intestinal tract following exposure to the antimicrobial new animal drug (resistance), and (2) changes in the number of enteric bacteria in the animal's intestinal tract that cause human illness (pathogen load).

The discussion paper that is the subject of this notice is the second step of the agency's consideration of these issues. It augments the draft guidance made available in November 1998 by setting out a conceptual risk-based framework for evaluating the microbial safety (relating to human health impact) of antimicrobial new animal drugs intended for use in food-producing animals. FDA is making the discussion paper available to the public in order to initiate discussions with the scientific community and other interested parties on the agency's thinking about appropriate underlying concepts to be used to develop policies that are protective of the public health. The agency is seeking comment from the public in two areas. The first is whether the concepts set out in this document, if implemented, will accomplish the goal of protecting the public health by ensuring that significant human antimicrobial therapies are not lost as a result of use of antimicrobial new animal drugs in food-producing animals, while providing for the safe use of antimicrobials in food-producing animals. The second is to obtain input on important areas of scientific complexity outlined in the discussion paper.

This will not be the only opportunity for public comment on these issues. The agency intends to solicit further public comments at the next meeting of FDA's Veterinary Medicine Advisory Committee in Rockville, MD, which is scheduled to be held on January 25 and 26, 1999. Also, comments regarding the draft guidance entitled ''Guidance for Industry: Evaluation of the Human Health Impact of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals'' may be submitted at any time.

II. Comments

Interested persons may, on or before April 6, 1999, submit to the Dockets Management Branch (address above) written comments regarding this discussion paper. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the discussion paper and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the discussion paper using the World Wide Web (WWW). For WWW access, connect to CVM at ''http://www.fda.gov/cvm''.

Dated: December 30, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–34842 Filed 12–31–98; 12:04 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0046]

Quarterly List of Guidance Documents at the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a quarterly update of all guidance documents issued and withdrawn since the compilation of the quarterly list that published on July 6, 1998. FDA committed to publishing quarterly updates in its February 1997 ''Good Guidance Practices'' (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents. This list is intended to inform the public of the existence and availability of guidance documents issued during this quarter. This list also includes some guidance documents that were inadvertently not included on previously published lists.

DATES: General comments on this list and on agency guidance documents are welcome 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. Information on where to obtain single copies of listed guidance documents is provided for each agency center individually in the specific center's list of guidance documents.

FOR FURTHER INFORMATION CONTACT: Lisa L. Barclay, Office of Policy (HF–22), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 27, 1997 (62 FR 8961), FDA published a notice announcing its ''Good Guidance Practices'' (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents. The agency adopted the GGP's 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 publish an annual comprehensive list of guidance documents and quarterly **Federal Register** notices that list all guidance documents that were issued and withdrawn during that quarter, including ''Level 2'' guidance documents. The following list of guidance documents represents all guidances issued or withdrawn by FDA since the compilation of the July 6, 1998 (63 FR 36413) quarterly list and any guidance documents inadvertently not included on previously published lists. The guidance documents are organized by the issuing Center or Office within FDA, and are further grouped by the intended users or regulatory activities to which they pertain. Dates provided in the following list refer to the date of issuance or, where applicable, the date of last revision of the document. Document numbers are provided where available.

II. Guidance Documents Issued by the Center for Biologics Evaluation and Research (CBER)

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Draft Guidance for Industry: Manufacturing, Processing or Holding Active Pharmaceutical Ingredients	March 1998	FDA Regulated Industry	Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 1–800–835–4709 or 301–827–1800, FAX Information System: 1–888–CBER–FAX (within U.S.)or 301–827–3844 (outside U.S. and local to Rockville, MD). Internet access: http://www.fda.gov/cber
Draft Guidance for Industry: Instructions for Submitting Electronic Lot Release Protocols to the Center for Biologics Evaluation and Research	May 1998	Do	Do
Draft Guidance for Industry: Pilot Program for Electronic Investigational New Drug (eIND) Applications for Biological Products	May 1998	Do	Do
Draft Guidance for Industry: Electronic Submissions of Case Report Forms (CRF's), Case Report Tabulations (CRT's) and Data to the Center for Biologics Evaluation and Research	May 1998	Do	Do
Draft Guidance for Industry: Electronic Submissions of a Biologics License Application (BLA) or Product License Application (PLA)/Establishment License Application (ELA) to the Center for Biologics Evaluation and Research	May 1998	Do	Do
Guidance for Industry: Submitting and Reviewing Complete Responses to Clinical Holds	May 1998	Do	Do
Guidance for Industry: Classifying Resubmissions in Response to Action Letters	May 1998	Do	Do
Guidance for Industry: Pharmacokinetics in Patients with Impaired Renal Function—Study Design, Data Analysis and Impact on Dosing and Labeling	May 1998	Do	Do
Guidance for Industry: Standards for the Prompt Review of Efficacy Supplements, Including Priority Efficacy Supplements	May 1998	Do	Do
Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drugs and Biological Products	May 1998	Do	Do
Draft Guidance for Industry: Stability Testing of Drug Substances and Drug Products	June 1998	Do	Do
ICH Draft Guidance on Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products	June 9, 1998	Do	Do
ICH Guidance on Ethnic Factors in the Acceptability of Foreign Clinical Data	June 10, 1998	Do	Do
Draft Guidance for Industry: Exports and Imports Under the FDA Export Reform and Enhancement Act of 1996	June 12, 1998	Do	Do
Draft Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Vaccine or Related Product	June 1998	Do	Do
Guidance for Industry: Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug and Cosmetic Act	June 1998	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Draft Guidance for Industry: In the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Nucleic Acid Sequences of Human Immunodeficiency Virus Type 1	July 1998	Do	Do
Draft Guidance for Industry: For the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Blood and Blood Components Intended for Transfusion or for Further Manufacture and For the Completion of the FDA Form 356h ''Application to Market a New Drug, Biologic or an Antibiotic Drug for Human Use''	July 1998	Do	Do
Guidance for Industry: Implementation of Section 126 of the Food and Drug Administration Modernization Act of 1997—Elimination of Certain Labeling Requirements	July 1998	Do	Do
Guidance for Industry: Environmental Assessment of Human Drug and Biologics Applications	July 1998	Do	Do
Draft Guidance for Industry: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods	July 1998	Do	Do
Draft Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for an Allergenic Extract or Allergen Patch Test	August 1998	Do	Do
ICH Guidance on Statistical Principles for Clinical Trials	September 16, 1998	Do	Do
ICH Guidance on Quality of Biotechnological/Biological Products: Derivation and Characterization of Cell Substrates Used for Production of Biotechnological/Biological Products	September 21, 1998	Do	Do
Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Units from Prior Collections from Donors with Repeatedly Reactive Screening Tests for Antibody to Hepatitis C Virus (Anti–HCV); (2) Supplemental Testing, and the Notification of Consignees and Blood Recipients of Donor Test Results for Anti–HCV	September 1998	Do	Do
ICH Guidance on Viral Safety Evaluation of Biotechnology Products Derived From Cell Lines of Human or Animal Origin	September 24, 1998	Do	Do
Guidance for Industry: Errors and Accidents Regarding Saline Dilution of Samples Used for Viral Marker Testing **(Level 2)**	June 1998	Do	Do
Guidance for Industry: How to Complete the Vaccine Adverse Reporting System Form (VAERS–1) **(Level 2)**	September 1998	Do	Do
Withdrawn			
Guidance for Industry: Supplemental Testing and the Notification of Consignees of Donor Test Results for Antibody to Hepatitis C Virus (Anti–HCV)—March 1998	September 1998	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Memorandum: Revised Precautionary Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) by Blood and Blood Products—December 11, 1996 **(Partial Withdrawal) (Withdrawal of recommendations pertaining to retrieval, quarantine, destruction, and notification for plasma derivatives)**	September 1998	Do	Do

III. Guidance Documents Issued by the Center for Devices and Radiological (CDRH)

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Medical Devices: Draft Global Harmonization Task Force Study Group 3 Process Validation Guidance (Draft)	July 16, 1998	Office of Compliance (OC)	Division of Small Manufacturers Assistance, 1–800–638–2041 or 301–827–0111 or (FAX) Facts-on-Demand at 1–800–899–0381 or Internet at http://www.fda.gov/cdrh
Global Harmonization Task Force: Draft Document on the Essential Principles of Safety and Performance of Medical Devices on a Global Basis	October 28, 1998	Do	Do
Global Harmonization Task Force: Availability of Draft Documents on Adverse Event and Vigilance Reporting of Medical Device Events	August 31, 1998	OC/Office of Surveillance and Biometrics (OSB)	Do
Guidance for Industry—Contents of a PDP	April 25, 1998	Office of Device Evaluation (ODE)	
Medical Device Labeling—Suggested Format and Content	May 9, 1997	Do	Do
Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (replaces Reviewer Guidance for Computer-Controlled Medical Devices Undergoing 510(k) Review 8/29/91)	May 28, 1998	Do	Do
New Model Medical Device Development Process	June 3, 1998	Do	Do
Modifications to Devices Subject to Premarket Approval the PMA Supplement Decision Making Process	August 6, 1998	Do	Do
Guidance for Off-the Shelf Software Use in Medical Devices	August 17, 1998	Do	Do
Convenience Kits Interim Regulatory Guidance	May 20, 1997	Do	Do
Kit Certification for 510(k)s	July 1997	Do	Do
Guidance to Industry Supplements to Approved Applications for Class III Medical Devices: Use of Published Literature, Use of Previously Submitted Materials, and Priority Review	May 20, 1998	Do	Do
30-Day Notices and 135-Day PMA Supplements for Manufacturing Method or Process Changes, Guidance for Industry and CDRH	February 19, 1998	Do	Do
Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff	February 19, 1998	Do	Do
Guidance for Submission of Immunohistochemistry Applications to the FDA	June 6, 1998	ODE/Division of Clinical Laboratory Devices (DCLD)	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
In Vitro Diagnostic Creatinine Test System	July 2, 1998	Do	Do
In Vitro Diagnostic Bicarbonate/Carbon Dioxide Test System	July 6, 1998	Do	Do
In Vitro Diagnostic Chloride Test System	July 6, 1998	Do	Do
In Vitro Diagnostic Glucose Test System	July 6, 1998	Do	Do
In Vitro Diagnostic Potassium Test System	July 6, 1998	Do	Do
In Vitro Diagnostic Sodium Test System	July 6, 1998	Do	Do
In Vitro Diagnostic Urea Nitrogen Test System	July 6, 1998	Do	Do
In Vitro Diagnostic C-Reactive Immunological Test System	July 20, 1998	Do	Do
In Vitro Diagnostic Calibrators	July 20, 1998	Do	Do
Points To Consider For Hematology Quality Control Materials	September 30, 1997	Do	Do
Points to Consider for Approval of Home Drugs of Abuse Test Kits Draft	September 16, 1997	Do	Do
Review Criteria for Assessment of Professional Use Human Chorionic Gonadotropin (hCG) in Vitro Diagnostic Devices (IVD's)	November 6, 1996	Do	Do
Letter to IVD Manufacturers on Streamlined PMA	December 22, 1997	Do	Do
Reviewer Guidance for Premarket Notification (510(k)) Submissions—Labeling, Performance and Environmental Testing for Electronic Devices	July 19, 1995	ODE/Division of Cardiovascular, Respiratory, and Neurological Devices (DCRND)	Do
Draft Guidance for Format and Content for Premarket Notification 510(k)	July 19, 1995	Do	Do
Guidance on the Content and Format of Premarket Notifications [510(k)] Submissions for Liquid Chemical Sterilants and High Level Disinfectants	December 18, 1997	ODE/Division of Dental, Infection Control, and General Hospital Devices (DDIGD)	Do
Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for Surgical Masks	January 16, 1998	Do	Do
Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for Testing for Skin Sensitization to Chemicals in Latex Products	February 13, 1998	Do	Do
CDRH Regulatory Guidance Document for Preamendments Unclassified Washers and Washer-Disinfectors Intended for Processing Reusable Medical Devices	April 27, 1998	Do	Do
Guidance on the Content and Format of Premarket Notification [510(k)] Submissions of Washers and Washer-Disinfectors	August 4, 1998	Do	Do
Devices for the Treatment and/or Diagnosis of Temporomandibular Joint Dysfunction and/or Orofacial Pain	June 10, 1998	Do	Do
Dental Impression Materials Premarket Notification	August 17, 1998	Do	Do
OTC Denture Cushions, Pads, Reliners, Repair Kits, and Partially Fabricated Denture Kits	August 18, 1998	Do	Do
Dental Cements Premarket Notification	August 18, 1998	Do	Do
Further Information on the Regulation of Liquid Chemical Sterilants and High Level Disinfectants	August 18, 1997	Do	Do
Letter to Orthopedic Surgical Manufacturers Association	November 26, 1997	ODE/Division of General and Restorative Devices (DGRD)	Do
Letter to the Health Industry Manufacturers Association	November 26, 1997	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Guidance Document for Industry and CDRH Staff for the Preparation of Investigational Device Exemptions and Premarket Approval Applications for Bone Growth Stimulator Devices (Replaces: Guidance Document for the Preparation of Investigational Device Exemptions and Premarket Approval Applications for Bone Growth Stimulator Devices 8/12/88)	March 18, 1998	Do	Do
Guidance for Content of Premarket Notifications for Esophageal and Tracheal Prostheses	April 28, 1998	Do	Do
Guidance Document for Surgical Lamp 510ks	July 13, 1998	Do	Do
Retinoscope Guidance	July 8, 1998	ODE/Division of Opthalmic Devices (DOD)	Do
Opthalmoscope Guidance	July 8, 1998	Do	Do
Slit Lamp Guidance	July 8, 1998	Do	Do
Revised Procedures for Adding Lens Finishing Laboratories to Approved Premarket Approval Applications for Class III Rigid Gas Permeable Contact Lens for Extended Wear	August 11, 1998	Do	Do
Third Party Review Guidance for Vitreous Aspiration and Cutting Device Premarket Notification (510K)	January 31, 1997	Do	Do
Third Party Review Guidance for Phacofragmentation System Device Premarket Notification (510K)	January 31, 1997	Do	Do
Dear Sponsor Letter Concerning the Revocation of 21 CFR part 813 IOL IDE Regulations	May 20, 1997	Do	Do
Guidance for the Content of Premarket Notification for Conventional and High Permeability Hemodialyzers (replaces: Guidelines for Premarket Testing of New Conventional Hemodialyers, High Premeability Hemodialyzers and Hemofilters)	August 7, 1998	ODE/Division of Reproductive Abdominal, ENT, and Radiological Devices (DRAERD)	Do
Uniform Contraceptive Labeling	July 23, 1998	Do	Do
Guidance for the Content of Premarket Notifications for Conventional and High Permeability Hemodialyzers	August 7, 1998	Do	Do
Guidance for Industry and CDRH Reviewers on the Content of Premarket Notifications for Hemodialysis Delivery Systems	August 7, 1998	Do	Do
Devices Used for In Vitro Fertilization and Related Assisted Reproduction Procedures	September 10, 1998	Do	Do
Letter to Manufacturers of Falloposcopes	September 5, 1996	Do	Do
Letter to Manufacturers of Prescription Home Monitors for Non-Stress Tests	September 6, 1996	Do	Do
Continuing Education Credits for Reading/Writing Articles/Papers and Presenting Courses/Lectures	April 17, 1998	Office of Health and Industry Programs (OHIP)/Division of Mammography Quality and Radiation Programs (DMQRP)	Do
Accidental Radioactive Contamination of Human Food and Animal Feeds: Recommendations for State and Local Agencies	August 13, 1998	Do	Do
Additional Mammography Review Policy	March 26, 1998	Do	Do
Guidance For Review of Cases of Possible Suspension or Revocation of Mammography Facility Certificates Under the Mammography Quality Standards Act, 42. U.S.C. section 263b	March 26, 1998	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Guidance for Review of Requests for Reconsideration of Adverse Decisions on Accreditation of Mammography Facilities Under the Mammography Quality Standards Act, 42. U.S.C. section 263b	March 26, 1998	Do	Do
Guidance for Submission of Requests for Reconsideration of Adverse Decisions on Accreditation of Mammography Facilities Under the Mammography Quality Standards Act, 42. U.S.C. section 263b	March 26, 1998	Do	Do
Supplement to ''The Physician's Continuing Experience Requirement''	April 9, 1998	Do	Do
Requalification for Interpreting Physician's Continuing Experience	May 28, 1998	Do	Do
MQSA Policy Statements in a Question and Answer	June 2, 1998	Do	Do
Compliance Guidance: The Mammography Quality Standards Act Final Regulations	July 8, 1998	Do	Do
MQSA Policy Statements for the Interim Regulations	August 6, 1998	Do	Do
Policy for Facilities Changing Accreditation Bodies	April 15, 1998	Do	Do
Guidance on FDA's Expectations of Medical Device Manufacturers Concerning the Year 2000 Date	May 15, 1998	Office of Science and Technology (OST)/ Division of Electronics and Computer Science (DESC)	Do
Immunotoxicity Testing	1996	OST/Division of Life Sciences (DLS)	Do
Guidance on the Recognition and Use of Consensus Standards	February 19, 1998	OST/Office of the Director (OD)	Do
Deletions			
Biotechnology and FDA Regulation of Hybridoma In-Vitro Diagnostic Products: List of Current Devices and Guidelines for Manufacturers	January 1, 1986	ODE	Do
DCRND—Draft Guidance for Format and Content for Premarket Notification 510(k) [replaces 908] [cardiovascular, respiratory, neurological]	July 19, 1995	ODE/DCRND	Do
Guidance for Safety and Effectiveness Data Required in Premarket Notification (510(k)) Applications for Blood Oxygenators	March 1, 1983	Do	Do
Automated Defibrillators: Operator's Shift Checklist and Manual Defibrillators: Operator's Shift Checklist	August 8, 1991	Do	Do
Guidance for the Preparation and Content of Applications to the Food and Drug Administration for Ventricular Assist Devices and Total Artificial Hearts (draft)	December 4, 1987	Do	Do
Guidance Document for the Preparation of IDE and PMA Applications for Bone Growth Stimulator Devices	August 12, 1988	ODE/DGRD/ORDB	Do
Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review	August 29, 1991	ODE	Do
Guidelines for Premarket Testing of New Conventional Hemodialyzers, High Permeability Hemodialyzers, and Hemofilters	March 1, 1982	ODE/DRAERD/GRDB	Do
Frequently Asked Questions on Recognition of Consensus Standards	February 19, 1998	OST	Do
Corrections			

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Determining Equivalence of Intraaortic Balloon Catheters Under the 510(k) Regulations	December 8, 1993	ODE/DCRND	Do
Guidance for the Preparation of the Annual Report to the PMA Approved Heart Valve Prostheses	September 1, 1990	Do	Do
Electrocardiograph (ECG) Electrode	February 11, 1997	Do	Do
Electrocardiograph (ECG) Lead Switching Adapter	February 11, 1997	Do	Do
Electrocardiograph (ECG) Surface Electrode Tester	February 11, 1997	Do	Do
Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators	October 1, 1993	Do	Do
Reexamination of the Evaluation Process for Liquid Chemical Sterilant and Height Level Disinfectants	May 19, 1997	ODE/DDIGD	Do
FDA Guidelines for Multifocal Intraocular Lens IDE Studies and PMAs	May 29, 1997	ODE/DOD	Do
Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers	September 30, 1997	ODE/DRAERD/RDB	Do
Tympanostomy Tubes, Submission Guidance for a 510(k) Premarket Notification	January 14, 1998	ODE/DRAERD	Do

IV. Guidance Documents Issued by the Center for Drug Evaluation and Research (CDER)

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Topical Dermatological Drug Product NDA's and ANDA's—In Vivo Bioavailability, Bioequivalence, In Vitro Release and Associated Studies, Draft	June 18, 1998	Biopharmaceutic	Office of Training and Communication, Drug Information Branch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Internet access: http://www.fda.gov/cder/guidance/index.htm
Buspirone Hydrochloride Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing	May 15, 1998	Do	Do
SUPAC IR/MR: Immediate Release and Modified Release Solid Oral Dosage Forms Manufacturing Equipment Addendum, Draft	April 28, 1998	Chemistry	Do
Stability Testing of Drug Substances and Drug Products, Draft	June 8, 1998	Do	Do
PAC–ATLS: Postapproval Changes- Analytical Testing Laboratory Sites	April 28, 1998	Do	Do
Environmental Assessment of Human Drugs and Biologics Applications	July 27, 1998	Do	Do
Uncomplicated and Complicated Skin and Skin Structure Infections; Developing Antimicrobial Drugs for Treatment, Draft	July 22, 1998	Clinical Antimicrobial Guidances	Do
Acute Bacterial Meningitis; Developing Antimicrobial Drugs for Treatment, Draft	July 22, 1998	Do	Do
Uncomplicated Gonorrhea—Cervical, Urethral, Rectal, and/or Pharyngeal; Developing Antimicrobial Drugs for Treatment, Draft	July 22, 1998	Do	Do
Complicated Urinary Tract Infections and Pylonephritis; Developing Antimicrobial Drugs for Treatment, Draft	July 22, 1998	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Streptococcal Pharyngitis and Tonsillitis; Developing Antimicrobial Drugs for Treatment, Draft	July 22, 1998	Do	Do
Secondary Bacterial Infections of Acute Bronchitis; Developing Antimicrobial Drugs for Treatment, Draft	July 22, 1998	Do	Do
Uncomplicated Urinary Tract Infections; Developing Antimicrobial Drugs for Treatment, Draft	July 22, 1998	Do	Do
Nosocomial Pneumonia; Developing Antimicrobial Drugs for Treatment, Draft	July 22, 1998	Do	Do
Vulvovaginal Candidiasis; Developing Antimicrobial Drugs for Treatment, Draft	July 22, 1998	Do	Do
Lyme Disease; Developing Antimicrobial Drugs for Treatment, Draft	July 22, 1998	Do	Do
Empiric Therapy of Febrile Neutropenia; Developing Antimicrobial Drugs for Treatment, Draft	July 22, 1998	Do	Do
Community Acquired Pneumonia; Developing Antimicrobial Drugs for Treatment, Draft	July 22, 1998	Do	Do
Bacterial Vaginosis; Developing Antimicrobial Drugs for Treatment, Draft	July 22, 1998	Do	Do
Acute Otitis Media; Developing Antimicrobial Drugs for Treatment, Draft	July 22, 1998	Do	Do
Acute Bacterial Sinusitis; Developing Antimicrobial Drugs for Treatment, Draft	July 22, 1998	Do	Do
Acute Bacterial Exacerbation of Chronic Bronchitis; Developing Antimicrobial Drugs for Treatment, Draft	July 22, 1998	Do	Do
General Considerations for Clinical Trials; Developing Antimicrobial Drugs for Treatment, Draft	July 22, 1998	Do	Do
Acute or Chronic Bacterial Prostatitis; Developing Antimicrobial Drugs for Treatment, Draft	July 22, 1998	Do	Do
Submission of Abbreviated Reports and Synopses in Support of Marketing Applications; Draft	September 21, 1998	Clinical Medical	Do
Developing Medical Imaging Drugs and Biologics	October 13, 1998	Do	Do
Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products	May 15, 1998	Do	Do
Pharmacokinetics and Pharmacodynamics in Patients with Impaired Renal Function: Study Design, Data Analysis, and Impact on Dosing and Labeling	May 15, 1998	Clinical Pharmacology	Do
Manufacture, Processing or Holding of Active Pharmaceutical Ingredients, Draft	April 17, 1998	Compliance	Do
Investigating Out of Specification (OOS) Test Results for Pharmaceutical Production	September 30, 1998	Do	Do
ANDA's: Impurities in Drug Substances, Draft	July 24, 1998	Generic Drug	Do
E5 Ethnic Factors in the Acceptability of Foreign Clinical Data, Draft	June 10, 1998	ICH Efficacy	Do
E9 Statistical Principles for Clinical Trials	September 16, 1998	Do	Do
Q6B Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products, Draft	June 9, 1998	ICH Quality	Do
Q5D Quality of Biotechnological/Biological Products: Derivation and Characterization of Cell Substrates Used for Production of Biotechnological/Biological Products	September 21, 1998	Do	Do
Q5A Biotechnological/Biological Pharmaceutical Products; Viral Safety Evaluation	September 24, 1998	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
OTC Topical Drug Products for the Treatment of Vaginal Yeast Infections (Vulvovaginal Candidiasis), Draft	July 16, 1998	Labeling	Do
Dipirefrin Hydrochloride Opthalmic Solution USP	October 1, 1998	Do	Do
Non-Contraceptive Estrogen Class Labeling	October 15, 1998	Do	Do
Submitting Debarment Certification Statements, Draft	October 2, 1998	Procedural Guidances	Do
National Uniformity for Nonprescription Drugs Ingredient Labeling for OTC Drugs	April 9, 1998	Do	Do
Standards for the Prompt Review of Efficacy Supplements, Including Priority Efficacy Supplements	May 15, 1998	Do	Do
Repeal of Section 507 of the Federal Food, Drug, and Cosmetic Act	June 15, 1998	Do	Do
Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act	June 29, 1998	Do	Do
180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act	July 14, 1998	Do	Do
Implementation of Section 126, Elimination of Certain Labeling Requirements of the FDA Modernization Act of 1997	July 21, 1998	Do	Do
Advisory Committees: Implementing Section 120 of the FDA Modernization Act of 1997	November 2, 1998	Do	Do
Submitting and Reviewing Complete Responses to Clinical Holds	May 14, 1998	User Fee	Do
Classifying Resubmissions in Response to Action Letters	May 14, 1998	Do	Do
Withdrawn			
Pharmacokinetic Considerations in Drug Studies		Biopharmaceutic	
Carbamazepine (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	January 20, 1988	Do	
Evaluation of Controlled Release Drug Products; Division Guidelines	April 18, 1984	Do	
Approaches to Statistical Data Analysis of Bioavailability/Bioequivalence Studies	November 11, 1985	Do	
Controlled Release Dosage Forms: Issues and Controversies (Conference Report)	September 10, 1985	Do	
Submission of Data for Bioequivalence Studies in Computer Format		Do	
Albuterol Inhalation Aerosols (Metered Dose Inhalers) In Vivo Bioequivalence and In Vitro Dissolution Testing	January 27, 1994	Do	
Albuterol Sulfate (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	May 29, 1987	Do	
Amoxapine (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	August 5, 1988	Do	
Atenolol (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	October 6, 1988	Do	
Clindamycin Hydrochloride (capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	May 31, 1988	Do	
Diazepam In Vivo Bioequivalence Study	July 8, 1985	Do	
Dipyridamole Drug Products Bioavailability	September 25, 1987	Do	
Disopyramide Phosphate (Capsules)	July 9, 1985	Do	
Doxepin Hydrochloride Drug Products In Vivo Bioequivalence Study	October 9, 1986	Do	
Doxycycline Hyclate In Vivo Studies and In Vitro Dissolution Testing	April 11, 1988	Do	

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Erythromycin Capsules (Enteric Coated Pellets) In Vivo Bioequivalence Study and In Vitro Dissolution Testing	September 21, 1988	Do	
Fenoprofen (capsules and tablets) In Vivo Bioequivalence Study and In Vitro Dissolution Testing	February 3, 1988	Do	
Haloperidol (tablets) In Vivo Bioequivalence Study and In Vitro Dissolution Testing	April 30, 1987	Do	
Hydroxyzine Pamoate (capsules) In Vivo Bioequivalence Study and In Vitro Dissolution Testing	September 28, 1987	Do	
Isosorbide Dinitrate (chewable tablets, oral tablets, and sublingual tablets) In Vivo Bioequivalence Study and In Vitro Dissolution Testing	September 22, 1987	Do	
Isosorbide Dinitrate (Controlled Release) In Vivo Bioavailability Studies	November 6, 1985	Do	
Lorazepam (tablets) In Vivo Bioequivalence Study and In Vitro Dissolution Testing	September 16, 1987	Do	
Megestrol Acetate (tablets) In Vivo Bioequivalence Study and In Vitro Dissolution Testing	August 17, 1987	Do	
Methylprednisolone (tablets) In Vivo Bioequivalence Study and In Vitro Dissolution Testing	June 12, 1986	Do	
Minoxidil (tablets)	June 12, 1986	Do	
Nafcillin Sodium (Capsules and Tablets) In Vivo Bioequivalence Study and In Vitro Dissolution Testing	September 10, 1987	Do	
Norethindrone and Ethinyl Estradiol (tablets) In Vivo Bioequivalence Study and In Vitro Dissolution Testing	March 18, 1988	Do	
Norethindrone and Mestranol (tablets) In Vivo Bioequivalence Study and In Vitro Dissolution Testing	May 13, 1988	Do	
Orphenadrine Citrate (tablets) In Vivo Bioequivalence Study and In Vitro Dissolution Testing	July 22, 1983	Do	
Procainamide In Vivo Bioavailability Studies	September 28, 1987	Do	
Rifampin (capsules) In Vivo Bioequivalence Study and In Vitro Dissolution Testing	September 8, 1988	Do	
Silver Sulfadiazine (cream)	May 7, 1987	Do	
Spironolactone In Vivo Single Dose Studies and In Vitro Dissolution Testing	January 1, 1986	Do	
Sulfasalazine (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	October 8, 1987	Do	
Sulindac (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	July 18, 1988	Do	
Theophylline (conventional dosage form) In Vivo Bioequivalence and In Vitro Dissolution Testing	September 1, 1984	Do	
Timolol Maleate (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	August 9, 1988	Do	
Tolmetin Sodium (tablets and capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	October 6, 1994	Do	
Triazolam (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	December 24, 1992	Do	
Acetohexamide (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	August 1, 1988	Do	
Allopurinol (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	July 15, 1985	Do	

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Amiloride Hydrochloride (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	March 29, 1985	Do	
Aminophylline (suppositories) In Vivo Bioequivalence and In Vitro Dissolution Testing	July 5, 1983	Do	
Amitriptyline Hydrochloride (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	July 5, 1983	Do	
Amoxicillin (capsules, tablets, and suspensions) In Vivo Bioequivalence and In Vitro Dissolution Testing	July 10, 1988	Do	
Baclofen (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	May 5, 1988	Do	
Cefadroxil (capsules, tablets, and suspension) In Vivo Bioequivalence and In Vitro Dissolution Testing	October 7, 1988	Do	
Cephalexin (tablets and capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	March 19, 1987	Do	
Cephradine (capsule and suspension) In Vivo Bioequivalence Studies	September 10, 1986	Do	
Chlordiazepoxide and Chlordiazepoxide HCl Bioavailability and Dissolution Studies	July 5, 1983	Do	
Chlorpropamide In Vivo Bioavailability Studies	July 5, 1983	Do	
Chlorthalidone (tablets)	July 5, 1983	Do	
Clofibrate In Vivo Bioavailability Studies	April 7, 1986	Do	
Clonidine Hydrochloride Drug Products In Vivo Bioequivalence Study and In Vitro Dissolution Testing	December 5, 1984	Do	
Clorazepate In Vivo Bioequivalence Study and In Vitro Dissolution Testing	February 17, 1987	Do	
Cyclobenzaprine Hydrochloride (tablets) In Vivo Bioequivalence Study and In Vitro Dissolution Testing	January 25, 1988	Do	
Desipramine Hydrochloride (tablets) In Vivo Bioequivalence Studies	September 22, 1987	Do	
Dicyclomine Hydrochloride Drug Products In Vivo Bioequivalence	August 10, 1984	Do	
Dissolution Testing (General)	April 1, 1978	Do	
Estopipate Tablets In Vivo Bioequivalence Study and In Vitro Dissolution Testing	August 26, 1992	Do	
Flurazepam Hydrochloride (capsules) In Vivo Bioequivalence Study and In Vitro Dissolution Testing	October 15, 1985	Do	
Hydrochlorothiazide (tablets) In Vivo Bioequivalence Study and In Vitro Dissolution Testing	September 28, 1987	Do	
Hydroxyzine Hydrochloride (tablets) (dissolution only)	March 4, 1986	Do	
Indomethacin (capsules) In Vivo Bioequivalence Study and In Vitro Dissolution Testing	January 27, 1988	Do	
Isopropamide Iodide (tablets) In Vivo Bioequivalence Study and In Vitro Dissolution Testing	May 12, 1982	Do	
Loxapine Succinate (capsules) In Vivo Bioequivalence Study and In Vitro Dissolution Testing	September 10, 1987	Do	
Maprotiline Hydrochloride (tablets) In Vivo Bioequivalence Study and In Vitro Dissolution Testing	August 27, 1987	Do	
Meclofenamate Sodium (capsules) In Vivo Bioequivalence Study and In Vitro Dissolution Testing	November 12, 1986	Do	
Metaproterenol Sulfate (tablets) In Vivo Bioequivalence Study and In Vitro Dissolution Testing	March 18, 1986	Do	

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Metoclopramide Hydrochloride (tablets) In Vivo Bioequivalence Study and In Vitro Dissolution Testing	December 27, 1984	Do	
Nalidixic Acid In Vivo Bioequivalence Study and In Vitro Dissolution Testing	August 19, 1987	Do	
Nitrofurantion Macrocrystalline (capsules) In Vivo Bioequivalence Study and In Vitro Dissolution Testing	January 10, 1986	Do	
Nitroglycerin Ointment In Vivo Bioequivalence Studies	December 17, 1986	Do	
Perphenazine (tablets) In Vivo Bioequivalence Study and In Vitro Dissolution Testing	August 27, 1987	Do	
Perphenazine/Amitriptyline (tablets) In Vivo Bioequivalence Study and In Vitro Dissolution Testing	August 27, 1987	Do	
Phenylbutazone Oxyphenbutazone (capsules and tablets) In Vivo Bioequivalence Study and In Vitro Dissolution Testing	September 28, 1987	Do	
Prazepam (capsules and tablets) In Vivo Bioequivalence Study and In Vitro Dissolution Testing	July 26, 1988	Do	
Prednisone (tablets) (dissolution only)	July 10, 1985	Do	
Probenecid Drug Products Bioavailability Study	July 26, 1983	Do	
Propoxyphene Napsylate with Acetaminphen (tablets)	March 26, 1980	Do	
Propranolol Hydrochloride (tablets) In Vivo Bioequivalence Study and In Vitro Dissolution Testing	August 1, 1984	Do	
Propylthiouracil (tablets) In Vivo Bioequivalence Study and In Vitro Dissolution Testing	August 13, 1986	Do	
Quinidine Gluconate (tablets, controlled release) In Vivo Bioequivalence Study and In Vitro Dissolution Testing	September 22, 1987	Do	
Ritodrine Hydrochloride (tablets) In Vivo Bioequivalence Study and In Vitro Dissolution Testing	August 27, 1987	Do	
Sulfinpyrazone (Capsules and Tablets)	September 25, 1987	Do	
Sulfones (tablets) In Vivo Bioequivalence Study and In Vitro Dissolution Testing	November 7, 1986	Do	
Temazepam In Vivo Bioequivalence Study and In Vitro Dissolution Testing	August 8, 1985	Do	
Tolazamide (tablets) In Vivo Bioequivalence Study and In Vitro Dissolution Testing	May 30, 1986	Do	
Tolbutamide (tablets) In Vivo Bioequivalence Study and In Vitro Dissolution Testing	December 1, 1983	Do	
Trimipramine Maleate (capsules) In Vivo Bioequivalence Study and In Vitro Dissolution Testing	August 18, 1987	Do	
Verapamil Hydrochloride (tablets) In Vivo Bioequivalence Study and In Vitro Dissolution Testing	July 18, 1985	Do	
Clinical Evaluation of Drugs for the Treatment of Peripheral Vascular Disease		Clinical	
Clinical Evaluation of Bronchodilator Drugs	November 1, 1978	Clinical/Medical	
Topical Corticosteriod Class Labeling		Labeling	

V. Guidance Documents Issued by the Center for Food Safety and Applied Nutrition (CFSAN)

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Level I Guidances			
Draft Working Guide to Minimize Microbial Hazards for Fresh Fruits and Vegetables	1998	Farmers and Food Packers	Lou Carson (HFS–3), Food and Drug Administration, 200 C. St. SW., Washington, DC 20204 or jsaltsman@bangate.fda.gov
Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body	1998	Regulated Industry	Office of Food Labeling (HFS–150), Food and Drug Administration, 200 C. St. NW., Washington, DC 20204

VI. Guidance Documents Issued by the Center for Veterinary Medicine (CVM)

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Guidance for Industry: Use of Human Chorionic Gonadotropin (HCG) as a Spawning Aid for Fish	April 1998	FDA Regulated Industry	CVM Internet Home Page at http://www.fda.gov/cvm, or from CVM's Communications Staff (HFV–12), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1755, fax 301–594–1831
Guidance for Industry: GMP's For Medicated Feed Manufacturers Not Required to Register and Be Licensed With FDA	May 1998	Do	Do
VICH Draft Guidance for Industry: Stability Testing of New Animal Drug Substances and Products	July 1998	Do	Do
VICH Draft Guidance for Industry: Stability Testing for New Dosage Forms of New Animal Drugs: Draft Guidance	July 1998	Do	Do
VICH Draft Guidance for Industry: Stability Testing: Photostability Testing of New Animal Drug Substances and Products	July 1998	Do	Do
Guidance for Industry: Questions and Answers; BSE Feed Regulations	July 1998	Do	Do
Guidance for Industry: Interpretation of On-Farm Feed Manufacturing and Mixing Operations; Draft	August 1998	Do	Do
Tolerances Established for Tetracyclines in Milk	August 11, 1998 (Updated)	Do	Do
Withdrawn			
Points to Consider Guideline: Development of a Pharmacokinetic Guideline Enabling Flexible Labeling of Therapeutic Antimicrobials	1993	Do	

VII. Guidance Documents Issued by the Office of Regulatory Affairs

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Compliance Policy Guide Medical Device Warning Letter Draft Pilot	August 27, 1998	FDA Staff Personnel	Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0420 or via Internet at www.fda.gov/ora/compliance_ref/dev_pl.pdf
Compliance Policy Guide 675.400 (CPG 7126.24): REVISION Rendered Animal Feed Ingredients	November 13, 1998	Do	Do—Internet at www.fda.gov/ora/compliance_ref/cpg/cpgvet/cpg675.400.html
Regulatory Procedures Manual: UPDATE/REVISION Subchapter/Seizure	June 1998	Do	Do—Internet at www.fda.gov/ora/compliance_ref/rpm_new2/ch6.html
Regulatory Procedures Manual: UPDATE/REVISION Subchapter/Supervisory Charges	June 1998	Do	Do—Internet at www.fda.gov/ora/compliance_ref/rpm_new2/ch9chgs.html
Regulatory Procedures Manual: NEW Subchapter/Civil Penalties—Electronic Product Radiation Control	July 1998	Do	Do—Internet at www.fda.gov/ora/compliance_ref/ch6civpen.html
Guide to Traceback of Fresh Fruits and Vegetables Implicated in Epidemiological Investigations	August 1998	Do	Division of Emergency and Investigational Operations (HFC–130), Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 301–443–3276
Guide to Inspections of Computerized Systems in the Food Processing Industry	August 1998	Do	Do—Internet at www.fda.gov/ora/inspect_ref/igf/iglist.html
Import Alerts	Continuously	Do	Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or via Internet at www.fda.gov/ora/fiars/ora_import_alerts.html
Investigations Operations Manual-REVISION; Chapter 4—Sampling	July 1998	Do	Division of Emergency and Investigational Operations (HFC–130), Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 301–443–3276 or via internet at www.fda.gov/ora/inspect_ref/iom/iomtc.html
Investigations Operations Manual-REVISION; Chapter 5—Establishment Inspection	July 1998	Do	Do
Documents Not Included on Previously Published Lists			
Compliance Policy Guide—DRAFT Commercialization of In Vitro Diagnostic Devices (IVD's) Labeled for Research Use Only or Investigational Use Only	January 5, 1998	Do	Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 301–827–0420 or via internet at www.fda.gov/cdrh/comp/ivddrfg.html
Compliance Policy Guide—DRAFT Distributor Medical Device Reporting	August 28, 1998	Do	Do or via internet at www.fda/gov/ora/compliance_ref/cpg_mdr3.txt
Withdrawn			
Compliance Policy Guide 530.400 (CPG 7121.02) Vitamin Products for Human Use—Low Potency	September 23, 1997	Do	
Compliance Policy Guide 210.150 (CPG 7134.09)Importation of Licensed Biological Products for Human Use			
Corrections to July 6, 1998 Quarterly List			
Guideline for the Monitoring of Clinical Investigators	Revised November 1998	FDA Regulated Industry	Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0420
Computerized Systems Used in Clinical Trials Should be identified as a DRAFT	June 18, 1997	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
ComplianceProgram 7348.808, Bioresearch Monitoring; Good Laboratory Practices (Nonclinical)	Revised August 17, 1998	FDA Staff Personnel	Do—Internet http://www.fda.gov/ora/compliance_ref/bimo/default.html
Compliance Program 7348.810; Sponsors, Contract Research Organizations and Monitors	Revised October 30, 1998	Do	Do—Internet http://www.fda.gov/ora/compliance_ref/bimo/default.html
Compliance Program 7348.811; Bioresearch Monitoring; Clinical Investigations	Revised September 2, 1998	Do	Do—Internet http://www.fda.gov/ora/compliance_ref/bimo/default.html
The following documents are not available via the internet: Food Laboratory Practice Program (Nonclinical Laboratories) 7348.808A; EPA Data Audit Inspections	October 1, 1991	Do	Do
Compliance Program 7348.809; Bioresearch Monitoring; Institutional Review Board	August 18, 1994		

VIII. Guidance Documents Issued by the Office of the Commissioner and the Office of Policy

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Draft Guidance for Industry; Exports and Imports under the FDA Export Review and Enhancement Act of 1996	June 1998	FDA Regulated Industry	Via Internet at http://www.fda.gov/opacom/fedregister/frexport.html
Policy & Guidance Handbook for FDA Advisory Committees	1994	FDA Staff Personnel	National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161, 703–487–4650 (Order No. PB94–158854)

Dated: December 28, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–155 Filed 1–5–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing: Therapeutic Respiratory Syncytial Virus Monoclonal Antibodies

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: Respiratory Syncytial Virus (RSV) is the major cause of serious viral lower respiratory tract illness in infants and children worldwide. Research at the National Institutes of Health (NIH) has resulted in the discovery of several different anti-RSV monoclonal antibody (MAb) technologies important for the treatment of this disease. Used separately or in combination, these technologies could provide the basis for the commercial development of a new anti-RSV therapeutic. The therapeutic technologies available for licensing consist of a patented human MAb against RSV, a unpatented panel of murine MAbs against RSV and patent applications relating to methods of treating RSV infection utilizing more than one antibody. The human and murine MAbs bind the F glycoprotein of RSV at different nonoverlapping epitopes. A product combining the human MAb with a humanized version of a least one of the murine antibodies may provide an improvement to current single MAb therapies by reducing the likelihood of the formation of RSB escape mutants.

ADDRESSES: Questions about these licensing opportunities, copies of the patent and/or patent applications should be addressed to Peter Soukas, J.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; Telephone: 301/496–7735 ext. 268; Fax: 301/402–0220; E-mail: ps193c@nih.gov. A signed Confidential Disclosure Agreement will be required to receive copies of the patent application.

SUPPLEMENTARY INFORMATION: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 USC 207 and 37 CFR Part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patented applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.