Dated: December 19, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–30966 Filed 12–22–16; 8:45 am]

BILLING CODE 4164–01–P

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: 046

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: 046'' (Recognition List Number: 046), 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 December 23, 2016.

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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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: 046.'' 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 Division of Dockets Management 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: 046.

- 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

An electronic copy of Recognition List Number: 046 is available on the Internet 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: 046 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: 046'' 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, *standards@cdrh.fda.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 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**, can be accessed at *http://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. 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: 046

FDA is announcing the addition, withdrawal, correction, and revision of certain consensus standards the Agency will recognize for use in premarket submissions 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: 046'' to identify these 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			
1–44	1–117	ISO 5366 First edition 2016–10–01 Anaesthetic and respiratory equipment—Tracheostomy tubes and connectors.	Withdrawn and replaced with newer version.
1–93	1–118	ISO 5361 Third edition 2016–09–01 Anaesthetic and respiratory equipment—Tracheal tubes and connectors.	Withdrawn and replaced with newer version.
B. Biocompatibility			
2–93		ASTM F763–04 (Reapproved 2016) Standard Practice for Short-Term Screening of Implant Materials.	Reaffirmation.
2–94		ASTM F981–04 (Reapproved 2016) Standard Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Insertion into Bone.	Reaffirmation.
2–126	2–244	ASTM F748–16 Standard Practice for Selecting Generic Biological Test Methods for Materials and Devices.	Withdrawn and replaced with newer version, Extent of recognition.
2–134		ASTM F2065–00 (Reapproved 2010) Standard Practice for Testing for Alternative Pathway Complement Activation in Serum by Solid Materials.	Withdrawn.
2–189		ASTM F895–11 (Reapproved 2016) Standard Test Method for Agar Diffusion Cell Culture Screening for Cytotoxicity.	Reaffirmation.
2–225		ASTM F2567–06 (Reapproved 2010) Standard Practice for Testing for Classical Complement Activation in Serum by Solid Materials.	Withdrawn.
C. Cardiovascular			
3–58		ANSI/AAMI/ISO 5840:2005/(R)2010 Cardiovascular implants—Cardiac valve prostheses.	Withdrawn.
3–90	3–144	ISO 7198 Second edition 2016–08–01 Cardiovascular implants and extracorporeal systems—Vascular prostheses—Tubular vascular grafts and vascular patches.	Withdrawn and replaced with newer version.
3–91		ISO 5840 Fourth edition 2005–03–01 Cardiovascular implants—Cardiac valve prostheses.	Withdrawn.
D. Dental/Ear, Nose, and Throat (ENT)			
		No modifications at this time	
E. General I (Quality Systems/Risk Management) (QS/RM)			
5–79	5–113	ASTM D7386–16 Standard Practice for Performance Testing of Packages for Single Parcel Delivery Systems.	Withdrawn and replaced with newer version.
5–87		IEC 62366 Edition 1.1 2014–01 Consolidated Version Medical devices—Application of usability engineering to medical devices.	Transition.

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

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
5–95	5–114	IEC 62366–1 Edition 1.0 2015–02 Medical Devices—Part 1: Application of Usability Engineering to Medical Devices [Including CORRIGENDUM 1 (2016)].	Withdrawn and replaced with newer version including corrigendum.
F. General II (Electrical Safety/Electromagnetic Compatibility) (ES/EMC)			
		No modifications at this time	
G. General Hospital/General Plastic Surgery (GH/GPS)			
6–11		ISO 594–1 First edition 1986–06–15 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment—Part 1: General requirements.	Transition.
6–129		ISO 594–2 Second edition 1998–09–01 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment—Part 2: Lock fittings.	Transition.
6–165		ASTM D6977–04 (Reapproved 2016) Standard Specification for Polychloroprene Examination Gloves for Medical Application.	Reaffirmation.
6–282	6–383	ASTM D6499–16 Standard Test Method for The Immunological Measurement of Antigenic Protein in Natural Rubber and its Products.	Withdrawn and replaced with newer version.
H. In Vitro Diagnostics (IVD)			
7–149	7–267	CLSI C24 4th Edition Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions.	Withdrawn and replaced with newer version.
7–174	7–268	CLSI EP21 2nd Edition Evaluation of Total Analytical Error for Quantitative Medical Laboratory Measurement Procedures.	Withdrawn and replaced with newer version, Extent of recognition.
I. Materials			
8–350	8–435	ISO 5832–1 Fifth edition 2016–07–15 Implants for surgery—Metallic materials—Part 1: Wrought stainless steel.	Withdrawn and replaced with newer version.
8–368		ASTM F2625–10 (Reapproved 2016) Standard Test Method for Measurement of Enthalpy of Fusion, Percent Crystallinity, and Melting Point of Ultra-High-Molecular Weight Polyethylene by Means of Differential Scanning Calorimetry.	Reaffirmation.
8–376		ASTM F2102–13 Standard Guide for Evaluating the Extent of Oxidation in Ultra-High-Molecular-Weight Polyethylene Fabricated Forms Intended for Surgical Implants.	Withdrawn. See 8–382.
8–384	8–436	ASTM F2026–16 Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications.	Withdrawn and replaced with newer version.
8–392	8–437	ASTM F2082/F2082M–16 Standard Test Method for Determination of Transformation Temperature of Nickel-Titanium Shape Memory Alloys by Bend and Free Recovery.	Withdrawn and replaced with newer version.
8–407	8–438	ISO/ASTM 52915 Second edition 2016–02–15 Specification for Additive Manufacturing File Format (AMF) Version 1.2.	Withdrawn and replaced with newer version.
J. Nanotechnology			
		No modifications at this time	
K. Neurology			
		No modifications at this time	
L. Obstetrics-Gynecology/Gastroenterology/Urology (OB-Gyn/G/Urology)			
		No modifications at this time	
M. Ophthalmic			
		No modifications at this time	
N. Orthopedic			
11–223	11–311	ISO 14243–2 Third edition 2016–09–01 Implants for surgery—Wear of total knee-joint prostheses—Part 2: Methods of measurement.	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
11–225	11–312	ISO 7206–4 Third edition 2010–06–15 Implants for surgery—Components for partial and total knee joint prostheses—Part 2: Articulating surfaces made of metal, ceramic and plastics materials [Including AMENDMENT 1 (2016)].	Withdrawn and replaced with newer version including amendment.
11–231	11–313	ISO 7207–2 Second edition 2011–07–01 Implants for surgery—Components for partial and total knee joint prostheses—Part 2: Articulating surfaces made of metal, ceramic and plastics materials [Including AMENDMENT 1 (2016)].	Withdrawn and replaced with newer version including amendment.
11–249	11–314	ISO 14242–2 Second edition 2016–09–15 Implants for surgery—Wear of total hip-joint prostheses—Part 2: Methods of measurement.	Withdrawn and replaced with newer version.
11–268	11–315	ASTM F1829–16 Standard Test Method for Static Evaluation of Anatomic Glenoid Locking Mechanism in Shear.	Withdrawn and replaced with newer version.
11–287		ASTM F382–14 Standard Specification and Test Method for Metallic Bone Plates.	Withdrawn. See 11–297.
11–298	11–316	ASTM F1264–16 Standard Specification and Test Methods for Intramedullary Fixation Devices.	Withdrawn and replaced with newer version.
		O. Physical Medicine	
		No modifications at this time	
		P. Radiology	
12–49	12–303	IEC 61303 Edition 1.0 1994–09 Medical electrical equipment—Radionuclide calibrators—Particular methods for describing performance [Including CORRIGENDUM 1 (2016)].	Withdrawn and replaced with new version including corrigendum.
12–235	12–304	IEC 60731 Edition 3.1 2016–04 Consolidated Version Medical electrical equipment—Dosimeters with ionization chambers as used in radiotherapy.	Withdrawn and replaced with newer version.
12–263	12–305	ISO 13694 Second edition 2015–11–15 Optics and Photonics—Lasers and laser-related equipment—Test methods for laser beam power (energy) density distribution.	Withdrawn and replaced with newer version.
		Q. Software/Informatics	
13–27	13–85	CLSI AUTO11–A2 October 2014 Information Technology Security of In Vitro Diagnostic Instruments and Software Systems; Approved Standard—Second Edition.	Withdrawn and replaced with newer version.
		R. Sterility	
14–169		ASTM F2391–05 (Reapproved 2016) Standard Test Method for Measuring Package and Seal Integrity Using Helium as the Tracer Gas.	Reaffirmation.
14–197	14–496	ASTM F1608–16 Standard Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method).	Withdrawn and replaced with newer version.
14–229	14–497	ASTM F1980–16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.	Withdrawn and replaced with newer version.
14–285		ANSI/AAMI/ISO 14161–2009/(R)2014 Sterilization of health care products—Biological indicators—Guidance for the selection, use and interpretation of results.	Reaffirmation.
14–311		ANSI/AAMI ST55:2010/(R)2014 Table-top steam sterilizers	Reaffirmation.
14–339		ANSI/AAMI/ISO 20857:2010/(R)2015 (Revision of ANSI/AAMI/ST63:2002) Sterilization of health care products—Dry heat—Requirements for the development, validation and routine control of a sterilization process for medical devices.	Reaffirmation.
14–349		ANSI/AAMI/ISO 13408–3:2006/(R)2015 Aseptic processing of health care products—Part 3: Lyophilization.	Reaffirmation.
14–360		ANSI/AAMI ST72:2011/(R)2016 Bacterial endotoxins—Test methods, routine monitoring, and alternatives to batch testing.	Reaffirmation.
14–453	14–498	ASTM F2097–16 Standard Guide for Design and Evaluation of Primary Flexible Packaging for Medical Products.	Withdrawn and replaced with newer version.
14–462	14–499	ASTM D4169–16 Standard Practice for Performance Testing of Shipping Containers and Systems.	Withdrawn and replaced with newer version.
14–479	14–500	ISO 14644–1 Second edition 2015–12–15 Cleanrooms and associated controlled environments—Part 1: Classification of air cleanliness by particle concentration.	Withdrawn and replaced with new recognition number.
14–489		USP 39–NF34:2016 Biological Indicator for Steam Sterilization—Self Contained.	Withdrawn.
14–490		USP 39–NF34:2016 Biological Indicator for Dry-Heat Sterilization, Paper Carrier.	Withdrawn.

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

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
14–491		USP 39–NF34:2016 Biological Indicator for Ethylene Oxide Sterilization, Paper Carrier.	Withdrawn.
14–492		USP 39–NF34:2016 Biological Indicator for Steam Sterilization, Paper Carrier.	Withdrawn.
S. Tissue Engineering			
15–34	15–48	ASTM F2605–16 Standard Test Method for Determining the Molar Mass of Sodium Alginate by Size Exclusion Chromatography with Multi-angle Light Scattering Detection (SEC–MALS).	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: 046.

TABLE 2—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS

Recognition No.	Title of standard [1]	Reference No. and date
A. Anesthesiology		
1–119	Tracheal tubes designed for laser surgery—Requirements for marking and accompanying information.	ISO 14408 Third edition 2016–02–15.
1–120	Anaesthetic and respiratory equipment—General requirements for airways and related equipment.	ISO 18190 First edition 2016–11–01.
B. Biocompatibility		
2–245	Biological evaluation of medical devices—Part 5: Tests for *in vitro* cytotoxicity	ISO 10993–5 Third edition 2009–06–01.
C. Cardiovascular		
3–145	Cardiovascular implants—Cardiac valve prostheses—Part 1: General requirements.	ISO 5840–1:2015 First edition 2015–09–15.
3–146	Cardiovascular implants—Cardiac valve prostheses—Part 1: General requirements.	ANSI/AAMI/ISO 5840–1: 2015.
3–147	Cardiovascular implants—Cardiac valve prostheses—Part 2: Surgically implanted heart valve substitutes.	ISO 5840–2: 2015 First edition 2015–09–15.
3–148	Cardiovascular implants—Cardiac valve prostheses — Part 2: Surgically implanted heart valve substitutes.	ANSI/AAMI/ISO 5840–2: 2015.
D. Dental/Ear, Nose, and Throat (ENT)		
4–229	Medical electrical equipment—Part 2–60: Particular requirements for the basic safety and essential performance of dental equipment.	IEC 80601–2–60 Edition 1.0 2012–02.
E. General I (Quality Systems/Risk Management) (QS/RM)		
5–115	Small-bore connectors for liquids and gases in healthcare applications—Part 7: Connectors for intravascular or hypodermic applications.	ISO 80369–7 First edition 2016–10–15.
5–116	Graphical symbols—Safety colours and safety signs—Registered safety signs [Including AMENDMENT 1 (2012) through AMENDMENT 7 (2016)].	ISO 7010 Second edition 2011–06–01.
F. General II (Electrical Safety/Electromagnetic Compatibility) (ES/EMC)		
19–19	Medical electrical equipment—Part 4–2: Guidance and interpretation—Electromagnetic immunity: Performance of medical electrical equipment and medical electrical systems.	IEC TR 60601–4–2 Edition 1.0 2016–05.
19–20	American National Standard Guide for Electrostatic Discharge Test Methodologies and Acceptance Criteria for Electronic Equipment.	ANSI C63.16–2016 (Revision of ANSI C63.16–1993).
19–21	Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers—An AIM Standard.	AIM Standard Rev. 1.00 2016–08–22.
G. General Hospital/General Plastic Surgery (GH/GPS)		
	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
	H. In Vitro Diagnostics (IVD)	
7–269	Molecular Diagnostic Methods for Solid Tumors (Nonhematological Neoplasms) ...	CLSI MM23 1st Edition.
	I. Materials	
8–439	Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) with Powder Bed Fusion.	ASTM F3001–14.
8–440	Standard Specification for Powder Bed Fusion of Plastic Materials	ASTM F3091/F3091M–14.
8–441	Standard Test Method for Verification of Multi-Axis Force Measuring Platforms	ASTM F3109–16.
8–442	Standard Guide for Validating Cleaning Processes Used During the Manufacture of Medical Devices.	ASTM F3127–16.
8–443	Standard Guide for Metallurgical Characterization of Absorbable Metallic Materials for Medical Implants.	ASTM F3160–16.
8–444	Additive manufacturing—General principles—Part 2: Overview of process categories and feedstock.	ISO 17296–2 First edition 2015–01–15.
8–445	Additive manufacturing—General principles—Part 4: Overview of data processing	ISO 17296–4 First edition 2014–09–01.
8–446	Standard Specification for Medical-Grade Ultra-High Molecular Weight Polyethylene Yarns.	ASTM F2848–16.
	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	
	No new entries at this time.	
	N. Orthopedic	
11–317	Standard Guide for Characterization of Material Loss from Conical Taper Junctions in Total Joint Prostheses.	ASTM F3129—16.
11–318	Standard Guide for Total Knee Replacement Loading Profiles	ASTM F3141—15.
11–319	Implants for surgery—Partial and total hip joint prostheses—Part 12: Deformation test method for acetabular shells.	ISO 7206–12 First edition 2016–10–01.
11–320	Implants for surgery—Partial and total hip joint prostheses—Part 13: Determination of resistance to torque of head fixation of stemmed femoral components..	ISO 7206–13 First edition 2016–07–01.
	O. Physical Medicine	
16–199	Wheelchairs Part 28: Requirements and test methods for stairclimbing devices	ISO 7176–28 First edition 2012–10–1.
	P. Radiology	
	No new entries at this time.	
	Q. Software/Informatics	
13–86	Systems and software engineering—Systems and software assurance—Part 1: Concepts and vocabulary.	ISO/IEC 15026–1 First edition 2013–11–01.
13–87	Systems and software engineering—Systems and software assurance—Part 2: Assurance case.	ISO/IEC 15026–2 First edition 2011–02–15.
	R. Sterility	
	No new entries at this time.	
	S. Tissue Engineering	
	No new entries at this time.	

[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 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 revisions to the list of recognized consensus standards, as needed, in the **Federal Register** once a year, or more often if necessary. Beginning with Recognition List 033, FDA no longer announces minor revisions to the list of recognized consensus standards such as technical contact person, devices affected, processes affected, Code of Federal Regulations citations, and product codes.

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 *standards@cdrh.fda.gov.* 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. The Center for Devices and Radiological Health (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, *http://www.fda.gov/MedicalDevices,* includes a link to standards-related documents including the guidance and the current list of recognized standards. After publication in the **Federal Register**, this notice announcing ''Modification to the List of Recognized Standards, Recognition List Number: 046'' will be available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm.* You may access ''Guidance on the Recognition and Use of Consensus Standards,'' and the searchable database for ''FDA Recognized Consensus Standards'' at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards.*

Dated: December 19, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–31008 Filed 12–22–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Bioequivalence Recommendations; Draft and Revised Draft Guidances for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of additional draft and revised draft product-specific bioequivalence (BE) recommendations. The recommendations provide product-specific guidance on the design of BE studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site. The BE recommendations identified in this notice were developed using the process described in that guidance.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 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'').

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Submit written/paper submissions as follows:

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- For written/paper comments submitted to the Division of Dockets Management, 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–2007–D–0369 for ''Product-Specific Bioequivalence Recommendations; Draft and Revised Draft Guidances for Industry.'' 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 Division of Dockets Management 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