

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.*

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**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/>.

Further information regarding the Webcast, including the Web address for the Webcast, will be made available at least 2 days in advance of the meeting at the following Web site: <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/Gastroenterology-UrologyDevicesPanel/default.htm>. Select the link for 2015 Meeting Materials.

**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 30, 2015. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on May 14 and between approximately 9 a.m. and 10 a.m. on May 15. 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 15, 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 20, 2015.

FDA is opening a docket for public comment on this document. The Docket No. is FDA-2015-N-0722. The docket will close on May 28, 2015. Interested persons are encouraged to use the docket to submit electronic or written comments regarding this meeting. Comments received on or before April 30, 2015, will be provided to the committee. Comments received after that date will be taken into consideration by the Agency. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit a single copy of electronic comments or two paper copies of any mailed comments. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Divisions 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>.

For press inquiries, please contact the Office of Media Affairs at [fdaoma@fda.hhs.gov](mailto:fdaoma@fda.hhs.gov) or 301-796-4540.

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 AnnMarie Williams, at [AnnMarie.Williams@fda.hhs.gov](mailto:AnnMarie.Williams@fda.hhs.gov) or 301-796-5966 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. 2015-05710 Filed 3-12-15; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Proposed Collection; 60 Day Comment Request; Assessment of NHLBI's Global Health Initiative Collaborating Centers of Excellence (NHLBI)

**SUMMARY:** In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH), will publish periodic summaries of proposed projects to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the

proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

**To Submit Comments and For Further Information:** To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Deshree Belis, 6705 Rockledge Drive, Suite 6070, Bethesda, MD 20892, or call non-toll-free number (301)-435-1032, or Email your request to: [deshree.belis@nih.gov](mailto:deshree.belis@nih.gov). Formal requests for additional plans and instruments must be requested in writing.

**Comments Due Date:** Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

**Proposed Collection:** Assessment of NHLBI's Global Health Initiative Collaborating Centers of Excellence, 0925-New, National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH).

**Need and Use of Information Collection:** This collection proposes to conduct a one-time outcome evaluation of the NHLBI Global Health Initiative Collaborating Centers of Excellence (GHI COE) Program to examine the extent to which the program achieved its intended objectives in developing sustainable research and research training capacity, and advancing information about the prevention and treatment of chronic non-communicable chronic cardiovascular and pulmonary diseases (CVPD) in low- and middle-income country (LMIC) populations. The outcome evaluation will utilize a mixed-methods approach to comprehend each COE's processes, short term outcomes, and sustainability outcomes/efforts. Specifically, the evaluation will involve triangulating quantitative data sources (e.g., archived systematic reporting data), and qualitative data sources (e.g., archival data and key informant interview data). Data collected will be used to develop a Case Study report for each COE outlining their experience with implementing their program as well as a comprehensive cross-site Lessons Learned Report describing knowledge and experiences from the overall program, including similarities and differences across a variety of