Meeting Announcement: June 13, 2013 Microbiology Devices Panel of the Medical Devices Advisory Committee

U.S. Food & Drug Administration

Hilton Washington DC North/Gaithersburg
Salons A, B, C, and D
620 Perry Pkwy.
Gaithersburg, MD 20877
301–977–8900

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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

Microbiology 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: Microbiology 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.

Contact Person: Shanika Craig, Shanika.Craig@fda.hhs.gov [1], Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-6639, Food and Drug Administration, 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 [2] 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 13, 2013, the committee will discuss and make recommendations

regarding the possible reclassification of influenza detection devices, currently regulated as class I. The committee's discussion will involve making recommendations regarding regulatory classification to either confirm class I or reclassify these devices into class II with special controls. The committee will address issues such as device performance and public health impact to determine whether special controls are needed to ensure the safety and effectiveness of these tests through their total product life cycle. The proposed special controls will be discussed to support the possible reclassification.

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/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/default.htm [3]. 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 June 4, 2013. 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 30, 2013. 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 31, 2013.

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 AnnMarie Williams, Committee Management Staff, at annmarie.williams@fda.hhs.gov [4] or 301-796-5966, 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 [5] 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: May 3, 2013.

Peter Lurie,
Acting Associate Commissioner for Policy and Planning.

Links:
[1] http://www.fda.gov/AdvisoryCommittees/Calendar/mailto:Shanika.Craig@fda.hhs.gov
[2] http://www.fda.gov/AdvisoryCommittees/default.htm
[3] http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/default.htm
[4] http://www.fda.gov/AdvisoryCommittees/Calendar/mailto:annmarie.williams@fda.hhs.gov
[5] http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm