DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Next-Generation Sequencing Technology, Data Formats Standardization and Promotion of Interoperability Protocols; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA), is announcing a public workshop entitled ''Next-Generation Sequencing (NGS) Technology, Data Format Standardization and Promotion of Interoperability Protocols.'' The goal of this public workshop is to facilitate establishing protocols for ensuring the safety and quality of next-generation sequencing (NGS)-related information without sacrificing scientific merit or interfering with innovative processes. The purpose of the workshop is to engage NGS stakeholders in a forum to discuss the current use of the technology and the development of data standards of NGS-related information.

Date and Time: The public workshop will be held on September 24 and 25, 2014, from 8:30 a.m. to 4:30 p.m.

Location: The public workshop will be held at the National Institute of Health Campus, 9000 Rockville Pike, Bldg. 35, Rm. 610, Bethesda, MD 20892. Pre-registered participants will receive additional information on parking and public transportation with their email registration confirmation.

Contact Person: Khaled Bouri, Office of Regulatory Science and Innovation, Food and Drug Administration, 10903 New Hampshire Ave., Rm. 4164, Silver Spring, MD 20903, 301–796–8476, email: *Khaled.Bouri@fda.hhs.gov.*

Registration: Please go to http://ngs-data-standardization.eventbrite.com to register. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration will be confirmed by email. Registration on the day of the public workshop will be provided on a space available basis beginning at 8 a.m. This workshop will also be accessible via Webcast by following this link: *https://collaboration.fda.gov/NGSStandards/.*

If you need special accommodations due to a disability, please contact Khaled Bouri (see *Contact Person*) at least 7 days in advance.

Transcripts and Additional Information About the Workshop: The workshop agenda and additional background materials will be accessible at: *http://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/ucm227840.htm.* Please be advised that as soon as possible after the public workshop a transcript will be available at the same Web site. Transcripts of the public workshop may also be requested in writing from the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Building, Rockville, MD 20857.

Dated: April 15, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–08969 Filed 4–18–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

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 June 17, 2014, from 8 a.m. to 6 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building. 1.

Contact Person: Abbas Bandukwala, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1535, Silver Spring MD 20993–0002, 301–796–6386, email: *Abbas.Bandukwala@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 June 17, 2014, the committee will discuss, make recommendations, and vote on information regarding the premarket application (PMA) for the Maestro® Rechargeable System sponsored by Enteromedics, Inc. The Maestro® Rechargeable System provides VBLOC Therapy. The implantable device is a neuromodulator, which delivers high frequency (5000 Hertz), controllable electrical pulses to the intra-abdominal vagus nerve trunks. The effect of VBLOC therapy is reported to suppress neural signals carried by the vagus nerve trunks, resulting in decreased hunger pangs, decreased digestive enzyme secretion and calorie absorption, and increased satiety. The device consists of implantable electronic device components that deliver VBLOC therapy, and external components that regulate device performance.

The proposed indication for use for the Maestro® Rechargeable System, as stated in the PMA, is as follows:

The Maestro® Rechargeable System is indicated for use in weight reduction in adult patients with obesity that have a Body Mass Index (BMI) of at least 40 kilograms per square meter (kg/m^2), or a BMI of at least 35 kg/m^2 with one or more obesity related comorbid conditions, and have failed a more conservative weight reduction alternative.

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 May 13, 2014. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. 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 May 5, 2014. 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 May 6, 2014.

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 James Clark at *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: April 15, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–08970 Filed 4–18–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Request for Notification From Industry Organizations Interested in Participating in the Selection Process for Nonvoting Industry Representatives; Reopening of Notification Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the period for industry organizations interested in participating in the selection of nonvoting industry representatives to represent the interests of the pharmaceutical manufacturing industry and the pharmacy compounding industry on the Pharmacy Compounding Advisory Committee for the Center for Drug Evaluation and Research to notify FDA of such interest. FDA announced a request for notification of interest in selection of industry representatives and for nominations in the **Federal Register** on January 13, 2014. This notice requested industry organizations that were interested in participation in the selection process to notify FDA in writing by February 12, 2014, and stated that nominations would be accepted for the two nonvoting vacancies by the same date. Industry organizations that did not notify FDA by the deadline of their interest in participating in the selection of nonvoting pharmacy compounding and pharmaceutical manufacturing industry representatives have now expressed interest in participating. Therefore, FDA is reopening the notification period for an additional two weeks so that any interested industry organizations wanting to participate can notify the Agency of their interest.

DATES: Any industry organization interested in participating in the selection of appropriate nonvoting members to represent the interests of the pharmacy compounding industry and the pharmaceutical manufacturing industry on the Pharmacy Compounding Advisory Committee should send a letter stating the interest to FDA by *May 5, 2014,* for the vacancies announced in the **Federal Register** on January 13, 2014 (79 FR 2177).

ADDRESSES: All letters of interest should be submitted electronically to *PCAC@fda.hhs.govmailto:,* or in writing by mail to Jayne E. Peterson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 31, Rm. 2417, Silver Spring, MD 20993.

FOR FURTHER INFORMATION CONTACT: Jayne E. Peterson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993, 301–796–9001, FAX: 301–847–8533, email: *PCAC@fda.hhs.gov*.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: April 15, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–08968 Filed 4–18–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Fogarty International Center; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Fogarty International Center Advisory Board.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting 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 materials, 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: Fogarty International Center Advisory Board.

Date: May 13, 2014.

Closed: May 13, 2014 8:00 a.m. to 9:45 a.m.

Agenda: To review and evaluate grant applications.