DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Circulatory System Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 10 and 11, 2007, from 8 a.m. to 6 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B, and C, 620 Perry Pkwy, Gaithersburg, MD.

Contact Person: James Swink, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4179, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512625. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On October 10, 2007, the committee will discuss; make recommendations; and vote on a premarket approval application, sponsored by Medtronic, Inc., for the Endeavor Zotarolimus-Eluting Coronary Stent System, which is indicated for improving coronary luminal diameter in patients with ischemic heart disease due to de novo lesions of length ≤ 27 millimeters (mm) in native coronary arteries with reference vessel diameters of ≥ 2.5 mm to ≤ 3.5 mm.

On October 11, 2007, the committee will discuss and make recommendations regarding clinical trial designs for carotid artery stenting in patients not at high risk for adverse events from surgical revascularization.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year 2007 and scroll down to the appropriate advisory committee link.

Procedure: On October 10, 2007, from 8 a.m. to 6 p.m., and on October 11, 2007, from 10:15 a.m. to 6 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before September 26, 2007. Oral presentations from the public will be scheduled for approximately 30 minutes at the beginning of committee deliberations on each day and for approximately 30 minutes near the end of the deliberations on each day. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before September 18, 2007. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by September 19, 2007.

Closed Presentation of Data: On October 11, 2007, from 8 a.m. to 10:15 a.m., the meeting will be closed to permit discussion and review of clinical trial design issues for carotid artery stents intended to reopen stenotic carotid arteries in the neck. Information regarding trial designs and actual experience in conducting ongoing trials is considered trade secret and/or confidential information (5 U.S.C. 552b(c)(4)).

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, at 240–276–8932, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/oc/advisory/default.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 5, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E7–17983 Filed 9–11–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0226]

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 018

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: 018'' (Recognition List Number: 018), 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: 018'' to the Division of Small Manufacturers,

International and Consumer Assistance, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your requests, or FAX your request to 301–443–8818. 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.hhs.gov*. This document may also be accessed on FDA's Web 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: 018 modifications and other standards related information.

FOR FURTHER INFORMATION CONTACT: Carol L. Herman, Center for Devices and Radiological Health (HFZ–84), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240–276–0533.

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.

Federal Register Cite
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)

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: 018

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: 018'' 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.

Old Item No.	Standard	Change	Replacement Item No.
A. Anesthesia			
3	ASTM F1161–88, Standard Specification for Minimum Performance and Safety Requirements for Components and Systems of Anesthesia Gas Machines	Withdrawn	
15	ISO 5361–4:1987, Tracheal Tubes—Part 4: Cole Type	Contact person	
35	ISO 5361:1999, Anaesthetic and Respiratory Equipment—Tracheal Tubes and Connectors	Contact person	
36	ISO 5366–3:2001, Anaesthetic and Respiratory Equipment—Tracheostomy Tubes—Part 3: Pediatric Tracheostomy Tubes	Contact person	
42	ISO 5360:2006, Anaesthetic Vaporizers—Agent Specific Filling Systems	Withdrawn and replaced with newer version	74

TABLE 2.—Continued

Old Item No.	Standard	Change	Replacement Item No.
43	ISO 5362:2006, Anaesthetic Reservoir Bags	Withdrawn and replaced with newer version	75
44	ISO 5366–1:2000, Anaesthetic and Respiratory Equipment—Tracheostomy Tubes—Part 1: Tubes and Connectors for Use in Adults	Contact person	
46	ISO 5367:2000, Breathing Tubes Intended for Use With Anaesthetic Apparatus and Ventilators	Contact person	
50	ASTM F920–93(1999): Standard Specification for Minimum Performance and Safety Requirements for Resuscitators Intended for Use with Humans	Withdrawn	
55	ASTM F1054–01: Standard Specification for Conical Fittings	Withdrawn	
61	IEC 60601–2–13(2003–05), Medical Electrical Equipment—Part 2–13: Particular Requirements for the Safety and Essential Performance of Anaesthetic Systems	Contact person	
62	ISO 5356–1:2004, Anaesthetic and Respiratory Equipment—Conical Connectors: Part 1: Cones and Sockets	Contact person	
B. Biocompatibility			
21	AAMI / ANSI / ISO 10993–11:1993, Biological Evaluation of Medical Devices—Part 11: Tests for Systemic Toxicity	Contact person	
63	AAMI / ANSI / ISO 10993–6:1995/(R) 2001, Biological Evaluation of Medical Devices—Part 6: Test for Local Effects After Implantation	Contact person	
64	AAMI / ANSI / ISO 10993–5:1999, Biological Evaluation of Medical Devices—Part 5: Tests for In Vitro Cytotoxicity	Contact person	
68	ASTM F719–81(2002)e1: Standard Practice for Testing Biomaterials in Rabbits for Primary Skin Irritation	Contact person	
70	ASTM F750–87 (2002)e1: Standard Practice for Evaluating Material Extracts by Systemic Injection in the Mouse	Contact person	
71	ASTM F1408–02e1: Standard Practice for Subcutaneous Screening Test for Implant Materials	Contact person	
83	ASTM E1262–88(2003): Standard Guide for Performance of the Chinese Hamster Ovary Cell/Hypoxanthine Guanine Phosphoribosyl Transferase Gene Mutation Assay	Contact person	
84	ASTM E1263–97(2003): Standard Guide for Conduct of Micronucleus Assays in Mammalian Bone Marrow Erythrocytes	Contact person	
85	ASTM E1280–97 (2003): Standard Guide for Performing the Mouse Lymphoma Assay for Mammalian Cell Mutagenicity	Contact person	
87	AAMI / ANSI / ISO 10993–10:2002, Biological Evaluation of Medical Devices—Part 10: Tests for Irritation and Sensitization	Contact person	
88	AAMI / ANSI / ISO 10993–12: 2002(E), Biological Evaluation of Medical Devices—Part 12: Sample Preparation and Reference materials	Contact person	
89	ASTM F749–98 (2002)e2: Standard Practice for Evaluating Material Extracts by Intracutaneous Injection in the Rabbit	Contact person	
90	ASTM E1397–91(2003): Standard Practice for the in vitro Rat Hepatocyte DNA Repair Assay	Contact person	
91	ASTM E1398–91(2003): Standard Practice for the in vivo Rat Hepatocyte DNA Repair Assay	Contact person	
92	ASTM F748–04: Standard Practice for Selecting Generic Biological Test Methods for Materials and Devices	Contact person	
93	ASTM F763–04: Standard Practice for Short-Term Screening of Implant Materials	Contact person	

TABLE 2.—Continued

Old Item No.	Standard	Change	Replacement Item No.
94	ASTM F981–04: Standard Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone	Contact person	
97	ASTM F1983–99(2003): Standard Practice for Assessment of Compatibility of Absorbable/Resorbable Biomaterials for Implant Applications	Contact person	
98	AAMI / ANSI / ISO 10993–1:2003(E), Biological evaluation of medical devices—Part 1: Evaluation and Testing	Contact person	
99	ASTM F1904–98(2003): Standard Practice for Testing the Biological Responses to Particles In Vivo	Contact person	
100	ASTM E1372–95(2003): Standard Test Method for Conducting a 90–Day Oral Toxicity Study in Rats	Contact person	
106	ASTM F619–03: Standard Practice for Extraction of Medical Plastics	Contact person	
109	USP 29–NF21 Biological Tests <87>, Biological Reactivity Test, In Vitro—Direct Contact Test	Contact person	
110	USP 29–NF21 Biological Tests <87>, Biological Reactivity Test, In Vitro—Elution Test	Contact person	
111	USP 29–NF21 Biological Tests <88>, Biological Reactivity Tests, In Vivo, Procedure—Preparation of Sample	Contact person	
112	USP 29–NF21 Biological Tests <88>, Biological Reactivity Test, In Vitro, Classification of Plastics—Intracutaneous Test	Contact person	
113	USP 29–NF21 Biological Tests <88>, Biological Reactivity Tests, In Vivo, Classification of Plastics—Systemic Injection Test	Contact person	
114	ASTM F1877–05: Standard Practice for Characterization of Particles	Contact person	
115	ASTM F895–84(2006): Standard Test Method for Agar Diffusion cell Culture Screening for Cytotoxicity	Contact person	
116	ASTM F1439–03: Standard Guide for Performance of Lifetime Bioassay for the Tumorigenic Potential of Implant Materials	Contact person	
C. General			
2	IEC 60601-1, Medical electrical equipment — Part 1: General requirements for safety	Withdrawn	
11	ISO 2859–1:1999: Sampling Procedures for Inspection By Attributes—Part 1: Sampling Schemes Indexed by Acceptance Quality Limit (AQL)for Lot-by-Lot Inspection	Withdrawn and replaced with newer year version	37
14	ANSI/ASQ Z1.4–2003: Sampling Procedures and Tables for Inspection by Attributes	Withdrawn and replaced with newer year version	38
22	ISO 2768–1: 1989, General Tolerances—Part 1: Tolerances for Linear and Angular Dimensions Without Individual Tolerance Indications	Contact name	
23	ISO 2768–2: 1989, General Tolerances—Part 2: Geometrical Tolerances for Features Without Individual Tolerance Indications	Contact name	
24	IEC 60812, edition 2.0: 2006–01, Analysis Technique for System Reliability—Procedure for Failure Mode and Effects Analysis	Withdrawn and replaced with newer year version	39
26	ISO 14971:2007: Medical devices—Application of Risk Management to Medical Devices	Withdrawn and replaced with newer year version	40
28	IEC 60601–1–2, (Second Edition, 2001), Medical Electrical Equipment—Part 1–2: General Requirements for Safety; Electromagnetic Compatibility—Requirements and Tests	Extent of recognition	

TABLE 2.—Continued

Old Item No.	Standard	Change	Replacement Item No.
30	AAMI/ANSI/IEC 60601–1–2, Medical Electrical Equipment—Part 1–2: General Requirements for Safety—Collateral Standard: Electromagnetic Compatibility—Requirements and Tests. (The AAMI/ANSI/IEC 60601–1–2:2001 is the U.S. version of IEC 60601–1–2:2001 with identical requirements for electromagnetic compatibility (EMC) of medical electrical equipment.)	Title change Type of standard Extent of recognition	
34	IEC 60601–1–2, Medical Electrical Equipment—Part 1–2: General Requirements for Safety—Collateral Standard: Electromagnetic Compatibility—Requirements and Tests (Edition 2:2001 with Amendment 1:2004; Edition 2.1 (Edition 2:2001 consolidated with Amendment 1:2004))	Extent of recognition	
35	AAMI/ANSI/IEC 60601–1–2, Medical Electrical Equipment—Part 1–2: General Requirements for Safety—Collateral Standard: Electromagnetic Compatibility—Requirements and Tests (Edition 2:2001 with Amendment 1:2004) (AAMI/ANSI/IEC 60601–1–2:2001 is the U.S. version of IEC 60601–1–2:2001, with identical requirements for electromagnetic compatibility (EMC) of medical electrical equipment.)	Extent of recognition	
D. General Hospital/ General Plastic Surgery			
18	ISO 8537:1991 Sterile Single-use Syringes, With or Without Needle, for Insulin	Withdrawn duplicate	
20	ISO 10555–1–1995 Sterile, Single-use Intravascular Catheters—Part 1: General Requirements	Withdrawn duplicate	
46	IEC 60601–2–2 2006 Medical Electrical Equipment—Part 2–2: Particular Requirements for the Safety of High Frequency Surgical Equipment	Withdrawn and replaced with newer version	197
69	ISO 9626–1991: Stainless Steel Needle Tubing for the Manufacture of Medical Devices	Withdrawn duplicate	
72	ISO 10555–5 1996–06–15 Sterile, Single-use Intravascular Catheters—Part 5: Over-needle Peripheral Catheters	Withdrawn duplicate	
96	ASTM F2101–07 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus Aureus	Withdrawn and replaced with newer version	199
113	ASTM F2100–07 Standard Specification for Performance of Materials Used in Medical Face Masks	Withdrawn and replaced with newer version	198
108	ASTM F754–00 Standard Specification for Implantable Polytetrafluoroethylene (PTFE) Polymer Fabricated in Sheet, Tube and Rod Shapes	Transferred to materials	
109	ASTM F881–94(2006) Standard Specification for Silicone Elastomer Facial Implants	Withdrawn and replaced with newer version	185
128	ASTM F1670–07 Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood	Withdrawn and replaced with newer version	186
130	ASTM F1671–07 Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System	Withdrawn and replaced with newer version	187
151	USP 30:2007 Nonabsorbable Surgical Suture	Withdrawn and replaced with newer version	188
152	USP 30<11>: 2007 Sterile Sodium Chloride for Irrigation	Withdrawn and replaced with newer version	189
153	USP 30:2007 Absorbable Surgical Suture	Withdrawn and replaced with newer version	190
154	USP 30<881>:2007 Tensile Strength	Withdrawn and replaced with newer version	191
155	USP 30<861>:2007 Sutures—Diameter	Withdrawn and replaced with newer version	192
156	USP 30<871>:2007 Sutures Needle Attachment	Withdrawn and replaced with newer version	193

TABLE 2.—Continued

Old Item No.	Standard	Change	Replacement Item No.
157	USP 30<11>: 2007 Sterile Water for Irrigation	Withdrawn and replaced with newer version	194
158	USP 30<11>: 2007 Heparin Lock Flush Solution	Withdrawn and replaced with newer version	195
159	USP 30<11>: 2007 Sodium Chloride Injection	Withdrawn and replaced with newer version	196
181	ASTM F1862–07: Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)	Withdrawn and replaced with newer version	184
E. Materials			
2	ASTM F75–07: Standard Specification for Cobalt–28 Chromium–6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075)	Withdrawn and replaced with newer year version	137
15	ASTM F745–07: Standard Specification for 18 Chromium–12.5 Nickel–2.5 Molybdenum Stainless Steel for Cast and Solution-Annealed Surgical Implant Applications	Withdrawn and replaced with newer year version	138
26	ASTM F1314–07: Standard Specification for Wrought Nitrogen Strengthened 22 Chromium—13 Nickel—5 Manganese—2.5 Molybdenum Stainless Steel Alloy Bar and Wire for Surgical Implants (UNS S20910)	Withdrawn and replaced with newer year version	139
37	ASTM F1813–06: Standard Specification for Wrought Titanium—12 Molybdenum—6 Zirconium—2 Iron Alloy for Surgical Implant (UNS R58120)	Withdrawn and replaced with newer year version	140
43	ASTM F2146–07: Standard Specification for Wrought Titanium–3Aluminum–2.5Vanadium Alloy Seamless Tubing for Surgical Implant Applications (UNS R56320)	Withdrawn and replaced with newer year version	141
67	ISO 7153–1:1991/Amd. 1:1999, Surgical Instruments—Metallic Materials—Part 1: Stainless Steel	Contact person	
87	ASTM F1978–00(2007)e2: Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber Abraser	Withdrawn and replaced with newer year version	142
89	ASTM F1873–98: Standard Specification for High-Purity Dense Yttria Tetragonal Zirconium Oxide Polycrystal (Y-TZP) for Surgical Implant Applications	Withdrawn	
106	ASTM F648–07: Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants	Withdrawn and replaced with newer year version	143
128	ASTM F2213–06: Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment	Title	
GH/GPS 108	ASTM F754–00: Standard Specification for Implantable Polytetrafluoroethylene (PTFE) Polymer Fabricated in Sheet, Tube, and Rod Shapes	Transferred from GH/GPS to Materials	144
F. OB-GYN/Gastroenterology			
20	ISO 8600–3:1997 Amendment 1 2003, Optics and Optical Instruments—Medical Endoscopes and Endoscopic Accessories Part 3: Determination of Field of View and Direction of View of Endoscopes with Optics	Withdraw duplicate	
32	ASTM D3492–03 Standard Specification for Rubber Contraceptives (Male Condoms)	Extent of recognition, processes impacted, relevant guidance	
33	ASTM F623–99(2006) Standard Performance Specification for Foley Catheter	Withdrawn and replaced with newer version	44
34	ISO 4074:2002/Cor.1:2003(E) Natural Latex Rubber Condoms—Requirements and Test Methods, Technical Corrigendum 1	Extent of recognition, relevant guidance	
G. Ophthalmic			
1	ISO 9338:1996 Optics and Optical Instruments—Contact Lenses—Determination of the Diameters	Withdrawn	

TABLE 2.—Continued

Old Item No.	Standard	Change	Replacement Item No.
2	ISO 9339–1:1996 Optics and Optical Instruments—Contact Lenses—Determination of the Thickness—Part 1: Rigid Contact Lenses	Withdrawn	
4	ISO 9341:1996 Optics and Optical Instruments—Contact Lenses—Determination of Inclusions and Surface Imperfections for Rigid Contact Lenses	Withdrawn	
7	ISO 9913–1:1996 Optics and Optical Instruments—Contact Lenses—Part 1: Determination of Oxygen Permeability and Transmissibility with the FATT Method	Withdrawn	
8	ISO 10338:1996 Optics and Optical Instruments—Contact Lenses—Determination of Curvature	Withdrawn	
9	ISO 10339:1997 Ophthalmic Optics—Contact Lenses—Determination of Water Content of Hydrogel Lenses	Withdrawn	
10	ISO 10340:1995 Optics and Optical Instruments—Contact Lenses—Method for Determining the Extractable Substances	Withdrawn	
11	ISO 10344:1996 Optics and Optical Instruments—Contact Lenses—Saline Solution for Contact Lens Testing	Withdrawn	
16	ISO 9913–2:2000 Optics and Optical Instruments—Contact Lenses—Part 2: Determination of Oxygen Permeability and Transmissibility by the Coulometric Method	Withdrawn	
17	ISO 10939:2007 Ophthalmic Instruments—Slit-lamp Microscopes	Withdrawn and replaced with newer version	35
19	ISO 11539:1999 Ophthalmic Optics—Contact Lenses—Classification of Contact Lenses and Contact Lens Materials	Withdrawn	
22	ISO 11979–3:2006 Ophthalmic Implants—Intraocular Lenses—Part 3: Mechanical Properties and Test Methods	Withdrawn and replaced with newer version	36
25	ISO 12865:2006 Ophthalmic Instruments—Retinoscopes	Withdrawn and replaced with newer version	39
27	ISO 11979–7:2006 Ophthalmic Implants—Intraocular Lenses—Part 7: Clinical Investigations	Withdrawn and replaced with newer version	41
H. Orthopedic/ Physical Medicine			
121	ISO 7207–1:1994, Implants for Surgery—Components for Partial and Total Knee Joint Prostheses—Part 1: Classification, Definitions and Designation of Dimensions	Withdrawn	
I. Radiology			
57 & 132	IEC 60731 (1997), (2002) Amendment 1, Medical Electrical Equipment—Dosimeters with Ionization Chambers as Used in Radiotherapy	Withdrawn and combine	162
59	IEC 61168:1993, Radiotherapy Simulators—Functional Performance Characteristics	Contact person	
63	IEC 60601–2–43—Ed. 1.0, Medical Electrical Equipment—Part 2–43: Particular Requirements for the Safety of X-ray Equipment for Interventional Procedures	Contact person	
91	IEC 60601–2–8 (1997–08), Amendment 1—Medical Electrical Equipment—Part 2: Particular Requirements for the Safety of Therapeutic X-ray Equipment Operating in the Range of 10 kV to 1 MV	Withdrawn duplicate	
103	ANSI / IESNA RP–27.3–1996, Recommended Practice for Photobiological Safety for Lamps—Risk Group Classification and Labeling	Title	
130 & 148	IEC 60601–2–37 (2004), (2005) Amendment 2, Medical Electrical Equipment—Part 2–37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment	Withdrawn and combine	164
131	IEC 61217 2002:, Radiotherapy Equipment—Coordinates, Movements, and Scales Consolidated Ed. 1.1	Contact person	

TABLE 2.—Continued

Old Item No.	Standard	Change	Replacement Item No.
133	IEC 60601–2–11 (1997), (2004) Amendment 1, Medical Electrical Equipment—Part 2–11: Particular Requirements for the Safety of gamma Beam Therapy Equipment	Title	
145	IEC 61674 (1997), (2002) Amendment 1, Medical Electrical Equipment—Dosimeters with Ionization Chambers and/or Semi-conductor Detectors as Used in X-ray Diagnostic Imaging	Contact person	
J. Sterility			
28	ANSI/AAMI/ISO 11737–1:2006, Sterilization of Medical Devices—Microbiological Methods—Part 1: Determination of a Population of Microorganisms on Products, 2nd ed.	Withdrawn and replaced with newer version	227
47	ANSI/AAMI ST37:1996, Flash Sterilization: Steam Sterilization of Patient Care Items for Immediate Use	Withdrawn	
49	ANSI/AAMI ST41:1999/(R) 2005, Ethylene Oxide Sterilization in Health Care Facilities: Safety and Effectiveness	Reaffirmation	
50	ANSI/AAMI ST42:1998, Steam Sterilization and Sterility Assurance Using Table-top Sterilizers in Office-based, Ambulatory-care Medical, Surgical, and Dental Facilities.	Withdrawn	
52	ANSI/AAMI ST59:1999, Sterilization of Health Care Products—Biological Indicators—Part 1: General	Withdrawn	
53	ANSI/AAMI ST66:1996, Sterilization of Health Care Products—Chemical Indicators—Part 2: Indicators for Air Removal Test Sheets and Packs	Contact person	
54	ANSI/AAMI/ISO 11737–2:1998, Sterilization of Medical Devices—Microbiological Methods—Part 2: Tests of Sterility Performed in the Validation of a Sterilization Process	Contact person	
60	ASTM F1327:1998, Standard Terminology Relating to Barrier Materials for Medical Packaging	Contact person	
63	ASTM F1886: 1998 (2004), Standard Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection	Contact person	
64	ASTM F1929:1998 (2004), Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	Contact person	
72	ANSI/AAMI ST33:1996, Guidelines for the Selection and Use of Reusable Rigid Sterilization Container Systems for Ethylene Oxide Sterilization and Steam Sterilization in Health Care Facilities	Withdrawn	
75	ANSI/AAMI/ISO 11137:1994, Sterilization of Health Care Products—Requirements for Validation and Routine Control—Radiation Sterilization and ANSI/AAMI/ISO 11137:1994 (Amendment 1:2002)	Withdrawn	
77	ANSI/AAMI ST24:1999/(R) 2005, Automatic, General Purpose Ethylene Oxide Sterilizers and Ethylene Oxide Sterilant Sources Intended for use in Health Care Facilities, 3rd ed.	Reaffirmation	
86	ASTM F1980:2002, Standard Guide for Accelerated Aging of Sterile Medical Device Packages	Contact person	
88	ANSI/AAMI/ISO 14937:2000, Sterilization of Health Care Products—General Requirements for Characterization of a Sterilizing Agent and the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices	Extent of recognition	
90	ASTM F2095–01, Standard Test Methods for Pressure Decay Leak Test for Nonporous Flexible Packages With and Without Restraining Plates	Contact person	
105	ANSI/AAMI ST46:2002, Steam Sterilization and Sterility Assurance in Health Care Facilities	Withdrawn	
116	ANSI/AAMI ST72:2002, Bacterial Endotoxins—Test Methodologies, Routine Monitoring, and Alternatives to Batch Testing	Contact person	

TABLE 2.—Continued

Old Item No.	Standard	Change	Replacement Item No.
117	ANSI/AAMI ST35:2003, Safe Handling and Biological Decontamination of Reusable Medical Devices in Health Care Facilities and in Nonclinical Settings	Extent of recognition	
120	ASTM D3078:2002, Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission	Contact person	
123	ASTM F2096–04, Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test)	Contact person	
134	ANSI/AAMI ST44:2002, Resistometers Used for Characterizing the Performance of Biological and Chemical Indicators	Withdrawn	
135	ANSI/AAMI ST63:2002, Sterilization of Health Care Products—Requirements for the Development, Validation and Routine Control of an Industrial Sterilization Process for Medical Devices—Dry heat	Extent of recognition	
136	ANSI/AAMI ST67:2003, Sterilization of Health Care Products—Requirements for Products Labeled 'sterile'	Contact person	
137	ANSI/AAMI/ISO TIR 11139:2006, Sterilization of Health Care Products—Vocabulary	Withdrawn and replaced with newer version	221
144	ASTM F2203–02e1, Standard Test Method for Linear Measurement Using Precision Steel Rule	Contact person	
145	ASTM F2217–02, Standard Practice for Coating/Adhesive Weight Determination	Contact person	
146	ASTM F2227–02, Standard Test Method of Leaks in Non-sealed and Empty Medical Packaging Trays by C02 Tracer Gas Method	Contact person	
147	ASTM F2228–02, Standard Test Method for Non-Destructive Detection of Leaks in Medical Packaging Which Incorporates Porous Barrier Material by C02 Tracer Gas Method	Contact person	
148	ASTM F2250–03, Standard Practice for Evaluation of Chemical Resistance of Printed Inks and Coatings on Flexible Packaging Materials	Contact person	
149	ASTM F2251–03e1, Standard Test Method for Thickness Measurement of Flexible Packaging Material	Contact person	
150	ASTM F2252–03, Standard Practice for Evaluating Ink or Coating Adhesion to Flexible Packaging Materials Using Tape	Contact person	
163	ANSI/AAMI/ISO 11737–3:2004, Sterilization of Medical Devices—Microbiological Methods—Part 3: Guidance on Evaluation and Interpretation of Bioburden Data	Withdrawn	
167	ASTM F2097–05, Standard Guide for Design and Evaluation of Primary Packaging for Medical Products	Contact person	
168	ASTM F2338–05, Standard Test Method for Nondestructive Detection of Leaks in Packages by Vacuum Decay Method	Contact person	
169	ASTM F2391–05, Standard Test Method for Measuring Package and Seal Integrity Using Helium as Tracer Gas	Contact person	
170	ASTM F2475–05, Standard Guide for Biocompatibility Evaluation of Medical Device Packaging Materials	Contact person	
171	ANSI/AAMI/ISO 15882:2003, Chemical Indicators—Guidance on the Selection, Use, and Interpretation of Results	Contact person	
172	AOAC 6.2.01:2006, Official Method 955.14, Testing Disinfectants Against Salmonella choleraesuis, Use-Dilution Method	Withdrawn and replaced with newer version	211
173	AOAC 6.2.02:2006, Official Method 991.47, Testing Disinfectants Against Salmonella choleraesuis, Hard Surface Carrier Test Method	Withdrawn and replaced with newer version	212
174	AOAC 6.2.03:2006, Official Method 991.48, Testing Disinfectants Against Staphylococcus aureus, Hard Surface Carrier Test Method	Withdrawn and replaced with newer version	213

TABLE 2.—Continued

Old Item No.	Standard	Change	Replacement Item No.
175	AOAC 6.2.04:2006, Official Method 955.15, Testing Disinfectants Against Staphylococcus aureus, Use-Dilution Method	Withdrawn and replaced with newer version	214
176	AOAC 6.2.05:2006, Official Method 991.49, Testing Disinfectants Against Pseudomonas aeruginosa, Hard Surface Carrier Test Method	Withdrawn and replaced with newer version	215
177	AOAC 6.2.06:2006, Official Method 964.02, Testing Disinfectants Against Pseudomonas aeruginosa, Use-Dilution Method	Withdrawn and replaced with newer version	216
178	AOAC 6.3.02:2006, Official Method 955.17, Fungicidal Activity of Disinfectants Using Trichophyton mentagrophytes	Withdrawn and replaced with newer version	217
179	AOAC 6.3.05:2006, Official Method 966.04, Sporicidal Activity of Disinfectants, Method I	Withdrawn and replaced with newer version	218
180	AOAC 6.3.06:2006, Official Method 965.12, Tuberculocidal Activity of Disinfectants	Withdrawn and replaced with newer version	219
181	ANSI/AAMI ST58:2005, Chemical Sterilization and High-Level Disinfection in Health Care Facilities	Title, Devices affected and Relevant guidance	
182	USP 30:2007, Biological Indicator for Dry-Heat Sterilization, Paper Carrier	Withdrawn and replaced with newer version	202
183	USP 30:2007, Biological Indicator for Ethylene Oxide Sterilization, Paper Carrier	Withdrawn and replaced with newer version	203
184	USP 30:2007, Biological Indicator for Steam Sterilization, Paper Carrier	Withdrawn and replaced with newer version	204
185	USP 30:2007, <61> Microbial Limits Test	Withdrawn and replaced with newer version	205
186	USP 30:2007, <71> Microbiological Tests, Sterility Tests	Withdrawn and replaced with newer version	206
187	USP 30:2007, <85> Biological Tests and Assays, Bacterial Endotoxin Test (LAL)	Withdrawn and replaced with newer version	207
188	USP 30:2007, <151> Pyrogen Test (USP Rabbit Test)	Withdrawn and replaced with newer version	208
189	USP 30:2007, <161> Transfusion and Infusion Assemblies and Similar Medical Devices	Withdrawn and replaced with newer version	209
190	USP 30:2007, Biological Indicator for Steam Sterilization, Self-Contained	Withdrawn and replaced with newer version	210
193	ANSI/AAMI/ISO 11607–1:2006, Packaging for Terminally Sterilized Medical Devices—Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems, 3rd ed.	Contact person	
194	ANSI/AAMI/ISO 11607–2:2006, Packaging for Terminally Sterilized Medical Devices—Part 2: Validation Requirements for Forming, Sealing and Assembly Processes, 1st ed.	Contact person	
196	ASTM F1140–2005, Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages for Medical Applications	Contact person	
197	ASTM F1608:2004, Standard Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method)	Contact person	
198	ASTM F2054–05, Standard Test Method for Burst Testing of Flexible Package Seals Using Internal Air Pressurization Within Restraining Plates	Contact person	
199	ASTM D4169–05, Standard Practice for Performance Testing of Shipping Containers and Systems	Contact person	
200	ASTM F88–2005, Standard Test Method for Seal Strength of Flexible Barrier Materials	Contact person	

TABLE 2.—Continued

Old Item No.	Standard	Change	Replacement Item No.
K. Tissue Engineering			
3	ASTM F2212–02(2007)e1, Standard Guide for Characterization of Type I Collagen as Starting Material for Surgical Implants and Substrates for Tissue Engineered Medical Products (TEMPs)	Withdrawn and replaced with newer version	11

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: 018.

TABLE 3.

Item No.	Title of Standard	Reference No. and Date
A. Anesthesia		
72	Lung Ventilators for Medical Use—Particular Requirements for Basic Safety and Essential Performance—Part 5: Gas-powered Emergency Resuscitators	ISO 10651–5:2006
73	Lung Ventilators—Part 4: Particular Requirements for Operator Powered Resuscitators	ISO 10651–4:2002
B. Biocompatibility		
117	Biological Evaluation of Medical Devices—Part 3: Tests for Genotoxicity, Carcinogenicity, and Reproductive Toxicity	ANSI/AAMI/ISO 10993–3: 2003
C. Dental/ ENT		
144	Dentistry-Mercury and Alloys for Dental Amalgam	ISO 24234: 2004(E)
D. OB-GYN/Gastroenterology		
45	Standard Test Methods for Enteral Feeding Devices with a Retention Balloon	ASTM F2528–06
E. Ophthalmic		
42	Ophthalmic Implants—Intraocular lenses—Part 2: Optical Properties and Test Methods	ISO 11979–2:1999/ Corrigendum1:2003
43	Ophthalmic Optics—Contact Lenses and Contact Lens Care Products—Determination of Physical Compatibility of Contact Lens Care Products with Contact Lenses	ISO 11981:1999/ Corrigendum1:2005
45	Ophthalmic Optics—Contact Lenses—Part 2: Tolerances	ISO 18369–2:2006
46	Ophthalmic Optics—Contact Lenses—Part 3: Measurement Methods	ISO 18369–3:2006
48	Ophthalmic Implants—Intraocular Lenses—Part 5: Biocompatibility	ISO 11979–5:2006
49	Ophthalmic Implants—Intraocular Lenses—Part 9: Multifocal Intraocular Lenses	ISO 11979–9:2006
50	Ophthalmic implants—Intraocular lenses—Part 10: Phakic Intraocular Lenses	ISO 11979–10:2006
51	Ophthalmic Instruments—Fundamental Requirements and Test Methods Part 2: Light Hazard Protection	ISO 15004–2:2007
F. Radiology		
165	''Quality Control Manual'' Template for Manufacturers of Displays and Workstations Labeled for Final Interpretation in Full-field Digital Mammography	NEMA XR 22–2006
166	''Quality Control Manual'' Template for Manufacturers of Hardcopy Output Devices Labeled for Final Interpretation in Full-field Digital Mammography	NEMA XR 23–2006
G. Sterility		
201	Containment Devices for Reusable Medical Device Sterilization	ANSI/AAMI ST77:2006
220	Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities	ANSI/AAMI ST79:2006

TABLE 3.—Continued

Item No.	Title of Standard	Reference No. and Date
222	Sterilization of Health Care Products—Biological and Chemical Indicators—Test Equipment	ANSI/AAMI/ISO 18472:2006
223	Sterilization of Health Care Products—Biological Indicators—Part 1: General Requirements	ANSI/AAMI/ISO 11138–1:2006
224	Sterilization of Health Care Products—Radiation—Part 1: Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices	ANSI/AAMI/ISO 11137–1:2006
225	Sterilization of Health Care Products—Radiation—Part 2: Establishing the Sterilization Dose	ANSI/AAMI/ISO 11137–2:2006
226	Sterilization of Health Care Products—Radiation—Part 3: Guidance on Dosimetric Aspects	ANSI/AAMI/ISO 11137–3:2006
H. Tissue Engineering		
9	Standard Guide for Classification of Therapeutic Skin Substitutes	ASTM F2311–06
10	Standard Guide for *in vivo* Assessment of Implantable Devices Intended to Repair or Regenerate Articular Cartilage	ASTM F2451–05

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 Web 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 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. The Center for Devices and Radiological Health (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: 018'' 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.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/cdrhnew.cfm*.

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. 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. 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: 018. These modifications to the list or recognized standards are effective upon publication of this notice in the **Federal Register**.

Dated: August 30, 2007.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

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BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; The Hispanic Community Health Study (HCHS)/ Study of Latinos (SOL)

SUMMARY: Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on July 11, 2007, pages 37789–37790, and allowed 60-days for public comment. No comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may