TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Item	Nunber of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
MedSun facilities participating in the electronic reporting of adverse events program	400	15	6,000	0.75	4,500
MedSun facilities' electronic responses to Public Health Questions (PHQs)	400	10	4,000	0.5	2,000
Total hours					6,500

[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.

[FR Doc. 2010–30583 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–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 Presley, 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.*

Dated: December 1, 2010.

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

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

Annual Guidance Agenda

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Submit 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 (HFA–305), 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: For general information regarding FDA's GGP policy contact: Lisa Helmanis, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., WO32, rm. 3216, Silver Spring, MD 20993–0002, 301–796–9135.

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)

Title/topic of guidance	Contact
CATEGORY—BLOOD AND BLOOD COMPONENTS: Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture Implementation of an Acceptable Abbreviated Donor History Questionnaire and Accompanying Materials for Use in Screening Frequent Donors of Blood and Blood Components Implementation of Acceptable Full-Length and Abbreviated Donor History Questionnaire and Accompanying Materials for Use in Screening Source Plasma Donors Use of Nucleic Acid Tests on Pooled and Individual Samples From Donors of Whole Blood and Blood Components (Including Recovered Plasma, Source Plasma and Source Leukocytes) to Adequately and Appropriately Reduce the Risk of Transmission of Hepatitis B Virus.	Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (HFM–40), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–1800.
CATEGORY—CELLULAR, TISSUE, AND GENE THERAPY: Preclinical Safety Assessment of Investigational Cellular, Gene Therapy, and Certain Related Products Characterization and Qualification of Cell Banks Used in the Production of Cellular and Gene Therapy Products Clinical Study Design for Early Phase Studies of Cellular and Gene Therapies.	Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (HFM–40), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–1800.
CATEGORY—OTHER Early Clinical Trials With Live Biotherapeutic Products: Chemistry, Manufacturing, and Control Information Bar Code Label Requirements—Question and Answer (Update for Vaccines).	Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (HFM–40), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–1800.

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
- 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

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
- 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 Supplements: Content and Inspectional

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
- Invasive Portable Blood Glucose Monitoring Systems
- Ovarian Adnexal Mass Surgery Referral Index
- Percutaneous Transluminal Coronary Angioplasty Catheters
- Suction Apparatus Device Intended for Negative Pressure Wound Therapy
- Tissue Adhesive With Adjunct Wound Closure Device
- Topical Oxygen Chamber for Extremities
- Transcranial Magnetic Stimulation Systems
- Yersinia
- Zonisamide and Lamotrigine Assays

Global Harmonization or Standards Related Guidances

- Application of IEC 60601–1 Third Edition in Premarket Applications
- Global Harmonization Task Force: Quality Management System; Process

Validation

- Global Harmonization Task Force: Postmarket Surveillance; National Competent Authority Report Exchange Criteria and Report Form

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)

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

Title/topic of guidance	Contact
New Dietary Ingredient Notifications	Constance Hardy, CFSAN (HFS–810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2375, *Constance.Hardy@fda.hhs.gov*.
Fish and Fishery Products Hazards and Controls Guidance (Edition 4)	Thomas Latt, CFSAN (HFS–325), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1423, *Thomas.Latt@fda.hhs.gov*.
Use of Dietary Guidance Statements	Blakeley Denkinger, CFSAN (HFS–830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, (301–436–2176), *Blakeley.Denkinger@fda.hhs.gov*.
Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 5).	Rhonda Kane, CFSAN (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1803, *Rhonda.Kane@fda.hhs.gov*.
Processing of Acidified Foods	Michael Mignogna, CFSAN (HFS–302), Food and Drug Administration, 5100 Paint Branch Pkwy, College Park, MD 20740, 301–436–1515, *Michael.Mignogna@fda.hhs.gov*.
Calorie Declaration	Vincent DeJesus, CFSAN (HFS–830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1774, *Vincent.Dejesus@fda.hhs.gov*.
Compliance Policy Guide Sec. 527.300 Dairy Products-Microbial Contaminants and Alkaline Phosphatase Activity (Compliance Policy Guide 7106.08).	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*.
Questions and Answers Regarding the Final Rule, Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation.	Nancy Bufano, CFSAN (HFS–315), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740., 301–436–1493, *Nancy.Bufano@fda.hhs.gov*.
Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation.	Nancy Bufano, CFSAN (HFS–315), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1493, *Nancy.Bufano@fda.hhs.gov*.

Title/topic of guidance	Contact
Positive Tests for Salmonella	Michael Kashtock, CFSAN (HFS–317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2022, *Michael.Kashtock@fda.hhs.gov*.
Compliance Policy Guide Sec. 550.050 Canned Ackee, Frozen Ackee, and Ackee Products—Adulteration With Hypoglycin A.	Joyce Saltzman, CFSAN (HFS–317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2041, *Joyce.Saltzman@fda.hhs.gov*.
Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients That are Color Additives.	Annette McCarthy, CFSAN (HFS–205), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1057, *Annette.McCarthy@fda.hhs.gov*.
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*.
The Safety of Imported Traditional Pottery Intended for Use With Food and the Improper Use of the Terms "Lead Free," and the Proper Identification of Ornamental and Decorative Ware.	Michael Kashtock, CFSAN (HFS–317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2022, *Michael.Kashtock@fda.hhs.gov*.

VI. Center for Tobacco Products (CTP)

Title/topic of guidance	Contact
Enforcement Policy Concerning Rotational Warning Plans for Smokeless Tobacco Products.	Office of Regulations, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–796–9250.
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	
Civil Money Penalties for Tobacco Retailers	

VII. Center for Veterinary Medicine (CVM)

Title of Guidance	Contact
Draft Guidance for Industry—Safe Animal Feeding	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, *phares.okelo@fda.hhs.gov.*
Draft Compliance Policy Guide—Glucosamine/Chondroitin Animal Products.	Paul Bachman, Center for Veterinary Medicine (HFV–230), Food and Drug Administration, 7519 Standish Pl., MPN–4, rm. 143, Rockville, MD 20855, 240–276–9225, *paul.bachman@fda.hhs.gov.*
Final Guidance for Industry—Comparability Protocols	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, *dennis.bensley@fda.hhs.gov.*
Draft Guidance for Industry—Fermentation Derived Intermediates, Drug Substances, and Related Drug Products for Veterinary Medicinal Use—Chemistry, Manufacturing, and Controls Information.	Michael Popek, Center for Veterinary Medicine (HFV–144), Food and Drug Administration, 7500 Standish Pl., MPN–2, rm. E335, Rockville, MD 20855, 240–276–8269, *michael.popek@fda.hhs.gov.*
Final Guidance for Industry—Drug Substance Chemistry, Manufacturing, and Controls Information.	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, *dennis.bensley@fda.hhs.gov.*
Draft Guidance for Industry—Active Controls in Studies to Demonstrate Effectiveness of a New Animal Drug for Use in Companion Animals.	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, *urvi.desai@fda.hhs.gov.*
Draft Guidance for Industry—Judicious Use of Antimicrobial Drugs in Food-Producing Animals.	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, *William.flynn@fda.hhs.gov.*

Title of Guidance	Contact
Draft Guidance for Industry—Active Controls in Studies to Demonstrate the Effectiveness of a New Drug for Use in Companion Animals.	Lisa Troutman, Center for Veterinary Medicine (HFV–116), Food and Drug Administration, 7500 Standish Pl., MPN–2, rm. N319, Rockville, MD 20855, 240–276–8322, *lisa.troutman@fda.hhs.gov.*
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.*
Draft Guidance for Industry—Updating Labeling of Certain Antimicrobial New Animal Drug Products for Use in the Feed or Water of Food-Producing Animals.	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, *William.flynn@fda.hhs.gov.*
Final Guidance for Industry—Bracketing and Matrixing Designs for Stability Testing of New Veterinary Drug Substances and Medicinal Products, VICH GL–45.	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, *dennis.bensley@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

Guidance title/TOPIC	OC Contact
• Classification of products as biological products, devices, and drugs	John Weiner, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave, Silver Spring, MD 20993 301–796–8941.
• Interpretation of the term "chemical action' in definition of device under section 201(h) of the Federal Food, Drug, and Cosmetic Act.	Do.
• Types of submissions for postapproval changes to combination products	Do.
• Information Sheet Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors—FDA Inspections of Clinical Investigators Describes FDA's inspectional process when the agency inspects the site of an investigator who is conducting a clinical study regulated by FDA.	Bridget Foltz, Office of Good Clinical Practices, Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993, 301–796–8348.
• Draft Information Sheet Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors—A Guide to Informed Consent 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.	Sara Goldkind (301–796–8342), Marsha Melvin (301–796–8345), Office of Good Clinical Practices, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993.
• Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors—Exception From Informed Consent Requirements for Emergency Research 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.	Sara Goldkind, Office of Good Clinical Practices, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–8348.

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, HHS.

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.