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: 047

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) 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: 047'' (Recognition List Number: 047), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit electronic or written comments concerning this document at any time. These modifications to the list of recognized standards are effective August 21, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2004–N–0451 for ''Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 047.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday. 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: 047.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

An electronic copy of Recognition List Number: 047 is available on the Internet at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm.* See Section IV for electronic access to the searchable database for the current list of FDA recognized consensus standards, including Recognition List Number: 047 modifications and other standards related information. Submit written requests for a single hard copy of the document entitled ''Modifications to the List of Recognized Standards, Recognition List Number: 047'' to Scott Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5514, Silver Spring, MD 20993, 301–796–6287. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8144.

FOR FURTHER INFORMATION CONTACT: Scott Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5514, Silver Spring, MD 20993, 301–796–6287, *CDRHStandardsStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

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 the **Federal Register** notice 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. The guidance was updated in September 2007 and is available at *https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077295.pdf.*

Modifications to the initial list of recognized standards published in the **Federal Register** can be accessed at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm.*

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. Additional information on the Agency's standards program is available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm.*

II. Modifications to the List of Recognized Standards, Recognition List Number: 047

FDA is announcing the addition, withdrawal, correction, and revision of certain consensus standards the Agency is recognizing for use in premarket submissions and other requirements for devices. FDA is incorporating these modifications to the list of FDA Recognized Consensus Standards in the Agency's searchable database. FDA is using the term ''Recognition List Number: 047'' to identify the current modifications.

In table 1, FDA describes the following modifications: (1) The withdrawal of standards and their replacement by others, if applicable; (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, FDA lists modifications the Agency is making that involve the initial addition of standards not previously recognized by FDA.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
A. Anesthesiology			
		No new entries at this time.	
B. Biocompatibility			
2–114	2–246	ASTM F1877—16 Standard Practice for Characterization of Particles.	Withdrawn and replaced with newer version.
2–155		ASTM F2147—01 (Reapproved 2016) Standard Practice for Guinea Pig: Split Adjuvant and Closed Patch Testing for Contact Allergens.	Reaffirmation.
2–177	2–247	ISO 10993–6 Third edition 2016–12–01 Biological evaluation of medical devices—Part 6: Tests for local effects after implantation.	Withdrawn and replaced with newer version.
2–235	2–248	ISO 10993–4 Third edition 2017–04 Biological evaluation of medical devices—Part 4: Selection of tests for interactions with blood.	Withdrawn and replaced with newer version. Extent of recognition.
C. Cardiovascular			
3–121	3–149	ISO 25539–1 Second edition 2017–02 Cardiovascular implants—Endovascular devices—Part 1: Endovascular prostheses.	Withdrawn and replaced with newer version.
3–142		ISO/TS 17137 First edition 2014–05–15 Cardiovascular implants and extracorporeal systems—Cardiovascular absorbable implants.	Extent of recognition.
D. Dental/Ear, Nose, and Throat (ENT)			
4–96	4–230	ANSI/ADA Standard No. 30–2013/ISO 3107 Dental Zinc Oxide/Eugenol & Zinc Oxide/Non-Eugenol Cements.	Withdrawn and replaced with newer version. Extent of recognition.
4–193		ANSI/ADA Standard No. 15–2008 (R2013)/ISO 22112 Artificial Teeth for Dental Prostheses.	Extent of recognition.
4–215		ANSI/ADA Standard No. 96–2012 Dental Water-based Cements.	Extent of recognition.
E. General I (Quality Systems/Risk Management) (QS/RM)			
5–90	5–117	ISO 15223–1 Third edition 2016–11–01 Medical devices—symbols to be used with medical device labels, labelling, and information to be supplied—part 1: General requirements.	Withdrawn and replaced with newer version.
5–91	5–118	ANSI/AAMI/ISO 15223–1: 2016 Medical devices—symbols to be used with medical device labels, labelling, and information to be supplied—part 1: General requirements.	Withdrawn and replaced with newer version.
5–107		IEC 80369–5: Edition 1.0 2016–03 Small-bore connectors for liquids and gases in healthcare applications—Part 5: Connectors for limb cuff inflation applications [Including CORRIGENDUM 1 (2017)].	Technical corrigendum added.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
F. General II (Electrical Safety/Electromagnetic Compatibility) (ES/EMC)			
		No new entries at this time.	
G. General Hospital/General Plastic Surgery (GH/GPS)			
6–70		ASTM E825–98 (Reapproved 2016) Standard Specification for Phase Change-Type Disposable Fever Thermometer for Intermittent Determination of Human Temperature.	Reaffirmation.
6–124		ASTM E1104–98 (Reapproved 2016) Standard Specification for Clinical Thermometer Probe Covers and Sheaths.	Reaffirmation
6–125		ASTM E1965–98 (Reapproved 2016) Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature.	Reaffirmation.
6–297	6–384	ISO 1135–4 Sixth edition 2015–12–01 Transfusion equipment for medical use-Part 4: Transfusion sets for single use, gravity feed.	Withdrawn and replaced with newer version.
6–319	6–385	IEC 60601–2–19 Edition 2.1 2016–04 CONSOLIDATED VERSION Medical electrical equipment—Part 2–19: Particular requirements for the basic safety and essential performance of infant incubators [Including AMENDMENT 1 (2016)].	Withdrawn and replaced with newer version including amendment.
6–320	6–386	IEC 60601–2–20 Edition 2.1 2016–04 CONSOLIDATED VERSION Medical electrical equipment—Part 2–20: Particular requirements for the basic safety and essential performance of infant transport incubators [Including AMENDMENT 1 (2016)].	Withdrawn and replaced with newer version including amendment.
6–324	6–387	IEC 60601–2–50 Edition 2.1 2016–04 CONSOLIDATED VERSION Medical electrical equipment—Part 2–50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment [Including AMENDMENT 1 (2016)].	Withdrawn and replaced with newer version including amendment.
6–325	6–388	IEC 60601–2–21 Edition 2.1 2016–04 CONSOLIDATED VERSION Medical electrical equipment—Part 2–21: Particular requirements for the basic safety and essential performance of infant radiant warmers [Including AMENDMENT 1 (2016)].	Withdrawn and replaced with newer version including amendment.
6–336	6–389	IEC 60601–2–2 Edition 6.0 2017–03 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.	Withdrawn and replaced with newer version.
6–342	6–390	IEC 80601–2–35 Edition 2.1 2016–04 CONSOLIDATED VERSION 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 [Including AMENDMENT 1 (2016)].	Withdrawn and replaced with newer version including amendment.
6–367	6–391	USP 40–NF35:2017, Sodium Chloride Irrigation	Withdrawn and replaced with newer version.
6–368	6–392	USP 40–NF35:2017, Sodium Chloride Injection	Withdrawn and replaced with newer version.
6–369	6–393	USP 40–NF35:2017, Nonabsorbable Surgical Suture	Withdrawn and replaced with newer version.
6–370	6–394	USP 40–NF35:2017, <881> Tensile Strength	Withdrawn and replaced with newer version.
6–371	6–395	USP 40–NF35:2017, <861> Sutures—Diameter	Withdrawn and replaced with newer version.
6–372	6–396	USP 40–NF35:2017, <871> Sutures—Needle Attachment	Withdrawn and replaced with newer version.
6–373	6–397	USP 40–NF35:2017, Sterile Water for Irrigation	Withdrawn and replaced with newer version.
6–374	6–398	USP 40–NF35:2017, Heparin Lock Flush Solution	Withdrawn and replaced with newer version.
6–375	6–399	USP 40–NF35:2017, Absorbable Surgical Suture	Withdrawn and replaced with newer version.
H. In Vitro Diagnostics (IVD)			
7–206	7–270	I/LA–20 3rd Edition Analytical Performance Characteristics, Quality Assurance, and Clinical Utility of Immunological Assays for Human Immunoglobulin E Antibodies of Defined Allergen Specificities.	Withdrawn and replaced with newer version.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
7–263	7–271	CLSI M100 27th Edition Performance Standards for Antimicrobial Susceptibility Testing.	Withdrawn and replaced with newer version.
		I. Materials	
8–58	8–447	ISO 5832–3 Fourth edition 2016–10–15 Implants for surgery—Metallic materials—Part 3: Wrought titanium 6-aluminium 4-vanadium alloy.	Withdrawn and replaced with newer version. Extent of recognition.
8–125	8–448	ASTM F2004–16 Standard Test Method for Transformation Temperature of Nickel-Titanium Alloys by Thermal Analysis.	Withdrawn and replaced with newer version.
8–165	8–449	ASTM F1058–16 Standard Specification for Wrought 40Cobalt-20 Chromium-16Iron-15Nickel-7Molybdenum Alloy Wire, Strip, and Strip Bar for Surgical Implant Applications (UNS R30003 and UNS R30008).	Withdrawn and replaced with newer version.
8–185	8–450	ASTM F451–16 Standard Specification for Acrylic Bone Cement.	Withdrawn and replaced with newer version.
8–187		ISO 13779–1:2008 Second edition 2008–10–01 Implants for surgery—Hydroxyapatite—Part 1: Ceramic hydroxyapatite.	Withdrawn.
8–195		ASTM F2024–10 (Reapproved 2016) Standard Practice for X-ray Diffraction Determination of Phase Content of Plasma-Sprayed Hydroxyapatite Coatings.	Reaffirmation.
8–201	8–451	ASTM F2214–16 Standard Test Method for *In Situ* Determination of Network Parameters of Crosslinked Ultra High Molecular Weight Polyethylene (UHMWPE).	Withdrawn and replaced with newer version.
8–202		ASTM F2183–02 (Reapproved 2008) Standard Test Method for Small Punch Testing of Ultra-High Molecular Weight Polyethylene Used in Surgical Implants (Withdrawn 2017).	Withdrawn.
8–205	8–452	ASTM F1635–16 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.
8–216	8–453	ASTM F1295–16 Standard Specification for Wrought Titanium-6 Aluminum-7Niobium Alloy for Surgical Implant Applications (UNS R56700).	Withdrawn and replaced with newer version.
8–226		ASTM F603–12 (Reapproved 2016) Standard Specification for High-Purity Dense Aluminum Oxide for Medical Application.	Reaffirmation.
8–333		ASTM F2393–12 (Reapproved 2016) Standard Specification for High-Purity Dense Magnesia Partially Stabilized Zirconia (Mg-PSZ) for Surgical Implant Applications.	Reaffirmation.
8–396	8–454	ASTM F2129–17 Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices.	Withdrawn and replaced with newer version.
8–428		ASTM F1581–08 (Reapproved 2016) Standard Specification for Composition of Anorganic Bone for Surgical Implants.	Reaffirmation.
8–410	8–455	ASTM F2902–16 Standard Guide for Assessment of Absorbable Polymeric Implants.	Withdrawn and replaced with newer version.
		J. Nanotechnology	
		No new entries at this time.	
		K. Neurology	
		No new entries at this time.	
		L. Obstetrics-Gynecology/Gastroenterology/Urology (OB-Gyn/G/Urology)	
		No new entries at this time.	
		M. Ophthalmic	
10–69	10–103	ANSI Z80.18–2016 American National Standard for Ophthalmics—Contact Lens Care Products—Vocabulary, Performance Specifications, and Test Methodology.	Withdrawn and replaced with newer version.
10–92	10–104	ANSI Z80.20–2016 American National Standard for Ophthalmics—Contact Lenses—Standard Terminology, Tolerances, Measurements and Physicochemical Properties.	Withdrawn and replaced with newer version.
		N. Orthopedic	
11–175		ASTM F1582–98 (Reapproved 2016) Standard Terminology Relating to Spinal Implants.	Reaffirmation.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
11–242	.....	ASTM F1839–08 (Reapproved 2016) Standard Specification for Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopaedic Devices and Instruments.	Reaffirmation.
11–269	.....	ASTM F2423–11 (Reapproved 2016) Standard Guide for Functional, Kinematic, and Wear Assessment of Total Disc Prostheses.	Reaffirmation.
11–280	.....	ASTM F2624–12 (Reapproved 2016) Standard Test Method for Static, Dynamic, and Wear Assessment of Extra-Discal Single Level Spinal Constructs.	Reaffirmation.
11–309	.....	ASTM F116–12 (Reapproved 2016) Standard Specification for Medical Screwdriver Bits.	Reaffirmation.
		O. Physical Medicine	
		No new entries at this time.	
		P. Radiology	
12–234	12–306	NEMA MS 12–2016 Quantification and Mapping of Geometric Distortion for Special Applications.	Withdrawn and replaced with newer version.
		Q. Software/Informatics	
13–66	13–88	ISO/IEEE 11073–10417 Third edition 2017–04 Health informatics—Personal health device communication—Part 10417: Device specialization—Glucose meter.	Withdrawn and replaced with newer version.
13–67	.....	ISO/IEEE 11073–10418 First edition 2014–03–01 Health informatics—Personal health device communication—Part 10418: Device specialization: International Normalized Ratio (INR) monitor [including TECHNICAL CORRIGENDUM 1 (2016)].	Technical Corrigendum added.
		R. Sterility	
14–288	14–501	ASTM F1886/F1886M–16 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection.	Withdrawn and replaced with newer version.
14–338	14–502	ISO 11138–1 Third edition 2017–03 Sterilization of health care products—Biological indicators—Part 1: General requirements.	Withdrawn and replaced with newer version.
14–358	.....	ANSI/AAMI/ISO 14160:2011/(R)2016 Sterilization of health care products—Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives—Requirements for characterization, development, validation and routine control of a sterilization process for medical devices.	Reaffirmation. Extent of recognition.
14–361	.....	ISO 14160 Second edition 2011–07–01 Sterilization of health care products—Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives—Requirements for characterization, development, validation and routine control of a sterilization process for medical devices.	Extent of recognition.
14–485	14–503	USP 40–NF35:2017, <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests.	Withdrawn and replaced with newer version.
14–486	14–504	USP 40–NF35:2017, <71> Sterility Tests	Withdrawn and replaced with newer version.
14–487	14–505	USP 40–NF35:2017, <85> Bacterial Endotoxins Test	Withdrawn and replaced with newer version.
14–488	14–506	USP 40–NF35:2017, <161> Medical Devices-Bacterial Endotoxin and Pyrogen Tests.	Withdrawn and replaced with newer version.
14–493	14–507	USP 40–NF35:2017, <62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms.	Withdrawn and replaced with newer version.
14–494	14–508	USP 40–NF35:2017, <55> Biological Indicators—Resistance Performance Tests.	Withdrawn and replaced with newer version.
14–495	14–509	USP 40–NF35:2017, <1229.5> Biological Indicators for Sterilization.	Withdrawn and replaced with newer version.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
S. Tissue Engineering			
15–20	15–49	ASTM F2027–16 Standard Guide for Characterization and Testing of Raw or Starting Materials for Tissue-Engineered Medical Products.	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 2, FDA provides the listing of new entries and consensus standards added as modifications to the list of recognized standards under Recognition List Number: 047.

TABLE 2—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS

Recognition No.	Title of standard [1]	Reference No. and date
A. Anesthesiology		
1–121	Anaesthetic and respiratory equipment—Low-pressure hose assemblies for use with medical gases.	ISO 5359 Fourth edition 2014–10–01.
1–122	Anaesthetic and respiratory equipment—Oropharyngeal airways	ISO 5364 Fifth edition 2016–09–01.
1–123	Anaesthetic and respiratory equipment—Laryngoscopes for tracheal intubation	ISO 7376 Second edition 2009–08–15.
1–124	Inhalational anaesthesia systems—Part 7: Anaesthetic systems for use in areas with limited logistical supplies of electricity and anaesthetic gases.	ISO 8835–7 First edition 2011–11–01.
1–125	Suction catheters for use in the respiratory tract	ISO 8836 Fourth edition 2014–10–15.
1–126	Anaesthetic and respiratory equipment—Supralaryngeal airways and connectors.	ISO 11712 First edition 2009–05–15.
1–127	Tracheobronchial tubes—Sizing and marking	ISO 16628 First edition 2008–11–15.
1–128	Anaesthetic and respiratory equipment—Dimensions of noninterchangeable screw-threaded (NIST) low-pressure connectors for medical gases.	ISO 18082 First edition 2014–06–15.
B. Biocompatibility		
	No new entries at this time.	
C. Cardiovascular		
	No new entries at this time.	
D. Dental/Ear, Nose, and Throat (ENT)		
4–231	Dentistry—Testing of adhesion to tooth structure	ISO/TS 11405 Third edition 2015–02–01.
4–232	Dentistry—Base polymers—Part 1: Denture base polymers	ISO 20795–1 Second edition 2013–03–01.
4–233	Dentistry—Base polymers—Part 2: Orthodontic base polymers	ISO 20795–2 Second edition 2013–03–01.
4–234	Dental Base Polymers	ANSI/ADA Standard No.139–2012.
4–235	Orthodontic Brackets and Tubes	ANSI/ADA Standard No.100–2012/ISO 27020.
4–236	Manual Toothbrushes	ANSI/ADA Standard No.119–2015.
4–237	Powered Toothbrushes	ANSI/ADA Standard No.120–2009 (R2014)/ISO 20127.
4–238	Dentistry—Powered toothbrushes—General requirements and test methods	ISO 20127 First edition 2005–03–15.
4–239	Cochlear Implant Systems: Requirements for Safety, Functional Verification, Labeling and Reliability Reporting.	ANSI/AAMI CI 86:2017.
E. General I (Quality Systems/Risk Management) (QS/RM)		
5–119	Small-bore connectors for liquids and gases in healthcare applications—Part 5: Connectors for limb cuff inflation applications.	ANSI/AAMI/ISO 80369–5: 2016.
F. General II (Electrical Safety/Electromagnetic Compatibility) (ES/EMC)		
19–22	Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems.	AAMI TIR69: 2017.
19–23	Primary batteries—Part 4: Safety of lithium batteries	IEC 60086–4 Edition 4.0 2014–09.
19–24	Primary batteries—Part 5: Safety of batteries with aqueous electrolyte	IEC 60086–5 Edition 4.0 2016–07.
19–25	Safety requirements for secondary batteries and battery installations—Part 1: General safety information.	IEC 62485–1 Edition 1.0 2015–04.
19–26	Safety requirements for secondary batteries and battery installations—Part 2: Stationary batteries.	IEC 62485–2 Edition 1.0 2010–06.
19–27	Safety requirements for secondary batteries and battery installations—Part 3: Traction batteries.	IEC 62485–3 Edition 2.0 2014–07.
19–28	Safety requirements for secondary batteries and battery installations—Part 4: Valve-regulated lead-acid batteries for use in portable appliances.	IEC 62485–4 Edition 1.0 2015–01.
19–29	American National Standard for Evaluation of Wireless Coexistence	IEEE/ANSI C63.27–2017.

TABLE 2—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS—Continued

Recognition No.	Title of standard [1]	Reference No. and date
G. General Hospital/General Plastic Surgery (GH/GPS)		
6–400	Standard Test Method for Coring Testing of Huber Needles	ASTM F3212–16.
H. In Vitro Diagnostics (IVD)		
7–272	Mass Spectrometry for Androgen and Estrogen Measurements in Serum	CLSI C57 First edition.
7–273	Methods for the Identification of Cultured Microorganisms Using Matrix-Assisted Laser Desorption/Ionization Time-of-Flight Mass Spectrometry.	CLSI M58.
I. Materials		
8–456	Implants for surgery—Plasma-sprayed unalloyed titanium coatings on metallic surgical implants—Part 1: General requirements.	ISO 13179–1 First edition 2014–06–01.
8–457	Implants for surgery—Calcium phosphates—Part 3: Hydroxyapatite and beta-tricalcium phosphate bone substitutes.	ISO 13175–3 First edition 2012–10–01.
8–458	Standard Reference Test Method for Making Potentiodynamic Anodic Polarization Measurements.	ASTM G5–14.
8–459	Pyrometry	SAE/AMS2750 Rev. E 2012–07.
J. Nanotechnology		
18–5	Standard Guide for Size Measurement of Nanoparticles Using Atomic Force Microscopy.	ASTM E2859–11.
18–6	Standard Guide for Measurement of Electrophoretic Mobility and Zeta Potential of Nanosized Biological Materials.	ASTM E2865–12.
18–7	Standard Guide for Measurement of Particle Size Distribution of Nanomaterials in Suspension by Nanoparticle Tracking Analysis (NTA).	ASTM E2834–12.
18–8	Standard Practice for Calculation of Mean Sizes/Diameters and Standard Deviations of Particle Size Distributions.	ASTM E2578–07 (Reapproved 2012).
K. Neurology		
	No new entries at this time.	
L. Obstetrics-Gynecology/Gastroenterology/Urology (OB-Gyn/G/Urology)		
	No new entries at this time.	
M. Ophthalmic		
	No new entries at this time.	
N. Orthopedic		
11–321	Standard Specification for Total Elbow Prostheses	ASTM F2887–17.
O. Physical Medicine		
16–200	Wheelchairs—Part 19: Wheeled mobility devices for use as seats in motor vehicles.	ISO 7176–19 Second edition 2008–07–15.
P. Radiology		
	No new entries at this time.	
Q. Software/Informatics		
13–89	Health informatics—Personal health device communication—Part 10406: Device specialization—Basic electrocardiograph (ECG) (1- to 3-lead ECG).	ISO/IEEE 11073–10406 First edition 2012–12–01.
13–90	Health Informatics—Personal Health Device Communication, Part 10417: Device Specialization—Glucose Meter.	IEEE Std 11073–10417–2015.
13–91	Health informatics—Personal health device communication—Part 10419: Device specialization—Insulin pump.	ISO/IEEE 11073–10419 First edition 2016–06–15.
13–92	Health informatics—Personal health device communication—Part 10421: Device specialization—Peak expiratory flow monitor (peak flow).	ISO/IEEE 11073–10421 First edition 2012–11–01.
13–93	Health informatics—Personal health device communication, Part 10422: Device Specialization—Urine Analyzer.	IEEE Std 11073–10422–2016.
13–94	Health informatics—Personal health device communication—Part 10424: Device specialization—Sleep Apnoea Breathing Therapy Equipment (SABTE).	ISO/IEEE 11073–10424 First edition 2016–06–15.
13–95	Health informatics—Personal health device communication—Part 10425: Device specialization—Continuous glucose monitor (CGM).	ISO/IEEE 11073–10425 First edition 2016–06–15.
13–96	Standard for Software Cybersecurity Network-Connectable Products, Part 1: General Requirements.	UL 2900–1 Ed.1 2017.
13–97	Health software—Part 1: General requirements for product safety	IEC 82304–1 Edition 1.0 2016–10.
R. Sterility		
	No new entries at this time.	

TABLE 2—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS—Continued

Recognition No.	Title of standard [1]	Reference No. and date
S. Tissue Engineering		
15–50	Standard Guide for Quantifying Cell Viability within Biomaterial Scaffolds	ASTM F2739–16.

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

IV. List of Recognized Standards

FDA maintains the current list of FDA Recognized Consensus Standards in a searchable database that may be accessed at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.* FDA will be incorporating the modifications and 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 be announcing additional modifications and revisions to the list of recognized consensus standards in the **Federal Register**, as needed, 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 section 514 of the FD&C Act by submitting such recommendations, with reasons for the recommendation, to *CDRHStandardsStaff@fda.hhs.gov.* To be 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 electronic or mailing address of the requestor, (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.

Dated: August 16, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–17603 Filed 8–18–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–2936]

Content of Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements; Establishment of a Public Docket; Request for Information and Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for information and comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is establishing a public docket to assist with its development of recommendations regarding the communication of risk information in direct-to-consumer (DTC) broadcast advertisements for prescription drugs and biologics.

DATES: Although you can comment at any time, to ensure that the Agency considers your comment in our development of recommendations, submit either electronic or written information and comments by November 20, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–N–2936 for ''Content of Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly