DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 024

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: 024" (Recognition List Number: 024), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit either electronic or written 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: 024" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4617, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label 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: 024 modifications and other standards related information.

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

SUPPLEMENTARY INFORMATION:

I. Background

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

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

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

TABLE 1.—PREVIOUS PUBLICATIONS OF STANDARD RECOGNITION LISTS

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

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: 024

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: 024" 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. Dental/ENT			
4–122	4–187	IEC 60601–2–18 Edition 3.0 2009–08 Medical electrical equipment—Part 2–18: Particular requirements for the basic safety and essential performance of endoscope equipment	Newer version with transition period
B. General			
5–4	5–52	ANSI/AAMI ES60601–1:2005, Medical Electrical Equipment—Part 1: General requirements for basic safety and essential performance	Newer version with transition period
5–28	5–53	IEC 60601–1–2 Third edition 2007–03 Medical electrical equipment—Part 1–2: General requirements for basic safety and essential performance—Collateral standard: Electromagnetic compatibility—Requirements and tests	Newer version with transition period
5–30	5–54	ANSI/AAMI/IEC 60601–1–2:2007 Medical electrical equipment—Part 1–2: General requirements for basic safety and essential performance—Collateral standard: Electromagnetic compatibility—Requirements and tests	Newer version with transition period
5–34	5–53	IEC 60601–1–2 Third edition 2007–03 Medical electrical equipment—Part 1–2: General requirements for basic safety and essential performance—Collateral standard: Electromagnetic compatibility—Requirements and tests	Newer version with transition period
5–35	5–54	ANSI/AAMI/IEC 60601–1–2:2007 Medical electrical equipment—Part 1–2: General requirements for basic safety and essential performance—Collateral standard: Electromagnetic compatibility—Requirements and tests	Newer version with transition period
5–49	5–55	IEC 60601–1–8 Second edition 2006–10 Medical electrical equipment—Part 1–8: General requirements for basic safety and essential performance—Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	Newer version with transition period
C. General Hospital/General Plastic Surgery			
6–9	6–227	ANSI/AAMI/IEC 60601–2–21: 2009 Medical electrical equipment—Part 2–21: Particular requirements for the basic safety and essential performance of infant radiant warmers	Newer version with transition period
6–29		ANSI/AAMI/IEC 60601–2–19: 2009 Medical Electrical Equipment—Part 2–19: Particular requirements for the basic safety and essential performance of infant incubators	Newer version with transition period Refer to recognition no. 6–230
6–32		ANSI/AAMI/IEC60601–2–20: 2009 Medical Electrical Equipment—Part 2–20: Particular requirements for the basic safety and essential performance of infant transport incubators	Newer version with transition period Refer to recognition no. 6–231
6–142		AAMI/ANSI II36:2004 Medical electrical equipment—Part 2: Particular requirements for safety of baby incubators	Newer version with transition period. Refer to recognition no. 6–230
6–143		AAMI/ANSI II51:2004 Medical electrical equipment—Part 2: Particular requirements for safety of transport incubators	Newer version with transition period. Refer to recognition no. 6–231
6–146	6–227	ANSI/AAMI/IEC 60601–2–21:2009 Medical Electrical Equipment—Part 2–21: Particular requirements for the basic safety and essential performance of infant radiant warmers	Newer version with transition period
6–182		IEC 60601–2–38 1996/Amendment 1:1999 Medical electrical—Part 2–38: Particular requirements for the safety of electrically operated hospital beds	Newer version with transition period. Refer to recognition no. 6–233
6–197	6–228	IEC 60601–2–2 Edition 5.0 2009–02 Medical electrical equipment—Part 2–2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	Newer version with transition period
D. OB–GYN/Gastroenterology			

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

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
9–4	9–60	IEC 60601–2–16 Edition 3.0 2008–04 Medical electrical equipment—Part 2–16: Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment	Newer version with transition period
9–42	9–61	IEC 60601–2–18 Edition 3.0 2009–08 Medical electrical equipment—Part 2–18: Particular requirements for the basic safety and essential performance of endoscopic equipment	Newer version with transition period
9–46	9–62	IEC 60601–2–2 Edition 5.0 2009–02 Medical electrical equipment—Part 2–2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	Newer version with transition period
E. Radiology			
12–34		IEC 60601–2–7 Second edition 1998–02 Medical electrical equipment—Part 2–7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators	Newer version with transition period. Refer to recognition no. 12–201
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
12–63	12–202	IEC 60601–2–43 Edition 2.0 2010–03 Medical electrical equipment—Part 2–43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures	Newer version with transition period
12–120	12–203	IEC 60601–2–44 Edition 3.0 2009–02 Medical electrical equipment—Part 2–44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography	Newer version with transition period
12–126	12–204	IEC 60601–2–28 Edition 2.0 2010–03 Medical electrical equipment—Part 2–28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis	Newer version with transition period
12–127		IEC 60601–2–32 First edition 1994–03 Medical electrical equipment Part 2: Particular requirements for the safety of associated equipment of X-ray equipment	Newer version with transition period. Refer to recognition no. 12–201
12–147	12–205	IEC 60601–2–5 Edition 3.0 2009–07 Medical electrical equipment Part 2–5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment	Newer version with transition period
12–152	12–206	IEC 60601–2–1 Edition 3.0 2009–10 Medical electrical equipment Part 2–1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV	Newer version with transition period
12–189	12–207	IEC 60601–2–33 Edition 3.0 2010–03 Medical electrical equipment—Part 2–33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis	Newer version with transition period
12–197	12–208	IEC 60601–2–22 Third edition 2007–05 Medical electrical equipment—Part 2–22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment	Newer version with transition period
12–198	12–209	IEC 60601–2–37 Edition 2.0 2007–08 Medical electrical equipment—Part 2–37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment	Newer version with transition period
12–199	12–210	IEC 60601–1–3 Edition 2.0 2008–01 Medical electrical equipment—Part 1–3: General requirements for basic safety and essential performance—Collateral Standard: Radiation protection in diagnostic X-ray equipment	Newer version with transition period
12–200	12–211	IEC 60601–2–29 Edition 3.0 2008–06 Medical electrical equipment—Part 2–29: Particular requirements for the basic safety and essential performance of radiotherapy simulators	Newer version with transition period

[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: 024.

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

Recognition No.	Title of Standard[1]	Reference No. & Date
A. Cardiology		
3–78	Medical electrical equipment—Part 2–30: Particular requirements for the basic safety and essential performance of automated noninvasive sphygmomanometers	ANSI/AAMI/IEC 80601–2–30:2009
B. General Hospital/General Plastic Surgery		
6–229	Medical electrical equipment—Part 2–2: Particular requirements for the basic safety and essential performance of high frequency surgery equipment and high frequency surgical accessories	ANSI/AAMI/IEC 60601–2–2:2009
6–230	Medical Electrical Equipment—Part 2–19: Particular requirements for the basic safety and essential performance of infant incubators	ANSI/AAMI/IEC 60601–2–19:2009
6–231	Medical Electrical Equipment—Part 2–20: Particular requirements for the basic safety and essential performance of infant transport incubators	ANSI/AAMI/IEC 60601–2–20:2009
6–232	Medical electrical equipment—Part 2–56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement	ISO 80601–2–56 First Edition 2009–10–01
6–233	Medical electrical equipment—Part 2–52: Particular requirements for the basic safety and essential performance of medical beds	IEC 60601–2–52 Edition 1.0 2009–12
6–234	Medical Electrical Equipment—Part 2–50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment	IEC 60601–2–50 Edition 2.0 2009–03
6–235	Medical Electrical Equipment—Part 2–50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment	ANSI/AAMI/IEC 60601–2–50: 2009
6–236	Medical electrical equipment—Part 2–59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening	IEC 80601–2–59 Edition 1.0 2008–10
6–237	CORRIGENDUM 1 Medical electrical equipment—Part 2–59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening	IEC 80601–2–59 Edition 1.0 2008–10
6–238	Medical electrical equipment—Part 2–35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use	IEC 80601–2–35 Edition 2.0 2009–10
C. OB–GYN/Gastroenterology		
9–63	Medical electrical equipment—Part 2–16: Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment CORRIGENDUM 1	IEC 60601–2–16 (Third edition—2008)
9–64	Medical electrical equipment—Part 2–2: Particular requirements for the basic safety and essential performance of high frequency surgery equipment and high frequency surgical accessories	ANSI/AAMI/IEC 60601–2–2:2009
D. Radiology		
12–201	Medical electrical equipment—Part 2–54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy	IEC 60601–2–54 Edition 1.0 2009–06

[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 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: 024" 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" through the hyperlink 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: 024. These modifications to the list or recognized standards are effective upon publication of this notice in the **Federal Register**.

Dated: June 4, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–13874 Filed 6–9–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: Cross-community Evaluation of the Native Aspirations Project—NEW

The Substance Abuse and Mental Health Services Administration's (SAMHSA), Center for Mental Health Services (CMHS) will conduct the Cross-Community Evaluation of the Native Aspirations Project. The cross-community evaluation has two tiers. Community-specific activities (Tier 1) are tied to key components of a community plan developed in each participating community that guides program planning and local evaluation through data-driven frameworks and inquiry. Tier I activities will include process and impact evaluation activities to determine the stage of readiness of communities to implement programs, how accurately community plans reflect the needs and characteristics of each community, how well local resources for American Indian/Alaska Native (AI/AN) youth are mobilized, the experience and impact of the Gathering of Native Americans (GONA), and the impact of the Native Aspirations program on the community. Core cross-community data collection activities (Tier II) are cross-community and include process and impact indicators such as community-level knowledge and awareness of suicide, violence, bullying, and substance abuse; pro-social and help-seeking behaviors among Native youth; and the provision of services specific to Native youth through existing service systems. Tier II activities are directly tied to the primary objectives of the Native Aspirations Project and are designed to augment data collection through the collection of community- and systems-level change measurement. Activities include the Service Provider Focus Groups and the Community Knowledge, Awareness, and Behavior Survey (C–KABS).

Data will be collected from Native adults and youth involved in the Community Mobilization Plan (CMP) meeting and the Gathering of Native Americans (GONA), key program stakeholders, Native youth service providers (*e.g.,* teachers, mental health providers, case workers, juvenile justice providers), and other community members (Native youth and adults). Data collection will take place in 25 AI/AN communities across three cohorts. Data collection for the Native Aspirations Cross-community Evaluation will occur over a three-year period of funding for each cohort. Clearance is requested for a three-year period of data collection that spans FY2009 through FY2012 during which Cohorts 3 and 4 will receive three years of data collection and Cohort 5 will receive two years of data collection with the final year to be submitted in an OMB renewal package. The following describes the specific data collection activities and the nine data collection instruments to be used, followed by a summary table of respondents and respondent burden.

Community Specific Data Collection Activities—Tier I

• *GONA—Baseline Interviews (1 Version).* Each participating community will have the opportunity to hold a GONA focused on youth violence, bullying, substance abuse, and suicide concerns. Community GONAs follow four themes that correspond to indigenous values and are core resiliency factors for Native people. These values—belonging, mastery, interdependence, and generosity—are the framework for this collaborative community event that focuses on individual and community healing, envisioning community wellness, mapping the assets of the community, and committing action in the community toward prevention efforts centered on youth violence, bullying, substance abuse, and suicide. Baseline GONA interviews will be conducted prior to the GONA in each community and will center on the four values and how respondents view and describe their relationships in and with the community; how people in the community deal with youth violence, bullying, substance abuse, and suicide; community members' willingness to work together to address these issues;