Dated: July 30, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–N–0056] (formerly Docket No. 2004N–0234)

Annual Guidance Agenda

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing its annual guidance document agenda. This list is being published under FDA's good guidance practices (GGPs) regulations. It is intended to seek public comment on possible topics for future guidance document development or revisions of existing ones.

DATES: Submit comments on this list and on any agency guidance documents at any time.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2004–N–0056, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and docket number for this notice. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: *For general information regarding FDA's GGP policy contact*: Lisa Helmanis, Office of Policy (HF–26), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3480.

For information regarding specific topics or guidances: Please see contact persons listed in the table in the **SUPPLEMENTARY INFORMATION** section.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 19, 2000 (65 FR 56468), FDA issued its final rule on GGPs (21 CFR 10.115). GGPs are intended to ensure involvement of the public in the development of guidance documents and to enhance understanding of the availability, nature, and legal effect of such guidance documents.

As part of FDA's effort to ensure meaningful interaction with the public regarding guidance documents, the agency committed to publishing an annual guidance document agenda of possible guidance topics or documents for development or revision during the coming year. The agency also committed to soliciting public input regarding these and additional ideas for new topics or revisions to existing guidance documents (65 FR 56468 at 56477; 21 CFR 10.115(f)(5)).

The agency is neither bound by this list of possible topics nor required to issue every guidance document on this list or precluded from issuing guidance documents not on the list set forth in this document.

The following list of guidance topics or documents represents possible new topics or revisions to existing guidance documents that the agency is considering. The agency solicits comments on the topics listed in this document and also seeks additional ideas from the public.

The guidance documents are organized by the issuing Center or Office within FDA, and are further grouped by topic categories. The agency's contact persons for each specific area are listed in the tables that follow.

II. Center for Biologics Evaluation and Research (CBER)

Title/Topic of Guidance	Contact
CATEGORY—BLOOD AND BLOOD COMPONENTS	Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210
Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion	Same as above (Do)
Assessment of Donors of Blood and Blood Components for Transfusion Transmitted Malaria Risk	Do
Use of Serological of Tests on Samples from Donors of Whole Blood and Blood Components for Transfusion and Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) to Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection	Do
CATEGORY—VACCINES AND ALLERGENICS	
Considerations for the Development of Vaccines to Protect Against Global Infectious Diseases	Do

Title/Topic of Guidance	Contact
Considerations for the Development of Products that Contain Whole, Live Microorganisms with an Intended Therapeutic or Preventive Effect in Humans	Do
CATEGORY—CELLULAR, TISSUE, AND GENE THERAPY	
Potency Tests for Cell and Gene Therapy Products	Do
Characterization and Qualification of Cell Banks Used in the Production of Cellular and Gene Therapy Products	Do
Current Good Tissue Practice for Human Cell, Tissue, and Cellular and Tissue-Based Product Establishments	Do
Preparation of INDs for Certain Unlicensed Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Products (HPC-C)	Do
Clinical Study Design for Early Phase Studies of Cellular and Gene Therapies	Do
Clinical Study Design Considerations for Cancer Vaccine Development	Do
Somatic Cell Therapy for Cardiac Disease	Do
Determination of Homologous Use Designation	Do
Devices Involved in Manufacture, Storage and Administration of Cellular Products and Tissues	Do
Preparation of Investigational Device Exemptions and Investigational New Drugs for Tissue Engineered and Regenerative Medicine Products	Do

III. Center for Drug Evaluation and Research (CDER)

Title/Topic of Guidance	Contact
CATEGORY—ADVERTISING	
Amendment of the Brief Summary	Emily T. Thakur, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–3601
Presentation of Risk Information in Prescription Drug and Medical Device Promotion	Do
CATEGORY—CHEMISTRY	
Assay Development for Immunogenicity Testing	Do
CMC Post-Approval Changes Reportable in an Annual Report	Do
Immunogenicity Assessment for Therapeutic Protein Products	Do
Incorporation of Physical-chemical Indentifiers (PCID) into Solid Oral Dosage Form Drug Products for Anticounterfeiting	Do
Standards Recognition	Do
Submission of Documentation in Applications for Parametric Release of Human and Veterinary Drug Products Terminally Sterilized by Moist Heat Processes	Do
CATEGORY—CLINICAL/MEDICAL	
Adaptive Trial Designs	Do
Diabetes Mellitus: Developing Drugs and Therapeutic Biologics for Treatment and Prevention	Do
Oncology Endpoints: Non-Small Cell Lunch Cancer	Do
Pain Management: Developing Drug and Biological Products	Do
Risk Management of Highly Suspect or Known Human Teratogens: Pregnancy Prevention Strategies	Do

Title/Topic of Guidance	Contact
CATEGORY—CLINICAL/PHARMACOLOGY	
End of Phase 2a Meeting	Do
CATEGORY—CLINICAL/STATISTICAL	
Non-Inferiority Trials	Do
CATEGORY—COMBINATION PRODUCTS	
Drug Diagnostic Co-Development	Do
CATEGORY—COMPLIANCE	
Active Pharmaceutical Ingredient (API)	Do
Medical Gas	Do
Non-Penicillin Beta-Lactam Contamination	Do
Pharmacy Compounding of Human Drugs: Compliance Policy Guide, Section 460.200	Do
Penicillins and Their Definition	Do
PET CGMPs	Do
Pre-Launch Activities Importation Request (PLAIR)	Do
Process Validation: General Principles and Practices	Do
CATEGORY—DRUG SAFETY INFORMATION	
Contents of a Complete Submission Package for a Proposed Proprietary Drug or Biologic Name	Do
Dear Healthcare Professional Letters	Do
Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During Pandemic Influenza	Do
CATEGORY—ELECTRONIC SUBMISSIONS	
Providing Regulatory Submissions in Electronic Format—Analysis Datasets and Documentation	Do
CATEGORY—GENERICS	
Submission of Summary Bioequivalence Data for ANDAs	Do
CATEGORY—IND	
Consumer Product Safety Commission—Tamper Resistant Packaging for INDs	Do
Determining Whether Human Research Studies Can Be Conducted Without an IND	Do
CATEGORY—LABELING	
Content and Format of the Clinical Pharmacology Section	Do
Drug Names and Dosage Forms	Do
Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims	Do
Labeling Dietary Supplements for Women Who are or Could be Pregnant	Do
Labeling Guidance for Inclusion and Placement of Safe Handling Statements in Package Inserts for Human Pharmaceuticals	Do
CATEGORY—OTC	
Label Comprehension Studies for OTC Drug Products	Do
Labeling of OTC Skin Protectant Drug Products	Do
CATEGORY—PHARMACOLOGY/TOXICOLOGY	
Biotechnology-Derived Pharmaceuticals: Nonclinical Safety Evaluation	Do

Title/Topic of Guidance	Contact
Genotoxic and Carcinogenic Impurities in Drug Substances and Products: Recommended Approaches	Do
Nonclinical Safety Evaluation of Reformulated Drug Products and Products Intended for Administration by an Alternate Route	Do
CATEGORY—PROCEDURAL	
Assessment of Abuse Potential of Drugs	Do
Determining Whether Human Research With a Radioactive Drug Can Be Conducted Under a Radioactive Drug Research Committee (RDRC)	Do
Formal Meeting Between CDER/CBER Staff and Sponsors	Do
Integrated Summary of Effectiveness	Do

IV. Center for Devices and Radiological Health (CDRH)

Title	Contact Person
Office of Compliance	
Implementation of Medical Device Establishment Registration and Device Listing Requirements Established by the Food and Drug Administration Amendments Act of 2007 (FDAAA)	Tim Ulatowski, Center for Devices and Radiological Health (HFZ–300), 2094 Gaither Rd., Rockville, MD 20850, 240–276–0100
Surveillance and Detention Without Physical Examination of Condoms	Do
Surveillance and Detention Without Physical Examination of Surgeons' and/or Patient Examination Gloves	Do
Medical Devices Containing Materials Derived from Animal Sources (Except for In Vitro Diagnostic Devices)	Do
Manufacturing Site Change Supplements: Content and Inspectional Considerations	Do
Using the Global Harmonization Task Force (GHTF) Clinical Evaluation Guidance (SG5/N2R8:2007) for Medical Devices	Do
Using the Global Harmonization Task Force (GHTF) Quality Management System—Process Validation SG3/N99–10:2004 for Medical Devices	Do
Guidance on the Third Party Inspection Program for Medical Devices (FDAAA)	Do
Guidance on Submitting International Standards Organization (ISO) 13485 Audits to FDA for Medical Devices Under the Food and Drug Administration Amendments Act of 2007 (FDAAA)	Do
30-Day Notices and 135-Day PMA Supplements (FDAAA)	Do
Regulatory Requirements for Foreign and Domestic Dental Laboratories	Do
Using the Global Harmonization Task Force (GHTF) SG1/N041:2005 Essential Principles of Safety & Performance for Medical Devices	Do
Using the Global Harmonization Task Force (GHTF) SG1 PD/N0011 Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles for Medical Devices	Do
Using the Global Harmonization Task Force (GHTF) SG3N17 (Proposed) Quality Management System Medical Devices management of procured products, outsourced processes and their suppliers	Do
Using the Global Harmonization Task Force (GHTF) SG3 (Proposed) Criteria for Characterizing the Significance of Quality Management System Deficiencies for Medical Devices	Do
Using the Global Harmonization Task Force (GHTF) SG1 (Proposed) Multi-site Audits and Audits of Suppliers (Suppl 1. to Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers—Part 2: Regulatory Auditing Strategy)	Do
Office of Communication, Education, and Radiation Programs (OCER)	

Title	Contact Person
Guidance Regarding Hand-Held X-Ray Equipment	Sean Boyd, Center for Devices and Radiological Health (HFZ–240), 1350 Piccard Dr., Rockville, MD 20850, 240–276–3287
Impact Resistant Lenses Q&A	John Stigi, Center for Devices and Radiological Health (HFZ–220), 1350 Piccard Dr., Rockville, MD 20850, 240–276–3150
Office of Science and Engineering Laboratories (OSEL)	
Medical Device Electromagnetic Compatibility Guidance	Joel Myklebust, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Silver Spring, MD 20933, 301–796–2491
Bone Sonometers	Keith Wear, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Silver Spring, MD 20933, 240–796–2538
Risk Management Information in Premarket Submissions	William Midgette, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Silver Spring, MD 20933, 301–796–2583
Application of IEC 60601–1 Third Edition in Premarket Applications	Alford Taylor, Jr. Center for Devices and Radiological Health, 10903 New Hampshire Ave., Silver Spring, MD 20933, 301–796–2583
Premarket Clearance of Diagnostic Ultrasound Imaging Systems	Larry Grossman, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Silver Spring, MD 20933, 301–796–2502
Guidance on the use of the IEC standard(s) for ultrasound therapy systems in lieu of older BRH mandatory standard	Do
Stereotactic Devices	Alford Taylor, Jr., Center for Devices and Radiological Health, 10903 New Hampshire Ave., Silver Spring, MD 20933, 301–796–2583
Electroconvulsive Therapy Device Class III Premarket Notification (510k) and Investigational Device Exemption Submissions	Joel Myklebust, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Silver Spring, MD 20933, 301–796–2491
Office of Surveillance and Biometrics	
Bayesean Statistics	Gerry Grey, Center for Devices and Radiological Health (HFZ–530), 1350 Piccard Dr., Rockville, MD 20850, 240–276–3451
Electronic Premarket Statistical Data Submission	Do
Electronic Medical Device Reporting	Howard Press, Center for Devices and Radiological Health (HFZ–530), 1350 Piccard Dr., Rockville, MD 20850, 240–276–3457
CDRH Postmarket Problem Codes	Do

Title	Contact Person
Global Harmonization Task Force (GHTF) Guidance on How to Handle Information Concerning Vigilance Reporting Related to Medical Devices	Do
FDA's Use of Global Harmonization Task Force (GHTF) Medical Devices: Post Market Surveillance: National Competent Authority Report Exchange Criteria and Report Form for Medical Devices	Do
Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)	
Invasive Portable Blood Glucose Monitoring System	Pat Bernhardt, Center for Devices and Radiological Health (HFZ–440), 2098 Gaither Rd., Rockville MD 20850, 240–276–0397
Class II Special Control Guidance Document: Human Metapneumovirus (hMPV) Nucleic Acid Assays	Sally Hojvat, Center for Devices and Radiological Health (HFZ–440), 2098 Gaither Rd., Rockville MD 20850, 240–276–0711
Class II Special Control Guidance Document: Respiratory Viral Panel Multiplex Nucleic Acid Assay	Do
Class II Special Controls Guidance Document: Nucleic Acid Assay for Detection and Differentiation of Influenza A Virus Subtypes	Do
Special Controls Guidance Document: Bacillus spp. Serological Reagents; Guidance for Industry and FDA	Do
Adverse Event Reporting for IVD's (with appendix on glucose meters)	Claudia Gaffey, Center for Devices and Radiological Health (HFZ–440), 2098 Gaither Rd., Rockville MD 20850, 240–276–0718
Class II Special Control Guidance Document: Enterovirus Nucleic Acid Assays	Uwe Scherf, Center for Devices and Radiological Health (HFZ–440), 2098 Gaither Rd., Rockville MD 20850, 240–276–0725
Therapeutic Drug Monitoring Assays: Zonisamide and Lamotrigine	Avis Danishefsky, Center for Devices and Radiological Health (HFZ–440), 2098 Gaither Rd., Rockville MD 20850, 240–276–0687
Assay Migration Studies for IVD's	Sally Hojvat, Center for Devices and Radiological Health (HFZ–440), 2098 Gaither Rd., Rockville MD 20850, 240–276–0711
Administrative Procedures for CLIA Categorization Procedures	Carol Benson, Center for Devices and Radiological Health (HFZ–440), 2098 Gaither Rd., Rockville MD 20850, 240–276–0396
Class II Special Control Guidance Document: Plasmodium Species Antigen Detection Assays	Freddie Poole, Center for Devices and Radiological Health (HFZ–440), 2098 Gaither Rd., Rockville MD 20850, 240–276–0712
IVD Multivariate Index Assays	Courtney Harper, Center for Devices and Radiological Health (HFZ–440), 2098 Gaither Rd., Rockville MD 20850, 240–276–0694
Office of Device Evaluation (ODE)	
Pediatric HDEs—Guidance for IRBs	Stephen Rhodes, Center for Devices and Radiological Health (HFZ–403), 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4036

Title	Contact Person
Sex Differences in Clinical Evaluation of Cardiovascular Devices	Bram Zuckerman, Center for Devices and Radiological Health (HFZ–450), 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4038
Condom Labeling, Special Controls	Nancy Brogdon, Center for Devices and Radiological Health (HFZ–470), 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3650
ECG Electrodes SCGD	Bram Zuckerman, Center for Devices and Radiological Health (HFZ–450), 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4038
Dental Amalgam	Susan Runner, Center for Devices and Radiological Health (HFZ–480), 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3776
Antimicrobial Agent Devices; Premarket Notification Submissions	Chiu Lin, Center for Devices and Radiological Health (HFZ–480), 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3742
Absorbable Hemostatic Devices	Mark Melkerson, Center for Devices and Radiological Health (HFZ–410), 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3737
FDA and Industry Actions on Premarket Notification Submissions	Samie Niver Allen, Center for Devices and Radiological Health (HFZ–402), 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4013
Annual Reports for PMAs	Do
MDUFMA: Disputes Concerning Payment or Refund of Medical Device User Fees	Les Weinstein, Center for Devices and Radiological Health (HFZ–5), 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3962
Topical Oxygen Chamber for Extremities	Mark Melkerson, Center for Devices and Radiological Health (HFZ–410), 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3737
MDUFMA: User Fees and Refunds for Premarket Notification Submissions	Heather Rosecrans, Center for Devices and Radiological Health (HFZ–404), 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4021
Pulse Oximeters; Submissions	Chiu Lin, Center for Devices and Radiological Health (HFZ–480), 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3742
Tracking Pediatric Device Approvals Sec. 302 FDAAA	Barbara Buch, Center for Devices and Radiological Health (HFZ–410), 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4000

Title	Contact Person
Trial Considerations for Hip Joint Replacement Systems	Mark Melkerson, Center for Devices and Radiological Health (HFZ–410), 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3737
Replacement Heart Valves; IDE & PMA Applications	Bram Zuckerman, Center for Devices and Radiological Health (HFZ–450), 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4038
Retina Prostheses; Preclinical & Clinical Recommendations	Malvina Eydelman, Center for Devices and Radiological Health (HFZ–400), 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3783
Bone Graft SCGD Adding Intra-Oral Barrier Membrane Indication	Chiu Lin, Center for Devices and Radiological Health (HFZ–480), 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3742
Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities	Do
Pacing Leads Guidance	Bram Zuckerman, Center for Devices and Radiological Health (HFZ–450), 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3783
Powered Wheelchairs	Mark Melkerson, Center for Devices and Radiological Health (HFZ–410), 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3737
Tissue Adhesive for the Topical Approximation of Skin	Do
FDA and Industry Actions on Premarket Approval Application	Samie Niver Allen, Center for Devices and Radiological Health (HFZ–402), 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4013
Pacemaker Lead Adaptor 510(k) Submissions	Bram Zuckerman, Center for Devices and Radiological Health (HFZ–450), 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4038
510(k) Paradigm	Heather Rosecrans, Center for Devices and Radiological Health (HFZ–404), 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4021
Urinary Incontinence Devices; Clinical Recommendations	Nancy Brogdon, Center for Devices and Radiological Health (HFZ–470), 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3650
Guidance on Dental Mouthguards	Chiu Lin, Center for Devices and Radiological Health (HFZ–480), 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3742
Tissue Expander	Mark Melkerson, Center for Devices and Radiological Health (HFZ–410), 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3737

Title	Contact Person
PTCA Devices	Bram Zuckerman, Center for Devices and Radiological Health (HFZ–450), 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4038
TENS, Muscle Stimulator, and Conductive Gel Guidances	Mark Melkerson, Center for Devices and Radiological Health (HFZ–410), 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3737
Sterile Devices in Premarket Notification (510(k)) Submissions	Chiu Lin, Center for Devices and Radiological Health (HFZ–480), 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3742
Full Field Digital Mammography	Nancy Brogdon, Center for Devices and Radiological Health (HFZ–470), 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3650
Coronary Drug Eluting Stents Guidance Document	Ashley Boam, Center for Devices and Radiological Health (HFZ–450), 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4222
Modifications to PMA Devices	Samie Niver Allen, Center for Devices and Radiological Health (HFZ–402), 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4013

V. Center for Safety and Applied Nutrition (CFSAN)

Title/Topic of Guidance	Contact
New Dietary Ingredient Notifications Guidance	Linda Pellicore, CFSAN (HFS–810), 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1448, *linda.pellicore@fda.hhs.gov*
Fish and Fishery Products Hazards and Control Guidance (Edition 4)	Robert Samuels, CFSAN (HFS–325), 5100 Paint Branch Pkwy., College Park, MD 20740 301–436–1418, *robert.samuels@fda.hhs.gov*
Dietary Guidance Statements	Kathy Ellwood, CFSAN (HFS–830), 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1450, *kathy.ellwood@fda.hhs.gov*
Providing Regulatory Submissions in Electronic Format—Food Additive Petitions, Color Additive Petitions, Food Contact Notifications, Food Master Files, GRAS Notices, Biotechnology Consultations, and New Protein Consultations	Berhane Girmay, CFSAN (HFS–205), 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1194, *berhane.girmay@fda.hhs.gov*
Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 5)	Rhonda Kane, CFSAN (HFS–820), 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1803, *rhonda.Kane@fda.hhs.gov*

Title/Topic of Guidance	Contact
The Seafood List—FDA's Guide to Acceptable Market Names for Seafood Sold in Interstate Commerce	Spring Randolph, CFSAN (HFS–325), 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1421, *spring.randolph@fda.hhs.gov*
Small Entity Compliance Guide: ''Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements''	Vasilios Frankos, CFSAN (HFS–810), 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1850, *vasilios.frankos@fda.hhs.gov*
Pathogens in Diary Products Draft CPG	Bob Childers, CFSAN (HFS–316), 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1494, *bob.childers@fda.hhs.gov*
Prior Notice CPG	May Nelson, CFSAN (HFS–024), 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1722, *may.nelson@fda.hhs.gov*

VI. Center for Veterinary Medicine

Title of Guidance	Contact
Regulation of Genetically Engineered (GE) Animals Containing Heritable nDNA Constructs	Larisa Rudenko, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8245, e-mail: *larisa.rudenko@fda.hhs.gov*
Labeling and Marketing of Nutritional Products for Dogs and Cats Intended to Diagnose, Cure, Mitigate, Treat, or Prevent Diseases—Compliance Policy Guide—Final	William J. Burkholder, Center for Veterinary Medicine (HFV–228), Food and Drug Administration, 7519 Standish Pl., MPN–4, rm. 2642, Rockville, MD 20855, *william.burkholder@fda.hhs.gov*
Veterinary Drug Compounding Compliance Policy Guide	Neal Bataller, Center for Veterinary Medicine (HFV–230), Food and Drug Administration, 7519 Standish Pl., MPN–4, rm. 143, Rockville, MD 20855, 240–276–9201, *neal.bataller@fda.hhs.gov*
Voluntary Self Inspection of Medicated Feed Manufacturing Facilities—Compliance Policy Guide	Paul Bachman, Center for Veterinary Medicine (HFV–230), Food and Drug Administration, 7519 Standish Pl., MPN–4, rm. 128, Rockville, MD 20855, 240–276–9225, *paul.bachman@fda.hhs.gov*
Salmonella Contamination of Feeds Compliance Policy Guide	Xin Li, Center for Veterinary Medicine (HFV–222), Food and Drug Administration, 7519 Standish Pl., MPN–4, rm. 221, Rockville, MD 20855, 240–453–6863, *Xin.Lin@fda.hhs.gov*
Criteria for Evaluating Tests for Detection of Animal Proteins Prohibited in Ruminant Feed	Dragan Momcilovic, Center for Veterinary Medicine (HFV–220), 7519 Standish Pl., MPN–4, rm. 227, Rockville, MD 20855, 240–453–6856, *dragan.momcilovic@fda.hhs.gov*

Title of Guidance	Contact
Glucosamine/Chondroitin Animal Products Compliance Policy Guide	Paul Bachman, Center for Veterinary Medicine (HFV–230), Food and Drug Administration, 7519 Standish Pl., MPN–4, rm. 128, Rockville, MD 20855, 240–276–9225, *paul.bachman@fda.hhs.gov*
International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Final Guidance for Industry on Target Animal Safety for Veterinary Pharmaceutical Products GL–43	Laura Hungerford, Center for Veterinary Medicine (HFV–143), Food and Drug Administration, 7500 Standish Pl., MPN–2, rm. E375, Rockville, MD 20855, 240–276–8232, *laura.hungerford@fda.hhs.gov*
Guidance for Industry, Submission of Veterinary Adverse Drug Event Reports to the Center for Veterinary Medicine, Form FDA 1932	Lynn Post, Center for Veterinary Medicine (HFV–210), Food and Drug Administration, 7519 Standish Pl., MPN–4, rm. 2612, Rockville, MD 20855, 240–276–9062, *lynn.post@fda.hhs.gov*
Guidance for Industry, Submission of Drug Experience Reports (DER) to the Center for Veterinary Medicine, Form FDA 2301	Lynn Post, Center for Veterinary Medicine (HFV–210), Food and Drug Administration, 7519 Standish Pl., MPN–4, rm. 2612, Rockville, MD 20855, 240–276–9062, *lynn.post@fda.hhs.gov*
Draft Guidance for Industry—Documenting Statistical Analyses	Bob Abugov, Center for Veterinary Medicine (HFV–105), Food and Drug Administration, 7500 Standish Pl., MPN–2, rm. N416, Rockville, MD 20855, 240–276–8168, *robert.abugov@fda.hhs.gov*
Draft Guidance for Industry—Changes to Approved NADAs—New NADA or Supplemental NADA	Suzanne Sechen, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., MPN–2, rm. N448, Rockville, MD 20855, 240–276–8108, *suzanne.sechen@fda.hhs.gov*
Draft Guidance for Industry—Anesthetics for Companion Animals	Germaine Connolly, Center for Veterinary Medicine (HFV–116), Food and Drug Administration, 7500 Standish Pl., MPN–2, rm. N331, Rockville, MD 20855, 240–276–8331, *germaine.connolly@fda.hhs.gov*
Draft Guidance for Industry: Drug Residues Resulting From the Extralabel Use of Approved New Animal Drugs #186	Deborah Cera, Center for Veterinary Medicine (HFV–235), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9209, *deborah.cera@fda.hhs.gov*
Common or Usual Names for Animal Feed Ingredients and Their Use in Animal Feed (CPG 7126.08); Draft Compliance Policy Guide	Sharon Benz, Center for Veterinary Medicine (HFV–220), Food and Drug Administration, 7519 Standish Pl., rm. 2648, Rockville, MD 20855, 240–453–6864, *esharon.benz@fda.hhs.gov*
Importation of New Animal Drugs by Licensed Veterinarians; Draft Compliance Policy Guide	Nadine Steinberg, Center for Veterinary Medicine (HFV–200), Food and Drug Administration, MPN4, rm. 2658, Rockville, MD 20855, 240–453–6846 *nadine.steinberg@fda.hhs.gov*

Title of Guidance	Contact
Marketed Unapproved New Animal Drugs; Draft Compliance Policy Guide	Nadine Steinberg, Center for Veterinary Medicine (HFV–200), Food and Drug Administration, MPN4, rm. 2658, Rockville, MD 20855, 240–453–6846 *nadine.steinberg@fda.hhs.gov*

VII. Office of the Commissioner

Title/Topic of Guidance	Contact
Guidance for Sponsors, Clinical Investigators, and IRBs; Frequently Asked Questions—Statement of Investigator (Form FDA 1572)	Patricia Beers Block, Office of the Commissioner (HF–34), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3340, FAX: 301–827–1169
Guidance for Sponsors, Clinical Investigators, and IRBs; Data Retention When Subjects Voluntarily Withdraw from FDA-Regulated Clinical Trials	Sara Goldkind, Office of the Commissioner (HF–34), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3340, FAX: 301–827–1169
Guidance for Sponsors, Clinical Investigators, and IRBs; A Guide to Informed Consent	Marsha Melvin, Office of the Commissioner (HF–34), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3340, FAX: 301–827–1169
Guidance for Sponsors, Clinical Investigators, and IRBs; IRBs Continuing Review After Study Approval	Carolyn Hommel, Office of the Commissioner (HF–34), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3340, FAX: 301–827–1169
Final Guidance for Sponsors, Industry, Researchers, Investigators, and FDA Staff: Certifications to Accompany Drug, Biological Product, and Device Applications/Submissions: Compliance With Section 402(j) of the Public Health Service Act, Added by Title VII of the Food and Drug Administration Amendments Act of 2007	Jarilyn Dupont, Office of Policy (HF–11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360
Final Guidance on Good Reprint Practices	Do
Guidance on Good Importer Practices	Sharon Mayl, Office of Policy (HF–11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360
Guidance on Private Labs	Phil Chao, Office of Policy (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360

Dated: July 30, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–18126 Filed 8–6–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–M–0208]

Medical Devices Regulated by the Center for Biologics Evaluation and Research; Availability of Summaries of Safety and Effectiveness Data for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved by the Center for Biologics Evaluation and Research (CBER). This list is intended to inform the public of the availability through the Internet and FDA's Division of Dockets Management of summaries of safety and effectiveness data of approved PMAs.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness data to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please include the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness data.

FOR FURTHER INFORMATION CONTACT: Tiffany Brown, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, suite 200N, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the **Federal Register**, providing instead to post this information on the Internet at *http://www.fda.gov*. In addition, the regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during the quarter. FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting administrative reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The following is a list of PMAs approved by CBER for which summaries of safety and effectiveness data were placed on the Internet from April 1, 2008, through June 30, 2008. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1. LIST OF SUMMARIES OF SAFETY AND EFFECTIVENESS DATA FOR APPROVED PMAS MADE AVAILABLE APRIL 1, 2008, THROUGH JUNE 30, 2008

PMA No./Docket No.	Applicant	Trade Name	Approval Date
BP050051/0/FDA–2008–M–0208	Ortho-Clinical Diagnostics, Inc.	VITROS Immunodiagnostics Products Anti-HIV 1+2 Calibrator, and VITROS Immunodiagnostics Products Anti-HIV 1+2 Reagent Pack	March 27, 2008

II.Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/cber/products.htm*.

Dated: July 29, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–18125 Filed 8–6–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0413]

Draft Guidance for Industry on Residual Solvents in Drug Products Marketed in the United States; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Control of Residual Solvents in Drug Products Marketed in the United States.'' On July 1, 2008, the United States Pharmacopeia (USP) published a new test requirement for the control of residual solvents, General Chapter <467> ''Residual Solvents,'' which replaced USP General Chapter <467> ''Organic Volatile Impurities.'' The change affects all compendial drug products marketed in the United States. This draft guidance reflects FDA's recommendations on how to comply with those USP changes.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit