

DMB

Display Date 1-22-04
Publication Date 1-23-04
Certifier J. Coyle

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 February 3, 2004, from 8:30 a.m. to 5 p.m.

Location: Gaithersburg Marriott, Salons A, B, C, and D, 9751 Washingtonian Blvd., Gaithersburg, MD.

Contact Person: Robert J. Doyle, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1212, 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.

oc03398

4024

NM /

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application for a computer aided detection device that identifies nodules in CT (computerized tomography) images of the lung. Background information, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting, on the Internet at <http://www.fda.gov/cdrh/panelmtg.html>. Material will be posted on February 2, 2004.

Procedure: On February 3, 2004, from 9 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 by January 27, 2004. On February 3, 2004, oral presentations from the public will be scheduled between approximately 9:20 a.m. and 9:50 a.m., and for an additional 30 minutes near the end of the committee deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 27, 2004, 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.

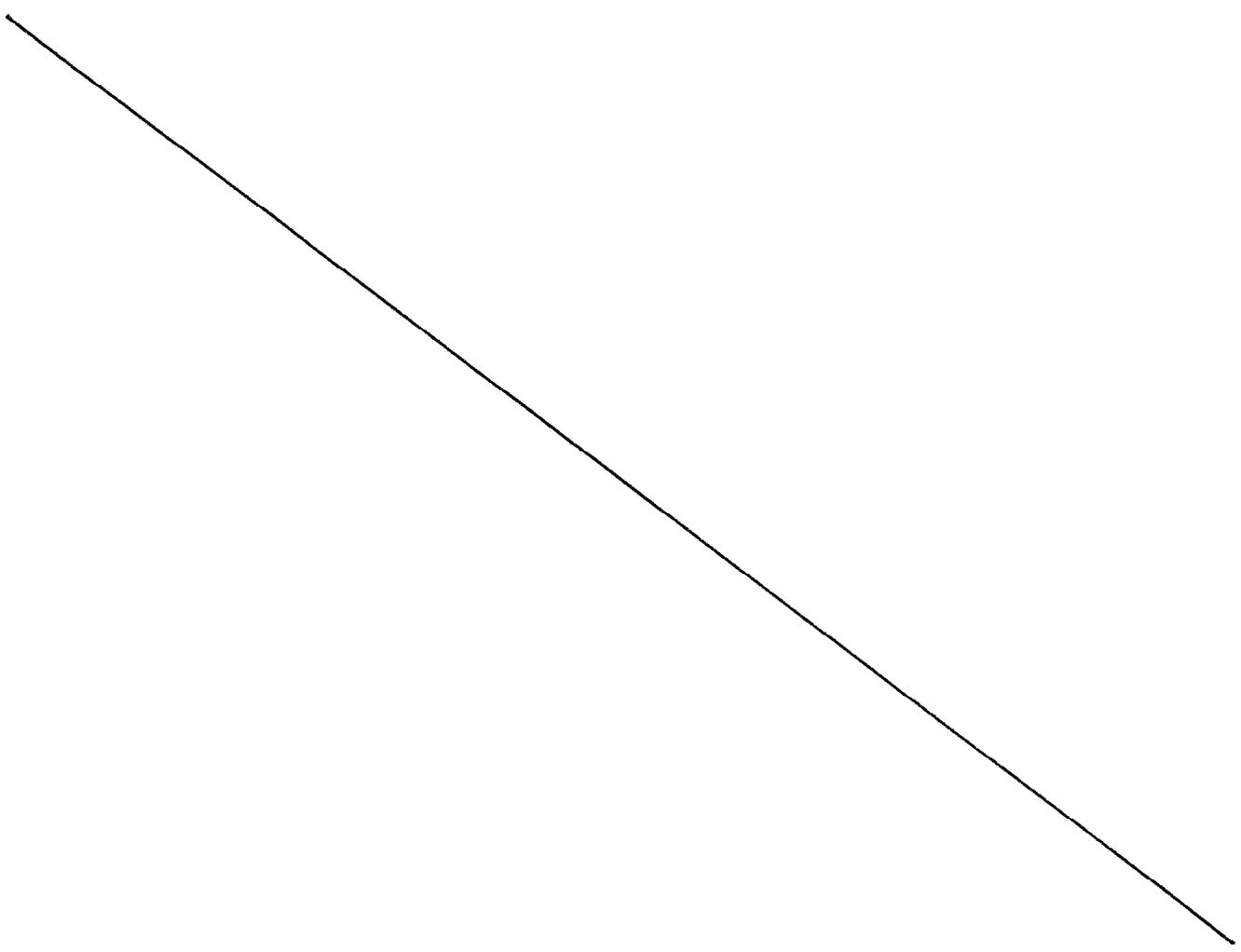
Closed Committee Deliberations: On February 3, 2004, from 8:30 a.m. to 9 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)).

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 AnnMarie Williams, Conference Management Staff, at 301-594-1283, ext. 113, at least 7 days in advance of the meeting.

FDA regrets that it was unable to publish this notice 15 days prior to the Radiological Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Radiological Devices Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.



Notice of this meeting is given under the Federal Advisory Committee Act
(5 U.S.C. app. 2).

Dated: 1/5/04
January 5, 2004.



William K. Hubbard,
Associate Commissioner for Policy and Planning.

COPIES OF THE ORIGINAL


[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

BILLING CODE 4160-01-S