TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

	Total number of waiver requests annually	Annual frequency per response	Number of sponsors/ applicants	Total average burden hours	Total hours
Federal Food, Drug, and Cosmetic Act Section 736	90	1.2	75	16	1,440
Reconsideration Requests	3	1	3	24	72
Appeal Requests	1	1	1	12	12
Total					1,524

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

III. Comments

Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) written or electronic comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov.BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/guidances/default.htm,* or *http://www.regulations.gov.*

Dated: March 4, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–5737 Filed 3–11–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–N–0451]

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 026

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: 026" (Recognition List Number: 026), 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: 026" 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, Silver Spring, MD 20993. 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.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm. 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: 026 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, 301–796–6574.

I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (the FD&C 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 as follows:

TABLE 1—PREVIOUS PUBLICATIONS OF STANDARD RECOGNITION LISTS

February 25, 1998 (63 FR 9561).
October 16, 1998 (63 FR 55617).
July 12, 1999 (64 FR 37546).
November 15, 2000 (65 FR 69022).
May 7, 2001 (66 FR 23032).
January 14, 2002 (67 FR 1774).
October 2, 2002 (67 FR 61893).
April 28, 2003 (68 FR 22391).
March 8, 2004 (69 FR 10712).
June 18, 2004 (69 FR 34176).
October 4, 2004 (69 FR 59240).
May 27, 2005 (70 FR 30756).
November 8, 2005 (70 FR 67713).
March 31, 2006 (71 FR 16313).
June 23, 2006 (71 FR 36121).
November 3, 2006 (71 FR 64718).
May 21, 2007 (72 FR 28500).
September 12, 2007 (72 FR 52142).
December 19, 2007 (72 FR 71924).
September 9, 2008 (73 FR 52358).
March, 18, 2009 (74 FR 11586).
September 8, 2009 (74 FR 46203).
May 5, 2010 (75 FR 24711).
June 10, 2010 (75 FR 32943).
October 4, 2010 (75 FR 61148).

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: 026

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: 026" 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.	Title of standard [1]	Change
		A. Anesthesia	
1–56		CGA V–7.1 1997 (R2003) (2008) Standard Method of Determining Cylinder Valve Outlet Connections for Medical Gases—First Edition.	Reaffirmation.
		B. Biocompatibility	
2–96	2–162	ASTM F1903–10 Standard Practice for Testing For Biological Responses to Particles In Vitro.	Withdrawn and replaced with newer version.
2–117		ANSI/AAMI/ISO 10993–3:2003/(R)2009 Biological evaluation of medical devices—Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity.	Extent of recognition.
		C. Cardiovascular	
3–54		ANSI/AAMI/ISO 7198:1998/2001/(R)2010 Cardiovascular implants—Tubular vascular prostheses.	Reaffirmation.
3–58		ANSI/AAMI/ISO 5840:2005/(R)2010 Cardiovascular implants—Cardiac valve prostheses.	Reaffirmation.
3–66		ASTM F 2081–06 Standard Guide for Characterization and Presentation of the Dimensional Attributes of Vascular Stents.	Device affected, Processes impacted, Type of standard, CFR citation and product codes, and Contact person.
		D. Dental/ENT	
4–89		ADA Specification No. 53 Polymer-Based Crowns and Bridge Resins	Reaffirmation.
4–111		ADA Specification No. 13 Denture Cold-Curing Repair Resins: 1981 (Reaffirmed 2006).	Withdrawn.
4–112		ADA Specification No. 16 Dental Impression Paste—Zinc Oxide Eugenol Type.	Withdrawn.
4–124	4–191	ANSI/ASA S3.22–2009 American National Standard Specification of Hearing Aid Characteristics.	Withdrawn and replaced with newer version.
4–127	4–192	ADA Specification 58 Root Canal Files, Type H (Hedstrom) 2007	Withdrawn and replaced with newer version.
4–138	4–193	ADA Specification No. 15 Artificial Teeth for Dental Prostheses	Withdrawn and replaced with newer version.
4–148	4–194	ADA Specification No. 78 Dental Obturating Cones	Withdrawn and replaced with newer version.
4–158		ISO 10139–1:2005 Dentistry—Soft lining materials for removable dentures—Part 1: Materials for short-term use Technical Corrigendum 1:2006.	Withdrawn duplicate. *See* 4–189.
		E. General Hospital/General Plastic Surgery	
6–144	6–243	ASTM D5712–10 Standard Test Method for Analysis of Aqueous Extractable Protein in Natural Rubber and Its Products Using the Modified Lowry Method.	Withdrawn and replaced with a newer version.
6–145		ASTM D3578–05 Standard Specification for Rubber Examination Gloves	Reaffirmation.
6–149		ASTM D7160–05 (Reapproved 2010) Standard Practice for Determination of Expiration Dating for Medical Gloves.	Reaffirmation.

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

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
6–150		ASTM D7161–05 (Reapproved 2010) Standard Practice for Determination of Real Time Expiration Dating of Mature Medical Gloves Stored Under Typical Warehouse Conditions.	Reaffirmation.
6–165		ASTM D6977–04 (Reapproved 2010) Standard Specification for Polychloroprene Examination Gloves for Medical Application.	Reaffirmation.
6–167	6–244	ASTM D6319–10 Standard Specification for Nitrile Examination Gloves for Medical Application.	Withdrawn and replaced with newer version.
6–169		ASTM D3772–01 (Reapproved 2010) Standard Specification for Natural Rubber Finger Cots.	Reaffirmation.
6–201	6–245	ISO 8536–4 Fifth edition 2010–10–01 Infusion equipment for medical use—Part 4: Infusion sets for single use, gravity feed.	Withdrawn and replaced with newer version.
6–218	6–246	USP 33–NF 28 2010 <11> Nonabsorbable Surgical Suture	Withdrawn and replaced with newer version.
6–220	6–247	USP 33–NF 28 2010 Absorbable Surgical Suture	Withdrawn and replaced with newer version.
6–221	6–248	USP 33–NF 28 2010 <881> Tensile Strength	Withdrawn and replaced with newer version.
6–222	6–249	USP 33–NF 28 2010 <861> Suture–Diameter	Withdrawn and replaced with newer version.
6–223	6–250	USP 33–NF 28 2010 <871> Sutures—Needle Attachment	Withdrawn and replaced with newer version.
6–224	6–251	USP 33 NF–28 2010 <11> Sterile Water for Irrigation	Withdrawn and replaced with newer version.
6–225	6–252	USP 33 NF–28 2010 <11> Heparin Lock Flush Solution	Withdrawn and replaced with newer version.
		F. IVD	
7–183		CLSI M38–A2 Reference Method for Broth Dilution Antifungal Susceptibility Testing of Filamentous Fungi.	Withdrawn duplicate. *See* 7–171.
7–188	7–218	CLSI M45–A2 Methods for Antimicrobial Dilution and Disk Susceptibility Testing of Infrequently Isolated or Fastidious Bacteria; Approved Guideline—Second Edition.	Withdrawn and replaced with newer version.
		G. Materials	
8–10		ASTM F603–00 Standard Specification for High-Purity Dense Aluminum Oxide for Surgical Implant Application.	Withdrawn.
8–88	8–195	ASTM F2024–10 Standard Practice for X–Ray Diffraction Determination of Phase Content of Plasma-Sprayed Hydroxyapatite Coatings.	Withdrawn and replaced with newer version.
8–101		ASTM F 2118—03 (Reapproved 2009) Standard Test Method for Constant Amplitude of Force Controlled Fatigue Testing of Acrylic Bone Cement Materials.	Reaffirmation.
8–103		ASTM F1801—97 (Reapproved 2009)ε[1] Standard Practice for Corrosion Fatigue Testing of Metallic Implant Materials.	Reaffirmation.
8–107		ASTM F746—04 (Reapproved 2009) ε[1] Standard Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials.	Reaffirmation.
8–117		ASTM F86—04 (Reapproved 2009) Standard Practice for Surface Preparation and Marking of Metallic Surgical Implants.	Reaffirmation.
		H. OB–GYN/Gastroenterology	
9–47		AAMI RD16 Cardiovascular implants and artificial organs—Hemodialyzers, hemodiafilters.	Withdrawn. *See* 9–65.
9–48		AAMI RD17 Cardiovascular implants and artificial organs—Extracorporeal blood circuit for hemodialyzers, hemodiafilters, and hemofilters.	Withdrawn. *See* 9–66.
9–50		ANSI/AAMI RD52:2004/(R)2010 and ANSI/AAMI RD52:2004/A1:2007/(R)2010, A2:2007/(R)2010, A3:2009, & A4:2009 (Consolidated Text) Dialysate for haemodialysis.	Reaffirmation.
9–51	9–65	ANSI/AAMI/ISO 8637:2010 Cardiovascular implants and extracorporeal systems—Hemodialyzers, hemodiafilters, hemofilters and hemoconcentrators.	Withdrawn and replaced with newer version.
9–52	9–66	ANSI/AAMI/ISO 8638:2010 Cardiovascular implants and extracorporeal systems—Extracorporeal blood circuit for hemodialyzers, hemodiafilters and hemofilters.	Withdrawn and replaced with newer version.
9–55		ANSI/AAMI RD62:2006 and ANSI/AAMI RD62:2006/A1:2009 Water treatment equipment for haemodialysis applications.	Reaffirmation.

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

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
		I. Orthopedics	
11–168	.....	ASTM F 1781–03 (Reapproved 2009) Standard Specification for Elastomeric Flexible Hinge Finger Total Joint Implants.	Reaffirmation.
11–183	.....	ASTM F1875–98 (Reapproved 2009) Standard Practice for Fretting Corrosion Testing of Modular Implant Interfaces: Hip Femoral Head-Bore and Cone Taper Interface.	Reaffirmation.
		J. Physical Medicine	
16–30	16–167	ISO 7176–9: Third edition, 2009–11–15 Wheelchairs—Part 9: Climatic tests for electric wheelchairs.	Withdrawn and replaced with newer version.
16–31	16–168	RESNA WC–1: 2009 American National Standard for Wheelchairs-Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 1: Determination of static stability.	Withdrawn and replaced with newer version.
16–32	16–169	RESNA WC–2: 2009 American National Standard for Wheelchairs-Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 2: Determination of dynamic stability of electrically powered wheelchairs.	Withdrawn and replaced with newer version.
16–33	16–170	RESNA WC–2: 2009 American National Standard for Wheelchairs-Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 3: Determination of effectiveness of brakes.	Withdrawn and replaced with newer version.
16–34	16–171	RESNA WC–2: 2009 American National Standard for Wheelchairs-Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 4: Energy consumption of electrically powered wheelchairs and scooters for determination of theoretical distance range.	Withdrawn and replaced with newer version.
16–35	16–172	RESNA WC–1: 2009 American National Standard for Wheelchairs-Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 5: Determination of dimensions, mass and maneuvering space.	Withdrawn and replaced with newer version.
16–36	16–173	RESNA WC–2: 2009 American National Standard for Wheelchairs-Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 6: Determination of maximum speed, acceleration and deceleration of electrically powered wheelchairs.	Withdrawn and replaced with newer version.
16–37	16–174	RESNA WC–1: 2009 American National Standard for Wheelchairs-Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 7: Method of Measurement of Seating and Wheel Dimensions.	Withdrawn and replaced with newer version.
16–38	16–175	RESNA WC–1: 2009 American National Standard for Wheelchairs-Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 8: Requirements and test methods for static, impact and fatigue strengths.	Withdrawn and replaced with newer version.
16–39	16–176	RESNA WC–2: 2009 American National Standard for Wheelchairs-Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 9: Climatic tests for electrically powered wheelchairs.	Withdrawn and replaced with newer version.
16–40	16–177	RESNA WC–2: 2009 American National Standard for Wheelchairs-Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 10: Determination of obstacle-climbing ability of electrically powered wheelchairs.	Withdrawn and replaced with newer version.
16–41	16–178	RESNA WC–1: 2009 American National Standard for Wheelchairs-Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 11: Test dummies.	Withdrawn and replaced with newer version.
16–42	16–179	RESNA WC–1: 2009 American National Standard for Wheelchairs-Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 13: Determination of coefficient of friction of test surfaces.	Withdrawn and replaced with newer version.
16–43	16–180	RESNA WC–2: 2009 American National Standard for Wheelchairs-Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 14: Power and control systems for electrically powered wheelchairs—Requirements and test methods.	Withdrawn and replaced with newer version.
16–44	16–181	RESNA WC–1: 2009 American National Standard for Wheelchairs-Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 15: Requirements for information disclosure, documentation and labeling.	Withdrawn and replaced with newer version.

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

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
16–45	16–182	RESNA WC–1: 2009 American National Standard for Wheelchairs-Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 16: Resistance to ignition of upholstered parts—Requirements and test methods.	Withdrawn and replaced with newer version.
16–46	16–183	RESNA WC–1: 2009 American National Standard for Wheelchairs-Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 20: Determination of the performance of stand-up type wheelchairs.	Withdrawn and replaced with newer version.
16–47	16–184	RESNA WC–1: 2009 American National Standard for Wheelchairs-Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 22: Set-up procedures.	Withdrawn and replaced with newer version.
16–48		ANSI/RESNA WC/Volume 1–1998, Section 93: Maximum Overall Dimensions.	Withdrawn.
16–49		ANSI/RESNA WC/Volume 1–1998, Section 0: Nomenclature, Terms, and Definitions.	Withdrawn.
16–160	16–185	RESNA WC–2: 2009 American National Standard for Wheelchairs-Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and motorized scooters.	Withdrawn and replaced with newer version.
16–161	16–186	ASME A18.1–2008 (Revision of ASME A18.1–2005) Safety Standard for Platform Lifts and Stairway Chairlifts.	Withdrawn and replaced with newer version.
		K. Radiology	
12–122	12–217	IEC 62083 Edition 2.0:2009–09 Medical electrical equipment—Requirements for the safety of radiotherapy treatment planning systems.	Withdrawn and replaced with newer version.
12–36		IEC 60601–2–9 (1996–10) Medical electrical equipment—Part 2: Particular requirements for the safety of patient contact dosimeters used in radiotherapy with electrically connected radiation detectors—Ed. 2.0..	Withdrawn.
12–183	12–218	NEMA PS 3.1—3.18 (2009) Digital Imaging and Communications in Medicine (DICOM) Set.	Withdrawn and replaced with newer version.
		L. Software/Informatics	
13–4		UL 1998 Standard for Safety Software in Programmable Components, Second Edition.	Reaffirmation.
		M. Sterility	
14–265	14–301	USP 33:2010 <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests.	Withdrawn and replaced with newer version.
14–266	14–302	USP 33: 2010 <71> Sterility Tests	Withdrawn and replaced with newer version.
14–267	14–303	USP 33:2010 <85> Bacterial Endotoxins Test	Withdrawn and replaced with newer version.
14–268	14–304	USP 33:2010 <151> Pyrogen Test	Withdrawn and replaced with newer version.
14–269	14–305	USP 33:2010 <161> Transfusion and Infusion Assemblies and Similar Medical Devices.	Withdrawn and replaced with newer version.
14–270	14–306	USP 33:2010 Biological Indicators for Steam Sterilization, Self-Contained.	Withdrawn and replaced with newer version.
14–271	14–307	USP 33:2010 Biological Indicator for Dry-Heat Sterilization, Paper Carrier.	Withdrawn and replaced with newer version.
14–272	14–308	USP 33:2010 Biological Indicator for Ethylene Oxide Sterilization, Paper Carrier.	Withdrawn and replaced with newer version.
14–273	14–309	USP 33:2010 Biological Indicator for Steam Sterilization, Paper Carrier	Withdrawn and replaced with newer version.
14–278	14–310	USP 33:2010 <62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms.	Withdrawn and replaced with newer version.

[1] All standard titles in this table conform to the style requirements of the respective organizations.

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: 026.

TABLE 3—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS

Recognition No.	Title of standard [1]	Reference No. and date
	A. Anesthesia	
1–84	Anaesthetic and respiratory equipment—Tracheostomy tubes—Part 3: Paediatric tracheostomy tubes TECHNICAL CORRIGENDUM 1.	ISO 5366–3:2001 TECHNICAL CORRIGENDUM 1.
	B. Biocompatibility	
2–163	Biological evaluation of medical devices—Part 9: Framework for identification and quantification of potential degradation products.	ANSI/AAMI/ISO 10993–9:2009.
2–164	Biological evaluation of medical devices—Part 13: Identification and quantification of degradation products from polymeric medical devices.	ANSI/AAMI/ISO 10993–13:2010.
2–165	Biological evaluation of medical devices—Part 14: Identification and quantification of degradation products from ceramics.	ANSI/AAMI/ISO 10993–14:2001.
2–166	Biological evaluation of medical devices—Part 16: Toxicokinetic study design for degradation products and leachables.	ANSI/AAMI/ISO 10993–16:2010.
2–167	Biological evaluation of medical devices—Part 19: Physico-chemical, morphological and topographical characterization of materials.	ISO/TS 10993–19 First edition 2006–06–01.
2–168	Biological evaluation of medical devices— Part 9: Framework for identification and quantification of potential degradation products.	ISO 10993–9 Second edition 2009–12–15.
2–169	Biological evaluation of medical devices—Part 13: Identification and quantification of degradation products from polymeric medical devices.	ISO 10993–13 First edition 1998–11–15.
2–170	Biological evaluation of medical devices—Part 14: Identification and quantification of degradation products from ceramics.	ISO 10993–14 First edition 2001–11–15.
2–171	Biological evaluation of medical devices—Part 16: Toxicokinetic study design for degradation products and leachables.	ISO 10993–16 Second edition 2010–02–15.
2–172	Biological evaluation of medical devices—Part 19: Physico-chemical, morphological, and topographical characterization of materials.	ANSI/AAMI/ISO TIR10993–19:2006.
	C. Cardiovascular	
3–83	Implants for surgery—Active implantable medical devices—Part 5: Circulatory support devices.	ANSI/AAMI/ISO 14708–5:2010.
3–84	Cardiovascular implants—Endovascular devices—Part 1: Endovascular prostheses Amendment 1: Test methods.	ANSI/AAMI/ISO 25539–1:2003/A1:2005/(R)2009.
3–85	Cardiovascular implants—Endovascular devices—Part 2: Vascular stents.	ANSI/AAMI/ISO 25539–2:2008.
3–86	Standard Guide for Measuring Securement of Balloon Expandable Vascular Stent Mounted on Delivery System.	ASTM F 2394–07.
3–87	Standard Test Methods for in vitro Pulsatile Durability Testing of Vascular Stents.	ASTM F 2477–07.
3–88	Standard Guide for Finite Element Analysis (FEA) of Metallic Vascular Stents Subjected to Uniform Radial Loading.	ASTM F 2514–08.
3–89	Active implantable medical devices—Four-pole connector system for implantable cardiac rhythm management devices—Dimensional and test requirements.	ISO 27186 First edition 2010–03–15.
3–90	Cardiovascular implants—Tubular vascular prostheses	ISO 7198 First edition 1998–08–01.
3–91	Cardiovascular implants—Cardiac valve prostheses	ISO 5840 Fourth edition 2005–03–01.
3–92	Implants for surgery—Active implantable medical devices—Part 5: Circulatory support devices.	ISO 14708–5 First edition 2010–02–01.
3–93	Cardiovascular implants—Endovascular device—Part 1: Endovascular prostheses AMENDMENT 1: Test methods.	ISO 25539–1 First edition 2001–11–13 AMENDMENT 1 2005–07–15.
3–94	Cardiovascular implants—Endovascular devices—Part 2: Vascular stents.	ISO 25539–2 First edition 2008–09–01.
	D. General	
5–63	Small-bore connectors for liquids and gases in healthcare applications—Part 1: General requirements.	ISO 80369–1 First edition 2010–12–15.
5–64	Small bore connectors for liquids and gases in healthcare applications—Part 1: General requirements.	AAMI/ISO/FDS–1 80369–01 2010.
	E. Materials	
8–196	Implants for surgery—Metallic materials—Part 1: Wrought stainless steel TECHNICAL CORRIGENDUM 1.	ISO 5832–1:2007 TECHNICAL CORRIGENDUM 1 2008–04–15.
8–197	Implants for surgery—Metallic materials—Part 12: Wrought cobalt-chromium-molybdenum alloy TECHNICAL CORRIGENDUM 1.	ISO 5832–12:2007 TECHNICAL CORRIGENDUM 1 2008–09–15.
8–198	Standard Guide for Evaluating the Extent of Oxidation in Ultra-High-Molecular-Weight Polyethylene Fabricated Forms Intended for Surgical Implants.	ASTM F 2102–06ε[1].

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

Recognition No.	Title of standard [1]	Reference No. and date
8–199	Standard Specification for Wrought Seamless Nickel-Titanium Shape Memory Alloy Tube for Medical Devices and Surgical Implants.	ASTM F 2633–07.
8–200	Standard Practice for Accelerated Aging of Ultra-High Molecular Weight Polyethylene after Gamma Irradiation in Air.	ASTM F 2003–02 (Reapproved 2008).
8–201	Standard Test Method for In Situ Determination of Network Parameters of Crosslinked Ultra High Molecular Weight Polyethylene (UHMWPE).	ASTM F 2214–02 (Reapproved 2008).
8–202	Standard Test Method for Small Punch Testing of Ultra-High Molecular Weight Polyethylene Used in Surgical Implants.	ASTM F 2183–02 (Reapproved 2008).
	F. Nanotechnology	
18–1	Standard Guide for Measurement of Particle Size Distribution of Nanomaterials in Suspension by Photon Correlation Spectroscopy (PCS).	ASTM E 2490–09.
	G. Ophthalmic	
10–62	Ophthalmics—Ophthalmic Instruments—Tonometers	ANSI Z80.10–2009.
10–63	Ophthalmic implants—Intraocular lenses—Guidance on assessment of the need for clinical investigation of intraocular lens design modifications.	ISO/TR 22979–2006.
	H. Radiology	
12–219	Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots CORRIGENDUM 1.	IEC 60336 (Fourth edition—2005).
12–220	Safety of laser products—Part 1: Equipment classification and requirements CORRIGENDUM 1.	IEC 60825–1 (Second edition—2007).
12–221	Evaluation and routine testing in medical imaging departments—Part 3–4: Acceptance tests—Imaging performance of dental X-ray equipment.	IEC 61223–3–4 First edition 2000–03.
12–222	Evaluation and routine testing in medical imaging departments—Part 3–5: Acceptance tests—Imaging performance of computed tomography X-ray equipment.	IEC 61223–3–5 First edition 2004–08.
12–223	Evaluation and routine testing in medical imaging departments—Part 3–5: Acceptance tests—Imaging performance of computed tomography X-ray equipment CORRIGENDUM 1.	IEC 61223–3–5 (First edition 2004).
12–224	Medical electrical equipment—Part 2–44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography CORRIGENDUM 1.	IEC 60601–2–44 (Third edition—2009).
12–225	Computed Tomography Dose Check	NEMA XR 25 2010.
12–226	Evaluation and routine testing in medical imaging departments—Part 2–6: Constancy tests—Imaging performance of computed tomography X-ray equipment.	IEC 61223–2–6 Second edition 2006–11.
	I. Tissue Engineering	
15–25	ASTM F2312—10 Standard Terminology Relating to Tissue Engineered Medical Products.	ASTM F2312–10.
15–26	ASTM F2211—04 Standard Classification for Tissue Engineered Medical Products (TEMPs).	ASTM F2211–04.

[1] All standard titles in this table conform to the style requirements of the respective organizations.

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 FD&C 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 device(s) 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: 026" will be available on the CDRH home page. You may access the CDRH home page at *http://www.fda.gov/MedicalDevices.*

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

This **Federal Register** document on modifications in FDA's recognition of consensus standards is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm.*

VII. Submission of Comments and Effective Date

Interested persons may submit to the contact person (*see* **FOR FURTHER INFORMATION CONTACT**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. 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: 026. These modifications to the list or recognized standards are effective upon publication of this notice in the **Federal Register.**

Dated: March 8, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–5815 Filed 3–11–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0135]

Ensuring the Safety of Imported Foods and Animal Feed: Comparability of Food Safety Systems and Import Practices of Foreign Countries; Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public hearing regarding new FDA initiatives for ensuring the safety of foods and animal feed imported into the United States. The purpose of the public hearing is to provide stakeholders the opportunity to discuss FDA's use of international comparability assessments as a mechanism to enhance the safety of imported foods and animal feed and lessons learned through equivalence determinations. In addition, there will be a separate discussion of FDA's efforts to gather information from regulators in other countries regarding the regulatory policies, practices, and programs they currently use to ensure the safety of foods and animal feed imported into their countries. In a separate notice published elsewhere in this issue of the **Federal Register**, FDA is announcing a 1-day public meeting to discuss implementation of the imports provisions found in the FDA Food Safety Modernization Act (FSMA).

DATES: *See* "How to Participate in the Hearing" in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: *For questions about registration, to register orally, or to submit a notice of participation by mail, fax, or by e-mail:* Courtney Treece, Planning Professionals Ltd., 1210 W. McDermott, suite 111, Allen, TX 75013, 704–258–4983, FAX: 469–854–6992, e-mail: *ctreece@planningprofessionals.com.*

For questions about the hearing, if special accommodations are needed due to a disability, to request onsite parking, or to submit the full text, comprehensive outline, or summary of an oral presentation: Juanita Yates, Center for Food Safety and Applied Nutrition, Food and Drug Administation, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1731, e-mail: *Juanita.Yates@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Government and the food industry are pursuing proactive efforts to reduce the incidence of food borne illness. The President's Food Safety Working Group (FSWG) has recommended that food regulators shift towards prioritizing prevention and move aggressively to implement sensible measures designed to prevent problems before they occur (Ref. 1). The newly enacted FSMA (Pub. L. 111–353) also embodies the principle of prevention by requiring those who produce and import food to have systems of preventive controls in place and empowering FDA to hold them accountable to meet their new responsibilities.

FDA recognizes that to ensure the safety of imported foods and animal feed and fulfill its public health mission in a global age, it must embrace new approaches that take into account the entire supply chain and its complexity. Consistent with FSMA and the recommendation of the President's FSWG, FDA is focusing on preventing problems at appropriate points along the global food supply chain. This public hearing is an opportunity for the Agency to obtain views from interested persons concerning certain key aspects of these food safety initiatives: (1) International comparability assessments and (2) gathering information on the policies, practices, and programs used by foreign regulators to ensure the safety of imported foods and animal feed. The public hearing will be conducted in accordance with part 15 (21 CFR part 15), as described in the following paragraphs. (*See* "Notice of Hearing Under Part 15" in section III of this document.)

FDA's initiatives discussed at the 2-day public hearing align with and help support FSMA implementation. Day One of the hearing will open with a general discussion of FSMA from the perspectives of consumers, industry, legislators, and U.S. trading partners. Day Two will cover policies, practices, and programs used by foreign regulators to ensure the safety of imported foods and animal feed. In a separate notice published elsewhere in this issue of the **Federal Register**, FDA is announcing a 1-day public meeting to discuss implementation of the imports provisions found in title III of FSMA.

II. Topics for Discussion at the Hearing

A. Day One of Hearing: International Comparability Assessments

Under FDA's proposed model, FDA will consider the food safety system of a foreign country to be "comparable" to