DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1094]

2018 Center for Biologics Evaluation and Research Science Symposium

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public symposium.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public symposium entitled ''2018 Center for Biologics Evaluation and Research Science Symposium.'' The purpose of the public symposium is to discuss scientific topics related to the regulation of biologics and highlight science conducted at the Center for Biologics Evaluation and Research (CBER) by showcasing how scientific research informs regulatory decision making and to provide a forum for developing collaborations within FDA and with external organizations. The symposium will include presentations by experts from academic institutions, government agencies, and research institutions.

DATES: The public symposium will be held on June 25 and 26, 2018, from 9 a.m. to 3 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public symposium will be held at FDA's White Oak campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public symposium participants (non-FDA employees) is through Bldg. 1, where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

FOR FURTHER INFORMATION CONTACT: Sherri Revell or Loni Warren Henderson, Food and Drug Administration, Center for Biologics Evaluation and Research, 10903 New Hampshire Ave., Bldg. 71, Rm. 1118, Silver Spring, MD 20993, 240–402–8010, email: *CBERPublicEvents@fda.hhs.gov* (subject line: CBER Science Symposium).

SUPPLEMENTARY INFORMATION:

I. Background

The purpose of the public symposium is to discuss scientific topics related to the regulation of biologics and highlight science conducted at CBER by showcasing how scientific research informs regulatory decision making and to provide a forum for developing collaborations within FDA and with external organizations.

II. Topics for Discussion at the Public Symposium

The public symposium will include presentations on the following topics: (1) Emerging and re-emerging diseases; (2) diverse types of data in regulatory decision making; (3) immune response to vaccination; (4) immunotherapy; (5) new technologies for research and treatments; (6) the role of the microbiome in human disease; and (7) regenerative medicine.

III. Participating in the Public Symposium

Registration: To register for the public symposium, please visit the following website: *https://www.eventbrite.com/e/2018-center-for-biologics-evaluation-and-research-cber-science-symposium-tickets-39525851887.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public symposium (either in person or by webcast) (see *Streaming Webcast of the Public Symposium)* must register online by June 18, 2018, midnight Eastern Time. Early registration is recommended because seating is limited. There will be no onsite registration; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted.

If you need special accommodations, due to a disability, please contact Sherri Revell or Loni Warren Henderson no later than June 11, 2018.

Streaming Webcast of the Public Symposium: This public symposium will also be webcast. A link to the live webcast of this symposium will be provided upon registration at *https://www.eventbrite.com/e/2018-center-for-biologics-evaluation-and-research-cber-science-symposium-tickets-39525851887.* Persons interested in viewing the live webcast must register online by June 18, 2018. Early registration is recommended because webcast connections are limited. A video record of the public symposium will be available at *https://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/default.htm* for 1 year.

If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the website addresses in this document as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Dated: March 1, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–05805 Filed 3–21–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2014–N–1027; FDA–2017–N–1064; FDA–2014–D–0329; FDA–2013–N–1429; FDA–2009–N–0505; and FDA–2014–N–0192]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB Control No.	Date approval expires
Infant Formula Recall Regulations	0910–0188	12/31/2020
State Petitions for Exemptions from Preemption	0910–0277	12/31/2020
Guidance for Industry: Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the Federal Food, Drug, and Cosmetic Act	0910–0776	12/31/2020
Guidance for Industry: Registration of Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act	0910–0777	12/31/2020
Reporting and Recordkeeping Requirements for Human Food and Cosmetics Manufactured from, Processed With, or Otherwise Containing, Material from Cattle	0910–0623	1/31/2021
Establishing and Maintaining a List of U.S. Milk and Milk Product, Seafood, Infant Formula, and Formula for Young Children Manufactured/Processors with Interest in Exporting to China	0910–0839	1/31/2021

Dated: March 16, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–05797 Filed 3–21–18; 8:45 am]

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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 Act, as amended. The Committee is governed by the provisions of the Federal Advisory Committee Act, Public Law 92–463, as amended (5 U.S.C. App.), 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 six qualified candidates to be considered for appointment as members 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).

DATES: Applications for individuals to be considered for appointment to the Committee must be received no later than 5 p.m. EDT on April 23, 2018 at the address listed below.

ADDRESSES: All nominations should be mailed or delivered to Commander (CDR) Gustavo Ceinos, MPH, 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 728F6, Washington, DC 20201. Nomination materials, including attachments, may be submitted electronically to *cfsac@hhs.gov.*

FOR FURTHER INFORMATION CONTACT: CDR Gustavo Ceinos, 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 728F6, Washington, DC 20201. Inquiries may also be made to *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. The CFSAC advises and makes recommendations on a broad range of topics including: (1) Opportunities to improve knowledge and research about the epidemiology, etiologies, biomarkers and risk factors for ME/CFS; (2) research on the diagnosis, treatment, and management of ME/CFS and potential impact of treatment options; (3) strategies to inform the public, health care professionals, and the biomedical academic and research communities about ME/CFS advances; (4) partnerships to improve the quality of life of ME/CFS patients; and (5) strategies to insure that input from ME/CFS patients and caregivers is incorporated into HHS policy and research. The CFSAC charter is available at: *http://www.hhs.gov/advcomcfs/charter/index.html.*

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

Nominations: OASH is requesting nominations to fill six CFSAC positions. The Committee composition consists of thirteen members:

- Seven biomedical research scientists with demonstrated expertise in biomedical research applicable to ME/CFS;
- at least three patients or caregivers affected by ME/CFS; and
- three individuals with expertise in health care delivery, private health care services or insurers, or voluntary organizations concerned with the problems of individuals with ME/CFS.

The breakdown of the six vacant positions OASH is seeking is as follows:

- Four positions for biomedical research scientists with demonstrated expertise in biomedical research applicable to ME/CFS;
- one position for patients or caregivers affected by ME/CFS; and
- one position for an individual with expertise in health care delivery, private health care services or insurers, or voluntary organizations concerned with the problems of individuals with ME/CFS.

Individuals selected for appointment to the Committee will serve as voting members and may be invited to serve for a period of four years. CFSAC members are authorized to receive a stipend for conducting committee related business including attending Committee meetings. Committee members also are authorized to receive per diem and reimbursement for travel expenses incurred for conducting Committee related business. 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.

Nomination materials should be typewritten. If mailed, please submit original documents. The nomination materials should be submitted (postmarked or received) no later than 5:00 p.m. EDT on the specified date. The following information must be part