whether BREVIBLOC (esmolol HCl) Injection, 250 mg/mL, 10-mL ampule, was withdrawn from sale for reasons of safety or effectiveness. Bedford noted that Baxter has publicly stated that the product was discontinued due to safety issues surrounding medication errors and asked the agency to determine the cause of the discontinuation.

We have carefully reviewed our files for records concerning the withdrawal from sale of BREVIBLOC (esmolol HCl) Injection, 250 mg/mL, 10-mL ampule, including the NDA file for this drug product. We have also independently evaluated relevant literature and data for possible postmarketing adverse event reports. FDA's review shows that the product was withdrawn from sale because of reports of serious adverse events, including deaths.

Although the application holder has made several labeling revisions (including a warning sticker on the ampule) and issued Dear Healthcare Provider letters to reduce the potential for medication errors, there have been additional reports of medication errors. In addition, alternative presentations of the product are available that are not associated with the same potential for medication errors.

After considering the citizen petition (and comments submitted) and reviewing agency records concerning the drug product, analyses of adverse event reports, and relevant literature, FDA has determined under § 314.161 that BREVIBLOC (esmolol HCl) Injection, 250 mg/mL, 10-mL ampule, was withdrawn from sale for reasons of safety or effectiveness. FDA has reviewed the latest approved labeling for BREVIBLOC (esmolol HCl) Injection, 250 mg/mL, 10-mL ampule, and has determined that this labeling is inadequate to reduce medication errors to an acceptable level. FDA has determined that Human Factors studies (i.e., Failure Mode and Effects Analysis and usability studies to test the product in a typical practice setting) are necessary before this product could be considered for reintroduction to the market.

Therefore, the agency has determined, under § 314.161, that BREVIBLOC (esmolol HCl) Injection, 250 mg/mL, 10-mL ampule, was withdrawn from sale for reasons of safety. BREVIBLOC (esmolol HCl) Injection, 250 mg/mL, 10-mL ampule, will be removed from the list of drug products published in the Orange Book. FDA will not accept or approve ANDAs that refer to BREVIBLOC (esmolol HCl) Injection, 250 mg/mL, 10-mL ampule.

Dated: April 30, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–10559 Filed 5–4–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 2010 Funding Opportunity

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice of intent to award a Single Source Grant to the grantee of the Technical Assistance Center for Mental Health Promotion and Youth Violence Prevention.

SUMMARY: This notice is to inform the public that the Substance Abuse and Mental Health Services Administration (SAMHSA) intends to award approximately $620,000 for up to three years to the grantee of the Technical Assistance Center for Mental Health Promotion and Youth Violence Prevention. This is not a formal request for applications. Assistance will be provided only to the current grantee of the Technical Assistance Center for Mental Health Promotion and Youth Violence Prevention based on the receipt of a satisfactory application that is approved by an independent review group.

Funding Opportunity Title: SM–10–018.

Catalog of Federal Domestic Assistance (CFDA) Number: 93.243.

Authority: Section 520A of the Public Health Service Act, as amended.

Justification: Only an application from the grantee for the Technical Assistance Center for Mental Health Promotion and Youth Violence Prevention will be considered for funding under this announcement. Three-year funding has become available to assist because this funding supplement is intended to support the technical assistance needs of Project LAUNCH grantees to be newly funded in FY 2010. The current grantee provides technical assistance to the other cohorts for Project LAUNCH and is in a unique position to address the grant implementation needs of communities to be funded this fiscal year. There is no other potential organization with the required access and expertise.

Eligibility for this program supplement is restricted to the current grantee, Technical Assistance Center for Mental Health Promotion and Youth Violence Prevention. This supplement will serve to maximize efficiencies created under the current services infrastructure. It would be inefficient and duplicative to fund additional technical assistance services for Project LAUNCH grantees through a second organization.

Contact: Shelly Hara, Substance Abuse and Mental Health Services Administration, 1 Choke Cherry Road, Room 8–1095, Rockville, MD 20857; telephone: (240) 276–2321; E-mail: *shelly.hara@samhsa.hhs.gov.*

Toian Vaughn,

SAMHSA Committee Management Officer.

[FR Doc. 2010–10502 Filed 5–4–10; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–N–0451] (formerly Docket No. 2004N–0226)

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 023

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a publication containing modifications the agency is making to the list of standards FDA recognizes for use in premarket reviews (FDA recognized consensus standards). This publication, entitled "Modifications to the List of Recognized Standards, Recognition List Number: 023" (Recognition List Number: 023), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit written or electronic comments concerning this document at any time. See section VII of this document for the effective date of the recognition of standards announced in this document.

ADDRESSES: Submit written requests for single copies of "Modifications to the List of Recognized Standards, Recognition List Number: 023" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66,

rm. 4613, Silver Spring, MD 20993–0002. Send two self-addressed adhesive labels to assist that office in processing your requests, or fax your request to 301–847–8149. Submit written comments concerning this document, or recommendations for additional standards for recognition, to the contact person (see **FOR FURTHER INFORMATION CONTACT**). Submit electronic comments by e-mail: *standards@cdrh.fda.gov*. This document may also be accessed on FDA's Internet site at *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/cdrhnew.cfm*. See section VI of this document for electronic access to the searchable database for the current list of FDA recognized consensus standards, including Recognition List Number: 023 modifications and other standards related information.

FOR FURTHER INFORMATION CONTACT: Carol L. Herman, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3632, Silver Spring, MD 20993–0002, 301–796–6574.

SUPPLEMENTARY INFORMATION:

I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360d). Amended section 514 allows FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device premarket review submissions or other requirements.

In a notice published in the **Federal Register** of February 25, 1998 (63 FR 9561), FDA announced the availability of a guidance entitled "Recognition and Use of Consensus Standards." The notice described how FDA would implement its standard recognition program and provided the initial list of recognized standards.

Modifications to the initial list of recognized standards, as published in the **Federal Register**, are identified in table 1 of this document.

TABLE 1.—PREVIOUS PUBLICATIONS OF STANDARD RECOGNITION LISTS

February 25, 1998 (63 FR 9561)	May 27, 2005 (70 FR 30756)
October 16, 1998 (63 FR 55617)	November 8, 2005 (70 FR 67713)
July 12, 1999 (64 FR 37546)	March 31, 2006 (71 FR 16313)
November 15, 2000 (65 FR 69022)	June 23, 2006 (71 FR 36121)
May 7, 2001 (66 FR 23032)	November 3, 2006 (71 FR 64718)
January 14, 2002 (67 FR 1774)	May 21, 2007 (72 FR 28500)
October 2, 2002 (67 FR 61893)	September 12, 2007 (72 FR 52142)
April 28, 2003 (68 FR 22391)	December 19, 2007 (72 FR 71924)
March 8, 2004 (69 FR 10712)	September 9, 2008 (73 FR 52358)
June 18, 2004 (69 FR 34176)	March, 18, 2009 (74 FR 11586)
October 4, 2004 (69 FR 59240)	September 8, 2009 (74 FR 46203)

These notices describe the addition, withdrawal, and revision of certain standards recognized by FDA. The agency maintains "hypertext markup language (HTML)" and "portable document format (PDF)" versions of the list of "FDA Recognized Consensus Standards." Both versions are publicly accessible at the agency's Internet site. See section VI of this document for electronic access information. Interested persons should review the supplementary information sheet for the standard to understand fully the extent to which FDA recognizes the standard.

II. Modifications to the List of Recognized Standards, Recognition List Number: 023

FDA is announcing the addition, withdrawal, correction, and revision of certain consensus standards the agency will recognize for use in satisfying premarket reviews and other requirements for devices. FDA will incorporate these modifications in the list of FDA Recognized Consensus Standards in the agency's searchable database. FDA will use the term "Recognition List Number: 023" to identify these current modifications.

In table 2 of this document, FDA describes the following modifications: (1) The withdrawal of standards and their replacement by others; (2) the correction of errors made by FDA in listing previously recognized standards; and (3) the changes to the supplementary information sheets of recognized standards that describe revisions to the applicability of the standards.

In section III of this document, FDA lists modifications the agency is making that involve the initial addition of standards not previously recognized by FDA.

TABLE 2.—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS

Old Recognition No.	Replacement Recognition No.	Standard	Change
A. Biocompatibility			
2–64	2–153	ANSI/AAMI/ISO 10993–5:2009 Biological Evaluation of Medical Devices—Part 5: Tests for *in vitro* Cytotoxicity	Withdrawn and replaced with newer version
2–67	2–154	ASTM F756—08 Standard Practice for Assessment of Hemolytic Properties of Materials	Withdrawn and replaced with newer version
2–82	2–155	ASTM F2147–01 (Reapproved 2006) Standard Practice for Guinea Pig: Split Adjuvant and Closed Patch Testing for Contact Allergens	Withdrawn and replaced with newer version
2–87		ISO 10993–10:2002 Biological Evaluation of Medical Devices—Part 10: Tests for Irritation and Delayed-Type Hypersensitivity	Title, Extent of recognition, and Relevant guidance
2–93		ASTM F 763—04 Standard Practice for Short-Term Screening of Implant Materials	Extent of recognition

TABLE 2.—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old Recognition No.	Replacement Recognition No.	Standard	Change
2–94		ASTM F 981—04 Standard Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone	Extent of recognition
2–96		ASTM F 1903—98 (Reapproved 2003) Standard Practice for Testing For Biological Responses to Particles *in vitro*	Title and Extent of recognition
2–98		ANSI/ AAMI/ ISO 10993–1:2003 Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing	Title, Extent of recognition, and Relevant guidance
2–100		ASTM E 1372—95 (Reapproved 2003) Standard Test Method for Conducting a 90-Day Oral Toxicity Study in Rats	Title and Extent of recognition
2–108		ASTM F 1905—98 (Reapproved 2003) Standard Practice For Selecting Tests for Determining the Propensity of Materials to Cause Immunotoxicity	Title and Extent of recognition
2–114		ASTM F 1877—05 Standard Practice for Characterization of Particles	Extent of recognition
2–115		ASTM F 895—84 (Reapproved 2006) Standard Test Method for Agar Diffusion Cell Culture Screening for Cytotoxicity	Title, Extent of recognition, and Relevant guidance
2–117		ANSI/AAMI/ISO 10993–3:2003 Biological Evaluation of Medical Devices—Part 3: Tests for Genotoxicity, Carcinogenicity, and Reproductive Toxicity	Title, Extent of recognition, and contact person
2–118		ANSI/AAMI/ISO 10993–11:2006 Biological Evaluation of Medical Devices—Part 11: Tests for Systemic Toxicity	Title, Extent of recognition, and Relevant guidance
2–119		ASTM F813–07 Standard Practice for Direct Contact Cell Culture Evaluation of Materials for Medical Devices	Extent of recognition
2–120		ANSI/AAMI/ISO 10993–6:2007 Biological Evaluation of Medical Devices—Part 6: Tests for Local Effects after Implantation	Title and Extent of recognition
2–122		ASTM F 719–81 (Reapproved 2007)$^{\varepsilon}$ Standard Practice for Testing Biomaterials in Rabbits for Primary Skin Irritation	Title, Extent of recognition, and Relevant guidance
2–123		ASTM F 720–81 (Reapproved 2007) Standard Practice for Testing Guinea Pigs for Contact Allergens: Guinea Pig Maximization Test	Title, Extent of recognition, and Relevant guidance
2–124		ASTM F 750–87 (Reapproved 2007)$^{\varepsilon}$ Standard Practice for Evaluating Material Extracts by Systemic Injection in the Mouse	Title, Extent of recognition, and Relevant guidance
2–125		ASTM F749–98 (Reapproved 2007)$^{\varepsilon 1}$ Standard Practice for Evaluating Material Extracts by Intracutaneous Injection in the Rabbit	Title, Extent of recognition, and Relevant guidance
2–126		ASTM F748–06 Standard Practice for Selecting Generic Biological Test Methods for Materials and Devices	Extent of recognition and Relevant guidance
2–133		ASTM F1408–97 (Reapproved 2008) Standard Practice for Subcutaneous Screening Test for Implant Materials	Extent of recognition
2–134		ASTM F2065–00 (Reapproved 2006) Standard Practice for Testing for Alternative Pathway Complement Activation in Serum by Solid Materials	Extent of recognition
2–135		ANSI/ AAMI/ ISO 10993–12:2007 Biological Evaluation of Medical Devices—Part 12: Sample Preparation and Reference Materials	Title, Extent of recognition, and Relevant guidance
2–136		ASTM E1262–88 (Reapproved 2008) Standard Guide for Performance of Chinese Hamster Ovary Cell/Hypoxanthine Guanine Phosphoribosyl Transferase Gene Mutation Assay	Title, Extent of recognition, and Relevant guidance
2–137		ASTM E1263–97 (Reapproved 2008) Standard Guide for Conduct of Micronucleus Assays in Mammalian Bone Marrow Erythrocytes	Extent of recognition
2–138		ASTM E1280–97 (Reapproved 2008) Standard Guide for Performing the Mouse Lymphoma Assay for Mammalian Cell Mutagenicity	Extent of recognition and Relevant guidance
2–139		ASTM E1397–91 (Reapproved 2008) Standard Practice for the *In Vitro* Rat Hepatocyte DNA Repair Assay	Extent of recognition

TABLE 2.—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old Recognition No.	Replacement Recognition No.	Standard	Change
2–140		ASTM E1398–91 (Reapproved 2008) Standard Practice for the *In Vivo* Rat Hepatocyte DNA Repair Assay	Extent of recognition
2–141		ASTM F1984–99 (Reapproved 2008) Standard Practice for Testing for Whole Complement Activation in Serum by Solid Materials	Extent of recognition, Relevant guidance and Contact person
2–142		ASTM F1983–99 (Reapproved 2008) Standard Practice for Assessment of Compatibility of Absorbable/Resorbable Biomaterials for Implant Applications	Extent of recognition
2–143		ASTM F1904–98 (Reapproved 2008) Standard Practice for Testing the Biological Responses to Particles *in vivo*	Extent of recognition
2–144		ASTM F619–03 (Reapproved 2008) Standard Practice for Extraction of Medical Plastics	Extent of recognition and Relevant guidance
2–145		ASTM F1439–03 (Reapproved 2008) Standard Guide for Performance of Lifetime Bioassay for the Tumorigenic Potential of Implant Materials	Extent of recognition
2–146		ASTM F2148–07$^{\varepsilon 1}$ Standard Practice for Evaluation of Delayed Contact Hypersensitivity Using the Murine Local Lymph Node Assay (LLNA)	Extent of recognition and Relevant guidance
2–147		USP 32–NF26 Biological Tests <87> 2009 Biological Reactivity Test, In Vitro—Direct Contact Test	Extent of recognition and Relevant guidance
2–148		USP 32–NF26 Biological Tests <87> Biological Reactivity Test, In Vitro—Elution Test	Extent of recognition and Relevant guidance
2–149		USP 32–NF26 Biological Tests <88> Biological Reactivity Tests, In Vivo, Procedure—Preparation of Sample	Extent of recognition and Relevant guidance
2–150		USP 32–NF26 Biological Tests <88> Biological Reactivity Tests, In Vivo, Classification of Plastics—Intracutaneous Test	Extent of recognition and Relevant guidance
2–151		USP 32–NF26 Biological Tests <88> Biological Reactivity Tests, In Vivo, Classification of Plastics—Systemic Injection Test	Extent of recognition and Relevant guidance
2–152		ISO 10993–10:2002/Amd.1:2006(E) Biological Evaluation of Medical Devices—Part 10: Tests for Irritation and Delayed-Type Hypersensitivity AMENDMENT 1	Extent of recognition and Relevant guidance
B. Cardiology			
3–2	3–72	ANSI/AAMI EC53:1995/(R) 2008 ECG Cables and Leadwires	Withdrawn and replaced with newer version
3–29		IEC 60601–2–30 (1999–12) Medical Electrical Equipment, Part 2: Particular Requirements for the Safety, Including Essential Performance, of Automatic Cycling Non-Invasive Blood Pressure Monitoring Equipment	Withdrawn
3–45	3–73	ANSI/AAMI/ISO EC57:1998/(R)2008 Testing and Reporting Performance Results of Cardiac Rhythm and ST-Segment Measurement Algorithms	Withdrawn and replaced with newer version
3–49	3–74	ASTM F2079–02 (Reapproved 2008) Standard Test Method for Measuring Intrinsic Elastic Recoil of Balloon-Expandable Stents[1]	Withdrawn and replaced with newer version
3–50		AAMI/ANSI DF2–1996 (Revision of ANSI/AAMI DF2–1989) Cardiac Defibrillator Devices	Withdrawn
3–51		AAMI /ANSI DF–39–1993 Automatic External Defibrillators and Remote-Control Defibrillators	Withdrawn
3–53	3–75	ANSI/AAMI SP10:2002/(R)2008 & ANSI/AAMI SP10:2002/A1:2003/(R)2008 & ANSI/AAMI SP10:2002/A2:2006/(R)2008, ANSI/AAMI SP10:2002/(R)2008 & ANSI/AAMI SP10:2002/A1:2003/(R)2008 & ANSI/AAMI SP10:2002/A2:2006/(R)2008 Manual, Electronic, or Automated Sphygmomanometers	Withdrawn and replaced with newer version

TABLE 2.—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old Recognition No.	Replacement Recognition No.	Standard	Change
3–63		ISO 11318:2002 Cardiac Defibrillators—Connector Assembly DF–1 for Implantable Defibrillators—Dimensions and Test Requirements	Contact person
3–67	3–76	ASTM F2129–08 Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices	Withdrawn and replaced with newer version
3–70		AAMI/ANSI SP10:2002/A1:2003—Amendment 1 to ANSI/AAMI SP10:2002 Manual, Electronic, or Automated Sphygmomanometers	Withdrawn
3–71		AAMI/ANSI SP10:2002/A2:2006—Amendment 2 to ANSI/AAMI SP10:2002 Manual, Electronic, or Automated Sphygmomanometers	Withdrawn
C. Dental/ENT			
4–78	4–180	ISO 9168:2009 Dentistry—Hose Connectors for Air Driven Dental Handpieces	Withdrawn and replaced with newer version
4–87		ADA/ANSI ADA Specification No. 69 - Dental Ceramic:1999	Reaffirmation
4–91		ADA/ANSI ADA Specification No. 80 - Dental Material-Determination of Color Stability:2001	Reaffirmation
4–99	4–181	ISO 4049:2009 Dentistry-Polymer-Based Filling, Restorative and Luting Materials	Withdrawn and replaced with newer version
4–117		ADA/ANSI Specification No. 12 - Denture Base Polymers:2002	Reaffirmation
4–119		ADA/ANSI Specification No. 82 - Dental Reversible/Irreversible Hydrocolloid Impression Material Systems: 1998/Reaffirmed 2003	Reaffirmation
4–120	4–182	ISO 10139–2:2009 Dentistry—Soft Lining Materials for Removable Dentures—Part 2: Materials for Long-Term Use	Withdrawn and replaced with newer version
4–160		ANSI/ASA S3.1–1999 (R 2003) Maximum Permissible Ambient Noise Levels for Audiometric Test Rooms	Reaffirmation
4–161	4–183	ANSI/ASA S3.2–2009 Method for Measuring the Intelligibility of Speech Over Communication Systems	Withdrawn and replaced with newer version
4–164		ANSI/ASA S3.7–1995 (R 2003) Method for Coupler Calibration of Earphones	Reaffirmation
4–166		ANSI/ASA S3.20–1995 (R2003) Bioacoustical Terminology	Reaffirmation
4–167		ANSI/ASA S3.21–2004 Methods for Manual Pure-Tone threshold Audiometry	Reaffirmation
4–168	4–184	ANSI/ASA S3.25–2009 Occluded Ear Simulator	Withdrawn and replaced with newer version
4–174	4–185	ANSI/ASA S3.45–2009 Procedures for Testing Basic Vestibular Function	Withdrawn and replaced with newer version
4–176	4–186	ANSI/ASA S12.2–2008 Criteria for Evaluating Room Noise	Withdrawn and replaced with newer version
D. General			
5–18	5–51	ASTM D–4332–01 (Reapproved 2006) Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing	Withdrawn and replaced with newer version
5–29		AAMI/ANSI HE74–2001/ Human Factors Design Process for Medical Devices	Reaffirmation
E. In Vitro Diagnostics			
7–35	7–205	CLSI H47–A2 One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test	Withdrawn and replaced with newer version

TABLE 2.—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old Recognition No.	Replacement Recognition No.	Standard	Change
7–42	7–206	CLSI I/LA20–A2 Analytical Performance Characteristics and Clinical Utility of Immunological Assays for Human Immunoglobulin E (IgE) Antibodies and Defined Allergen Specificities	Withdrawn and replaced with newer version
7–97	7–207	CLSI GP16–A3 Urinalysis	Withdrawn and replaced with newer version
7–187	7–208	CLSI M44–S2 Zone Diameter Interpretive Standards, Corresponding Minimal Inhibitory Concentration (MIC) Interpretive Breakpoints, and Quality Control Limits for Antifungal Disk Diffusion Susceptibility Testing of Yeasts	Withdrawn and replaced with newer version
7–37		NCCLS I/LA06–A Detection and Quantitation of Rubella IgG Antibody: Evaluation and Performance Criteria for Multiple Component Test Products, Specimen Handling, and Use of Test Products in the Clinical Laboratory	Withdrawn
F. Materials			
8–104	8–189	ASTM F 1108—04 (Reapproved 2009) Standard Specification for Titanium-6Aluminum-4Vanadium Alloy Castings for Surgical Implants (UNS R56406)	Withdrawn and replaced with newer version
8–145	8–190	ASTM F 90–09 Standard Specification for Wrought Cobalt-20Chromium-15Tungsten-10Nickel Alloy for Surgical Implant Applications (UNS R30605)	Withdrawn and replaced with newer version
G. Physical Medicine			
16–19	16–162	ISO 7176–4:2008 Wheelchairs—Part 4: Energy Consumption of Electric Wheelchairs and Scooters for Determination of Theoretical Distance Range	Withdrawn and replaced with newer version
16–20	16–163	ISO 7176–5:2008 Wheelchairs—Part 5: Determination of Dimensions, Mass and Manoeuvring Space	Withdrawn and replaced with newer version
16–23	16–164	ISO 7176–10:2008 Wheelchairs—Part 10: Determination of Obstacle-Climbing Ability of Electrically Powered Wheelchairs	Withdrawn and replaced with newer version
16–26	16–165	ISO 7176–14:2008 Wheelchairs—Part 14 Power and Control Systems for Electrically Powered Wheelchairs and Scooters—Requirements and Test Methods	Withdrawn and replaced with newer version
H. Sterility			
14–117		ANSI/AAMI ST35:2003 Handling and Biological Decontamination of Reusable Medical Devices in Health Care Facilities and in Nonclinical Settings	Withdrawn
14–263	14–280	ANSI/AAMI ST79:2006 and A1:2008, A2:2009 (Consolidated Text) Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities	Withdrawn and replaced with newer version
14–256	14–286	ASTM F2095–07e1 Standard Test Methods for Pressure Decay Leak Test for Flexible Packages With and Without Restraining Plates	Withdrawn and replaced with newer version
14–255	14–281	ASTM F17–08 Standard Terminology Relating to Flexible Barrier Packaging[1]	Withdrawn and replaced with newer version
14–245	14–282	ASTM F2338–09 Standard Test Method for Nondestructive Detection of Leaks in Packages by Vacuum Decay Method[1]	Withdrawn and replaced with newer version
14–237	14–283	ASTM F 88/F 88M—09 Standard Test Method for Seal Strength of Flexible Barrier Materials[1]	Withdrawn and replaced with newer version
14–199	14–284	ASTM D4169–08 Standard Practice for Performance Testing of Shipping Containers and Systems[1]	Withdrawn and replaced with newer version
14–228		ANSI/AAMI/ISO 11135–1:2007 Sterilization of Health Care Products - Ethylene oxide - Part 1: Requirements for Development, Validation, and Routine Control of a Sterilization Process for Medical Devices	Guidance

TABLE 2.—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old Recognition No.	Replacement Recognition No.	Standard	Change
14–70	14–285	ANSI/AAMI/ISO 14161:2009 Sterilization of Health Care Products - Biological Indicators - Guidance for the Selection, Use and Interpretation of Results	Withdrawn and replaced with newer version
I. Tissue Engineering			
15–6	15–16	ASTM F2450–09 Standard Guide for Assessing Microstructure of Polymeric Scaffolds for Use in Tissue Engineered Medical Products[1]	Withdrawn and replaced with newer version
15–9	15–17	ASTM F2311–08 Standard Guide for Classification of Therapeutic Skin Substitutes[1]	Withdrawn and replaced with newer version
15–13	15–18	ASTM F2212–09 Standard Guide for Characterization of Type I Collagen as Starting Material for Surgical Implants and Substrates for Tissue Engineered Medical Products (TEMPs)[1]	Withdrawn and replaced with newer version

III. Listing of New Entries

In table 3 of this document, FDA provides the listing of new entries and consensus standards added as modifications to the list of recognized standards under Recognition List Number: 023.

TABLE 3.—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS

Recognition No.	Title of Standard	Reference No. & Date
A. Cardiology		
3–77	Active Implantable Medical Devices—Electromagnetic Compatibility—EMC Test Protocols for Implantable Cardiac Pacemakers and Implantable Cardioverter Defibrillators	ANSI/AAMI PC69:2007
B. In Vitro Diagnostics		
7–209	Performance Metrics for Continuous Interstitial Glucose Monitoring	POCT 05–A
C. Orthopedics		
11–219	Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications	ASTM F 2026–08
D. Physical Medicine		
16–166	Wheelchairs—Requirements and Test Methods for Electromagnetic Compatibility of Electrically Powered Wheelchairs and Scooters, and Battery Chargers	ISO 7176–21:2009
E. Sterility		
14–286	Processing of Reusable Surgical Textiles for Use in Health Care Facilities	ANSI/AAMI ST65:2008

IV. List of Recognized Standards

FDA maintains the agency's current list of FDA recognized consensus standards in a searchable database that may be accessed directly at FDA's Internet site at *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm*. FDA will incorporate the modifications and minor revisions described in this notice into the database and, upon publication in the **Federal Register**, this recognition of consensus standards will be effective. FDA will announce additional modifications and minor revisions to the list of recognized consensus standards, as needed, in the **Federal Register** once a year, or more often, if necessary.

V. Recommendation of Standards for Recognition by FDA

Any person may recommend consensus standards as candidates for recognition under the new provision of section 514 of the act by submitting such recommendations, with reasons for the recommendation, to the contact person (See **FOR FURTHER INFORMATION CONTACT**). To be properly considered such recommendations should contain, at a minimum, the following information: (1) title of the standard; (2) any reference number and date; (3) name and address of the national or international standards development organization; (4) a proposed list of devices for which a declaration of conformity to this standard should routinely apply; and (5) a brief identification of the testing or performance or other characteristics of the devices that would be addressed by a declaration of conformity.

VI. Electronic Access

You may obtain a copy of "Guidance on the Recognition and Use of Consensus Standards" by using the Internet. CDRH maintains a site on the Internet for easy access to information including text, graphics, and files that you may download to a personal

computer with access to the Internet. Updated on a regular basis, the CDRH home page includes the guidance as well as the current list of recognized standards and other standards related documents. After publication in the **Federal Register**, this notice announcing "Modification to the List of Recognized Standards, Recognition List Number: 023" will be available on the CDRH home page. You may access the CDRH home page at *http://www.fda.gov/cdrh*.

You may access "Guidance on the Recognition and Use of Consensus Standards," and the searchable database for "FDA Recognized Consensus Standards" through the hyperlink at *http://www.fda.gov/cdrh/stdsprog.html*.

This **Federal Register** document on modifications in FDA's recognition of consensus standards is available at *http://www.fda.gov/cdrh/fedregin.html*.

VII. Submission of Comments and Effective Date

Interested persons may submit to the contact person (see **FOR FURTHER INFORMATION CONTACT**) written or electronic comments regarding this document. Two copies of any mailed comments are to be submitted, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. FDA will consider any comments received in determining whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 023. These modifications to the list or recognized standards are effective upon publication of this notice in the **Federal Register**.

Dated: April 30, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–10562 Filed 5–4–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0052]

Guidance for Industry on Documenting Statistical Analysis Programs and Data Files; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry #197 entitled "Documenting Statistical Analysis Programs and Data Files." This guidance is provided to inform study statisticians of recommendations for documenting statistical analyses and data files submitted to the Center for Veterinary Medicine (CVM) for the evaluation of safety and effectiveness in new animal drug applications. These recommendations are intended to encompass the most complex data submissions to CVM, to reduce the number of revisions that may be required for CVM to effectively review statistical analyses and to simplify submission preparation by providing a uniform documentation system.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Anna Nevius, Center for Veterinary Medicine (HFV–163), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8170, *anna.nevius@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 16, 2009 (74 FR 11118), FDA published the notice of availability for a draft guidance entitled "Draft Guidance for Industry on Documenting Statistical Analysis Programs and Data Files; Availability" giving interested persons until June 1, 2009, to comment on the draft guidance. FDA received no comments on the draft guidance. Minor editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated April 27, 2009.

II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 514 have been approved under OMB control no. 0910–0032.

IV. Comments

Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/AnimalVeterinary/default.htm* or *http://www.regulations.gov*.

Dated: April 29, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–10582 Filed 5–4–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0224]

Town Hall Discussion With the Director of the Center for Devices and Radiological Health and Other Senior Center Management

AGENCY: Food and Drug Administration, HHS