TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

<table>
<thead>
<tr>
<th>Item</th>
<th>Number of respondents</th>
<th>Annual frequency per response</th>
<th>Total annual responses</th>
<th>Hours per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>MedSun facilities participating in the electronic reporting of adverse events program</td>
<td>400</td>
<td>15</td>
<td>6,000</td>
<td>0.75</td>
<td>4,500</td>
</tr>
<tr>
<td>MedSun facilities' electronic responses to Public Health Questions (PHQs)</td>
<td>400</td>
<td>10</td>
<td>4,000</td>
<td>0.5</td>
<td>2,000</td>
</tr>
<tr>
<td>Total hours</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>6,500</td>
</tr>
</tbody>
</table>

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

Dated: December 1, 2010.

Leslie Kux, Acting Assistant Commissioner for Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0083]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled “Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed” has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Denver Presly, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

SUPPLEMENTARY INFORMATION: In the Federal Register of June 18, 2010 (75 FR 34744), the Agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0339. The approval expires on November 30, 2013. A copy of the supporting statement for this information collection is available on the Internet at http://www.reginfo.gov/public/do/PRAMain.

For information regarding specific topics or guidances, please see contact persons or specific offices listed in the table in the SUPPLEMENTARY INFORMATION section of this document.

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 in some cases are further grouped within the issuing Center or Office by topic categories.

II. Center for Biologics Evaluation and Research (CBER)
<table>
<thead>
<tr>
<th>Title/topic of guidance</th>
<th>Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early Clinical Trials With Live Biotherapeutic Products: Chemistry, Manufacturing, and Control Information Bar Code Label Requirements—Question and Answer (Update for Vaccines).</td>
<td></td>
</tr>
</tbody>
</table>

### III. Center for Drug Evaluation and Research (CDER)

For information on the list of topics contact: Office of Training and Communications, Division of Drug Information, 10903 New Hampshire Ave., WO51, rm. 2201, Silver Spring, MD 20993, 301–796–3400, FAX: 301–847–8714, e-mail: druginfo@fda.hhs.gov.

**Category—Advertising**
- Amendment of the Brief Summary
- Comparative Claims in Prescription Drug Promotion
- Direct to Consumer (DTC) Television Advertisements—Food and Drug Administration Amendments Act of 2007 (FDAAA) DTC Television Pre-Review Program
- Promotion of Prescription Drug Products Using Social Media Tools

**Category—Chemistry**
- Chemistry, Manufacturing, and Controls (CMC)—Postmarketing Plan
- CMC Postapproval Changes Reportable in an Annual Report
- Comparability Protocols for Approved Drugs: CMC Information
- Standards Recognition
- Residual Drug in Transdermal Drug Delivery Systems

**Category—Clinical/Medical**
- Clinical Development of Drugs for Irritable Bowel Syndrome
- Oncology Endpoints: Non-Small Cell Lung Cancer
- Qualification Process for Drug Development Tools
- Responsible Inclusion of Pregnant Women in Clinical Trials

**Category—Clinical Pharmacology**
- Bioanalytical Methods Validation
- Clinical Pharmacogenomics: Study Design and Premarketing Evaluation
- Clinical Pharmacology Consideration for Therapeutics Proteins
- General Clinical Pharmacology Considerations for Pediatric Studies for Drugs and Biological Products
- Development of Extended Released Formulations

**Category—Clinical/Statistical**
- Adaptive Trial Designs
- Multiple Endpoints
- Non-Inferiority Trials

**Category—Combination Products**
- Drug Diagnostic Co-Development
- Development of Drugs in Combination

**Category—Current Good Manufacturing Practices (CGMPs)/Compliance**
- Contract Manufacturing
- Control of Components
- Control of Highly Potent Compounds
- Expiration Dating of Unit-Dose Repackaged Drugs: Compliance Policy Guide
- Importation of Active Pharmaceutical Ingredients (API) for Use in Human Drugs
- Medical Gas, General CGMP
- Non-Penicillin Beta-Lactam Contamination
- Outsourcer Pharmacy Operations Compliance Policy Guide
- Pharmaceutical Component Quality Control
- Pharmaceutical Manufacturing Statistics
- Pre-Launch Activities Importation Request (PLAIR)
- Prevention and Control of Viral Contamination
- Validation of Air Separation Processes for Medical Gas

**Category—Drug Safety Information**
- Best Practices for Conducting Pharmacovigilance Studies Using Electronic Healthcare Data
- Dear Healthcare Professional Letters
- Good Naming, Labeling, and Packaging Practices to Reduce Medication Errors

**Category—Electronic Submissions**
- Electronic Submission of Summary Level Clinical Site Data for Data Integrity Review and Inspection Planning in New Drug Application (NDA) and Biologics License Application (BLA) Submissions
- Providing Regulatory Submissions in Electronic Format—Analysis Datasets and Documentation

**Category—Investigational New Drug Application (IND)**
- Adverse Events: Collection and Reporting for Secondary Endpoints
IV. Center for Devices and Radiological Health (CDRH)

FDA has established a docket for CDRH, Docket No. FDA–2007–N–0270, for comments on any or all of the proposed fiscal year 2010 guidance documents. FDA invites interested persons to submit comments, draft language on the proposed topics, and/or suggestions for new or different guidance documents. FDA believes this docket is an important tool for receiving information from interested parties and for making information available to the public.

Guidance Related to FDAAA or General Premarket Issues

- 30–Day notices and 135-day Premarket Approval Application (PMA) Supplements
- Actions on 510(k) Submissions
- Annual Reports for PMAs
- Determining Whether Human Research Studies Can Be Conducted Without an IND
- IND Safety Reporting

Category—Labeling

- Drug Names and Dosage Forms
- Pediatric Information: Incorporating into Human Prescription Drug and Biological Products Labeling

Category—Procedural

- INDs prepared and submitted by Clinical Sponsor Investigators

Title/topic of guidance

<table>
<thead>
<tr>
<th>New Dietary Ingredient Notifications</th>
<th>Constance Hardy, CFSAN (HFS–810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2375, <a href="mailto:Constance.Hardy@fda.hhs.gov">Constance.Hardy@fda.hhs.gov</a></th>
</tr>
</thead>
<tbody>
<tr>
<td>Fish and Fishery Products Hazards and Controls Guidance (Edition 4)</td>
<td>Thomas Latt, CFSAN (HFS–325), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1423, <a href="mailto:Thomas.Latt@fda.hhs.gov">Thomas.Latt@fda.hhs.gov</a></td>
</tr>
<tr>
<td>Use of Dietary Guidance Statements</td>
<td>Blakeley Denkingher, CFSAN (HFS–830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2176, <a href="mailto:Blakeley.Denkingher@fda.hhs.gov">Blakeley.Denkingher@fda.hhs.gov</a></td>
</tr>
<tr>
<td>Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 5)</td>
<td>Rhonda Kane, CFSAN (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1803, <a href="mailto:Rhonda.Kane@fda.hhs.gov">Rhonda.Kane@fda.hhs.gov</a></td>
</tr>
<tr>
<td>Processing of Acidified Foods</td>
<td>Michael Mignogna, CFSAN (HFS–302), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1515, <a href="mailto:Michael.Mignogna@fda.hhs.gov">Michael.Mignogna@fda.hhs.gov</a></td>
</tr>
<tr>
<td>Calorie Declaration</td>
<td>Vincent DeJesus, CFSAN (HFS–830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1774, <a href="mailto:Vincent.DeJesus@fda.hhs.gov">Vincent.DeJesus@fda.hhs.gov</a></td>
</tr>
<tr>
<td>Compliance Policy Guide Sec. 527.300 Dairy Products-Microbial Contaminants and Alkaline Phosphatase Activity (Compliance Policy Guide 7106.08)</td>
<td>Monica Metz, CFSAN (HFS–316), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2041, <a href="mailto:Monica.Metz@fda.hhs.gov">Monica.Metz@fda.hhs.gov</a></td>
</tr>
</tbody>
</table>
VII. Center for Veterinary Medicine (CVM)

<table>
<thead>
<tr>
<th>Title of Guidance</th>
<th>Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Draft Guidance for Industry—Safe Animal Feeding</td>
<td>Phares Okelo, Center for Veterinary Medicine (HFV–226), Food and Drug Administration, 7519 Standish Pl., MPN–4, rm. 2661, Rockville, MD 20855, 240–453–6862, <a href="mailto:phares.okelo@fda.hhs.gov">phares.okelo@fda.hhs.gov</a></td>
</tr>
<tr>
<td>Final Guidance for Industry—Comparability Protocols</td>
<td>Dennis Bensley, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish Pl., MPN–2, rm. E334, Rockville, MD 20855, 240–276–8268, <a href="mailto:dennis.bensley@fda.hhs.gov">dennis.bensley@fda.hhs.gov</a></td>
</tr>
<tr>
<td>Draft Guidance for Industry—Fermentation Derived Intermediates, Drug Substances, and Related Drug Products for Veterinary Medicinal Use—Chemistry, Manufacturing, and Controls Information</td>
<td>Michael Popen, Center for Veterinary Medicine (HFV–144), Food and Drug Administration, 7500 Standish Pl., MPN–2, rm. E335, Rockville, MD 20855, 240–276–8269, <a href="mailto:michael.popen@fda.hhs.gov">michael.popen@fda.hhs.gov</a></td>
</tr>
<tr>
<td>Final Guidance for Industry—Drug Substance Chemistry, Manufacturing, and Controls Information</td>
<td>Dennis Bensley, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish Pl., MPN–2, rm. E334, Rockville, MD 20855, 240–276–8268, <a href="mailto:dennis.bensley@fda.hhs.gov">dennis.bensley@fda.hhs.gov</a></td>
</tr>
<tr>
<td>Draft Guidance for Industry—Active Controls in Studies to Demonstrate Effectiveness of a New Animal Drug for Use in Companion Animals</td>
<td>Urvi Desai, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7520 Standish Pl., MPN–1, rm. 203, Rockville, MD 20855, 240–276–8297, <a href="mailto:urvi.desai@fda.hhs.gov">urvi.desai@fda.hhs.gov</a></td>
</tr>
<tr>
<td>Draft Guidance for Industry—Judicious Use of Antimicrobial Drugs in Food-Producing Animals</td>
<td>William Flynn, Center for Veterinary Medicine (HFV–1), Food and Drug Administration, 7519 Standish Pl., MPN–4, rm. 173, Rockville, MD 20855, 240–276–9084, <a href="mailto:william.flynn@fda.hhs.gov">william.flynn@fda.hhs.gov</a></td>
</tr>
</tbody>
</table>

VI. Center for Tobacco Products (CTP)

<table>
<thead>
<tr>
<th>Title of Guidance</th>
<th>Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enforcement Policy Concerning Rotational Warning Plans for Smokeless Tobacco Products.</td>
<td>Office of Regulations, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–976–9250</td>
</tr>
<tr>
<td>Compliance With Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents. Use of “Light,” “Mild,” “Low,” or Similar Descriptors in the Label, Labeling, or Advertising of Tobacco Products. “Harmful and Potentially Harmful Constituents” in Tobacco Products as Used in Section 904(e) of the Federal Food, Drug, and Cosmetic Act. Tobacco Product Retailer Training Program</td>
<td></td>
</tr>
<tr>
<td>Civil Money Penalties for Tobacco Retailers</td>
<td></td>
</tr>
</tbody>
</table>
Title of Guidance | Contact
---|---
Residual Solvents in Animal Drug Products; Questions and Answers .... | Sudesh Kamath, Center for Veterinary Medicine (HFV–145), Food and Drug Administration, 7500 Standish Pl., MPN–2, rm. E365, Rockville, MD 20855, 240–276–8260, sudesh.kamath@fda.hhs.gov.
Revised Draft Guidance for Industry—Impurities: Residual Solvents In New Veterinary Medicinal Products, Active Substances and Excipients, VICH GL18(R). | Mai Huynh, Center for Veterinary Medicine, (HFV–142), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8273, Mai.huynh@fda.hhs.gov.
Draft Guidance for Industry—Evaluating the Effectiveness of Anticoccidial Drugs in Food-Producing Animals. | Emily R. Smith, (HFV–135), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8344, e-mail: emily.smith2@fda.hhs.gov.
Draft Guidance for Industry—Protocol Submissions for the Division of Therapeutic Drugs for Non-Food Animals the Division of Production Drugs, and the Division of Therapeutic Drugs for Food Animals. | Angela Clarke, Center for Veterinary Medicine (HFV–105), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8318, e-mail: angela.clarke@fda.hhs.gov.

VIII. Office of the Commissioner

<table>
<thead>
<tr>
<th>Guidance title/TOPIC</th>
<th>OC Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Classification of products as biological products, devices, and drugs</td>
<td>John Weiner, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave, Silver Spring, MD 20993 301–796–8941.</td>
</tr>
<tr>
<td>- Interpretation of the term “chemical action” in definition of device under section 201(h) of the Federal Food, Drug, and Cosmetic Act.</td>
<td>Do.</td>
</tr>
<tr>
<td>- Types of submissions for postapproval changes to combination products</td>
<td>Do.</td>
</tr>
</tbody>
</table>

Dated: December 1, 2010.

Leslie Kux, Acting Assistant Commissioner for Policy.

[FR Doc. 2010–30623 Filed 12–6–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0551]

Compliance Policy Guide Sec. 393.200 Laser(s) as Medical Devices for Facelift, Wrinkle Removal, Acupuncture, Auricular Stimulation, etc.; Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of Compliance Policy Guide Sec. 393.200 Laser(s) as Medical Devices for Facelift, Wrinkle Removal, Acupuncture, Auricular Stimulation, etc. (CPG Sec. 393.200). CPG Sec. 393.200 is included in FDA’s Compliance Policy Guides Manual, which was listed in the Annual Comprehensive List of Guidance Documents that published on August 9, 2010.

DATES: The withdrawal is effective December 7, 2010.