

FOR FURTHER INFORMATION CONTACT:

Rudaina H. Alrefai, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3034.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 9M4695) has been filed by the USDA/FSIS, 300 12th St. SW., rm. 112, Washington, DC 20250. The petition proposes that the food additive regulations in § 179.26(b) Ionizing radiation for the treatment of food (21 CFR 179.26(b)) be amended to provide for the safe use of a 4.5 kGy maximum dose of ionizing radiation to treat unrefrigerated (as well as refrigerated) uncooked meat, meat products, and certain meat food products to reduce levels of foodborne pathogens and extend shelf-life. The current regulations in § 179.26(b) provide for the use of a maximum dose of 4.5 kGy to treat refrigerated products only.

The agency has determined under 21 CFR 25.32(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: December 3, 1999.

Alan M. Rulis,

*Director, Office of Premarket Approval,
Center for Food Safety and Applied Nutrition.*
[FR Doc. 99-33093 Filed 12-21-99; 8:45 am]

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**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

Food and Drug Administration

**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).

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.

Date and Time: The meeting will be held on January 20, 2000, 9:45 a.m. to 6:30 p.m., and January 21, 2000, 8 a.m. to 4:30 p.m.

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

Contact: 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: On January 20, 2000, the committee will discuss, make recommendations, and vote on six premarket approval applications (PMA's) for in vitro diagnostic qualitative devices to detect hepatitis B serological markers in human sera or plasma. The following hepatitis B serological marker assays, when used appropriately in combination, are indicated as an aid in the diagnosis and monitoring of disease and therapy in acute and chronic hepatitis B virus infection (HBV) in both low and high risk adult populations:

1. Hepatitis B surface antigen (HBsAg) (HBsAg assay may be used alone as an indicator of HBV infection when performing prenatal testing);
2. Antibodies to hepatitis B surface antigen (anti-HBs) (anti-HBs assay may be used alone to determine the immune status of HBV vaccine recipients);
3. Hepatitis B e antigen (HBeAg);
4. Antibodies to hepatitis B e antigen (anti-HBe);
5. Hepatitis B core antigen (anti-HBc); and
6. Immunoglobulin M antibodies to hepatitis B core antigen (IgM anti-HBc).

These tests are not intended for blood donor screening. Also, on January 20, 2000, the committee will discuss and make recommendations on issues concerning the use of characterized hepatitis panels in assessing the performance of in vitro diagnostic devices for the determination of hepatitis infection as an alternative to conducting intensive prospective clinical trials.

The following draft questions are proposed for discussion and may be subject to changes prior to the committee meeting:

1. Will the use of characterized hepatitis panels provide assurance of the safety and effectiveness of the assay in various populations?

2. What criteria should be used to include specimens in these panels?

3. Will panels be sufficient to support claims for the diagnosis of HBV infection or immunity for all indicated populations?

4. Who should control panel distribution and evaluation, e.g., device manufacturers, FDA, or an independent third party?

FDA will consider these recommendations in the future development of review criteria for in vitro diagnostic devices, for the detection of hepatitis antigen or antibodies to hepatitis antigen, as valid scientific evidence to determine whether there is reasonable assurance that these devices are safe and effective.

On January 21, 2000, the committee will discuss, make recommendations, and vote on a PMA for an in vitro diagnostic qualitative device for the detection of antibody to hepatitis C virus in human serum or plasma. This device is not intended for use in blood or plasma donor screening.

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 12, 2000. On January 20, 2000, oral presentations from the public will be scheduled between approximately 12 noon and 12:30 p.m., 3 p.m. and 3:30 p.m., and 5:30 p.m. and 6 p.m. On January 21, 2000, oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12:15 p.m., and 3:30 p.m. and 4 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 12, 2000, 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.

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

Dated: December 13, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

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