Food Standards (Peel)	11/25/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 585.890 Tomato Products - Adulteration with Drosophila Fly Eggs and Maggots	PDF (11.29 KB)PDF (11.29 KB) of CPG Sec. 585.890 Tomato Products - Adulteration with Drosophila Fly Eggs and Maggots	11/25/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 585.900 Tomato Products - Adulteration with Mold	PDF (20.94 KB)PDF (20.94 KB) of CPG Sec. 585.900 Tomato Products - Adulteration with Mold	11/25/2005		Investigation & Enforcement,	Final	No		
CVM GFI #135 Validation of Analytical Procedures for Type C Medicated Feeds	PDF (106.96 KB)PDF (106.96 KB) of CVM GFI #135 Validation of Analytical Procedures for Type C Medicated Feeds	11/07/2005	Center for Veterinary Medicine	Chemistry, Manufacturing, and Controls (CMC), Animal Feed	Final	No		FDA-2004-D-0370
Class II Special Controls Guidance Document: Low Energy Ultrasound Wound Cleaner - Guidance for Industry and FDA Staff		11/06/2005	Center for Devices and Radiological Health	Premarket,	Final	No		
Applicability of the Performance Standard for High-Intensity Mercury Vapor Discharge Lamps (21 CFR 1040.30)		11/05/2005			Final	No		
Guidance for Industry: Notice to Growers, Food Manufacturers, Food Warehouse Managers, and Transporters of Food Products on Decontamination of Transport Vehicles		11/01/2005	Office of Food Safety	Natural Disaster, Food & Beverage Safety, Sanitation, Transportation, Retail Food Protection	Final	No		FDA-2005-D-0337
Class II Special Controls Guidance Document: CFTR Gene Mutation Detection Systems - Guidance for Industry and FDA Staff		10/25/2005	Center for Devices and Radiological Health	Premarket,	Final	No		
Dental Composite Resin Devices - Premarket Notification [510(k)] Submissions - Guidance for Industry and FDA Staff		10/25/2005	Center for Devices and Radiological Health	Premarket,	Final	No		
E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs	PDF (97.84 KB)PDF (97.84 KB) of E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs	10/19/2005	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Efficacy	Final	No		
S7B Nonclinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals	PDF (51.75 KB)PDF (51.75 KB) of S7B Nonclinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals	10/19/2005	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Safety	Final	No		
Class II Special Controls Guidance Document: AFP-L3% Immunological Test Systems	PDF (63.03 KB)PDF (63.03 KB) of Class II Special Controls Guidance Document: AFP-L3% Immunological Test Systems	10/04/2005		Premarket,	Final	No		
Class II Special Controls Guidance Document: AFP-L3 Immunological Test Systems - Guidance for Industry and FDA Staff		10/03/2005	Center for Devices and Radiological Health	Premarket,	Final	No		

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Letter to State Regulatory Agencies and Firms That Produce Treated (but not Pasteurized) and Untreated Juice and Cider		09/22/2005	Office of Food Safety	Juice	Final	No		FDA-2013-S-0610
Review Criteria for Assessment of C-Reactive Protein (CRP), High Sensitivity C-Reactive Protein (hsCRP) and Cardiac C-Reactive Assays: Guidance for Industry and FDA Staff	PDF (175.75 KB)PDF (175.75 KB) of Review Criteria for Assessment of C-Reactive Protein (CRP), High Sensitivity C-Reactive Protein (hsCRP) and Cardiac C-Reactive Assays: Guidance for Industry and FDA Staff	09/22/2005	Center for Devices and Radiological Health	Postmarket, Cardiovascular	Final	No		
Review Criteria for Assessment of C Reactive Protein (CRP), High Sensitivity C-Reactive Protein (hsCRP) and Cardiac C-Reactive Protein (cCRP) Assays - Guidance for Industry and FDA Staff		09/21/2005	Center for Devices and Radiological Health		Final	No		
Class II Special Controls Document: Oral Rinse to Reduce the Adhesion of Dental Plaque - Guidance for Industry and FDA Staff		09/19/2005	Center for Devices and Radiological Health	Premarket,	Final	No		
Mammography Facility Surveys, Mammography Equipment Evaluations, and Medical Physicist Qualification Requirements under MQSA		09/12/2005			Final	No		
How to Comply with the Pediatric Research Equity Act	PDF (115.53 KB)PDF (115.53 KB) of How to Comply with the Pediatric Research Equity Act	09/07/2005	Center for Drug Evaluation and Research	Administrative / Procedural	Draft	No		
M5International Conference on Harmonisation; Draft Guidance on M5 Data Elements and Standards for Drug Dictionaries	PDF (405.51 KB)PDF (405.51 KB) of M5International Conference on Harmonisation; Draft Guidance on M5 Data Elements and Standards for Drug Dictionaries	09/01/2005	Center for Drug Evaluation and Research	ICH-Multidisciplinary	Draft	No		
Class II Special Controls Guidance Document: RNA Preanalytical Systems (RNA Collection, Stabilization and Purification Systems for RT-PCR used in Molecular Diagnostic Testing) - Guidance for Industry and FDA Staff		08/24/2005	Center for Devices and Radiological Health	Premarket,	Final	No		
Medical Devices with Sharps Injury Prevention Features - Guidance for Industry and FDA Staff		08/08/2005	Center for Devices and Radiological Health	Premarket,	Final	No		934
Estimating the Maximum Safe Starting Dose in Initial Clinical Trials for Therapeutics in Adult Healthy Volunteers	PDF (702.04 KB)PDF (702.04 KB) of Estimating the Maximum Safe Starting Dose in Initial Clinical Trials for Therapeutics in Adult Healthy Volunteers	07/28/2005		Pharm/Tox	Final	No		
Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s) - Guidance for Industry and FDA Staff		07/26/2005	Center for Devices and Radiological Health	Premarket, 510(k)	Final	No		
CPG Sec. 300.750 Class III Devices Subject to 515(b) Requirements	PDF (68.46 KB)PDF (68.46 KB) of CPG Sec. 300.750 Class III Devices Subject to 515(b) Requirements	07/01/2005		Investigation & Enforcement, Premarket Approval (PMA)	Final	No		
Nonclinical Pharmacology/Toxicology Development of Topical Drugs Intended to Prevent the Transmission of Sexually Transmitted Diseases (STD) and/or for the Development of Drugs Intended to Act as Vaginal Contraceptives		06/30/2005		Pharm/Tox	Final	No		
Assessing Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection: Guidance for Industry	PDF (39.62 KB)PDF (39.62 KB) of Assessing Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection: Guidance for Industry	06/23/2005	Center for Biologics Evaluation and Research	Blood Products	Final	No		2005D-0133
Q5E Comparability of Biotechnological/Biological Products Subject to Changes in Their Manufacturing Process	PDF (58.1 KB)PDF (58.1 KB) of Q5E Comparability of Biotechnological/Biological Products Subject to Changes in Their Manufacturing Process	06/01/2005	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Quality	Final	No		

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CPG Sec. 315.100 Illegal Interstate Commercial Shipment of Dentures (CPG retitled and revised 5/19/2005)	PDF (96.79 KB)PDF (96.79 KB) of CPG Sec. 315.100 Illegal Interstate Commercial Shipment of Dentures (CPG retitled and revised 5/19/2005)	05/19/2005		Investigation & Enforcement, Dental	Final	No		
CPG Sec. 315.100 Illegal Interstate Commercial Shipment of Dentures (CPG retitled and revised 5/19/2005)	PDF (97.34 KB)PDF (97.34 KB) of CPG Sec. 315.100 Illegal Interstate Commercial Shipment of Dentures (CPG retitled and revised 5/19/2005)	05/19/2005		Investigation & Enforcement, Dental	Final	No		
Guidance for Industry: Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals		05/18/2005	Office of Food Safety	Contaminants, Environmental Safety, Food & Beverage Safety, Potential Metal or Chemical Contaminant, Safety - Issues, Errors, and Problems, Potential Metal or Chemical Contaminant, Food & Beverage Safety	Final	No		FDA-2013-S-0610
Nonclinical Studies for the Safety Evaluation of Pharmaceutical Excipients	PDF (229.53 KB)PDF (229.53 KB) of Nonclinical Studies for the Safety Evaluation of Pharmaceutical Excipients	05/18/2005		Pharm/Tox	Final	No		
CPG 560.400 Imported Milk and Cream - Federal Import Milk Act	PDF (23.28 KB)PDF (23.28 KB) of CPG 560.400 Imported Milk and Cream - Federal Import Milk Act	05/12/2005		Investigation & Enforcement,	Final	No		
Guidance for Industry: Templates for Reporting Toxicology Data		05/11/2005	Office of Food Additive Safety	Food & Color Additives	Final	No		FDA-2013-S-0610
Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices: Guidance for Industry and FDA Staff	PDF (164.56 KB)PDF (164.56 KB) of Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices: Guidance for Industry and FDA Staff	05/11/2005	Center for Devices and Radiological Health	Premarket, 510(k), Digital Health	Final	No		
CPG Sec. 525.225 - Whole Cassia or Whole Cinnamon, Ground Cinnamon - Adulteration by Insect and Rodent Filth; Mold; Mammalian Excreta	PDF (11.84 KB)PDF (11.84 KB) of CPG Sec. 525.225 - Whole Cassia or Whole Cinnamon, Ground Cinnamon - Adulteration by Insect and Rodent Filth; Mold; Mammalian Excreta	05/01/2005		Investigation & Enforcement,	Final	No		
Class II Special Controls Guidance Document: Dental Bone Grafting Material Devices - Guidance for Industry and FDA Staff		04/27/2005	Center for Devices and Radiological Health	Premarket,	Final	No		
Evaluating the Risks of Drug Exposure in Human Pregnancies	PDF (3.08 MB)PDF (3.08 MB) of Evaluating the Risks of Drug Exposure in Human Pregnancies	04/27/2005	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		
CPG Sec. 100.700 GWQAP Pre-Award Evaluation - Inadequate Information to Evaluate Prospective Supplier		04/24/2005		Investigation & Enforcement, Food & Color Additives	Final	No		
Providing Regulatory Submissions in Electronic Format — Content of Labeling	PDF (42.75 KB)PDF (42.75 KB) of Providing Regulatory Submissions in Electronic Format — Content of Labeling	04/20/2005	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Electronic Submissions,	Final	No		
Guidance for Industry: Entry Types and Entry Identifiers in Prior Notice of Imported Food		04/07/2005	Center for Food Safety and Applied Nutrition, Office of Regulatory Affairs	Export	Final	No		FDA-2013-S-0610
Application User Fees for Combination Products: Guidance for Industry and FDA Staff	PDF (82.89 KB)PDF (82.89 KB) of Application User Fees for Combination Products: Guidance for Industry and FDA Staff	04/01/2005	Office of Combination Products	User Fees, Combination Products	Final	No		
CPG Sec. 390.300 Assessment of Civil Penalties Against Manufacturers and Importers of Electronic Products		04/01/2005		Investigation & Enforcement, Administrative / Procedural	Final	No		
Guidance for Industry: Pre-Petition Consultations for Food Additives and Color Additives		04/01/2005	Office of Food Additive Safety	Food & Color Additives, Ingredients	Final	No		FDA-2013-S-0610

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Guidance for Industry: Submitting Requests under 21 CFR 170.39 Threshold of Regulation for Substances Used in Food-Contact Articles		04/01/2005	Office of Food Additive Safety	Food & Color Additives, Ingredients	Final	No		FDA-2013-S-0610
Guidance for Review Staff and Industry Good Review Management Principles and Practices for PDUFA Products		04/01/2005	Center for Drug Evaluation and Research	Administrative / Procedural	Draft	No		
E2E Pharmacovigilance Planning	PDF (99.67 KB)PDF (99.67 KB) of E2E Pharmacovigilance Planning	03/31/2005	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Efficacy	Final	No		
Guidance for Industry: Dietary Supplement Labeling Guide		03/31/2005	Center for Food Safety and Applied Nutrition	Labeling	Final	No		
Development and Use of Risk Minimization Action Plans: Guidance for Industry	PDF (128.07 KB)PDF (128.07 KB) of Development and Use of Risk Minimization Action Plans: Guidance for Industry	03/24/2005	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Clinical - Medical, Good Clinical Practices (GCP)	Final	No		
Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment: Guidance for Industry	PDF (225.83 KB)PDF (225.83 KB) of Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment: Guidance for Industry	03/24/2005	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Clinical - Medical, Good Clinical Practices (GCP)	Final	No		
Premarketing Risk Assessment: Guidance for Industry	PDF (129.5 KB)PDF (129.5 KB) of Premarketing Risk Assessment: Guidance for Industry	03/24/2005	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Clinical - Medical, Good Clinical Practices (GCP)	Final	No		
Class II Special Controls Guidance Document: Automated Fluorescence in situ Hybridization (FISH) Enumeration Systems - Guidance for Industry and FDA Staff		03/22/2005	Center for Devices and Radiological Health	Premarket,	Final	No		
M2: eCTD Specification Questions and Answers and Change Requests	PDF (31.02 KB)PDF (31.02 KB) of M2: eCTD Specification Questions and Answers and Change Requests	03/14/2005	Center for Drug Evaluation and Research	ICH-Multidisciplinary	Final	No		
CPG Sec. 355.100 Cellutron Machine - Revoked on 3/10/05		03/10/2005		Investigation & Enforcement,	Final	No		
Class II Special Controls Guidance Document: Drug Metabolizing Enzyme Genotyping System - Guidance for Industry and FDA Staff		03/09/2005	Center for Devices and Radiological Health	Premarket,	Final	No		
Class II Special Controls Guidance Document: Instrumentation for Clinical Multiplex Test Systems - Guidance for Industry and FDA Staff		03/09/2005		Premarket,	Final	No		
E2B(M) Questions and Answers	PDF (61.07 KB)PDF (61.07 KB) of E2B(M) Questions and Answers	03/09/2005	Center for Drug Evaluation and Research, Center for Devices and Radiological Health	ICH-Efficacy	Final	No		
CPG Sec. 390.400 Examples of Electronic Products Subject to the Reporting Requirements Under 21 CFR 1000.15(a)		03/01/2005		Investigation & Enforcement, Administrative / Procedural	Final	No		
CPG Sec. 393.100 Enforcement Policy for Certain Laser Light Shows, Displays, and/or Devices. (21 CFR 1040.10 and 1040.11)		03/01/2005		Investigation & Enforcement,	Final	No		
Pharmacogenomic Data Submissions: Guidance for Industry	PDF (179.08 KB)PDF (179.08 KB) of Pharmacogenomic Data Submissions: Guidance for Industry	03/01/2005	Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Administrative / Procedural, Good Clinical Practices (GCP)	Final	No		

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Pharmacogenomic Data Submissions; Examples of Voluntary Submissions or Submissions Required Under 21 CFR 312, 314, or 601	PDF (63.39 KB)PDF (63.39 KB) of Pharmacogenomic Data Submissions; Examples of Voluntary Submissions or Submissions Required Under 21 CFR 312, 314, or 601	03/01/2005	Center for Drug Evaluation and Research	Administrative / Procedural	Final	No		
CPG Sec. 396.300 Defective Suntanning Booths and Bed		02/28/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 398.100 Definition of General Purpose Radiographic X-Ray System - 21 CFR 1020.30(b)		02/28/2005		Investigation & Enforcement, Radiology	Final	No		
CPG Sec. 398.325 Regulatory Actions Against Assemblers Noncompliant Diagnostic X-Ray Equipment		02/28/2005		Investigation & Enforcement,	Final	No		
CPG Sec. 398.425 Override of Positive Beam Limitation - 21 CFR 1020.31(g)(5)		02/28/2005		Investigation & Enforcement, Radiology	Final	No		
CPG Sec. 398.700 Reloaders of X-ray Tube Housing Assemblies; Applicability of Medical Device Establishment Registration, Device Listing and Biennial Inspection		02/28/2005		Investigation & Enforcement,	Final	No		
Clinical Lactation Studies--Study Design, Data Analysis, and Recommendations for Labeling	PDF (362.62 KB)PDF (362.62 KB) of Clinical Lactation Studies--Study Design, Data Analysis, and Recommendations for Labeling	02/08/2005	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Clinical - Pharmacology, Good Clinical Practices (GCP)	Draft	No		2005D-0030
Information for Healthcare Organizations about FDA's "Guidance for Industry: Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) Software"		02/08/2005		Digital Health	Final	No		
CVM GFI #173 Animal Drug Sponsor Fees Under the Animal Drug User Fee Act (ADUFA)	PDF (51.92 KB)PDF (51.92 KB) of CVM GFI #173 Animal Drug Sponsor Fees Under the Animal Drug User Fee Act (ADUFA)	02/07/2005	Center for Veterinary Medicine	User Fees,	Final	No		FDA-2004-D-0181
CVM GFI #173 Appendix for the Animal Drug Sponsor Fees Under ADUFA	PDF (43.8 KB)PDF (43.8 KB) of CVM GFI #173 Appendix for the Animal Drug Sponsor Fees Under ADUFA	02/07/2005	Center for Veterinary Medicine	User Fees,	Final	No		FDA-2004-D-0181
Gingivitis: Development and Evaluation of Drugs for Treatment or Prevention	PDF (112.67 KB)PDF (112.67 KB) of Gingivitis: Development and Evaluation of Drugs for Treatment or Prevention	01/28/2005	Center for Drug Evaluation and Research	Clinical - Medical	Draft	No		
Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software: Guidance for Industry	PDF (147.75 KB)PDF (147.75 KB) of Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software: Guidance for Industry	01/14/2005	Center for Devices and Radiological Health		Final	No		
Guidance for Industry: Labeling for Cosmetics Containing Alpha Hydroxy Acids		01/10/2005	Office of Cosmetics and Colors	Ingredients, Labeling	Final	No		FDA-2013-S-0610
Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees: Guidance for Industry	PDF (211.49 KB)PDF (211.49 KB) of Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees: Guidance for Industry	12/30/2004	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	User Fees,	Final	No		
Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices - Guidance for Industry and FDA Staff		12/28/2004	Center for Devices and Radiological Health		Final	No		
Class II Special Controls Guidance Document: Assisted Reproduction Laser Systems - Guidance for Industry and FDA Staff		12/27/2004	Center for Devices and Radiological Health	Premarket,	Final	No		
Class II Special Controls Guidance Document: External Penile Rigidity Devices - Guidance for Industry and FDA Staff		12/27/2004	Center for Devices and Radiological Health	Premarket,	Final	No		
M4: The CTD -- General Questions and Answers	PDF (44.82 KB)PDF (44.82 KB) of M4: The CTD -- General Questions and Answers	12/22/2004	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Multidisciplinary	Final	No		

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Class II Special Controls Guidance Document: Implantable Radiofrequency Transponder System for Patient Identification and Health Information - Guidance for Industry and FDA Staff		12/09/2004	Center for Devices and Radiological Health	Premarket,	Final	No		
Clinical Data Presentations for Orthopedic Device Applications - Guidance for Industry and FDA Staff		12/01/2004	Center for Devices and Radiological Health	Premarket,	Final	No		
M4: The CTD -- Efficacy Questions and Answers	PDF (165.46 KB)PDF (165.46 KB) of M4: The CTD -- Efficacy Questions and Answers	12/01/2004	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Multidisciplinary	Final	No		
Class II Special Controls Guidance Document: Newborn Screening Test Systems for Amino Acids, Free Carnitine, and Acylcarnitines Using Tandem Mass Spectrometry - Guidance for Industry and FDA Staff		11/23/2004	Center for Devices and Radiological Health	Premarket,	Final	No		
Changes to an Approved NDA or ANDA; Specifications – Use of Enforcement Discretion for Compendial Changes: Guidance for Industry	PDF (24.22 KB)PDF (24.22 KB) of Changes to an Approved NDA or ANDA; Specifications – Use of Enforcement Discretion for Compendial Changes: Guidance for Industry	11/19/2004	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		
CVM GFI #122 Manufacture and Labeling of Raw Meat Foods for Companion and Captive Noncompanion Carnivores and Omnivores	PDF (94.47 KB)PDF (94.47 KB) of CVM GFI #122 Manufacture and Labeling of Raw Meat Foods for Companion and Captive Noncompanion Carnivores and Omnivores	11/09/2004	Center for Veterinary Medicine	Animal Feed	Final	No		FDA-2002-D-0148
CPG Sec. 130.400 Use of Microfiche and/or Microfilm for Method of Records Retention		11/07/2004		Investigation & Enforcement, Food & Color Additives, Records	Final	No		
Frequently Asked Questions (FAQs) on the Status of Reprocessed Single Use Devices (SUDs) that receive a Not Substantially Equivalent (NSE) Letter		11/07/2004	Center for Devices and Radiological Health	Premarket,	Final	No		
Pharmacokinetics in Pregnancy — Study Design, Data Analysis, and Impact on Dosing and Labeling	PDF (324.06 KB)PDF (324.06 KB) of Pharmacokinetics in Pregnancy — Study Design, Data Analysis, and Impact on Dosing and Labeling	11/01/2004	Center for Drug Evaluation and Research	Clinical - Pharmacology	Draft	No		
Recommendations for Obtaining a Labeling Claim for Communicable Disease Donor Screening Tests Using Cadaveric Blood Specimens from Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps): Guidance for Industry	PDF (33.12 KB)PDF (33.12 KB) of Recommendations for Obtaining a Labeling Claim for Communicable Disease Donor Screening Tests Using Cadaveric Blood Specimens from Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps): Guidance for Industry	11/01/2004	Center for Biologics Evaluation and Research	Labeling, Tissue	Final	No		2005D-0056
Clinical Trial Considerations: Vertebral Augmentation Devices to Treat Spinal Insufficiency Fractures - Guidance for Industry and FDA Staff		10/23/2004	Center for Devices and Radiological Health	Premarket,	Final	No		
Use of Nucleic Acid Tests on Pooled and Individual Samples from Donors of Whole Blood and Blood Components (including Source Plasma and Source Leukocytes) to Adequately and Appropriately Reduce the Risk of Transmission of of HIV-1 and HCV: Guidance for Industry	PDF (54.21 KB)PDF (54.21 KB) of Use of Nucleic Acid Tests on Pooled and Individual Samples from Donors of Whole Blood and Blood Components (including Source Plasma and Source Leukocytes) to Adequately and Appropriately Reduce the Risk of Transmission of of HIV-1 and HCV: Guidance for Industry	10/21/2004	Center for Biologics Evaluation and Research	Blood Products	Final	No		2001D-0584
FDA Review of Vaccine Labeling Requirements for Warnings, Use Instructions, and Precautionary Information: Guidance for Industry	PDF (32.78 KB)PDF (32.78 KB) of FDA Review of Vaccine Labeling Requirements for Warnings, Use Instructions, and Precautionary Information: Guidance for Industry	10/01/2004	Center for Biologics Evaluation and Research	Vaccines	Final	No		2004D-0414

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Guidance for Industry: Recommendations to Processors of Apple Juice or Cider on the Use of Ozone for Pathogen Reduction Purposes		10/01/2004	Office of Food Safety	Juice	Final	No		FDA-2013-S-0610
Class II Special Controls Guidance Document: Sirolimus Test Systems - Guidance for Industry and FDA Staff		09/29/2004	Center for Devices and Radiological Health	Premarket,	Final	No		
PAT — A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance: Guidance for Industry	PDF (210.76 KB)PDF (210.76 KB) of PAT — A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance: Guidance for Industry	09/29/2004	Center for Veterinary Medicine, Office of Regulatory Affairs, Center for Drug Evaluation and Research	Current Good Manufacturing Practices (CGMP), Pharmaceutical Quality	Final	No		
Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice: Guidance for Industry	PDF (734.22 KB)PDF (734.22 KB) of Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice: Guidance for Industry	09/29/2004	Office of Regulatory Affairs, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Current Good Manufacturing Practices (CGMP), Pharmaceutical Quality	Final	No		
Guidance for Third Parties and FDA Staff; Third Party Review of Premarket Notifications		09/27/2004	Center for Devices and Radiological Health	Premarket,	Final	No		
Class II Special Controls Guidance Document: Serological Assays for the Detection of Beta-Glucan (PDF version)	PDF (55.39 KB)PDF (55.39 KB) of Class II Special Controls Guidance Document: Serological Assays for the Detection of Beta-Glucan (PDF version)	09/23/2004		Premarket,	Final	No		
Class II Special Controls Guidance Document: Serological Assays for the Detection of Beta-Glucan - Guidance for Industry and FDA Staff		09/22/2004	Center for Devices and Radiological Health	Premarket,	Final	No		
The Use of Clinical Holds Following Clinical Investigator Misconduct: Guidance for Industry and Clinical Investigators	PDF (37.48 KB)PDF (37.48 KB) of The Use of Clinical Holds Following Clinical Investigator Misconduct: Guidance for Industry and Clinical Investigators	09/01/2004	Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Administrative / Procedural, Good Clinical Practices (GCP)	Final	No		
Class II Special Controls Guidance Document: Dental Base Metal Alloys - Guidance for Industry and FDA Staff		08/22/2004	Center for Devices and Radiological Health		Final	No		
Class II Special Controls Guidance Document: Dental Noble Metal Alloys - Guidance for Industry and FDA Staff		08/22/2004	Center for Devices and Radiological Health	Premarket,	Final	No		
Guidance for Industry: Prior Notice of Imported Food Contingency Plan for System Outages		08/16/2004	Center for Food Safety and Applied Nutrition, Office of Regulatory Affairs	Export, Import	Final	No		FDA-2013-S-0610
Calcium DTPA and Zinc DTPA Drug Products-Submitting a New Drug Application	PDF (168.17 KB)PDF (168.17 KB) of Calcium DTPA and Zinc DTPA Drug Products-Submitting a New Drug Application	08/13/2004	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		
Independent Consultants for Biotechnology Clinical Trial Protocols: Guidance for Industry	PDF (39.87 KB)PDF (39.87 KB) of Independent Consultants for Biotechnology Clinical Trial Protocols: Guidance for Industry	08/01/2004	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Administrative / Procedural, Good Clinical Practices (GCP)	Final	No		
CPG Sec. 394.500 Importation of Television Products, Microwave Ovens, and Inherent Class I Laser Products for Investigation and Evaluation during Design Development	PDF (65.76 KB)PDF (65.76 KB) of CPG Sec. 394.500 Importation of Television Products, Microwave Ovens, and Inherent Class I Laser Products for Investigation and Evaluation during Design Development	07/29/2004		Investigation & Enforcement, Administrative / Procedural	Final	No		

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FDA Export Certificates: Guidance for Industry		07/12/2004	Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Export, Import	Final	No		
Developing Medical Imaging Drug and Biological Products Part 1: Conducting Safety Assessments	PDF (270.68 KB)PDF (270.68 KB) of Developing Medical Imaging Drug and Biological Products Part 1: Conducting Safety Assessments	06/17/2004	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Clinical - Medical, Pharm/Tox	Final	No		
Developing Medical Imaging Drug and Biological Products Part 2: Clinical Indications	PDF (231.4 KB)PDF (231.4 KB) of Developing Medical Imaging Drug and Biological Products Part 2: Clinical Indications	06/17/2004	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Clinical - Medical	Final	No		
Developing Medical Imaging Drug and Biological Products Part 3: Design, Analysis, and Interpretation of Clinical Studies	PDF (307.06 KB)PDF (307.06 KB) of Developing Medical Imaging Drug and Biological Products Part 3: Design, Analysis, and Interpretation of Clinical Studies	06/17/2004	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Clinical - Medical	Final	No		
CPG Sec. 690.300 Canned Pet Food (Withdrawn 4/30/2019)		06/10/2004	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Pet Food	Final	No		
M4: The CTD -- Quality Questions and Answers /Location Issues	PDF (85.61 KB)PDF (85.61 KB) of M4: The CTD -- Quality Questions and Answers /Location Issues	06/08/2004	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Multidisciplinary	Final	No		
Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices: Guidance for Industry and FDA Staff	PDF (133.23 KB)PDF (133.23 KB) of Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices: Guidance for Industry and FDA Staff	06/02/2004	Center for Devices and Radiological Health	User Fees, 510(k)	Final	No		
E5 Ethnic Factors in the Acceptability of Foreign Clinical Data	PDF (79.19 KB)PDF (79.19 KB) of E5 Ethnic Factors in the Acceptability of Foreign Clinical Data	06/01/2004	Center for Drug Evaluation and Research	ICH-Efficacy	Final	No		
Q1E Evaluation of Stability Data	PDF (220.51 KB)PDF (220.51 KB) of Q1E Evaluation of Stability Data	06/01/2004	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Quality	Final	No		
Handling and Retention of Bioavailability BA and Bioequivalence BE Testing Samples: Guidance for Industry	PDF (189.75 KB)PDF (189.75 KB) of Handling and Retention of Bioavailability BA and Bioequivalence BE Testing Samples: Guidance for Industry	05/25/2004	Center for Drug Evaluation and Research	Generic Drugs, Good Clinical Practices (GCP)	Final	No		
Class II Special Controls Guidance Document: Immunomagnetic Circulating Cancer Cell Selection and Enumeration System (PDF version)	PDF (64.19 KB)PDF (64.19 KB) of Class II Special Controls Guidance Document: Immunomagnetic Circulating Cancer Cell Selection and Enumeration System (PDF version)	05/11/2004		Premarket,	Final	No		
Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments - Guidance for Industry and FDA Staff		05/11/2004	Center for Devices and Radiological Health		Final	No		

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Class II Special Controls Guidance Document: Immunomagnetic Circulating Cancer Cell Selection and Enumeration System - Guidance for Industry and FDA Staff		05/10/2004	Center for Devices and Radiological Health	Premarket,	Final	No		
Submission and Resolution of Formal Disputes Regarding the Timeliness of Premarket Review of a Combination Product: Guidance for Industry and FDA Staff	PDF (39.09 KB)PDF (39.09 KB) of Submission and Resolution of Formal Disputes Regarding the Timeliness of Premarket Review of a Combination Product: Guidance for Industry and FDA Staff	05/03/2004	Office of Combination Products	Combination Products	Final	No		
Guidance for Industry and FDA Staff: Spinal System 510(k)s		05/02/2004		Premarket,	Final	No		
CVM GFI #144 (VICH GL27) Pre-Approval Information for Registration of New Veterinary Medicinal Products for Food-Producing Animals with Respect to Antimicrobial Resistance	PDF (179.67 KB)PDF (179.67 KB) of CVM GFI #144 (VICH GL27) Pre-Approval Information for Registration of New Veterinary Medicinal Products for Food-Producing Animals with Respect to Antimicrobial Resistance	04/27/2004	Center for Veterinary Medicine	Antimicrobial Resistance, VICH	Final	No		FDA-2003-D-0152
Changes to an Approved NDA or ANDA: Guidance for Industry	PDF (173.43 KB)PDF (173.43 KB) of Changes to an Approved NDA or ANDA: Guidance for Industry	04/01/2004	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		
Class II Special Controls Guidance Document: Factor V Leiden DNA Mutation Detection Systems - Guidance for Industry and FDA Staff		03/15/2004	Center for Devices and Radiological Health	Premarket,	Final	No		
CPG Sec. 490.100 Process Validation Requirements for Drug Products and Active Pharmaceutical Ingredients Subject to Pre-Market Approval	PDF (124.71 KB)PDF (124.71 KB) of CPG Sec. 490.100 Process Validation Requirements for Drug Products and Active Pharmaceutical Ingredients Subject to Pre-Market Approval	03/12/2004		Investigation & Enforcement,	Final	No		
Potassium Iodide Tablets - Shelf Life Extension	PDF (191.25 KB)PDF (191.25 KB) of Potassium Iodide Tablets - Shelf Life Extension	03/08/2004	Center for Drug Evaluation and Research	Administrative / Procedural	Final	No		
Surgical Masks - Premarket Notification [510(k)] Submissions: Guidance for Industry and FDA Staff	PDF (224.92 KB)PDF (224.92 KB) of Surgical Masks - Premarket Notification [510(k)] Submissions: Guidance for Industry and FDA Staff	03/04/2004	Center for Devices and Radiological Health	Premarket,	Final	No		
Guidance for Industry: Juice Hazard Analysis Critical Control Point Hazards and Controls Guidance, First Edition		03/03/2004	Office of Food Safety	HACCP, Juice	Final	No		FDA-2013-S-0610
Guidance for Industry and FDA Staff: Vocal Fold Medialization Devices - Premarket Notification [510(k)] Submissions		02/12/2004		Premarket,	Final	No		
Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products: Questions and Answers on Guidance for Industry	PDF (37.32 KB)PDF (37.32 KB) of Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products: Questions and Answers on Guidance for Industry	01/22/2004	Center for Biologics Evaluation and Research	Blood Products	Final	No		
IND Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer: Guidance for Industry	PDF (171.61 KB)PDF (171.61 KB) of IND Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer: Guidance for Industry	01/15/2004	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Clinical - Medical, Good Clinical Practices (GCP)	Final	No		
Guidance for Industry and FDA Staff: Clinical Study Designs for Percutaneous Catheter Ablation for Treatment of Atrial Fibrillation		01/08/2004		Premarket,	Final	No		
CPG Sec. 370.200 RIA Analysis of Hair to Detect the Prescence of Drugs of Abuse - Revoked		01/05/2004		Investigation & Enforcement, Clinical Chemistry & Clinical Toxicology	Final	No		

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Premarket Notification [510(k)] Submissions for Chemical Indicators - Guidance for Industry and FDA Staff		12/18/2003	Center for Devices and Radiological Health	Premarket,	Final	No		
Class II Special Controls Guidance Document: Human Dura Mater - Guidance for Industry and FDA Staff		12/17/2003	Center for Devices and Radiological Health	Premarket,	Final	No		
Replacement Reagent and Instrument Family Policy: Guidance for Industry and FDA Staff	PDF (276.81 KB)PDF (276.81 KB) of Replacement Reagent and Instrument Family Policy: Guidance for Industry and FDA Staff	12/11/2003	Center for Devices and Radiological Health	IVDs (In Vitro Diagnostic Devices), Laboratory Tests	Final	No		
Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices - Guidance for Industry and FDA Staff		12/01/2003	Center for Devices and Radiological Health	Premarket,	Final	No		
Premarket Approval Application Modular Review: Guidance for Industry and FDA Staff	PDF (213.36 KB)PDF (213.36 KB) of Premarket Approval Application Modular Review: Guidance for Industry and FDA Staff	11/03/2003	Center for Devices and Radiological Health	Premarket,	Final	No		
Q1A(R2) Stability Testing of New Drug Substances and Products	PDF (57.67 KB)PDF (57.67 KB) of Q1A(R2) Stability Testing of New Drug Substances and Products	11/01/2003	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Quality	Final	No		
Redbook 2000: IV.C.1.b. In vitro Mammalian Chromosomal Aberration Test		11/01/2003	Office of Food Additive Safety	Food & Color Additives	Final	No		
Redbook 2000: IV.C.3.a. Short-Term Toxicity Studies with Rodents		11/01/2003	Office of Food Additive Safety	Food & Color Additives	Final	No		
Redbook 2000: IV.C.3.b. Short-Term Toxicity Studies with Non-Rodents		11/01/2003	Office of Food Additive Safety	Food & Color Additives	Final	No		
Redbook 2000: IV.C.4.a. Subchronic Toxicity Studies with Rodents		11/01/2003	Office of Food Additive Safety	Food & Color Additives	Final	No		
Redbook 2000: IV.C.4.b. Subchronic Toxicity Studies with Non-Rodents		11/01/2003	Office of Food Additive Safety	Food & Color Additives	Final	No		
Redbook 2000: IV.C.5.b. One-Year Toxicity Studies with Non-Rodents		11/01/2003	Office of Food Additive Safety	Food & Color Additives	Final	No		
Class II Special Controls Guidance Document: Endotoxin Assay - Guidance for Industry and FDA Staff		10/30/2003	Center for Devices and Radiological Health	Premarket,	Final	No		
Class II Special Controls Guidance Document: Serological Reagents for the Laboratory Diagnosis of West Nile Virus - Guidance for Industry and FDA Staff		10/29/2003	Center for Devices and Radiological Health	Premarket,	Final	No		
Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm - Guidance for Industry and FDA Staff		10/27/2003	Center for Devices and Radiological Health	Premarket,	Final	No		
CVM GFI #152 Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern	PDF (474.32 KB)PDF (474.32 KB) of CVM GFI #152 Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern	10/23/2003	Center for Veterinary Medicine	Antimicrobial Resistance, Human Food Safety	Final	No		FDA-1998-D-0038
Small Entity Compliance Guide: Label Warning Statements for Iron-Containing Supplements and Drugs		10/17/2003	Office of Dietary Supplement Programs	Labeling	Final	No		FDA-2013-S-0610
Guidance for Industry: Iron-Containing Supplements and Drugs: Label Warning Statements: Small Entity Compliance Guide		10/16/2003	Center for Food Safety and Applied Nutrition	Food & Beverage Safety	Final	No		
Notifying FDA of Fatalities Related to Blood Collection or Transfusion: Guidance for Industry	PDF (38.29 KB)PDF (38.29 KB) of Notifying FDA of Fatalities Related to Blood Collection or Transfusion: Guidance for Industry	09/22/2003	Center for Biologics Evaluation and Research	Application & Approvals, Blood Products	Final	No		2002D-0124

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Revised Recommendations for the Assessment of Donor Suitability and Blood Product Safety in Cases of Suspected Severe Acute Respiratory Syndrome (SARS) or Exposure to SARS: Guidance for Industry	PDF (52.33 KB)PDF (52.33 KB) of Revised Recommendations for the Assessment of Donor Suitability and Blood Product Safety in Cases of Suspected Severe Acute Respiratory Syndrome (SARS) or Exposure to SARS: Guidance for Industry	09/16/2003	Center for Biologics Evaluation and Research	Blood Products	Final	No		2003D-0163
E2D Postapproval Safety Data Management: Definitions and Standards for Expedited Reporting	PDF (164.68 KB)PDF (164.68 KB) of E2D Postapproval Safety Data Management: Definitions and Standards for Expedited Reporting	09/12/2003	Center for Drug Evaluation and Research	ICH-Efficacy	Draft	No		
Information Disclosure by Manufacturers to Assemblers for Diagnostic X-ray Systems - Guidance for Industry and FDA Staff		09/04/2003	Center for Devices and Radiological Health	Postmarket,	Final	No		
Guidance for Industry: Questions and Answers on Juice HACCP Regulation (2003)		09/03/2003	Office of Food Safety	HACCP, Juice	Final	No		FDA-2013-S-0610
Small Entity Compliance Guide: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims		08/20/2003	Office of Nutrition and Food Labeling	Food & Beverage Safety, Labeling	Final	No		FDA-2013-S-0610
IRB Review of Stand-Alone HIPAA Authorizations Under FDA Regulations: Guidance for Industry	PDF (613.57 KB)PDF (613.57 KB) of IRB Review of Stand-Alone HIPAA Authorizations Under FDA Regulations: Guidance for Industry	08/16/2003	Office of the Commissioner		Final	No		
Part 11, Electronic Records; Electronic Signatures - Scope and Application: Guidance for Industry	PDF (43.9 KB)PDF (43.9 KB) of Part 11, Electronic Records; Electronic Signatures - Scope and Application: Guidance for Industry	08/01/2003	Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine, Office of Regulatory Affairs, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Postmarket, Compliance, Electronic Submissions, Administrative / Procedural, Current Good Manufacturing Practices (CGMP), Food & Color Additives, Good Clinical Practices (GCP)	Final	No		
Class II Special Controls Guidance Document: Breast Lesion Documentation System - Guidance for Industry and FDA Staff		07/27/2003	Center for Devices and Radiological Health		Final	No		
Frequently-Asked-Questions about the Reprocessing and Reuse of Single-Use Devices by Third-Party and Hospital Reprocessors - Three Additional Questions: Guidance for Industry, FDA Staff, Third-Party and Hospital Reprocessors	PDF (2.01 MB)PDF (2.01 MB) of Frequently-Asked-Questions about the Reprocessing and Reuse of Single-Use Devices by Third-Party and Hospital Reprocessors - Three Additional Questions: Guidance for Industry, FDA Staff, Third-Party and Hospital Reprocessors	07/16/2003	Office of Communication and Education		Final	No		
Coronary and Peripheral Arterial Diagnostic Catheters - Guidance for Industry and FDA Staff		07/14/2003	Center for Devices and Radiological Health	Premarket,	Final	No		1228
Guidance for Industry: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements		07/11/2003	Office of Nutrition and Food Labeling	Labeling	Final	No		FDA-2013-S-0610
Class II Special Controls Guidance Document: Breath Nitric Oxide Test System - Guidance for Industry and FDA Staff		07/06/2003	Center for Devices and Radiological Health	Premarket,	Final	No		
Streamlining the Donor Interview Process: Recommendations for Self-Administered Questionnaires: Guidance for Industry	PDF (48.42 KB)PDF (48.42 KB) of Streamlining the Donor Interview Process: Recommendations for Self-Administered Questionnaires: Guidance for Industry	07/03/2003	Center for Biologics Evaluation and Research	Application & Approvals, Blood Products	Final	No		2002D-0080
180-Day Exclusivity When Multiple ANDAs Are Submitted on the Same Day	PDF (138.08 KB)PDF (138.08 KB) of 180-Day Exclusivity When Multiple ANDAs Are Submitted on the Same Day	07/01/2003	Center for Drug Evaluation and Research	Generic Drugs	Final	No		2003D-0325

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510(k) Submissions for Coagulation Instruments: Guidance for Industry and FDA Staff	PDF (62.41 KB)PDF (62.41 KB) of 510(k) Submissions for Coagulation Instruments: Guidance for Industry and FDA Staff	06/19/2003	Center for Devices and Radiological Health	Premarket, 510(k)	Final	No		
Guidance for Industry: Standardized Training Curriculum for Application of HACCP Principles to Juice Processing		06/13/2003	Office of Food Safety	HACCP, Juice	Final	No		FDA-2013-S-0610
Drug Products Containing Ensulizole, Hypromellose, Meradimate, Octinoxate, and Octisalate — Labeling Enforcement Policy	PDF (159.11 KB)PDF (159.11 KB) of Drug Products Containing Ensulizole, Hypromellose, Meradimate, Octinoxate, and Octisalate — Labeling Enforcement Policy	06/03/2003	Center for Drug Evaluation and Research	Administrative / Procedural	Final	No		
Class II Special Controls Guidance Document: Surgical Sutures - Guidance for Industry and FDA Staff		06/02/2003	Center for Devices and Radiological Health	Premarket,	Final	No		
Pediatric Expertise for Advisory Panels - Guidance for Industry and FDA Staff		06/02/2003	Center for Devices and Radiological Health	Advisory Committees,	Final	No		
Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device - Guidance for Industry and FDA Staff		06/01/2003	Center for Devices and Radiological Health	Premarket,	Final	No		
Pharmacokinetics in Patients with Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosing and Labeling	PDF (222.32 KB)PDF (222.32 KB) of Pharmacokinetics in Patients with Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosing and Labeling	05/30/2003	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Clinical - Pharmacology	Final	No		
INDs for Phase 2 and Phase 3 Studies Chemistry, Manufacturing, and Controls Information: Guidance for Industry	PDF (283.35 KB)PDF (283.35 KB) of INDs for Phase 2 and Phase 3 Studies Chemistry, Manufacturing, and Controls Information: Guidance for Industry	05/20/2003	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Good Clinical Practices (GCP), Pharmaceutical Quality	Final	No		
Exposure-Response Relationships — Study Design, Data Analysis, and Regulatory Applications	PDF (220.68 KB)PDF (220.68 KB) of Exposure-Response Relationships — Study Design, Data Analysis, and Regulatory Applications	05/05/2003	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Clinical - Pharmacology	Final	No		
CVM GFI #118 Mass Spectrometry for Confirmation of Identity of Animal Drug Residues	PDF (112.22 KB)PDF (112.22 KB) of CVM GFI #118 Mass Spectrometry for Confirmation of Identity of Animal Drug Residues	05/01/2003	Center for Veterinary Medicine	Human Food Safety	Final	No		FDA-2001-D-0102
Guidance for Industry: Bulk Transport of Juice Concentrates and Certain Shelf-Stable Juices		04/24/2003	Office of Food Safety	Juice	Final	No		FDA-2013-S-0610
Class II Special Controls Guidance Document: Optical Impression Systems for Computer Assisted Design and Manufacturing (CAD/CAM) of Dental Restorations; Guidance for Industry and FDA		04/21/2003	Center for Devices and Radiological Health	Premarket,	Final	No		
Guidance for Industry: Recommendations for the Assessment of Donor Suitability and Blood Product Safety in Cases of Suspected Severe Acute Respiratory Syndrome (SARS) or Exposure to SARS	PDF (52.27 KB)PDF (52.27 KB) of Guidance for Industry: Recommendations for the Assessment of Donor Suitability and Blood Product Safety in Cases of Suspected Severe Acute Respiratory Syndrome (SARS) or Exposure to SARS	04/17/2003		Blood Products	Final	No		
Statistical Information from the June 1999 Draft Guidance and Statistical Information for In Vitro Bioequivalence Data Posted on August 18, 1999	PDF (190.76 KB)PDF (190.76 KB) of Statistical Information from the June 1999 Draft Guidance and Statistical Information for In Vitro Bioequivalence Data Posted on August 18, 1999	04/11/2003	Center for Drug Evaluation and Research	Biopharmaceutics	Draft	No		
Small Entity Compliance Guide: Juice HACCP		04/04/2003	Office of Food Safety	HACCP, Juice	Final	No		FDA-2013-S-0610

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action	PDF (727.41 KB)PDF (727.41 KB) of Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action	04/03/2003	Center for Drug Evaluation and Research	Biopharmaceutics	Draft	No		99D-1738
M2 eCTD: Electronic Common Technical Document Specification	PDF (1019.8 KB)PDF (1019.8 KB) of M2 eCTD: Electronic Common Technical Document Specification	04/01/2003	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Multidisciplinary	Final	No		
User Labeling for Devices that Contain Natural Rubber (21 CFR 801.437); Small Entity Compliance Guide - Guidance for Industry	PDF (40.65 KB)PDF (40.65 KB) of User Labeling for Devices that Contain Natural Rubber (21 CFR 801.437); Small Entity Compliance Guide - Guidance for Industry	04/01/2003	Center for Devices and Radiological Health	Radiological Health	Final	No		
Integration of Dose-Counting Mechanisms into MDI Drug Products	PDF (124.67 KB)PDF (124.67 KB) of Integration of Dose-Counting Mechanisms into MDI Drug Products	03/01/2003	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		
Comparability Protocols -- Chemistry, Manufacturing, and Controls Information	PDF (195.09 KB)PDF (195.09 KB) of Comparability Protocols -- Chemistry, Manufacturing, and Controls Information	02/25/2003	Center for Veterinary Medicine, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Draft	No		
CPG Sec. 160.850: Enforcement Policy: 21 CFR Part 11; Electronic Records; Electronic Signatures		02/24/2003		Investigation & Enforcement, Food & Color Additives, Records	Final	No	04/28/2003	03Dâ€“0060, 99Dâ€“1458
M4: The CTD -- Safety Questions and Answers	PDF (27 KB)PDF (27 KB) of M4: The CTD -- Safety Questions and Answers	02/04/2003	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Multidisciplinary	Final	No		
Quality System Information for Certain Premarket Application Reviews : Guidance for Industry and FDA Staff	PDF (548 KB)PDF (548 KB) of Quality System Information for Certain Premarket Application Reviews : Guidance for Industry and FDA Staff	02/03/2003	Center for Devices and Radiological Health	Premarket, Premarket Approval (PMA)	Final	No		
Estrogen and Estrogen/Progestin Drug Products to Treat Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms — Recommendations for Clinical Evaluation	PDF (166 KB)PDF (166 KB) of Estrogen and Estrogen/Progestin Drug Products to Treat Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms — Recommendations for Clinical Evaluation	01/31/2003	Center for Drug Evaluation and Research	Clinical - Medical	Draft	No		
Prussian Blue Drug Products — Submitting a New Drug Application	PDF (158.67 KB)PDF (158.67 KB) of Prussian Blue Drug Products — Submitting a New Drug Application	01/31/2003	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		
Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA		01/15/2003	Center for Devices and Radiological Health	Premarket,	Final	No		
Q1D Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products	PDF (30.59 KB)PDF (30.59 KB) of Q1D Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products	01/01/2003	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Quality	Final	No		
Recommendations for Deferral of Donors and Quarantine and Retrieval of Blood and Blood Products in Recent Recipients of Smallpox Vaccine (Vaccinia Virus) and Certain Contacts of Smallpox Vaccine Recipients: Guidance for Industry	PDF (46.65 KB)PDF (46.65 KB) of Recommendations for Deferral of Donors and Quarantine and Retrieval of Blood and Blood Products in Recent Recipients of Smallpox Vaccine (Vaccinia Virus) and Certain Contacts of Smallpox Vaccine Recipients: Guidance for Industry	12/30/2002	Center for Biologics Evaluation and Research	Blood Products	Final	No		02D-0362

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
(Potassium Iodide) KI in Radiation Emergencies-Questions and Answers	PDF (161.11 KB)PDF (161.11 KB) of (Potassium Iodide) KI in Radiation Emergencies-Questions and Answers	12/23/2002	Center for Drug Evaluation and Research	Administrative / Procedural	Final	No		
Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide (PcCO2) and Oxygen (PcO2) Monitors - Guidance for Industry and FDA		12/12/2002	Center for Devices and Radiological Health	Premarket, Laboratory Tests	Final	No		
Guidance for Industry: Implementation of Section 403(t) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(t)) Regarding the Use of the Term "Catfish"		12/06/2002	Office of Food Safety	Laser Notice, Seafood/Seafood Product	Final	No		FDA-2013-S-0610
Determination of Intended Use for 510(k) Devices - Guidance for CDRH Staff (Update to K98-1)		12/02/2002	Center for Devices and Radiological Health	Premarket,	Final	No		
Food-Effect Bioavailability and Fed Bioequivalence Studies: Guidance for Industry	PDF (216.55 KB)PDF (216.55 KB) of Food-Effect Bioavailability and Fed Bioequivalence Studies: Guidance for Industry	12/01/2002	Center for Drug Evaluation and Research	Biopharmaceutics, Good Clinical Practices (GCP)	Final	No		
CVM GFI #80 Evaluation the Utility of Anti-Salmonella Chemical Food Additives	PDF (78 KB)PDF (78 KB) of CVM GFI #80 Evaluation the Utility of Anti-Salmonella Chemical Food Additives	11/21/2002	Center for Veterinary Medicine	Animal Food Additives, Animal Feed	Final	No		FDA-1994-D-0007
CPG Sec. 555.600 Filth from Insects, Rodents, and Other Pests in Foods		11/13/2002		Investigation & Enforcement,	Final	No		
Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea - Guidance for Industry and FDA		11/11/2002	Center for Devices and Radiological Health	Premarket,	Final	No		
CPG Sec. 398.475 Minimum X-ray Field Size for Spot-Film Operation of Fluoroscopic Systems with Fixed SID and Without Stepless Adjustment of the Field Size - revoked 11/12/02		11/11/2002		Investigation & Enforcement, Radiology	Final	No		
Needlesticks - Medical Device Reporting Guidance for User Facilities, Manufacturers, and Importers		11/11/2002	Center for Devices and Radiological Health	Adverse Event Reporting System (FAERS),	Final	No		
Class II Special Controls Guidance Document: Transcutaneous Air Conduction Hearing Aid System (TACHAS) - Guidance for Industry and FDA		11/06/2002	Center for Devices and Radiological Health	Premarket,	Final	No		
Draft Guidance for Industry: Regulatory Procedures Manual Chapter 9 Subchapter on Recommending Customs' Seizure and Destruction of Imported Human and Animal Food That Has Not Been Reconditioned		11/05/2002	Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine, Office of Regulatory Affairs	Export, Import	Draft	No	01/06/2003	FDA-2013-S-0610
CVM GFI #82 Development of Supplemental Applications for Approved New Animal Drugs	PDF (842.86 KB)PDF (842.86 KB) of CVM GFI #82 Development of Supplemental Applications for Approved New Animal Drugs	10/28/2002	Center for Veterinary Medicine	New Animal Drug Application (NADA)	Final	No		FDA-1999-N-1881
Guidance for Small Businesses: Submission of Comments for CFSAN Rulemaking		10/20/2002	Center for Food Safety and Applied Nutrition	Electronic Submissions,	Final	No		
Guidance for Industry: Implementation of Section 10809 of the Farm Security and Investment Act of 2002 Regarding the Petition Process to Request Approval of Labeling for Foods that Have Been Treated with Irradiation		10/07/2002	Office of Nutrition and Food Labeling	Food & Beverage Safety, Labeling	Final	No		FDA-2013-S-0610
Guidance for Industry: Exemptions from the Warning Label Requirement for Juice		10/07/2002	Office of Food Safety	Food & Beverage Safety, Juice, Labeling	Final	No		FDA-2013-S-0610
CPG Sec. 300.700 Direct Reference Authority for Class III Medical Devices Without a Premarket Notification (510(k)) or an Approved Premarket Approval Application (PMA) REVOKED		10/06/2002		Investigation & Enforcement,	Final	No		
Immunotoxicology Evaluation of Investigational New Drugs	PDF (100.06 KB)PDF (100.06 KB) of Immunotoxicology Evaluation of Investigational New Drugs	10/01/2002		Pharm/Tox	Final	No		

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Labeling OTC Human Drug Products Updating Labeling in RLDs and ANDAs	PDF (29.54 KB)PDF (29.54 KB) of Labeling OTC Human Drug Products Updating Labeling in RLDs and ANDAs	10/01/2002	Center for Drug Evaluation and Research	Over-the-Counter Drugs	Final	No		
Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays - Guidance for Industry and FDA		09/15/2002	Center for Devices and Radiological Health	Premarket,	Final	No		
CVM GFI #119 How CVM Intends to Handle Deficient Submissions Filed During the Investigation of a New Animal Drug	PDF (32.96 KB)PDF (32.96 KB) of CVM GFI #119 How CVM Intends to Handle Deficient Submissions Filed During the Investigation of a New Animal Drug	08/29/2002	Center for Veterinary Medicine	Investigational New Animal Drug (INAD)	Final	No		FDA-2001-D-0011
Regulatory Status of Disinfectants Used to Process Dialysate Delivery Systems and Water Purification Systems for Hemodialysis - Guidance for Industry and FDA		08/29/2002	Center for Devices and Radiological Health	Premarket,	Final	No		
CPG Sec. 315.200 Status of Dental Supplies Such as Denture Cleaners Adhesives, Cushions, and Repair Materials as a Device or Cosmetic (CPG REVOKED effective 8/07/2002)		08/06/2002		Investigation & Enforcement, Dental	Final	No		
CPG Sec. 315.200 Status of Dental Supplies such as Denture Cleaners, Adhesives, Cushions, and Repair Materials as a Device or Cosmetic - revoked 8/7/02		08/06/2002		Investigation & Enforcement, Dental	Final	No		
Class II Special Controls Guidance Document: Apnea Monitors; Guidance for Industry and FDA		07/16/2002	Center for Devices and Radiological Health	Premarket,	Final	No		
Class II Special Controls Guidance Document: Polymethylmethacrylate (PMMA) Bone Cement - Guidance for Industry and FDA		07/16/2002	Center for Devices and Radiological Health	Premarket,	Final	No		
Guidance on the Department of Defense Exemption from the FDA Performance Standard for Laser Products: Guidance for Industry and FDA	PDF (318.25 KB)PDF (318.25 KB) of Guidance on the Department of Defense Exemption from the FDA Performance Standard for Laser Products: Guidance for Industry and FDA	07/12/2002	Center for Devices and Radiological Health		Final	No		
Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products--Chemistry, Manufacturing, and Controls Documentation: Guidance for Industry	PDF (285.16 KB)PDF (285.16 KB) of Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products--Chemistry, Manufacturing, and Controls Documentation: Guidance for Industry	07/01/2002	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		
CVM GFI #109 (VICH GL15) Effectiveness of Anthelmintics: Specific Recommendations for Equine	PDF (199.36 KB)PDF (199.36 KB) of CVM GFI #109 (VICH GL15) Effectiveness of Anthelmintics: Specific Recommendations for Equine	06/27/2002	Center for Veterinary Medicine	Anthelmintics, Target Animal – Effectiveness, VICH	Final	No		FDA-2000-D-0135
CVM GFI #110 (VICH GL16) Effectiveness of Anthelmintics: Specific Recommendations for Porcine	PDF (196.2 KB)PDF (196.2 KB) of CVM GFI #110 (VICH GL16) Effectiveness of Anthelmintics: Specific Recommendations for Porcine	06/27/2002	Center for Veterinary Medicine	Anthelmintics, Target Animal – Effectiveness, VICH	Final	No		FDA-2000-D-0135
CVM GFI #111 (VICH GL19) Effectiveness of Anthelmintics: Specific Recommendations for Canine	PDF (214.43 KB)PDF (214.43 KB) of CVM GFI #111 (VICH GL19) Effectiveness of Anthelmintics: Specific Recommendations for Canine	06/27/2002	Center for Veterinary Medicine	Anthelmintics, Target Animal – Effectiveness, VICH	Final	No		FDA-2000-D-0135
CPG Sec. 391.100 Advertisement Literature for High-Intensity Mercury Vapor Discharge Lamps - revoked 6/20/02		06/20/2002		Investigation & Enforcement, Advertising	Final	No		
CVM GFI #113 (VICH GL20) Effectiveness of Anthelmintics: Specific Recommendations for Feline	PDF (227.47 KB)PDF (227.47 KB) of CVM GFI #113 (VICH GL20) Effectiveness of Anthelmintics: Specific Recommendations for Feline	06/19/2002	Center for Veterinary Medicine	Anthelmintics, Target Animal – Effectiveness, VICH	Final	No		FDA-2000-D-0193

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CVM GFI #114 (VICH GL21) Effectiveness of Anthelmintics: Specific Recommendations for Poultry-Gallus Gallus	PDF (200.57 KB)PDF (200.57 KB) of CVM GFI #114 (VICH GL21) Effectiveness of Anthelmintics: Specific Recommendations for Poultry-Gallus Gallus	06/19/2002	Center for Veterinary Medicine	Anthelmintics, Target Animal – Effectiveness, VICH	Final	No		FDA-2000-D-0193
Guidance for Resorbable Adhesion Barrier Devices for Use in Abdominal and/or Pelvic Surgery - Guidance for Industry		06/17/2002	Center for Devices and Radiological Health	Premarket,	Final	No		
Guidance for Industry: Channels of Trade Policy for Commodities with Vinclozolin Residues		06/12/2002	Office of Food Safety	Contaminants, Food & Beverage Safety, Potential Metal or Chemical Contaminant, Contaminants, Potential Metal or Chemical Contaminant, Food & Beverage Safety	Final	No		FDA-2013-S-0610
Carcinogenicity Study Protocol Submissions	PDF (29.3 KB)PDF (29.3 KB) of Carcinogenicity Study Protocol Submissions	05/22/2002		Pharm/Tox	Final	No		
Container Closure Systems for Packaging Human Drugs and Biologics -- Questions and Answers: Guidance for Industry	PDF (34.31 KB)PDF (34.31 KB) of Container Closure Systems for Packaging Human Drugs and Biologics -- Questions and Answers: Guidance for Industry	05/01/2002	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		
Guidance for Industry: Preparation of Food Contact Notifications (Administrative)		05/01/2002	Office of Food Additive Safety	Food & Beverage Safety, Food & Color Additives, Ingredients, Food & Beverage Safety	Final	No		FDA-2013-S-0610
Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis; Guidance for Industry and FDA		04/29/2002	Center for Devices and Radiological Health	Premarket,	Final	No		
Class II Special Controls Guidance Document: Endolymphatic Shunt Tube with Valve - Guidance for Industry and FDA		04/28/2002	Center for Devices and Radiological Health	Premarket,	Final	No		
E2BM Data Elements for Transmission Of Individual Case Safety Reports	PDF (161.56 KB)PDF (161.56 KB) of E2BM Data Elements for Transmission Of Individual Case Safety Reports	04/04/2002	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Efficacy	Final	No		
Guidance for Industry: Preparation of Food Contact Notifications for Food Contact Substances (Toxicology Recommendations)		04/01/2002	Office of Food Additive Safety	Food & Color Additives, Ingredients	Final	No		FDA-2013-S-0610
Validation of Procedures for Processing of Human Tissues Intended for Transplantation: Guidance for Industry	PDF (16.71 KB)PDF (16.71 KB) of Validation of Procedures for Processing of Human Tissues Intended for Transplantation: Guidance for Industry	03/08/2002	Center for Biologics Evaluation and Research	Tissue	Final	No		02D-0073
Guidance for Industry: Providing Regulatory Submissions to CBER in Electronic Format -- Investigational New Drug Applications (INDs) (PDF)	PDF (97.52 KB)PDF (97.52 KB) of Guidance for Industry: Providing Regulatory Submissions to CBER in Electronic Format -- Investigational New Drug Applications (INDs) (PDF)	03/01/2002		Administrative / Procedural	Final	No		
Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors; Guidance for the Medical Device Industry and FDA Review Staff		02/06/2002	Center for Devices and Radiological Health	Premarket,	Final	No		
General Principles of Software Validation: Guidance for Industry and FDA Staff	PDF (367.23 KB)PDF (367.23 KB) of General Principles of Software Validation: Guidance for Industry and FDA Staff	01/11/2002	Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Premarket, Good Clinical Practices (GCP), Digital Health	Final	No		
Small Entity Compliance Guide on Structure/Function Claims		01/09/2002	Office of Dietary Supplement Programs	Food & Beverage Safety, Labeling	Final	No		FDA-2013-S-0610
Sterilized Convenience Kits for Clinical and Surgical Use: Final Guidance for Industry	PDF (99.94 KB)PDF (99.94 KB) of Sterilized Convenience Kits for Clinical and Surgical Use: Final Guidance for Industry	01/07/2002	Center for Devices and Radiological Health	Postmarket,	Final	No		

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies	PDF (39.94 KB)PDF (39.94 KB) of Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies	12/10/2001	Center for Drug Evaluation and Research	Administrative / Procedural	Final	No		
CVM GFI #142 (VICH GL29) Pharmacovigilance of Veterinary Medicinal Products: Management of Periodic Summary Update Reports (PSUs)	PDF (151.51 KB)PDF (151.51 KB) of CVM GFI #142 (VICH GL29) Pharmacovigilance of Veterinary Medicinal Products: Management of Periodic Summary Update Reports (PSUs)	12/06/2001	Center for Veterinary Medicine	Adverse Event Reporting, VICH	Draft	No		FDA-2001-D-0398
Class II Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells - Final Guidance for Industry and FDA		12/03/2001	Center for Devices and Radiological Health	Premarket,	Final	No		
Class II Special Controls Guidance Document: Ingestible Telemetric Gastrointestinal Capsule Imaging System; Final Guidance for Industry and FDA		11/27/2001	Center for Devices and Radiological Health	Premarket,	Final	No		
Guidance for Industry: Fumonisin Levels in Human Foods and Animal Feeds		11/09/2001	Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine	Contaminants, Food & Beverage Safety, Potential Metal or Chemical Contaminant, Contaminants, Potential Metal or Chemical Contaminant, Animal Feed, Food & Beverage Safety	Final	No		FDA-2013-S-0610
Sterility Requirement for Aqueous-Based Drug Products for Oral Inhalation — Small Entity Compliance Guide: Guidance for Industry	PDF (17.58 KB)PDF (17.58 KB) of Sterility Requirement for Aqueous-Based Drug Products for Oral Inhalation — Small Entity Compliance Guide: Guidance for Industry	11/07/2001	Center for Drug Evaluation and Research		Final	No		
Compliance Guidance: The Mammography Quality Standards Act Final Regulations: Preparing For MQSA Inspections; Final		11/04/2001			Final	No		
Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act: Guidance for Industry	PDF (26.99 KB)PDF (26.99 KB) of Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act: Guidance for Industry	11/01/2001	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	User Fees,	Final	No		
Recommendations for Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Possible Exposure to Anthrax: Guidance for Industry	PDF (37.18 KB)PDF (37.18 KB) of Recommendations for Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Possible Exposure to Anthrax: Guidance for Industry	10/17/2001	Center for Biologics Evaluation and Research	Application & Approvals, Blood Products	Final	No		01D-0545
Cancer Drug and Biological Products - Clinical Data in Marketing Applications	PDF (118.63 KB)PDF (118.63 KB) of Cancer Drug and Biological Products - Clinical Data in Marketing Applications	10/11/2001	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Clinical - Medical	Final	No		
CVM GFI #90 (VICH GL7) Effectiveness of Anthelmintics: General Recommendations	PDF (97.85 KB)PDF (97.85 KB) of CVM GFI #90 (VICH GL7) Effectiveness of Anthelmintics: General Recommendations	10/11/2001	Center for Veterinary Medicine	Anthelmintics, Target Animal – Effectiveness, VICH	Final	No		FDA-1999-D-0188
Class II Special Controls Guidance Document: Indwelling Blood Gas Analyzers - Final Guidance for Industry and FDA		10/04/2001	Center for Devices and Radiological Health	Premarket,	Final	No		
Content and Format for Geriatric Labeling	PDF (37.72 KB)PDF (37.72 KB) of Content and Format for Geriatric Labeling	10/01/2001	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Labeling	Final	No		
Redbook 2000: VI.B Epidemiology		10/01/2001	Office of Food Additive Safety	Food & Color Additives	Final	No		
Submitting Marketing Applications According to the ICH/CTD Format: General Considerations 2001		09/05/2001	Center for Drug Evaluation and Research	Administrative / Procedural	Draft	No		

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Submitting Marketing Applications According to the ICH/CTD Format: General Considerations	PDF (174.62 KB)PDF (174.62 KB) of Submitting Marketing Applications According to the ICH/CTD Format: General Considerations	09/01/2001	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Administrative / Procedural, ICH-Multidisciplinary	Draft	No		
Guidance for Industry: Questions and Answers on Juice HACCP Regulation		08/31/2001	Office of Food Safety	HACCP, Juice	Final	No		
M4: The CTD -- Efficacy	PDF (285.73 KB)PDF (285.73 KB) of M4: The CTD -- Efficacy	08/01/2001	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Multidisciplinary	Final	No		
M4: The CTD -- Quality	PDF (130.92 KB)PDF (130.92 KB) of M4: The CTD -- Quality	08/01/2001	Center for Drug Evaluation and Research	ICH-Multidisciplinary	Final	No		
M4S: The CTD -- Safety	PDF (115.51 KB)PDF (115.51 KB) of M4S: The CTD -- Safety	08/01/2001	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Multidisciplinary	Final	No		
M4S: The CTD -- Safety Appendices	PDF (1.96 MB)PDF (1.96 MB) of M4S: The CTD -- Safety Appendices	08/01/2001	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Multidisciplinary	Final	No		
Labeling Recommendations for Single-Use Devices Reprocessed by Third Parties and Hospitals: Final Guidance for Industry and FDA	PDF (45.56 KB)PDF (45.56 KB) of Labeling Recommendations for Single-Use Devices Reprocessed by Third Parties and Hospitals: Final Guidance for Industry and FDA	07/30/2001	Center for Devices and Radiological Health		Final	No		
Premarket Notification Submissions for Empty Containers for the Collection and Processing of Blood and Blood Components: Guidance for FDA Reviewers	PDF (29.88 KB)PDF (29.88 KB) of Premarket Notification Submissions for Empty Containers for the Collection and Processing of Blood and Blood Components: Guidance for FDA Reviewers	07/19/2001	Center for Biologics Evaluation and Research	Application & Approvals, Blood Products	Final	No		
Premarket Notification Submissions for Blood and Plasma Warmers: Guidance for FDA Reviewers	PDF (31.21 KB)PDF (31.21 KB) of Premarket Notification Submissions for Blood and Plasma Warmers: Guidance for FDA Reviewers	07/19/2001	Center for Biologics Evaluation and Research	Application & Approvals, Blood Products	Final	No		
Premarket Notification Submissions for Transfer Sets (Excluding Sterile Connecting Devices): Guidance for FDA Reviewers	PDF (29.87 KB)PDF (29.87 KB) of Premarket Notification Submissions for Transfer Sets (Excluding Sterile Connecting Devices): Guidance for FDA Reviewers	07/19/2001	Center for Biologics Evaluation and Research	Application & Approvals, Blood Products	Final	No		
Revised Recommendations Regarding Invalidation of Test Results of Licensed and 510(k) Cleared Bloodborne Pathogen Assays Used to Test Donors: Guidance for Industry	PDF (32.91 KB)PDF (32.91 KB) of Revised Recommendations Regarding Invalidation of Test Results of Licensed and 510(k) Cleared Bloodborne Pathogen Assays Used to Test Donors: Guidance for Industry	07/11/2001	Center for Biologics Evaluation and Research	Application & Approvals, Blood Products	Final	No		99D-2213
CVM GFI #104 Content and Format of Effectiveness and Target Animal Safety Technical Sections and Final Study Reports For Submission	PDF (173.8 KB)PDF (173.8 KB) of CVM GFI #104 Content and Format of Effectiveness and Target Animal Safety Technical Sections and Final Study Reports For Submission	07/10/2001	Center for Veterinary Medicine	New Animal Drug Application (NADA), Target Animal – Effectiveness, Target Animal – Safety, Investigational New Animal Drug (INAD)	Final	No		
CVM GFI #56 Protocol Development Guideline for Clinical Effectiveness and Target Animal Safety Trials	PDF (60.4 KB)PDF (60.4 KB) of CVM GFI #56 Protocol Development Guideline for Clinical Effectiveness and Target Animal Safety Trials	07/10/2001	Center for Veterinary Medicine	Environmental Safety, Target Animal – Effectiveness, Target Animal – Safety	Final	No		

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Frequently-Asked-Questions about the Reprocessing and Reuse of Single-Use Devices by Third-Party and Hospital Reprocessors: Final Guidance for Industry and FDA Staff	PDF (287.92 KB)PDF (287.92 KB) of Frequently-Asked-Questions about the Reprocessing and Reuse of Single-Use Devices by Third-Party and Hospital Reprocessors: Final Guidance for Industry and FDA Staff	07/06/2001	Center for Devices and Radiological Health	Premarket,	Final	No		
Guidance for Industry: Refusal of Inspection or Access to HACCP Records Pertaining to the Safe and Sanitary Processing of Fish and Fishery Products		07/01/2001	Office of Food Safety	Food & Beverage Safety, HACCP, Records, Seafood/Seafood Product, Food & Beverage Safety	Final	No		FDA-2013-S-0610
Levothyroxine Sodium Products Enforcement of August 14, 2001 Compliance Date and Submission of New Applications	PDF (24.32 KB)PDF (24.32 KB) of Levothyroxine Sodium Products Enforcement of August 14, 2001 Compliance Date and Submission of New Applications	07/01/2001	Center for Drug Evaluation and Research	Administrative / Procedural	Final	No		
S7A Safety Pharmacology Studies for Human Pharmaceuticals	PDF (44.06 KB)PDF (44.06 KB) of S7A Safety Pharmacology Studies for Human Pharmaceuticals	07/01/2001	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Safety	Final	No		
Small Entity Compliance Guide: Safe Handling Statements on Labeling of Shell Eggs and the Refrigeration of Shell Eggs Held for Retail Distribution		07/01/2001	Office of Nutrition and Food Labeling	Egg/Egg Product, Labeling, Nutrition Label, Retail Food Protection	Final	No		FDA-2013-S-0610
Small Entity Compliance Guide: Serving Sizes Reference Amount for Baking Powder, Baking Soda, and Pectin		07/01/2001	Office of Nutrition and Food Labeling	Bakery Product/Mix, Food & Beverage Safety, Labeling, Nutrition Label	Final	No		FDA-1998-N-0050
Information for Keratome Manufacturers Regarding LASIK - Final Guidance for Industry		06/20/2001	Center for Devices and Radiological Health	Postmarket,	Final	No		
Changes or Modifications During the Conduct of a Clinical Investigation; Final Guidance for Industry and CDRH Staff		05/28/2001	Center for Devices and Radiological Health	Premarket,	Final	No		1337
Responsibilities of Laser Light Show Projector Manufacturers, Dealers, and Distributors; (Laser Notice 51)		05/26/2001			Final	No		
Class II Special Controls Guidance Document: Tissue Culture Media for Human ex vivo Tissue and Cell Culture Processing Applications - Final Guidance for Industry and FDA Reviewers		05/15/2001	Center for Devices and Radiological Health	Premarket,	Final	No		
CVM GFI #85 (VICH GL9) Good Clinical Practice	PDF (355.95 KB)PDF (355.95 KB) of CVM GFI #85 (VICH GL9) Good Clinical Practice	05/09/2001	Center for Veterinary Medicine	Target Animal – Effectiveness, Target Animal – Safety, VICH	Final	No		FDA-1999-D-0754
Statistical Aspects of the Design, Analysis, and Interpretation of Chronic Rodent Carcinogenicity Studies of Pharmaceuticals	PDF (135.48 KB)PDF (135.48 KB) of Statistical Aspects of the Design, Analysis, and Interpretation of Chronic Rodent Carcinogenicity Studies of Pharmaceuticals	05/08/2001		Pharm/Tox	Final	No		
E10 Choice of Control Group and Related Issues in Clinical Trials	PDF (93.22 KB)PDF (93.22 KB) of E10 Choice of Control Group and Related Issues in Clinical Trials	05/01/2001	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Efficacy	Final	No		
IND Meetings for Human Drugs and Biologics Chemistry, Manufacturing, and Controls Information: Guidance for Industry	PDF (30.12 KB)PDF (30.12 KB) of IND Meetings for Human Drugs and Biologics Chemistry, Manufacturing, and Controls Information: Guidance for Industry	05/01/2001	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		
Hospital Reprocessors: Guidance on Adverse Event Reporting for Hospitals that Reprocess Devices Intended by the Original Equipment Manufacturer for Single Use		04/23/2001	Center for Devices and Radiological Health	Adverse Event Reporting System (FAERS),	Final	No		
Guidance on Medical Device Patient Labeling: Final Guidance for Industry and FDA Staff	PDF (333.25 KB)PDF (333.25 KB) of Guidance on Medical Device Patient Labeling: Final Guidance for Industry and FDA Staff	04/19/2001	Center for Devices and Radiological Health	Labeling	Final	No		

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Guidance for Hospitals, Nursing Homes, and Other Health Care Facilities - FDA Public Health Advisory: Guidance for Hospitals, Nursing Homes, and Other Health Care Facilities	PDF (18.7 KB)PDF (18.7 KB) of Guidance for Hospitals, Nursing Homes, and Other Health Care Facilities - FDA Public Health Advisory: Guidance for Hospitals, Nursing Homes, and Other Health Care Facilities	04/05/2001	Center for Drug Evaluation and Research	Current Good Manufacturing Practices (CGMP), Pharmaceutical Quality	Final	No		
CVM GFI #95 (VICH GL12) Efficacy of Anthelmintics: Specific Recommendations for Bovines	PDF (96.09 KB)PDF (96.09 KB) of CVM GFI #95 (VICH GL12) Efficacy of Anthelmintics: Specific Recommendations for Bovines	03/26/2001	Center for Veterinary Medicine	Anthelmintics, Target Animal – Effectiveness, VICH	Final	No		FDA-1999-D-0188
CVM GFI #96 (VICH GL13) Efficacy of Anthelmintics: Specific Recommendations for Ovines	PDF (85.63 KB)PDF (85.63 KB) of CVM GFI #96 (VICH GL13) Efficacy of Anthelmintics: Specific Recommendations for Ovines	03/26/2001	Center for Veterinary Medicine	Anthelmintics, Target Animal – Effectiveness, VICH	Final	No		FDA-1999-D-0188
CVM GFI #97 (VICH GL14) Efficacy of Anthelmintics: Specific Recommendations for Caprines	PDF (90.31 KB)PDF (90.31 KB) of CVM GFI #97 (VICH GL14) Efficacy of Anthelmintics: Specific Recommendations for Caprines	03/26/2001	Center for Veterinary Medicine	Anthelmintics, Target Animal – Effectiveness, VICH	Final	No		FDA-1999-D-0188
CVM GFI #99 (VICH GL17) Testing of New Biotechnological/Biological Products	PDF (118.25 KB)PDF (118.25 KB) of CVM GFI #99 (VICH GL17) Testing of New Biotechnological/Biological Products	03/26/2001	Center for Veterinary Medicine	Biotechnology, Chemistry, Manufacturing, and Controls (CMC), VICH	Final	No		
Acceptance of Foreign Clinical Studies: Guidance for Industry	PDF (37.17 KB)PDF (37.17 KB) of Acceptance of Foreign Clinical Studies: Guidance for Industry	03/13/2001	Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Premarket, Good Clinical Practices (GCP)	Final	No		
Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines: Draft Draft Guidance for Industry	PDF (380.54 KB)PDF (380.54 KB) of Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines: Draft Draft Guidance for Industry	03/12/2001	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Vaccines	Draft	No		01D-0056
Class II Special Controls Guidance Document: Pharmacy Compounding Systems; Final Guidance for Industry and FDA		03/11/2001	Center for Devices and Radiological Health	Premarket,	Final	No		
Class II Special Controls Guidance for Home Uterine Activity Monitors; Final Guidance for Industry and FDA Reviewers (PDF Version Only)	PDF (68.81 KB)PDF (68.81 KB) of Class II Special Controls Guidance for Home Uterine Activity Monitors; Final Guidance for Industry and FDA Reviewers (PDF Version Only)	03/09/2001		Premarket,	Final	No		
Class II Special Controls Guidance for Home Uterine Activity Monitors - Final Guidance for Industry and FDA Reviewers		03/08/2001	Center for Devices and Radiological Health	Premarket,	Final	No		
CVM GFI #89 (VICH GL6) EIAs for Veterinary Medicinal Products - Phase I	PDF (106.15 KB)PDF (106.15 KB) of CVM GFI #89 (VICH GL6) EIAs for Veterinary Medicinal Products - Phase I	03/07/2001	Center for Veterinary Medicine	Environmental Safety, VICH	Final	No		FDA-1999-D-3541
Monoclonal Antibodies Used as Reagents in Drug Manufacturing	PDF (28.78 KB)PDF (28.78 KB) of Monoclonal Antibodies Used as Reagents in Drug Manufacturing	03/01/2001	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		
Early Collaboration Meetings Under the FDA Modernization Act (FDAMA); Final Guidance for Industry and for CDRH Staff		02/27/2001		Premarket,	Final	No		

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods - Technical Correction February 2001: Guidance for Industry	PDF (28.7 KB)PDF (28.7 KB) of Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods - Technical Correction February 2001: Guidance for Industry	02/13/2001	Center for Biologics Evaluation and Research	Blood Products	Final	No		98D-0545
Clinical Development and Labeling of Anti-Infective Drug Products	PDF (5.11 MB)PDF (5.11 MB) of Clinical Development and Labeling of Anti-Infective Drug Products	02/12/2001	Center for Drug Evaluation and Research	Clinical - Antimicrobial	Final	No		
Implementation of Third Party Programs Under the FDA Modernization Act of 1997 - Final Guidance for Staff, Industry and Third Parties		02/01/2001	Center for Devices and Radiological Health		Final	No		
Levothyroxine Sodium Tablets - In Vivo Pharmacokinetic and Bioavailability Studies and In Vitro Dissolution Testing	PDF (27.48 KB)PDF (27.48 KB) of Levothyroxine Sodium Tablets - In Vivo Pharmacokinetic and Bioavailability Studies and In Vitro Dissolution Testing	02/01/2001	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		
Statistical Approaches to Establishing Bioequivalence	PDF (130.1 KB)PDF (130.1 KB) of Statistical Approaches to Establishing Bioequivalence	02/01/2001	Center for Drug Evaluation and Research	Biopharmaceutics	Final	No		01D-0027
Guidance for Annuloplasty Rings 510(k) Submissions - Final Guidance for Industry and FDA Staff		01/30/2001	Center for Devices and Radiological Health	Premarket,	Final	No		1358
PHS Guideline on Infectious Disease Issues in Xenotransplantation: PHS Guideline	PDF (521.29 KB)PDF (521.29 KB) of PHS Guideline on Infectious Disease Issues in Xenotransplantation: PHS Guideline	01/19/2001	Center for Biologics Evaluation and Research	Xenotransplantation	Final	No		96M-0311
Content of Investigational Device Exemptions for Solutions for Hypothermic Flushing, Transport and Storage of Organs for Transplantation - Guidance for Industry and FDA Reviewers		01/15/2001	Center for Devices and Radiological Health	Premarket, Device Exception (IDE)	Final	No		
Changes to an Approved NDA or ANDA: Questions and Answers: Guidance for Industry	PDF (35.44 KB)PDF (35.44 KB) of Changes to an Approved NDA or ANDA: Questions and Answers: Guidance for Industry	01/01/2001	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		
Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances		12/28/2000	Center for Drug Evaluation and Research	ICH-Quality	Final	No		
Alternate Source of the Active Pharmaceutical Ingredient in Pending ANDAs: Guidance for Industry	PDF (14.36 KB)PDF (14.36 KB) of Alternate Source of the Active Pharmaceutical Ingredient in Pending ANDAs: Guidance for Industry	12/01/2000	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		
E11 Clinical Investigation of Medicinal Products in the Pediatric Population	PDF (60.38 KB)PDF (60.38 KB) of E11 Clinical Investigation of Medicinal Products in the Pediatric Population	12/01/2000	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Efficacy	Final	No		
Labeling OTC Human Drug Products Using a Column Format	PDF (57 KB)PDF (57 KB) of Labeling OTC Human Drug Products Using a Column Format	12/01/2000	Center for Drug Evaluation and Research	Over-the-Counter Drugs	Final	No		
Guidance for Industry: Channels of Trade Policy for Commodities with Methyl Parathion Residues		11/30/2000	Office of Food Safety	Contaminants, Food & Beverage Safety, Potential Metal or Chemical Contaminant, Contaminants, Potential Metal or Chemical Contaminant, Food & Beverage Safety	Final	No		FDA-2013-S-0610
Class II Special Control Guidance Document for B-Type Natriuretic Peptide Premarket Notifications - Final Guidance for Industry and FDA Reviewers		11/29/2000	Center for Devices and Radiological Health	Premarket,	Final	No		
Guidance for Cardiopulmonary Bypass Arterial Line Blood Filter 510(k) Submissions - Final Guidance for Industry and FDA		11/28/2000	Center for Devices and Radiological Health	Premarket, 510(k)	Final	No		

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Guidance for Extracorporeal Blood Circuit Defoamer - 510(k) Submissions - Final Guidance for Industry and FDA		11/28/2000	Center for Devices and Radiological Health	Premarket, 510(k)	Final	No		
Use of Sterile Connecting Devices in Blood Bank Practices: Guidance for Industry	PDF (38.25 KB)PDF (38.25 KB) of Use of Sterile Connecting Devices in Blood Bank Practices: Guidance for Industry	11/22/2000	Center for Biologics Evaluation and Research	Application & Approvals, Blood Products	Final	No		
Potency Limits for Standardized Dust Mite and Grass Allergen Vaccines: A Revised Protocol: Guidance for Reviewers	PDF (49.14 KB)PDF (49.14 KB) of Potency Limits for Standardized Dust Mite and Grass Allergen Vaccines: A Revised Protocol: Guidance for Reviewers	11/20/2000	Center for Biologics Evaluation and Research	Allergenics	Final	No		00D-0218
Testing Limits in Stability Protocols for Standardized Grass Pollen Extracts: Guidance for Industry	PDF (55.32 KB)PDF (55.32 KB) of Testing Limits in Stability Protocols for Standardized Grass Pollen Extracts: Guidance for Industry	11/20/2000	Center for Biologics Evaluation and Research	Allergenics	Final	No		97D-3010
Guidance for Cardiopulmonary Bypass Oxygenators 510(k) Submissions - Final Guidance for Industry and FDA Staff		11/12/2000	Center for Devices and Radiological Health	Premarket,	Final	No		
Guidance Document for Dura Substitute Devices - Guidance for Industry		11/08/2000	Center for Devices and Radiological Health	Premarket,	Final	No		
Investigational Device Exemption (IDE) Study Enrollment for Cardiac Ablation of Typical Atrial Flutter - Final Guidance for Industry and FDA Reviewers		11/07/2000	Center for Devices and Radiological Health	Premarket, Device Exception (IDE)	Final	No		
Guidance Document for Vascular Prostheses 510(k) Submissions - Guidance for Industry and FDA Staff		10/31/2000	Center for Devices and Radiological Health	Premarket,	Final	No		
Guidance for the Submission of Research and Marketing Applications for Permanent Pacemaker Leads and for Pacemaker Lead Adaptor 510(k) Submissions - Guidance for Industry		10/31/2000	Center for Devices and Radiological Health	Premarket,	Final	No		372
Class II Special Controls Guidance: Shoulder Joint Metal/Polymer/Metal Nonconstrained or Semi-Constrained Porous-Coated Uncemented Prosthesis - Guidance for Industry and FDA Staff		10/30/2000	Center for Devices and Radiological Health	Premarket,	Final	No		
Content and Format of INDs for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-Derived Products. Questions and Answers: Guidance for Industry Q&A	PDF (14.19 KB)PDF (14.19 KB) of Content and Format of INDs for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-Derived Products. Questions and Answers: Guidance for Industry Q&A	10/01/2000	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Clinical - Medical, Investigational New Drug Application (INDA), Pharm/Tox	Final	No		
Submitting and Reviewing Complete Responses to Clinical Holds (Revised)	PDF (25.51 KB)PDF (25.51 KB) of Submitting and Reviewing Complete Responses to Clinical Holds (Revised)	10/01/2000	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Administrative / Procedural, Good Clinical Practices (GCP)	Final	No		
CVM GFI #106 Published Literature in Support of New Animal Drug Approval	PDF (41.01 KB)PDF (41.01 KB) of CVM GFI #106 Published Literature in Support of New Animal Drug Approval	08/31/2000	Center for Veterinary Medicine	New Animal Drug Application (NADA), Target Animal – Effectiveness, Target Animal – Safety, Investigational New Animal Drug (INAD)	Final	No		
Class II Special Control Guidance Document for Anti-Saccharomyces cerevisiae (S. cerevisiae) Antibody (ASCA) Premarket Notifications - Guidance for Industry and FDA Reviewers		08/22/2000	Center for Devices and Radiological Health	Premarket,	Final	No		
CPG Sec. 230.110- Registration of Blood Banks, Other Firms Collecting, Manufacturing, Preparing or Processing Human Blood or Blood Products		08/16/2000		Investigation & Enforcement,	Final	No		
Labeling for Electronic Anti-Theft Systems: Guidance for Industry	PDF (31.18 KB)PDF (31.18 KB) of Labeling for Electronic Anti-Theft Systems: Guidance for Industry	08/15/2000	Center for Devices and Radiological Health	Premarket, Labeling	Final	No		

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CPG Sec. 280.110- Microbiological Control Requirements-Licensed Anti-Human Globulin & Blood Grouping Reagents		08/14/2000		Investigation & Enforcement,	Final	No		
Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals: Guidance for Industry and for FDA Staff	PDF (110.45 KB)PDF (110.45 KB) of Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals: Guidance for Industry and for FDA Staff	08/14/2000	Center for Devices and Radiological Health	Postmarket,	Final	No		
CPG Sec. 280.100 - Stability Requirements - Licensed In Vitro Diagnostic Products		08/13/2000		Investigation & Enforcement,	Final	No		
Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi - Guidance for Industry and for FDA Reviewers		08/08/2000	Center for Devices and Radiological Health	Premarket,	Final	No		
Guidance on Section 216 of the Food and Drug Administration Modernization Act of 1997 - Guidance for Industry and for FDA Reviewers		08/08/2000	Center for Devices and Radiological Health		Final	No		
CPG Sec. 515.700 Chocolate & Chocolate Liquor - Adulteration with Insect and Rodent Filth	PDF (10.36 KB)PDF (10.36 KB) of CPG Sec. 515.700 Chocolate & Chocolate Liquor - Adulteration with Insect and Rodent Filth	08/01/2000		Investigation & Enforcement,	Final	No		
E12A Principles for Clinical Evaluation of New Antihypertensive Drugs	PDF (26.9 KB)PDF (26.9 KB) of E12A Principles for Clinical Evaluation of New Antihypertensive Drugs	08/01/2000	Center for Drug Evaluation and Research	ICH-Efficacy	Draft	No		
Guidance for the Submission of Premarket Notifications for Photon-Emitting Brachytherapy Sources - Guidance for Industry		08/01/2000	Center for Devices and Radiological Health	Premarket,	Final	No		
CPG Sec. 220.100 - IS Shipment Biologicals for Medical Emergency		07/31/2000		Investigation & Enforcement, Investigational New Drug Application (INDA)	Final	No		
CPG Sec. 270.100 Final Container Labels - Allergenic Extracts Containing Glycerin; Reporting Changes		07/31/2000		Investigation & Enforcement, Allergenics	Final	No		
Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed		07/31/2000	Center for Food Safety and Applied Nutrition	Sanitation, Animal Feed	Final	No		FDA-1998-N-0050
Guidance for Over-the-Counter (OTC) Human Chorionic Gonadotropin (hCG) 510(k)s - Guidance for Industry and FDA Reviewers/Staff		07/21/2000		Premarket,	Final	No		
1-Consolidated Annual Report for a Device product line (1-CARD) - Guidance for Industry and CDRH Reviewers		07/05/2000	Center for Devices and Radiological Health		Final	No		
Class II Special Control Guidance Document for Acute Upper Airway Obstruction Devices - Guidance for Industry and FDA Reviewers		07/02/2000	Center for Devices and Radiological Health	Premarket,	Final	No		
Class II Special Controls Guidance Document for Clitoral Engorgement Devices - Guidance for Industry and FDA Reviewers		07/02/2000	Center for Devices and Radiological Health		Final	No		
Redbook 2000: IV.C.1.d. Mammalian Erythrocyte Micronucleus Test		07/01/2000	Office of Food Additive Safety	Food & Color Additives	Final	No		
Redbook 2000: IV.C.9.b. Guidelines for Developmental Toxicity Studies		07/01/2000	Office of Food Additive Safety	Food & Color Additives	Final	No		
CPG Sec. 100.950 International Partnership Agreements for Compliance Activities		06/28/2000		Investigation & Enforcement, Food & Color Additives	Final	No		
Availability of Licensed Donor Screening Tests Labeled for Use with Cadaveric Blood Specimens: Guidance for Industry	PDF (18.29 KB)PDF (18.29 KB) of Availability of Licensed Donor Screening Tests Labeled for Use with Cadaveric Blood Specimens: Guidance for Industry	06/01/2000	Center for Biologics Evaluation and Research	Tissue	Final	No		
Revising ANDA Labeling Following Revision of the RLD Labeling	PDF (18.83 KB)PDF (18.83 KB) of Revising ANDA Labeling Following Revision of the RLD Labeling	04/26/2000	Center for Drug Evaluation and Research	Generic Drugs	Final	No		

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
CPG Sec. 110.100 Certification for Exports		04/13/2000	Office of Regulatory Affairs	Investigation & Enforcement, Food & Color Additives	Final	No		
CVM GFI #98 Dioxin In Anti-Caking Agents In Animal Feed And Feed Ingredients	PDF (35.15 KB)PDF (35.15 KB) of CVM GFI #98 Dioxin In Anti-Caking Agents In Animal Feed And Feed Ingredients	04/12/2000	Center for Veterinary Medicine	Animal Feed	Final	No		FDA-1999-D-2441
Guidance for Premarket Submissions of Orthokeratology Rigid Gas Permeable Contact Lenses - Guidance for Industry		04/09/2000	Center for Devices and Radiological Health	Premarket,	Final	No		
Patient Instructions (Part 2) After Your TN (generic name) Rigid Gas Permeable Contact Lenses For Orthokeratology Have Been Fitted		04/09/2000		Premarket,	Final	No		
Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act	PDF (25.28 KB)PDF (25.28 KB) of Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act	03/27/2000		Administrative / Procedural	Final	No		
CPG Sec. 215.100 IND Filings; Completion of Applicable Portions Prior to Final Action on License Applications or License Supplements, Deleted 03/28/2000, Outdated and Obsolete		03/27/2000		Investigation & Enforcement,	Final	No		
Guidance for Manufacturers Seeking Marketing Clearance of Ear, Nose, and Throat Endoscope Sheaths Used as Protective Barriers: Guidance for Industry		03/11/2000	Center for Devices and Radiological Health	Premarket,	Final	No		954
CPG Sec. 252.110 Volume Limits for Automated Collection of Source Plasma (Obsolete, Withdrawn on 11/28/2017)		03/05/2000		Investigation & Enforcement, Blood Products	Final	No		
Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act.	PDF (25.28 KB)PDF (25.28 KB) of Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act.	03/01/2000	Center for Drug Evaluation and Research	Generic Drugs	Final	No		
CVM GFI #91 (VICH GL8) Stability Testing for Medicated Premixes	PDF (47.42 KB)PDF (47.42 KB) of CVM GFI #91 (VICH GL8) Stability Testing for Medicated Premixes	03/01/2000	Center for Veterinary Medicine	Chemistry, Manufacturing, and Controls (CMC), VICH, Animal Feed	Final	No		
Street Drug Alternatives	PDF (10.51 KB)PDF (10.51 KB) of Street Drug Alternatives	03/01/2000	Center for Drug Evaluation and Research	Compliance, Current Good Manufacturing Practices (CGMP)	Final	No		
Reprocessing and Reuse of Single-Use Devices : Guidance for Industry and FDA Reviewers	PDF (2.14 MB)PDF (2.14 MB) of Reprocessing and Reuse of Single-Use Devices : Guidance for Industry and FDA Reviewers	02/08/2000	Center for Devices and Radiological Health	Premarket,	Final	No		
Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements - Guidance for Industry and for FDA Reviewers/Staff		02/01/2000	Center for Devices and Radiological Health	Postmarket,	Final	No		
NDAs: Impurities in Drug Substances	PDF (11.2 KB)PDF (11.2 KB) of NDAs: Impurities in Drug Substances	02/01/2000		Chemistry, Manufacturing, and Controls (CMC)	Final	No		
Guidance Document for Premarket Notification Submissions for Nitric Oxide Delivery Apparatus, Nitric Oxide Analyzer and Nitrogen Dioxide Analyzer: Guidance for Industry and for FDA Reviewers	PDF (1.57 MB)PDF (1.57 MB) of Guidance Document for Premarket Notification Submissions for Nitric Oxide Delivery Apparatus, Nitric Oxide Analyzer and Nitrogen Dioxide Analyzer: Guidance for Industry and for FDA Reviewers	01/24/2000	Center for Devices and Radiological Health	Premarket, 510(k)	Final	No		
Alternative to Certain Prescription Device Labeling Requirements : Guidance for Industry	PDF (22.13 KB)PDF (22.13 KB) of Alternative to Certain Prescription Device Labeling Requirements : Guidance for Industry	01/21/2000	Center for Devices and Radiological Health	Labeling	Final	No		
Guidance for the Content of Premarket Notifications for Penile Rigidity Implants - Guidance for Industry and for FDA Staff		01/15/2000	Center for Devices and Radiological Health	Premarket, 510(k)	Final	No		

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Guidance Document for the Preparation of IDEs for Spinal Systems - Guidance for Industry and/or FDA Staff		01/12/2000	Center for Devices and Radiological Health	Labeling	Final	No		
CPG Sec. 300.200 - Reconditioners/Rebuilders of Medical Devices - Revoked-Deletion 01/04/2000		01/03/2000		Investigation & Enforcement,	Final	No		
Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants - Guidance for Industry and FDA Reviewers		01/02/2000	Center for Devices and Radiological Health	Premarket, 510(k)	Final	No		
In the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Nucleic Acid Sequences of Human Immunodeficiency Viruses Types 1 and 2: Guidance for Industry	PDF (53.29 KB)PDF (53.29 KB) of In the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Nucleic Acid Sequences of Human Immunodeficiency Viruses Types 1 and 2: Guidance for Industry	12/14/1999	Center for Biologics Evaluation and Research	Blood Products	Final	No		98D-0483
Applications Covered by Section 505(b)(2)	PDF (41.41 KB)PDF (41.41 KB) of Applications Covered by Section 505(b)(2)	12/08/1999	Center for Drug Evaluation and Research	Administrative / Procedural	Draft	No		
Guidance for Industry: Seafood HACCP Transition Guidance		12/01/1999	Office of Food Safety	Food & Beverage Safety, HACCP, Seafood/Seafood Product, Food & Beverage Safety	Final	No		FDA-2013-S-0610
Guidance for Cardiovascular Intravascular Filter 510(k) Submissions - Guidance for Industry and FDA Staff		11/25/1999	Center for Devices and Radiological Health	Premarket, Cardiovascular	Final	No		
Disclosure of Materials Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Convened by the Center for Drug Evaluation and Research Beginning on January 1, 2000	PDF (10.32 KB)PDF (10.32 KB) of Disclosure of Materials Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Convened by the Center for Drug Evaluation and Research Beginning on January 1, 2000	11/01/1999	Center for Drug Evaluation and Research	Administrative / Procedural	Final	No		
Drug Master Files for Bulk Antibiotic Drug Substances: Guidance for Industry	PDF (23.23 KB)PDF (23.23 KB) of Drug Master Files for Bulk Antibiotic Drug Substances: Guidance for Industry	11/01/1999	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		
Providing Regulatory Submissions to the Center for Biologics Evaluation and Research (CBER) in Electronic Format - Biologics Marketing Applications: Guidance for Industry	PDF (713.82 KB)PDF (713.82 KB) of Providing Regulatory Submissions to the Center for Biologics Evaluation and Research (CBER) in Electronic Format - Biologics Marketing Applications: Guidance for Industry	11/01/1999	Center for Biologics Evaluation and Research	Administrative / Procedural	Final	No		
CVM GFI #74 (VICH GL4) Stability Testing of New Veterinary Dosage Forms	PDF (78.51 KB)PDF (78.51 KB) of CVM GFI #74 (VICH GL4) Stability Testing of New Veterinary Dosage Forms	09/01/1999	Center for Veterinary Medicine	Chemistry, Manufacturing, and Controls (CMC), VICH	Final	No		FDA -2006-D-0299
CVM GFI #75 (VICH GL5) Stability Testing-Photostability Testing of New Veterinary Drug Substances and Medicinal Products	PDF (76.02 KB)PDF (76.02 KB) of CVM GFI #75 (VICH GL5) Stability Testing-Photostability Testing of New Veterinary Drug Substances and Medicinal Products	09/01/1999	Center for Veterinary Medicine	Chemistry, Manufacturing, and Controls (CMC), VICH	Final	No		FDA-1998-D-1165
CVM GFI #102 Manufacture and Distribution of Unapproved Piperazine Products		08/26/1999	Center for Veterinary Medicine	Anthelmintics	Final	No		
Possible Dioxin/PCB Contamination of Drug and Biological Products	PDF (7.73 KB)PDF (7.73 KB) of Possible Dioxin/PCB Contamination of Drug and Biological Products	08/23/1999		Current Good Manufacturing Practices (CGMP), Pharmaceutical Quality	Final	No		
Consumer-Directed Broadcast Advertisements	PDF (35.57 KB)PDF (35.57 KB) of Consumer-Directed Broadcast Advertisements	08/09/1999	Center for Veterinary Medicine, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Advertising	Final	No		97D-0302

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Consumer-Directed Broadcast Advertisements Questions and Answers	PDF (83.18 KB)PDF (83.18 KB) of Consumer-Directed Broadcast Advertisements Questions and Answers	08/01/1999	Center for Veterinary Medicine, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Advertising	Final	No		
Q6B Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products	PDF (54 KB)PDF (54 KB) of Q6B Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products	08/01/1999	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Quality	Final	No		
Submission of Abbreviated Reports and Synopses in Support of Marketing Applications.	PDF (43.08 KB)PDF (43.08 KB) of Submission of Abbreviated Reports and Synopses in Support of Marketing Applications.	08/01/1999	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Clinical - Medical	Final	No		
Consumer-Directed Broadcast Advertisements: Guidance for Industry	PDF (25.43 KB)PDF (25.43 KB) of Consumer-Directed Broadcast Advertisements: Guidance for Industry	07/31/1999	Center for Veterinary Medicine, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Advertising	Final	No		
CPG Sec. 230.140 Evaluation and Processing Post Donation Information Reports is obsolete and was withdrawn on 7/16/2018.	PDF (131.44 KB)PDF (131.44 KB) of CPG Sec. 230.140 Evaluation and Processing Post Donation Information Reports is obsolete and was withdrawn on 7/16/2018.	07/09/1999		Investigation & Enforcement, Blood Products	Final	No		
CVM GFI #63 (VICH GL1) Validation of Analytical Procedures: Definition and Terminology	PDF (118.41 KB)PDF (118.41 KB) of CVM GFI #63 (VICH GL1) Validation of Analytical Procedures: Definition and Terminology	07/01/1999	Center for Veterinary Medicine	Chemistry, Manufacturing, and Controls (CMC), VICH	Final	No		
CVM GFI #64 (VICH GL2) Validation of Analytical Procedures: Methodology: Final Guidance	PDF (218.47 KB)PDF (218.47 KB) of CVM GFI #64 (VICH GL2) Validation of Analytical Procedures: Methodology: Final Guidance	07/01/1999	Center for Veterinary Medicine	Chemistry, Manufacturing, and Controls (CMC), VICH	Final	No		
Guidance for Industry: Antimicrobial Food Additives		06/30/1999	Office of Food Additive Safety	Food & Color Additives, Ingredients	Final	No		FDA-2013-S-0610
S4A Duration of Chronic Toxicity Testing in Animals (Rodent and Nonrodent Toxicity Testing)	PDF (20.77 KB)PDF (20.77 KB) of S4A Duration of Chronic Toxicity Testing in Animals (Rodent and Nonrodent Toxicity Testing)	06/25/1999	Center for Drug Evaluation and Research	ICH-Safety	Final	No		
Guidance Document for Powered Muscle Stimulator 510(k)s - Guidance for Industry, FDA Reviewers/Staff and Compliance		06/08/1999	Center for Devices and Radiological Health	Premarket,	Final	No		2246
Fees-Exceed-the-Costs Waivers Under the Prescription Drug User Fee Act	PDF (48.22 KB)PDF (48.22 KB) of Fees-Exceed-the-Costs Waivers Under the Prescription Drug User Fee Act	06/01/1999	Center for Drug Evaluation and Research	User Fees,	Final	No		
Efficacy Studies to Support Marketing of Fibrin Sealant Products Manufactured for Commercial Use: Guidance for Industry	PDF (12.05 KB)PDF (12.05 KB) of Efficacy Studies to Support Marketing of Fibrin Sealant Products Manufactured for Commercial Use: Guidance for Industry	05/20/1999	Center for Biologics Evaluation and Research	Blood Products	Final	No		97D-0528
For the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Blood and Blood Components Intended for Transfusion or for Further Manufacture and For the Completion of the Form FDA 356h: Guidance for Industry	PDF (94.13 KB)PDF (94.13 KB) of For the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Blood and Blood Components Intended for Transfusion or for Further Manufacture and For the Completion of the Form FDA 356h: Guidance for Industry	05/10/1999	Center for Biologics Evaluation and Research	Blood Products	Final	No	05/10/1999	98D-0512

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Recommended Clinical Study Design for Ventricular Tachycardia Ablation	PDF (1.14 MB)PDF (1.14 MB) of Recommended Clinical Study Design for Ventricular Tachycardia Ablation	05/07/1999	Center for Devices and Radiological Health		Final	No		
Immunotoxicity Testing Guidance		05/05/1999	Center for Devices and Radiological Health	Premarket,	Final	No		
Container Closure Systems for Packaging Human Drugs and Biologics: Guidance for Industry	PDF (164.05 KB)PDF (164.05 KB) of Container Closure Systems for Packaging Human Drugs and Biologics: Guidance for Industry	05/01/1999	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		
In Vitro Diagnostic Fibrin Monomer Paracoagulation Test - Final Guidance for Industry and FDA Reviewers/Staff		04/26/1999	Center for Devices and Radiological Health	Premarket, Laboratory Tests	Final	No		
CPG Sec. 210.100 Deleted 4/26/99, Outdated and Obsolete		04/25/1999		Investigation & Enforcement,	Final	No		
On the Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for an Allergenic Extract or Allergen Patch Test: Guidance for Industry	PDF (44.57 KB)PDF (44.57 KB) of On the Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for an Allergenic Extract or Allergen Patch Test: Guidance for Industry	04/23/1999	Center for Biologics Evaluation and Research	Allergenics	Final	No		98D-0693
Public Health Issues Posed by the Use of Non-Human Primate Xenografts in Humans: Guidance For Industry	PDF (29.47 KB)PDF (29.47 KB) of Public Health Issues Posed by the Use of Non-Human Primate Xenografts in Humans: Guidance For Industry	04/06/1999	Center for Biologics Evaluation and Research	Xenotransplantation	Final	No		96M-0311
Preparing Notices of Availability of Investigational Medical Devices and for Recruiting Study Subjects: Guidance for Industry and FDA Staff	PDF (25.84 KB)PDF (25.84 KB) of Preparing Notices of Availability of Investigational Medical Devices and for Recruiting Study Subjects: Guidance for Industry and FDA Staff	03/19/1999	Center for Devices and Radiological Health	Premarket, Device Exception (IDE)	Final	No		
Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Biological In Vitro Diagnostic Product: Guidance for Industry	PDF (47.63 KB)PDF (47.63 KB) of Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Biological In Vitro Diagnostic Product: Guidance for Industry	03/08/1999	Center for Biologics Evaluation and Research	Blood Products	Final	No		98D-0964
Guidance on 510(k) Submissions for Keratoprostheses - Guidance for Industry and for FDA Reviewers/Staff		03/02/1999	Center for Devices and Radiological Health	Premarket,	Final	No		
Guidance for Dermabrasion Devices - Guidance for Industry		03/01/1999	Center for Devices and Radiological Health	Premarket,	Final	No		
Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh - Guidance for Industry and/or for FDA Reviewers/Staff and/or Compliance		03/01/1999	Center for Devices and Radiological Health		Final	No		
Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators : Guidance for Industry	PDF (41.9 KB)PDF (41.9 KB) of Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators : Guidance for Industry	02/22/1999	Center for Devices and Radiological Health	Premarket, 510(k), IVDs (In Vitro Diagnostic Devices), Laboratory Tests	Final	No		
For the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Plasma-Derived Biological Products, Animal Plasma or Serum-Derived Products: Guidance for Industry:	PDF (39.77 KB)PDF (39.77 KB) of For the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Plasma-Derived Biological Products, Animal Plasma or Serum-Derived Products: Guidance for Industry:	02/17/1999	Center for Biologics Evaluation and Research	Blood Products	Final	No		98D-0007

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Premarket Notification [510(k)] Submissions for Testing for Skin Sensitization To Chemicals In Natural Rubber Products - Guidance for Industry and FDA Reviewers/Staff		01/12/1999	Center for Devices and Radiological Health	Premarket,	Final	No		
Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Vaccine or Related Product: Guidance for Industry	PDF (92.87 KB)PDF (92.87 KB) of Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Vaccine or Related Product: Guidance for Industry	01/05/1999	Center for Biologics Evaluation and Research	Vaccines	Final	No		98D-0401
Small Entity Compliance Guide: Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements		01/03/1999	Office of Dietary Supplement Programs	Food & Beverage Safety, Labeling	Final	No		FDA-2013-S-0610
Clinical Development Programs for Drugs, Devices, and Biological Products for the Treatment of Rheumatoid Arthritis (RA)	PDF (369.2 KB)PDF (369.2 KB) of Clinical Development Programs for Drugs, Devices, and Biological Products for the Treatment of Rheumatoid Arthritis (RA)	01/01/1999	Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Clinical - Medical	Final	No		
Guidance for Industry: Questions and Answers for Guidance to Facilitate the Implementation of a HACCP System in Seafood Processing		01/01/1999	Office of Food Safety	HACCP, Seafood/Seafood Product	Final	No		
Providing Regulatory Submissions in Electronic Format; General Considerations	PDF (54.31 KB)PDF (54.31 KB) of Providing Regulatory Submissions in Electronic Format; General Considerations	01/01/1999	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Electronic Submissions,	Final	No		
CPG Sec. 205.100 Deleted 12/21/98, Obsolete		12/20/1998		Investigation & Enforcement,	Final	No		
Guidance for the Submission of Premarket Notifications for Emission Computed Tomography Devices and Accessories (SPECT and PET) and Nuclear Tomography Systems : Guidance for Industry		12/02/1998	Center for Devices and Radiological Health	Premarket, Radiology	Final	No		
FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products	PDF (58.39 KB)PDF (58.39 KB) of FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products	12/01/1998	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Clinical - Medical	Final	No		
Variations in Drug Products that May Be Included in a Single ANDA	PDF (106.73 KB)PDF (106.73 KB) of Variations in Drug Products that May Be Included in a Single ANDA	12/01/1998	Center for Drug Evaluation and Research	Generic Drugs	Final	No		
Guidance for the Content of Premarket Notifications for Intracorporeal Lithotripters - Guidance for Industry		11/29/1998	Center for Devices and Radiological Health	Premarket,	Final	No		
Guidance for the Submission of Premarket Notifications For Radionuclide Dose Calibrators - Guidance for Industry		11/19/1998	Center for Devices and Radiological Health	Premarket,	Final	No		2238
Non-Automated Sphygmomanometer (Blood Pressure Cuff) Guidance - Version 1 - Guidance for Industry		11/18/1998	Center for Devices and Radiological Health	Premarket,	Final	No		
Aqueous Shunts - 510(k) Submissions - Guidance for Industry and for FDA Reviewers/Staff		11/15/1998	Center for Devices and Radiological Health	Premarket,	Final	No		
CPG Sec. 675.400 Rendered Animal Feed Ingredients (Withdrawn 4/30/2019)		11/12/1998	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Animal Feed	Final	No		
FDA Animal Products Database Data Entry Form	PDF (106.72 KB)PDF (106.72 KB) of FDA Animal Products Database Data Entry Form	11/06/1998	Center for Devices and Radiological Health		Final	No		
Cardiac Monitor Guidance (including Cardiotachometer and Rate Alarm) - Guidance for Industry		11/04/1998	Center for Devices and Radiological Health	Premarket, Cardiovascular	Final	No		2233

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Diagnostic ECG Guidance (Including Non-Alarming ST Segment Measurement) - Guidance for Industry		11/04/1998	Center for Devices and Radiological Health	Premarket,	Final	No		
General/Specific Intended Use - Guidance for Industry		11/03/1998	Center for Devices and Radiological Health	Premarket,	Final	No		
Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables	PDF (98.28 KB)PDF (98.28 KB) of Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables	10/25/1998	Office of Food Safety	Fruit/Fruit Product , Produce, Safety - Issues, Errors, and Problems, Vegetable Products	Final	No		FDA-1997-N-0152
Noise Claims in Hearing Aid Labeling - Guidance for Industry		10/20/1998	Center for Devices and Radiological Health	Premarket,	Final	No		
Year 2000 Letter from Dr. Janet Woodcock		10/18/1998	Center for Drug Evaluation and Research		Final	No		
Guidance Document For Nonprescription Sunglasses - Guidance for Industry		10/08/1998	Center for Devices and Radiological Health	Premarket,	Final	No		
Submitting Debarment Certification Statements	PDF (143.85 KB)PDF (143.85 KB) of Submitting Debarment Certification Statements	10/02/1998	Center for Drug Evaluation and Research	Administrative / Procedural	Draft	No		
Implementation of Section 120 of the Food and Drug Administration Modernization Act of 1997-Advisory Committees	PDF (62.13 KB)PDF (62.13 KB) of Implementation of Section 120 of the Food and Drug Administration Modernization Act of 1997-Advisory Committees	10/01/1998	Center for Drug Evaluation and Research	Administrative / Procedural	Final	No		
Guidance Document for Powered Suction Pump 510(k)s - Guidance for Industry and FDA Reviewers/Staff		09/29/1998	Center for Devices and Radiological Health		Final	No		
CPG Sec. 615.100 Extralabel Use of New Animal Drugs in Food Producing Animals - Revoked on 09/24/1998 (63 FR 51074)		09/24/1998	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Animal Drugs	Final	No		
Q5D Quality of Biotechnological/Biological Products: Derivation and Characterization of Cell Substrates Used for Production of Biotechnological/Biological Products; Availability	PDF (52.35 KB)PDF (52.35 KB) of Q5D Quality of Biotechnological/Biological Products: Derivation and Characterization of Cell Substrates Used for Production of Biotechnological/Biological Products; Availability	09/21/1998	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Quality	Final	No		
How to Complete the Vaccine Adverse Event Reporting System Form (VAERS-1): Guidance for Industry	PDF (82.14 KB)PDF (82.14 KB) of How to Complete the Vaccine Adverse Event Reporting System Form (VAERS-1): Guidance for Industry	09/09/1998	Center for Biologics Evaluation and Research	Vaccines	Final	No		
E9 Statistical Principles for Clinical Trials	PDF (109.86 KB)PDF (109.86 KB) of E9 Statistical Principles for Clinical Trials	09/01/1998	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Efficacy	Final	No		
Q5A Viral Safety Evaluation of Biotechnology Products Derived From Cell Lines of Human or Animal Origin	PDF (70.81 KB)PDF (70.81 KB) of Q5A Viral Safety Evaluation of Biotechnology Products Derived From Cell Lines of Human or Animal Origin	09/01/1998	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Quality	Final	No		
Dental Cements - Premarket Notification - Guidance for Industry and FDA Staff		08/17/1998	Center for Devices and Radiological Health	Premarket,	Final	No		2204
OTC Denture Cushions, Pads, Reliners, Repair Kits, and Partially Fabricated Denture Kits - Guidance for Industry and FDA Staff		08/17/1998	Center for Devices and Radiological Health	Premarket,	Final	No		

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Dental Impression Materials Premarket Notification - Guidance for Industry and FDA Staff		08/16/1998	Center for Devices and Radiological Health	Premarket,	Final	No		
Accidental Radioactive Contamination of Human Food and Animal Feeds: Recommendations for State and Local Agencies	PDF (231.36 KB)PDF (231.36 KB) of Accidental Radioactive Contamination of Human Food and Animal Feeds: Recommendations for State and Local Agencies	08/13/1998	Center for Devices and Radiological Health	Radiological Health	Final	No		
Accidental Radioactive Contamination of Human Food and Animal Feeds: Recommendations for State and Local Agencies	PDF (231.36 KB)PDF (231.36 KB) of Accidental Radioactive Contamination of Human Food and Animal Feeds: Recommendations for State and Local Agencies	08/13/1998	Center for Devices and Radiological Health		Final	No		
Revised Procedures for Adding Lens Finishing Laboratories to Approved Premarket Approval Applications for Class III Rigid Gas Permeable Contact Lenses for Extended Wear - Guidance for Industry and FDA Staff		08/10/1998	Center for Devices and Radiological Health	Premarket,	Final	No		
Guidance for the Content of Premarket Notifications for Conventional and High Permeability Hemodialyzers - Guidance for Industry and CDRH Reviewers		08/06/1998	Center for Devices and Radiological Health	Premarket, 510(k)	Final	No		
Guidance for the Content of Premarket Notifications for Hemodialysis Delivery Systems - Guidance for Industry and CDRH Reviewers		08/06/1998	Center for Devices and Radiological Health	Premarket,	Final	No		
Latex Condoms for Men - Information for 510(k) Premarket Notifications: Use of Consensus Standards for Abbreviated Submissions: Guidance for Industry	PDF (145.88 KB)PDF (145.88 KB) of Latex Condoms for Men - Information for 510(k) Premarket Notifications: Use of Consensus Standards for Abbreviated Submissions: Guidance for Industry	07/23/1998	Center for Devices and Radiological Health	Premarket, 510(k)	Final	No		
Uniform Contraceptive Labeling - Guidance for Industry		07/22/1998	Center for Devices and Radiological Health	Premarket,	Final	No		
Women and Minorities Guidance Requirements	PDF (30.17 KB)PDF (30.17 KB) of Women and Minorities Guidance Requirements	07/20/1998		Administrative / Procedural	Final	No		
Ophthalmoscope Guidance - (Direct and Indirect) - Guidance for Industry		07/07/1998	Center for Devices and Radiological Health	Premarket,	Final	No		
Slit Lamp Guidance - Guidance for Industry		07/07/1998	Center for Devices and Radiological Health	Premarket,	Final	No		1242
CVM GFI #76 Questions and Answers BSE Feed Regulations	PDF (152.28 KB)PDF (152.28 KB) of CVM GFI #76 Questions and Answers BSE Feed Regulations	07/01/1998	Center for Veterinary Medicine	Current Good Manufacturing Practices (CGMP)	Final	No		
Environmental Assessment of Human Drug and Biologics Applications: Guidance for Industry	PDF (187.76 KB)PDF (187.76 KB) of Environmental Assessment of Human Drug and Biologics Applications: Guidance for Industry	07/01/1998	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		
Implementation of Section 126 of the Food and Drug Administration Modernization Act of 1997 — Elimination of Certain Labeling Requirements	PDF (979.25 KB)PDF (979.25 KB) of Implementation of Section 126 of the Food and Drug Administration Modernization Act of 1997 — Elimination of Certain Labeling Requirements	07/01/1998	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Administrative / Procedural	Final	No		
Errors and Accidents Regarding Saline Dilution of Samples Used for Viral Marker Testing: Guidance for Industry	PDF (11.9 KB)PDF (11.9 KB) of Errors and Accidents Regarding Saline Dilution of Samples Used for Viral Marker Testing: Guidance for Industry	06/11/1998	Center for Biologics Evaluation and Research	Blood Products	Final	No		
Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body		06/11/1998	Office of Nutrition and Food Labeling	Food & Beverage Safety, Labeling, Nutrition Label, Food & Beverage Safety	Final	No		FDA-2013-S-0610

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Guidance for Submission of Immunohistochemistry Applications to the FDA - Final Guidance for Industry		06/02/1998	Center for Devices and Radiological Health	Premarket,	Final	No		
180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act	PDF (77.08 KB)PDF (77.08 KB) of 180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act	06/01/1998	Center for Drug Evaluation and Research	Administrative / Procedural	Final	No		
Guidance Document For Washers And Washer-Disinfectors Intended For Processing Reusable Medical Devices		06/01/1998	Center for Devices and Radiological Health	Premarket,	Final	No		
Supplements to Approved Applications for Class III Medical Devices: Use of Published Literature, Use of Previously Submitted Materials, and Priority Review : Guidance for Industry		05/19/1998	Center for Devices and Radiological Health	Premarket,	Final	No		
Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products.	PDF (129.17 KB)PDF (129.17 KB) of Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products.	05/14/1998	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		
CVM GFI #72 GMP'S For Medicated Feed Manufacturers Not Required to Register and be Licensed with FDA	PDF (56.67 KB)PDF (56.67 KB) of CVM GFI #72 GMP'S For Medicated Feed Manufacturers Not Required to Register and be Licensed with FDA	05/01/1998	Center for Veterinary Medicine	Current Good Manufacturing Practices (CGMP), Animal Feed	Final	No		
Repeal of Section 507 of the Federal Food, Drug and Cosmetic Act _1	PDF (84.7 KB)PDF (84.7 KB) of Repeal of Section 507 of the Federal Food, Drug and Cosmetic Act _1	05/01/1998	Center for Drug Evaluation and Research	Administrative / Procedural	Final	No		
PAC-ATLS: Postapproval Changes - Analytical Testing Laboratory Sites: Guidance for Industry	PDF (76.47 KB)PDF (76.47 KB) of PAC-ATLS: Postapproval Changes - Analytical Testing Laboratory Sites: Guidance for Industry	04/28/1998	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		
Guidance For The Content Of Premarket Notifications For Esophageal And Tracheal Prostheses - Guidance For Industry		04/27/1998	Center for Devices and Radiological Health	Premarket,	Final	No		
National Uniformity for Nonpresciption Drugs - Ingredient Listing for OTC Drugs	PDF (73.83 KB)PDF (73.83 KB) of National Uniformity for Nonpresciption Drugs - Ingredient Listing for OTC Drugs	04/01/1998	Center for Drug Evaluation and Research	Administrative / Procedural	Final	No		
Q3C: Appendix 4	PDF (120.43 KB)PDF (120.43 KB) of Q3C: Appendix 4	03/18/1998	Center for Drug Evaluation and Research	ICH-Quality	Draft	No		
Q3C: Appendix 5	PDF (216.11 KB)PDF (216.11 KB) of Q3C: Appendix 5	03/18/1998		ICH-Quality	Draft	No		
Q3C: Appendix 6	PDF (127.67 KB)PDF (127.67 KB) of Q3C: Appendix 6	03/18/1998	Center for Drug Evaluation and Research	ICH-Quality	Draft	No		
Continuation of a series of letters communicating interim and informal generic drug policy and guidance. Availability of Policy and Procedure Guides, and further operational changes to the generic drug review program	PDF (611.4 KB)PDF (611.4 KB) of Continuation of a series of letters communicating interim and informal generic drug policy and guidance. Availability of Policy and Procedure Guides, and further operational changes to the generic drug review program	03/02/1998	Center for Drug Evaluation and Research		Final	No		
FDA Requirements for Approval of Drugs to Treat Non-Small Cell Lung Cancer	PDF (1.56 MB)PDF (1.56 MB) of FDA Requirements for Approval of Drugs to Treat Non-Small Cell Lung Cancer	03/02/1998	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Fifth of a series of letters providing informal notice about the Act, discussing the statutory mechanism by which ANDA applicants may make modifications in approved drugs where clinical data is required	PDF (242.97 KB)PDF (242.97 KB) of Fifth of a series of letters providing informal notice about the Act, discussing the statutory mechanism by which ANDA applicants may make modifications in approved drugs where clinical data is required	03/02/1998	Center for Drug Evaluation and Research		Final	No		
Fourth of a series of letters providing informal notice to all affected parties about policy developments and interpretations regarding the Act. Three year exclusivity provisions of Title I	PDF (839.39 KB)PDF (839.39 KB) of Fourth of a series of letters providing informal notice to all affected parties about policy developments and interpretations regarding the Act. Three year exclusivity provisions of Title I	03/02/1998	Center for Drug Evaluation and Research		Final	No		
Good Laboratory Practice Regulations Questions and Answers	PDF (2.19 MB)PDF (2.19 MB) of Good Laboratory Practice Regulations Questions and Answers	03/02/1998	Center for Drug Evaluation and Research	Compliance, Current Good Manufacturing Practices (CGMP)	Final	No		
Guidance for the Development of Vaginal Contraceptive Drugs (NDA)	PDF (465.1 KB)PDF (465.1 KB) of Guidance for the Development of Vaginal Contraceptive Drugs (NDA)	03/02/1998	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		
Implementation of the Drug Price Competition and Patent Term Restoration Act. Preliminary Guidance	PDF (643.9 KB)PDF (643.9 KB) of Implementation of the Drug Price Competition and Patent Term Restoration Act. Preliminary Guidance	03/02/1998			Final	No		
Implementation Plan USP injection nomenclature	PDF (247.02 KB)PDF (247.02 KB) of Implementation Plan USP injection nomenclature	03/02/1998	Center for Drug Evaluation and Research		Final	No		
Local Anesthetics--Clinical Evaluation	PDF (1.02 MB)PDF (1.02 MB) of Local Anesthetics--Clinical Evaluation	03/02/1998	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		
Nuclear Pharmacy Guideline Criteria for Determining When to Register as a Drug Establishment	PDF (3.46 MB)PDF (3.46 MB) of Nuclear Pharmacy Guideline Criteria for Determining When to Register as a Drug Establishment	03/02/1998	Center for Drug Evaluation and Research	Compliance, Current Good Manufacturing Practices (CGMP)	Final	No		
Oncologic Drugs Advisory Committee Discussion on FDA Requirements or Approval of New Drugs for Treatment of Colon and Rectal Cancer	PDF (1.51 MB)PDF (1.51 MB) of Oncologic Drugs Advisory Committee Discussion on FDA Requirements or Approval of New Drugs for Treatment of Colon and Rectal Cancer	03/02/1998	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		
Psychoactive Drugs in Infants and Children--Clinical Evaluation	PDF (17.9 MB)PDF (17.9 MB) of Psychoactive Drugs in Infants and Children--Clinical Evaluation	03/02/1998	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		
Reference Guide for the Nonclinical Toxicity Studies of Antivial Drugs Indicated for the Treatment of N/A Non-Life Threatening Disease Evaluation of Drug Toxicity Prior to Phase I Clinical Studies	PDF (836.93 KB)PDF (836.93 KB) of Reference Guide for the Nonclinical Toxicity Studies of Antivial Drugs Indicated for the Treatment of N/A Non-Life Threatening Disease Evaluation of Drug Toxicity Prior to Phase I Clinical Studies	03/02/1998		Pharm/Tox	Final	No		
Seventh of a series of letters about the Act providing guidance on the "130-day exclusivity" provision of section 505(j)(4)(B)(iv) of the FD&C	PDF (729.93 KB)PDF (729.93 KB) of Seventh of a series of letters about the Act providing guidance on the "130-day exclusivity" provision of section 505(j)(4)(B)(iv) of the FD&C	03/02/1998	Center for Drug Evaluation and Research		Final	No		

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Sixth of a series of informal notice letters about the Act discussing 3-and 5-year exclusivity provisions of sections 505(c)(3)(D) and 505(j)(4)(D) of the FD&C Act	PDF (537.9 KB)PDF (537.9 KB) of Sixth of a series of informal notice letters about the Act discussing 3-and 5-year exclusivity provisions of sections 505(c)(3)(D) and 505(j)(4)(D) of the FD&C Act	03/02/1998	Center for Drug Evaluation and Research		Final	No		
Supplement to 10/11/1984 letter about policies, procedures and implementation of the Act (Q&A format)	PDF (740.37 KB)PDF (740.37 KB) of Supplement to 10/11/1984 letter about policies, procedures and implementation of the Act (Q&A format)	03/02/1998	Center for Drug Evaluation and Research		Final	No		
Third of a series of letters regarding the implementation of the Act	PDF (393.27 KB)PDF (393.27 KB) of Third of a series of letters regarding the implementation of the Act	03/02/1998	Center for Drug Evaluation and Research		Final	No		
Guidance for Human Somatic Cell Therapy and Gene Therapy: Guidance for Industry	PDF (93.25 KB)PDF (93.25 KB) of Guidance for Human Somatic Cell Therapy and Gene Therapy: Guidance for Industry	03/01/1998	Center for Biologics Evaluation and Research	Cellular & Gene Therapy, Gene Therapy	Final	No		
Guidance for Industry: Guide for Developing and Using Data Bases for Nutrition Labeling		03/01/1998	Office of Nutrition and Food Labeling	Labeling, Nutrition Label	Final	No		FDA-2013-S-0610
S1B Testing for Carcinogenicity of Pharmaceuticals	PDF (144.62 KB)PDF (144.62 KB) of S1B Testing for Carcinogenicity of Pharmaceuticals	02/28/1998	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Safety	Final	No		
Guidance on PMA Interactive Procedures for Day-100 Meetings and Subsequent Deficiencies - for Use by CDRH and Industry		02/18/1998	Center for Devices and Radiological Health	Premarket, Administrative / Procedural, Premarket Approval (PMA)	Final	No		
Overview of FDA Modernization Act of 1997, Medical Device Provisions		02/18/1998			Final	No		
Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff		02/18/1998	Center for Devices and Radiological Health	Premarket,	Final	No		
CVM GFI #67 Small Entities Compliance Guide for Renderers	PDF (65.79 KB)PDF (65.79 KB) of CVM GFI #67 Small Entities Compliance Guide for Renderers	02/01/1998	Center for Veterinary Medicine	Current Good Manufacturing Practices (CGMP)	Final	No		
CVM GFI #68 Small Entities Compliance Guide for Protein Blenders, Feed Manufacturers, and Distributors	PDF (65.92 KB)PDF (65.92 KB) of CVM GFI #68 Small Entities Compliance Guide for Protein Blenders, Feed Manufacturers, and Distributors	02/01/1998	Center for Veterinary Medicine	Current Good Manufacturing Practices (CGMP)	Final	No		
CVM GFI #69 Small Entities Compliance Guide for Feeders of Ruminant Animals with On-Farm Feed Mixing Operations	PDF (62 KB)PDF (62 KB) of CVM GFI #69 Small Entities Compliance Guide for Feeders of Ruminant Animals with On-Farm Feed Mixing Operations	02/01/1998	Center for Veterinary Medicine	Animal Feed	Final	No		
E2B International Conference on Harmonisation; Guidance on Data Elements for Transmission of Individual Case Safety Reports	PDF (69.65 KB)PDF (69.65 KB) of E2B International Conference on Harmonisation; Guidance on Data Elements for Transmission of Individual Case Safety Reports	01/15/1998	Center for Drug Evaluation and Research	ICH-Efficacy	Final	No		
Tympanostomy Tubes, Submission Guidance for a 510(k) Premarket Notification: Final	PDF (145.72 KB)PDF (145.72 KB) of Tympanostomy Tubes, Submission Guidance for a 510(k) Premarket Notification: Final	01/14/1998	Center for Devices and Radiological Health	Premarket, 510(k)	Final	No		
Year 2000 Date Change for Computer Systems and Software Applications Used in the Manufacture of Blood Products: Guidance for Industry	PDF (20.61 KB)PDF (20.61 KB) of Year 2000 Date Change for Computer Systems and Software Applications Used in the Manufacture of Blood Products: Guidance for Industry	01/08/1998	Center for Biologics Evaluation and Research	Application & Approvals, Blood Products	Final	No		

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"Off-Label" and Investigational Use Of Marketed Drugs, Biologics, and Medical Devices: Guidance for Institutional Review Boards and Clinical Investigators		01/01/1998	Office of Good Clinical Practice, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research	Good Clinical Practices (GCP)	Final	No		
A Guide to Informed Consent: Guidance for Institutional Review Boards and Clinical Investigators		01/01/1998	Office of Good Clinical Practice	Good Clinical Practices (GCP)	Final	No		
Charging for Investigational Products: Guidance for Institutional Review Boards and Clinical Investigators		01/01/1998	Office of Good Clinical Practice	Good Clinical Practices (GCP)	Final	No		
Clinical Investigator Regulatory Sanctions - Information Sheet		01/01/1998			Final	No		
Cooperative Research: Guidance for Institutional Review Boards and Clinical Investigators		01/01/1998	Office of Good Clinical Practice	Good Clinical Practices (GCP)	Final	No		
Drug Study Designs: Guidance for Institutional Review Boards and Clinical Investigators		01/01/1998	Office of Good Clinical Practice, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Good Clinical Practices (GCP)	Final	No		
Emergency Use of an Investigational Drug or Biologic: Guidance for Institutional Review Boards and Clinical Investigators		01/01/1998	Office of Good Clinical Practice	Good Clinical Practices (GCP)	Final	No		
Evaluation of Gender Differences in Clinical Investigations: Guidance for Institutional Review Boards and Clinical Investigators		01/01/1998	Office of Good Clinical Practice	Good Clinical Practices (GCP)	Final	No		
Institutional Review Boards Frequently Asked Questions: Guidance for Institutional Review Boards and Clinical Investigators		01/01/1998	Office of Good Clinical Practice	Good Clinical Practices (GCP)	Final	No		
Non-local IRB Review : Guidance for Institutional Review Boards and Clinical Investigators		01/01/1998	Office of Good Clinical Practice	Good Clinical Practices (GCP)	Final	No		
Recruiting Study Subjects: Guidance for Institutional Review Boards and Clinical Investigators		01/01/1998	Office of Good Clinical Practice	Good Clinical Practices (GCP)	Final	No		
Screening Tests Prior to Study Enrollment: Guidance for Institutional Review Boards and Clinical Investigators		01/01/1998	Office of Good Clinical Practice	Good Clinical Practices (GCP)	Final	No		
Sponsor - Investigator - IRB Interrelationship: Guidance for Institutional Review Boards and Clinical Investigators		01/01/1998	Office of Good Clinical Practice	Good Clinical Practices (GCP)	Final	No		
Treatment Use of Investigational Drugs: Guidance for Institutional Review Boards and Clinical Investigators		01/01/1998	Office of Good Clinical Practice	Good Clinical Practices (GCP)	Final	No		
Use of Investigational Products When Subjects Enter a Second Institution: Guidance for Institutional Review Boards and Clinical Investigators		01/01/1998	Office of Good Clinical Practice	Good Clinical Practices (GCP)	Final	No		
Q3C Impurities: Residual Solvents_2011	PDF (40.56 KB)PDF (40.56 KB) of Q3C Impurities: Residual Solvents_2011	12/24/1997	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Quality	Final	No		
Industry-Supported Scientific and Educational Activites	PDF (428.5 KB)PDF (428.5 KB) of Industry-Supported Scientific and Educational Activites	12/03/1997	Office of Policy	Administrative / Procedural, Advertising	Final	No		92N-0434
E8 General Considerations for Clinical Trials	PDF (66.91 KB)PDF (66.91 KB) of E8 General Considerations for Clinical Trials	12/01/1997	Center for Drug Evaluation and Research	ICH-Efficacy	Final	No		
S2B Genotoxicity: A Standard Battery for Genotoxicity Testing of Pharmaceuticals	PDF (131.49 KB)PDF (131.49 KB) of S2B Genotoxicity: A Standard Battery for Genotoxicity Testing of Pharmaceuticals	11/21/1997	Center for Drug Evaluation and Research	ICH-Safety	Final	No		
Direct Final Rule Procedures: Guidance for FDA and Industry		11/20/1997	Office of Policy	Administrative / Procedural, Food & Color Additives	Final	No		

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Industry Supported Scientific and Educational Activities: Guidance for Industry	PDF (428.5 KB)PDF (428.5 KB) of Industry Supported Scientific and Educational Activities: Guidance for Industry	11/01/1997	Office of Policy	Administrative / Procedural	Final	No		
S6 Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals	PDF (137.18 KB)PDF (137.18 KB) of S6 Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals	11/01/1997		ICH-Safety	Final	No		
SUPAC-MR: Modified Release Solid Oral Dosage Forms Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls; In Vitro Dissolution Testing and In Vivo Bioequivalence Documentation: Guidance for Industry	PDF (214.71 KB)PDF (214.71 KB) of SUPAC-MR: Modified Release Solid Oral Dosage Forms Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls; In Vitro Dissolution Testing and In Vivo Bioequivalence Documentation: Guidance for Industry	10/06/1997	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		
Notice to Manufacturers of Bone Mineral Densitometers	PDF (47.13 KB)PDF (47.13 KB) of Notice to Manufacturers of Bone Mineral Densitometers	09/25/1997	Center for Devices and Radiological Health	Premarket,	Final	No		
Extended Release Oral Dosage Forms: Development, Evaluation, and Application of In Vitro/In Vivo Correlations	PDF (170.47 KB)PDF (170.47 KB) of Extended Release Oral Dosage Forms: Development, Evaluation, and Application of In Vitro/In Vivo Correlations	09/01/1997	Center for Drug Evaluation and Research	Biopharmaceutics	Final	No		
Dissolution Testing of Immediate Release Solid Oral Dosage Forms	PDF (129.83 KB)PDF (129.83 KB) of Dissolution Testing of Immediate Release Solid Oral Dosage Forms	08/25/1997	Center for Drug Evaluation and Research	Biopharmaceutics	Final	No		FDA-1997-D-0187
Donor Screening for Antibodies to HTLV-II: Guidance for Industry	PDF (65.24 KB)PDF (65.24 KB) of Donor Screening for Antibodies to HTLV-II: Guidance for Industry	08/15/1997	Center for Biologics Evaluation and Research	Blood Products	Final	No		
Postmarketing Adverse Experience Reporting for Human Drug and Licensed Biological Products: Clarification of What to Report	PDF (95.35 KB)PDF (95.35 KB) of Postmarketing Adverse Experience Reporting for Human Drug and Licensed Biological Products: Clarification of What to Report	08/01/1997	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Clinical - Medical	Final	No		
Changes to an Approved Application for Specified Biotechnology and Specified Synthetic Biological Products	PDF (32.75 KB)PDF (32.75 KB) of Changes to an Approved Application for Specified Biotechnology and Specified Synthetic Biological Products	07/01/1997	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		
Changes to an Approved Application: Biological Products: Guidance for Industry	PDF (57.79 KB)PDF (57.79 KB) of Changes to an Approved Application: Biological Products: Guidance for Industry	07/01/1997	Center for Biologics Evaluation and Research	Blood Products	Final	No		95D-0052
Screening and Testing of Donors of Human Tissue Intended for Transplantation: Guidance for Industry	PDF (41.4 KB)PDF (41.4 KB) of Screening and Testing of Donors of Human Tissue Intended for Transplantation: Guidance for Industry	07/01/1997	Center for Biologics Evaluation and Research	Tissue	Final	No		93N-0453
Kit Certification for 510(k)s		06/30/1997		Premarket,	Final	No		
Expiration Dating and Stability Testing of Solid Oral Dosage Form Drugs Containing Iron: Guidance for Industry	PDF (88.67 KB)PDF (88.67 KB) of Expiration Dating and Stability Testing of Solid Oral Dosage Form Drugs Containing Iron: Guidance for Industry	06/27/1997	Center for Drug Evaluation and Research	Current Good Manufacturing Practices (CGMP), Pharmaceutical Quality	Final	No		
Information about Lasers: An Important Letter to Ophthalmologists About Lasers for Refractive Surgery		06/26/1997		Postmarket, Radiology	Final	No		
Content of Premarket Notifications for Water Purification Components and Systems for Hemodialysis: Guidance	PDF (35.49 KB)PDF (35.49 KB) of Content of Premarket Notifications for Water Purification Components and Systems for Hemodialysis: Guidance	05/30/1997	Center for Devices and Radiological Health		Final	No		

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Convenience Kits Interim Regulatory Guidance		05/19/1997	Center for Devices and Radiological Health	Premarket,	Final	No		
Q2B Validation of Analytical Procedures: Methodology	PDF (132.18 KB)PDF (132.18 KB) of Q2B Validation of Analytical Procedures: Methodology	05/19/1997	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Quality	Final	No		
Q1C Stability Testing for New Dosage Forms	PDF (101.12 KB)PDF (101.12 KB) of Q1C Stability Testing for New Dosage Forms	05/09/1997	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Quality	Final	No		
Premarket Notification 510(k) Guidance for Contact Lens Care Products	PDF (359.53 KB)PDF (359.53 KB) of Premarket Notification 510(k) Guidance for Contact Lens Care Products	05/01/1997	Center for Devices and Radiological Health	Premarket, 510(k), Ophthalmic	Final	No		
SUPAC-SS: Nonsterile Semisolid Dosage Forms; Scale-Up and Post-Approval Changes: Chemistry, Manufacturing and Controls; In Vitro Release Testing and In Vivo Bioequivalence Documentation: Guidance for Industry	PDF (117.66 KB)PDF (117.66 KB) of SUPAC-SS: Nonsterile Semisolid Dosage Forms; Scale-Up and Post-Approval Changes: Chemistry, Manufacturing and Controls; In Vitro Release Testing and In Vivo Bioequivalence Documentation: Guidance for Industry	05/01/1997	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		
Guidance for Industry for the Evaluation of Combination Vaccines for Preventable Diseases: Production, Testing and Clinical Studies: Guidance for Industry	PDF (80.89 KB)PDF (80.89 KB) of Guidance for Industry for the Evaluation of Combination Vaccines for Preventable Diseases: Production, Testing and Clinical Studies: Guidance for Industry	04/10/1997	Center for Biologics Evaluation and Research	Vaccines	Final	No		97N-0029
Design Control Guidance For Medical Device Manufacturers: Guidance for Industry	PDF (178.93 KB)PDF (178.93 KB) of Design Control Guidance For Medical Device Manufacturers: Guidance for Industry	03/11/1997	Center for Devices and Radiological Health	Good Clinical Practices (GCP)	Final	No		
Non-Invasive Blood Pressure (NIBP) Monitor Guidance		03/09/1997	Center for Devices and Radiological Health	Premarket,	Final	No		
Proposed Approach to Regulation of Cellular and Tissue-Based Products	PDF (452.22 KB)PDF (452.22 KB) of Proposed Approach to Regulation of Cellular and Tissue-Based Products	02/28/1997	Center for Biologics Evaluation and Research		Final	No	04/17/1997	97N-0068
Reviewers Guidance Checklist For Orthopedic External Fixation Devices Version #5		02/20/1997	Center for Devices and Radiological Health	Premarket,	Final	No		
510(K) Information Needed for Hydroxyapatite Coated Orthopedic Implants		02/19/1997	Center for Devices and Radiological Health	Premarket,	Final	No		
SUPAC-IR Questions and Answers about SUPAC-IR Guidance		02/17/1997		Chemistry, Manufacturing, and Controls (CMC)	Final	No		
Electrocardiograph (ECG) Lead Switching Adapter	PDF (294.96 KB)PDF (294.96 KB) of Electrocardiograph (ECG) Lead Switching Adapter	02/11/1997	Center for Devices and Radiological Health	Premarket, Cardiovascular	Final	No		
Electrocardiograph (ECG) Surface Electrode Tester	PDF (258.9 KB)PDF (258.9 KB) of Electrocardiograph (ECG) Surface Electrode Tester	02/11/1997	Center for Devices and Radiological Health	Premarket, Cardiovascular	Final	No		
Third Party Review Guidance for Phacofragmentation System Device Premarket Notification (510(k))	PDF (149.04 KB)PDF (149.04 KB) of Third Party Review Guidance for Phacofragmentation System Device Premarket Notification (510(k))	01/31/1997	Center for Devices and Radiological Health		Final	No		

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Third Party Review Guidance For Vitreous Aspiration and Cutting Device Premarket Notification (510(k))		01/30/1997	Center for Devices and Radiological Health	Premarket,	Final	No		
General Considerations for the Clinical Evaluation of Drugs	PDF (1.37 MB)PDF (1.37 MB) of General Considerations for the Clinical Evaluation of Drugs	01/01/1997	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		
CPG Sec. 540.400 Shrimp - Fresh or Frozen, Raw, Headless, Peeled or Breaded (Revoked 12/24/96)		12/23/1996		Investigation & Enforcement,	Final	No		
Q1B Photostability Testing of New Drug Substances and Products	PDF (339.22 KB)PDF (339.22 KB) of Q1B Photostability Testing of New Drug Substances and Products	11/01/1996	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Quality	Final	No		
Prospective Manufacturers of Barrier Devices Used During Oral Sex for STD Protection		10/30/1996			Final	No		
Checklist of Information Usually Submitted in an Investigational Device Exemptions (IDE) Application for Refractive Surgery Lasers [excimer]		10/09/1996	Center for Devices and Radiological Health	Premarket, Device Exception (IDE)	Final	No		
Emitted Laser Beam as Emission Indicator for Class II and Class IIIa Laser Products (Laser Notice 49)	PDF (58.9 KB)PDF (58.9 KB) of Emitted Laser Beam as Emission Indicator for Class II and Class IIIa Laser Products (Laser Notice 49)	09/05/1996	Center for Devices and Radiological Health		Final	No		
Identification Labels for Certain Class I Laser Products (Laser Notice 48)	PDF (86.6 KB)PDF (86.6 KB) of Identification Labels for Certain Class I Laser Products (Laser Notice 48)	09/05/1996	Office of In Vitro Diagnostics and Radiological Health		Final	No		
CPG Sec. 540.100 Capelin: Prohibited from Being Labeled as Smelt (Revoked 8/23/96)		08/22/1996		Investigation & Enforcement,	Final	No		
CPG Sec. 540.300 Crabmeat - Product Name (Revoked 8/23/96)		08/22/1996		Investigation & Enforcement,	Final	No		
CPG Sec. 540.350 Common or Usual Names for Crustaceans (Revoked 8/23/96)		08/22/1996		Investigation & Enforcement,	Final	No		
CPG Sec. 110.900 Imported Products - Lack of English Labeling		08/20/1996		Investigation & Enforcement, Food & Color Additives, Labeling	Final	No		
Variance from Manufacturer Report Number Format - No. 5		08/11/1996	Center for Devices and Radiological Health	Postmarket,	Final	No		
CPG Sec. 500.250 Food Additives - Labeling Directions Necessary for Safe Use		08/01/1996		Investigation & Enforcement,	Final	No		
CPG Sec. 500.300 "Approved by FDA" - Use of Phrase Objectionable in Marketing or Labeling of a Food Additive		08/01/1996		Investigation & Enforcement,	Final	No		
CPG Sec. 505.400 Chow Mein Noodles, Chinese Noodles and Other Oriental Noodles; Labeling		08/01/1996		Investigation & Enforcement,	Final	No		
CPG Sec. 505.500 Macaroni and Noodle Products - Adulteration Involving Insect Fragments and Rodent Hairs	PDF (12 KB)PDF (12 KB) of CPG Sec. 505.500 Macaroni and Noodle Products - Adulteration Involving Insect Fragments and Rodent Hairs	08/01/1996		Investigation & Enforcement,	Final	No		
CPG Sec. 510.450 Labeling - Diluted Wines and Cider with Less Than 7% Alcohol		08/01/1996		Investigation & Enforcement,	Final	No		
CPG Sec. 510.700 Fortification of Standardized Juices		08/01/1996		Investigation & Enforcement,	Final	No		
CPG Sec. 515.200 Malt Extract; Malt Syrup; Malted Cereal Syrup; Liquid Malt; Dried Malt		08/01/1996		Investigation & Enforcement,	Final	No		
CPG Sec. 527.200 Cheese & Cheese Products - Adulteration with Filth	PDF (12.21 KB)PDF (12.21 KB) of CPG Sec. 527.200 Cheese & Cheese Products - Adulteration with Filth	08/01/1996		Investigation & Enforcement,	Final	No		
CPG Sec. 585.675 Popcorn - Adulteration with Rodent Filth and Field Corn	PDF (10.94 KB)PDF (10.94 KB) of CPG Sec. 585.675 Popcorn - Adulteration with Rodent Filth and Field Corn	08/01/1996		Investigation & Enforcement,	Final	No		

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CPG Sec. 654.300 Chloramphenicol as an Unapproved New Animal Drug - Direct Reference Seizure Authority	PDF (70.36 KB)PDF (70.36 KB) of CPG Sec. 654.300 Chloramphenicol as an Unapproved New Animal Drug - Direct Reference Seizure Authority	08/01/1996	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Unapproved Animal Drugs, Animal Drugs	Final	No		
CPG Sec. 690.600 Rodent Contaminated Pet Foods - *Direct Reference Seizure Authority*		08/01/1996	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Pet Food	Final	No		
Guidance for Industry for the Submission of Chemistry, Manufacturing, and Controls Information for a Therapeutic Recombinant DNA-Derived Product or a Monoclonal Antibody Product for In Vivo Use	PDF (69.41 KB)PDF (69.41 KB) of Guidance for Industry for the Submission of Chemistry, Manufacturing, and Controls Information for a Therapeutic Recombinant DNA-Derived Product or a Monoclonal Antibody Product for In Vivo Use	08/01/1996		Administrative / Procedural	Final	No		
Guide for Preparing Product Reports for Ultrasonic Therapy Products (physical therapy only)	PDF (439.94 KB)PDF (439.94 KB) of Guide for Preparing Product Reports for Ultrasonic Therapy Products (physical therapy only)	08/01/1996	Center for Devices and Radiological Health		Final	No		
Single Dose Acute Toxicity Testing for Pharmaceuticals	PDF (62.7 KB)PDF (62.7 KB) of Single Dose Acute Toxicity Testing for Pharmaceuticals	08/01/1996		Pharm/Tox	Final	No		
CPG Sec. 160.500 Answering Inquiries on Status of Criminal Referrals		07/31/1996		Investigation & Enforcement, Food & Color Additives	Final	No		
CPG Sec. 160.750 Drug and Device Products (Including Biologics and Animal Drugs) Found in Violation of GMPRs - Reconditioning		07/31/1996		Investigation & Enforcement,	Final	No		
CPG Sec. 527.500 Malted Milk		07/31/1996		Investigation & Enforcement,	Final	No		
CPG Sec. 527.600 Use of DDVP (dichlorvos) Strips in Milkhouses and Milkrooms		07/31/1996		Investigation & Enforcement,	Final	No		
Variance from Manufacturer Report Number Format [MDR letter]		07/15/1996	Center for Devices and Radiological Health	Adverse Event Reporting System (FAERS),	Final	No		
E3 Structure and Content of Clinical Study Reports	PDF (239.72 KB)PDF (239.72 KB) of E3 Structure and Content of Clinical Study Reports	07/01/1996	Center for Drug Evaluation and Research	ICH-Efficacy	Final	No		
E4 Dose-Response Information to Support Drug Registration	PDF (49.35 KB)PDF (49.35 KB) of E4 Dose-Response Information to Support Drug Registration	07/01/1996	Center for Drug Evaluation and Research	ICH-Efficacy	Final	No		
Q5C Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products	PDF (70.17 KB)PDF (70.17 KB) of Q5C Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products	07/01/1996	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	ICH-Quality	Final	No		
Effective Visual Control of Laser Projections (Laser Notice 47)	PDF (147.45 KB)PDF (147.45 KB) of Effective Visual Control of Laser Projections (Laser Notice 47)	06/06/1996	Center for Devices and Radiological Health	Radiological Health	Final	No		
Suggested Format For IDE Progress Report		05/31/1996	Center for Devices and Radiological Health	Premarket,	Final	No		
Pediatric Use Supplements--Content and Format	PDF (23.69 KB)PDF (23.69 KB) of Pediatric Use Supplements--Content and Format	05/01/1996	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		
Guidance Document for Testing Biodegradable Polymer Implant Devices		04/19/1996	Center for Devices and Radiological Health	Premarket,	Final	No		
CVM GFI #49 Target Animal Safety And Drug Effectiveness Studies for Anti-Microbial Bovine Mastitis Products (Lactating and Non-Lactating Cow Products)		04/03/1996	Center for Veterinary Medicine	Target Animal – Effectiveness, Target Animal – Safety	Final	No		FDA-1993-D-0285
Medical Device Reporting for User Facilities	PDF (313.13 KB)PDF (313.13 KB) of Medical Device Reporting for User Facilities	04/01/1996	Center for Devices and Radiological Health	Radiological Health	Final	No		

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S2A Specific Aspects of Regulatory Genotoxicity Tests for Pharmaceuticals	PDF (123.21 KB)PDF (123.21 KB) of S2A Specific Aspects of Regulatory Genotoxicity Tests for Pharmaceuticals	04/01/1996	Center for Drug Evaluation and Research	ICH-Safety	Final	No		
S5B Detection of Toxicity to Reproduction for Medicinal Products: S5(R2) Detection of Toxicity to Reproduction for Medicinal Products Toxicity to Male Fertility In November 2005, the ICH incorporated the S5B addendum with S5A and retitled the combined	PDF (97.7 KB)PDF (97.7 KB) of S5B Detection of Toxicity to Reproduction for Medicinal Products: S5(R2) Detection of Toxicity to Reproduction for Medicinal Products Toxicity to Male Fertility In November 2005, the ICH incorporated the S5B addendum with S5A and retitled the combined	04/01/1996	Center for Drug Evaluation and Research	ICH-Safety	Final	No		
Demonstration of Comparability of Human Biological Products, Including Therapeutic Biotechnology-derived Products		03/31/1996	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		
Thermal Endometrial Ablation Devices (Submission Guidance for an IDE)		03/13/1996	Center for Devices and Radiological Health	Premarket,	Final	No		
Hysteroscopes and Gynecology Laparoscopes - Submission Guidance for a 510(k)	PDF (1.15 MB)PDF (1.15 MB) of Hysteroscopes and Gynecology Laparoscopes - Submission Guidance for a 510(k)	03/07/1996	Center for Devices and Radiological Health	Premarket, 510(k)	Final	No		
A Guide For The Submission Of Abbreviated Initial Reports On Image Receptor Support Devices For Mammographic X-Ray Systems	PDF (158.46 KB)PDF (158.46 KB) of A Guide For The Submission Of Abbreviated Initial Reports On Image Receptor Support Devices For Mammographic X-Ray Systems	03/01/1996	Center for Devices and Radiological Health	Radiology	Final	No		
S1A The Need for Long-term Rodent Carcinogenicity Studies of Pharmaceuticals	PDF (99.78 KB)PDF (99.78 KB) of S1A The Need for Long-term Rodent Carcinogenicity Studies of Pharmaceuticals	03/01/1996	Center for Drug Evaluation and Research	ICH-Safety	Final	No		
A Guide for the Submission of An Abbreviated Radiation Safety Reports on Cephalometric Devices Intended for Diagnostic Use		02/29/1996		Premarket, Postmarket, Radiology	Final	No		
Points to Consider for Portable Blood Glucose Monitoring Devices Intended for Bedside Use in the Neonate Nursery	PDF (438.71 KB)PDF (438.71 KB) of Points to Consider for Portable Blood Glucose Monitoring Devices Intended for Bedside Use in the Neonate Nursery	02/20/1996	Center for Devices and Radiological Health		Final	No		
Indications for Use Statement		02/05/1996	Center for Devices and Radiological Health	Postmarket,	Final	No		
Q5B Quality of Biotechnological Products: Analysis of the Expression Construct in Cells Used for Production of r-DNA Derived Protein Products	PDF (108.58 KB)PDF (108.58 KB) of Q5B Quality of Biotechnological Products: Analysis of the Expression Construct in Cells Used for Production of r-DNA Derived Protein Products	02/01/1996	Center for Drug Evaluation and Research	ICH-Quality	Final	No		
Reuse of Medical Disposable Devices Policy		12/26/1995			Final	No		
All Holders of Approved Variances For Laser Light Shows and Displays (Laser Notice 46)	PDF (123.16 KB)PDF (123.16 KB) of All Holders of Approved Variances For Laser Light Shows and Displays (Laser Notice 46)	12/11/1995	Office of In Vitro Diagnostics and Radiological Health	Radiological Health	Final	No		
Guidance on the Content of Premarket Notification [510(K)] Submissions for Protective Restraints		11/30/1995	Center for Devices and Radiological Health	Premarket,	Final	No		
Cover Letter: 510(k) Requirements During Firm-Initiated Recalls; Attachment A: Guidance on Recall and Premarket Notification Review Procedures During Firm-Initiated Recalls of Legally Marketed Devices (blue book memo #K95-1) (Text Only)		11/20/1995		Premarket,	Final	No		

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Content and Format of Investigational New Drug Applications (INDs) for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-derived Products: Guidance for Industry	PDF (42.07 KB)PDF (42.07 KB) of Content and Format of Investigational New Drug Applications (INDs) for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-derived Products: Guidance for Industry	11/01/1995	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Clinical - Medical, Investigational New Drug Application (INDA), Pharm/Tox	Final	No		
SUPAC-IR: Immediate-Release Solid Oral Dosage Forms: Scale-Up and Post-Approval Changes: Chemistry, Manufacturing and Controls, In Vitro Dissolution Testing, and In Vivo Bioequivalence Documentation	PDF (59.87 KB)PDF (59.87 KB) of SUPAC-IR: Immediate-Release Solid Oral Dosage Forms: Scale-Up and Post-Approval Changes: Chemistry, Manufacturing and Controls, In Vitro Dissolution Testing, and In Vivo Bioequivalence Documentation	11/01/1995	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		
Addendum to: Guidance on Premarket Notification [510(k)] Submissions for Sterilizers Intended for Use in Health Care Facilities		09/18/1995	Center for Devices and Radiological Health	Premarket,	Final	No		
Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products	PDF (55.74 KB)PDF (55.74 KB) of Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products	09/01/1995	Center for Devices and Radiological Health	Postmarket, Radiological Health	Final	No		
Guide for Preparing Product Reports on Sunlamps and Sunlamp Products (21-CFR 1002)	PDF (111.41 KB)PDF (111.41 KB) of Guide for Preparing Product Reports on Sunlamps and Sunlamp Products (21-CFR 1002)	09/01/1995	Center for Devices and Radiological Health		Final	No		
Revised Guide for Preparing Annual Reports on Radiation Safety Testing of Laser and Laser Light Show Products (replaces FDA 82-8127)	PDF (50.95 KB)PDF (50.95 KB) of Revised Guide for Preparing Annual Reports on Radiation Safety Testing of Laser and Laser Light Show Products (replaces FDA 82-8127)	09/01/1995	Center for Devices and Radiological Health	Postmarket, Radiological Health	Final	No		
User Instruction for Medical Products (Laser Notice 44)	PDF (122.52 KB)PDF (122.52 KB) of User Instruction for Medical Products (Laser Notice 44)	08/11/1995	Center for Devices and Radiological Health		Final	No		
Hysteroscopic and Laparoscopic Insufflators: Submission Guidance for a 510(k)		07/31/1995	Center for Devices and Radiological Health	Premarket,	Final	No		
Guidance Document for the Preparation of Premarket Notification [510(K)] Applications for Exercise Equipment		07/25/1995	Center for Devices and Radiological Health	Premarket,	Final	No		
Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Heating and Cooling Devices		07/25/1995	Center for Devices and Radiological Health	Premarket,	Final	No		
Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Mechanical and Powered Wheelchairs, and Motorized Three-Wheeled Vehicles		07/25/1995	Center for Devices and Radiological Health	Premarket,	Final	No		
Guidance for 510(k)s on Cholesterol Tests for Clinical Laboratory, Physicians' Office Laboratory and Home Use		07/12/1995	Center for Devices and Radiological Health	Premarket,	Final	No		
FDA Guidance Document Concerning Use of Pilot Manufacturing Facilities for the Development and Manufacture of Biological Products; Availability	PDF (30.62 KB)PDF (30.62 KB) of FDA Guidance Document Concerning Use of Pilot Manufacturing Facilities for the Development and Manufacture of Biological Products; Availability	07/11/1995		Administrative / Procedural	Final	No		
Goals and Initiatives for the IDE Program #D95-1 (blue book memo)		07/11/1995	Center for Devices and Radiological Health	Premarket, Device Exception (IDE)	Final	No		
Guideline for Quality Assurance in Blood Establishments	PDF (120.3 KB)PDF (120.3 KB) of Guideline for Quality Assurance in Blood Establishments	07/11/1995	Center for Biologics Evaluation and Research	Blood Products	Final	No		91N-0450

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Testing Guidance for Male Condoms Made From New Material (Non-Latex)		06/28/1995	Center for Devices and Radiological Health	Premarket,	Final	No		
Guidance for Industry: Letter to Manufacturers, Importers, and Distributors of Imported Candy and Candy Wrappers		06/13/1995	Office of Food Safety	Candy/Gum (without chocolate), Contaminants, Export, Food & Beverage Safety, Import, Potential Metal or Chemical Contaminant, Potential Metal or Chemical Contaminant, Food & Beverage Safety	Final	No		FDA-2013-S-0610
CPG Sec. 100.900 International Memoranda of Understanding		06/06/1995		Investigation & Enforcement, Food & Color Additives	Final	No		
Topical Dermatologic Corticosteroids: in Vivo Bioequivalence	PDF (2.59 MB)PDF (2.59 MB) of Topical Dermatologic Corticosteroids: in Vivo Bioequivalence	06/02/1995	Center for Drug Evaluation and Research	Biopharmaceutics	Final	No		
Guidance on the Content and Organization of a Premarket Notification for a Medical Laser		05/31/1995	Center for Devices and Radiological Health	Premarket, Radiology	Final	No		
Guidance Document for Testing Non-Articulating, 'Mechanically Locked', Modular Implant Components		04/30/1995	Center for Devices and Radiological Health	Premarket,	Final	No		
Guidance on Premarket Notification [510(K)] Submissions for Short-Term and Long-Term Intravascular Catheters	PDF (895.5 KB)PDF (895.5 KB) of Guidance on Premarket Notification [510(K)] Submissions for Short-Term and Long-Term Intravascular Catheters	03/15/1995	Center for Devices and Radiological Health	Premarket, 510(k)	Final	No		
CPG 230.130- Adequate Space for Determination of Donor Suitability (Obsolete, Withdrawn on 7/16/2018)		03/01/1995		Investigation & Enforcement, Blood Products	Final	No		
CPG Sec. 515.100 Confectionery - Use of Non-Nutritive Substances as Ingredients	PDF (16.2 KB)PDF (16.2 KB) of CPG Sec. 515.100 Confectionery - Use of Non-Nutritive Substances as Ingredients	03/01/1995		Investigation & Enforcement,	Final	No		
CPG Sec. 231.100- *Platelets, Pooled* is obsolete and was withdrawn on 7/16/2018.		03/01/1995		Investigation & Enforcement, Blood Products	Final	No		
CPG Sec. 231.120- Time Period for Separation of Platelets from Platelet-Rich Plasma When Preparing *Platelets* and Fresh Frozen Plasma* is obsolete and was withdrawn on 7/16/2018.		03/01/1995		Investigation & Enforcement, Blood Products	Final	No		
CPG Sec. 231.130- Storage of *Platelets* [ ] for up to five (5) Days is obsolete and was withdrawn on 7/16/2018.		03/01/1995		Investigation & Enforcement, Blood Products	Final	No		
CPG Sec. 250.500- Plasma Brokers - Registration and Compliance with Good Manufacturing Practices is obsolete and was withdrawn on 7/16/2018.	PDF (132.7 KB)PDF (132.7 KB) of CPG Sec. 250.500- Plasma Brokers - Registration and Compliance with Good Manufacturing Practices is obsolete and was withdrawn on 7/16/2018.	03/01/1995		Investigation & Enforcement, Blood Products	Final	No		
CPG Sec. 300.400 Contamination of Devices Labeled as Sterile	PDF (62.53 KB)PDF (62.53 KB) of CPG Sec. 300.400 Contamination of Devices Labeled as Sterile	03/01/1995		Investigation & Enforcement, Labeling	Final	No		
CPG Sec. 335.500 Razor Blades, Manicuring Instruments - Not Considered Devices Under 201(h)		03/01/1995		Investigation & Enforcement,	Final	No		
CPG Sec. 345.100 Condoms; Defects - Criteria for Direct Reference Seizure	PDF (73.78 KB)PDF (73.78 KB) of CPG Sec. 345.100 Condoms; Defects - Criteria for Direct Reference Seizure	03/01/1995		Investigation & Enforcement, Administrative / Procedural	Final	No		
CPG Sec. 345.300 Menstrual Sponges		03/01/1995		Investigation & Enforcement, Physical Medicine	Final	No		
CPG Sec. 355.200 Electrical Muscle Stimulators	PDF (62.43 KB)PDF (62.43 KB) of CPG Sec. 355.200 Electrical Muscle Stimulators	03/01/1995		Investigation & Enforcement,	Final	No		
CPG Sec. 355.300 Ion Generating Devices		03/01/1995		Investigation & Enforcement, Radiological Health	Final	No		

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CPG Sec. 370.100 Cytotoxic Testing for Allergic Diseases		03/01/1995		Investigation & Enforcement, Clinical Chemistry & Clinical Toxicology	Final	No		
CPG Sec. 390.425 Records and Reports; Applicability - 21 CFR 1002.1		03/01/1995		Investigation & Enforcement, Records	Final	No		
CPG Sec. 391.200 Warning Statement in Advertisements for High-Intensity Mercury Vapor Discharge Lamps that are not Self-Extinguishing (21 CFR 1040.30(e)(3)*)		03/01/1995		Investigation & Enforcement, Advertising	Final	No		
CPG Sec. 398.350 Regulatory Actions Against Assemblers of X-ray Equipment that Fail to File Reports of Assembly	PDF (67.05 KB)PDF (67.05 KB) of CPG Sec. 398.350 Regulatory Actions Against Assemblers of X-ray Equipment that Fail to File Reports of Assembly	03/01/1995		Investigation & Enforcement, Radiology	Final	No		
CPG Sec. 400.100 Drugs, Human - Failure to Register	PDF (60.89 KB)PDF (60.89 KB) of CPG Sec. 400.100 Drugs, Human - Failure to Register	03/01/1995		Registration,	Final	No		
CPG Sec. 400.500 Identical or Similar Product Names		03/01/1995		Investigation & Enforcement, Labeling	Final	No		
CPG Sec. 448.100 Reconditioning of New Drugs Which Do Not Have Approved NDAs/ANDAs	PDF (70.36 KB)PDF (70.36 KB) of CPG Sec. 448.100 Reconditioning of New Drugs Which Do Not Have Approved NDAs/ANDAs	03/01/1995		Investigation & Enforcement,	Final	No		
CPG Sec. 480.300 Lack of Expiration Date of Stability Data	PDF (66.71 KB)PDF (66.71 KB) of CPG Sec. 480.300 Lack of Expiration Date of Stability Data	03/01/1995		Investigation & Enforcement,	Final	No		
CPG Sec. 500.400 Use of Calcium Chloride as a Drying Agent in Such Products as Packaged Potato Chips and Peanuts		03/01/1995		Investigation & Enforcement,	Final	No		
CPG Sec. 515.400 Raw Sugar		03/01/1995		Investigation & Enforcement,	Final	No		
CPG Sec. 515.600 Candied Citron - Labeling		03/01/1995		Investigation & Enforcement,	Final	No		
CPG Sec. 525.425 Hops - Adulteration Involving Aphid Infestation	PDF (8.77 KB)PDF (8.77 KB) of CPG Sec. 525.425 Hops - Adulteration Involving Aphid Infestation	03/01/1995		Investigation & Enforcement,	Final	No		
CPG Sec. 525.825 Vinegar, Definitions - Adulteration with Vinegar Eels	PDF (15.1 KB)PDF (15.1 KB) of CPG Sec. 525.825 Vinegar, Definitions - Adulteration with Vinegar Eels	03/01/1995		Investigation & Enforcement,	Final	No		
CPG Sec. 550.235 Cherry Jam - Adulteration with Mold	PDF (8.68 KB)PDF (8.68 KB) of CPG Sec. 550.235 Cherry Jam - Adulteration with Mold	03/01/1995		Investigation & Enforcement,	Final	No		
CPG Sec. 550.250 Citrus Fruit Juices, Canned - Adulteration with Fly Filth and Mold	PDF (10.23 KB)PDF (10.23 KB) of CPG Sec. 550.250 Citrus Fruit Juices, Canned - Adulteration with Fly Filth and Mold	03/01/1995		Investigation & Enforcement,	Final	No		
CPG Sec. 550.260 Cranberry Sauce - Adulteration with Mold	PDF (8.83 KB)PDF (8.83 KB) of CPG Sec. 550.260 Cranberry Sauce - Adulteration with Mold	03/01/1995		Investigation & Enforcement,	Final	No		
CPG Sec. 550.270 Currants - Adulteration Involving Wormy Fruits	PDF (8.77 KB)PDF (8.77 KB) of CPG Sec. 550.270 Currants - Adulteration Involving Wormy Fruits	03/01/1995		Investigation & Enforcement,	Final	No		
CPG Sec. 550.450 Jam, Black Currant - Adulteration with Mold	PDF (8.77 KB)PDF (8.77 KB) of CPG Sec. 550.450 Jam, Black Currant - Adulteration with Mold	03/01/1995		Investigation & Enforcement,	Final	No		
CPG Sec. 550.590 Cloudberries (Multer Berries), Canned - Adulteration by Insects	PDF (8.89 KB)PDF (8.89 KB) of CPG Sec. 550.590 Cloudberries (Multer Berries), Canned - Adulteration by Insects	03/01/1995		Investigation & Enforcement,	Final	No		
CPG Sec. 550.680 Pineapple, Canned; Pineapple Juice - Adulteration with Mold	PDF (9.34 KB)PDF (9.34 KB) of CPG Sec. 550.680 Pineapple, Canned; Pineapple Juice - Adulteration with Mold	03/01/1995		Investigation & Enforcement,	Final	No		

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CPG Sec. 555.300 Foods, Except Dairy Products - Adulteration with Salmonella	PDF (10.78 KB)PDF (10.78 KB) of CPG Sec. 555.300 Foods, Except Dairy Products - Adulteration with Salmonella	03/01/1995		Investigation & Enforcement,	Final	No		
CPG Sec. 585.225 Black-Eyed Peas (Cow Peas, Field Peas); Dried-Adulteration with Lygus Bug Damage	PDF (11.03 KB)PDF (11.03 KB) of CPG Sec. 585.225 Black-Eyed Peas (Cow Peas, Field Peas); Dried-Adulteration with Lygus Bug Damage	03/01/1995		Investigation & Enforcement,	Final	No		
CPG Sec. 587.200 Uncertified or Delisted Colors in Foods for Export - (e.g., FD&C Red #2)		03/01/1995		Investigation & Enforcement,	Final	No		
CPG Sec. 608.500 Illegal Sales of Veterinary Prescription Drugs Direct Reference Authority for *Warning* Letter Issuance	PDF (69.87 KB)PDF (69.87 KB) of CPG Sec. 608.500 Illegal Sales of Veterinary Prescription Drugs Direct Reference Authority for *Warning* Letter Issuance	03/01/1995	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Animal Drugs	Final	No		
CPG Sec. 625.300 Unapproved New Animal Drugs - Follow-up Action to Approved Warning Letter - Direct Reference Seizure Authority	PDF (66.15 KB)PDF (66.15 KB) of CPG Sec. 625.300 Unapproved New Animal Drugs - Follow-up Action to Approved Warning Letter - Direct Reference Seizure Authority	03/01/1995	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Unapproved Animal Drugs, Animal Drugs	Final	No		
CPG Sec. 625.500 Failure to Register *and/or Drug List*	PDF (71.45 KB)PDF (71.45 KB) of CPG Sec. 625.500 Failure to Register *and/or Drug List*	03/01/1995	Center for Veterinary Medicine, Office of Regulatory Affairs	Registration, Investigation & Enforcement, Animal Drugs	Final	No		
E1A The Extent of Population Exposure to Assess Clinical Safety: For Drugs Intended for Long-term Treatment of Non-Life-Threatening Conditions	PDF (17 KB)PDF (17 KB) of E1A The Extent of Population Exposure to Assess Clinical Safety: For Drugs Intended for Long-term Treatment of Non-Life-Threatening Conditions	03/01/1995	Center for Drug Evaluation and Research	ICH-Efficacy	Final	No		
E2A Clinical Safety Data Management: Definitions and Standards for Expedited Reporting	PDF (48.84 KB)PDF (48.84 KB) of E2A Clinical Safety Data Management: Definitions and Standards for Expedited Reporting	03/01/1995	Center for Drug Evaluation and Research	ICH-Efficacy	Final	No		
Q2 (R1) Validation of Analytical Procedures: Text and Methodology		03/01/1995	Center for Drug Evaluation and Research	ICH-Quality	Final	No		
Q2A Text on Validation of Analytical Procedures	PDF (24.76 KB)PDF (24.76 KB) of Q2A Text on Validation of Analytical Procedures	03/01/1995	Center for Drug Evaluation and Research	ICH-Quality	Final	No		
S3A Toxicokinetics: The Assessment of Systemic Exposure in Toxicity Studies	PDF (45.65 KB)PDF (45.65 KB) of S3A Toxicokinetics: The Assessment of Systemic Exposure in Toxicity Studies	03/01/1995	Center for Drug Evaluation and Research	ICH-Safety	Final	No		
S3B Pharmacokinetics: Guidance for Repeated Dose Tissue Distribution Studies	PDF (13.92 KB)PDF (13.92 KB) of S3B Pharmacokinetics: Guidance for Repeated Dose Tissue Distribution Studies	03/01/1995	Center for Drug Evaluation and Research	ICH-Safety	Final	No		
CPG Sec. 120.500 Health Fraud - Factors in Considering Regulatory Action		02/28/1995		Investigation & Enforcement, Food & Color Additives, Medical Food/Beverage	Final	No		
CPG Sec. 140.500 Metric Declarations of Quantity of Contents on Product Labels		02/28/1995		Investigation & Enforcement, Food & Color Additives, Labeling	Final	No		
CPG Sec. 150.500 Analytical Methodology Used by FDA - Drugs		02/28/1995		Investigation & Enforcement, Food & Color Additives, Medical Food/Beverage	Final	No		
CPG Sec. 231.110- Quality Control Testing of *Platelets* [ ] and Cryoprecipitated Antihemophilic Factor [ ]		02/28/1995		Investigation & Enforcement, Blood Products	Final	No		
CPG Sec. 250.100 Source Plasma – Guidelines for Informed Consent Forms (Obsolete, Withdrawn on 11/28/2017)		02/28/1995		Investigation & Enforcement, Blood Products	Final	No		

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CPG Sec. 252.100 Source Plasma - Regulatory Action Based on Overbleeding (Obsolete, Withdrawn on 11/28/2017)		02/28/1995		Investigation & Enforcement, Blood Products	Final	No		
CPG Sec. 253.100- Use of Units of *Plasma and Fresh Frozen Plasma* Which Have Been Thawed		02/28/1995		Investigation & Enforcement, Blood Products	Final	No		
CPG Sec. 254.100 Source Plasma - Use of Units from Donors Subsequently Found to be Reactive to a Serologic Test for Syphilis (Obsolete, Withdrawn on 11/28/2017)		02/28/1995		Investigation & Enforcement, Blood Products	Final	No		
CPG Sec. 255.100 Quantitative Testing for Serum Proteins in Plasmapheresis Donors (Obsolete, Withdrawn on 11/28/2017)		02/28/1995		Investigation & Enforcement, Blood Products	Final	No		
CPG Sec. 256.100 Plasmapheresis - 48-hour Period Between Plasmapheresis Procedures (Obsolete, Withdrawn on 11/28/2017)		02/28/1995		Investigation & Enforcement, Blood Products	Final	No		
CPG Sec. 275.100- Immune Milk		02/28/1995		Investigation & Enforcement, Laser Notice	Final	No		
CPG Sec. 300.300 Ineffective Devices - 502(f)(I) Labeling Requirements		02/28/1995		Investigation & Enforcement, Labeling	Final	No		
CPG Sec. 310.100 Pacemaker Reuse		02/28/1995		Investigation & Enforcement, Cardiovascular	Final	No		
CPG Sec. 393.200 Laser(s) as Medical Devices for Facelift, Wrinkle Removal, Acupuncture, Auricular Stimulation, etc.		02/28/1995		Investigation & Enforcement,	Final	No		
CPG Sec. 394.100 Retention of Microwave Oven Test Records		02/28/1995		Investigation & Enforcement, Records	Final	No		
CPG Sec. 396.100 Applicability of the Sunlamp Performance Standard To UVA Tanning Products		02/28/1995		Investigation & Enforcement,	Final	No		
CPG Sec. 396.200 Exemption for Certain Sunlamp Product Purchaser Records		02/28/1995		Investigation & Enforcement,	Final	No		
CPG Sec. 396.400 Policy on Warned on Sunlamp Products		02/28/1995		Investigation & Enforcement, Labeling	Final	No		
CPG Sec. 397.100 Accuracy Requirements for Indication of Temporal-Maximum Ultrasonic Power, 21 CFR 1050.10(c)(1)(ii)		02/28/1995		Investigation & Enforcement,	Final	No		
CPG Sec. 398.200 Hazardous Diagnostic X-ray Systems		02/28/1995		Investigation & Enforcement, Radiology	Final	No		
CPG Sec. 398.300 Registration of Assemblers of Diagnostic X-Ray Systems as Device Manufacturers		02/28/1995		Investigation & Enforcement, Radiology	Final	No		
CPG Sec. 398.375 Obligations of Factory-based Manufacturers and Assemblers of Diagnostic X-ray Equipment Under the Performance Standard for Diagnostic X-ray Equipment		02/28/1995		Investigation & Enforcement, Radiology	Final	No		
CPG Sec. 398.600 Certification and Identification of X-ray Components - Sections 1010.2 and 1020.30(e)		02/28/1995		Investigation & Enforcement,	Final	No		
CPG Sec. 400.200 Consistent Application of CGMP Determinations		02/28/1995		Investigation & Enforcement,	Final	No		
CPG Sec. 430.400 Urinary Preparations - Misbranding - Lack of Rx Legend and Claims		02/28/1995		Investigation & Enforcement,	Final	No		
CPG Sec. 450.200 Drugs - General Provisions and Administrative Procedures for Recognition as Safe and Effective		02/28/1995		Investigation & Enforcement,	Final	No		
CPG Sec. 450.300 OTC Drugs - General Provisions and Administrative Procedures for Marketing Combination Products		02/28/1995		Investigation & Enforcement,	Final	No		
CPG Sec. 456.100 Non-Rx Drugs Anti-Obesity Preparations		02/28/1995		Investigation & Enforcement,	Final	No		
CPG Sec. 457.100 Pangamic Acid and Pangamic Acid Products Unsafe for Food and Drug Use		02/28/1995		Investigation & Enforcement,	Final	No		
CPG Sec. 480.100 Requirements for Expiration Dating and Stability Testing		02/28/1995		Investigation & Enforcement,	Final	No		

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
CPG Sec. 480.200 Expiration Dating of Unit Dose Repackaged Drugs		02/28/1995		Investigation & Enforcement,	Final	No		
CPG Sec. 515.425 Sugar - Water Damaged - Reconditioning		02/28/1995		Investigation & Enforcement,	Final	No		
CPG Sec. 520.100 Canned Foods, Use of the Term "Solid Pack"		02/28/1995		Investigation & Enforcement,	Final	No		
CPG Sec. 525.400 Hollandaise Sauce - Common or Usual Name		02/28/1995		Investigation & Enforcement,	Final	No		
CPG Sec. 550.400 Grenadine		02/28/1995		Investigation & Enforcement,	Final	No		
CPG Sec. 555.650 Reconditioning Foods by Diversion for Animal Feed		02/28/1995		Investigation & Enforcement,	Final	No		
CPG Sec. 562.400 Foreign Language Declarations on Food Labels		02/28/1995		Investigation & Enforcement,	Final	No		
CPG Sec. 578.600 Unapproved Additives for Exported Grains		02/28/1995		Investigation & Enforcement,	Final	No		
CPG Sec. 607.100 - Adequate Directions for Use (Species Designation) - Animal Drugs and Veterinary Devices		02/28/1995	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Labeling, Animal Devices, Animal Drugs	Final	No		
CPG Sec. 608.300 Lay Use of *Animal Capture and Euthanasia* Drugs		02/28/1995	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Animal Drugs	Final	No		
CPG Sec. 637.100 Plastic Containers for Injectable Animal Drugs		02/28/1995	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Animal Drugs	Final	No		
CPG Sec. 638.100 Process Validation Requirements for Drug Products Subject to Pre-Market Approval		02/28/1995	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Animal Drugs	Final	No		
CPG Sec. 640.100 Anthelmintics		02/28/1995	Center for Veterinary Medicine, Office of International Programs	Investigation & Enforcement, Anthelmintics	Final	No		
CPG Sec. 641.100 *Products for Control of Fleas and Ticks* Containing a Pesticide		02/28/1995	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement,	Final	No		
CPG Sec. 642.100 *Drugs for Odor Control and Conception in Pet Animals*		02/28/1995	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Animal Drugs	Final	No		
CPG Sec. 643.100 Oral Iron Products for Baby Pigs		02/28/1995	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement,	Final	No		
CPG Sec. 650.100 Animal Drugs for Euthanasia		02/28/1995	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Animal Drugs	Final	No		
CPG Sec. 654.100 Dimethyl Sulfoxide (DMSO) for Animal Use		02/28/1995	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Animal Drugs	Final	No		
CPG Sec. 654.200 Teat Dips and Udder Washes for Dairy Cows and Goats		02/28/1995	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement,	Final	No		
CPG Sec. 665.100 Common or Usual Names for Animal Feed Ingredients		02/28/1995	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Labeling, Animal Feed	Final	No		
CPG Sec. 665.200 Checklist Labeling for Custom Mixed Medicated Feeds (Withdrawn 7/23/2019)		02/28/1995	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Labeling, Medicated Feed	Final	No		
CPG Sec. 670.500 Ammoniated Cottonseed Meal - Interpretation of 21 CFR		02/28/1995	Center for Veterinary Medicine, Office of Regulatory Affairs	Animal Feed	Final	No		
CPG Sec. 675.100 Diversion of Contaminated Food for Animal Use		02/28/1995	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Animal Feed	Final	No		

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
CPG Sec. 675.200 Diversion of Adulterated Food to Acceptable Animal Feed Use		02/28/1995	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Animal Feed	Final	No		
CPG Sec. 675.300 Moisture Damaged Grain		02/28/1995	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Animal Feed	Final	No		
CPG Sec. 680.500 Unsafe Contamination of Animal Feed from Drug Carryover		02/28/1995	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Animal Feed	Final	No		
CPG Sec. 680.600 Sequencing as a Means to Prevent Unsafe Drug Contamination in the Production, Storage, and Distribution of Feeds		02/28/1995	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Animal Feed	Final	No		
CPG Sec. 685.100 Recycled Animal Waste		02/28/1995	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Animal Feed	Final	No		
CPG Sec. 687.500 Silage Ingredients		02/28/1995	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Animal Feed	Final	No		
CPG Sec. 689.100 Direct-Fed Microbial Products		02/28/1995	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Animal Feed	Final	No		
CPG Sec. 690.100 Nutritional Supplements for Companion Animals		02/28/1995	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Animal Feed	Final	No		
CPG Sec.625.400 Reconditioning of New Animal Drugs Seized Under Section 501(a)(5)		02/28/1995	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Animal Drugs	Final	No		
Guidance Document For The Preparation of Premarket Notification For Ceramic Ball Hip Systems		01/09/1995	Center for Devices and Radiological Health	Premarket,	Final	No		
Coronary and Cerebrovascular Guidewire Guidance	PDF (184.17 KB)PDF (184.17 KB) of Coronary and Cerebrovascular Guidewire Guidance	01/01/1995	Center for Devices and Radiological Health	Premarket,	Final	No		
CVM GFI #57 Preparation and Submission of Veterinary Master Files	PDF (109.53 KB)PDF (109.53 KB) of CVM GFI #57 Preparation and Submission of Veterinary Master Files	01/01/1995	Center for Veterinary Medicine	Chemistry, Manufacturing, and Controls (CMC)	Final	No		
Checklist for Mechanical Lithotripters and Stone Dislodgers used in Gastroenterology and Urology	PDF (14.79 KB)PDF (14.79 KB) of Checklist for Mechanical Lithotripters and Stone Dislodgers used in Gastroenterology and Urology	11/01/1994	Center for Devices and Radiological Health	Premarket,	Final	No		
Reviewer Guidance, Validation of Chromatographic Methods	PDF (702.85 KB)PDF (702.85 KB) of Reviewer Guidance, Validation of Chromatographic Methods	11/01/1994	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		
Submission Documentation for Sterilization Process Validation in Applications for Human and Veterinary Drug Products: Guidance for Industry	PDF (57.36 KB)PDF (57.36 KB) of Submission Documentation for Sterilization Process Validation in Applications for Human and Veterinary Drug Products: Guidance for Industry	11/01/1994	Center for Veterinary Medicine, Center for Drug Evaluation and Research	Microbiology, Pharmaceutical Quality	Final	No		
Letter describing efforts by the CDER and the ORA to clarify the responsibilities of CDER chemistry review scientists and ORA field investigators in the new and abbreviated drug approval process in order to reduce duplication or redundancy in the process	PDF (273.82 KB)PDF (273.82 KB) of Letter describing efforts by the CDER and the ORA to clarify the responsibilities of CDER chemistry review scientists and ORA field investigators in the new and abbreviated drug approval process in order to reduce duplication or redundancy in the process	10/01/1994	Center for Drug Evaluation and Research	Generic Drugs	Final	No		
Points to Consider for Collection of Data in Support of In-Vitro Device Submissions for 510(k) Clearance	PDF (564.38 KB)PDF (564.38 KB) of Points to Consider for Collection of Data in Support of In-Vitro Device Submissions for 510(k) Clearance	09/26/1994	Center for Devices and Radiological Health	Premarket, 510(k)	Final	No		

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
510(k) Checklist for Sterile Lubricating Jelly Used With Transurethral Surgical Instruments		09/18/1994	Center for Devices and Radiological Health	Premarket,	Final	No		
Guidance for the Content of Premarket Notifications for Conventional and Antimicrobial Foley Catheters		09/11/1994	Center for Devices and Radiological Health	Premarket, Antimicrobial Resistance	Final	No		
Format and Content for the CMC Section of an Annual Report	PDF (29.3 KB)PDF (29.3 KB) of Format and Content for the CMC Section of an Annual Report	09/01/1994	Center for Drug Evaluation and Research	Chemistry, Manufacturing, and Controls (CMC), Pharmaceutical Quality	Final	No		
Letter on incomplete Abbreviated Applications, Convictions Under GDEA, Multiple Supplements, Annual Reports for Bulk Antibiotics, Batch Size for Transdermal Drugs, Bioequivalence Protocols, Research, Deviations from OGD Policy	PDF (1.87 MB)PDF (1.87 MB) of Letter on incomplete Abbreviated Applications, Convictions Under GDEA, Multiple Supplements, Annual Reports for Bulk Antibiotics, Batch Size for Transdermal Drugs, Bioequivalence Protocols, Research, Deviations from OGD Policy	09/01/1994	Center for Drug Evaluation and Research	Generic Drugs	Final	No		
S5A Detection of Toxicity to Reproduction for Medicinal Products S5(R2) Detection of Toxicity to Reproduction for Medicinal Products Toxicity to Male Fertility In November 2005, the ICH incorporated the S5B addendum with S5A and retitled the combined	PDF (86.89 KB)PDF (86.89 KB) of S5A Detection of Toxicity to Reproduction for Medicinal Products S5(R2) Detection of Toxicity to Reproduction for Medicinal Products Toxicity to Male Fertility In November 2005, the ICH incorporated the S5B addendum with S5A and retitled the combined	09/01/1994	Center for Drug Evaluation and Research	ICH-Safety	Final	No		
Guidance for the Preparation of a Premarket Notification for Extended Laparoscopy Devices (ELD)		08/29/1994	Center for Devices and Radiological Health	Premarket,	Final	No		
CPG Sec. 634.100 Drugs Packaged for Infusion or Injection of Food-Producing Animals		08/22/1994	Center for Veterinary Medicine, Office of International Programs	Investigation & Enforcement, Animal Drugs	Final	No		
E7 Studies in Support of Special Populations: Geriatrics	PDF (24.71 KB)PDF (24.71 KB) of E7 Studies in Support of Special Populations: Geriatrics	08/01/1994	Center for Drug Evaluation and Research	ICH-Efficacy	Final	No		
Guidance For The Content Of Premarket Notifications For Urodynamic/Uroflowmetry Systems		07/28/1994	Center for Devices and Radiological Health	Premarket,	Final	No		
Points to Consider for Cervical Cytology Devices	PDF (660.62 KB)PDF (660.62 KB) of Points to Consider for Cervical Cytology Devices	07/25/1994	Center for Devices and Radiological Health		Final	No		
Pesticide Regulation Notice 94-4 Interim Measures for the Registration of Antimicrobial Products/Liquid Chemical Germicides with Medical Device Use Claims	PDF (938.52 KB)PDF (938.52 KB) of Pesticide Regulation Notice 94-4 Interim Measures for the Registration of Antimicrobial Products/Liquid Chemical Germicides with Medical Device Use Claims	06/30/1994	Center for Devices and Radiological Health	Postmarket,	Final	No		
Premarket Notification (510(k)) Guidance Document for Daily Wear Contact Lenses (Part 1)	PDF (1.14 MB)PDF (1.14 MB) of Premarket Notification (510(k)) Guidance Document for Daily Wear Contact Lenses (Part 1)	06/28/1994	Center for Devices and Radiological Health	Premarket, 510(k)	Final	No		
Premarket Notification (510(k)) Guidance Document for Daily Wear Contact Lenses (Part 5)	PDF (1.58 MB)PDF (1.58 MB) of Premarket Notification (510(k)) Guidance Document for Daily Wear Contact Lenses (Part 5)	06/28/1994	Center for Devices and Radiological Health	Premarket, 510(k), Ophthalmic	Final	No		
Premarket Notification [510(k)] Guidance Document for Class II Daily Wear Contact Lenses		06/27/1994	Center for Devices and Radiological Health	Premarket,	Final	No		
Guidance for the Content of Premarket Notifications for Urine Drainage Bags	PDF (500.32 KB)PDF (500.32 KB) of Guidance for the Content of Premarket Notifications for Urine Drainage Bags	06/07/1994	Center for Devices and Radiological Health	Premarket, 510(k)	Final	No		

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
CVM GFI #55 Supportive Data for Cat Food Labels Bearing "Reduces Urinary pH Claims: Protocol Development		05/31/1994	Center for Veterinary Medicine	Animal Feed	Final	No		FDA-1994-D-0230
CVM GFI #53 Evaluation of the Utility of Food Additives in Diet Fed to Aquatic Animals		04/30/1994	Center for Veterinary Medicine	Animal Food Additives, Aquaculture	Final	No		
Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone Or Bone Cement		04/27/1994	Center for Devices and Radiological Health	Premarket,	Final	No		
Preamendments Class III Strategy		04/18/1994	Center for Devices and Radiological Health	Premarket,	Final	No		
Letter - Condom Manufacturers and Distributors	PDF (124.08 KB)PDF (124.08 KB) of Letter - Condom Manufacturers and Distributors	04/05/1994	Center for Devices and Radiological Health	Premarket,	Final	No		
Letter - Manufacturers, Distributors and Importers of Condom Products (included in Condom Packet 398) : Letter - Manufacturers, Distributors and Importers of Condom Products	PDF (74.51 KB)PDF (74.51 KB) of Letter - Manufacturers, Distributors and Importers of Condom Products (included in Condom Packet 398) : Letter - Manufacturers, Distributors and Importers of Condom Products	02/23/1994	Center for Devices and Radiological Health	Postmarket, Premarket,	Final	No		
Manufacturers And Initial Distributors Of Sharps Containers And Destroyers Used By Health Care Professionals	PDF (199.29 KB)PDF (199.29 KB) of Manufacturers And Initial Distributors Of Sharps Containers And Destroyers Used By Health Care Professionals	02/03/1994	Center for Devices and Radiological Health		Final	No		
Review Criteria for In Vitro Diagnostic Devices for the Assessment of Thyroid Autoantibodies using Indirect Immunofluorescence Assay (IFA), Indirect Hemagglutination Assay (IHA), Radioimmunoasay (RIA), and Enzyme Linked Immunosorbent Assay (ELISA)		01/31/1994	Center for Devices and Radiological Health	Premarket, Laboratory Tests	Final	No		
Manufacturers/Assemblers of Diagnostic X-ray Systems: Enforcement Policy for Positive-Beam Limitation (PBL) Requirements in 21 CFR 1020.31(g) :	PDF (321.29 KB)PDF (321.29 KB) of Manufacturers/Assemblers of Diagnostic X-ray Systems: Enforcement Policy for Positive-Beam Limitation (PBL) Requirements in 21 CFR 1020.31(g) :	10/13/1993	Center for Devices and Radiological Health	Postmarket, Investigation & Enforcement,	Final	No		
Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for Sharps Containers	PDF (296.78 KB)PDF (296.78 KB) of Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for Sharps Containers	10/01/1993	Center for Devices and Radiological Health	Premarket, 510(k)	Final	No		
Guidance for Industry: Guidelines for Determining Metric Equivalents of Household Measures		09/30/1993	Center for Food Safety and Applied Nutrition	Food & Beverage Safety, Labeling, Nutrition Label, Packaging, Ingredients, Food & Beverage Safety	Final	No		FDA-2013-S-0610
Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators		09/30/1993	Center for Devices and Radiological Health	Premarket,	Final	No		
1993 Draft Redbook II		08/01/1993	Office of Food Additive Safety	Food & Color Additives	Draft	No		
Guidance on Premarket Notification [510(k)] Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Health Care Facilities	PDF (954.92 KB)PDF (954.92 KB) of Guidance on Premarket Notification [510(k)] Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Health Care Facilities	08/01/1993	Center for Devices and Radiological Health	Premarket, 510(k)	Final	No		
Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes	PDF (635.1 KB)PDF (635.1 KB) of Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes	08/01/1993	Center for Devices and Radiological Health	Premarket, 510(k)	Final	No		

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Letter to regulated industry notifying interested parties about important detailed information regarding labeling, scale-up, packaging, minor/major amendment criteria and bioequivalence requirements	PDF (907.64 KB)PDF (907.64 KB) of Letter to regulated industry notifying interested parties about important detailed information regarding labeling, scale-up, packaging, minor/major amendment criteria and bioequivalence requirements	08/01/1993	Center for Drug Evaluation and Research	Generic Drugs	Final	No		
CVM GFI #45 Guideline for Uniform Labeling of Drugs for Dairy and Beef Cattle		07/31/1993	Center for Veterinary Medicine	Labeling	Final	No		
Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs: Guidance for Industry	PDF (1.83 MB)PDF (1.83 MB) of Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs: Guidance for Industry	07/22/1993	Center for Drug Evaluation and Research	Clinical - Medical, Good Clinical Practices (GCP)	Final	No		
CPG Sec. 615.200 Proper Drug Use and Residue Avoidance by Non-Veterinarians		07/08/1993	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Human Food Safety, Animal Drugs	Final	No		
Beam Attenuators and Emission Indicators for Class II and IIIa Laser Systems (Laser Notice 43)	PDF (90.36 KB)PDF (90.36 KB) of Beam Attenuators and Emission Indicators for Class II and IIIa Laser Systems (Laser Notice 43)	06/07/1993	Center for Devices and Radiological Health	Radiological Health	Final	No		
Letter to Industry, Powered Wheelchair Manufacturers from RMJohnson	PDF (47.17 KB)PDF (47.17 KB) of Letter to Industry, Powered Wheelchair Manufacturers from RMJohnson	05/10/1993	Center for Devices and Radiological Health		Final	No		
CPG Sec. 680.100 Tracers in Animal Feed		04/04/1993	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Animal Feed	Final	No		
Guidance on the Content of Premarket Notification [510(K)] Submissions for Hypodermic Single Lumen Needles		03/31/1993	Center for Devices and Radiological Health	Premarket, 510(k)	Final	No		
Guidance on the Content of Premarket Notification [510(K)] Submissions for Piston Syringes		03/31/1993	Center for Devices and Radiological Health	Premarket,	Final	No		
Guidance on Premarket Notification 510(k) for Sterilizers Intended for Use in Health Care Facilities	PDF (843.41 KB)PDF (843.41 KB) of Guidance on Premarket Notification 510(k) for Sterilizers Intended for Use in Health Care Facilities	03/01/1993	Center for Devices and Radiological Health	Premarket, 510(k)	Final	No		
Guidance on the Content of Premarket Notification [510(K)] Submissions for Clinical Electronic Thermometers		02/28/1993	Center for Devices and Radiological Health	Premarket,	Final	No		
Guidance Document for the Preparation of IDE and PMA Applications for Intra-Articular Prosthetic Knee Ligament Devices		02/17/1993	Center for Devices and Radiological Health	Premarket,	Final	No		
Guidance for the Content of Premarket Notifications for Biopsy Devices Used in Gastroenterology and Urology		02/09/1993	Center for Devices and Radiological Health	Premarket,	Final	No		
Guidance for the Content of Premarket Notifications for Ureteral Stents		02/09/1993	Center for Devices and Radiological Health	Premarket,	Final	No		
CVM GFI #50 Target Animal and Human Food Safety, Drug Efficacy, Environmental and Manufacturing Studies for Teat Antiseptic Products		01/31/1993	Center for Veterinary Medicine	Chemistry, Manufacturing, and Controls (CMC), Environmental Safety, Human Food Safety, Target Animal – Effectiveness, Target Animal – Safety	Final	No		
Letter to all ANDA and AADA applicants about the Generic Drug Enforcement Act of 1992 (GDEA), and the Office of Generic Drugs intention to refuse-to-file incomplete submissions as required by the new law	PDF (232.94 KB)PDF (232.94 KB) of Letter to all ANDA and AADA applicants about the Generic Drug Enforcement Act of 1992 (GDEA), and the Office of Generic Drugs intention to refuse-to-file incomplete submissions as required by the new law	01/01/1993	Center for Drug Evaluation and Research	Generic Drugs	Final	No		

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Preparation of Investigational New Drug Products (Human and Animal): Guidance for Industry	PDF (795.48 KB)PDF (795.48 KB) of Preparation of Investigational New Drug Products (Human and Animal): Guidance for Industry	11/01/1992	Center for Drug Evaluation and Research	Current Good Manufacturing Practices (CGMP), Pharmaceutical Quality	Final	No		
Dental Handpiece Sterilization (Dear Doctor Letter)	PDF (73.17 KB)PDF (73.17 KB) of Dental Handpiece Sterilization (Dear Doctor Letter)	09/28/1992	Center for Devices and Radiological Health		Final	No		
Important Information About Rophae Intraocular Lenses	PDF (121.72 KB)PDF (121.72 KB) of Important Information About Rophae Intraocular Lenses	08/20/1992	Center for Devices and Radiological Health	Postmarket,	Final	No		
Review Criteria for In Vitro Diagnostic Devices for Detection of IGM Antibodies to Viral Agents	PDF (939.3 KB)PDF (939.3 KB) of Review Criteria for In Vitro Diagnostic Devices for Detection of IGM Antibodies to Viral Agents	08/01/1992	Center for Devices and Radiological Health		Final	No		
Letter on the Provision of new information pertaining to new bioequivalence guidelines and refuse-to-file letters	PDF (253.87 KB)PDF (253.87 KB) of Letter on the Provision of new information pertaining to new bioequivalence guidelines and refuse-to-file letters	07/01/1992	Center for Drug Evaluation and Research	Generic Drugs	Final	No		
CPG Sec. 470.100 Orders for Post-Approval Record Reviews	PDF (67.35 KB)PDF (67.35 KB) of CPG Sec. 470.100 Orders for Post-Approval Record Reviews	06/24/1992		Investigation & Enforcement,	Final	No		
CPG Sec. 625.600 Orders for Post-Approval Record Reviews		06/24/1992	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Records, Animal Drugs	Final	No		
CPG Sec. 681.100 Order for Post-Approval Record Reviews		06/24/1992	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Records, Animal Feed	Final	No		
Guidance for Peak Flow Meters for Over-the-Counter Sale	PDF (801.01 KB)PDF (801.01 KB) of Guidance for Peak Flow Meters for Over-the-Counter Sale	06/23/1992	Center for Devices and Radiological Health	Premarket,	Final	No		
Compliance Guide for Laser Products (FDA 86-8260)	PDF (104.98 KB)PDF (104.98 KB) of Compliance Guide for Laser Products (FDA 86-8260)	06/01/1992	Office of In Vitro Diagnostics and Radiological Health	Radiological Health	Final	No		
Statement of Policy - Foods Derived from New Plant Varieties		05/29/1992	Office of Food Additive Safety		Final	No		
CPG Sec. 450.500 Tamper-Resistant Packaging Requirements for Certain Over-the-Counter Human Drug Products		05/20/1992		Investigation & Enforcement,	Final	No		
Review Criteria For Premarket Approval of In Vitro Diagnostic Devices for Detection of Antibodies to Parvovirus B19	PDF (697.97 KB)PDF (697.97 KB) of Review Criteria For Premarket Approval of In Vitro Diagnostic Devices for Detection of Antibodies to Parvovirus B19	05/15/1992	Center for Devices and Radiological Health	Premarket, IVDs (In Vitro Diagnostic Devices), Laboratory Tests	Final	No		
CPG Sec. 420.100 Adulteration of Drugs Under Section 501(b) and 501(c) of the Act. *Direct Reference Seizure Authority for Adulterated Drugs Under Section 501(b)*	PDF (71.02 KB)PDF (71.02 KB) of CPG Sec. 420.100 Adulteration of Drugs Under Section 501(b) and 501(c) of the Act. *Direct Reference Seizure Authority for Adulterated Drugs Under Section 501(b)*	05/01/1992		Investigation & Enforcement, Laser Notice	Final	No		
Development of New Stereoisomeric Drugs		04/30/1992			Final	No		
CPG Sec. 450.100 CGMP Enforcement Policy - OTC vs Rx Drugs	PDF (59.71 KB)PDF (59.71 KB) of CPG Sec. 450.100 CGMP Enforcement Policy - OTC vs Rx Drugs	04/01/1992		Investigation & Enforcement,	Final	No		
Draft Recommended Methods for Blood Grouping Reagents Evaluation	PDF (1.8 MB)PDF (1.8 MB) of Draft Recommended Methods for Blood Grouping Reagents Evaluation	03/01/1992	Center for Biologics Evaluation and Research	Blood Products	Final	No		84S-0181
Draft Recommended Methods for Evaluating Potency, Specificity, and Reactivity of Anti-Human Globulin	PDF (1 MB)PDF (1 MB) of Draft Recommended Methods for Evaluating Potency, Specificity, and Reactivity of Anti-Human Globulin	03/01/1992	Center for Biologics Evaluation and Research	Blood Products	Final	No		84S-0182

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Guideline for Postmarketing Reporting of Adverse Drug Experiences	PDF (3.63 MB)PDF (3.63 MB) of Guideline for Postmarketing Reporting of Adverse Drug Experiences	03/01/1992	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		
Draft Points to Consider in the Design and Implementation of Field Trials for Blood Grouping Reagents and Anti-Human Globulin	PDF (210.56 KB)PDF (210.56 KB) of Draft Points to Consider in the Design and Implementation of Field Trials for Blood Grouping Reagents and Anti-Human Globulin	01/01/1992	Center for Biologics Evaluation and Research	Blood Products	Final	No		91N-0467
Review Criteria for Devices Intended for the Detection of Hepatitis B 'e' Antigen and Antibody to HBe	PDF (559.54 KB)PDF (559.54 KB) of Review Criteria for Devices Intended for the Detection of Hepatitis B 'e' Antigen and Antibody to HBe	12/30/1991	Center for Devices and Radiological Health		Final	No		
Review Criteria for Assessment of Glycohemoglobin (Glycated or Glycosylated) Hemoglobin In Vitro Diagnostic Devices		09/29/1991	Center for Devices and Radiological Health	Premarket, Laboratory Tests	Final	No		
Heated Humidifier Review Guidance	PDF (165.9 KB)PDF (165.9 KB) of Heated Humidifier Review Guidance	08/30/1991	Center for Devices and Radiological Health	Premarket,	Final	No		
Review Criteria for Blood Culture Systems	PDF (860.18 KB)PDF (860.18 KB) of Review Criteria for Blood Culture Systems	08/12/1991	Center for Devices and Radiological Health		Final	No		
Review Criteria for Assessment of Cytogenetic Analysis Using Automated and Semi-Automated Chromosome Analyzers		07/14/1991	Center for Devices and Radiological Health		Final	No		
CPG Sec. 120.100 Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities		06/30/1991		Investigation & Enforcement, Food & Color Additives	Final	No		
CPG Sec. 335.800 Clinical Thermometer - Adulteration; Misbranding Defects	PDF (64.91 KB)PDF (64.91 KB) of CPG Sec. 335.800 Clinical Thermometer - Adulteration; Misbranding Defects	05/31/1991		Investigation & Enforcement, Administrative / Procedural	Final	No		
Shelf Life of Medical Devices	PDF (1.75 MB)PDF (1.75 MB) of Shelf Life of Medical Devices	04/01/1991	Center for Devices and Radiological Health		Final	No		
Device Labeling Guidance #G91-1 (Blue Book Memo)		03/07/1991	Center for Devices and Radiological Health	Premarket, Labeling	Final	No		
Quality Assurance Guidelines for Hemodialysis Devices	PDF (12.72 MB)PDF (12.72 MB) of Quality Assurance Guidelines for Hemodialysis Devices	02/01/1991	Center for Devices and Radiological Health	Gastroenterology-Urology	Final	No		
CPG Sec. 446.100 Regulatory Action Regarding Approved New Drugs and Antibiotic Drug Products Subjected to Additional Processing or other Manipulations		01/17/1991		Investigation & Enforcement,	Final	No		
Letter on the request for cooperation of regulated industry to improve the efficiency and effectiveness of the generic drug review process, by assuring the completeness and accuracy of required information and data submissions	PDF (917.21 KB)PDF (917.21 KB) of Letter on the request for cooperation of regulated industry to improve the efficiency and effectiveness of the generic drug review process, by assuring the completeness and accuracy of required information and data submissions	11/01/1990	Center for Drug Evaluation and Research	Generic Drugs	Final	No		
Consolidated Review of Submissions for Lasers and Accessories #G90-1 (Blue Book Memo)		10/18/1990	Center for Devices and Radiological Health	Premarket, Radiology	Final	No		
Guidance on 510(k) Submissions for Implanted Infusion Ports	PDF (786.74 KB)PDF (786.74 KB) of Guidance on 510(k) Submissions for Implanted Infusion Ports	10/01/1990	Center for Devices and Radiological Health	Premarket, 510(k)	Final	No		
Review Criteria for Devices Assisting in the Diagnosis of C. Difficile Associated Diseases	PDF (375.54 KB)PDF (375.54 KB) of Review Criteria for Devices Assisting in the Diagnosis of C. Difficile Associated Diseases	05/31/1990	Center for Devices and Radiological Health		Final	No		

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Premarket Testing Guidelines for Female Barrier Contraceptive Devices Also Intended to Prevent Sexually Transmitted Diseases	PDF (713.69 KB)PDF (713.69 KB) of Premarket Testing Guidelines for Female Barrier Contraceptive Devices Also Intended to Prevent Sexually Transmitted Diseases	04/04/1990	Center for Devices and Radiological Health	Premarket,	Final	No		
Reviewer Guidance for Automatic X-Ray Film Processor 510(k)	PDF (85.84 KB)PDF (85.84 KB) of Reviewer Guidance for Automatic X-Ray Film Processor 510(k)	02/01/1990	Center for Devices and Radiological Health	Premarket, 510(k), Radiology	Final	No		
Implantable Pacemaker Testing Guidance	PDF (489.14 KB)PDF (489.14 KB) of Implantable Pacemaker Testing Guidance	01/12/1990	Center for Devices and Radiological Health	Premarket,	Final	No		
Format and Content of the Microbiology Section of an Application*: Guidance for Industry	PDF (545.53 KB)PDF (545.53 KB) of Format and Content of the Microbiology Section of an Application*: Guidance for Industry	01/01/1990	Center for Drug Evaluation and Research	Microbiology, Pharmaceutical Quality	Final	No		
Clarification of Compliance Requirements for Certain Manufacturers Who Incorporate Certified Class I Laser Products into Their Products (Laser Notice 42)	PDF (57.9 KB)PDF (57.9 KB) of Clarification of Compliance Requirements for Certain Manufacturers Who Incorporate Certified Class I Laser Products into Their Products (Laser Notice 42)	12/18/1989	Center for Devices and Radiological Health	Radiological Health	Final	No		
Review of FDA's Implementation of the Drug Export Amendments of 1986	PDF (2 MB)PDF (2 MB) of Review of FDA's Implementation of the Drug Export Amendments of 1986	11/01/1989	Center for Veterinary Medicine, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Compliance, Current Good Manufacturing Practices (CGMP)	Final	No		
Study of Drugs Likely to be used in the Elderly	PDF (1.18 MB)PDF (1.18 MB) of Study of Drugs Likely to be used in the Elderly	11/01/1989	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		
CPG Sec. 540.450 *Imitation Breaded Shrimp*		10/30/1989		Investigation & Enforcement,	Final	No		
CPG Sec. 540.550 Kipper and Kipper Unsplit - Definitions		10/30/1989		Investigation & Enforcement,	Final	No		
CPG Sec. 540.150 Caviar, Use of Term - Labeling		10/29/1989		Investigation & Enforcement,	Final	No		
CPG Sec. 540.390 Canned Shrimp - Labeling, Size Designations and Corresponding Counts		10/29/1989		Investigation & Enforcement,	Final	No		
Guideline for Collection of Blood or Blood Products from Donors with Positive Tests for Infectious Disease Markers ("High Risk" Donors)	PDF (488.31 KB)PDF (488.31 KB) of Guideline for Collection of Blood or Blood Products from Donors with Positive Tests for Infectious Disease Markers ("High Risk" Donors)	10/01/1989	Center for Biologics Evaluation and Research	Blood Products	Final	No		
CPG Sec. 560.250 Imports - Importer can be Required to Reveal Identity of Ingredients		09/19/1989		Investigation & Enforcement,	Final	No		
Labeling - Regulatory Requirements for Medical Devices (FDA 89-4203)	PDF (2.98 MB)PDF (2.98 MB) of Labeling - Regulatory Requirements for Medical Devices (FDA 89-4203)	09/01/1989	Center for Devices and Radiological Health		Final	No		
CPG Sec. 100.200 FDA Jurisdiction Over Products Composed of Interstate Ingredients		08/31/1989		Investigation & Enforcement, Administrative / Procedural, Food & Color Additives	Final	No		
CPG Sec. 100.500 - Common Carrier as a Relabeler, Repacker, Reprocessor, etc.		08/30/1989		Investigation & Enforcement, Food & Color Additives	Final	No		
CPG Sec. 100.600 Status of Facial Tissues, Paper Napkins, Paper Towels and Similar Paper Products		08/30/1989		Investigation & Enforcement,	Final	No		
CPG Sec. 100.800 Guaranties Over Printed Signatures		08/30/1989		Investigation & Enforcement, Food & Color Additives, Records	Final	No		
CPG Sec. 110.200 Export of FDA Regulated Products from U.S. Foreign Trade Zones		08/30/1989		Investigation & Enforcement, Food & Color Additives	Final	No		
CPG Sec. 110.600 FDA Authority Over Products of Foreign Origin Located in Foreign Trade Zones, Bonded Warehouses or on Bonded Carriers		08/30/1989		Investigation & Enforcement, Food & Color Additives	Final	No		

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CPG Sec. 110.700 Seizures by the U.S. Customs Service of Prohibited Articles of Foreign Origin Not Intended for Entry into the United States		08/30/1989		Investigation & Enforcement, Food & Color Additives	Final	No		
CPG Sec. 110.800 Imports, Post Detention Sampling		08/30/1989		Investigation & Enforcement, Food & Color Additives	Final	No		
CPG Sec. 130.200 Inspection of Firms when Legal Action is Pending		08/30/1989		Investigation & Enforcement, Food & Color Additives	Final	No		
CPG Sec. 140.100 Seizure of Books that Constitute Misleading Labeling		08/30/1989		Investigation & Enforcement, Food & Color Additives, Labeling	Final	No		
CPG Sec. 160.300 Requests for Records Under Section 703		08/30/1989		Investigation & Enforcement, Food & Color Additives	Final	No		
CPG Sec. 160.400 *Section 305 Meeting* Before Report of Criminal Violation		08/30/1989		Investigation & Enforcement, Food & Color Additives	Final	No		
CPG Sec. 400.700 Drug Product Entries in Periodic Publications		08/15/1989		Investigation & Enforcement,	Final	No		
Draft Points to Consider in the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Antibodies to the Human Immunodeficiency Virus Type 1	PDF (1 MB)PDF (1 MB) of Draft Points to Consider in the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Antibodies to the Human Immunodeficiency Virus Type 1	08/01/1989	Center for Biologics Evaluation and Research	Blood Products	Final	No		
CPG Sec. 160.700 Reconditioning of Foods Adulterated Under 402(a)(4)		07/20/1989		Investigation & Enforcement,	Final	No		
CPG Sec. 560.300 Reconditioning of Imported, Insect Infested, Insect Damaged or Moldy Coffee Beans		07/19/1989		Investigation & Enforcement,	Final	No		
CPG Sec. 560.350 Coffee and Cocoa Bean Sweeps		07/19/1989		Investigation & Enforcement,	Final	No		
CPG Sec. 560.100 Importation of Unlabeled Foods - Exemption Under *21 CFR 101.100(d)*		07/18/1989		Investigation & Enforcement,	Final	No		
Metaproterenol Sulfate and Albuterol Metered Dose Inhalers In Vitro	PDF (743.81 KB)PDF (743.81 KB) of Metaproterenol Sulfate and Albuterol Metered Dose Inhalers In Vitro	06/27/1989	Center for Drug Evaluation and Research	Biopharmaceutics	Final	No		
New FDA Recommendations and Results of Contact Lens Study (7 day letter)	PDF (146.89 KB)PDF (146.89 KB) of New FDA Recommendations and Results of Contact Lens Study (7 day letter)	05/30/1989	Center for Devices and Radiological Health	Premarket,	Final	No		
CPG Sec. 690.500 Uncooked Meat for Animal Food (Withdrawn 4/30/2019)		05/23/1989	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Animal Feed	Final	No		
Review of IDEs for Feasibility Studies #D89-1 (Blue Book Memo)		05/16/1989	Center for Devices and Radiological Health	Premarket, Device Exception (IDE)	Final	No		
Clarification of Radiation Control Regulations for Diagnostic X-Ray Equipment (Part 1)	PDF (925.48 KB)PDF (925.48 KB) of Clarification of Radiation Control Regulations for Diagnostic X-Ray Equipment (Part 1)	03/01/1989	Center for Devices and Radiological Health	Radiology	Final	No		
Clarification of Radiation Control Regulations for Diagnostic X-Ray Equipment (Part 2)	PDF (1.08 MB)PDF (1.08 MB) of Clarification of Radiation Control Regulations for Diagnostic X-Ray Equipment (Part 2)	03/01/1989	Center for Devices and Radiological Health	Radiology	Final	No		
Clarification of Radiation Control Regulations for Diagnostic X-Ray Equipment (Part 3)	PDF (1.08 MB)PDF (1.08 MB) of Clarification of Radiation Control Regulations for Diagnostic X-Ray Equipment (Part 3)	03/01/1989	Center for Devices and Radiological Health		Final	No		
Letter on the provision of new procedures and policies affecting the generic drug review process	PDF (608.39 KB)PDF (608.39 KB) of Letter on the provision of new procedures and policies affecting the generic drug review process	03/01/1989	Center for Drug Evaluation and Research	Generic Drugs	Final	No		
Clarification of Radiation Control Regulations for Diagnostic X-Ray Equipment (FDA 89-8221)		02/28/1989		Radiology	Final	No		
Premarket Notification - Consistency of Reviews #K89-1 (Blue Book Memo)		02/27/1989	Center for Devices and Radiological Health	Premarket,	Final	No		

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Letter - Manufacturers, Importers, and Repackagers of Condoms for Contraception or Sexually-Transmitted Disease Prevention (Holt)	PDF (76.27 KB)PDF (76.27 KB) of Letter - Manufacturers, Importers, and Repackagers of Condoms for Contraception or Sexually-Transmitted Disease Prevention (Holt)	02/13/1989	Center for Devices and Radiological Health	Postmarket, Premarket,	Final	No		
CPG Sec. 562.800 Vending Machine Food - Labeling		02/01/1989		Investigation & Enforcement,	Final	No		
CPG Sec. 555.550 Foods, Standardized; Enriched or Fortified - Adulteration Involving Misbranding - Potency	PDF (9.24 KB)PDF (9.24 KB) of CPG Sec. 555.550 Foods, Standardized; Enriched or Fortified - Adulteration Involving Misbranding - Potency	02/01/1989		Investigation & Enforcement,	Final	No		
CPG Sec. 555.850 Water Damaged Food Products in Screw-Top, Crimped-Cap and Similar Containers	PDF (11.42 KB)PDF (11.42 KB) of CPG Sec. 555.850 Water Damaged Food Products in Screw-Top, Crimped-Cap and Similar Containers	02/01/1989		Investigation & Enforcement,	Final	No		
CPG Sec. 562.100 Acetic Acid - Use in Foods - Labeling of Foods in Which Used		02/01/1989		Investigation & Enforcement,	Final	No		
CPG Sec. 562.600 Preservatives; Use in Nonstandardized Foods; Label Declaration		02/01/1989		Investigation & Enforcement,	Final	No		
CPG Sec. 562.700 Labeling of Food Bearing Residues of Pesticide Chemicals		02/01/1989		Investigation & Enforcement,	Final	No		
CPG Sec. 562.750 Labeling of Food Articles Distributed Solely in Puerto Rico		02/01/1989		Investigation & Enforcement,	Final	No		
Guidance for Oxygen Conserving Device 510(k) Review 73 BZD 868.5905 Non-continuous Ventilator Class II	PDF (99.57 KB)PDF (99.57 KB) of Guidance for Oxygen Conserving Device 510(k) Review 73 BZD 868.5905 Non-continuous Ventilator Class II	02/01/1989	Center for Devices and Radiological Health	Premarket, 510(k)	Final	No		
COMPRESSED MEDICAL GASES GUIDELINE		01/31/1989	Center for Drug Evaluation and Research	Current Good Manufacturing Practices (CGMP), Pharmaceutical Quality	Final	No		
CPG Sec. 555.100 Alcohol; Use of Synthetic Alcohol in Foods		01/31/1989		Investigation & Enforcement,	Final	No		
CPG Sec. 555.750 Seeds for Sprouting Prior to Food Use, i.e., Dried Mung Beans, Alfalfa Seeds, Etc.		01/31/1989		Investigation & Enforcement,	Final	No		
CPG Sec. 555.800 Polysorbates 20, 40, 60, 65, 80, 85 - Common or Usual Names		01/31/1989		Investigation & Enforcement,	Final	No		
CPG Sec. 555.875 Water in Food Products (Ingredient or Adulterant)		01/31/1989		Investigation & Enforcement,	Final	No		
CPG Sec. 562.650 "Processing" - Use of Term in Section 405 of the FD&C Act		01/31/1989		Investigation & Enforcement,	Final	No		
Balloon Valvuloplasty Guidance For The Submission Of an IDE Application and a PMA Application		12/31/1988	Center for Devices and Radiological Health	Premarket,	Final	No		
CPG Sec. 570.550 Reconditioning - Tree Nuts Contaminated with E. coli		12/09/1988		Investigation & Enforcement,	Final	No		
CPG Sec. 585.100 Artichoke; Jerusalem Artichoke - Common or Usual Name		12/08/1988		Investigation & Enforcement,	Final	No		
CPG Sec. 585.150 Asparagus, Canned or Frozen - Adulteration with Insect Filth	PDF (9.84 KB)PDF (9.84 KB) of CPG Sec. 585.150 Asparagus, Canned or Frozen - Adulteration with Insect Filth	12/08/1988		Investigation & Enforcement,	Final	No		
CPG Sec. 585.260 Broccoli, Frozen - Adulteration with Insects	PDF (8.85 KB)PDF (8.85 KB) of CPG Sec. 585.260 Broccoli, Frozen - Adulteration with Insects	12/08/1988		Investigation & Enforcement,	Final	No		
CPG Sec. 585.350 Corn Husks (for Tamales) - Adulteration with Filth	PDF (8.76 KB)PDF (8.76 KB) of CPG Sec. 585.350 Corn Husks (for Tamales) - Adulteration with Filth	12/08/1988		Investigation & Enforcement,	Final	No		
CPG Sec. 585.450 Greens, Canned - Adulteration by Mildew	PDF (8.82 KB)PDF (8.82 KB) of CPG Sec. 585.450 Greens, Canned - Adulteration by Mildew	12/08/1988		Investigation & Enforcement,	Final	No		

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CPG Sec. 585.600 Peas and Carrots, Labeling of Canned Mixture		12/08/1988		Investigation & Enforcement,	Final	No		
CPG Sec. 585.625 Canned Peas - Label Designation of Sizes		12/08/1988		Investigation & Enforcement,	Final	No		
CPG Sec. 585.650 Canned Pimentos and Red Sweet Peppers - Seeds Should be Removed		12/08/1988		Investigation & Enforcement,	Final	No		
CPG Sec. 585.700 Potato Chips - Adulteration with Rot	PDF (8.71 KB)PDF (8.71 KB) of CPG Sec. 585.700 Potato Chips - Adulteration with Rot	12/08/1988		Investigation & Enforcement,	Final	No		
CPG Sec. 585.710 Potato Chips, Ingredients - Labeling		12/08/1988		Investigation & Enforcement,	Final	No		
CPG Sec. 585.725 "Pumpkin" - Labeling Articles Made from Certain Varieties of Squash		12/08/1988		Investigation & Enforcement,	Final	No		
CPG Sec. 585.800 Squash Seeds - Labeling as Pumpkin Seeds		12/08/1988		Investigation & Enforcement,	Final	No		
CPG Sec. 585.850 Sweet Potatoes - Sirup Pack		12/08/1988		Investigation & Enforcement,	Final	No		
CPG Section 585.525: Mushroom Mycelium - Fitness for Food; Labeling		12/08/1988		Investigation & Enforcement,	Final	No		
CPG Sec. 570.100 Jordan Almonds - Common or Usual Name		12/02/1988		Investigation & Enforcement,	Final	No		
CPG Sec. 570.250 Cashews, Insect Infested - Reconditioning		12/02/1988		Investigation & Enforcement,	Final	No		
CPG Sec. 350.100 Packaging Technologies and Tamper-Resistant Packaging Requirements for Contact Lens Solutions and Tablets		11/21/1988		Investigation & Enforcement, Ingredients	Final	No		
CPG Sec. 510.100 Beverage Bases		11/01/1988		Investigation & Enforcement,	Final	No		
Low Power Laser Reporting Exemption (Laser Notice 41)	PDF (68.06 KB)PDF (68.06 KB) of Low Power Laser Reporting Exemption (Laser Notice 41)	08/09/1988	Center for Devices and Radiological Health		Final	No		
Format and Content of the Clinical and Statistical Sections of an Application	PDF (1.09 MB)PDF (1.09 MB) of Format and Content of the Clinical and Statistical Sections of an Application	07/01/1988	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		
CPG Sec. 545.200 Confectionery Decorations (Nutritive and Non-Nutritive)		06/27/1988		Investigation & Enforcement,	Final	No		
CPG Sec. 578.200 Corn Meal - Adulteration by Insect and Rodent Filth	PDF (10.3 KB)PDF (10.3 KB) of CPG Sec. 578.200 Corn Meal - Adulteration by Insect and Rodent Filth	06/06/1988		Investigation & Enforcement,	Final	No		
CPG Sec. 578.300 Wheat - Adulteration by Insect and Rodent filth	PDF (12.18 KB)PDF (12.18 KB) of CPG Sec. 578.300 Wheat - Adulteration by Insect and Rodent filth	06/06/1988		Investigation & Enforcement,	Final	No		
CPG Sec. 515.800 Labeling of Products Purporting to be "Chocolate" or "Chocolate Flavored"		05/12/1988		Investigation & Enforcement,	Final	No		
Guidance for Studies for Pain Therapy Devices - General Consideration in the Design of Clinical Studies for Pain-Alleviating Devices		05/11/1988	Center for Devices and Radiological Health	Premarket,	Final	No		
CPG Sec. 160.200 FDA Use of Income Tax Information from IRS in Compliance Activity		04/20/1988		Investigation & Enforcement, Food & Color Additives	Final	No		
CPG Sec. 150.100 Requests for Portions of Intermediate or End Products Resulting from FDA Sample Analysis		03/22/1988		Investigation & Enforcement, Food & Color Additives	Final	No		
CPG Sec. 505.200 "Butter" Featured in Product Name		03/08/1988		Investigation & Enforcement,	Final	No		
CPG Sec. 505.300 "Butter-Nut" Bread		03/08/1988		Investigation & Enforcement,	Final	No		
CPG Sec. 505.350 Honey Bread, Honey Buns		03/08/1988		Investigation & Enforcement,	Final	No		
Guide for Establishing and Maintaining a Calibration Constancy Intercomparison System for Microwave Oven Compliance Survey Instruments (FDA 88-8264)] (PDF Only)	PDF (826.14 KB)PDF (826.14 KB) of Guide for Establishing and Maintaining a Calibration Constancy Intercomparison System for Microwave Oven Compliance Survey Instruments (FDA 88-8264)] (PDF Only)	03/01/1988		Radiological Health	Final	No		

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Quality Control Guide for Sunlamp Products (FDA 88-8234)	PDF (4.17 MB)PDF (4.17 MB) of Quality Control Guide for Sunlamp Products (FDA 88-8234)	03/01/1988	Center for Devices and Radiological Health	Tanning Lamps, Booths & Beds	Final	No		
CPG Sec. 578.450 Wheat Flour-Adulteration with Insect Fragments and Rodent Hairs	PDF (10.09 KB)PDF (10.09 KB) of CPG Sec. 578.450 Wheat Flour-Adulteration with Insect Fragments and Rodent Hairs	12/31/1987		Investigation & Enforcement,	Final	No		
CPG Sec. 565.200 Red Meat Adulterated with PCBs		11/10/1987		Investigation & Enforcement,	Final	No		
Class II and IIIA Laser Light Show Projectors and Shows (Laser Notice 40)	PDF (194.21 KB)PDF (194.21 KB) of Class II and IIIA Laser Light Show Projectors and Shows (Laser Notice 40)	10/29/1987	Center for Devices and Radiological Health	Laser Notice, Laser Notice	Final	No		
CPG Sec. 160.600 Payment of Expert Witnesses		10/15/1987		Investigation & Enforcement, Food & Color Additives	Final	No		
CPG Sec. 460.600 Content Uniformity Testing of Tablets and Capsules		10/01/1987		Investigation & Enforcement,	Final	No		
CPG Sec. 567.200 Pork and Beans and Similar Bean Products - Labeling		10/01/1987		Investigation & Enforcement,	Final	No		
CPG Sec. 310.200 Sphygmomanometers - Rx Legend		09/26/1987		Investigation & Enforcement, Labeling	Final	No		
CPG Sec. 325.100 Karaya Gum Powder and Related Devices for Use by Ostomates		09/24/1987		Investigation & Enforcement, Safety - Issues, Errors, and Problems	Final	No		
CPG Sec. 345.200 Diaphragms - Rx Devices		09/24/1987		Investigation & Enforcement, Labeling	Final	No		
CPG Sec. 300.100 Inspection of Manufacturers of Device Components		09/23/1987		Investigation & Enforcement,	Final	No		
CPG Sec. 300.600 Commercial Distribution with Regard to Premarket Notification (Section 510(k))		09/23/1987		Investigation & Enforcement,	Final	No		
CPG Sec. 320.100 Ear Piercing Devices		09/23/1987		Investigation & Enforcement,	Final	No		
CPG Sec. 410.100 *Finished Dosage Form Drug Products in Bulk Containers - Applications of Current Good Manufacturing Practice Regulations*		09/04/1987		Investigation & Enforcement,	Final	No		
CPG Sec. 425.400 Computerized Drug Processing; Input/Output Checking		09/03/1987		Investigation & Enforcement,	Final	No		
CPG Sec. 425.500 Computerized Drug Processing; Identification of "Persons" on Batch Production and Control Records		09/03/1987		Investigation & Enforcement,	Final	No		
CPG Sec. 100.100 Responsibility for Reporting Possible or Potential Violations of Laws Administered by FDA, Regulations Issued by FDA, Other Possible or Potential Hazards to the Public Health		09/01/1987		Investigation & Enforcement, Administrative / Procedural, Food & Color Additives	Final	No		
CPG Sec. 100.300 *Non-FDA Regulated Products Involving Communicable Disease Hazards*		09/01/1987		Investigation & Enforcement, Food & Color Additives, Safety - Issues, Errors, and Problems	Final	No		
CPG Sec. 567.100 Antipasto, Common or Usual Name		09/01/1987		Investigation & Enforcement,	Final	No		
CPG Sec. 567.300 *Bouillon, Bouillon Cubes, Granulated Bouillon*		09/01/1987		Investigation & Enforcement,	Final	No		
CPG Sec. 100.350 FDA Jurisdiction on Indian Reservations		08/31/1987		Investigation & Enforcement, Food & Color Additives	Final	No		
User Instructions - Multi Axis Workstations (Laser Notice 39)	PDF (101.68 KB)PDF (101.68 KB) of User Instructions - Multi Axis Workstations (Laser Notice 39)	06/24/1987	Center for Devices and Radiological Health		Final	No		
Color Additive Petitions - Medical Devices	PDF (90.74 KB)PDF (90.74 KB) of Color Additive Petitions - Medical Devices	06/01/1987	Center for Devices and Radiological Health		Final	No		
CPG Sec. 655.100 Devices for Use in Animals		06/01/1987	Center for Veterinary Medicine, Office of International Programs	Investigation & Enforcement, Animal Devices	Final	No		
CPG Sec. 655.300 Barking Dog Collar		06/01/1987	Center for Veterinary Medicine, Office of International Programs	Investigation & Enforcement, Animal Devices	Final	No		

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CPG Sec. 655.400 The Status of Syringes and Needles for Animal Use		06/01/1987	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Animal Devices	Final	No		
Master Files Part III - Guidance on Scientific and Technical Information	PDF (317.65 KB)PDF (317.65 KB) of Master Files Part III - Guidance on Scientific and Technical Information	06/01/1987	Center for Devices and Radiological Health	Premarket,	Final	No		
CPG Sec. 400.335 Fructose-Containing Drugs		05/22/1987		Investigation & Enforcement, Labeling	Final	No		
CPG Sec. 430.300 Labeling Shipping Containers of Drugs		05/21/1987		Investigation & Enforcement,	Final	No		
CPG Sec. 450.400 Labeling and Distribution of OTC Drugs in Vending Machines		05/21/1987		Investigation & Enforcement,	Final	No		
CPG Sec. 454.100 OTC Ear Drop Preparations		05/21/1987		Investigation & Enforcement,	Final	No		
CPG Sec. 455.100 Inert Glandular Preparations *(OTC)*, Inadequate Full Disclosure and Claims		05/21/1987		Investigation & Enforcement,	Final	No		
CPG Sec. 460.450 Status of Mail-Order Filling of Prescriptions		05/21/1987		Investigation & Enforcement,	Final	No		
CPG Sec. 425.200 Computerized Drug Processing; Vendor Responsibility		04/15/1987		Investigation & Enforcement,	Final	No		
CPG Sec. 425.300 Computerized Drug Processing; Source Code for Process Control Application Programs		04/15/1987		Investigation & Enforcement,	Final	No		
All U.S. Condom Manufacturers, Importers and Repackagers	PDF (93.76 KB)PDF (93.76 KB) of All U.S. Condom Manufacturers, Importers and Repackagers	04/07/1987	Center for Devices and Radiological Health	Postmarket, Premarket,	Final	No		
Format and Content of the Human Pharmacokinetics and Bioavailability Section of an Application	PDF (519.21 KB)PDF (519.21 KB) of Format and Content of the Human Pharmacokinetics and Bioavailability Section of an Application	02/01/1987	Center for Drug Evaluation and Research	Clinical - Pharmacology	Final	No		
Format and Content of the Nonclinical Pharmacology/Toxicology Section of an Application*: Guidance for Industry	PDF (1.27 MB)PDF (1.27 MB) of Format and Content of the Nonclinical Pharmacology/Toxicology Section of an Application*: Guidance for Industry	02/01/1987	Center for Drug Evaluation and Research	Pharm/Tox	Final	No		
Formatting, Assembling and Submitting New Drug and Antibiotic Applications*	PDF (1.7 MB)PDF (1.7 MB) of Formatting, Assembling and Submitting New Drug and Antibiotic Applications*	02/01/1987	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		
GUIDELINE FOR SUBMITTING SUPPORTING DOCUMENTATION IN DRUG APPLICATIONS FOR THE MANUFACTURE OF DRUG PRODUCTS	PDF (739.87 KB)PDF (739.87 KB) of GUIDELINE FOR SUBMITTING SUPPORTING DOCUMENTATION IN DRUG APPLICATIONS FOR THE MANUFACTURE OF DRUG PRODUCTS	02/01/1987	Center for Drug Evaluation and Research		Final	No		FDA-1985-D-0033
Summary for New Drug and Antibiotic Applications--Format and Content of the Summary for New Drug and Antibiotic Applications	PDF (1.25 MB)PDF (1.25 MB) of Summary for New Drug and Antibiotic Applications--Format and Content of the Summary for New Drug and Antibiotic Applications	02/01/1987	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		
Policy on Lamp Compatibility (sunlamps)	PDF (65.83 KB)PDF (65.83 KB) of Policy on Lamp Compatibility (sunlamps)	09/02/1986	Center for Devices and Radiological Health		Final	No		
CPG Sec. 605.100 - Use of Statements Regarding NADA Approval by FDA in Labeling and Advertising of New Animal Drugs		08/31/1986	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Labeling, Animal Drugs	Final	No		
CPG Sec. 680.200 CGMP Regulations for Medicated Feeds - Daily Inventory Requirements		06/30/1986	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Medicated Feed	Final	No		
CPG Sec. 670.100 Refusals of Formula Information During Inspection of Feed Mills Manufacturing Feeds Requiring Approved Medicated Feed Applications		05/31/1986	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Medicated Feed	Final	No		

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CPG Sec. 670.200 Status of Vitamins and Minerals in Type B and C Medicated Feed and in Non-Medicated Feed		05/31/1986	Center for Veterinary Medicine, Office of Regulatory Affairs	Medicated Feed	Final	No		
CPG Sec. 680.400 Medicated Feeds -- Combined Batches		05/31/1986	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Medicated Feed	Final	No		
Guide for the Submission of Initial Reports on Computed Tomography X-Ray Systems		11/30/1985			Final	No		
Walk-In Workstations (Laser Notice 37)	PDF (85.64 KB)PDF (85.64 KB) of Walk-In Workstations (Laser Notice 37)	10/21/1985	Center for Devices and Radiological Health		Final	No		
Policy On Maximum Timer Interval and Exposure Schedule For Sunlamp Products	PDF (182.17 KB)PDF (182.17 KB) of Policy On Maximum Timer Interval and Exposure Schedule For Sunlamp Products	08/21/1985	Center for Devices and Radiological Health	Tanning Lamps, Booths & Beds	Final	No		
Guideline for the Uniform Labeling of Blood and Blood Components	PDF (3.34 MB)PDF (3.34 MB) of Guideline for the Uniform Labeling of Blood and Blood Components	08/01/1985	Center for Biologics Evaluation and Research	Blood Products	Final	No		
CVM GFI #23 Medicated Free Choice Feeds--Manufacturing Control		06/30/1985	Center for Veterinary Medicine	Chemistry, Manufacturing, and Controls (CMC), Current Good Manufacturing Practices (CGMP)	Final	No		
Policy on Warning Label Required on Sunlamp Products	PDF (71.19 KB)PDF (71.19 KB) of Policy on Warning Label Required on Sunlamp Products	06/25/1985	Center for Devices and Radiological Health		Final	No		
Letter on the response to 12/20/1984 letter from the Pharmaceutical Manufacturers Association about the Drug Price Competition and Patent Term Restoration Act	PDF (392.06 KB)PDF (392.06 KB) of Letter on the response to 12/20/1984 letter from the Pharmaceutical Manufacturers Association about the Drug Price Competition and Patent Term Restoration Act	03/01/1985	Center for Drug Evaluation and Research	Generic Drugs	Final	No		
User Instruction Hazard Warnings (Laser Notice 35)	PDF (62.8 KB)PDF (62.8 KB) of User Instruction Hazard Warnings (Laser Notice 35)	02/05/1985	Center for Devices and Radiological Health	Laser Notice	Final	No		
Medical Laser Delivery System Interlocks (Laser Notice 34)	PDF (90.27 KB)PDF (90.27 KB) of Medical Laser Delivery System Interlocks (Laser Notice 34)	01/20/1985	Center for Devices and Radiological Health		Final	No		
CVM GFI #13 Evaluation of Effectiveness of New Animal Drugs for Use in Free-Choice Feeds-Medicated Block		12/31/1984	Center for Veterinary Medicine	Target Animal – Effectiveness, Animal Feed	Final	No		
CVM GFI #38 Guideline for Effectiveness Evaluation of Topical/Otic Animal Drugs		08/20/1984	Center for Veterinary Medicine	Target Animal – Effectiveness	Final	No		
Enforcement Policy on Marketing OTC Combination Products (CPG 7132b.16).	PDF (293.59 KB)PDF (293.59 KB) of Enforcement Policy on Marketing OTC Combination Products (CPG 7132b.16).	05/01/1984	Center for Drug Evaluation and Research	Over-the-Counter Drugs	Final	No		
CVM GFI #37 Evaluation of Effectiveness of New Animal Drugs for Use in Poultry Feed for Pigmentation		02/29/1984	Center for Veterinary Medicine	Target Animal – Effectiveness, Animal Feed	Final	No		
CPG Sec 430.100 Unit Dose Labeling for Solid and Liquid Oral Dosage Forms		01/31/1984		Investigation & Enforcement,	Final	No		
Application of the Device Good Manufacturing Practice (GMP) Regulation to the Manufacture of Sterile Devices	PDF (715.85 KB)PDF (715.85 KB) of Application of the Device Good Manufacturing Practice (GMP) Regulation to the Manufacture of Sterile Devices	12/01/1983	Center for Devices and Radiological Health	Premarket,	Final	No		
CVM GFI #24 Drug Combinations for Use in Animals		09/30/1983	Center for Veterinary Medicine	Target Animal – Effectiveness	Final	No		
CPG Sec. 398.450 Applicability of Positive Beam Limitation (PBL) Requirements When PBL is Provided on "Other than Stationary General Purpose" Radiographic System		07/31/1983		Investigation & Enforcement, Radiology	Final	No		
Reporting of New Model Numbers to Existing Model Families	PDF (258.4 KB)PDF (258.4 KB) of Reporting of New Model Numbers to Existing Model Families	06/14/1983	Center for Devices and Radiological Health		Final	No		

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CPG Sec. 450.550 Control and Accountability of Labeling Associated with Tamper-Resistant Packaging of Over-the-Counter Drug Products		02/28/1983		Investigation & Enforcement,	Final	No		
CPG Sec. 682.200 The Use of Antibiotic Drug Residue By-Products in Animal Feed Feed		09/30/1982	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Animal Feed	Final	No		
CPG Sec. 615.300 Responsibility for Illegal Drug Residues in Meat, Milk and Eggs		06/30/1982	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Human Food Safety, Animal Drugs	Final	No		
Clinical Evaluation of General Anesthetics	PDF (889.63 KB)PDF (889.63 KB) of Clinical Evaluation of General Anesthetics	05/01/1982	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		
CPG Sec. 688.100 Unapproved Additives for Exported Grains		01/31/1982	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Export, Animal Feed	Final	No		
Procedures for Laboratory Testing of Microwave Ovens	PDF (704.99 KB)PDF (704.99 KB) of Procedures for Laboratory Testing of Microwave Ovens	10/01/1981	Center for Devices and Radiological Health		Final	No		
Exemption from Reporting and Record keeping Requirements for Certain Sunlamp Product Manufacturers	PDF (74.01 KB)PDF (74.01 KB) of Exemption from Reporting and Record keeping Requirements for Certain Sunlamp Product Manufacturers	09/16/1981	Center for Devices and Radiological Health		Final	No		
CPG Sec. 430.200 Repacking of Drug Products - Testing/Examination under CGMPs		06/30/1981		Investigation & Enforcement,	Final	No		
Investigational Medical Laser Significant Risk Device (Laser Notice 31)	PDF (116.98 KB)PDF (116.98 KB) of Investigational Medical Laser Significant Risk Device (Laser Notice 31)	05/18/1981	Center for Devices and Radiological Health	Laser Notice	Final	No		
Clinical Evaluation of Antiepileptic Drugs (adults and children)	PDF (1007.13 KB)PDF (1007.13 KB) of Clinical Evaluation of Antiepileptic Drugs (adults and children)	01/01/1981		Clinical - Medical	Final	No		
Laser Diodes Used in Fiber Optics Communication Systems (Laser Notice 27)	PDF (100.85 KB)PDF (100.85 KB) of Laser Diodes Used in Fiber Optics Communication Systems (Laser Notice 27)	10/16/1980	Center for Devices and Radiological Health		Final	No		
CPG 560.450 Imported Low-Acid Canned Foods (Manufacturer Not Registered and/or No Scheduled Process Filed)		10/01/1980		Investigation & Enforcement,	Final	No		
CPG Sec. 400.325 Candy "Pills" Representation as Drug		10/01/1980		Investigation & Enforcement, Laser Notice	Final	No		
CPG Sec. 400.600 Drugs - Declaration of Quantity of Active Ingredient by Both Metric and Apothecary Systems		10/01/1980		Investigation & Enforcement, Labeling	Final	No		
CPG Sec. 400.800 Collection and Charitable Distribution of Drugs		10/01/1980		Investigation & Enforcement,	Final	No		
CPG Sec. 500.100 Additives - Labeling with Adequate Directions for Many Uses		10/01/1980		Investigation & Enforcement,	Final	No		
CPG Sec. 510.200 Brandy Containing Methyl Alcohol - Food Additive		10/01/1980		Investigation & Enforcement,	Final	No		
CPG Sec. 510.300 Unfermented Beverages - Use of Word "Champagne"		10/01/1980		Investigation & Enforcement,	Final	No		
CPG Sec. 515.300 Honey - Source Declaration		10/01/1980		Investigation & Enforcement,	Final	No		
CPG Sec. 515.350 Candy - Mixed with Trinkets and Sold in Vending Machines		10/01/1980		Investigation & Enforcement,	Final	No		
CPG Sec. 515.500 Barley Sugar - Definition, and Barley Sugar Candy		10/01/1980		Investigation & Enforcement,	Final	No		
CPG Sec. 525.750 Spices - Definitions		10/01/1980		Investigation & Enforcement,	Final	No		
CPG Sec. 540.475 Snapper - Labeling		10/01/1980		Investigation & Enforcement,	Final	No		

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CPG Sec. 555.500 All Food Sanitation (Including Bacteriological) Inspections - Classification of Establishment	PDF (10.31 KB)PDF (10.31 KB) of CPG Sec. 555.500 All Food Sanitation (Including Bacteriological) Inspections - Classification of Establishment	10/01/1980		Investigation & Enforcement,	Final	No		
CPG Sec. 560.500 Jams, Jellies and Related Products - Imports		10/01/1980		Investigation & Enforcement,	Final	No		
CPG Sec. 562.450 Identity of Foods - Use of Terms Such as Fresh, Frozen, Dried, Canned, Etc.		10/01/1980		Investigation & Enforcement,	Final	No		
CPG Sec. 578.100 Starches - Common or Usual Names		10/01/1980		Investigation & Enforcement,	Final	No		
CPG Sec. 578.350 Wheat for Human Consumption - Reconditioning		10/01/1980		Investigation & Enforcement,	Final	No		
CPG Sec. 578.400 Treated Grain Seed - Mercury Residue	PDF (8.55 KB)PDF (8.55 KB) of CPG Sec. 578.400 Treated Grain Seed - Mercury Residue	10/01/1980		Investigation & Enforcement,	Final	No		
CPG Sec. 690.400 Water and Gravy in Pet Food		10/01/1980	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Pet Food	Final	No		
CPG 230.120- Human Blood and Blood Products as Drugs		09/30/1980		Investigation & Enforcement, Blood Products	Final	No		
CPG Sec. 110.500 Food and Drug Guaranty - Imports		09/30/1980		Investigation & Enforcement, Food & Color Additives	Final	No		
CPG Sec. 130.100 Inspectional Authority; Refusal to Permit Inspection.		09/30/1980		Investigation & Enforcement, Food & Color Additives	Final	No		
CPG Sec. 251.100 Schedule of Physical Examination for Donors Receiving Immunization Injections (Obsolete, Withdrawn on 11/28/2017)		09/30/1980		Investigation & Enforcement, Blood Products	Final	No		
CPG Sec. 398.400 Automatic Adjustment of the X-ray Field Size to the Selected Spot-Film Size - 21 CFR 1020.31(g)(1)		09/30/1980		Investigation & Enforcement, Radiology	Final	No		
CPG Sec. 420.200 Compendium Revisions and Deletions		09/30/1980		Investigation & Enforcement,	Final	No		
CPG Sec. 420.300 Changes in Compendial Specifications and NDA Supplements withdrawn on 8/30/12		09/30/1980		Investigation & Enforcement,	Final	No		
CPG Sec. 442.100 New Drugs - Export		09/30/1980		Investigation & Enforcement,	Final	No		
CPG Sec. 444.100 Recovery of Investigational New Drugs from Clinical Investigators		09/30/1980		Investigation & Enforcement,	Final	No		
CPG Sec. 460.100 Hospital Pharmacies - Status as Drug Manufacturer		09/30/1980		Investigation & Enforcement,	Final	No		
CPG Sec. 460.300 Return of Unused Prescription Drugs to Pharmacy Stock		09/30/1980		Investigation & Enforcement,	Final	No		
CPG Sec. 460.400 Computerized Prescription Recordkeeping by Pharmacies		09/30/1980		Investigation & Enforcement,	Final	No		
CPG Sec. 460.425 Prescription Status when Telephoned to Recording Machine		09/30/1980		Investigation & Enforcement,	Final	No		
CPG Sec. 460.500 Prescription Drugs for Ship's Medicine Chests		09/30/1980		Investigation & Enforcement,	Final	No		
CPG Sec. 520.200 Canned Foods - Seam Defects		09/30/1980		Investigation & Enforcement,	Final	No		
CPG Sec. 525.650 Labeling of Seasonings		09/30/1980		Investigation & Enforcement,	Final	No		
CPG Sec. 527.450 Milk & Milk Products Containing Penicillin		09/30/1980		Investigation & Enforcement,	Final	No		
CPG Sec. 540.285 Crabmeat Products - Labeling; Crabmeat Products with Added Fish or Other Seafood Ingredients - Labeling		09/30/1980		Investigation & Enforcement,	Final	No		
CPG Sec. 550.550 Maraschino Cherries		09/30/1980		Investigation & Enforcement,	Final	No		
CPG Sec. 550.575 Marmalade		09/30/1980		Investigation & Enforcement,	Final	No		
CPG Sec. 550.625 Oranges - Artificial Coloring		09/30/1980		Investigation & Enforcement,	Final	No		
CPG Sec. 555.200 Adulterated Food Mixed with Good Food		09/30/1980		Investigation & Enforcement,	Final	No		

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CPG Sec. 625.200 Availability of Bulk Chemicals for Animal Drug Use		09/30/1980	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Animal Drugs	Final	No		
CPG Sec. 655.200 Adequate Directions for Use - Animal Drugs & Veterinary Devices		09/30/1980	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Labeling, Animal Devices, Animal Drugs	Final	No		
CPG Sec. 660.100 Failure to Register		09/30/1980	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement,	Final	No		
CPG Sec. 682.100 Use of Drug-Contaminated Products in Animal Feed		09/30/1980	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Animal Feed	Final	No		
CPG Sec. 690.200 Pet Food Labeling		09/30/1980	Center for Veterinary Medicine, Office of Regulatory Affairs	Investigation & Enforcement, Labeling, Pet Food	Final	No		
Alternate Wording For Caution Statement (Laser Notice 30)	PDF (70.66 KB)PDF (70.66 KB) of Alternate Wording For Caution Statement (Laser Notice 30)	08/25/1980	Center for Devices and Radiological Health	Radiology	Final	No		
Guidelines for Immunization of Source Plasma (Human) Donors with Blood Substances	PDF (243.45 KB)PDF (243.45 KB) of Guidelines for Immunization of Source Plasma (Human) Donors with Blood Substances	06/01/1980	Center for Biologics Evaluation and Research	Blood Products	Final	No		
Quality Control Practices for Compliance with the Federal Mercury Vapor Lamp Performance Standard	PDF (1.81 MB)PDF (1.81 MB) of Quality Control Practices for Compliance with the Federal Mercury Vapor Lamp Performance Standard	05/01/1980	Center for Devices and Radiological Health		Final	No		
Open Door Operation of Microwave Ovens as a Result of Oven Miswiring	PDF (178.41 KB)PDF (178.41 KB) of Open Door Operation of Microwave Ovens as a Result of Oven Miswiring	03/28/1980	Center for Devices and Radiological Health	Radiological Health	Final	No		
Exemption of Certain Lasers Used By DOE, NOAA and U.S. Dept. of Commerce (Laser Notice 25)	PDF (116.62 KB)PDF (116.62 KB) of Exemption of Certain Lasers Used By DOE, NOAA and U.S. Dept. of Commerce (Laser Notice 25)	09/14/1979	Center for Devices and Radiological Health	Radiological Health	Final	No		
General Guidelines for OTC Combination Products	PDF (270.2 KB)PDF (270.2 KB) of General Guidelines for OTC Combination Products	11/01/1978	Center for Drug Evaluation and Research	Over-the-Counter Drugs	Final	No		
Upgrading Category III Antiperspirants to Category I (43 FR 46728-46731)	PDF (582.91 KB)PDF (582.91 KB) of Upgrading Category III Antiperspirants to Category I (43 FR 46728-46731)	10/01/1978	Center for Drug Evaluation and Research	Over-the-Counter Drugs	Final	No		
Guidance ('Guidelines') for Evaluation of Hysteroscopic Sterilization Devices		05/09/1978	Center for Devices and Radiological Health	Premarket,	Final	No		
Guidance ('Guidelines') for Evaluation of Laparoscopic Bipolar and Thermal Coagulators (and Accessories)	PDF (229.75 KB)PDF (229.75 KB) of Guidance ('Guidelines') for Evaluation of Laparoscopic Bipolar and Thermal Coagulators (and Accessories)	05/01/1978	Center for Devices and Radiological Health	Premarket,	Final	No		
Laser Light Shows Subject to Laser Product Performance Standard (Laser Notice 22)	PDF (154.43 KB)PDF (154.43 KB) of Laser Light Shows Subject to Laser Product Performance Standard (Laser Notice 22)	11/23/1977	Center for Devices and Radiological Health		Final	No		
Emission Delay - Remote Interlock Connector (Laser Notice 21)	PDF (93.58 KB)PDF (93.58 KB) of Emission Delay - Remote Interlock Connector (Laser Notice 21)	11/11/1977	Center for Devices and Radiological Health	Radiological Health	Final	No		
Antianxiety Drugs--Clinical Evaluation	PDF (2.04 MB)PDF (2.04 MB) of Antianxiety Drugs--Clinical Evaluation	09/01/1977	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		
Antidepressant Drugs--Clinical Evaluation	PDF (1.95 MB)PDF (1.95 MB) of Antidepressant Drugs--Clinical Evaluation	09/01/1977	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		

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Clinical Evaluation of Anti-Infective Drugs (Systemic)	PDF (1.13 MB)PDF (1.13 MB) of Clinical Evaluation of Anti-Infective Drugs (Systemic)	09/01/1977	Center for Drug Evaluation and Research	Clinical - Antimicrobial	Final	No		
General Considerations for the Clinical Evaluation of Drugs in Infants and Children	PDF (2.2 MB)PDF (2.2 MB) of General Considerations for the Clinical Evaluation of Drugs in Infants and Children	09/01/1977	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		
Hypnotic Drugs--Clinical Evaluation		09/01/1977	Center for Drug Evaluation and Research	Clinical - Medical	Final	No		
Procedures for Field Testing Microwave Ovens	PDF (2.73 MB)PDF (2.73 MB) of Procedures for Field Testing Microwave Ovens	08/01/1977	Center for Devices and Radiological Health		Final	No		
Optional Interlocks - Labeling (Laser Notice 17)	PDF (95.6 KB)PDF (95.6 KB) of Optional Interlocks - Labeling (Laser Notice 17)	03/02/1977	Center for Devices and Radiological Health		Final	No		
Warning Labels For Dye And Multiple Wavelength Lasers (Laser Notice 16)	PDF (83.75 KB)PDF (83.75 KB) of Warning Labels For Dye And Multiple Wavelength Lasers (Laser Notice 16)	03/02/1977	Center for Devices and Radiological Health	Radiological Health	Final	No		
Review Guidelines for Oxygen Generators and Oxygen Equipment for Emergency Use		01/01/1977	Center for Devices and Radiological Health	Premarket,	Final	No		
Lasers Manufactured and Used In-House (Laser Notice 14)	PDF (54.95 KB)PDF (54.95 KB) of Lasers Manufactured and Used In-House (Laser Notice 14)	11/23/1976	Center for Devices and Radiological Health	Laser Notice	Final	No		
Manufacture and Certification of Laser Kits (Laser Notice 13)	PDF (85.79 KB)PDF (85.79 KB) of Manufacture and Certification of Laser Kits (Laser Notice 13)	10/14/1976	Center for Devices and Radiological Health		Final	No		
Remote Interlock Connectors (Laser Notice 11)	PDF (62.34 KB)PDF (62.34 KB) of Remote Interlock Connectors (Laser Notice 11)	10/07/1976	Center for Devices and Radiological Health		Final	No		
Interlock Design (Laser Notice 12)	PDF (263.77 KB)PDF (263.77 KB) of Interlock Design (Laser Notice 12)	09/09/1976	Center for Devices and Radiological Health		Final	No		
Emission Indicator - Visibility (Laser Notice 10)	PDF (80.74 KB)PDF (80.74 KB) of Emission Indicator - Visibility (Laser Notice 10)	08/31/1976	Center for Devices and Radiological Health	Radiological Health	Final	No		
Certain Military Lasers Exempt From 21 CFR 1040.10 & .11 (Laser Notice 9)	PDF (89.53 KB)PDF (89.53 KB) of Certain Military Lasers Exempt From 21 CFR 1040.10 & .11 (Laser Notice 9)	08/23/1976	Center for Devices and Radiological Health	Radiological Health	Final	No		
Viewing Optics - Sighting Telescope (Laser Notice 8)	PDF (70.59 KB)PDF (70.59 KB) of Viewing Optics - Sighting Telescope (Laser Notice 8)	08/05/1976	Center for Devices and Radiological Health		Final	No		
Components and Repair (Laser Notice 7)	PDF (86.1 KB)PDF (86.1 KB) of Components and Repair (Laser Notice 7)	06/23/1976	Center for Devices and Radiological Health	Radiological Health	Final	No		
Emission Indicators - Brightness (Laser Notice 6)	PDF (54.65 KB)PDF (54.65 KB) of Emission Indicators - Brightness (Laser Notice 6)	06/22/1976	Center for Devices and Radiological Health	Radiological Health	Final	No		
Quality Control Practices for Compliance with the Federal Laser Performance Standard	PDF (1.07 MB)PDF (1.07 MB) of Quality Control Practices for Compliance with the Federal Laser Performance Standard	03/01/1976	Center for Devices and Radiological Health		Final	No		
Tabulated Values of Accessible Emission Limits for Laser Products	PDF (1.72 MB)PDF (1.72 MB) of Tabulated Values of Accessible Emission Limits for Laser Products	03/01/1976	Center for Devices and Radiological Health		Final	No		
Emission Indicators on Energy Source (Laser Notice 3)	PDF (60.96 KB)PDF (60.96 KB) of Emission Indicators on Energy Source (Laser Notice 3)	11/21/1975	Center for Devices and Radiological Health	Radiology	Final	No		
Laser Energy Source (Laser Notice 2)	PDF (39.92 KB)PDF (39.92 KB) of Laser Energy Source (Laser Notice 2)	11/21/1975	Center for Devices and Radiological Health		Final	No		

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Protective Eyewear - Visibility of Emission Indicator (Laser Notice 4)	PDF (71.85 KB)PDF (71.85 KB) of Protective Eyewear - Visibility of Emission Indicator (Laser Notice 4)	11/21/1975	Center for Devices and Radiological Health		Final	No		
Guidance for the Submission of Cabinet X-Ray System Reports Pursuant to 21-CFR 1020.40	PDF (651.51 KB)PDF (651.51 KB) of Guidance for the Submission of Cabinet X-Ray System Reports Pursuant to 21-CFR 1020.40	02/01/1975	Center for Devices and Radiological Health	Radiological Health	Final	No		
Guide for Submission of Information on Industrial X-Ray Equipment Required Pursuant to 21-CFR 1002.10	PDF (316.63 KB)PDF (316.63 KB) of Guide for Submission of Information on Industrial X-Ray Equipment Required Pursuant to 21-CFR 1002.10	03/01/1973	Center for Devices and Radiological Health	Medical Food/Beverage	Final	No		
5-13 SUBSTANTIALLY EQUIVALENT MEDICAL DEVICES	PDF (80.86 KB)PDF (80.86 KB) of 5-13 SUBSTANTIALLY EQUIVALENT MEDICAL DEVICES			Compliance, Inspection,	Final	No		
590.600 WigsCompliance Policy Guide 7128.05				Investigation & Enforcement,	Final	No		
Chapter 1 - General				Investigation & Enforcement,	Final	No		
Chapter 2 - Biologics				Investigation & Enforcement,	Final	No		
Chapter 3 - Devices				Investigation & Enforcement,	Final	No		
Chapter 4 - Human Drugs				Investigation & Enforcement,	Final	No		
CHAPTER 48 - 7348.809 Bioresearch Monitoring	PDF (474.42 KB)PDF (474.42 KB) of CHAPTER 48 - 7348.809 Bioresearch Monitoring				Final	No		
Chapter 48 7348.809A Radioactive Drug Research Committee	PDF (537.33 KB)PDF (537.33 KB) of Chapter 48 7348.809A Radioactive Drug Research Committee				Final	No		
Chapter 53 - 7353.001c Risk Evaluation and Mitigation Strategies	PDF (471.94 KB)PDF (471.94 KB) of Chapter 53 - 7353.001c Risk Evaluation and Mitigation Strategies				Final	No		
Compliance Policy Guide 7124.01				Investigation & Enforcement,	Final	No		
Compliance Policy Guide 7124.27				Investigation & Enforcement,	Final	No		
Compliance Policy Guide 7133.21				Investigation & Enforcement,	Final	No		
Compliance Policy Guide Sec. 100.101	PDF (221.83 KB)PDF (221.83 KB) of Compliance Policy Guide Sec. 100.101			Investigation & Enforcement,	Final	No		
Compliance Policy Guide Sec. 150.200 Compliance Review of Private Laboratory Analytical Packages (PLAPs)	PDF (34.49 KB)PDF (34.49 KB) of Compliance Policy Guide Sec. 150.200 Compliance Review of Private Laboratory Analytical Packages (PLAPs)			Investigation & Enforcement,	Final	No		
Compliance Policy Guide Sec. 335.700 Surgeons' Gloves and Patient Examination Gloves; Defects - Criteria for Direct Reference Seizure	PDF (17.19 KB)PDF (17.19 KB) of Compliance Policy Guide Sec. 335.700 Surgeons' Gloves and Patient Examination Gloves; Defects - Criteria for Direct Reference Seizure			Investigation & Enforcement,	Final	No		
Compliance Policy Guide Sec. 390.100 Definition of “Commerce” -21 CFR 1000.3(d) 2	PDF (16.41 KB)PDF (16.41 KB) of Compliance Policy Guide Sec. 390.100 Definition of “Commerce” -21 CFR 1000.3(d) 2			Investigation & Enforcement,	Final	No		
Compliance Policy Guide Sec. 390.200 Determination by Secretary that Product Fails to Comply or has Defect -21 CFR 1003.11	PDF (44.63 KB)PDF (44.63 KB) of Compliance Policy Guide Sec. 390.200 Determination by Secretary that Product Fails to Comply or has Defect -21 CFR 1003.11			Investigation & Enforcement,	Final	No		
Compliance Policy Guide Sec. 550.050 Canned Ackee, Frozen Ackee, and Other Ackee Products- Hypoglycin A Toxin	PDF (17.18 KB)PDF (17.18 KB) of Compliance Policy Guide Sec. 550.050 Canned Ackee, Frozen Ackee, and Other Ackee Products- Hypoglycin A Toxin			Investigation & Enforcement,	Final	No		

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
Compliance Policy Guide Sec. 575.100 Pesticide Residues in Food and Feed - Enforcement Criteria (Compliance Policy Guide 7141.01)				Investigation & Enforcement,	Final	No		
Compliance Policy Guides Index	PDF (396.94 KB)PDF (396.94 KB) of Compliance Policy Guides Index			Investigation & Enforcement,	Final	No		
CPG Sec 100 250 Food Facility Registration - Human and Animal Food	PDF (47.42 KB)PDF (47.42 KB) of CPG Sec 100 250 Food Facility Registration - Human and Animal Food			Investigation & Enforcement,	Final	No		
CPG Sec. 110.300 Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002				Investigation & Enforcement,	Final	No		
CPG Sec. 110.310 Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Issued 12/11/2003, revised 06/24/2004; 08/16/2004; 11/02/2004; 11/10/2005)				Investigation & Enforcement,	Final	No		
CPG Sec. 160.800, Year 2000 (Y2K) Computer Compliance				Investigation & Enforcement,	Final	No		
CPG Sec. 257.100 Deferral of Source Plasma Donors Due To Red Cell Loss During Collection of Source Plasma by Automated Plasmapheresis (Obsolete, Withdrawn on 11/28/2017)				Investigation & Enforcement,	Final	No		
CPG Sec. 300.500 *Reprocessing of Single Use* Devices	PDF (86.4 KB)PDF (86.4 KB) of CPG Sec. 300.500 *Reprocessing of Single Use* Devices			Investigation & Enforcement,	Final	No		
CPG Sec. 305.100 - Acupuncture Devices and Accessories - Revoked-Deletion 01/24/2000				Investigation & Enforcement,	Final	No		
CPG Sec. 310.210 Blood Pressure Measurement Devices (Sphygmomanometers) - Accuracy	PDF (63.87 KB)PDF (63.87 KB) of CPG Sec. 310.210 Blood Pressure Measurement Devices (Sphygmomanometers) - Accuracy			Investigation & Enforcement,	Final	No		
CPG Sec. 335.300 Hypnotherapy Devices - Self Hypnotic Tape Recordings				Investigation & Enforcement,	Final	No		
CPG Sec. 335.300 Hypnotherapy Devices - Self-Hypnotic Tape Recordings	PDF (89.52 KB)PDF (89.52 KB) of CPG Sec. 335.300 Hypnotherapy Devices - Self-Hypnotic Tape Recordings			Investigation & Enforcement,	Final	No		
CPG Sec. 335.700 Surgeons' Gloves and Patient Examination Gloves; Defects - Criteria for Direct Reference Seizure	PDF (17.19 KB)PDF (17.19 KB) of CPG Sec. 335.700 Surgeons' Gloves and Patient Examination Gloves; Defects - Criteria for Direct Reference Seizure			Investigation & Enforcement,	Final	No		
CPG Sec. 335.700A Surgeon's Gloves and Patient Examination Gloves; Defects - Criteria for Direct Reference Seizure				Investigation & Enforcement,	Final	No		
CPG Sec. 390.100 Definition of "Commerce" - 21 CFR 1000.3(d)				Investigation & Enforcement,	Final	No		
CPG Sec. 390.200 Determination by Secretary that Product Fails to Comply or has Defect - 21 CFR 1003.11				Investigation & Enforcement,	Final	No		
CPG Sec. 400.900 Class I Recalls of Prescription Drugs				Investigation & Enforcement,	Final	No		
CPG Sec. 420.400 Performance of Tests for Compendial Requirements on Compendial Products				Investigation & Enforcement,	Final	No		
CPG Sec. 420.500 *Interference with Compendial Tests* (revised 11/14/2012)	PDF (90.51 KB)PDF (90.51 KB) of CPG Sec. 420.500 *Interference with Compendial Tests* (revised 11/14/2012)			Investigation & Enforcement,	Final	No		
CPG Sec. 420.500 Interference with Compendial Tests				Investigation & Enforcement,	Final	No		
CPG Sec. 425.100 Computerized Drug Processing; CGMP Applicability to Hardware and Software*				Investigation & Enforcement,	Final	No		

Summary	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
CPG Sec. 460.700 Controlled Release Dosage Form Drugs - Rate of Release of Active Ingredients				Investigation & Enforcement,	Final	No		
CPG Sec. 490.200 Parametric Release of Parenteral Drug Products Terminally Sterilized by Moist Heat				Investigation & Enforcement,	Final	No		
CPG Sec. 510.800 Beverages-Serving Size Labeling				Investigation & Enforcement,	Final	No		
CPG Sec. 540.750 - Common or Usual Names for Seafood in Interstate Commerce				Investigation & Enforcement,	Final	No		
CPG Sec. 550.050 Canned Ackee, Frozen Ackee, and Other Ackee Products – Hypoglycin A Toxin	PDF (22.47 KB)PDF (22.47 KB) of CPG Sec. 550.050 Canned Ackee, Frozen Ackee, and Other Ackee Products – Hypoglycin A Toxin			Investigation & Enforcement,	Final	No		
CPG Sec. 555.250 Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens (New 4/2001)	PDF (24.45 KB)PDF (24.45 KB) of CPG Sec. 555.250 Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens (New 4/2001)			Investigation & Enforcement,	Final	No		
CPG Sec. 555.320 Listeria monocytogenes				Investigation & Enforcement,	Final	No		
CPG Sec. 555.425 Foods, Adulteration Involving hard or Sharp Foreign Objects	PDF (15.56 KB)PDF (15.56 KB) of CPG Sec. 555.425 Foods, Adulteration Involving hard or Sharp Foreign Objects			Investigation & Enforcement,	Final	No		
CPG Sec. 555.700 Revocation of Tolerances for Cancelled Pesticides (Withdrawn 1/8/2008)				Investigation & Enforcement,	Final	No		
CPG Sec. 562.300 Foods - Net Weight				Investigation & Enforcement,	Final	No		
CPG Sec. 575.100 Pesticide Residues in Food and Feed - Enforcement Criteria	PDF (68.52 KB)PDF (68.52 KB) of CPG Sec. 575.100 Pesticide Residues in Food and Feed - Enforcement Criteria			Investigation & Enforcement,	Final	No		
cpg1ap3 - Sample WHO Certificate for Quality of a Pharmaceutical Product	PDF (104.47 KB)PDF (104.47 KB) of cpg1ap3 - Sample WHO Certificate for Quality of a Pharmaceutical Product			Investigation & Enforcement,	Final	No		
Dairy Products Sec. 527.300 Microbial Contaminants & Alkaline Phosphatase Activity	PDF (99.92 KB)PDF (99.92 KB) of Dairy Products Sec. 527.300 Microbial Contaminants & Alkaline Phosphatase Activity			Investigation & Enforcement,	Final	No		
Draft Compliance Policy Guide Sec. 527.300 Dairy Products	PDF (103.82 KB)PDF (103.82 KB) of Draft Compliance Policy Guide Sec. 527.300 Dairy Products			Investigation & Enforcement,	Final	No		
Draft Compliance Policy Guide Sec. 540.275 Crabmeat - Fresh and Frozen - Adulteration with Filth, Involving the Presence of Escherichia coli	PDF (53.66 KB)PDF (53.66 KB) of Draft Compliance Policy Guide Sec. 540.275 Crabmeat - Fresh and Frozen - Adulteration with Filth, Involving the Presence of Escherichia coli			Investigation & Enforcement,	Final	No		
Draft CPG Sec. 110.310 Prior Notice of Imported Food	PDF (94.78 KB)PDF (94.78 KB) of Draft CPG Sec. 110.310 Prior Notice of Imported Food			Investigation & Enforcement,	Final	No		
Draft of Revised Compliance Policy Guide Sec. 575.100 Pesticide Chemical Residues in Food - Enforcement Criteria	PDF (807.66 KB)PDF (807.66 KB) of Draft of Revised Compliance Policy Guide Sec. 575.100 Pesticide Chemical Residues in Food - Enforcement Criteria			Investigation & Enforcement,	Final	No		
Draft Seafood List CPG 540.750 Reg.Action Guidance	PDF (58.23 KB)PDF (58.23 KB) of Draft Seafood List CPG 540.750 Reg.Action Guidance			Investigation & Enforcement,	Final	No		
eCTD v4.0 Implementation Package DRAFT Specification for Submission Formats v2.0	PDF (144.02 KB)PDF (144.02 KB) of eCTD v4.0 Implementation Package DRAFT Specification for Submission Formats v2.0			ICH-Multidisciplinary	Draft	No		
Final In Vivo Bioavailability-Bioequivalence Studies-Analytical	PDF (664.54 KB)PDF (664.54 KB) of Final In Vivo Bioavailability-Bioequivalence Studies- Analytical				Final	No		

	Document (Click to download)	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment	Comment Closing Date on Draft	Docket Number
					Final	No		
					Final	No		
					Final	No		
				Investigation & Enforcement,	Final	No		
	PDF (127.24 KB)PDF (127.24 KB) of Guidance for Industry: Questions and Answers on FDA's Fortification Policy PDF				Final	No		
	PDF (131.42 KB)PDF (131.42 KB) of Guidance for Industry: Sanitary Transportation of Human and Animal Food: What You Need to Know About the FDA Regulation - Small Entity Compliance Guide PDF		Center for Food Safety and Applied Nutrition		Final	No		FDA-2013-N-0013
				Investigation & Enforcement,	Final	No		
	PDF (17.8 KB)PDF (17.8 KB) of Labeling of Processed and Blended Seafood Products Made Primarily with Fish Protein			Investigation & Enforcement,	Final	No		
	PDF (130.65 KB)PDF (130.65 KB) of Nano Cosmetics Guidance to OMB PDF				Final	No		
	PDF (41.92 KB)PDF (41.92 KB) of NEPA_Final_Guidance				Final	No		
	PDF (46.79 KB)PDF (46.79 KB) of New/Revised/Withdrawn Guidances 2014				Final	No		
	PDF (115.95 KB)PDF (115.95 KB) of Nutrients and Dietary Ingredients on Nutrition Labels (PDF)			Nutrition Label	Final	No		FDA-2015-D-1839
					Final	No		
	PDF (104.47 KB)PDF (104.47 KB) of Sample WHO Certificate for Quality of a Pharmaceutical Product			Investigation & Enforcement,	Final	No		

Other protocols

Adeno-associated Virus (AAV) Production Protocols: https://www.genemedi.net/pdf/AAV production protocol-packaging concentration and purification-GeneMedi.pdf

Adenovirus Production Protocols: https://www.genemedi.net/pdf/Adenovirus production protocol-packaging concentration and purification-GeneMedi.pdf

Lentivirus Production Protocols: https://www.genemedi.net/pdf/lentivirus production protocol-packaging concentration and purification-GeneMedi.pdf

CRISPR/Cas9 AAV Production-User Manual: https://www.genemedi.net/pdf/Genemedi-AAV-SaCas9%20User%20Manual.pdf

Recombinant Adenovirus-CRISPR/Cas9 Knockout System-User Manual: https://www.genemedi.net/pdf/Genemedi-Adenovirus-crispr%20User%20Manual.pdf

Recombinant Lentivirus-CRISPR/Cas9 Knockout System-User Manual: https://www.genemedi.net/pdf/Genemedi-Lentivirus-crispr%20User%20Manual.pdf

Protocol of AAV, Adenovirus, lentivirus and transfection: https://www.genemedi.net/i/technical-resources

Contact Information

Genemedi Biotech. Inc.

For more information about AAV, please visit: www.genemedi.net/i/aav-packaging?n-1

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www.genemedi.net For additional information or technical assistance, please call or email us

Worldwide：+86-21-50478399

Fax：+86-21-50478399

E-mail: support@genemedi.net

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