

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

| Recognition No.                | Title of standard <sup>1</sup>                                                                                                                                     | Reference No. and date                 |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|
| 11–304 .....                   | Measuring Accuracy after Mechanical Disturbances.                                                                                                                  | ASTM F3107–14.                         |
| <b>K. Physical Medicine</b>    |                                                                                                                                                                    |                                        |
| 16–196 .....                   | Wheelchairs—Part 7: Measurement of seating and wheel dimensions.                                                                                                   | ISO 7176–7 First Edition 1998–05–15.   |
| 16–197 .....                   | Wheelchairs—Part 8: Requirements and test methods for static, impact, and fatigue strengths.                                                                       | ISO 7176–8 Second Edition 2014–12–15.  |
| 16–198 .....                   | Wheelchairs—Part 22: Set-up procedures .....                                                                                                                       | ISO 7176–22 Second Edition 2014–09–01. |
| <b>L. Software/Informatics</b> |                                                                                                                                                                    |                                        |
| 13–81 .....                    | Health informatics—Personal health device communication—Part 10419: Device Specialization—Insulin Pump.                                                            | IEEE Std. 11073–10419: 2015.           |
| <b>M. Sterility</b>            |                                                                                                                                                                    |                                        |
| 14–479 .....                   | Sterilization of health care products—Ethylene oxide—Requirements for development, validation, and routine control of a sterilization process for medical devices. | ANSI/AAMI/ISO 11135:2014.              |
| <b>N. Tissue Engineering</b>   |                                                                                                                                                                    |                                        |
| 15–44 .....                    | Standard Guide for in vivo Evaluation of Osteoinductive Potential for Materials Containing Demineralized Bone (DBM) Active Standard.                               | ASTM F2529–13.                         |

<sup>1</sup> 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](mailto: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: 041" 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: March 29, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Solicitation for Applications From Individuals Interested in Being Appointed to the Chronic Fatigue Syndrome Advisory Committee

**AGENCY:** Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

**ACTION:** Notice.

*Authority:* 42 U.S.C. 217a, section 222 of the Public Health Service (PHS) Act, as amended. The Committee is governed by the provisions of Public Law 92-463, as amended (5 U.S.C. App 2), which sets forth standards for the formation and use of advisory committees.

**SUMMARY:** The Office of the Assistant Secretary for Health (OASH), within the Department of Health and Human Services (HHS), is seeking nominations of qualified candidates to be considered for appointment as a member of the Chronic Fatigue Syndrome Advisory Committee (CFSAC). CFSAC provides advice and recommendations to the Secretary of HHS, through the Assistant Secretary for Health (ASH), on a broad range of issues and topics related to myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS). The appointments of several Committee members are scheduled to end during the 2016 calendar year. Nominations of qualified candidates are being sought to fill the positions that are scheduled to be vacated.

**DATES:** Applications for individuals to be considered for appointment to the Committee must be received no later than 5 p.m. ET on April 25, 2016 at the address listed below.

**ADDRESSES:** All nominations should be mailed or delivered to Nancy C. Lee, Designated Federal Officer, Chronic Fatigue Syndrome Advisory Committee, Office on Women's Health, Office of the Assistant Secretary for Health, Department of Health and Human Services, 200 Independence Avenue SW., Room 712E, Washington, DC 20201. Nomination materials, including attachments, may be submitted electronically to [cfsac@hhs.gov](mailto:cfsac@hhs.gov).

**FOR FURTHER INFORMATION CONTACT:** Nancy C. Lee, Designated Federal Officer, Chronic Fatigue Syndrome Advisory Committee, Office on Women's Health, Office of the Assistant Secretary for Health, Department of Health and Human Services, 200 Independence Ave. SW., Room 712E, Washington, DC 20201. Inquiries may also be made to [cfsac@hhs.gov](mailto:cfsac@hhs.gov).

**SUPPLEMENTARY INFORMATION:** CFSAC was established on September 5, 2002. The purpose of the CFSAC is to provide advice and recommendations to the Secretary of HHS, through the ASH, on issues related to ME/CFS. CFSAC advises and makes recommendations on a broad range of topics including: (1) The current state of knowledge and research; the relevant gaps in knowledge and research about the epidemiology, etiologies, biomarkers, and risk factors

relating to ME/CFS; and identifying potential opportunities in these areas; (2) impact and implications of current and proposed diagnostic and treatment methods for ME/CFS; (3) development and implementation of programs to inform the public, health care professionals, and the biomedical, academic, and research communities about ME/CFS advances; and (4) strategies to improve the quality of life of ME/CFS patients. The CFSAC charter is available at <http://www.hhs.gov/advcomcfs/charter/index.html>.

Management and support services for Committee activities are provided by staff within the OASH. The ASH provides directions and guidance for services performed to support CFSAC activities and operation.

*Nominations:* OASH is requesting nominations to fill CFSAC positions that are scheduled to be vacated during 2016. The Committee composition consists of seven scientists with demonstrated expertise in biomedical research applicable to ME/CFS, and four individuals with demonstrated expertise in health care delivery, private health care services, or insurance, or voluntary organizations concerned with the problems of individuals living with ME/CFS. The vacant positions are in the biomedical research, health care services and delivery categories.

Individuals selected for appointment to the Committee will serve as voting members and may be invited to serve terms of up to four years.

To qualify for consideration of appointment to the Committee, an individual must possess demonstrated experience and knowledge in the designated fields or disciplines, as well as expert knowledge of the broad issues and topics pertinent to ME/CFS.

CFSAC members are authorized to receive a stipend for attending Committee meetings. Committee members also are authorized to receive per diem and reimbursement for travel expenses incurred for conducting Committee business.

Nomination materials should be typewritten. If mailed, please submit original documents. The nomination materials should be submitted (postmarked or received) no later than 5:00p.m. EDT on the date specified under **DATES**. The following information must be part of the nomination package submitted for each individual being nominated: (1) A letter of nomination that clearly states the name and affiliation of the nominee, the basis for the nomination (*i.e.*, specific attributes which qualify the nominee for service in this capacity), and a statement that the nominee is willing to serve as a member

of the Committee; (2) the nominator's name, address, and daytime telephone number; (3) the home and/or work address, telephone number, and email address of the individual being nominated; and (4) a current copy of the nominee's curriculum vitae or resume. An individual may self-nominate. Federal employees should not be nominated for consideration of appointment to this Committee. Nominations that do not contain all the above information will not be considered.

*Electronic submissions:* Nomination materials, including attachments, may be submitted electronically to [cfsac@hhs.gov](mailto:cfsac@hhs.gov).

Telephone and facsimile submissions cannot be accepted.

*Regular, Express, or Overnight Mail:* Written documents may be submitted to the following addressee only: Nancy C. Lee, Designated Federal Officer, CFSAC, Office on Women's Health, Office of the Assistant Secretary for Health, Department of Health and Human Services, 200 Independence Ave. SW., Room 712E, Washington, DC 20201.

Appointment to the Committee is made by the Secretary of HHS. The Department makes every effort to ensure that the membership of federal advisory committees is fairly balanced in terms of points of view represented. Every effort is made to ensure that a broad representation of geographic areas, females, ethnic and minority groups, and people with disabilities are given consideration for membership on federal advisory committees. Appointment to this Committee shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, disability, and cultural, religious, or socioeconomic status. Nominations must state that the nominee is willing to serve as a member of CFSAC and appears to have no conflict of interest that would preclude membership. Potential candidates are required to provide detailed information concerning such matters as financial holdings, consultancies, and research grants or contracts for an ethics analysis to be conducted to identify potential conflicts of interest.

Dated: March 25, 2016.

**Nancy C. Lee,**

*Designated Federal Officer, Chronic Fatigue Syndrome Advisory Committee*

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