

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: On July 27, 2000, the committee will discuss and make recommendations on issues concerning the appropriate types of data and information required to assess the safety and effectiveness of diagnostic tests intended to identify biothreat agents, or to provide evidence of exposure to biothreat agents, when used on different specimen types and under different conditions for use.

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

1. What types of data and information would be recommended to evaluate effectiveness when the assay is used:

(a) To definitively identify or rule-out identification of isolates;

(b) to identify biothreat agents directly in specimens from individuals suspected (clinically or using other diagnostic procedures) to have been infected with the agent of interest; and

(c) to identify/detect the biothreat agent directly in specimens from individuals without clinical or other diagnostic evidence of infection, who may have been exposed to the biothreat agent.

2. For each of these potential uses what is the level of inaccuracy that can be tolerated, or would the same criteria apply to all?

3. To determine or infer effectiveness for these devices, can specimens from naturally- or experimentally-infected animals be used when appropriate specimens from humans cannot be obtained? What are the constraints/limitations for use of animal data as evidence for effectiveness?

4. Are there any other issues not addressed in the previous questions that would affect the reliable use of these assays for human diagnosis?

FDA will consider these recommendations in the future development of review criteria for in vitro diagnostic devices, developed in response to the threat of bioterrorism, for the identification of biothreat agents, as valid scientific evidence to determine whether there is reasonable assurance that these devices are safe and effective.

On July 28, 2000, the committee will discuss, make recommendations, and

vote on a premarket approval application (PMA) for an in vitro diagnostic nucleic acid amplification test for the qualitative detection of hepatitis C virus (HCV) ribonucleic acid (RNA) in human serum or plasma. On the same day the committee will discuss, make recommendations, and vote on a PMA for an automated in vitro diagnostic nucleic acid amplification test for the qualitative detection of HCV RNA in human serum or plasma. These devices are not intended for use in blood or plasma donor screening.

Procedure: On July 27, 2000, from 10:30 a.m. to 5:30 p.m. and on July 28, 2000, 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 July 12, 2000. Oral presentations from the public will be scheduled between approximately 11:45 a.m. and 12:30 p.m. on July 27, 2000, and between approximately 11:30 a.m. and 12:15 p.m., and 3 p.m. and 3:30 p.m. on July 28, 2000. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 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.

Closed Committee Deliberations: On July 28, 2000, from 8 a.m. to 9 a.m., the meeting will be closed to permit FDA staff to present to the committee trade secret and/or confidential commercial information regarding pending and future device submissions. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

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

Dated: June 26, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00-16809 Filed 7-3-00; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Ear, Nose, and Throat 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: Ear, Nose, and Throat 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 July 20, 2000, 9:45 a.m. to 5 p.m., and July 21, 2000, 8:30 a.m. to 5 p.m.

Location: Holiday Inn, Goshen Room, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Sara M. Thornton, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, SMT@CDRH.FDA.GOV, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12522. Please call the Information Line for up-to-date information on this meeting.

Agenda: On July 20, 2000, the committee will discuss, make recommendations, and vote on a premarket approval application (PMA) for a direct-drive implantable middle ear hearing device intended to provide a useful level of sound perception via mechanical stimulation of the ossicles. On July 21, 2000, the committee will discuss, make recommendations and vote on a PMA for an implant intended to restore useful hearing to individuals with Neurofibromatosis Type II who have become deaf as a result of surgery to remove bilateral auditory nerve tumors.

Procedure: On July 20, 2000, from 9:45 a.m. to 5 p.m., and on July 21, 2000, from 9:15 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 July 13, 2000. Oral presentations from the public will be

scheduled between approximately 10 a.m. and 10:30 a.m. on July 20, 2000, and between approximately 9:30 a.m. and 10 a.m. on July 21, 2000. On both days, near the end of the committee deliberations on the PMA, a 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 13, 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.

Closed Committee Deliberations: On July 21, 2000, from 8:30 a.m. to 9:15 a.m., the meeting will be closed to permit FDA to present to the committee trade secret and/or confidential commercial information regarding pending issues and applications. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

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

Dated: June 26, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00-16810 Filed 7-3-00; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

The FDA Review Process for New Product Applications: An Interactive Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of workshop.

The Food and Drug Administration (FDA), Los Angeles District Office, in cosponsorship with the Orange County Regulatory Affairs Discussion Group (OCRA) is announcing a workshop intended to give the medical products industry (drugs and medical devices) an opportunity to learn and discuss the process by which the FDA centers and district offices review new product applications. Reviewing staff from the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health will make presentations to provide guidance on

the elements of submissions to make the review process more effective.

Date and Time: The workshop will be held on July 10 and 11, 2000, from 7:30 a.m. to 5 p.m.

Location: The workshop will be held at the Doubletree Hotel, 3050 Bristol St., Costa Mesa, CA 92626.

Contact: Ramlah Oma, FDA Los Angeles District Office, 19900 MacArthur Blvd., Irvine, CA 92612-2445, 949-798-7612, or FAX 949-798-7771, for further information including a registration form.

Registration: Space is limited. Preregistration and confirmation is required. Registration forms can be obtained on the Internet at <http://www.ocra-dg.org> by clicking on "OCRA Meetings" or from the contact person listed above. There is a \$325 registration fee if postmarked by June 30, 2000 (\$375 on or after July 1) payable to OCRA. Send the registration fee and form to PeriAnn DiRocco at OCRA Submissions Conference, PMB 624, 5405 Alton Pkwy., suite 5A, Irvine, CA 92604, FAX and voice 949-348-9141. The registration fee will cover actual expenses including refreshments, lunch, materials, and speaker expenses. After July 4, 2000, please call 949-348-9141 to check for space availability.

If you need special accommodations due to a disability, please contact Ramlah Oma at least 7 days in advance.

Dated: June 28, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00-16963 Filed 6-29-00; 4:37 pm]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Joint Meeting of the Transmissible Spongiform Encephalopathies Advisory Committee and the Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming joint meeting of two public advisory committees of the Food and Drug Administration (FDA). At least one portion of the joint meeting will be closed to the public.

Names of Committees: Transmissible Spongiform Encephalopathies Advisory Committee and the Vaccines and

Related Biological Products Advisory Committee.

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

Date and Time: The meeting will be held on July 27, 2000, 8 a.m. to 4 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: William Freas or Sheila D. Langford; Nancy Cherry or Denise H. Royster, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852; 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), codes 12392 and 12391. Please call the Information Line for up-to-date information on this meeting.

Agenda: On July 27, 2000, in joint session, the committees will discuss bovine spongiform encephalopathy issues related to the manufacture of vaccines, specifically the use of European fetal calf serum in cell banks and viral seeds, and the use of European beef skeletal muscle and other tissues in manufacturing vaccines.

Procedure: On July 27, 2000, from 9 a.m. to 4 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 July 13, 2000. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 17, 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 presentations.

Closed Committee Deliberations: On July 27, 2000, from 8 a.m. to 9 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)).

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

Dated: June 23, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00-16811 Filed 7-3-00; 8:45 am]

BILLING CODE 4160-01-F