DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–N–0451]

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 027

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: 027'' (Recognition List Number: 027), 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: 027'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993–0002. Send two self-addressed adhesive labels to assist that office in processing your requests, or fax your request to 301–847–8149. Submit written comments concerning this document, or recommendations for additional standards for recognition, to the contact person (see **FOR FURTHER INFORMATION CONTACT**). Submit electronic comments by *e-mail: standards@cdrh.fda.gov.* This document may also be accessed on FDA's Internet site at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm.* See section VI of this document for electronic access to the searchable database for the current list of FDA recognized consensus standards, including Recognition List Number: 027 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.

I. Background

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

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

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

TABLE 1—PREVIOUS PUBLICATIONS OF STANDARD RECOGNITION LISTS

February 25, 1998 (63 FR 9561).	March 31, 2006 (71 FR 16313).
October 16, 1998 (63 FR 55617).	June 23, 2006 (71 FR 36121).
July 12, 1999 (64 FR 37546).	November 3, 2006 (71 FR 64718).
November 15, 2000 (65 FR 69022).	May 21, 2007 (72 FR 28500).
May 7, 2001 (66 FR 23032).	September 12, 2007 (72 FR 52142).
January 14, 2002 (67 FR 1774).	December 19, 2007 (72 FR 71924).
October 2, 2002 (67 FR 61893).	September 9, 2008 (73 FR 52358)
April 28, 2003 (68 FR 22391).	March 18, 2009 (74 FR 11586).
March 8, 2004 (69 FR 10712).	September 8, 2009 (74 FR 46203).
June 18, 2004 (69 FR 34176).	May 5, 2010 (75 FR 24711).
October 4, 2004 (69 FR 59240).	June 10, 2010 (75 FR 32943).
May 27, 2005 (70 FR 30756).	October 4, 2010 (75 FR 61148).
November 8, 2005 (70 FR 67713).	March 14, 2011 (76 FR 13631).

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: 027

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: 027'' 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. Cardiovascular:			

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

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
3–75		ANSI/AAMI SP10:2002/(R) 2008 & ANSI/AAMI SP10:2002/A1:2003 Manual, electronic or automated sphygmomanometers.	Extent of recognition, Type of standard.
3–78		ANSI/AAMI/IEC 80601–2–30:2009 Medical electrical equipment—Part 2–30: Particular requirements for the basic safety and essential performance of automated noninvasive sphygmomanometers.	Extent of recognition and Type of standard.
3–80		ANSI/AAMI/ISO 81060–1:2007 Non-invasive sphygmomanometers—Part 1: Requirements and test methods for non-automated measurement type.	Extent of recognition and Type of standard.
3–81		ANSI/AAMI/ISO 81060–2:2009 Non-invasive sphygmomanometers—Part 2: Clinical validation of automated measurement type.	Extent of recognition and Type of standard.
B. General:			
5–64	5–65	ANSI/AAMI/ISO 80369–1: 2010 Small bore connectors for liquids and gases in health care applications—Part 1: General requirements.	Withdrawn and replaced with newer version.
C. Materials:			
8–101		ASTM F2118–03 (Reapproved 2009), Standard Test Method for Constant Amplitude of Force Controlled Fatigue Testing of Acrylic Bone Cement.	Contact Person.
D. Ophthalmic:			
10–43		ISO 11979–8 Second Edition 2006–07–01 Ophthalmic implants—Intraocular lenses—Part 8: Fundamental requirements.	Extent of recognition.
10–56		ANSI Z80.12–2007 Ophthalmics—Multifocal Intraocular Lenses.	Title, Extent of recognition.
10–57		ANSI Z80.13–2007 Ophthalmics—Phakic Intraocular Lenses.	Title, Extent of recognition.
E. Orthopedics:			
11–79		ISO 7206–8:1995, Implants for Surgery—Partial and Total Hip Joint Prostheses—Part 8: Endurance Performance of Stemmed Femoral Components with Application of Torsion.	Withdrawn. See item 11–225.
11–220		ASTM F 2068–09, Standard Specification for Femoral Prostheses—Metallic Implants.	Extent of Recognition, Type of standard and Related CFR Citations and Procodes.
F. Sterility:			
14–228		ANSI/AAMI/ISO 11135–1:2007 Sterilization of health care products—Ethylene oxide—Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.	Relevant Guidance.
14–295		ANSI/AAMI ST81:2004/(R)2010 Sterilization of medical devices—Information to be provided by the manufacturer for the processing of resterilizable medical devices.	Relevant Guidance.
14–119	14–311	ANSI/AAMI ST55:2010 Table-top steam sterilizers	Withdrawn and replaced with newer version.
14–280	14–312	ANSI/AAMI ST79:2010 & A1:2010 (Consolidated Text) Comprehensive guide to steam sterilization and sterility assurance in health care facilities.	Withdrawn and replaced with newer version.

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

III. Listing of New Entries

In table 3 of this document, FDA provides the listing of new entries and consensus standards added as modifications to the list of recognized standards under Recognition List Number: 027.

TABLE 3—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS

Recognition No.	Title of standard [1]	Reference No. and date
A. Anesthesia:		
1–85	Medical electrical equipment—Part 2–61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.	ISO 80601–2–61 First edition 2011–04–01.
B. Dental/ENT:		
4–195	Dentistry-Implants-Dynamic fatigue test for endosseous dental implants.	ISO 14801 Second Edition 2007–11–15.
C. General:		

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

Recognition No.	Title of standard [1]	Reference No. and date
5–66	Medical electrical equipment—Part 1–10: General requirements for basic safety and essential performance—Collateral Standard: Requirements for the development of physiologic closed-loop controllers.	IEC 60601–1–10 Edition 1.0 2007–11.
5–67	Medical devices—Application of usability engineering to medical devices.	ANSI/AAMI/IEC 62366:2007.
D. General Hospital/General Plastic Surgery:		
6–253	Hoists for the transfer of disabled persons—Requirements and test methods.	ISO 10535 Second edition 2006–12–15.
E. IVD:		
7–219	Quality Assurance for Design Control and Implementation of Immunohistochemistry Assays; Approved Guideline—Second Edition.	CLSI I/LA28–A2.
7–220	Quantitative D-dimer for the Exclusion of Venous Thromboembolic Disease; Approved Guideline.	CLSI H59–A.
F. Nanotechnology:		
18–2	Standard Guide for Handling Unbound Engineered Nanoscale Particles in Occupational Settings.	ASTM E 2535–07.
G. OB–GYN/GU:		
9–67	Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms.	ASTM D7661–10.
9–68	Male condoms—Requirements and test methods for condoms made from synthetic materials.	ISO 23409 First edition 2011–02–15.
H. Ophthalmic:		
10–64	Ophthalmics Optics—Intraocular Lenses	ANSI Z80.7–2002.
10–65	Ophthalmic instruments—Endoilluminators—Fundamental requirements and test methods for optical radiation safety.	ISO 15752 Second edition 2010–01–15.
10–66	Optics and photonics—Operation microscopes—Part 2: Light hazard from operation microscopes used in ocular surgery.	ISO 10936–2 Second edition 2010–01–15.
I. Orthopedic		
11–225	Implants for surgery—Partial and total hip joint prostheses—Part 4: Determination of endurance properties and performance of stemmed femoral components.	ISO 7206–4 Third edition 2010–06–15.
J. Radiology		
12–227	Ultrasonics—Pulse-echo scanners—Part 1: Techniques for calibrating spatial measurement systems and measurement of system point-spread function response.	IEC 61391–1 First edition 2006–07.
12–228	Ultrasonics—Pulse-echo scanners—Part 2: Measurement of maximum depth of penetration and local dynamic range.	IEC 61391–2 Edition 1.0 2010–01.
12–229	Medical electrical equipment—Radiation dose documentation—Part 1: Equipment for radiography and radioscopy.	IEC PAS 61910–1 First edition 2007–07.
12–230	Primary user controls for interventional angiography x-ray equipment	NEMA XR 24–2008.

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

IV. List of Recognized Standards

FDA maintains the Agency's current list of FDA recognized consensus standards in a searchable database that may be accessed directly at FDA's Internet site at *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm*. FDA will incorporate the modifications and minor revisions described in this notice into the database and, upon publication in the **Federal Register**, this recognition of consensus standards will be effective. FDA will announce additional modifications and minor revisions to the list of recognized consensus standards, as needed, in the **Federal Register** once a year, or more often, if necessary.

V. Recommendation of Standards for Recognition by FDA

Any person may recommend consensus standards as candidates for recognition under the new provision of section 514 of the FD&C Act by submitting such recommendations, with reasons for the recommendation, to the contact person (see **FOR FURTHER INFORMATION CONTACT**). To be properly considered such recommendations should contain, at a minimum, the following information: (1) Title of the standard; (2) any reference number and date; (3) name and address of the national or international standards development organization; (4) a proposed list of devices for which a declaration of conformity to this standard should routinely apply; and (5) a brief identification of the testing or performance or other characteristics of the device(s) that would be addressed by a declaration of conformity.

VI. Electronic Access

You may obtain a copy of ''Guidance on the Recognition and Use of Consensus Standards'' by using the Internet. CDRH maintains a site on the Internet for easy access to information including text, graphics, and files that you may download to a personal computer with access to the Internet. Updated on a regular basis, the CDRH

home page includes the guidance as well as the current list of recognized standards and other standards related documents. After publication in the **Federal Register**, this notice announcing ''Modification to the List of Recognized Standards, Recognition List Number: 027'' 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 sent 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: 027. These modifications to the list or recognized standards are effective upon publication of this notice in the **Federal Register**.

Dated: July 28, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0490]

Guidance for Industry and Food and Drug Administration Staff: Investigational New Drug Applications for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic Reconstitution for Specified Indications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry and FDA Staff: Investigational New Drug Applications (INDs) for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic Reconstitution for Specified Indications,'' dated June 2011. The guidance document provides advice to potential sponsors to assist in the submission of an IND for certain minimally manipulated hematopoietic stem/progenitor cells from placental/umbilical cord blood, from an unrelated allogeneic cord blood donor and intended for hematopoietic reconstitution in patients with specified indications (HPC–Cs), when such HPC–Cs are not licensed and when a suitable human leukocyte antigen (HLA) matched cord blood transplant is needed for treatment of a patient with a serious or life-threatening disease or condition, and there is no satisfactory alternative treatment. If such HPC–Cs are made available for clinical use, they must be distributed under an IND. The guidance announced in this notice finalizes the draft guidance of the same title dated October 2009.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Tami Belouin, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry and FDA Staff: Investigational New Drug Applications (INDs) for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic Reconstitution for Specified Indications,'' dated June 2011. The guidance document provides advice to potential sponsors (*e.g.,* cord blood banks or registries, transplant centers, and individual physicians serving as sponsor-investigators) to assist in the submission of an IND for certain HPC–Cs, when such HPC–Cs are not licensed in accordance with 21 CFR Part 601, and when a suitable HLA matched cord blood transplant is needed for treatment of a patient with a serious or life-threatening disease or condition, and there is no satisfactory alternative treatment. The guidance document is applicable only to HPC–Cs intended for hematopoietic reconstitution in patients with the clinical indications listed in the guidance. If such HPC–Cs are made available for clinical use, they must be distributed under an IND meeting all of the applicable requirements in part 312 (21 CFR Part 312).

In the **Federal Register** of October 20, 2009 (74 FR 53751), FDA announced the availability of the draft guidance of the same title dated October 2009. FDA received a few comments on the draft guidance, and those comments were considered as the guidance was finalized. Changes incorporated in the final guidance include simplifying table A, which sets forth certain regulatory requirements and current best practices with respect to what should be included in an IND. In addition, organizational and editorial revisions were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated October 2009.

In the October 20, 2009, notice announcing the availability of the draft