

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<sup>1</sup>

| 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      |

<sup>1</sup>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]

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## 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 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) Infection  | 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 Bio-terrorism 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: <i>Absorbable Hemostatic Agent</i>  | 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 <i>Listeria Monocytogenes</i> 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: <a href="mailto:melanie.berson@fda.hhs.gov">melanie.berson@fda.hhs.gov</a> . |

| TITLE OF GUIDANCE   | CONTACT  |
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| 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: <a href="mailto:gail.schmerfeld@fda.hhs.gov">gail.schmerfeld@fda.hhs.gov</a> . |
| 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: <a href="mailto:dragan.momcilovic@fda.hhs.gov">dragan.momcilovic@fda.hhs.gov</a> .                         |
| Chemistry, Manufacturing, and Control Changes to an Approved NADA or ANADA (t83)  | 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: <a href="mailto:dennis.bensley@fda.hhs.gov">dennis.bensley@fda.hhs.gov</a> .    |
| 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: <a href="mailto:rebecca.owen@fda.hhs.gov">rebecca.owen@fda.hhs.gov</a> .         |
| 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: <a href="mailto:neal.bataller@fda.hhs.gov">neal.bataller@fda.hhs.gov</a> .       |
| 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: <a href="mailto:gloria.dunnavan@fda.hhs.gov">gloria.dunnavan@fda.hhs.gov</a> . |
| 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: <a href="mailto:michelle.stull@fda.hhs.gov">michelle.stull@fda.hhs.gov</a> . |
| 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: <a href="mailto:gloria.dunnavan@fda.hhs.gov">gloria.dunnavan@fda.hhs.gov</a> . |
| <i>Salmonella</i> 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: <a href="mailto:henry.ekperigin@fda.hhs.gov">henry.ekperigin@fda.hhs.gov</a> . |
| 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: <a href="mailto:dragan.momcilovic@fda.hhs.gov">dragan.momcilovic@fda.hhs.gov</a> .                         |
| 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: <a href="mailto:dennis.bensley@fda.hhs.gov">dennis.bensley@fda.hhs.gov</a> .    |
| 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: <a href="mailto:David.Newkirk@fda.hhs.gov">David.Newkirk@fda.hhs.gov</a> .       |
| 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: <a href="mailto:Lynn.Post@fda.hhs.gov">Lynn.Post@fda.hhs.gov</a> .                   |

| TITLE OF GUIDANCE   | CONTACT   |
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| 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 FDA 2301   | Do  |
| Guidance for Industry, Submission of Veterinary Adverse Drug Event Reports to the Center for Veterinary Medicine, Form FDA 1932   | Do  |
| <i>Salmonellain</i> 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: <a href="mailto:joseph.paige@fda.hhs.gov">joseph.paige@fda.hhs.gov</a> . |
| 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: <a href="mailto:mark.hackman@fda.hhs.gov">mark.hackman@fda.hhs.gov</a> . |

#### 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  |
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| 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,