any person and will not operate to bind FDA or the public. Alternative methods may be used as long as they satisfy the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60–day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing a notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: How to Use E-mail to Submit a Protocol

Description: CVM may review protocols for safety and effectiveness studies of new animal drugs submitted by sponsors. The review of protocols facilitates the drug review and approval processes.

Protocols for nonclinical laboratory studies (safety studies) are required under 21 CFR 58.120. Protocols for effectiveness studies are required under § 514.117(b). The burden hours associated with preparing the protocols and appendices were reported and approved under OMB control number 0910–0119 for nonclinical laboratory studies and OMB control number 0910–0346 for adequate and well-controlled effectiveness studies. In this guidance document CVM is giving sponsors the option to submit a protocol as an attachment via the Internet.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Form FDA No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3536	190	0.52	100	0.20	20

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

The burden estimate was calculated as the time it takes to submit the protocol which consists of filling out the form and pressing the ''insertsubmission'' button, adding the password and pressing the ''mail to'' button, since the burden for protocol is already estimated under OMB control number 0910–0119 for nonclinical laboratory studies and OMB control number 0910–0346 for efficacy studies. The number of approved sponsors is 190, we routinely receive about 100 protocols a year, and the 12 minutes (.2 *60 minutes/hour) is an estimate based on talking to participating sponsors and our testing the use of the form.

IV. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments* or two hard copies of any written comments, except that individuals may submit one hard copy. Comments are to be identified with the docket number found in brackets in the heading of this document.

Written comments concerning the information collection requirements must be received by the Dockets Management Branch by June 3, 2003. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Electronic comments on the guidance document may be submitted on the Internet at *http://www.fda.gov/dockets/ecomments.* Once on the Internet site, select ''03D–0057 How to Use E-mail to Submit a Protocol'' and follow the directions. A copy of this document may be obtained on the Internet at *http://www.fda.gov/cvm.*

Dated: March 21, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03–8166 Filed 4–3–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N–0094]

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. FDA committed to publishing, on an annual basis, a list of possible topics for future guidance document development or revision during the next year, and seeking public comment on additional ideas for new guidance documents or revisions of existing ones. This commitment was made in FDA's September 2000 good guidance practices (GGPs) final rule, which sets forth the agency's policies and procedures for the development, issuance, and use of guidance documents. This list is intended to seek public comment on possible topics for guidance documents and possible revisions to existing guidance.

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

ADDRESSES: Submit written comments to the Dockets Management Branch (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 GGPs contact: Diane Sullivan-Ford, Office of Policy (HF–26), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3480. For information regarding specific topics or guidance, please see contact persons listed in the table in the **SUPPLEMENTARY INFORMATION** section.

SUPPLEMENTARY INFORMATION:

Background

In the **Federal Register** of September 19, 2000 (65 FR 56468), FDA published a final rule announcing its GGPs, which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents. The agency adopted the GGPs to ensure public involvement in the development of guidance documents and to enhance public understanding of the availability, nature, and legal effect of such guidance.

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 topic or documents are organized by the issuing center or office within FDA and are further grouped by topic categories. The agency's contact persons are listed for each guidance in the following table.

TITLE/TOPIC OF GUIDANCE	CONTACT
I. CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)	
CATEGORY—COMPLIANCE AND INSPECTION	
Guidance for Industry: Reprocessing, Reworking and Blending of Biological Drug Substances and Drug Products	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
Guidance for Industry: Process Validation Considerations for Biological Drug Substances and Biological Drug Products	Same as above (Do)
Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing	Do
Guidance for Industry: Design, Installation and Operation 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	Do
Guidance for Industry: Content and Format of the Warnings/Precautions Section of Labeling for Drugs and Biologics	Do
Guidance for Industry: Content and Format of the Pregnancy and Lactation Sections of Labeling for Drugs and Biologics	Do
Guidance for Industry and Reviewers: Measuring Patient Reported Outcomes to Support Medical Product Claims in Labeling and Advertising	Do
Compliance Program 7341.001 Inspections of Licensed Therapeutic Drug Products	Do
Compliance Program 7341.002—Inspection of Tissue Establishments	Do
Compliance Program 7342.001—Inspection of Licensed and Unlicensed Blood Banks, Brokers, Reference Laboratories, and Contractors	Do
Compliance Program 7342.002—Inspection of Source Plasma Establishments	Do
Compliance Program 7342.006—Inspection of Plasma Derivatives of Human Origin	Do
Compliance Program 7342.008—Inspections of Licensed Viral Marker Test Kits	Do

TITLE/TOPIC OF GUIDANCE	CONTACT
Compliance Program 7345.001—Inspection of Licensed Allergenic Products	Do
Compliance Program 7345.002—Inspection of Licensed Vaccines	Do
CATEGORY—THERAPEUTICS	
Submission of Information for the National Xenotransplantation Database (NXD)	Do
Guidance for Reviewers: Instructions and Template for Chemistry, Manufacturing, and Controls Reviewers of Human Gene Therapy Investigational New Drug Applications	Do
Guidance for Reviewers: Instructions and Template for Chemistry, Manufacturing, and Controls Reviewers of Human Somatic Cell Therapy Investigational New Drug Applications	Do
Potency Assays for Therapeutic Vaccines	Do
Good Review Practices—Track IV	Do
Submission of Information for Adverse Event and Annual Reports for Gene Therapy Investigational New Drug Applications	
Mechanisms of Regulation for Products Used in the Manufacture of Cellular Products	Do
Submission of Chemistry, Manufacturing, and Controls Information for a Therapeutic Recombinant DNA-Derived Product or a Monoclonal Antibody for In Vivo Use	Do
Submission of Chemistry, Manufacturing, and Controls Information for Synthetic Peptide Substances	Do
Submission of Chemistry, Manufacturing, and Controls Information and Establishment Description for Autologous Somatic Therapy Products	Do
CATEGORY—BLOOD AND BLOOD COMPONENTS	
Blood Establishment Software	Do
Apheresis Guidance	Do
Uniform Donor History Questionnaire	Do
Quality Control of Bacterial Contamination	Do
Content of Premarket Submissions (Instruments)	Do
Medication Deferrals	Do
Validation of Computer Crossmatch	Do
Blood Contact Materials	Do
Red Blood Cell Repositories	Do
Rapid Human Immunodeficiency Virus Tests	Do
Submission of Chemistry, Manufacturing, and Controls and Establishment Description Information for Human Plasma-Derived Biological Products, Animal Plasma or Serum-Derived Products Blood Donor Testing for Syphilis Format and Content of a Biologics License Application for Immune Globulin Intravenous Recommendations for Deferral of Donors of Vaccinated With Smallpox Nucleic Acid Testing for Human Immunodeficiency Virus and Hepatitis C Virus; Testing, Product Disposition, Donor Deferral and Reentry	Do
CATEGORY—VACCINES	
Guidance for Industry: Characterization and Qualification of Cell Substances and Viral Seeds Used to Produce Viral Vaccines	Do

TITLE/TOPIC OF GUIDANCE	CONTACT
Guidance for Industry: Preclinical Toxicity Studies for Prophylactic Vaccines	Do
Guidance for Industry: Immunization Human Plasma Donors to Obtain Source Plasma for Preparation of Specific Immune Globulins	Do
Guidance for Industry: Content and Format of Chemistry, Manufacturing, and Controls Information and Establishment Description Information for a Vaccine or Related Product	Do
Guidance for Industry on the Content and Format of Chemistry, Manufacturing, and Controls Information and Establishment Description Information for an Allergenic Extract or Allergen Patch Test	Do
CATEGORY—OTHER	
Providing Regulatory Submission in Electronic Format—Stability	Do
Environmental Assessment/National Environmental Policy Act	Do
Requests for Engagement of Independent Consultant	Do
Eligibility Determination for Donors of Human Cells, Tissue and Cellular and Tissue-Based Products (HCT/Ps)	Do
Filing and Application When the Applicant Protests a Refusal to File Action	Do
Guidance for Industry: Multi-Product Manufacturing With Spore-Forming Microorganisms	Do
II. CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)	
CATEGORY—PREMARKET REVIEW—PROCEDURAL	
Delegation of Investigational Device Exemption (Withdrawal)	Joanne R. Less, Center for Devices and Radiological Health (HFZ–403), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190
Overdue Investigational Device Exemption Annual Progress Report Procedures (Withdrawal)	Do
Humanitarian Device Exemptions (HDE) Regulation: Questions and Answers (Revised)	Do
Guidance for the Medical Device Industry on Premarket Approval Application Shell Development and Modular Review (Revised)	Thinh Nguyen, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186
Modifications to Devices Subject to Premarket Approval Application—The Premarket Approval Application Supplement Decision Making Process (Final)	Do
Real-Time Review Program for Premarket Approval Application (PMA) Supplements (Revised)	Do
Pre-Premarket Approval Application Meetings	Do
A New 510(k) Paradigm—Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications (Revised)	Heather Rosecrans, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190
Frequently Asked Questions on the New 510(k) Paradigm (Revised)	Do
New Section 513(f)(2)—Evaluation of Automatic Class III Designation (Revised)	Do
Implementation of Third Party Programs Under the Food and Drug Modernization Act of 1997 (Revised)	Ronald Parr, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–6597, ext. 109
Statistical Guidance on Reporting Results From Studies Evaluating Diagnostic Tests: Draft Guidance for Industry and FDA Reviewers	Kristen Meier, Center for Devices and Radiological Health (HFZ–542), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–827–4369

TITLE/TOPIC OF GUIDANCE	CONTACT
CATEGORY—PREMARKET REVIEW ANESTHESIOLOGY, DENTAL, INFECTION CONTROL, AND GENERAL HOSPITAL DEVICES	
Biological Indicator (Final)	Chiu S. Lin, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8913
Chemical Indicator (Draft)	Do
Medical Sterilization Packaging (Final)	Do
Antimicrobial Coated Medical Devices (Draft)	Do
Surgical Masks (Final)	Do
Surgical Drapes and Gowns (Draft)	Do
Disinfectants to Reprocess Hemodialyzer Machine and Water Treatment Systems (Draft)	Do
Medical Glove Expiration Dating (Final)	Do
Chemotherapy Glove (Draft)	Do
Intraoral Snoring and Sleep Apnea Devices (Final)	Kevin Mulry, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–5283, ext. 185
Sonography and Jaw Tracking (Final)	Mary S. Runner, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–5283
Precious Metal Dental Alloys	Mike Adjodha, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–5283
Base Dental Alloys	Do
Dental Curing Light	Do
Periodontal Membrane Guidance	Robert Betz, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–5283
Guidance for Bone Filling and Augmentation Devices	Pam Scott, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–5283
Cutaneous O_2 and CO_2 Monitors (Final)	Joanna Weitershausen, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8611
General Anesthesia Guidance Document	Do
Pulse Oximeter Guidance Document (Revised)	Do
Vascular Access Flush Devices	Patricia Cricenti, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1287, ext. 169
Needleless Injection Devices	Von Nakayama, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1287
CATEGORY—PREMARKET REVIEW FOR CARDIOVASCULAR DEVICES	
Intravascular Stents (Revised)	Ashley Boam, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8243
Percutaneous Transluminal Coronary Angioplasty Catheters, Class II Special Control Guidance	Do

TITLE/TOPIC OF GUIDANCE	CONTACT
Cardiovascular Intravascular Filters (Revised)	Elisa Harvey, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8262
Arrhythmia Detectors	Elias Mallis, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8517
Medical Device Labeling—Suggested Format and Content (Withdrawal)	Robert Gatling, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190, ext. 140
Class II Special Control Guidance Document: Extracorporeal Life Support Devices (Draft)	Dina J. Fleischer, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8517, ext. 176
CATEGORY—PREMARKET REVIEW FOR CLINICAL LABORATORY DEVICES	
Over-the-Counter (OTC) Drugs of Abuse	Arleen Pinkos, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1243
Glucose Test Systems	Pat Bernhardt, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1243
Automated Coagulation Devices	Valerie Dada, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1293
Analytical and Clinical Validation of Multiplex Tests for Heritable DNA Markers and/or Mutations	Elizabeth Mansfield and Michele Schoonmaker, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1293
Class II Special Controls Guidance Document: Specific Bacteriophage, Antibody Conjugates, and Antigens for Antibody Detection for *Bacillus anthracis* and *Yersinia pestis*	Roxanne Shively, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2096
Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems (Final)	Sally Selepak, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2096
Draft Guidance on In Vitro Diagnostic (IVD) Device Studies	Jean Toth-Allen, Center for Devices and Radiological Health (HFZ–312), Food and Drug Administration, 2904 Gaither Rd., Rockville, MD 20850, 301–594–4723, ext. 141
CATEGORY—PREMARKET REVIEW FOR GENERAL, RESTORATIVE AND NEUROLOGICAL DEVICES	
Guidance for Thermal Ablation Device 510(k)s; Draft Guidance for Industry and FDA	Binita Ashar, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1307
Class II Exempt Special Controls Guidance for Various Orthopedic Fixation Devices; Final Guidance for Industry	Hollace Rhodes, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2036
Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses	Peter Allen, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2036
Class II Special Controls Guidance Document: Surgical Suture	Anthony Watson, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090
Class II Special Controls Guidance Document: Processed Human Dura Mater (Draft)	Charles Durfor, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090
Class II Special Controls Guidance Document: Vascular and Neurological Embolization Devices (Draft)	Stephen Rhodes, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090

TITLE/TOPIC OF GUIDANCE	CONTACT
Guidance for Saline, Silicone Gel, and Alternative Breast Implants (Revised)	Samie Allen, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090
Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device (Final)	Nadine Sloan, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1296
Class II Special Controls Guidance Document: Transcutaneous Electrical Stimulator for Cosmetic Use (Draft)	Robert DeLuca, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1296
Class II Special Controls Guidance Document: Cutaneous Electrode (Draft)	Do
Class II Special Controls Guidance Document: Electroconductive Media (Draft)	Do
Class II Special Controls Guidance Document: Powered Muscle Stimulator for Muscle Conditioning (Draft)	Do
Class II Special Controls Guidance Document: Powered Muscle Stimulator for Rehabilitation (Draft)	Do
Class II Special Controls Guidance Document: Transcutaneous Electrical Nerve Stimulator for Pain Relief (Draft)	Do
Special Control Guidance for Premarket Notifications for Totally Implanted Spinal Cord Stimulators for Pain Relief (Withdrawal)	Kristen Bowsher, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1296
Guidance for Technical Reporting in the Submission of Research and Marketing Applications for Totally Implanted Spinal Cord Stimulators (Draft)	Do
CATEGORY—PREMARKET REVIEW FOR OPHTHALMIC AND ENT DEVICES	
Class II Special Controls Guidance Document: Rigid Gas Permeable (RGP) by Contact Lens Finishing Laboratories	James F. Saviola, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1744
Premarket Notification (510(k)) Guidance Document for Class II Daily Wear Contact Lenses (Revised)	Do
Class II Special Controls Guidance Document: Artificial Eye Care Products	Do
Class II Special Controls Guidance Document: Intraocular Gases for Retina Tamponade	Do
Retinal Implants: Guidance for Investigational Device Exemptions (IDE) and Premarket Approval (PMA) Applications (Draft)	Do
Guidance for Premarket Approval Applications of Class III Extended Wear Contact Lenses	Do
Guidance for Post Approval Studies of Class III Extended Wear Contact Lenses Worn Beyond Seven Continuous Nights	Do
Labeling Guidance for Ultraviolet Absorbing Contact Lenses	Do
Intraocular Lens Guidance Document	Donna R. Lochner, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2053
Refractive Implants Guidance Document	Do
Guidance Document for Keratomes and Keratome Blades	Everette T. Beers, Chief, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2018

TITLE/TOPIC OF GUIDANCE	CONTACT
Implantable Middle Ear Hearing Device (Final)	Eric C. Mann, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2018
Tinnitis Masking Devices	Do
Laryngoplastic Phonosurgery Devices	Do
Ear Plug Devices	Do
CATEGORY—PREMARKET REVIEW FOR REPRODUCTIVE, ABDOMINAL AND RADIOLOGICAL DEVICES	
Devices for Assisted Reproduction Technologies (ART)	Colin M. Pollard, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1180, ext. 115
Embolization Agents for Uterine Fibroid Embolization	Do
Condoms	Do
Menstrual Tampons	Do
Devices for Vacuum Assisted Delivery	Do
Device Systems for Endometrial Ablation	Do
Class II Special Controls Guidance Document: External Penile Rigidity Devices	Janine Morris, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2194, ext. 117
Guidance for the Treatment of Prostate Cancer	Do
Guidance for Urethral Stents	Do
Class II Special Controls Guidance for Home Uterine Activity Monitors (Revised)	Do
Ultrasound Coupling Gel	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
Diagnostic Ultrasound	Do
Cleaning and Disinfection of Radiological Devices	Do
Sheaths and Covers for Ultrasound Transducers	Do
Bone Sonometers (Revised)	Do
Class II Special Controls Guidance Document: Sorbent Hemoperfusion Systems (Draft) Bone Sonometers (Revised)	Carolyn Neuland, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1220, ext. 131
Content of Premarket Notification Submissions for Conventional and High Permeability Hemodialyzers, Hemoconcentrators, Hemofilters and Hemodiafilters (Revised)	Do
Guidance for the Content of Premarket Notifications for Hemodialysis Delivery Systems	Do
Automated Blood Cell Separators for Therapeutic Purposes (Draft)	Do
Blood Access Devices for Hemodialysis (Draft)	Do
CATEGORY—COMPLIANCE AND INSPECTIONS	
Impact Resistance Lenses: Questions and Answers	Walter Snesko, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–6597, ext. 120
Medical Device Quality Systems Manual for Small Entities (Update)	Joseph Puleo, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–6597, ext. 116

TITLE/TOPIC OF GUIDANCE	CONTACT
Medical Glove Guidance Manual (Update)	Arthur Yellin, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–6597, ext. 146
Draft Guidance on Cabinet X-ray Systems Performance Specifications	Daniel Kassidy, Center for Devices and Radiological Health (HFZ–342), Food and Drug Administration, 2904 Gaither Rd., Rockville, MD 20850, 301–594–4654, ext. 141
Final Guidance on Civil Money Penalties	Casper Uldriks, Center for Devices and Radiological Health (HFZ–300), Food and Drug Administration, 2904 Gaither Rd., Rockville, MD 20850, 301–594–4692
Draft Guidance on the Reports of Corrections and Removals Regulation	Do
Draft Guidance for Field Clinical Engineers	Marian Surge, Center for Devices and Radiological Health (HFZ–300), Food and Drug Administration, 2904 Gaither Rd., Rockville, MD 20850, 301–594–4720, ext. 139
Draft Guidance on Good Laboratory Practice (GLP) for Nonclinical Laboratory Studies	Rodney Allnutt, Center for Devices and Radiological Health (HFZ–300), Food and Drug Administration, 2904 Gaither Rd., Rockville, MD 20850, 301–594–4723, ext. 140
Draft Guidance on the Submission of Abbreviated Reports on Bone Densitometer Devices Utilizing Electronic Product Radiation	Tom Jakub, Center for Devices and Radiological Health (HFZ–333), Food and Drug Administration, 2904 Gaither Rd., Rockville, MD 20850, 301–594–4591, ext. 151
Implementation of the Third Party Domestic Quality System Program	Ronald Parr, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–6597, ext. 109
CATEGORY: CONSUMER INFORMATION	
Breast Implants: An Information Update	Nancy Leonard, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–6597, ext. 141
Modifications and Additions to the Policy Guidance Help System #6	Charles A. Finder, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–827–0009
Modifications and Additions to the Policy Guidance Help System #7	Do
Modifications and Additions to the Policy Guidance Help System #8	Do
Modifications and Additions to the Policy Guidance Help System #9	Do
Modifications and Additions to the Policy Guidance Help System #10	Do
CATEGORY—MEDICAL DEVICE REPORTING	
Needlesticks; Medical Device Reporting Guidance for User Facilities, Manufacturers, and Importers	Sharon Kapsch, Center for Devices and Radiological Health (HFZ–533), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–827–2982
CATEGORY—POSTMARKET SURVEILLANCE	
Preparing a Postmarket Surveillance Plan: Guidance for Manufacturers	Laura Alonge, Center for Devices and Radiological Health (HFZ–510), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3060
CATEGORY—OTHER	
Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment: For Industry and Health Care Facilities	Jay A. Rachlin, Center for Devices and Radiological Health (HFZ–230), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3174
III. CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)	
CATEGORY—ADVERTISING	
Advertising and Labeling of Treatment Investigational New Drug Application Protocols	Nancy E. Derr, Center for Drug Evaluation and Research (HFD–5), Food and Drug Administration, 1451 Rockville Pike, Rockville, MD 20852, 301–594–5400

TITLE/TOPIC OF GUIDANCE	CONTACT
Patient Reported Outcomes	Do
Promotion of Combination Oral Contraceptive Products	Do
CATEGORY—BIOPHARMACEUTICS	
Clozapine Tablets—In Vivo Bioequivalence and In Vitro Dissolution Testing	Do
CATEGORY—CHEMISTRY	
Documentation for Antibiotics and Other Cellular Metabolites Produced by Microorganisms Modified Using Recombinant DNA Technology	Do
Drug Products: Chemistry, Manufacturing, and Control Documentation	Do
Drug Substance: Chemistry, Manufacturing, and Control Documentation	Do
CATEGORY—CLINICAL/MEDICAL	
Acne Vulgaris	Do
Analgesics	Do
Clinical Development Programs for Metered Dose Inhaler and Dry Powder Inhalers Products—Revised	Do
Clinical Evaluation of Drugs for the Treatment of Acute Coronary Syndrome	Do
Clinical Evaluation of Combination Estrogen/Progestin-Containing Drug Products Used for Hormone Replacement Therapy in Postmenopausal Women—Revised	Do
Clinical Evaluation of Drugs for Neuropathic Pain	Do
Clinical Evaluation of Drugs for the Treatment of Heart Failure	Do
Collection and Use of Race and Ethnicity Data in Clinical Trials for FDA Regulated Products	Do
Development of New Opiate Formulations	Do
Developing Antiviral Drug for the Mitigation of Complication Associated Vaccine Immunization	Do
Developing Antiviral Drugs for the Treatment of Smallpox	Do
Drug-Coated Cardiovascular Stents	Do
Evaluation of New Treatments for Diabetes Mellitus	Do
Gingivitis	Do
Safety Review of Clinical Data	Do
CATEGORY—CLINICAL/PHARMACOLOGY	Do
Content and Format of the Clinical Pharmacology Section	Do
Content and Format of the Warnings and Precautions, Contradictions and Boxed Warning Sections of Prescription Drugs	Do
Immediate Release to Modified Release Dosage Forms	Do
In Vitro Drug Metabolism/Drug Interaction—Guidance for Reviewers	Do
CATEGORY—COMPLIANCE	
Current Good Manufacturing Practices for Compressed Medical Gases—Revised	Do
Maintaining Adequate and Accurate Records During Clinical Investigations	Do

TITLE/TOPIC OF GUIDANCE	CONTACT
National Drug Code Number and Drug Product Labels	Do
Describing How Positron Emission Tomography Drug Products May Comply With New Current Good Manufacturing Process Requirements—Revised	Do
Sterile Drug Products Produced by Aseptic Processing	Do
CATEGORY—ELECTRONIC SUBMISSIONS	
Providing Electronic Submissions to the Division of Drug Marketing, Advertising, and Communications	Do
Providing Electronic Submissions in Electronic Format: Marketing Applications and Related Submissions	
Providing Regulatory Submissions in Electronic Format—Annual Reports for Approved New Drug Applications	Do
Providing Regulatory Submissions in Electronic Format—General Considerations	Do
Providing Regulatory Submissions in Electronic Format: Postmarketing Periodic Adverse Drug Experience Report	Do
Scope and Implementation of 21 CFR Part 11: Archiving	Do
Scope and Implementation of 21 CFR Part 11: Audit Trails	Do
Standards for Clinical Data Submissions	Do
CATEGORY—GENERICS	
Bioequivalence Studies With Clinical Endpoints for Vaginal Antifungal Drug Products	Do
Chemistry, Manufacturing, and Controls Documentation Unique to Radiopharmaceuticals Submitted in Abbreviated New Drug Applications	Do
Generic Drug Labeling When Pediatric Labeling Information Has Been Added to the Innovator Labeling	Do
CATEGORY—GOOD REVIEW PRACTICES	
General Clinical Review Template	Do
CATEGORY—INVESTIGATIONAL NEW DRUG APPLICATIONS	
Consumer Product Safety Commission—Tamper Resistant Packaging for Investigational New Drug Applications	Do
Pediatric Safety and Efficacy Data in Investigational New Drug Applications	Do
CATEGORY—LABELING	
Drug Names and Dosage Forms	Do
Pregnancy Labeling Revisions	Do
Submitting Proprietary Names for Evaluation	Do
CATEGORY–OVER–THE–COUNTER	
Actual Use Trials	Do
Labeling Comprehension Studies for Over-the-Counter Drug Products	Do
Labeling for Over-the-Counter Human Drug Products	Do
Labeling Over-the-Counter Human Drug Products; Questions and Answers	Do
Time and Extent Applications	Do

TITLE/TOPIC OF GUIDANCE	CONTACT
CATEGORY—PRESCRIPTION DRUG USER FEE AMENDMENTS OF 2002	
Continuous Marketing Application: Pilot 1—Reviewable Units for Fast Track Products Under the Prescription Drug User Fee Amendments of 2002	Do
Continuous Marketing Application: Pilot 2—Scientific Feedback and Interactions During Drug Development of Fast Track Products Under the Prescription Drug User Fee Amendments of 2002	Do
First Cycle Review Performance: Good Review Management Principles	Do
CATEGORY—PHARMACOLOGY/TOXICOLOGY	
Drug-Induced Vasculitis in Nonclinical Studies	Do
Estimating the Safe Starting Dose for Clinical Trials of Therapeutics in Adult Healthy Volunteers	Do
Immunotoxicology Evaluation of Investigational New Drug Applications	Do
Nonclinical Safety Evaluation of Pediatric Drug Products	Do
CATEGORY—PROCEDURAL	
Assessment of Abuse Potential of Drugs	Do
Dispute Resolution Involving Pediatric Labeling	Do
Exocrine Pancreatic Insufficiency Drug Products—New Drug Application Requirements	Do
Process for Contracts and Written Requests Under the Best Pharmaceuticals for Children Act	Do
Qualifying for Pediatric Exclusivity Under Section 505a of the Federal Food, Drug, and Cosmetic Act	Do
Reports on the Status of Postmarketing Studies—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997	Do
IV. CENTER FOOD SAFETY AND APPLIED NUTRITION (CFSAN)	
CATEGORY: OFFICE OF PLANTS, DAIRY FOODS, AND BEVERAGES	
Final Guidance on Juice Transport	Amy Green, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2025
Draft Guidance on Use of Food Allergen Test Kits	Jennifer Burnham, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2030
Draft Guidance to Harmonize U.S. Aflatoxin Levels in Peanuts With Codex Levels	Lauren Posnick, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1639
Compliance Policy Guide for Lead Levels in Food Based on Levels Adopted by Codex	Do
Additional Questions and Answers on Juice Hazard Analysis and Critical Control Point	Samir Assar, Center for Food Safety and Applied Nutrition (HFS–235), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1636
Update the Pesticide Compliance Policy Guide to Bring It in Line With the Food Quality Protection Act of 1996 and Changes in Pesticide Programs and Policy Over the Past Few Years	Mike Kashtock, Center for Food Safety and Applied Nutrition (HFS–305), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2022
Guidance for Industry: Standardized Training Curriculum for Application of Hazard Analysis and Critical Control Point Principles to Juice Processing	Do

TITLE/TOPIC OF GUIDANCE	CONTACT
Listeria monocytogenes Draft Guidance	Andreas Keller, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2029
Fresh-Cut Produce Draft Guidance	Julie Schrimpf, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. 301–436–2031
Small Entities Guide for the Juice Hazard Analysis and Critical Control Point Regulations	Amy Green, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2025
Juice Hazard Analysis and Critical Control Point Compliance Program	Dale Wohlers, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2029
Final Compliance Policy Guide 555.600 Filth From Insects, Rodents, and Other Pests in Food	Douglas Park, Center for Food Safety and Applied Nutrition (HFS–345), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2401
Draft Compliance Policy Guide 555.525—Fly Infestations	Do
Draft Compliance Policy Guide 555.500—Classification of Establishment Inspection Report	Do
Draft Compliance Policy Guide 580.100—Pest Infestations	Do
Rescind Compliance Policy Guide 527.600 Use of Dichlorvos Strips in Milk Houses and Milk Rooms	Esther Lazar, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1485
Rescind Compliance Policy Guide 527.450 Milk and Milk Products Containing Penicillin	Do
Update Compliance Policy Guide 527.400 Whole Milk, Low Fat Milk, Skim Milk—Aflatoxin M1	Do
Update Compliance Policy Guide 527.300 Pathogens in Dairy Products	Do
Update Compliance Policy Guide 527.200 Cheese and Cheese Products—Adulteration With Filth	Do
New Compliance Policy Guide on Vitamins A and D in Milk Products	Monica Metz, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2041
New Compliance Policy Guide on Vat Pasteurization	Do
New Compliance Policy Guide on High Temperature/Short Time Pasteurization	Do
New Compliance Policy Guide on Soft Cheeses	Do
We may either update or rescind the following:	Do
Compliance Policy Guide 527.250 Cheese Misbranding Due to Moisture and Fat	To be determined (TBD)
Compliance Policy Guide 527.500 Malted Milk	TBD
Compliance Policy Guide 527.100 Butter—Adulteration Involving Insufficient Fat Content	TBD
Compliance Policy Guide 527.250 Cheese and Cheese Products: Misbranding Involving Net Weights	TBD
CATEGORY: OFFICE OF FIELD PROGRAMS	
Allergen Questions and Answers	Donald Kautter, Center for Food Safety and Applied Nutrition (HFS–615), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1629

TITLE/TOPIC OF GUIDANCE	CONTACT
Allergen Recall Classification Guidance	Do
Juice Hazard Analysis and Critical Control Point Regulator Guide and Training	Do
Spice Reconditioning Inspection Guidance	Do
Spice Reconditioning Industry Guidance	Do
Interstate Travel Handbooks on Sanitation of: • Railroad Servicing Areas • Vessels in Operation • Vessel Construction • Vessel Watering Points • Buses • Airlines Railroad Passenger Cars	Do (pending Office of Field Programs reorganization)
International Travel Program—Guide to Inspections of Interstate Carriers and Support Facilities	Do
Compliance Programs for Milk, Retail Food, and Molluscan Shellfish	Faye Feldstein, Center for Food Safety and Applied Nutrition (HFS–615), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1564
Electronic Inspection System With Model Code Database, Model Inspection Form, Users' Manual	Do
Food Recovery Guidelines	Do
Permanent Outdoor Cooking Guidelines	Do
Temporary Food Establishments Guidance	Do
Voluntary National Retail Regulatory Program Standards and Annexes	Do
Program Standards Clearinghouse Questions and Answers	Do
Conference Position Papers (Shellfish and Milk for 2003)	Do
Food Code Supplements	Do
Center for Food Safety and Applied Nutrition Response to Conference for Food Protection Recommendations	Do
Food Code Interpretations; Questions and Answers	Do
Opinion Letters in Response to Correspondence	Do
Backgrounders	Do
Program Information Manual Additions and Revised	Do
Letters to Industry Alerting Them to a Commodity Problem, Emerging Situations, and How to Respond	Do
Managing Food Safety: A Regulator's Guide for Applying Hazard Analysis and Critical Control Point Principles to Risk-Based Retail and Food Service Inspections	Do
Managing Food Safety: A Guide for the Voluntary Use of Hazard Analysis and Critical Control Point Principles for Operators of Food Service and Retail Establishments	Do
Combined Pasteurized Milk and Dry Milk Ordinance	Do
Annual Report Regarding State Program Evaluations (Milk and Shellfish)	Do
Rescind Guidance Regarding Blending of Milk Products (Compliance Policy Guide?)	Office of Plant and Dairy Foods and Beverages
Compliance Policy Guide—Criteria for Refusal for Entry of Food Products From Firms That Refuse to Allow Inspections	Do

TITLE/TOPIC OF GUIDANCE	CONTACT
Listeria Action Plan	Donald Kautter, Center for Food Safety and Applied Nutrition (HFS–615), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1629
Food Registration Implementation	Do
Molluscan Shellfish: Guide for the Control of Molluscan Shellfish • Model Ordinance • Public Health Reasons and Program Requirements for State Administrative Procedures; Laboratory Procedures; Growing Area Survey and Classification; Controlled Relaying; Patrol of Shellfish Harvesting Areas; Control of Harvesting; Aquaculture; Harvesting, Handling and Shipping Shellfish; Shellfish Processing • Guidance Documents on Growing Areas, Harvesting, Processing, and Distribution • Suggested Forms • Manual of FDA Interpretations of Model Ordinance Requirements	Faye Feldstein, Center for Food Safety and Applied Nutrition (HFS–615), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1564
Program No. 7303.003: Import Acidified and Low Acid Canned Foods Program	TBD
Program No. 7303.037: Domestic and Imported Cheese and Cheese Products	TBD
Program No. 7303.039: National Drug Residue Milk Monitoring Program	TBD
Program No. 7303.803: Domestic Food Safety	TBD
Program No. 7303.803A: Domestic Acidified and Low-Acid Canned Foods	TBD
Program No. 7303.819: Import Foods—General Program	TBD
Program No. 7303.842: Domestic Fish and Fishery Products Inspection Program (Fiscal Years 2001 and 2002)	TBD
Program No. 7303.844: Import Seafood Products	TBD
Program No. 7304.004: Pesticides and Industrial Chemicals in Domestic Foods	TBD
Program No. 7304.016: Pesticides and Industrial Chemicals in Imported Foods	TBD
Program No. 7304.018: Chemotherapeutic in Seafood Compliance Program	TBD
Program No. 7304.019: Toxic Elements in Foods and Foodware Import and Domestic	TBD
Program No. 7304.839: Total Diet Study	TBD
Program No. 7304.803: Domestic Food Safety Program—Primary Project Filed in Chapter 3	TBD
Program No. 7307.001: Mycotoxins in Domestic Foods	TBD
Program No. 7307.002: Mycotoxins in Imported Foods	TBD
Program No.7309.006: Imported Foods and Color Additives	TBD
Program No. 7309.803: Domestic Food Safety Program—Primary Project Filed in Chapter 3)	TBD
Program No. 7309.808: Good Laboratory Practice (Nonclinical Laboratories)—Primary Project Filed in Chapter 48	TBD
Program No. 7309.809: Institutional Review Board Program—Primary Project Filed in Chapter 48	TBD

TITLE/TOPIC OF GUIDANCE	CONTACT
Program No. 7309.810: Sponsors, Contract Research Organizations and Monitors—Compliance With Regulations—Primary Project Filed in Chapter 48	TBD
Program No. 7309.811: Clinical Investigators—Primary Project Filed in Chapter 48	TBD
Program No. 7318.002: Retail Food Protection—State	TBD
Program No. 7318.003: Milk Safety Program	TBD
Program No. 7318.004: Molluscan Shellfish Evaluation	TBD
Program No. 7318.029: Interstate Travel Program	TBD
Program No. 7321.002: Medical Foods—Import and Domestic	TBD
Program No. 7321.005: Domestic Nutrition Labeling and Education Act of 1990, Nutrient Sample Analysis, General Food Labeling Program	TBD
Program No. 7321.006: Infant Formula Program—Import and Domestic	TBD
Program No. 7321.007: Nutrition Labeling and Education Act of 1990 and Enforcement—Imports	TBD
Program No. 7321.008: Dietary Supplements—Imports and Domestic	TBD
Program No. 7329.001: Domestic Cosmetics Program	TBD
Program No. 7329.002: Imported Cosmetics Compliance Program	TBD
CATEGORY: OFFICE OF NUTRITION, PRODUCTS, LABELING AND DIETARY SUPPLEMENTS	
Soy Formulas and Preterm Infants—Draft Guidance	Shawne Suggs-Anderson, Center for Food Safety and Applied Nutrition (HFS–831), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1783
Petition Process for Requesting Labeling of Foods That Have Been Treated With Irradiation—Final Guidance published October 7, 2002	Loretta Carey, Center for Food Safety and Applied Nutrition (HFS–822), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2371
Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering—Final Guidance	Cataline Ferre-Hockensmith, Center for Food Safety and Applied Nutrition (HFS–822), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2371
Compliance Programs	John Foret, Center for Food Safety and Applied Nutrition (HFS–810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1761
Summary of Regulatory Requirements for Dietary Supplements	Robert Moore, Center for Food Safety and Applied Nutrition (HFS–811), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1441
Dietary Supplement Labeling Guide	Do
CATEGORY: OFFICE FOOD ADDITIVE AND SAFETY	
Points to Consider for the Use of Recycled Plastics in Food Packaging: Chemistry Considerations	Kristina Paquette, Center for Food Safety and Applied Nutrition (HFS–275), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 202–436–3020
Guidance for Industry: Testing Protocols for Determining Exposure to Radiolysis Products From Packaging Materials Irradiated in Contact With Food	Do
Revised of Four Chapters of ''Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food'' (Redbook 2000)	Carolyn Young, Center for Food Safety and Applied Nutrition (HFS–275), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 202–418–3059

TITLE/TOPIC OF GUIDANCE	CONTACT
Guidance to Industry: Evaluation of Allergenicity of Proteins Introduced into Bioengineered Foods	Kathleen Jones, Center for Food Safety and Applied Nutrition (HFS–013), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1856. Guidance document reassigned with Kathleen Jones Office of Regulation and Policy (HFS–013)
Preparing a Color Additive Petition for Submission to the Center for Food Safety and Applied Nutrition for Color Additives Used in or on Contact Lenses	Judy Kidwell, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 202–418–3354
Compliance Policy Guideline on Chloropropanols in Soy Sauces and Hydrolyzed Vegetable Protein	Do
Guidance for Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submissions to the Center for Food Safety and Applied Nutrition	Layla Batarseh, Center for Food Safety and Applied Nutrition (HFS–245), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 202–418–3016
Guidance for Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submissions to the Center for Food Safety and Applied Nutrition (Appendix D)	Do
Guidance for Industry: Submission of Food Contact Notifications in Electronic Format	Ken McAdams, Center for Food Safety and Applied Nutrition (HFS–205), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 202–418–3392
Submission of Premarket Biotechnology Notices (PBNs) to FDA's Office of Food Addictive Safety—Electronic Copies in Portable Document Format (PDF)	Linda Kahl, Center for Food Safety and Applied Nutrition (HFS–255) Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 202–418–3101
Submission of Premarket Biotechnology Notices (PBNs) to FDA's Office of Food Addictive Safety—Electronic Copies in Hypertest Markup Language (HTML)	Do
Providing Food and Color Additive Petitions in Electronic Format	Do
Guidances Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Title III, Subtitle A	
CATEGORY: OFFICE OF COSMETICS AND COLORS	
Labeling for Topically Applied Cosmetic Products Containing Alpha Hydroxy Acids as Ingredients—Draft Guidance	Julie Barrows, Center for Food Safety and Applied Nutrition (HFS–105), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 202–418–3407
Cosmetics Handbook for Industry—Draft Guidance	Beth Meyers, Center for Food Safety and Applied Nutrition (HFS–105), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 202–418–3174
Strategy for Enforcement of 21 CFR 740.10: Required Warning Statement for Cosmetics With Insufficient Data to Substantiate Safety—Draft Guidance	Do
V. CENTER FOR VETERINARY MEDICINE (CVM)	
CATEGORY—HUMAN FOOD SAFETY	
Evaluating the Safety of Antimicrobial New Animal Drugs With Regard to Their Microbiological Effects on Bacteria of Human Health Concern	William Flynn, Center for Veterinary Medicine (HFV–2), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–4514
Mass Spectroscopy Spectrometry for Confirmation of the Identity of Drug Residues	David Heller, Center for Veterinary Medicine (HFV–511), Food and Drug Administration, 8401 Muirkirk Rd., Beltsville, MD 20855, 301–827–8156
Assessment of the Effects of Antimicrobial Drug Residues From Food of Animal Origin on the Human Intestinal Flora	Haydee Fernandez, Center for Veterinary Medicine (HFV–153), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6981
Studies to Evaluate the Utility of Anti-Salmonella Chemical Food Additives in Feed	Henry Ekperigin, Center for Veterinary Medicine (HFV–222), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0174
CATEGORY—NEW ANIMAL DRUG APPLICATIONS	

TITLE/TOPIC OF GUIDANCE	CONTACT
Development of Supplemental Applications for Approved New Animal Drugs (Section 403(b) of the Food and Drug Administration Modernization Act of 1997)	Marilyn Martinez, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7577
Administrative New Animal Drug Application Process	Gail Schmerfeld, Center for Veterinary Medicine (HFV–112), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0205
CATEGORY—LABELING	
Manufacture and Labeling of Raw Meat Diets for Consumption by Dogs, Cats, and Captive Non-Companion Animal Carnivores and Omnivores	William Burkholder, Center for Veterinary Medicine (HFV–228), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0179
Labeling and Professional Flexible Labeling	Douglass Oeller, Center for Veterinary Medicine (HFV–112), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0131
CATEGORY—TARGET ANIMAL SAFETY	
New Drug Dosage or Dosage Range Characterization	Gail Schmerfeld, Center for Veterinary Medicine (HFV–112), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0205
Use of Field Studies to Demonstrate the Effectiveness of a New Animal Drug	Steven Vaughn and Gail Schmerfeld, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7584
CATEGORY—STATUTORY REQUIREMENTS	
Dispute Resolution—Food and Drug Administration Modernization Act of 1997	Marcia Larkins, Center for Veterinary Medicine (HFV–1), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–4535
CATEGORY—INTERNATIONAL HARMONIZATION	
Guidance GL27 International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products	William Flynn, Center for Veterinary Medicine (HFV–2), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–4514
VI. OFFICE OF THE COMMISSIONER, OFFICE FOR GOOD CLINICAL PRACTICE (OGCP)	
CATEGORY—GOOD CLINICAL PRACTICE; GUIDANCE FOR INSTITUTIONAL REVIEW BOARDS AND CLINICAL INVESTIGATORS	
Cooperative Arrangements for Institutional Review Board's Review of Research	Bonnie M. Lee, Office of the Commissioner, Office for Good Clinical Practice (HF–34), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3340
Institutional Review Board's Review of Research Conducted at Other Sites	Do
Continuing Review After Study Approval	Do
Dates of Continuing Review	Do
Interactions Among FDA, Sponsor, Investigator, and Institutional Review Board	Do
Acceptance of Clinical Studies Conducted Outside the United States	Do
Charging for Investigational Products	Do
Recruiting Study Subjects	Do
Payment to Research Subjects	Do
Screening Tests Prior to Study Enrollment	Do
A Guide to Informed Consent	Do
Use of Investigational Products When Subjects Enter a Second Institution	Do

TITLE/TOPIC OF GUIDANCE	CONTACT
Personal Importation of and Use of Drug Products Not Approved in the United States	Do
Investigational Use of Marketed Drugs, Biologics, and Medical Devices	Do
Emergency Use: Exceptions From the Requirements for Institutional Review Board (IRB) Review and Informed Consent	Do
Emergency Use of an Investigational Drug or Biologic Under 21 CFR Part 312	Do
Expanded Access of Investigational Drugs	Do
Waiver of Institutional Review Board Requirements for Drug and Biologic Studies	Do
Drug Study Designs	Do
Evaluation of Gender Differences in Clinical Investigations	Do
Medical Devices 21 CFR Part 812	Do
Significant Risk and Nonsignificant Risk Medical Device Studies	Do
Emergency Use of Unapproved Medical Devices	Do
FDA Institutional Review Board Inspections	Do
Clinical Investigator Regulatory Sanctions	Do
Recordkeeping in Clinical Investigations	Do
Significant Differences in FDA's and the Department of Health and Human Services' Regulations	Do
A Self-Evaluation Checklist for Institutional Review Boards	Do
VII. OFFICE OF REGULATORY AFFAIRS (ORA)	
INSPECTION GUIDES	
Techniques for Detecting False Data During Bioresearch Monitoring Inspections	Gerald Miller, Division of Field Investigations (HFC–130), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5655
Guide to Inspections of Bulk Pharmaceutical Chemicals	Do
Guide to International Inspections and Travel	Rebecca Hackett, Division of Field Investigations, (HFC–130), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD, 20857, 301–827–3777
Guide to Produce Farm Investigations	Ellen Morrison, Emergency Operations (HFC–160), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5660

Dated: March 28, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03D–0093]

Small Entity Compliance Guide: ''Juice HACCP''; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a small entity compliance guide (SECG) for a final rule published in the **Federal Register** of January 19, 2001, entitled ''Hazard Analysis and Critical Control Point (HACCP); Procedures for the Safe and Sanitary Processing and Importing of Juice.'' This SECG, entitled ''Juice HACCP,'' is intended to set forth in plain language the requirements of that final rule and to help small businesses understand the regulation.

DATES: Submit written or electronic comments on the SECG at any time.

ADDRESSES: Submit written comments concerning this SECG to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers