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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Radiological 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Radiological 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 March 4, 2008, from 8 a.m. to 5:30 p.m., and March 5, 2008, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B, and C, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Nancy Wersto, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3666, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512526. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be

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published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On March 4 and 5, 2008, the committee intends to discuss and make recommendations about computer aided detection and diagnosis (CAD) devices for radiological images, e.g., mammograms, chest x-rays, and computed tomography (CT) images of the lungs or colon. There will be a general discussion focusing on the general methodologies for CAD, including how CAD devices are used in clinical decision-making, how the devices are tested, and the information needed to properly assess their safety and effectiveness. The general discussion will be followed by specific discussions related to mammography CAD devices, colon CAD devices, and lung CAD devices. These discussions will include how the different types of CAD devices are used and the literature published regarding these devices, with focus on testing issues related to the different devices.

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/ohrms/dockets/ac/acmenu.htm*, click on the year 2008 and scroll down to the appropriate advisory committee link.

Procedure: On March 4, 2008, from 8 a.m. to 5:30 p.m., and on March 5, 2008, from 8:30 a.m. to 5 p.m., the meeting is open to the public. 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 February 19, 2008. Oral presentations from the public will be scheduled between approximately 10 a.m. and 10:30 a.m., and between 3:15 p.m. and 3:45 p.m. on March 4, 2008, and between approximately 9:10 a.m. and 9:40 a.m., and between 2:15 p.m. and 2:45 p.m. on March 5, 2008. Those desiring to make 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 February 11, 2008. 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 February 12, 2008.

Closed Presentation of Data: On March 5, 2008, from 8 a.m. to 8:30 a.m., the meeting will be closed so that the committee may receive an update from FDA about devices under evaluation that may be brought before the committee in the near future. This portion of the meeting will be closed because it involves the discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)).

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 Shirley Meeks, Conference Management Staff, at 240–276–8931, 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/oc/advisory/default.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: 1/28/08

January 28, 2008.

Randall W. Lutter,
Deputy Commissioner for Policy.

[FR Doc. 08–????? Filed ??–??–08; 8:45 am]

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