Dated: May 24, 2005.

Kimberly Romine,

Deputy Commissioner, Administration for Native Americans.

[FR Doc. 05–10660 Filed 5–26–05; 8:45 am]

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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: 012

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: 012'' (Recognition List Number: 012), 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 on a 3.5″ diskette of ''Modifications to the List of Recognized Standards, Recognition List Number: 012'' 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.gov*. This document may also be accessed on FDA's Internet 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: 012 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., 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 will implement its standard recognition program and provided the initial list of FDA recognized consensus 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), and October 4, 2004 (69 FR 59240), FDA modified its initial list of FDA recognized consensus standards. These notices described 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 at *http://www.fda.gov/cdrh/stdsprog.html*. 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 Recognition List Number: 012

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: 012'' 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			
3	ASTM F1161–88, Standard Specification for Minimum Performance and Safety Requirements for Components and Systems of Anesthesia Gas Machines	Contact person	
4	ASTM F1242–96, Standard Specification for Cuffed and Uncuffed Tracheal Tubes	Withdrawn	
7	ASTM F1627–95, Standard Specification for Pediatric Tracheostomy Tubes	Withdrawn	

TABLE 1.—Continued

Old Item No.	Standard	Change	Replacement Item No.
9	IEC 60601–2–12 (2001–10), Medical Electrical Equipment—Part 2–12: Particular Requirements for the Safety of Lung Ventilators—Critical Care Ventilators	Withdrawn and replaced with newer version	60
15	ISO 5361–4: 1987, Tracheal Tubes—Part 4: Cole Type	Contact person	
18	ISO 8359: 1996, Oxygen Concentrators for Medical Use—Safety Requirements	Contact person	
19	ISO 8382: 1988, Resuscitators Intended for Use With Humans	Contact person	
20	ISO 9703–1: 1992, Anesthesia and Respiratory Care Alarm Signals—Part 1: Visual Alarm Signals	Withdrawn	
21	ISO 9703–2: 1994, Anesthesia and Respiratory Care Alarm Signals—Part 2: Auditory Alarm Signals	Withdrawn	
30	IEC 60601–2–13 (2003–05), Medical Electrical Equipment—Part 2–13: Particular Requirements for the Safety and Essential Performance of Anesthetic Systems	Withdrawn and replaced with newer version	61
31	ISO 5356–1: 2004, Anaesthetic and Respiratory Equipment—Conical Connectors—Part 1: Cones and Sockets	Withdrawn and replaced with newer version	62
35	ISO 5361: 1999, Anaesthetic and Respiratory Equipment—Tracheal Tubes and Connectors	Contact person	
38	CGA V–1: 2003, Standard for Compressed Gas Cylinder Valve Outlet and Inlet Connections	Withdrawn and replaced with newer version	63
42	ISO 5360: 1993, Anaesthetic Vaporizers—Agent Specific Filling Systems	Contact person	
44	ISO 5366–1: 2000, Anaesthetic and Respiratory Equipment—Tracheostomy Tubes—Part 1: Tubes and Connectors for Use in Adults	Contact person and type of standard	
50	ASTM F920–93 (1999), Standard Specification for Minimum Performance and Safety Requirements for Resuscitators Intended for Use With Humans	Contact person	
52	ASTM F1463–93 (1999), Standard Specification for Alarm Signals in Medical Equipment Used in Anesthesia and Respiratory Care	Contact person	
53	ASTM F1464–93 (1999), Standard Specification for Oxygen Concentrators for Domiciliary Use	Contact person	
54	ASME PVHO–1–2002–2003, Safety Standard for Pressure Vessels for Human Occupancy	Withdrawn and replaced with newer version	64
55	ASTM F1054–01, Standard Specification for Conical Fittings	Contact person	
57	ASTM F1101–90 (2003)e1, Standard Specification for Ventilators Intended for Use During Anesthesia	Contact person	
59	ASTM F1456–01, Standard Specification for Minimum Performance and Safety Requirements for Capnometers	Contact person	
B. Cardiovascular/Neurology			
3	AAMI NS28: 1988/(R)1993, Intracranial Pressure Monitoring	Contact person	
18	IEC 60601–2–27 (1994), Medical Electrical Equipment—Part 2: Particular Requirements for the Safety of Electrocardiographic Monitoring Equipment	Contact person and processes affected	
43	ANSI/AAMI EC38: 1998, Ambulatory Electrocardiographs	Contact person, processes affected and extent of recognition	
C. Dental/Ear, Nose, and Throat			
61	ISO 1562: 1993, Dental Casting Gold Alloys	Contact person	
116	ISO 10139–1: 1991, Dentistry—Resilient Lining Materials for Removable Dentures—Part 1: Short-Term Materials	Date of standard	
D. General Hospital/General Plastic Surgery			

TABLE 1.—Continued

Old Item No.	Standard	Change	Replacement Item No.
1	AAMI BF7: (R2002), Blood Transfusion Micro-Filters	Withdrawn and replaced with newer version	119
29	IEC 60601–2–19 1996–10, ''Amendment 1''—Medical Electrical Equipment—Part 2: Particular Requirements for Safety of Baby Incubators	Title	
32	IEC 60601–2–20 1996–10, ''Amendment 1''—Medical Electrical Equipment—Part 2: Particular Requirements for the Safety of Transport Incubators	Title	
37	ASTM F1054–01, Standard Specification for Conical Fittings	Withdrawn and replaced with newer version	120
63	ISO 8536–7–1999, Infusion Equipment for Medical Use—Part 7: Caps Made of Aluminum-Plastics Combinations for Infusion Bottles	Title	
65	ISO 8536–2–2001, Infusion Equipment for Medical Use—Part 2: Closures for Infusion Bottles	Withdrawn and replaced with newer version	121
67	ISO 8536–5–2004, Infusion Equipment for Medical Use—Part 5: Burette Type Infusion Sets for Single Use, Gravity Feed	Withdrawn and replaced with newer version	122
71	ASTM E667–03, Standard Specification for Mercury-in-Glass, Maximum Self-Registering Clinical Thermometers	Withdrawn and replaced with newer version	123
73	ASTM E1104–03, Standard Specification for Clinical Thermometer Probe Covers and Sheaths	Withdrawn and replaced with newer version	124
74	ASTM E1965–03, Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature	Withdrawn and replaced with newer version	125
75	ISO 8536–4–2004, Infusion Equipment for Medical Use—Part 4: Infusion Sets for Single Use, Gravity Feed	Withdrawn and replaced with newer version	126
76	ISO 1135–4–2004, Transfusion Equipment for Medical Use—Part 4: Transfusion Sets for Single Use	Withdrawn and replaced with newer version	127
78	ASTM F1670–03, Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood	Withdrawn and replaced with newer version	128
79	ISO 594/2–1998, Conical Fittings With a 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment—Part 2: Lock Fittings	Withdrawn and replaced with newer version	129
E. Materials			
36	ASTM F1801–97 (2004), Standard Practice for Corrosion Fatigue Testing of Metallic Implant Materials	Withdrawn and replaced with newer version	103
51	ASTM F1108–04, Standard Specification for Titanium-6Aluminum-4Vanadium Alloy Castings for Surgical Implants (UNS R56406)	Withdrawn and replaced with newer version	104
69	Title: ISO 5832–10: 1996, Implants for Surgery—Metallic Materials—Part 10: Wrought Titanium 5-Aluminum 2,5-Iron	Withdrawn	
70	Title: ASTM F2052–02, Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment	Error in October 4, 2004 FEDERAL REGISTER Notice (69 FR 59240) (Recognition List Number: 011) [Docket No. 2004N–0226]—not withdrawn	70
96	ASTM F1635–04(a), Standard Test Method for In Vitro Degradation Testing of Hydrolytically Degradable Polymer Resins and Fabricated Forms for Surgical Implants	Withdrawn and replaced with newer version	105
F. Ophthalmic			
5	ISO 9363–1: 1994, Optics and Optical Instruments—Contact Lenses—Determination of Cytotoxicity of Contact Lens Material—Part 1: Agar Overlay Test and Growth Inhibition Test	Withdrawn	

TABLE 1.—Continued

Old Item No.	Standard	Change	Replacement Item No.
14	ANSI Z80.20–2004, Ophthalmics—Contact Lenses—Standard Terminology, Tolerances, Measurements and Physicochemical Properties	Withdrawn and replaced with newer version	34
15	ISO 9394:1998, Ophthalmic Optics—Contact Lenses and Contact Lens Care Products—Determination of Biocompatibility by Ocular Study Using Rabbit Eyes	Title	
30	ANSI Z80.7–2002, Ophthalmics—Intraocular Lenses	Title	
G. Radiology			
1	ANSI PH 2.43–1982, Method for Sensitometry/Medical X-Ray Screen-Film	Title	
5	ANSI PH 2.50–1983, Method/Sensitometry Direct-Exposure Medical/Dental	Title	
7	IEC/ISO 10918–1: 1994, Information Technology—Digital Compression and Coding of Continuous-Tone Still Images—Part 1: Requirements and Guidelines	Title	
8	IEC 60336 (R1993), X-Ray Tube Assemblies for Medical Diagnosis—Characteristics of Focal Spots	Title and standards development organization	
14	NEMA MS 5–2003, Determination of Slice Thickness in Diagnostic Magnetic Resonance Imaging	Withdrawn and replaced with newer version	125
22	IEC NEMA XR5–1992 (R1999), Measurement of Dimensions and Properties of Focal Spots of Diagnostic X-Ray Tubes	Withdrawn	
23	NEMA XR 10–1986 (R1992, R1998), Measurement of the Maximum Symmetrical Radiation Field From a Rotating Anode X-Ray Tube Used for Medical Diagnosis	Contact person, title, and standards development organization	
33	IEC 60601–2–1: 1998, Medical Electrical Equipment—Part 2: Particular Requirements for Medical Electron Accelerators in the Range 1 MeV to 50 MeV	Withdrawn	
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	Title	
40	IEC 60601–2–28: 2003, Medical Electrical Equipment—Part 2: Particular Requirements for the Safety of X-Ray Source Assemblies and X-Ray Tube Assemblies for Medical Diagnosis—ed. 1.0	Withdrawn and replaced with newer version	126
42	IEC 60601–2–32: 2003, Medical Electrical Equipment—Part 2: Particular Requirements for the Safety of Associated Equipment of X-Ray Equipment—ed. 1.0	Withdrawn and replaced with newer version	127
50	IEEE N42.13–1993, Calibration and Usage of ''Dose Calibrator'' Ionization Chambers for the Assay of Radionuclides	Withdrawn and replaced with newer version	128
52	UL 544 (1998), Standard for Medical and Dental Equipment—ed. 4.0	Title	
58	ANSI N43.6–1997, Sealed Radioactive Sources, Classification	Title and standards development organization	
61	UL 122 (1999), Standard for Photographic Equipment—ed. 4.0	Title	
62	UL 187 (1998), Standard for X-Ray Equipment—ed. 7.0	Title	
74	NEMA MS 7–1998, Measurement Procedure for Time-Varying Gradient Fields (dB/dt) for Magnetic Resonance Imaging Systems	Withdrawn	
75	NEMA NU 1–2004, Performance Measurements of Scintillation Cameras	Withdrawn and replaced with newer version	129
83	IEC 60601–2–37 2004, Medical Electrical Equipment—Part 2–37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment Consolidated, ed. 1.1	Withdrawn and replaced with newer version	130
87	IEC 61217 2003, Radiotherapy Equipment—Coordinates, Movements and Scales Consolidated, ed. 1.1	Withdrawn and replaced with newer version	131

TABLE 1.—Continued

Old Item No.	Standard	Change	Replacement Item No.
90	IEC 60601–2–1 (1998–06), Medical Electrical Equipment—Part 2–1: Particular Requirements for the Safety of Electron Accelerators in the Range 1 MeV to 50 MeV	Title	
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 10 kV to 1 MV	Title	
98	IEC 60731 (2002–06), Amendment 1—Medical Electrical Equipment—Dosimeters With Ionization Chambers as Used in Radiotherapy	Withdrawn and replaced with newer version	132
120	IEC 60601–2–44 (2002–11), Medical Electrical Equipment—Part 2–44: Particular Requirements for the Safety of X-Ray Equipment for Computed Tomography—ed. 2.1	Title	
H. Sterility			
121	ASTM D4169–04a, Standard Practice for Performance Testing of Shipping Containers and Systems	Extent of recognition	
123	ASTM F2096–04, Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test)	Title	
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	Title	

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: 012, follows:

TABLE 2.

Item No.	Title of Standard	Reference No. and Date
A. General Hospital/General Plastic Surgery		
114	Pen-Injectors for Medical Use—Part 1: Pen-Injectors—Requirements and Test Methods	ISO 11608–1: 2000
115	Pen-Injectors for Medical Use—Part 2: Needles—Requirements and Test Methods	ISO 11608–2: 2000
116	Pen-Injectors for Medical Use—Part 3: Finished Cartridges—Requirements and Test Methods	ISO 11608–3: 2000
117	Standard Specification for Blood/Intravenous Fluid/Irrigation Fluid Warmers	ASTM F2172–02
118	Standard Specification for Circulating Liquid and Forced Air Patient Temperature Management Devices	ASTM F2196–02
B. Radiology		
121	Ultrasonics—Surgical Systems—Measurement and Declaration of the Basic Output Characteristics, ed. 1.0	IEC 61847: 1998
122	Medical Electrical Equipment—Requirements for the Safety of Radiotherapy Treatment Planning Systems, ed. 1.0	IEC 62083: 2000
123	Ultrasonics—Physiotherapy Systems—Performance Requirements and Methods of Measurement in the Frequency Range 0.5 MHz to 5 MHz, ed. 1.0	IEC 61689: 1996
C. Sterility		
144	Standard Test Method for Linear Measurement Using Precision Steel Rule	ASTM F2203–02$^{\varepsilon 1}$
145	Standard Practice for Coating/Adhesive Weight Determination	ASTM F2217–02
146	Standard Test Method of Leaks in Non-Sealed and Empty Medical Packaging Trays by CO_2 Tracer Gas Method	ASTM F2227–02
147	Standard Test Method for Non-Destructive Detection of Leaks in Medical Packaging Which Incorporates Porous Barrier Material by CO_2 Tracer Gas Method	ASTM F2228–02

TABLE 2.—Continued

Item No.	Title of Standard	Reference No. and Date
148	Standard Practice for Evaluation of Chemical Resistance of Printed Inks and Coatings on Flexible Packaging Materials	ASTM F2250–03
149	Standard Test Method for Thickness Measurement of Flexible Packaging Materials	ASTM F2251–03$^{\varepsilon 1}$
150	Standard Practice for Evaluating Ink or Coating Adhesion to Flexible Packaging Materials Using Tape	ASTM F2252–03
151	Standard Test Method for Nondestructive Detection of Leaks in Packages by Vacuum Decay Method	ASTM F2338–04

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 document 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'' via 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 document announcing ''Modification to the List of Recognized Standards, Recognition List Number: 012'' will be available on the CDRH home page. You may access the CDRH home page at *http://www.fda.gov/cdrh*.

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

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

VII. Submission of Comments and Effective Date

Interested persons may submit to the contact person (see **FOR FURTHER INFORMATION CONTACT**) written or electronic comments regarding this document. Two copies of any mailed comments are to be submitted, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. FDA will consider any comments received in determining whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 012. These modifications to the list or recognized standards are effective upon publication of this notice in the **Federal Register**.

Dated: May 16, 2005.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 05–10626 Filed 5–26–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0199]

International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Draft Guidance for Industry on Specifications: Test Procedures and Acceptance Criteria for New Veterinary Drug Substances and New Medicinal Products: Chemical Substances; Request for Comments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for comments of a draft guidance document for industry (#176) entitled ''Specifications: Test Procedures and Acceptance Criteria for New Veterinary Drug Substances and New Medicinal Products: Chemical Substances'' (VICH GL39). This draft guidance has been developed for veterinary use by the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This draft VICH guidance document is intended to assist to the extent possible, in the establishment of a single set of recommended global