

hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1-800-741-8138 or 301-443-0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

**MEETINGS:** The following advisory committee meetings are announced:

#### **Ophthalmic Devices Panel of the Medical Devices Advisory Committee**

*Date, time, and place.* January 22, 1996, 9:30 a.m., Holiday Inn—Gaithersburg, Two Montgomery Village Ave., Gaithersburg, MD. A limited number of overnight accommodations have been reserved at the hotel. Attendees requiring overnight accommodations may contact the hotel at 301-948-8900 or 1-800-465-4329 and reference the FDA Panel meeting block. Reservations will be confirmed at the group rate based on availability. Attendees with a disability requiring special accommodations should contact Sociometrics, Inc., 8300 Colesville Rd., suite 550, Silver Spring, MD 20910, 301-608-2151. The availability of appropriate accommodations cannot be assured unless prior notification is received.

*Type of meeting and contact person.* Open public hearing, 9:30 a.m. to 10:30 a.m., unless public participation does not last that long; open committee discussion, 10:30 a.m. to 1:30 p.m.; closed presentation of data, 1:30 p.m. to 5:30 p.m.; Sara M. Thornton, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2053, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Ophthalmic Devices Panel, code 12396.

*General function of the committee.* The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

*Agenda—Open public hearing.* Interested persons may present data,

information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before December 29, 1995, 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 required to make their comments.

*Open committee discussion.* The committee will review and recommend the classification status for currently unclassified devices which may include lacrimal system plugs, lacrimal system repair devices, and scleral plugs. The Intraocular and Corneal Implants Branch will request committee discussion on the clinical annex of the draft American National Standards Institute (ANSI) standard for glaucoma drainage devices.

*Closed committee deliberations.* The committee will discuss trade secret and/or confidential commercial information relevant to investigational device exemption applications and premarket approval applications for vitreo-retinal, surgical, and diagnostic devices, intraocular and corneal implants, and contact lenses. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

#### **Microbiology Devices Panel of the Medical Devices Advisory Committee**

*Date, time, and place.* January 25, 1996, 9:45 a.m., and January 26, 1996, 8:45 a.m., Gaithersburg Hilton, Grand Ballroom, 620 Perry Pkwy., Gaithersburg, MD. A limited number of overnight accommodations have been reserved at the Gaithersburg Hilton. Attendees requiring overnight accommodations may contact the hotel at 301-977-8900 and reference the FDA Panel meeting block. Reservations will be confirmed at the group rate based on availability. Attendees with a disability requiring special accommodations should contact Sociometrics, Inc., 8300 Colesville Rd., suite 550, Silver Spring, MD 20910, 301-608-2151. The availability of appropriate accommodations cannot be assured unless prior notification is received.

*Type of meeting and contact person.* Open public hearing, January 25, 1996, 9:45 a.m. to 10:45 a.m., unless public participation does not last that long; open committee discussion, 10:45 a.m. to 6:30 p.m.; closed committee deliberations, January 26, 1996, 8:45 a.m. to 9:45 a.m.; open public hearing, 9:45 a.m. to 10:45 a.m., unless public

participation does not last that long; open committee discussion, 10:45 a.m. to 5 p.m.; 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 Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Microbiology Devices Panel, code 12517.

*General function of the committee.*

The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

*Agenda—Open public hearing.*

Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before January 10, 1996, 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 required to make their comments.

*Open committee discussion.* On January 25, 1996, the committee will discuss a premarket approval application (PMA) for an in vitro diagnostic, target-amplified nucleic acid device for the detection of *Mycobacterium tuberculosis* complex in digested, decontaminated human respiratory specimens. On January 26, 1996, the committee will discuss issues concerning the accuracy of commercially available serological kits for the detection of human anti-Toxoplasma IgM and anti-Borrelia burgdorferi antibodies in relation to their indication for use.

*Closed committee deliberations.* On January 26, 1996, FDA staff will 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)).

#### **Science Advisory Board to the National Center for Toxicological Research**

*Date, time, and place.* January 29, 1996, 1 p.m., and January 30, 1996, 9 a.m., Bldg. 12, conference room, National Center for Toxicological Research, Jefferson, AR.

*Type of meeting and contact person.* Open board discussion, January 29, 1996, 1 p.m. to 4:30 p.m.; open board