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: 044

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: 044 (Recognition List Number: 044), 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 [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://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 http://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: 044." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at

http://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: 043.

- 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 http://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: 044 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: 044 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: 044" to Scott A. Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5514, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149.

FOR FURTHER INFORMATION CONTACT: Scott A. 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: 044

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: 044" 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. Biocompatibility			
2-93	--	ASTM F763-04 (Reapproved 2010) Standard Practice for Short-Term Screening of Implant Materials	Extent of recognition, Relevant guidance
2-94	--	ASTM F981-04 (Reapproved 2010) Standard Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone	Extent of recognition, Relevant guidance
2-114	--	ASTM F1877-05 (Reapproved 2010) Standard Practice for Characterization of Particles	Extent of recognition, Relevant guidance
2-117	2-226	ANSI/AAMI/ISO 10993-3:2014 Biological evaluation of medical devices -- Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity	Withdrawn and replaced with newer version
2-118	--	ANSI/AAMI/ISO 10993-11:2006/ (R) 2014 Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity	Reaffirmation, Extent of recognition, Relevant guidance
2-119	--	ASTM F813-07 (Reapproved 2012) Standard Practice for Direct Contact Cell Culture Evaluation of Materials for Medical Devices	Extent of recognition, Relevant guidance
2-120	--	ANSI/AAMI/ISO 10993-6:2007/(R) 2014 Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation	Reaffirmation, Extent of recognition, Relevant guidance
2-122	--	ASTM F719-81 (Reapproved 2012) Standard Practice for Testing Biomaterials in Rabbits for Primary Skin Irritation	Extent of recognition, Relevant guidance
2-124	--	ASTM F750-87 (Reapproved 2012) Standard Practice for Evaluating Material Extracts By Systemic Injection in the Mouse	Extent of recognition, Relevant guidance
2-126	--	ASTM F748-06 (Reapproved 2010) Standard Practice for Selecting Generic Biological Test Methods for Materials and Devices	Extent of recognition, Relevant guidance
2-133	--	ASTM F1408-97 (Reapproved 2013) Standard Practice for Subcutaneous Screening Test for Implant Materials	Extent of recognition, Relevant guidance
2-134	--	ASTM F2065-00 (Reapproved 2010) Standard Practice for Testing for Alternative Pathway Complement Activation in Serum by Solid Materials	Extent of recognition, Relevant guidance
2-136	--	ASTM E1262-88 (Reapproved 2013) Standard Guide for Performance of Chinese Hamster Ovary Cell/Hypoxanthine Guanine Phosphoribosyl Transferase Gene Mutation Assay	Extent of recognition, Relevant guidance
2-141	--	ASTM F1984-99 (Reapproved 2013) Standard Practice for Testing for Whole Complement Activation in Serum by Solid Materials	Extent of recognition, Relevant guidance
2-142	2-227	ASTM F1983-14 Standard Practice for Assessment of Selected Tissue Effects of Absorbable Biomaterials for Implant Applications	Withdrawn and replaced with newer version

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Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
2-145	--	ASTM F1439-03 (Reapproved 2013) Standard Guide for Performance of Lifetime Bioassay for the Tumorigenic Potential of Implant Materials	Extent of recognition, Relevant guidance
2-153	--	ANSI/AAMI/ISO 10993-5:2009/(R) 2014 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity	Extent of recognition, Relevant guidance
2-155	--	ASTM F2147-01 (Reapproved 2010) Standard Practice for Guinea Pig: Split Adjuvant and Closed Patch Testing for Contact Allergens	Extent of recognition, Relevant guidance
2-156	--	ANSI/AAMI 10993-1:2009/(R) 2013 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process [Including: Technical Corrigendum 1 (2010)]	Extent of recognition, Relevant guidance
2-162	--	ASTM F1903-10 Standard Practice for Testing For Biological Responses to Particles In Vitro	Extent of recognition, Relevant guidance
2-163	--	ANSI/AAMI/ISO 10993-9: 2009/(R) 2014 Biological evaluation of medical devices -- Part 9: Framework for identification and quantification of potential degradation products	Reaffirmation, Extent of recognition, Relevant guidance
2-165	--	ANSI/AMMI/ISO 10993-14:2001/(R) 2011, Biological evaluation of medical devices -- Part 14: Identification and quantification of degradation products form ceramics	Relevant guidance
2-167	--	ISO TS 10993-19 First edition 2006-06-01 Biological evaluation of medical devices -- Part 19: Physio-chemical, morphological and topographical characterization of materials	Extent of recognition, Relevant guidance
2-168	--	ISO 10993-9 Second edition 2009-12-15 Biological evaluation of medical devices -- Part 9: Framework for identification and quantification of potential degradation products	Extent of recognition, Relevant guidance
2-169	--	ISO 10993-13 Second edition 2010-06-15, Biological evaluation of medical devices -- Part 13: Identification and quantification of degradation products from polymeric medical devices	Extent of recognition, Relevant guidance
2-170	--	ISO 10993-14 First edition 2001-11-15, Biological evaluation of medical devices -- Part 14: Identification and quantification of degradation products from ceramics	Relevant guidance
2-171	--	ISO 10993-16 Second edition 2010-02-15, Biological evaluation of medical devices -- Part 16: Toxicokinetic study design for degradation products and leachables	Relevant guidance
2-172	--	ANSI/AAMI/ISO TIR 10993-19:2006 Biological evaluation of medical devices -- Part 19: Physicochemical, morphological, and topographical characterization of materials	Extent of recognition, Relevant guidance
2-173	--	ANSI/AAMI/ISO 10993-10:2010/(R) 2014 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization	Reaffirmation, Extent of recognition, Relevant guidance
2-174	--	ISO 10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization	Extent of recognition, Relevant guidance

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Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
2-175	2-228	ISO 10993-3:2014 Third edition 2014-10-1 Biological evaluation of medical devices -- Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity	Withdrawn and replaced with newer version
2-176	--	ISO 10993-11 Second edition 2006-08-15 Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity	Extent of recognition, Relevant guidance
2-177	--	ISO 10993-06 Second edition 2007-04-15 Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation	Extent of recognition, Relevant guidance
2-180	--	ANSI/AAMI/ISO 10993-16:2010/(R) 2014, Biological evaluation of medical devices -- Part 16: Toxicokinetic study design for degradation products and leachables from medical devices	Relevant guidance
2-189	--	ASTM F895-11 Standard Test Method for Agar Diffusion Cell Culture Screening for Cytotoxicity	Extent of recognition, Relevant guidance
2-190	--	ANSI/AAMI/ISO 10993-13:2010/(R) 2014 Biological evaluation of medical devices -- Part 13: Identification and quantification of degradation products from polymeric medical devices	Reaffirmation, Extent of recognition, Relevant guidance
2-191	--	ISO 10993-12 Fourth edition 2012-07-01 Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials	Extent of recognition, Relevant guidance
2-197	--	ASTM F749-13 Standard Practice for Evaluating Material Extracts by Intracutaneous Injection in the Rabbit	Extent of recognition, Relevant guidance
2-198	--	ANSI/AAMI/ISO 10993-12:2012 Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials	Extent of recognition, Relevant guidance
2-204	--	ASTM F720-13 Standard Practice for Testing Guinea Pigs for Contact Allergens: Guinea Pig Maximization Test	Extent of recognition, Relevant guidance
2-206	--	ASTM F2148-13 Standard Practice for Evaluation of Delayed Contact Hypersensitivity Using the Murine Local Lymph Node Assay (LLNA)	Extent of recognition, Relevant guidance
2-207	--	ASTM F756-13 Standard Practice for Assessment of Hemolytic Properties of Materials	Extent of recognition, Relevant guidance
2-213	--	ASTM F1904-14 Standard Practice for Testing the Biological Responses to Particles In Vivo	Extent of recognition, Relevant guidance
2-214	--	ASTM F619-14 Standard Practice for Extraction of Medical Plastics	Extent of recognition, Relevant guidance
2-215	2-229	USP 39-NF34:2016 <87> Biological Reactivity test, In Vitro -- Direct Contact Test	Withdrawn and replaced with a newer version
2-216	2-230	USP 39-NF34:2016 <87> Biological Reactivity Test, In Vitro -- Elution Test	Withdrawn and replaced with a newer version
2-217	2-231	USP 39-NF34: 2016 <88> Biological Reactivity Tests, In Vivo	Change in title, Withdrawn and replaced with a newer version
2-218	--	USP 39-NF34: 2016 <88> Biological Reactivity Tests In Vivo, Classification of Plastics -- Intracutaneous Test	Withdrawn; See 2-231
2-219	--	USP 39-NF34: 2016 <88> Biological Reactivity Tests In Vivo, Classification of Plastics -- Systemic Injection Test	Withdrawn; See 2-231

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Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
2-220	--	ISO 10993-1 Fourth edition 2009-10-15 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process [Including: Technical Corrigendum 1 (2010)]	Extent of recognition, Relevant guidance
2-221	--	ANSI/AAMI/ISO 10993-2:2006/(R) 2014 Biological evaluation of medical devices -- Part 2: Animal welfare requirements	Extent of recognition, Relevant guidance
2-222	--	ISO 10993-2 Second edition 2006-07-15 Biological evaluation of medical devices -- Part 2: Animal welfare requirements	Extent of recognition, Relevant guidance
2-223	--	ASTM F2901-13, Standard guide for selecting tests to evaluate potential neurotoxicity of medical devices	Relevant guidance
2-225	--	ASTM F2567-06 (Reapproved 2010), Standard practice for testing for classical complement activation in serum by solid materials	Relevant guidance
B. Sterility			
14-477	2-232	USP 39-NF34:2016 <151> Pyrogen Test	Transferred to Biocompatibility; Relevant guidance

[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: 044.

Table 2.--New Entries to the List of Recognized Standards

Recognition No.	Title of Standard[1]	Reference No. and Date
A. Biocompatibility		
2-233	Standard Test Method for Assessment of Intravascular Medical Device Materials on Partial Thromboplastin Time (PTT)	F2382-04 (Reapproved 2010)
2-234	Biological Evaluation of Medical Devices -- Part 4: Selection of tests for interaction with blood [Including Amendment 1(2006)]	ANSI/AAMI/ISO 10993-4:2002/(R)2013 & A1:2006/(R)2013
2-235	Biological Evaluation of Medical Devices -- Part 4: Selection of tests for interaction with blood [Including Amendment 1(2006)]	ISO 10994-4 Second edition 2002-10-15 Amendment 1 2006-07-15
2-236	Biological evaluation of medical devices -- Part 17: Establishment of allowable limits for leachable substances	ANSI/AAMI/ISO 10993-17:2002/(R)2012
2-237	Biological evaluation of medical devices -- Part 17: Establishment of allowable limits for leachable substances	ISO 10993-17 First edition 2002-12-01
2-238	Biological evaluation of medical devices -- Part 18: Chemical characterization of materials	ANSI/AAMI BE 83: 2006/(R)2011
2-239	Biological evaluation of medical devices -- Part 20: Principles and methods for immunotoxicology testing of medical devices	ANSI/AAMI/ISO TIR 10993-20:2006
2-240	Biological evaluation of medical devices -- Part 20: Principles and methods for immunotoxicology testing of medical devices	ISO/TS 10993-20 First edition 2006-08-01

Table 2.--New Entries to the List of Recognized Standards

Recognition No.	Title of Standard[1]	Reference No. and Date
2-241	Cardiovascular biological evaluation of medical devices -- Guidance for absorbable implants	ISO/TR 37137 First edition 2014-05-15
2-242	Cardiovascular biological evaluation of medical devices -- Guidance for absorbable implants	ANSI/AAMI/ISO TR 37137: 2014
2-243	Biological evaluation of medical devices -- Part 33: Guidance on tests to evaluate genotoxicity	ISO/TR 10993-33:2015 First edition 2015-03-01

[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: 044" 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: July 19, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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