Dated: February 29, 2000.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 00–6118 Filed 3–13–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96G–0035]

Sankyo Co., Ltd.; Withdrawal of GRAS Affirmation Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a petition (GRASP 6G0420) proposing to affirm that the use of dextranase enzyme preparation derived from *Chaetomium gracile* is generally recognized as safe (GRAS) in cane and beet sugar processing.

FOR FURTHER INFORMATION CONTACT: Martha D. Peiperl, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW.,Washington, DC 20204, 202–418–3077.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of February 14, 1996 (61 FR 5787), FDA announced that a petition (GRASP 6G0420) had been filed by Solvay Enzymes, Inc., c/o 1001 G St. NW., suite 500 West, Washington, DC 20001 (now, Sankyo Co., Ltd., No. 7–12, Ginza 2-chome, Chuo-ku, Tokyo 104–8113, Japan). This petition proposed that the use of dextranase enzyme preparation derived from *Chaetomium gracile* in cane and beet sugar processing be affirmed as GRAS. Sankyo has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: March 1, 2000.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 00–6120 Filed 3–13–00; 8:45 am]

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SUMMARY: The Food and Drug Administration (FDA) is publishing an update of all guidance documents issued and withdrawn since we compiled the annual comprehensive list of guidance documents that published on June 10, 1999. FDA committed to publishing quarterly updates in its February 1997 ''Good Guidance Practices'' (GGP's) final rule, which set forth the agency's policies and procedures for developing, issuing, and using guidance documents. This list is intended to inform the public of the existence and availability of guidance documents issued since the annual comprehensive list was compiled.

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. For information on where to obtain single copies of guidance documents listed here, see the specific center's list of guidance documents.

FOR FURTHER INFORMATION CONTACT: LaJuana D. Caldwell, Office of Policy (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7010.

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 our policies and procedures for developing, issuing, and using 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 our guidance documents.

As part of FDA's effort to ensure meaningful interaction with the public regarding guidance documents, we committed to publishing 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 that we issued or withdrew since we published the annual comprehensive list on June 10,1999 (64 FR 31228). The guidance documents are organized by the issuing center or office within FDA, and are further grouped by the intended users or relevant regulatory activities. Dates provided in the following list refer to the date of the guidance was issued or, where applicable, the last date the document was revised. We provided document numbers 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: Monoclonal Antibodies Used as Reagents in Drug Manufacturing	May 1999	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, 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
Guidance for Industry: Container Closure Systems for Packaging Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Documentation	May 1999	Do	Do
Draft Guidance for Industry: Establishing Pregnancy Registries	June 1999	Do	Do
Draft Reviewer Guidance: Evaluation of Human Pregnancy Outcome Data	June 1999	Do	Do
Draft Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Prior Collections from donors with Repeatedly Reactive Screening Tests for Hepatitis C Virus (HCV); (2) Supplemental Testing, and the Notification of Consignees and Transfusion Recipients of donor Test Results for Antibody to HCV (Anti–HCV)	June 1999	Do	Do
ICH Guidance on the Duration of Chronic Toxicity Testing in Animals (Rodent and Nonrodent Toxicity Testing)	June 25, 1999	Do	Do
Draft Guidance for Industry: Clinical Development Programs for Drugs, Devices, and Biological Products Intended for the Treatment of Osteoarthritis (OA)	July 1999	Do	Do
Draft Guidance for Industry: Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations	July 1999	Do	Do
Draft Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics	August 1999	Do	Do
Guidance for Industry: Consumer-Directed Broadcast Advertisements	August 1999	Do	Do
Draft Guidance for Industry: Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act	August 1999	Do	Do
ICH Guidance on Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products	August 18, 1999	Do	Do
Guidance for Industry: Possible Dioxin/PCB Contamination of Drug and Biological Products	August 1999	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 Industry: Submission of Abbreviated Reports and Synopses in Support of Marketing Applications	August 1999	Do	Do
Draft Guidance for Industry: Revised Recommendations for the Invalidation of Test Results When Using Licensed and 510(k) Cleared Bloodborne Pathogen Assays to Test Donors	September 1999	Do	Do
International Conference on Harmonisation Draft Guidance; Choice of Control Group in Clinical Trials	September 24, 1999	Do	Do
Guidance for Industry: Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act	September 1999	Do	Do
Draft Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical Trials Using Retroviral Vectors	November 1999	Do	Do
Guidance for Industry: Providing Regulatory Submissions to the Center for Biologics Evaluation and Research (CBER) in Electronic Format—Biologics Marketing Applications [Biologics License Application (BLA), Product License Application (PLA) / Establishment License Application (ELA) and New Drug Application (NDA)]—Revised	November 1999	Do	Do
Guidance for Industry: Revised Precautionary Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and New Variant Creutzfeldt-Jakob Disease (nvCJD) by Blood and Blood Products	November 1999	Do	Do
Guidance for Industry: In Vivo Drug Metabolism / Drug Interaction Studies—Study Design, Data Analysis and Recommendations for Dosing and Labeling	November 1999	Do	Do
Draft Guidance for Industry: Application of Current Statutory Authority to Nucleic Acid Testing of Pooled Plasma	November 1999	Do	Do
Draft Guidance for Industry: Pharmacokinetics in Patients With Impaired Hepatic Function: Study Design, Data Analysis and Impact on Dosing and Labeling	November 1999	Do	Do
Guidance for Industry: In the Manufacture and Clinical Evaluation of *In Vitro* Tests to Detect Nucleic Acid Sequences of Human Immunodeficiency Viruses Types 1 and 2	December 1999	Do	Do
Draft Guidance for Industry: Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products from Xenotransplantation Product Recipients and Their Contacts	December 1999	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: Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture	January 2000	Do	Do

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

Name of Document	Date of Issuance	Group 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 and FDA Staff—Guidance on Medical Device Tracking (FDAMA) (Replaces: Guidance for Industry and FDA Staff—Guidance on Medical Device Tracking (FDAMA) 2/12/99)	January 24, 2000	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: http://www.fda.gov/cdrh
Guidance for FDA Staff—Civil Money Penalty Policy	June 8, 1999	Do	Do
Alternative to Certain Prescription Device Labeling Requirements	January 21, 2000	Do	Do
Guidance for Industry—Guidance on Information Disclosure by Manufacturers to Assemblers for Diagnostic X-ray Systems	October 18, 1999	OC/Division of Enforcement I (DOEI)	Do
Guidance on Electrosurgical Devices and the Application of the Performance Standard for Electrode Lead Wires and Patient Cables	November 15, 1999	Do	Do
Guidance for Industry—Draft Guidance on Quality System Regulation Information for Various Premarket Submissions	August 3, 1999	OC/Division of Enforcement II (DOE II)	Do
Guidance for FDA Staff—Regulating In Vitro Diagnostic Device (IVD) Studies	December 17, 1999	OC/Division of Bioresearch Monitoring (DBM)	Do
Guidance for Industry on the Likelihood of Facilities Inspections When Modifying Devices Subject to Premarket Approval	August 5, 1999	OC/Division of Program Operations (DPO)	Do
The FDA Export Reform and Enhancement Act of 1996/Export Certification Package including ''Instructions for Requests for Certificate to Foreign Governments'' (Replaces: The FDA Export Reform and Enhancement Act of 1996/Export Certification 10/1/96)	June 22, 1999	Do	Do
Draft Compliance Program Guidance Manual: Inspection of Medical Devices	August 12, 1999	Do	Do
Guidance for Off-the-Shelf Software Use in Medical Devices—Draft Guidance (Replaces: Guidance for Off-the-Shelf Software Use in Medical Devices—Draft Guidance August 17, 1998)	September 9, 1999	Office of Device Evaluation (ODE)	Do

Name of Document	Date of Issuance	Group 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 and FDA Reviewers on Evidence Models for the Least Burdensome Means to Market	September 1, 1999	DO	Do
Guidance on the Labeling for Over-the-Counter Sample Collection Systems for Drugs of Abuse Testing	December 21, 1999	ODE/Division of Clinical Laboratory Devices (DCLD)	Do
Guidance on Labeling for Laboratory Tests	June 24, 1999	DO	Do
Draft Guidance on Premarket Approval Applications for Assays Pertaining to Hepatitis C Viruses (HCV) that Are Indicated for Diagnosis or Monitoring of HCV Infection or Associated Disease	October 8, 1999	Do	Do
Guidance and Format of Premarket Notification (510(k)) Submissions for Liquid Chemical Sterilants/High Level Disinfectants (Replaces: Draft Guidance on the Content and Format of Premarket Notification (510(k)) Submission for Liquid Chemical Sterilants and High Level Disinfectants (12/18/97)	January 3, 2000	ODE/Division of Dental, Infection Control and General Hospital Devices (DDIGD)	Do
Reprocessing and Reuse of Single-Use Devices—Risk Categorization Scheme	December 9, 1999	Do	Do
Guidance for Conducting Stability Testing To Support An Expiration Date Labeling Claim for Medical Gloves	November 16, 1999	Do	Do
Guidance for Cardiovascular Intravascular Filter 510(k) Submission	November 26, 1999	ODE/Division of Cardiovascular, Respiratory & Neurological Devices (DCRND)	Do
Guidance for Industry and for FDA Reviewers: Recommended Clinical Study Design for Ventricular Tachycardia Ablation	May 7, 1999	Do	Do
Guidance Document for Vascular Prostheses 510(k) Submissions	November 26, 1999	Do	Do
Guidance for Annuloplasty Rings 510(k) Submissions	November 26, 1999	Do	Do
Guidance for Cardiovascular Intravascular Filter 510(k) Submissions	November 26, 1999	Do	Do
Guidance for Cardiopulmonary Bypass Oxygenators 510(k) Submissions	January 17, 2000	Do	Do
Guidance for the Submission of Research and Marketing Applications for Permanent Pacemaker Leads and for Pacemaker Lead Adaptor 510(k) Submissions (Replaces: Implantable Pacemaker Lead Testing Guidance for the Submission of a Section 510(k) Notification September 1, 1989)	January 14, 2000	Do	Do
Guidance for Industry and/or for FDA Reviewers/Staff and/or Compliance—Guidance for Spinal System 510(k)s	May 7, 1999	ODE/Division of General & Restorative Devices (DGRD)	Do

Name of Document	Date of Issuance	Group 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—Guidance for the Preparation of a Premarket Notification Application for Processed Human Dura Mater (Replaces: Guidance for Industry—Guidance for the Preparation of a Premarket Notification Application for Processed Human Dura Mater July 31, 1999)	August 30, 1999	Do	Do
Guidance for Industry—Guidance Document for Neurological Embolization Devices	August 13, 1999	Do	Do
Guidance for Industry—Guidance Document for Dura Substitute Devices	August 13, 1999	DO	Do
Guidance for Industry—Guidance on Preclinical and Clinical Data and Labeling for Breast Prostheses	October 5, 1999	Do	Do
Guidance for Industry, FDA Reviewers/Staff and Compliance—Guidance Document for Powered Muscle Stimulator 510(k)s	June 9, 1999	Do	Do
Guidance for Resorbable Adhesion Barrier Devices for Use in Abdominal and/or Pelvic Surgery	December 16, 1999	Do	Do
Intraocular Lens (IOL) Guidance Document; Draft (Replaces Intraocular Lens (IOL) Guidance Document Draft, September 10, 1997)	October 14, 1999	ODE/Division of Ophthalmic Devices (DOD)	Do
Guidance for Industry and for FDA Reviewers—Accountability for Clinical Studies for Ophthalmic Devices	August 4, 1999	Do	Do
Guidance for Industry and for FDA Reviewers/Staff—Guidance on 510(k) Submissions for Keratoprostheses	—	ODE/DOD	Do
Home Uterine Activity Monitors: Guidance for the Submission of 510(k) Premarket Notifications (Replaces: Premarket Testing Guidelines for Home Uterine Activity Monitors March 31, 1993)	July 30, 1999	ODE/Division of Reproductive, Abdominal, ENT & Radiological Devices (DRAERD)	Do
Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices	August 6, 1999	Do	Do
Guidance for Industry: Electro-optical Sensors for the In Vivo Detection of Cervical Cancer and its Precursors: Submission Guidance for an IDE/PMA; Draft	August 25, 1999	Do	Do
Announcement for FOD: Guidance for Industry and FDA—Medical Glove Guidance Manual; Draft FDA 99–4257	August 12, 1999	Office of Health and Industry Programs (OHIP)/Division of Small Manufacturers Assistance (DSMA)	Do
Guidance for Industry—Device Use Safety: Incorporating Human Factors in Risk Management	August 3, 1999	OHIP/Division of Device User Programs and Systems Analysis (DUPSA)	Do
Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #2	January 14, 2000	OHIP/Division of Mammography Quality and Radiation Programs (DMQRP)	

Name of Document	Date of Issuance	Group 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 Guidance: The Mammography Quality Standards Act Final Regulations Document #3	December 8, 1999	Do	Do
Compliance Guidance—Mammography Facility Survey and Medical Physicist Qualification Requirements Under MQSA	May 5, 1999	Do	Do
Compliance Guidance—The Mammography Quality Standards Act Final Regulations—Preparing for MQSA Inspections (Replaces: Compliance Guidance—Preparing for MQSA Inspections 6/30/95)	May 5, 1999	Do	Do
Guidance for Request and Issuance of Interim Notice Letters for Mammography Facilities Under the mammography Quality Standards Act, 42 U.S.C. Section 263(b)	May 4, 1999	Do	Do
Addendum to the Instructions for Completing FDA Form 3500A with Coding Manual (MEDWATCH) (MDR)	June 9, 1999	Office of Surveillance and Biometrics (OSB)	Do
Guidance for Industry and FDA Reviewers: Guidance on Immunotoxicity Testing	May 6, 1999	Office of Science and Technology (OST)/ Division of Life Science (DLS)	Do
Guidance for Industry—CDRH Standard Operating Procedures for the Identification and Evaluation of Candidate Consensus Standard for Recognition	August 6, 1999	OST/ODE	Do
Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket (Replaces: Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket—No Date Available)	February 22, 1999	OSB/Division of Postmarket Surveillance (DPS)	Do

Withdrawals

Name of Document	Date of Issuance	Group by Intended User or Regulatory Activity	Date Withdrawn
Guidance on Premarket Notification 510(k) for Sterilizers Intended for Use in Health Care Facilities March 3, 1993	March 3, 1993	OC	June 29, 1999
Global Harmonization Task Force Study Group 3—Draft Process Validation Guidance	1998	Do	June 22, 1999
Guidance for Industry and FDA Staff—Guidance on Medical Device Tracking (FDAMA) (Replaced by: Guidance for Industry and FDA Staff—Guidance on Medical Device Tracking (FDAMA) January 24, 2000)	February 12, 1999	Do	January 24, 2000
Regulatory Requirements for Medical Gloves—A Workshop Manual FDA Publication No 96.4257	September 1, 1996	OC/DOEII	July 7, 1999

Withdrawals			
Name of Document	Date of Issuance	Group by Intended User or Regulatory Activity	Date Withdrawn
The FDA Export Reform and Enhancement Act of 1996/Export Certification	October 1, 1996	OC/DPO	September 29, 1999
Guidance Document for Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators	1998	ODE	June 29, 1999
Freedom of Information/510(K) Process Changes	May 15, 1997	Do	May 26, 1999
Guidance for Off-the-Shelf Software Use in Medical Devices—Draft Guidance	August 17, 1998	Do	October 5, 1999
Reexamination of the Evaluation Process for Liquid Chemical Sterilants and High Level Disinfectants	May 19, 1997	Do	January 11, 2000
PMA Summaries of Safety and Effectiveness—Review by the Office of General Counsel (blue book memo #P85–1)	July 25, 1986	ODE/BlueBook	May 26, 1999
Guidance for the Submission of 510(k) Premarket Notifications for Cardiovascular Intravascular Filters—Version 1.0	February 11, 1997	ODE/DCRND	December 13, 1999
Guidance for Industry—Guidance For The Submission of Research and Marketing Applications for Permanent Pacemaker Leads	June 1, 1998	Do	October 18, 1999
Outline of Recommended Procedures for a Clinical Investigation of Endosseous Implants Under a 510(k)	1998	ODE/Division of Dental, Infection Control and General Hospital Devices (DDIGD)	May 5, 1999
Outline of Recommended Procedures for Animal Laboratory Studies of Endosseous Implants	1998	Do	May 5, 1999
510(k) Information Needed for Hydroxyapatite Coated Titanium Endosseous Implants	July 6, 1993	Do	Do
510(k) Information Needed for Ti-Powder Coated Titanium Endosseous Implants	July 13, 1993	Do	Do
510(k) Information Needed for Metallurgical Endosseous Implants	August 12, 1993	Do	Do
Guidance Document for the Preparation of Premarket Notifications [510(k)s] for Temporomandibular Joint Implants	January 23, 1995	Do	Do
Draft Guidance on the Content and Format of Premarket Notification (510(k)) Submission for Liquid Chemical Sterilants and High Level Disinfectants	December 18, 1997	Do	January 11, 2000
Draft Guideline for Reviewing Spinal Fixation Device Systems	January 9, 1997	ODE/DGRD	June 1, 1999
Guide for 510(k) Review of Processed Human Dura Mater	June 26, 1990	Do	August 9, 1999
Draft Guidance for Preparation of PMA Applications for Silicone Inflatable (Saline) Breast Prostheses	January 18, 1995	Do	August 16, 1999
Draft Guidance for Testing of Alternative Breast Prostheses (nonsilicone gel-filled)	September 1, 1994	Do	September 1, 1994

Withdrawals			
Name of Document	Date of Issuance	Group by Intended User or Regulatory Activity	Date Withdrawn
Draft Guidance for Preparation of FDA Submissions of Silicone Gel-Filled Breast Prostheses	May 11, 1992	Do	August 16, 1999
Guidance for Industry—Guidance for the Preparation of a Premarket Notification Application for Processed Human Dura Mater	July 31, 1999	Do	September 7, 1999
Technological Reporting For Powered Muscle Stimulator 510(k) (EMS)	January 1, 1993	DO	June 29, 1999
Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Powered Muscle Stimulators, and Ultrasound Diathermy and Muscle Stimulators	July 26, 1995	Do	June 29, 1999
Electrical Muscle Stimulator (EMS) Labeling Indications; Contraindications; Warnings; etc.	July 11, 1985	Do	June 29, 1999
Draft Intraocular Lens (IOL) Guidance Document	October 10, 1997	ODE/DOD	July 21, 1999
Guidance for the Content of Premarket Notifications for Metal Expandable Biliary Stents	February 5, 1998	ODE/DRAERD	June 29, 1999
In-vivo Devices for the Detection of Cervical Cancer and its Precursors: Submission Guidance for an IDE Draft Document	June 14, 1997	Do	May 26, 1999
Premarket Testing Guidelines for Home Uterine Activity Monitors	March 31, 1993	Do	June 2, 1999
Information for Manufacturers Seeking Marketing Clearance of Digital Mammography Systems	June 19, 1996	Do	June 29, 1999
Obtaining CDRH Guidance Documents	March 29, 1999	OHIP/DSMA	May 11, 1999
List of Current CDRH Addresses for Report Submission and Ordering of CDRH Forms	July 30, 1996	OHIP/DUPSA	October 20, 1999
Addendum to What a Mammography Facility Should do to Prepare for an MQSA Inspection	July 31, 1996	OHIP/DMQRP	May 12, 1999
Compliance Guidance—Preparing for MQSA Inspections	June 30, 1995	Do	May 13, 1999
Instructions for completing Semi-Annual Report, Form 3419 (MDR)	September 24, 1996	OSB	May 21, 1999
Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket	No date available	OSB/Division of Postmarket Surveillance (DPS)	January 7, 2000

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)
ANDAs: Blend Uniformity Analysis	August 26, 1999	Generic Drug Draft	Office of Training and Communication, Drug Information Branch, Food and Drug Administration, 5600 Fishers Lane, Rockville, Md 20857, Internet: http://www.fda.gov/cder/guidance/index.htm
ANDAs: Impurities in Drug Substances	December 3, 1999	Generic Drug	Do
Applications Covered by Section 505(b)(2)	December 8, 1999	Procedural Draft	Do
Average, Population, and Individual Approaches to Establishing Bioequivalence	August 27, 1999	Biopharmaceutic Draft	Do
BA and BE Studies for Orally Administered Drug Products	August 27, 1999	Do	Do
Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action	June 2, 1999	Do	Do
Catheter-Related Bloodstream Infections - Developing Antimicrobial Drugs for Treatment	October 18, 99	Clinical Antimicrobial Draft	Do
Changes to an Approved NDA or ANDA	November 23, 1999	Chemistry	Do
Clinical Considerations for Accelerated and Traditional Approval of Antiretroviral Drugs Using Plasma HIV RNA Measurements	September 1, 1999	Clinical Medical Draft	Do
Clinical Development Programs for Drugs, Devices, and Biological Products Intended for the Treatment of Osteoarthritis (OA)	July 15, 1999	Do	Do
Computerized Systems Used in Clinical Trials	May 10, 1999	Compliance	Do
Consumer-Directed Broadcast Advertisements	August 9, 1999	Advertising	Do
Disclosure of Materials Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Convened by the Center for Drug Evaluation and Research	November 30, 1999	Procedural	Do
Draft Guidance for Industry on Disclosing Information Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Related to the Testing or Approval of New Drugs and Convened by CDER, Beginning January 1, 2000; Availability	December 22, 1999	Procedural Draft	Do
Drug Master Files for Bulk Antibiotic Drug Substances: Availability	November 29, 1999	Chemistry	Do
E10 - Choice of Control Group in Clinical Trials	September 24, 1999	ICH Draft - Efficacy	Do
Establishing Pregnancy Registries	June 4, 1999	Clinical Medical Draft	Do
Evaluation of Human Pregnancy Outcome Data	June 4, 1999	Do	Do
In Vivo Metabolism/Drug Interaction Studies - Study Design, Data Analysis, and Recommendations for Dosing and Labeling	November 24, 1999	Clinical Pharmacology	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 Vivo Pharmacokinetics and Bioavailability Studies and In Vitro Dissolution Testing for Levothyroxine Sodium Tablets	June 10, 1999	Clinical Medical Draft	Do
Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act	August 17, 1999	Procedural Draft	Do
Labeling OTC Human Drug Products Using a Column Format	December 1, 1999	OTC Draft	Do
Levothyroxine Sodium	August 18, 1999	Clinical Medical Draft	Do
Major, Minor, Facsimile, and Telephone Amendments to Original Abbreviated New Drug Applications	August 11,1999	Generic Drug	Do
Monoclonal Antibodies Used as Reagents in Drug Manufacturing	June 24, 1999	Chemistry Draft	Do
Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products	June 2, 1999	Do	Do
Noncontraceptive Estrogen Class Labeling	September 27, 1999	Labeling Draft	Do
Pharmacokinetics in Patients With Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosing and Labeling	December 7, 1999	Clinical Pharmacology	Do
Photosafety Testing	January 10, 2000	Pharmacology/Toxicology	Do
Possible Dioxin/PCB Contamination of Drug and Biological Products	August 23, 1999	Compliance	Do
Preparing Data for Electronic Submission in ANDAs	September 21, 1999	Generic Drug	Do
Q6B-Test Procedures and Acceptance Criteria for Biotechnological/Biological Products	August 18, 1999	ICH-Quality	Do
Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act-Revised	October 1, 1999	Procedural	Do
S4A Duration of Chronic Toxicity Testing in Animals (Rodent and Nonrodent Toxicity Testing)	June 25, 1999	ICH-Safety	Do
Submission of Abbreviated Reports and Synopses in Support of Marketing Applications	September 13, 1999	Clinical Medical	Do
Submission of Documentation in Drug Applications for Container Closure Systems Used for the Packaging of Human Drugs and Biologics	July 7, 1999	Chemistry	Do

Withdrawals

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	Date Withdrawn
Alprazolam Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing	November 27, 1992	Biopharmaceutic	July 8, 1999
Bumetanide Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing	April 23, 1993	Do	Do
Carbidopa and Levodopa Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing	June 19, 1992	Do	Do
Cefaclor Capsules and Suspension In Vivo Bioequivalence and In Vitro Dissolution Testing	April 23, 1993	Do	Do

Withdrawals			
Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	Date Withdrawn
Diflunisal Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing	May 16, 1992	Do	Do
Diltiazem Hydrochloride Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing	May 16, 1992	Do	Do
Flurbiprofen (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	June 8, 1995	Do	Do
Gemfibrozil Capsules or Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing	June 16, 1992	Do	Do
Guanabenz Acetate Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing	April 23, 1993	Do	Do
Hydroxychloroquine Sulfate (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	December 28, 1995	Do	Do
Indapamide (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	April 23, 1993	Do	Do
Ketoprofen (capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	April 23, 1993	Do	July 8, 1999
Leucovorin Calcium (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	August 4, 1988	Do	Do
Medroxyprogesterone Acetate (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	September 17, 1987	Do	Do
Metoprolol Tartrate (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	June 12, 1992	Do	Do
Nadolol (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	May 16, 1992	Do	Do
Naproxen (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	June 8, 1995	Do	Do
Nortriptyline Hydrochloride (capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	June 12, 1992	Do	Do
Pentoxifylline (extended-release tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	December 22, 1995	Do	Do
Pindolol (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	April 23, 1993	Do	Do
Piroxicam (capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	June 15, 1999	Do	Do
Ranitidine Hydrochloride (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	April 23, 1993	Do	Do
Trazodone Hydrochloride (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	April 30, 1988	Do	Do
Waiver Policy	March 29, 1993	Biopharmaceutic Draft	Do
Bioavailability Policies and Guidelines	N/A	Biopharmaceutic Draft	Do
SUPAC–IR: Immediate Release and Solid Oral Dosage Forms; Manufacturing Equipment Addendum	October 21, 1997	Chemistry Draft	February 26, 1999
Selegiline Hydrochloride (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	December 22, 1995	Biopharmaceutic	December 27, 1999

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)
Antimicrobial Food Additives—Guidance	July 1999	Industry and Center for Food Safety and Applied Nutrition Staff	Mark Hepp, Ph.D., (HFS–215) OPA/CFSAN/FDA 200 C Street. S.W. Washington, DC 20204 202–418–3098 Internet: http://vm.cfsan.fda.gov/~dms/opa-antg.html
Guidance for Industry—Preparation of Premarket Notifications for Food Contact Substances—Chemistry Recommendations	Sept. 1999	Regulated Industry	Mitch Cheeseman, Ph.D., (HFS–215) OPA/CFSAN/FDA 200 C Street. S.W. Washington, DC 20204 202–418–3083 Internet: http://vm.cfsan.fda.gov/~dms/opa-pmnc.html
Guidance for Industry—Preparation of Premarket Notifications for Food Contact Substances—Toxicology Recommendations	Sept. 1999	Regulated Industry	Mitch Cheeseman, Ph.D., (HFS–215) OPA/CFSAN/FDA 200 C Street. S.W. Washington, DC 20204 202–418–3083 Internet: http://vm.cfsan.fda.gov/~dms/opa-pmnt.html

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: Chemistry, Manufacturing and Controls Changes to an Approved NADA or ANADA: Draft Guidance	June 1999	Animal Drug Industry	Communications Staff (HFV–12), FDA/CVM, 7500 Standish Pl., Rockville, MD 20855, 301–594–1755, FAX 301–594–1831 Internet: http://www.fda.gov/cvm
Draft Guidance for Industry: Good Clinical Practices	July 1999	Do	Do
Guidance for Industry: Efficacy of Anthelmintics: General Recommendations: Draft Guidance	July 1999	Do	Do
Guidance for Industry: Stability Testing for Medicated Premixes Draft Guidance	July 1999	Do	Do
Guidance for Industry: Impurities in New Veterinary Drug Substances Draft Guidance	July 1999	Do	Do
Guidance for Industry: Impurities in New Veterinary Medical Products Draft Guidance	July 1999	Do	Do
Guidance for Industry: Efficacy of Anthelmintics: Specific Recommendations for Bovines: Draft Guidance	July 1999	Do	Do
Guidance for Industry: Efficacy of Anthelmintics: Specific Recommendations for Ovines: Draft Guidance	July 1999	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 Industry—Validation of Analytical Procedures: Definition and Terminology	July 1999	Do	Do
Guidance for Industry—Validation of Analytical Procedures: Methodology: Final Guidance	July 1999	Do	Do
Guidance for Industry: Efficacy of Anthelmintics: Specific Recommendations for Caprines: Draft Guidance	July 1999	Do	Do
Guidance for Industry: Manufacture and Distribution of Unapproved Piperazine Products	August 1999	Do	Do
Guidance for Industry: Possible Dioxin/PCB Contamination of Drug and Biological Products	August 1999	Do	Do
Guidance for Industry—Consumer-Directed Broadcast Advertisements: Final Guidance	August 1999	Do	Do
Guidance for Industry: Stability Testing of New Veterinary Dosage Forms VICH GL4: Final Guidance	September 1999	Do	Do
Guidance for Industry: Stability Testing of New Veterinary Drug Substances and Medicinal Products VICH GL3: Final Guidance	September 1999	Do	Do
Guidance for Industry: Environmental Impact Assessments (EIA's) for Veterinary Medicinal Products (VMP's)—Phase I: Draft Guidance	September 1999	Do	Do
Guidance for Industry: Quality of Biotechnological Products in the Veterinary Field: Stability Testing of Biotechnological/ Biological Products VICH GL 17: Draft Guidance	September 1999	Do	Do
Guidance for Industry: Impurities: Residual Solvents VICH GL 18: Draft Guidance	September 1999	Do	Do
Guidance for Industry—Content and Format of Effectiveness and Target Animal Safety Technical Sections and Final Study Reports for Submission to the Division of Therapeutic Drugs for Non-Food Animals	September 1999	Do	Do
Guidance for Industry: Stability Testing: Photostability Testing of New Veterinary Drug Substances and Medicinal Products: Final Guidance	September 1999	Do	Do
Computerized Systems Used in Clinical Trials	October 1999	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)
Dioxin in Anti-Caking Agents Used in Animal Feed and Feed Ingredients	October 1999	Do	Do
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	December 1999	Do	Do

VII. Guidance Documents Issued by Office of Regulatory Affairs

Name of Document	Date of Issuance	Grouped by Intended User of Regulatory Activity	How to obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Guide to Inspections of Quality Systems	August 1999	FDA Personnel	Division of Emergency and Investigational Operations (HFC–130), Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5636 Internet: http://www.fda.gov/ora/inspect—ref/igs/qsit/QSITGUIDE.PDF
Import Alerts	Continuously	FDA Personnel	Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD Internet: http://www.fda.gov/ora/fiars/ora—import—alerts.html

Withdrawals	Date of Issuance	Grouped by Intended User or Regulatory Activity	Date Withdrawn
Compliance Policy Guide (CPG), Chapter 3, Sec. 305.100, Accupuncture Devices and Accessories (CPG 7124.11) Revoked: December 23, 1999.		FDA Personnel	December 23, 1999

Dated: March 7, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–6117 Filed 3–13–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2249]

International Cooperation on Harmonisation of Technical Requirements for Approval of Veterinary Medicinal Products (VICH); Final Guidance on Stability Testing for Medicated Premixes (VICH GL8); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance for industry (#91) entitled ''Stability Testing for Medicated Premixes (VICH GL8).'' This guidance document has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This final guidance document is an annex to the parent guidance VICH GL3 entitled ''Stability Testing of New Veterinary Drug Substances and