

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Ear, Nose, and Throat Devices Panel of the Medical Devices Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the Agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on April 30 and May 1, 2015 from 8 a.m. to 6 p.m.

*Location:* Hilton Washington DC North/Gaithersburg, Salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301-977-8900.

*Contact Person:* Patricio Garcia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1535, Silver Spring MD 20993-0002, [Patricio.Garcia@fda.hhs.gov](mailto:Patricio.Garcia@fda.hhs.gov), 301-796-6875, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

*Agenda:* On April 30, 2015, the committee will discuss and make recommendations regarding the classification of Hearing Protectors, Circumaural Hearing Protectors, Middle Ear Inflation Devices, Tactile Hearing Aid Devices, and Vestibular Analysis Apparatuses. These devices are considered preamendments devices since they were in commercial distribution prior to May 28, 1976, when the Medical Devices Amendments became effective. Hearing Protectors are currently regulated under the heading, "Protector, Hearing (Insert)," Product Code EWD, as unclassified under the 510(k) premarket notification authority. Circumaural Hearing Protectors are currently regulated under the heading, "Protector, Hearing (Circumaural)," Product Code EWE, as unclassified under the 510(k) premarket notification authority. Middle Ear Inflation Devices are currently regulated under the heading, "Device, Inflation, Middle Ear," Product Code MJV, as unclassified

under the 510(k) premarket notification authority. Tactile Hearing Aid Devices are currently regulated under the heading, "Hearing Aid, Tactile," Product Code LRA, as unclassified under the 510(k) premarket notification authority. Vestibular Analysis Apparatuses are currently regulated under the heading, "Apparatus, Vestibular Analysis," Product Code LXV, as unclassified under the 510(k) premarket notification authority. FDA is seeking committee input on the risks, safety and effectiveness and the regulatory classification of Hearing Protectors, Circumaural Hearing Protectors, Middle Ear Inflation Devices, Tactile Hearing Aid Devices, and Vestibular Analysis Apparatuses.

On May 1, 2015 the committee will discuss key issues related to a potential pre- to post-market shift in clinical data requirements for modifications to cochlear implants in pediatric patients. These issues are categorized into three broad areas for discussion:

1. Cochlear implant changes (e.g. sound processing features, patient characteristics) that may be suitable for this pre- to post-market shift in clinical data requirements.
2. Appropriate premarket clinical data requirements to support pre- to post-market shift (e.g. leveraging clinical data from adults and/or older children).
3. Clinical study design considerations (e.g. study endpoints and test metrics, subject characteristics) for post market studies to confirm safety and effectiveness and inform future labeling.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before April 22, 2015. Oral presentations from the public will be scheduled between approximately 8:45 a.m. and 9:45 a.m. on April 30, 2015 and between approximately 1 p.m. and 2 p.m. on May 1, 2015. Those individuals interested in making formal

oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 14, 2015. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 16, 2015.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact at James Clark at [James.Clark@fda.hhs.gov](mailto:James.Clark@fda.hhs.gov), or 301-796-5293 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 9, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015-05675 Filed 3-12-15; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Solicitation of Nominations for Organizations To Serve as Non-Voting Liaison Representatives to the Chronic Fatigue Syndrome Advisory Committee (CFSAC)

**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 the Federal Advisory Committee Act, 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 soliciting nominations from qualified organizations to be considered for non-voting liaison representative positions on 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 issues can include factors affecting access and care for persons with ME/CFS; the science and definition of ME/CFS; and broader public health, clinical, research, and educational issues related to ME/CFS. These three non-voting liaison representative positions will be occupied by individuals who are selected by their organizations to serve as representatives of organizations concerned with ME/CFS. Organizations will be designated to occupy the positions for a two-year term to commence during the 2015 calendar year. Nominations of qualified organizations are being sought for these three non-voting liaison representative positions. The organizations chosen for representation on CFSAC will be selected by the Designated Federal Officer (DFO) or designee during the 2015 calendar year. Details of nomination requirements are provided below.

**DATES:** Nominations must be received no later than 5 p.m. ET on April 20, 2015, at the address listed below.

**ADDRESSES:** All nominations should be sent to Barbara F. James, Designated Federal Officer, Chronic Fatigue Syndrome Advisory Committee, Office on Women's Health, Department of Health and Human Services, 200 Independence Avenue SW., Room 728F.3, Washington, DC 20201. Nomination materials, including attachments, may be submitted electronically to [cfsac@hhs.gov](mailto:cfsac@hhs.gov).

**FOR FURTHER INFORMATION CONTACT:** Barbara F. James, Designated Federal Officer, Chronic Fatigue Syndrome Advisory Committee, Office on Women's Health, Department of Health and Human Services, 200 Independence Avenue SW., Room 728F.3, Washington, DC 20201. Inquiries can be sent 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; and 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 diagnosis 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) partnering to improve the quality of life of ME/CFS patients. Management and support services for Committee activities are provided by staff from the HHS Office on Women's Health, within the OASH. The CFSAC charter is available at <http://www.hhs.gov/advcomcfs/charter/index.html>.

CFSAC meetings are held not less than two times per year. The CFSAC membership consists of 11 voting members, including the Chair. The voting members are composed of seven biomedical research scientists with demonstrated expertise in biomedical research applicable to ME/CFS and four 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. CFSAC also includes seven non-voting *ex officio* member representatives from the Agency for Healthcare Research and Quality, Centers for Disease Control and Prevention, Centers for Medicare and Medicaid Services, Food and Drug Administration, Health Resources and Services Administration, National Institutes of Health, and Social Security Administration.

In 2012, the CFSAC structure was expanded to include three non-voting liaison representative positions. Continued authorization was given for the Committee structure to include the three non-voting liaison representative positions when the charter was renewed on September 5, 2014. These positions will be occupied by individuals who are selected by their organizations to serve as the official representative for organizations that are concerned with ME/CFS. Organizations will occupy these positions for a two-year term.

## Nominations

The OASH is requesting nominations of organizations to fill three non-voting liaison representative positions for the CFSAC. The organizations will be selected by the DFO or designee during the 2015 calendar year.

Selection of organizations that will serve as non-voting liaison representatives will be based on the organization's qualifications to contribute to the accomplishment of the CFSAC mission, as described in the Committee charter. In selecting organizations to be considered for these positions, the OASH will give close attention to equitable geographic distribution and give priority to U.S.-chartered 501(c)(3) organizations that operate within the United States and have membership with demonstrated expertise in ME/CFS and related research, clinical services, or advocacy and outreach on issues concerning ME/CFS.

Organizations that currently have non-voting liaison representatives serving on CFSAC are also eligible for nomination or to nominate themselves for consideration.

The individual designated by the selected organization to serve as the official liaison representative will perform the associated duties without compensation, and will not receive per diem or reimbursement for travel expenses. The organizations that are selected will cover expenses for their designated representative to attend, at a minimum, one in-person CFSAC meeting per year during the designated term of appointment.

To qualify for consideration of selection to the Committee, an organization should submit the following items:

(1) A statement of the organization's history, mission, and focus, including information that demonstrates the organization's experience and expertise in ME/CFS and related research, clinical services, or advocacy and outreach on issues of ME/CFS, as well as expert knowledge of the broad issues and topics pertinent to ME/CFS. This information should demonstrate the organization's proven ability to work and communicate with the ME/CFS patient and advocacy community, and other public/private organizations concerned with ME/CFS, including public health agencies at the federal, state, and local levels.

(2) two to four letters of recommendation that clearly state why the organization is qualified to serve on CFSAC in a non-voting liaison representative position. These letters

should be from individuals who are not part of the organization.

(3) A statement that the organization is willing to serve as a non-voting liaison representative of the Committee and will cover expenses for their representative to attend in-person, at a minimum, one CFSAC meeting per year in Washington, DC, during the designated term of appointment.

(4) A current financial disclosure statement (or annual report) demonstrating the organization's ability to cover expenses for its selected representative to attend, at a minimum, one CFSAC meeting per year in Washington, DC, during the term of appointment.

Submitted nominations must include these critical elements in order for the organization to be considered for one of the liaison representative positions.

Nomination materials should be typewritten, using a 12-point font and double-spaced. All nomination materials should be submitted (postmarked or received) by April 20, 2015.

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: Barbara F. James, Designated Federal Officer, CFSAC, Office on Women's Health, Department of Health and Human Services, 200 Independence Avenue SW., Room 728F.3, Washington, DC 20201.

HHS 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, sex, ethnic and minority groups, and people with disabilities are given consideration for membership on federal advisory committees. Selection of the represented organizations shall be made without discrimination against the composition of an organization's membership on the basis of age, sex, race, ethnicity, sexual orientation, disability, and cultural, religious, or socioeconomic status.

Dated: February 24, 2015.

**Barbara F. James,**

*Designated Federal Officer, Chronic Fatigue Syndrome Advisory Committee.*

[FR Doc. 2015-05887 Filed 3-12-15; 8:45 am]

**BILLING CODE 4150-42-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-N-0722]

#### Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the Agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on May 14 and 15, 2015, from 8 a.m. to 6 p.m.

*Addresses:* FDA is opening a docket for interested persons to submit electronic or written comments regarding this meeting. The Docket No. is FDA-2015-N-0722. Please see the *Procedure* section of the notice for further information.

*Location:* FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

*Contact Person:* Natasha Facey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1552, Silver Spring, MD 20993-0002, 301-796-5290, [Natasha.Facey@fda.hhs.gov](mailto:Natasha.Facey@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line

to learn about possible modifications before coming to the meeting.

*Agenda:* On May 14 and 15, 2015, the committee will discuss recent reports and epidemiologic investigations of transmission of infections associated with the use of duodenoscopes in endoscopic retrograde cholangiopancreatography (ERCP) procedures in hospitals in the United States.

FDA is convening this committee to seek expert scientific and clinical opinion related to reprocessing of duodenoscopes and other endoscopes, as well as automated endoscope reprocessors, based on available scientific information. The committee will make recommendations on: (1) The effectiveness of cleaning, high level disinfection, and sterilization methods; (2) the amount and type of premarket validation data and information needed to support labeling claims and technical instructions; (3) the appropriate use of other risk mitigations, such as surveillance cultures; (4) best practices and guidelines for reprocessing duodenoscopes and endoscopes at user facilities to minimize the transmission of infections; and (5) recommended approaches for ensuring patient safety during ERCP procedures, including a discussion of appropriate patient selection.

Recommendations on these issues will assist FDA in minimizing patient exposure to infectious agents that may result from reprocessed duodenoscopes and endoscopes.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

CDRH plans to provide a live Webcast of the May 14 and 15, 2015, meeting of the Gastroenterology and Urology Devices Panel. While CDRH is working to make Webcasts available to the public for all advisory committee meetings held at the White Oak campus, there are instances where the Webcast transmission is not successful; staff will work to re-establish the transmission as soon as possible. The link for the Webcast is available at: <https://collaboration.fda.gov/gudpm052015/>.