Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received at the address below, no later than 5 p.m. on May 30, 2006.

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development—B, Attention: William N. Parham, III, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: March 24, 2006.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E6–4633 Filed 3–30–06; 8:45 am]

BILLING CODE 4120–01–P

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: 014

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: 014'' (Recognition List Number: 014), 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: 014'' 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.fda.gov/cdrh/fedregin.html*. 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: 014 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, 12720 Twinbrook Pkwy., Rockville, MD 20857, 301–827–0021.

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.

In **Federal Register** notices published on 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), and November 8, 2005 (70 FR 67713), FDA modified its initial list of FDA recognized consensus standards. 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 Web 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: 014

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: 014'' to identify these current modifications.

In table 1 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 1.

Old Item No.	Standard	Change	Replacement Item No.
A. Anesthesia			

TABLE 1.—Continued

Old Item No.	Standard	Change	Replacement Item No.
32	ISO 7767: 1997: Oxygen Monitors for Monitoring Patient Breathing Mixtures—Safety Requirements	Withdrawn	
33	ISO 9918: 1993: Capnometers for Use with Humans—Requirements	Withdrawn	
41	NFPA 99: 2005: Standard for Health Care Facilities Chapter 20—Hyperbaric Facilities	Withdrawn and replaced with newer version	67
B. Dental/Ear, Nose, and Throat			
52	ANSI/ADA Specification No. 27: 1997, Resin-Based Filling Materials	Date	
60	ANSI/ADA Specification No. 96: 2000, Dental-Water-Based Cements—Adoption of ISO 9917: 1991	Date and title	
114	ANSI/ADA Specification No. 48: 2004, Ultraviolet Activator and Disclosing Lights	Date	
C. General Hospital/General Plastic Surgery			
47	ASTM D5712–05 Standard Test Method for Analysis of Aqueous Extractable Protein in Natural Rubber and Its Products Using the Modified Lowry Method	Withdrawn and replaced with newer version	144
77	ASTM F1862–00a Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)	Contact person	
86	ASTM D3578–05 Standard Specification for Rubber Examination Gloves	Withdrawn and replaced with newer version	145
96	ASTM F2101–01 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus Aureus	Contact person	
112	AAMI/ANSI PB70: 2003 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities	Contact person	
113	ASTM F2100–04 Standard Specification for Performance of Materials Used in Medical Face Masks	Contact person	
120	ASTM F1054–01 Standard Specification for Conical Fittings	Withdrawn	
128	ASTM F1670–03 Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood	Contact person	
D. Materials			
14	ASTM F688–05: Standard Specification for Wrought Cobalt–35Nickel–20Chromium–10Molybdenum Alloy Plate, Sheet, and Foil for Surgical Implants (UNS R30035)	Withdrawn and replaced with newer version	119
38	ASTM F2005–00: Standard Terminology for Nickel-Titanium Shape Memory Alloys	Withdrawn	
78	ASTM F560–05: Standard Specification for Unalloyed Tantalum for Surgical Implant Applications (UNS R05200, UNS R05400)	Withdrawn and replaced with newer version	120
100	ASTM F2005–05: Standard Terminology for Nickel-Titanium Shape Memory Alloys	Withdrawn and replaced with newer version	121
E. OB-GYN/Gastroenterology			

TABLE 1.—Continued

Old Item No.	Standard	Change	Replacement Item No.
19	ISO 8600–1: 2005 Optics and photonics—Medical endoscopes and endotherapy devices—Part 1: General requirements	Withdrawn and replaced with newer version	37
F. Orthopedic/Physical Medicine			
162	ASTM F564–02: Standard Specification and Test Methods for Metallic Bone Staples	Extent of recognition, type of standard, contact person and related Code of Federal Regulations citation and product codes	
164	ASTM F1541–02: Standard Specification and Test Methods for External Skeletal Fixation Devices	Devices affected, processes affected, extent of recognition, type of standard, and contact person	
182	ASTM F1800–04: Standard Test Method for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements	Processes affected and relevant guidance	
G. Radiology			
1	ISO 9236–1: 2004 Photography—Sensitometry of screen/film systems for medical radiography—Part 1: Determination of sensitometric curve shape, speed and Average Gradient	Withdrawn and replaced with newer version	136
2	ISO 4090: 2001 Photography—Medical radiographic cassettes/screens/films and hard-copy imaging films—Dimensions and specifications	Withdrawn and replaced with newer version	137
5	ISO 5799: 1991 Photography—Direct-exposing medical and dental radiographic film/process systems—Determination of ISO Speed and ISO average gradient	Withdrawn and replaced with newer version	138
37	IEC 60601–2–11–2004 Amendment 1—Medical electrical equipment—Part 2–11: Particular requirements for the safety of gamma beam therapy equipment	Withdrawn and replaced with newer version	133
44	AOMS–2005 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment	Withdrawn and replaced with newer version	139
46	RTD1–2005 Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment Revision 1	Withdrawn and replaced with newer version	140
101	ANSI/IESNA RP–27.1–1996 Recommended Practice for Photobiological Safety for Lamps and Lamp Systems—General Requirements	Title	
102	ANSI/IESNA RP–27.2–2000 Recommended Practice for Photobiological Safety for Lamps and Lamp Systems—Measurement Techniques	Title	
103	ANSI/IESNA RP–27.3–1996 Recommended Practice for Photobiological Safety Lamps—Risk Group Classification and Labeling	Title	
128	IEEE N42.13–2004 Calibration and Usage of ''Dose Calibrator'' Ionization Chambers for the Assay of Radionuclides	Withdrawn and replaced with newer version	141
H. Sterility			
53	ANSI/AAMI ST66, Sterilization of health care products—Chemical indicators—Part 2: Indicators for Air Removal Test Sheets and Packs	Relevant guidance	
74	ANSI/AAMI ST60, Sterilization of health care products—Chemical indicators—Part 1: General requirements	Extent of recognition and relevant guidance	

TABLE 1.—Continued

Old Item No.	Standard	Change	Replacement Item No.
92	ASTM F2097–05, Standard Guide for Design and Evaluation of Primary Packaging for Medical Products	Withdrawn and replaced with newer version	167
151	ASTM F2338–05, Standard Test Method for Nondestructive Detection of Leaks in Packages by Vacuum Decay Method	Withdrawn and replaced with newer version	168

III. Listing of New Entries

The listing of new entries and consensus standards added as modifications to the list of recognized standards under Recognition List Number: 014, follows:

TABLE 2.

Item No.	Title of Standard	Reference No. and Date
A. Cardiovascular/Neurology		
58	Cardiovascular implants—Cardiac valve prostheses	ANSI/AAMI/ISO 5840: 2005
B. General Hospital/General Plastic Surgery		
146	Medical electrical equipment—Part 2: Particular requirements for safety of infant radiant warmers	ANSI/AAMI/IEC 60601–2–21 and 60601–2–21 amendment 1: 2000
147	Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs	ASTM D6978–05
148	Sterile hypodermic syringes for single use—Part 3: Auto-disable syringes for fixed-dose immunization	ISO 7886–3: 2005
149	Standard Practice for Determination of Expiration Dating for Medical Gloves	ASTM D7160–05
150	Standard Practice for Determination of Real Time Expiration Dating of Mature Medical Gloves Stored Under Typical Warehouse Conditions	ASTM D7161–05
C. Orthopedic/Physical Medicine		
183	Standard Practice for Fretting Corrosion Testing of Modular Implant Interfaces: Hip Femoral Head-bore and Cone Taper Interface	ASTM F1875–98 (2004)
184	Implants for Surgery—Staples with parallel legs for orthopaedic use—General requirements	ISO 8827: 1988
185	Standard Test Method for Measuring Load Induced Subsidence of an Intervertebral Body Fusion Device Under Static Axial Compression	ASTM F2267–04
186	Test Methods for Intervertebral Body Fusion Devices	ASTM F2077–03
187	Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System	ASTM F2193–02
188	Implants for surgery—Wear of total knee-joint prostheses—Part 1: Loading and displacement parameters for wear-testing machines with load control and corresponding environmental conditions for test	ISO 14243–1: 2002
189	Implants for surgery—wear of total knee-joint prostheses—Part 2: Methods of measurement	ISO 14243–2: 2000
190	Implants for surgery—wear of total knee-joint prostheses—Part 3: Loading and displacement parameters for wear-testing machines with displacement control and corresponding environmental conditions for test	ISO 14243–3: 2004
191	Implants for surgery—Total knee-joint prostheses—Part 1: Determination of endurance properties of knee tibial trays	ISO 14879–1: 2000
192	Standard Test Method for Determination of Total Knee Replacement Constraint	ASTM F1223–05
193	Standard Specification for Total Knee Prosthesis	ASTM F2083–04

TABLE 2.—Continued

Item No.	Title of Standard	Reference No. and Date
D. Radiology		
142	Lasers and laser-related equipment—Test methods for laser beam widths, Divergence angles, and beam propagation ratios—Part 2: General astigmatic beams	ISO 11146–2: 2005
143	Lasers and laser-related equipment—Test methods for determination of the shape of a laser beam wavefront—Part 2: Shack-Hartmann sensors	ISO 15367–2: 2005
E. Sterility		
169	Standard Test Method for Measuring Package and Seal Integrity Using Helium as Tracer Gas	ASTM F2391–05
170	Standard Guide for Biocompatibility Evaluation of Medical Device Packaging Materials	ASTM F2475–05
171	Chemical Indicators—Guidance on the selection, use, and interpretation of results	ANSI/AAMI/ISO 15882: 2003

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

In order to receive ''Guidance on the Recognition and Use of Consensus Standards'' on your fax machine, call the Center for Devices and Radiological Health (CDRH) Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number 321 followed by the pound sign. Follow the remaining voice prompts to complete your request.

You may also 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 ''Modifications to the List of Recognized Standards, Recognition List Number: 014'' 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. 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: 014. These modifications to the list of recognized standards are effective upon publication of this notice in the **Federal Register**.

Dated: March 23, 2006

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E6–4695 Filed 3–30–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0128]

Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Orphan-Drug and Humanitarian Use Device Designation Requests and Related Submissions; Availability

AGENCY: Food and Drug Administration, HHS.