complex chemistry, manufacturing, efficacy, and/or safety issues, the estimated time requirement per petition is approximately 10,000 hours. An average of one petition of this type is received on an annual basis, resulting in a burden of 10,000 hours.

Under § 571.6, for a food additive petition amendment, the estimated time requirement per petition is approximately 1,300 hours. An average of four petitions of this type are received on an annual basis, resulting in a burden of 5,200 hours.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency of Response	Total Annual Responses	Hours per Response	Total Hours
571.1(c) moderate category	1	1	1	3,000	3,000
571.1(c) complex category	1	1	1	10,000	10,000
571.6	2	2	4	1,300	5,200
Total					18,200

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: August 28, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–14510 Filed 8–31–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Annual Guidance Agenda

[Docket No. 2004N–0234]

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 written or electronic comments on this list and on any agency guidance documents at any time.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT:

For general information regarding FDA's GGP policy: 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's 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 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, in some cases, 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—COMPLIANCE AND INSPECTION	Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.
Design, Operation, and Validation of Heating, Ventilation, and Air Conditioning (HVAC) Systems Used in the Manufacture of Products Regulated by the Center for Biologics Evaluation and Research and the Center for Drug Evaluation and Research	Same as above (Do)
CATEGORY—BLOOD AND BLOOD COMPONENTS	
Reentry Algorithm for Donors Who Are Deferred Because of Reactive Test Results for Antibody to Hepatitis B Core Antigen (Anti-HBc)	Do

TITLE/TOPIC OF GUIDANCE	CONTACT
Implementation of a Licensed West Nile Virus Nucleic Acid Test (NAT) for Whole Blood Donor Screening	Do
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	Do
Recognition and Use of a Standard for the Uniform Labeling of Blood and Blood Components	Do
Use of Nucleic Acid Test (NAT) on Source and Recovered Plasma for Parvovirus B19	Do
CATEGORY—VACCINES AND ALLERGENICS	
Characterization and Qualification of Cell Substrates and Other Biological Starting Materials for the Production of Viral Vaccines	Do
CATEGORY—CELLULAR, TISSUE, AND GENE THERAPY	
Licensure of Minimally Manipulated, Unrelated, Allogeneic Placental/Umbilical Cord Blood Intended For Hematopoietic Reconstitution in Patients With Hematological Malignancies	Do
Preparation of Investigational Device Exemptions and Investigational New Drugs for Products Intended to Repair or Replace Knee Articular Cartilage	Do
Initiation and Conduct of Clinical Trials Using Cellular Therapies for Cardiac Disease	Do
Potency Measurements for Cell and Gene Therapy Products	Do
Considerations for Allogeneic Pancreatic Islet Cell Products	Do
Current Good Tissue Practice for Human Cell, Tissue, and Cellular and Tissue-Based Product Establishments	Do
Certain Distributed and Inventoried Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) Recovered From Donors Who Were Improperly Tested	Do
Clinical Study Design for Early Phase Studies of Cellular and Gene Therapies	Do
Devices Involved in Manufacture, Storage and Administration of Cellular Products and Tissues	Do
Validation of Rapid Microbiological Methods for Assessing Sterility of Cellular and Gene Therapy Products	Do
Submission of Information for the National Xenotransplantation Database	Do
Registration and Listing for Human Cell, Tissue, and Cellular and Tissue-Based Products Establishments	Do
Preparation of Investigational Device Exemptions and Investigational New Drugs for Tissue Engineered and Regenerative Medicine Products	Do
Facilities and Controls for Cellular and Gene Therapy Product Manufacturing Operations Guidance	Do
CATEGORY—OTHER	
Changes to an Approved Application: Biological Products	Do

III. Center for Drug Evaluation and Research (CDER)

TITLE/TOPIC OF GUIDANCE	CONTACT
CATEGORY—ADVERTISING	
Presentation of Risk Information in Prescription Drug and Medical Device	Emily T. Thakur, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5515 Security Lane, Rockville, MD 20852, 301–594–2041.
CATEGORY—CHEMISTRY	
Immunogenicity Assessment for Follow-on Protein Products	Do
Immunogenicity Assessment for Therapeutic Protein Products	Do
Individual Product Bioequivalence Recommendations	Do
Patient Specific Drug Products	Do
Quality by Design	Do
Recommendations for Determination of Bioequivalence of Vaginal Antifungal Products	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	
Androgens in Aging Males	Do
Clinical Development of Drugs for Irritable Bowel Syndrome	Do
Clinical Evaluation of Agents to Lower the Risk of Developing Sporadic Colorectal Adenomas	Do
Clinical Evaluation of Drugs for Female Infertility	Do
Clinical Evaluation of Drug Products for Inflammatory Bowel Disease	Do
Clinical Trial Design for the Treatment of Bacterial Blepharitis	Do
Clinical Trial Design for the Treatment of Bacterial Conjunctivitis	Do
Clinical Trial Design for the Treatment of Bacterial Corneal Ulcers	Do
Clinical Trial Design for the Treatment of Dry Eye	Do
Clinical Trial Design for the Treatment of Superficial Punctate Keratitis (SPK)	Do
Conducting and Submitting Virology Studies to the Division of Antiviral Drug Products	Do
Co-packaged Sodium Nitrite and Sodium Thiosulfate Drug Products—Submitting a New Drug Application	Do
Developing Analgesic Products for the Treatment of Pain	Do
Developing Drugs to Treat or Prevent Smallpox (Variola) Injection	Do
Development of Drugs for Chronic Obstructive Pulmonary Disease (COPD)	Do
Drug Development for the Treatment of Malaria	Do
Evaluation of New Treatments for Diabetes Mellitus	Do
Inhalational Anthrax (Symptomatic)—Developing Therapeutic Agents that Target Anthrax Toxin	Do
Obesity and Weight Loss	Do
Oral Mucositis	Do
Patient Reported Outcomes (PRO) Measures	Do

TITLE/TOPIC OF GUIDANCE	CONTACT
Periodontitis	Do
Peripheral Neuropathy	Do
Treatment of Congestive Heart Failure	Do
CATEGORY—CLINICAL/PHARMACOLOGY	
Immediate Release to Modified Release Dosage Forms	Do
In Vitro Drug Metabolism/Drug Interaction—Guidance for Reviewers	Do
CATEGORY—COMBINATION PRODUCTS	
Drug Diagnostic Co-Development	Do
CATEGORY—COMPLIANCE	
Registration Requirements Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002	Do
Process Validation: General Principles and Practices	Do
Penicillin as Defined in the CGMP Regulation Under 21 CFR 211 and Separation Requirements for Manufacturing	Do
Non-Penicillin Beta-Lactam Contamination	Do
Importation of Active Pharmaceutical Ingredients	Do
CATEGORY—DRUG SAFETY INFORMATION	
Good Naming, Labeling and Packaging (GNLP) Practices	Do
Premarketing Evaluation of Drug-Induced Liver Injury	Do
Risk Management of Highly Suspect or Known Human Teratogens: Pregnancy Prevention Strategies	Do
Selecting and Submitting Proprietary Names for Evaluation	Do
CATEGORY—ELECTRONIC SUBMISSIONS	
Providing Regulatory Submissions in Electronic Format—Analysis Datasets and Documentation	Do
CATEGORY—GOOD REVIEW PRACTICES	
Good Review Management Practices for Investigational New Drugs	Do
CATEGORY—INVESTIGATIONAL NEW DRUGS	
Consumer Product Safety Commission—Tamper Resistant Packaging for Investigational New Drugs	Do
Guidance for Clinical Investigators—Preparing and Submitting an Investigational New Drug Application	Do
CATEGORY—LABELING	
Content and Format of the Clinical Pharmacology Section	Do
Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products—Content and Format	Do
Drug Names and Dosage Forms	Do
Indication and Usage Section of Labeling for Human Prescription Drugs and Biological Products—Content and Format	Do
Labeling Dietary Supplements for Women Who Are or Could Be Pregnant	Do
Labeling for Human Prescription Drug and Biologic Products—Pharmacologic Classification for the Highlights Section of Labeling	Do

TITLE/TOPIC OF GUIDANCE	CONTACT
Labeling for Outcome Claims for Drugs to Treat Hypertension	Do
Pregnancy Labeling Revisions	Do
Use of Pharmacologic/Therapeutic Classification in Approved Labeling	Do
CATEGORY—OVER-THE-COUNTER	
Actual Use Trials	Do
Labeling Comprehension Studies for Over-the-Counter Drug Products	Do
Labeling of Skin Protectants	Do
Topical Drug Products for Vaginal Yeast Infections	Do
CATEGORY—PHARMACOLOGY/TOXICOLOGY	
Nonclinical Safety Evaluation of Reformulated Drug Products, Including Administration by an Alternate Route	Do
Nonclinical Studies for Anticancer Drugs	Do
CATEGORY—PROCEDURAL	
Assessment of Abuse Potential of Drugs	Do
Clinical Source Data	Do
Determining Whether Human Research With a Radioactive Drug Can be Conducted Under a Radioactive Drug Research Committee	Do
Good Meeting Management Guidance	Do
Nonclinical Evaluation of Late Radiation Toxicity of Therapeutic Radiopharmaceuticals	Do
Process for Contracts and Written Requests Under the Best Pharmaceutical for Children Act	Do
Qualifying for Pediatric Exclusivity Under Section 505a of the Federal Food, Drug, and Cosmetic Act	Do
Target Product Profile—A Strategic Development Process Tool	Do

IV. Center for Devices and Radiological Health (CDRH)

TITLE/TOPIC OF GUIDANCE	CONTACT
Class II Special Control Guidance Document: Full Field Digital Mammography (FFDM)	Robert A. Phillips, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1212, ext. 130.
Format Guidance (Table of Contents) for Special 510(k)s	Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.
Updated 510(k) Sterility Review Guidance K90–1; Final Guidance for Industry and FDA	Sheila A. Murphey, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8913.
Antimicrobials; Draft	Do
510(k) Paradigm Guidance	Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.
Replacement Heart Valve Premarket Approval Applications	Matthew Hillebrenner, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8517.

TITLE/TOPIC OF GUIDANCE	CONTACT
Breast Implant Guidance document	Stephen P. Rhodes, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090.
Class II Special Control Guidance Document: Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters	Ashley B. Boam, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4222.
Pulse Oximeter Premarket Notification [510(k)] Submissions	Ann A. Graham, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–4479.
Keratome and Keratome Blade 510ks	Everette T. Beers, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2018, ext. 136.
Coronary Drug Eluting Stents Guidance Document	Ashley B. Boam, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4222.
Metal Tracheal Stents	Stephen P. Rhodes, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090.
Class II Special Control Guidance Document: *Absorbable Hemostatic Agent*	Do
Preparation of Investigational Device Exemptions and Investigational New Drugs for Products Intended to Repair or Replace Articular Cartilage	Jonette Foy, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8262.
Premarket Approval Application Modifications	Thinh X. Nguyen, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186, ext. 152.
Medical Device User Fee Modernization Act of 2002 Validation Data in Premarket Notification (510(k)) Submissions for Reprocessed Single-Use Medical Devices	Ginette Y. Michaud, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8879, ext. 143.
Premarket Approval Application Performance Goals and Review Clock Guidance	Thinh X. Nguyen, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186, ext. 152.
Humanitarian Device Exemption Q and A Guidance	Elisa D. Harvey, Center for Devices and Radiological Health (HFZ–403), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.
Premarket Approval Application Annual Reports	Thinh X. Nguyen, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186, ext. 152.
Class II Special Control Guidance Document: Cutaneous Electrode	Theodore R. Stevens, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1296.
Class II Special Control Guidance Document: Electroconductive Media	Do
Class II Special Control Guidance Document: Powered Muscle Stimulators for Muscle Conditioning	Do
Class II Special Control Guidance Document: Powered Muscle Stimulators with Limited Output for Muscle Conditioning	Do
Class II Special Control Guidance Document: Powered Muscle Stimulators for Rehabilitation	Do
Class II Special Control Guidance Document: Powered Muscle Stimulators With Limited Output for Rehabilitation	Do
Class II Special Control Guidance Document: Transcutaneous Electrical Nerve Stimulators for Pain Relief	Do
Class II Special Control Guidance Document: Transcutaneous Electrical Nerve Stimulators With Limited Output for Pain Relief	Do

TITLE/TOPIC OF GUIDANCE	CONTACT
Class II Special Control Guidance Document: Transcutaneous Electrical Stimulators for Aesthetic Purposed	Do
Class II Special Control Guidance Document: Transcutaneous Electrical Stimulators With Limited Output for Aesthetic Purposes	Do
Office of Science and Engineering Laboratories	
Application of IEC 60601 Third Edition in Premarket Applications; Draft Guidance for Industry and FDA Staff	Jean M. Olson, Center for Devices and Radiological Health (HFZ–84), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–0952.
Establishing the Compatibility of Medical Devices in Magnetic Resonance Imaging Systems; Draft Guidance for Industry and FDA Staff	Do
Stereotactic Devices; Draft Guidance for Industry and FDA Staff	Do
Medical Device Electromagnetic Compatibility Guidance	Do
Diagnostic Spectroscopy for Detection of Cervical Disease Guidance	Do
Criteria for Establishing Labeling of Continuous Peripheral Anesthesia Devices for Austere Conditions	Do
Office of Compliance	
Site Change Supplements and Express Premarket Approval Application Supplements	Christy Foreman Center for Devices and Radiological Health (HFZ–340), Food and Drug Administration, 4 Oak Grove , Rockville, MD 20850, 240–276–0120.
Consumer Directed Broadcast Advertising	Deborah Wolf, Center for Devices and Radiological Health (HFZ–302), Food and Drug Administration, 4 Oak Grove, Rockville, MD 20850, 240–276–0100.
Decorative, Non-corrective Contact Lenses	Casper Uldriks, Center for Devices and Radiological Health (HFZ–300), Food and Drug Administration, 4 Oak Grove, Rockville, MD 20850, 240–276–0100.
Good Manufacturing Practice Inspectional Information (Medical Device User Fee Modernization Act of 2002)	Tim Ulatowski, Center for Devices and Radiological Health (HFZ–300), Food and Drug Administration, 4 Oak Grove, Rockville, MD 20850, 240–276–0100.
Bioresearch Monitoring Program Inspectional Information (Medical Device User Fee Modernization Act of 2002)	Matt Tarosky, Center for Devices and Radiological Health (HFZ–310), Food and Drug Administration, 4 Oak Grove, Rockville, MD 20850, 240–276–0243.
Office of Surveillance and Biometrics	
Instructions for Completing FDA Form 3500A With Coding Manual for Form 3500A	Howard A. Press, Center for Devices and Radiological Health (HFZ–530), Food and Drug Administration, 1350 Piccard Drive, Rockville, MD 20850, 240–276–3457.
Electronic Medical Device Adverse Event Reporting	Do
Office of Communication, Education, and Radiation Programs	
Medical Device Quality System Manual: A Small Entity Compliance Guide	John Stigi, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–0806.
Medical Device Reporting for Manufacturers	Do
Revision to Compliance Program 7386.001 Inspection of Manufacturers of Laser Products	Sean Boyd, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 240–276–3287.
Revision to Compliance Program 7386.002 Field Implementation of the Sunlamp and Sunlamp Products Performance Standard as Amended	Do
Revision to Compliance Program 7386.004 Field Compliance Testing of Cabinet X-Ray Equipment	Do

TITLE/TOPIC OF GUIDANCE	CONTACT
Revision to Compliance Program 7386.006 Compliance Testing of Electronic Products at Winchester Engineering and Analytical Center	Do
Revision to Compliance Program 7386.007 Imported Electronic Products	Do
Revision to Compliance Program 7386.007A Imported Non-certified Radiation-Emitting Electronic Products (Special Exemption for Television Receivers, Microwave Ovens, and Certain Class I Laser Products) Amending or Revoking as Appropriate Based on Guidance Published in Fiscal Year 2006 on Low Risk Product Reporting Exemptions	Do
Revision to Compliance Program 7386.008 Medical Device and Radiological Health Use Control and Policy Implementation	Do
Guidance to Allow Alternate Means of Labeling Certain Laser Products: Granting Approval to Include Labels for Small Laser Products in Packaging or in Product Literature, Rather Than on Product Itself, to Eliminate Burden on FDA and Industry	Do
Guidance to Exempt Laser Light Show Manufacturers From Variance Application Requirements Under Certain Conditions: Granting Light Show Variances by Guidance to Reduce Burden on FDA and Industry	Do
Guidance Regarding Risk Messaging for Implantable Cardioverter Defibrillator Dear Doctor Letters to Include Flow, Order of Presentation, Required Elements of Content, and Language	Margaret Tolbert, Center for Devices and Radiological Health (HFZ–230), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 240–276–3240.
Device Use Safety: Incorporating Human Factors into Risk Management	Ron Kaye, Center for Devices and Radiological Health (HFZ–230), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 240–276–3244.
Office of In Vitro Diagnostic Device Evaluation and Safety	
Analyte Specific Reagents: Frequently Asked Questions	Courtney Harper, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 8 Oak Grove , Rockville, MD 20850, 240–276–0443.
Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays	Sally Hojvat, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 8 Oak Grove, Rockville, MD 20850, 240–276–0496.
Draft guidance—Class II Special Controls Guidance Document: Bacillus spp. Serological Reagents	Roxanne Shively, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 8 Oak Grove , Rockville, MD 20850, 240–276–0496.
Draft guidance—Tumor Marker Assays	Maria Chan, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 8 Oak Grove , Rockville, MD 20850, 240–276–0493.
Recommendations for Gene Expression	Zivana Tezak, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 8 Oak Grove , Rockville, MD 20850, 240–276–0496.
Guidance for Administrative Procedures for Clinical Laboratory Improvement Amendments of 1988 Categorization	Carol Benson, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 8 Oak Grove , Rockville, MD 20850, 240–276–0496.
Guidance for Over-the-Counter Ovulation Tests	Veronica Calvin, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 8 Oak Grove , Rockville, MD 20850, 240–276–0496.
In Vitro Diagnostic Product Devices Under Development: Frequently Asked Questions	Sally Hojvat, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 8 Oak Grove , Rockville, MD 20850, 240–276–0496.
Medical Device Reporting for Self-Monitoring Blood Glucose Devices	Claudia Gaffey, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 8 Oak Grove , Rockville, MD 20850, 240–276–0496.

TITLE/TOPIC OF GUIDANCE	CONTACT
Migration Studies for Assays With Multiple Instrumentation Systems	Sally Hojvat, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 8 Oak Grove , Rockville, MD 20850, 240–276–0496.
Nucleic Acid Based In Vitro Diagnostic Devices for Detection of Microbial Pathogens	Roxanne Shively, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 8 Oak Grove , Rockville, MD 20850, 240–276–0496.
Pharmacogenetic Tests and Genetic Tests for Heritable Markers	Kathleen Simon, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 8 Oak Grove , Rockville, MD 20850, 240–276–0496.
Points to Consider on Assayed and Unassayed Quality Control Material	Carol Benson, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 8 Oak Grove , Rockville, MD 20850, 240–276–0496
Recommendations for Therapeutic Drug Monitoring Assays	Avis Danishefsky, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 8 Oak Grove , Rockville, MD 20850, 240–276–0496.
Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications	Carol Benson, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 8 Oak Grove , Rockville, MD 20850, 240–276–0496.
Serologic Assays for the Detection of Antibodies to Viral Agents	Sally Hojvat, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 8 Oak Grove , Rockville, MD 20850, 240–276–0496.
Total Product Life Cycle for Portable Invasive Blood Glucose Monitoring Systems	Carol Benson, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 8 Oak Grove , Rockville, MD 20850, 240–276–0496.

V. Center for Food Safety and Applied Nutrition (CFSAN)

TITLE/TOPIC OF GUIDANCE	CONTACT
New Dietary Ingredient Notifications	Linda Pellicore, Center for Food Safety and Applied Nutrition (HFS–810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1448.
Evidence-Based Scientific Review System for Health Claims (Including Qualified Health Claims)	Kathy Ellwood, Center for Food Safety and Applied Nutrition (HFS–830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1450.
Fish and Fishery Products Hazards and Control Guidance	Robert Samuels, Kathy Ellwood, Center for Food Safety and Applied Nutrition (HFS–417), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1418.
Steps to Reduce *Listeria Monocytogenes* Contamination in Ready-to-Eat Foods	Nega Beru, Kathy Ellwood, Center for Food Safety and Applied Nutrition (HFS–300), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1700.
Dietary Guidance Statements	Kathy Ellwood, Center for Food Safety and Applied Nutrition (HFS–830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1450.
Microbiological Considerations for Antimicrobial Food Additive Submissions	Paul DeLeo, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1302.

VI. Center for Veterinary Medicine (CVM)

TITLE OF GUIDANCE	CONTACT
Key Elements in Labeling of Prescription Antimicrobial Drug Products	Melanie Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., MPN–2, Rockville, MD 20855, 301–827–7540, e-mail: *melanie.berson@fda.hhs.gov*.

TITLE OF GUIDANCE	CONTACT
Meetings With the Office of New Animal Drug Evaluation (ONADE)	Gail Schmerfeld, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., MPN–2, Rockville, MD 20855, 301–827–1796, e-mail: *gail.schmerfeld@fda.hhs.gov*.
Blue Bird Medicated Feed Labels	Dragan Momcilovic, Center for Veterinary Medicine (HFV–220), 7519 Standish Pl., MPN–4, Rockville, MD 20855, 240–453–6856, e-mail: *dragan.momcilovic@fda.hhs.gov*.
Chemistry, Manufacturing, and Control Changes to an Approved NADA or ANADA (ı83)	Dennis Bensley, Center for Veterinary Medicine (HFV–143), Food and Drug Administration, 7500 Standish Pl., MPN–2, Rockville, MD 20855, 301–827–6956, e-mail: *dennis.bensley@.fda.hhs.gov*.
Analytical Methods Description for Type C Medicated Feeds (#137)	Rebecca Owen, Center for Veterinary Medicine (HFV- 141), Food and Drug Administration, 7500 Standish Pl., MPN–2, Rockville, MD 20855, 240–276–9842, e-mail: *rebecca.owen@fda.hhs.gov*.
Veterinary Drug Compounding Compliance Policy Guide	Neal Bataller, Center for Veterinary Medicine (HFV–235), Food and Drug Administration, 7519 Standish Pl., MPN–4, Rockville, MD 20855, 240–276–9202, e-mail: *neal.bataller@fda.hhs.gov*.
Voluntary Self Inspection of Medicated Feed Manufacturing Facilities Compliance Policy Guide	Gloria Dunnavan, Center for Veterinary Medicine (HFV–230), Food and Drug Administration, 7519 Standish Pl., MPN–4, Rockville, MD 20855, 240–276–9200, e-mail: *gloria.dunnavan@fda.hhs.gov*.
Recommended Study Design and Evaluation of Effectiveness Studies for Swine Respiratory Disease Claims (#178)	Michelle L. Stull, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., MPN–2, Rockville, MD 20855, 301–827–5058, e-mail: *michelle.stull@fda.hhs.gov*.
Extra-label Use of Drugs in Animals	Gloria Dunnavan, Center for Veterinary Medicine (HFV–230), Food and Drug Administration, 7519 Standish Pl., MPN–4, Rockville, MD 20855, 240–276–9200, e-mail: *gloria.dunnavan@fda.hhs.gov*.
Salmonella Contamination of Feeds Compliance Policy Guide	Henry Ekperigin, Center for Veterinary Medicine (HFV–222), Food and Drug Administration, 7500 Standish Pl., MPN–4, Rockville, MD 20855, 240–453–6868, e-mail: *henry.ekperigin@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, Rockville, MD 20855, 240–453–6856, e-mail: *dragan.momcilovic@fda.hhs.gov*.
International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH)GL–39 Specifications: Test Procedures and Acceptance Criteria for New Veterinary Drug Substances and New Medicinal Products: Chemical Substances	Dennis Bensley, Center for Veterinary Medicine (HFV–143), Food and Drug Administration, 7500 Standish Pl., MPN–2, Rockville, MD 20855, 301–827–6956, e-mail: *dennis.bensley@fda.hhs.gov*.
International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) GL–40 Specifications: Test Procedures and Acceptance Criteria for New Biotechnological/Biological Veterinary Medicinal Products	Do
International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Draft Revised Guidance for Industry on Impurities in New Veterinary Drug Substances (Revision) VICH GL10(R)	Do
International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Draft Revised Guidance for Industry on Impurities in New Veterinary Medicinal Products (Revision) VICH GL11(R)	Do
Animal Drug User Fees: Fees Exceed Costs Waivers and Reductions	Dave Newkirk, Center for Veterinary Medicine (HFV–100) , Food and Drug Administration, 7500 Standish Pl., MPN–2, Rockville, MD 20855, 301–827–6967, e-mail: *David.Newkirk@fda.hhs.gov*.
International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) GL–24 Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports	Lynn Post, Center for Veterinary Medicine (HFV–210), Food and Drug Administration, 7519 Standish Pl., MPN–4, Rockville, MD 20855, 240–276–9062, e-mail: *Lynn.Post@fda.hhs.gov*.

TITLE OF GUIDANCE	CONTACT
International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) GL–42 Pharmacovigilance of Veterinary Medicinal Products: Data Elements for Submission of Adverse Event Reports	Do
International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) GL–29 Pharmacovigilance of Veterinary Medicinal Products: Management of Periodic Summary Update Reports (PSUs)	Do
International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) GL–30 Pharmacovigilance of Veterinary Medicinal Products: Controlled Lists of Terms	Do
International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) GL–35 Pharmacovigilance of Veterinary Medicinal Products: Electronic Standards for Transfer of Data	Do
Guidance for Industry, Submission of Drug Experience Reports (DER) to the Center for Veterinary Medicine, Form Form FDA 2301	Do
Guidance for Industry, Submission of Veterinary Adverse Drug Event Reports to the Center for Veterinary Medicine, Form FDA 1932	Do
*Salmonella*in Pet Turtles Compliance Policy Guide	Joseph Paige, Center for Veterinary Medicine (HFV–230), Food and Drug Administration, 7519 Standish Pl., MPN–4, Rockville, MD 20855, 240–276–9210, e-mail: *joseph.paige@fda.hhs.gov*.
Glucosamine/Chondroitin Animal Products Compliance Policy Guide	Mark Hackman, Center for Veterinary Medicine (HFV–232), Food and Drug Administration, 7519 Standish Pl., MPN–4, Rockville, MD 20855, 240–276–9215, e-mail: *mark.hackman@fda.hhs.gov*.

VII. Office of Regulatory Affairs (ORA)

TITLE/TOPIC OF GUIDANCE	CONTACT
21 CFR Part 58: Closure of Nonclinical Laboratories	Director, Office of Regulatory Affairs (HFC–230), Food and Drug Administration, 15800 Crabbs Branch Way, Rockville, MD 20855, 240–632–6860.
Disqualification of Clinical Investigators	Do
Compliance Policy Guide, Section 310.210, Blood Pressure Measurement Devices (Sphygmomanometers)—Accuracy (CPG 7124.23)	Jeffrey B. Governale, Office of Regulatory Affairs (HFC–230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–632–6851.
Untrue Statements of Material Facts	Director, Office of Regulatory Affairs (HFC–230), Food and Drug Administration, 15800 Crabbs Branch Way, Rockville, MD 20855, 240–632–6860.
Application Integrity Policy	Do

VIII. Office of the Commissioner (OC)

TOPIC/TITLE OF GUIDANCE	CONTACT
Information Sheet Guidances for Institutional Review Boards, Clinical Investigators, and Sponsors	David Lepay, Office of the Commissioner (HF–34), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3340.
Guidance for Industry Computerized Systems Used in Clinical Trials	Patricia M. Beers Block, Office of the Commissioner (HF–34), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6473.
Guidance for FDA Staff Compliance Program 7348.811, Inspection of Clinical Investigators and Sponsor Investigators	Do

TOPIC/TITLE OF GUIDANCE	CONTACT
Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors, Exception from Informed Consent Requirements for Emergency Research	Carolyn Hommel, Office of the Commissioner (HF–34), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–9105.

Dated: August 23, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–14549 Filed 8–31–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) notifies Federal agencies of the laboratories currently certified to meet the standards of subpart C of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines). The Mandatory Guidelines were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908), on September 30, 1997 (62 FR 51118), and on April 13, 2004 (69 FR 19644).

A notice listing all currently certified laboratories is published in the **Federal Register** during the first week of each month. If any laboratory's certification is suspended or revoked, the laboratory will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end, and will be omitted from the monthly listing thereafter.

This notice is also available on the Internet at *http://workplace.samhsa.gov* and *http://www.drugfreeworkplace.gov.*

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh or Dr. Walter Vogl, Division of Workplace Programs, SAMHSA/CSAP, Room 2–1035, 1 Choke Cherry Road, Rockville, Maryland 20857; 240–276–2600 (voice), 240–276–2610 (fax).

SUPPLEMENTARY INFORMATION: The Mandatory Guidelines were developed in accordance with Executive Order 12564 and section 503 of Pub. L. 100–71. Subpart C of the Mandatory Guidelines, ''Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies,'' sets strict standards that laboratories must meet in order to conduct drug and specimen validity tests on urine specimens for Federal agencies. To become certified, an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a laboratory must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories which claim to be in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines. A laboratory must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA) which attests that it has met minimum standards.

In accordance with Subpart C of the Mandatory Guidelines dated April 13, 2004 (69 FR 19644), the following laboratories meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

ACL Laboratories, 8901 W. Lincoln Ave., West Allis, WI 53227, 414–328–7840/800–877–7016 (Formerly: Bayshore Clinical Laboratory).

ACM Medical Laboratory, Inc., 160 Elmgrove Park, Rochester, NY 14624, 585–429–2264.

Advanced Toxicology Network, 3560 Air Center Cove, Suite 101, Memphis, TN 38118, 901–794–5770/888–290–1150.

Aegis Analytical Laboratories, Inc., 345 Hill Ave., Nashville, TN 37210, 615–255–2400.

Baptist Medical Center-Toxicology Laboratory, 9601 I–630, Exit 7, Little Rock, AR 72205–7299, 501–202–2783 (Formerly: Forensic Toxicology Laboratory Baptist Medical Center).

Clinical Reference Lab, 8433 Quivira Road, Lenexa, KS 66215–2802, 800–445–6917.

Diagnostic Services, Inc., dba DSI, 12700 Westlinks Drive, Fort Myers, FL 33913, 239–561–8200/800–735–5416.

Doctors Laboratory, Inc., 2906 Julia Drive, Valdosta, GA 31602, 229–671–2281.

DrugScan, Inc., P.O. Box 2969, 1119 Mearns Road, Warminster, PA 18974, 215–674–9310.

Dynacare Kasper Medical Laboratories *, 10150–102 St., Suite 200, Edmonton, Alberta, Canada T5J 5E2, 780–451–3702/800–661–9876.

ElSohly Laboratories, Inc., 5 Industrial Park Drive, Oxford, MS 38655, 662–236–2609.

Gamma-Dynacare Medical Laboratories,* A Division of the Gamma-Dynacare, Laboratory Partnership, 245 Pall Mall Street, London, ONT, Canada N6A 1P4, 519–679–1630.

General Medical Laboratories, 36 South Brooks St., Madison, WI 53715, 608–267–6225.

Kroll Laboratory Specialists, Inc., 1111 Newton St., Gretna, LA 70053, 504–361–8989/800–433–3823 (Formerly: Laboratory Specialists, Inc.).

Kroll Scientific Testing Laboratories, Inc., 450 Southlake Blvd., Richmond, VA 23236, 804–378–9130 (Formerly: Scientific Testing Laboratories, Inc.).

Laboratory Corporation of America Holdings, 7207 N. Gessner Road, Houston, TX 77040, 713–856–8288/800–800–2387.

Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 908–526–2400/800–437–4986 (Formerly: Roche Biomedical Laboratories, Inc.).

Laboratory Corporation of America Holdings, 1904 Alexander Drive, Research Triangle Park, NC 27709, 919–572–6900/800–833–3984 (Formerly: LabCorp Occupational Testing Services, Inc., CompuChem Laboratories, Inc.; CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory; Roche CompuChem Laboratories, Inc., A Member of the Roche Group).

Laboratory Corporation of America Holdings, 10788 Roselle St., San Diego, CA 92121, 800–882–7272 (Formerly: Poisonlab, Inc.).

Laboratory Corporation of America Holdings, 550 17th Ave., Suite 300, Seattle, WA 98122, 206–923–7020/800–898–0180 (Formerly: DrugProof, Division of Dynacare/Laboratory of Pathology, LLC; Laboratory of Pathology of Seattle, Inc.; DrugProof,