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 publishing its annual guidance agenda for the upcoming year. 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.

FOR FURTHER INFORMATION CONTACT: Leslie Kux, Acting Assistant Commissioner for Policy, [FR Doc. 2010–30556 Filed 12–6–10; 8:45 am] BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration


Annual Guidance Agenda

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Submit either electronic or written comments on this list and on any agency guidance document at any time.

ADDRESSES: Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Leslie Kux, Acting Assistant Commissioner for Policy, [FR Doc. 2010–30556 Filed 12–6–10; 8:45 am] BILLING CODE 4160–01–P

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

<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</td>
<td>400</td>
<td>15</td>
<td>6,000</td>
<td>0.75</td>
<td>4,500</td>
</tr>
<tr>
<td>adverse events program</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></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>

† 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.

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>
</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
• Determining Whether Human Research Studies Can Be Conducted Without an IND
• INDS prepared and submitted by Clinical Sponsor Investigators

**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

**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

**Category—Labeling**
• Protocol Review Guidance for In Vitro Diagnostics (IVDs)
• Tracking Pediatric Device Approvals
• Premarket Notification Submissions for Medical Devices That Include Antimicrobial Agents

**Guidance on Postmarket and Compliance Issues**
• Medical Device Reporting for Manufacturers
• Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act
• Electronic Registration and Listing
• Manufacturing Site Change Considerations
• Quality Systems for Laboratory Developed Tests

**Device Specific Guidances**
• Bacillus spp. Serological Reagents
• Clinical Performance Assessment: Considerations for Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data
• Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data—Premarket Notification (510(k)) Submissions
• Coronary Drug Eluting Stents
• Dental Mouthguards
• Helicobacter Pylori
• Herpes Simplex Virus
• Impact-Resistant Lenses

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

<table>
<thead>
<tr>
<th>Title/topic of guidance</th>
<th>Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Dietary Ingredient Notifications</td>
<td>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>.</td>
</tr>
<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 Denkinger, CFSAN (HFS–302), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2041, <a href="mailto:Blakeley.Denkinger@fda.hhs.gov">Blakeley.Denkinger@fda.hhs.gov</a>.</td>
</tr>
<tr>
<td>Calorie Declaration</td>
<td>Vincent DeJesus, CFSAN (HFS–316), 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>
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</table>

**Compliance Policy Guide Sec. 527.300 Dairy Products-Microbial Contaminants and Alkaline Phosphatase Activity** (Compliance Policy Guide 7106.08).

| Questions and Answers Regarding the Final Rule, Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation. | Monica Metz, CFSAN (HFS–316), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2041, Monica.Metz@fda.hhs.gov. |

**Global Harmonization or Standards Related Guidelines**
• Application of IEC 60601–1 Third Edition in Premarket Applications
• Global Harmonization Task Force: Quality Management System; Process Validation

**Crosscutting, Process, and Other Guidances**
• Radio-Frequency Wireless Technology in Medical Devices
• Medical Device Appeals and Complaints: Guidance on Dispute Resolution
• Medical Devices Containing Materials From Animal Sources (Except IVDs)


**Title/topic of guidance** | **Contact**
--- | ---
Questions and Answers Regarding Voluntary Registration by Authorized Officials of Retail Food Establishments and by Vending Machine Operators Electing to be Subject to the Menu and Vending Machine Labeling Requirements Established by Section 4205 of the Patient Protection and Affordable Care Act | Felicia Billingslea, CFSAN (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2371, Felicia.Billingslea@fda.hhs.gov.
Questions and Answers Regarding the Effect of Section 4205 of the Patient Protection and Affordable Care Act on State and Local Menu and Vending Machine Labeling Laws. | Felicia Billingslea, CFSAN (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2371, Felicia.Billingslea@fda.hhs.gov.
Safety of Nanoscale Materials in Cosmetic Products | Kapal Dewan, CFSAN (HFS–100), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1130, Kapal.Dewan@fda.hhs.gov.

**VI. Center for Tobacco Products (CTP)**

<table>
<thead>
<tr>
<th>Title/topic of guidance</th>
<th>Contact</th>
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</thead>
<tbody>
<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>
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<tr>
<td>Civil Money Penalties for Tobacco Retailers</td>
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**VII. Center for Veterinary Medicine (CVM)**

<table>
<thead>
<tr>
<th>Title of Guidance</th>
<th>Contact</th>
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</table>
### 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. Do.</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>Bridget Foltz, Office of Good Clinical Practices, Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993, 301–796–8345.</td>
</tr>
<tr>
<td>* Description of FDA’s inspectional process when the agency inspects the site of an investigator who is conducting a clinical study regulated by FDA.</td>
<td>Sara Goldkind, Office of Good Clinical Practices, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–8348.</td>
</tr>
<tr>
<td>* Information Sheet Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors—A Guide to Informed Consent <strong>Describes in detail basic and additional elements of informed consent and includes topics such as review of patient records, children as subjects, and subject participation in more than one study.</strong></td>
<td>Sara Goldkind, Office of Good Clinical Practices, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993.</td>
</tr>
<tr>
<td>* Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors—Exception From Informed Consent Requirements for Emergency Research <strong>This final guidance is intended to assist sponsors, clinical investigators, and IRBs in the development, conduct, and oversight of research involving FDA-regulated products (e.g., drugs, biological products, devices) in emergency settings when an exception from the informed consent requirements is requested under 21 CFR 50.24. In particular, the guidance clarifies FDA’s expectations related to planning and conducting community consultation and public disclosure activities, and the establishment of informed consent procedures to be used when feasible.</strong></td>
<td>Sara Goldkind, Office of Good Clinical Practices, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–8348.</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**