VII. Special Accommodations

Individuals requiring special accommodations must include the request for these services during registration.

VIII. Panel Recommendations and Discussions

The Panel's recommendations at any Panel meeting generally are not final until they have been reviewed and approved by the Panel on the last day of the meeting, before the final adjournment. These recommendations will be posted to our Web site after the meeting.

IX. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

Dated: October 7, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2014–24755 Filed 10–16–14; 8:45 am]

BILLING CODE 4120–01–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: 037

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: 037'' (''Recognition List Number: 037''), 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 for the effective date of the recognition of standards announced in this document.

ADDRESSES: An electronic copy of Recognition List Number: 037 is available on the Internet at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm.* See section VI for electronic access to the searchable database for the current list of FDA recognized consensus standards, including Recognition List Number: 037 modifications and other standards related information.

Submit written requests for single copies of the document entitled ''Modifications to the List of Recognized Standards, Recognition List Number: 037'' to the Division of Industry and Consumer Education, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–847–8149.

Submit electronic comments on this document 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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Scott A. Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3632, 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 (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 we would implement our 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 HTML and 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: 037

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. We will incorporate these modifications in the list of FDA Recognized Consensus Standards in the Agency's searchable database. We will use the term ''Recognition List Number: 037'' to identify these current modifications.

In Table 1, we describe 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.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
A. General I (ES/EMC)			
5–90		ISO 15223–1 Second edition 2012–07–01 Medical devices—Symbols to be used with medical device labels, labeling, and information to be supplied—Part 1: General requirements.	Extent of recognition.
5–91		AAMI/ANSI/ISO 15223–1:2012 Medical devices—Symbols to be used with medical devices labels, labeling, and information to be supplied—Part 1: General requirements.	Extent of recognition.
B. General II (ES/EMC)			
19–1		IEC 60601–1–2 Edition 3: 2007–03 Medical Electrical Equipment—Part 1–2: General Requirements for Basic Safety and Essential Performance—Collateral Standard: Electromagnetic Compatibility—Requirements and Tests.	Extent of recognition and transition period.
19–2		ANSI/AAMI/IEC 60601–1–2:2007/(R)2012 Medical Electrical Equipment—Part 1–2: General requirements for basic safety and essential performance—Collateral Standard: Electromagnetic compatibility—requirements and tests.	Extent of recognition and transition period.
19–8		IEC 60601–1–2 Edition 4.0 2014–02 Medical electrical equipment—Part 1–2: General requirements for basic safety and essential performance—Collateral Standard: Electromagnetic disturbances—Requirements and tests.	Transition period extended.
C. In Vitro Diagnostics			
7–246		CLSI POCT12–A3 Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline—Third Edition.	Withdrawn.

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

III. Listing of New Entries

In Table 2 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: 037.

TABLE 2—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS

Recognition No.	Title of standard [1]	Reference No. and date
A. General II (ES/EMC)		
19–12	Medical electrical equipment—Part 1–2: General requirements for basic safety and essential performance—Collateral Standard: Electromagnetic disturbances—Requirements and tests.	ANSI/AAMI/IEC 60601–1–2:2014.
19–13	Secondary cells and batteries containing alkaline or other non-acid electrolytes—Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications [Including: Corrigendum 1 (2013)].	IEC 62133 Edition 2.0 2012–12.
B. OB–GYN/Gastroenterology		
9–95	Enteral Feeding Catheters and Enteral Giving Sets for Single Use and their Connectors—Design and Testing.	EN 1615:2000.
9–96	Catheters Other Than Intravascular Catheters—Test Methods for Common Properties.	EN 1618:1997.

[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: 037'' 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*.

VII. Submission of Comments and Effective Date

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*. 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: 037. These modifications to the list of recognized standards are effective upon publication of this notice in the **Federal Register**.

Dated: October 10, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–24714 Filed 10–16–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis NIAAA Member Conflict Applications—Biomedical Sciences.

Date: October 28, 2014.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant proposals.

Place: NIAAA, 5635 Fishers Lane; Room 2085, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Ranga Srinivas, Ph.D., Chief, Extramural Project Review Branch, National Institute on Alcohol Abuse and Alcoholism, NIH, 5365 Fishers Lane; Room 2085, Rockville, MD 20852, (301) 451–2067, *srinivar@mail.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis NIAAA Member Conflict Applications—Epidemiology & Behavioral Sciences.

Date: October 30, 2014.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant proposals.

Place: NIAAA, 5635 Fishers Lane; Room 2085, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Ranga Srinivas, Ph.D., Chief, Extramural Project Review Branch, National Institute on Alcohol Abuse and Alcoholism, NIH, 5365 Fishers Lane; Room 2085, Rockville, MD 20852, (301) 451–2067, *srinivar@mail.nih.gov*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis NIAAA Member Conflict Applications—Treatment and Health Services.

Date: November 5, 2014.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant proposals.

Place: NIAAA, 5635 Fishers Lane; Room 2085, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Ranga Srinivas, Ph.D., Chief, Extramural Project Review Branch, National Institute on Alcohol Abuse and Alcoholism, NIH, 5365 Fishers Lane; Room 2085, Rockville, MD 20852, (301) 451–2067, *srinivar@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 92.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Supports Awards, National Institutes of Health, HHS)

Dated: October 14, 2014.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–24790 Filed 10–16–14; 8:45 am]

BILLING CODE 4140–01–P