4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-2214]

Next Generation Sequencing Diagnostic Tests; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public workshop entitled "Optimizing FDA's Regulatory Oversight of Next Generation Sequencing Diagnostic Tests." The purpose of this workshop is to discuss and receive feedback from the community on the questions in the discussion paper on diagnostic tests for human genetics or genomics using next generation sequencing (NGS) technology.

DATES: The public workshop will be held on February 20, 2015, from 8:30 a.m. to 5 p.m.

ADDRESSES: The public workshop will be held at the Natcher Center at the National Institutes of Health Campus, 9000 Rockville Pike, Bldg. 45 Auditorium, Bethesda, MD 20814. For parking and security information, please refer to http://www.nih.gov/about/visitor/.

FOR FURTHER INFORMATION CONTACT: David Litwack, Office of In Vitro Diagnostics and Radiological Health, Center for Devices and Radiological Health, Food and Drug Administration, Bldg. 66, rm. 5544, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-6697, email: ernest.litwack@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 4 p.m. February 12,

2015. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the public workshop will be provided beginning at 7:30 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan, 301-796-5661, email: Susan.Monahan@fda.hhs.gov no later than February 6, 2015.

To register for the public workshop, please visit FDA's Medical Devices News & Events--Workshops & Conferences calendar at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm. (Select this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. If you are unable to register online, please contact Susan Monahan (see Registration.) Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by February 12, 2015. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after February 13, 2015. 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 http://www.adobe.com/go/connectpro_overview.

(FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

Comments: FDA is holding this public workshop to obtain feedback from the community on the questions in the discussion paper. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments related to this public workshop is March 20, 2015.

Regardless of attendance at the public workshop, interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific questions as outlined in section II, please identify the question you are addressing. Received comments may be seen in the Division 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.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at http://www.regulations.gov. It may be viewed at the Division of Dockets Management (see Comments). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at

http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm. (Select this public workshop from the posted events list).

I. Background

In vitro diagnostic devices, including laboratory-developed tests that utilize NGS technology to generate information on an individual's genome, are rapidly transforming healthcare. Because NGS tests generate large amounts of data and consequently may have relatively broad or undefined intended uses or indications, these tests pose certain challenges during review of premarket submissions. At the same time, this large amount of data provides opportunities for novel approaches to assure the analytical and clinical validity of NGS tests. FDA is committed to providing efficient and effective oversight for NGS tests to assure their safety and effectiveness. By doing so, FDA will promote innovation and advance precision medicine. The Agency is therefore requesting public input on the regulatory strategy for NGS tests that produce results on variation in the human genome. Further details of current and new approaches that may be considered in the workshop are outlined in the discussion paper entitled "Optimizing FDA's Regulatory Oversight of Next Generation Sequencing Diagnostic Tests" available at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm. (Select this public workshop from the posted events list).

II. Topics for Discussion at the Public Workshop

The workshop discussion will focus on regulatory strategies to assure the analytical and clinical validity of NGS tests. Specific topics to be discussed at the workshop are outlined in the discussion paper entitled "Optimizing FDA's Regulatory Oversight of Next Generation Sequencing Diagnostic Tests" available at

http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm. (Select this public workshop from the posted events list). A detailed agenda will be posted on this Web site in advance of the workshop.

Dated: December 22, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014-30308 Filed 12/22/2014 at 4:15 pm; Publication Date: 12/29/2014]