4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0001]

Molecular and Clinical Genetics 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: Molecular and Clinical Genetics 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 March 26 and 27, 2014, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B, and C, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301-977-8900.

Contact Person: Jamie Waterhouse, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-3063, 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 March 26, 2014, the committee will discuss, make recommendations and vote on information related to the premarket approval application sponsored by Epigenomics, Inc. for the Epi proColon. The Epi proColon test is a qualitative in vitro diagnostic method for the detection of methylated Septin 9 DNA in plasma derived from patient whole blood specimens. Methylation of the target Septin 9 DNA sequence has been associated with the occurrence of colorectal cancer (CRC). The test is indicated to screen patients for CRC who are defined as average risk for CRC by current screening guidelines. The Epi proColon test is not intended to replace colorectal screening by colonoscopy. Patients with a positive Epi proColon test result should be referred for diagnostic colonoscopy. The Epi proColon test results are intended to be used in conjunction with the physician's assessment of history, other risk factors, and professional guidelines.

On March 27, 2014, the committee will discuss, make recommendations and vote on information related to the premarket approval application for the Cologuard device, sponsored by Exact Sciences. Cologuard is an in vitro diagnostic device designed to analyze patients' stool for detection of hemoglobin, multiple DNA methylation and mutational markers, and the total amount of human DNA. Cologuard is intended for use as an adjunctive screening test for the detection of colorectal neoplasia associated DNA markers and for the presence of occult hemoglobin in human stool. A positive result may indicate the presence of colorectal cancer or premalignant colorectal neoplasia. Cologuard is not intended as a replacement for colonoscopy.

Cologuard is intended to be used in conjunction with colonoscopy and other test methods in accordance with recognized screening guidelines.

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 March 17, 2014. On March 26 and 27, 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 March 10, 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 March 13, 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, Conference Management Staff, 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: January 29, 2014.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

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