## 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.*

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**[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/*