DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Joint Meeting of the Microbiology Devices Panel, the Clinical Chemistry and Clinical Toxicology Devices Panel, the Hematology and Pathology Devices Panel, and the Immunology 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: Joint meeting of the Microbiology Devices Panel, the Clinical Chemistry and Clinical Toxicology Devices Panel, the Hematology and Pathology Devices Panel, and the Immunology Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on February 11, 1998, 11 a.m. to 5 p.m.

Location: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

Contact Person: Freddie M. Poole, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–2096, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12517. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will provide advice and recommendations to the agency on issues concerning appropriate data collection, analysis, and resolution of discrepant results, using sound scientific and statistical analysis to support indications for use of in vitro diagnostic devices. After hearing a series of presentations on the subject, the committee will discuss appropriate recommended analysis of data when the new device is compared to another device, a recognized reference method or ''gold standard,'' other procedures not commonly used, and/or clinical criteria for diagnosis. The committee will be asked: (1) How the FDA should proceed in this area of discrepant resolution when new technology such as nucleic acid amplification is perceived to be more accurate than the reference or ''gold standard'' methods, (2) for guidance to implement their recommendations, and (3) for the appropriate approach to address these issues in the product labeling (package insert). These draft questions proposed for discussion may be subject to modifications or additions prior to the advisory committee meeting. FDA will consider these recommendations in the future development of review criteria for the collection and analysis of data to support the indications for use of in vitro diagnostic devices.

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 by January 28, 1998. Oral presentations from the public will be scheduled between approximately 1:45 p.m. and 2:45 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 28, 1998 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.

FDA regrets that it was unable to publish this notice 15 days prior to the February 11, 1998, Joint meeting of the Microbiology Devices Panel, the Clinical Chemistry and Clinical Toxicology Devices Panel, the Hematology and Pathology Devices Panel, and the Immunology Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Joint meeting of the Microbiology Devices Panel, the Clinical Chemistry and Clinical Toxicology Devices Panel, the Hematology and Pathology Devices Panel, and the Immunology Devices Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner 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: January 23, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–2264 Filed 1–26–98; 4:24 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0022]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Hearing Aid Devices: Professional and Patient Package Labeling and Conditions for Sale—21 CFR 801.420 and 801.421'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 15, 1997 (62 FR 48291), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0171. The approval expires on November 30, 1998.

Dated: January 21, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–2115 Filed 1–28–98; 8:45 am]

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