4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-3015]

Use of Databases for Establishing the Clinical Relevance of Human Genetic Variants; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing the following public workshop entitled "Use of Databases for Establishing the Clinical Relevance of Human Genetic Variants." The purpose of this workshop is to obtain feedback on ways in which FDA can use curated databases containing information about human genetic variation as sources of valid clinical evidence for the Agency's oversight of the next-generation sequencing (NGS)-based in vitro diagnostic tests (IVDs). Comments and suggestions generated through this workshop will guide the development of best practices and regulatory standards for reliance on external curated databases.

Date and Time: The public workshop will be held on November 13, 2015, from 8 a.m.to 5 p.m.

Location: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, rm. 1503 (the Great Room), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building

1, where routine security check procedures will be performed. For parking and security information, please refer to http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

Contact Person: David Litwack, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4548, Silver Spring, MD 20993, 301-796-6697, email: ernest.litwack@fda.hhs.gov.

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. on October 30, 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 permit, onsite registration on the day of the public workshop will be provided beginning at 7 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 4 p.m. on October 29, 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. Those without Internet access should contact Susan Monahan to register. 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 October 30, 2015, at 4 p.m.

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 November 3, 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.)

Requests for Oral Presentations: This public workshop includes a public comment session. During online registration you may indicate if you wish to present during a public comment session, and which topics you wish to address. FDA has included general topics in this document which will be addressed in greater detail in a subsequent discussion paper (see SUPPLEMENTARY INFORMATION). FDA will do its best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. All requests to make oral presentations must be received by October 26, 2015. FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by October 30, 2015. If selected for presentation, any presentation materials must be emailed to David Litwack (see Contact Person) no later than November 5, 2015, at 5 p.m. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Comments: FDA is holding this public workshop to obtain feedback on how it may use databases that contain information linking human genetic variations to disease, where such information has been curated by qualified professionals, to inform regulatory oversight of the clinical performance of genetic tests. Specifically, the information gained from the workshop will be used to optimize FDA's regulatory approach for NGS-based IVDs. 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 November 25, 2015, at 4 p.m.

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 topics as described in section II of this document, please identify the topic 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. The Freedom of Information office address is available on the Agency's Web site at http://www.fda.gov. 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.)

SUPPLEMENTARY INFORMATION:

I. Background

IVDs, including laboratory-developed tests that utilize NGS technology to reveal information about an individual's genome, are rapidly becoming a major driver of modern healthcare. As part of the White House's Precision Medicine Initiative, FDA is exploring a novel approach for NGS test regulation that includes leveraging well-curated databases of genetic variation to provide evidence about the clinical relevance of test results. To open this discussion, FDA drafted a discussion paper and held an open public workshop titled "Optimizing FDA's Regulatory Oversight of Next Generation Sequencing Diagnostic Tests" in February 2015 to discuss and receive feedback from the community on possible regulatory approaches to NGS-based diagnostic tests. (Workshop material, including the discussion paper, can be accessed at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm427296.htm.) The workshop announced in this document seeks to build on the feedback FDA received at the public workshop in February 2015. The Agency is therefore requesting public input on strategies for the regulatory use of databases for NGS tests that produce results on variation in the human genome.

II. Topics for Discussion at the Public Workshop

This public workshop will consist of brief presentations that will frame the goals of the workshop and interactive discussions of key topics with several panel sessions. Following the presentations and panel discussions, there will be a moderated discussion where participants will

be asked to provide their individual perspectives. The workshop discussion will focus on the development, operation (including curation), and use of databases of genetic variants.

In advance of the meeting, FDA plans to post a discussion paper outlining FDA's most current thinking about the possible uses of databases of genetic variants for NGS test regulation and a summary of the issues FDA believes need consideration at the workshop at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm. (Select this public workshop from the posted events list.) FDA will place the discussion paper on file in the public docket (docket number found in brackets in the heading of this document) and will post it at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.

The deadline for submitting comments on this document for presentation at the public workshop is October 26, 2015, although comments related to this document can be submitted until November 25, 2015. A detailed agenda will be posted on this Web site in advance of the workshop.

Dated: September 2, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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