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 July 28, 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 discuss two premarket approval applications for automated cervical cytology readers intended for use in the quality control and rescreening of previously read Papanicolaou smears.

Closed committee deliberations. FDA staff will present to the committee trade secret and/or confidential commercial information regarding pending or future device submissions. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Dental Products Panel of the Medical Devices Advisory Committee

Date, time, and place. August 8 and 9, 1995, 8:30 a.m., Bethesda Marriott Hotel, Grand Ballroom Salons A, B, and C, 5151 Pooks Hill Rd., Bethesda, MD. A limited number of overnight accommodations have been reserved at the hotel. Attendees requiring overnight accommodations may contact the hotel at 301–897–9400 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 Ed Rugenstein, Sociometrics, Inc., 301–608–2151. The availability of appropriate accommodations cannot be assured unless prior written notification is received.

Type of meeting and contact person. Closed presentation of data, August 8, 1995, 8:30 a.m. to 1 p.m.; open public hearing, 1 p.m. to 2 p.m., unless public participation does not last that long; open committee discussion, 2 p.m. to 6 p.m.; open public hearing, August 9, 1995, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 6 p.m.; Carolyn A. Tylenda, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–8897, or FDA Advisory Committee Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Dental Products Panel, code 12518.

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 August 1, 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 Dental Products Panel began the process of classification of bone filling and augmentation devices on February 11, 1993. On August 8, 1995, the committee will continue the discussion of the proposed classification status for bone filling and augmentation devices. The discussion will focus on streamlining the groupings and descriptions of materials before making final classification recommendations, which are expected to be completed at this meeting. On August 9, 1995, the committee will continue the discussion of bone filling and augmentation devices for oral use, if necessary, and will discuss and vote on dental device recommendations for ingredient labeling, and will discuss a guidance document for dental handpieces.

Closed presentation of data. On August 8, 1995, a sponsor will present to the committee trade secret and/or confidential commercial information regarding a dental product. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Circulatory System Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. August 21, 1995, 8:30 a.m., and August 22, 1995, 9 a.m., Holiday Inn—Gaithersburg, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD. A limited number of overnight accommodations have been reserved at the Holiday Inn—Gaithersburg. Attendees requiring overnight accommodations may contact the hotel at 301–984–8900 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 Ed Rugenstein, Sociometrics, Inc., 301–608–2151. The availability of appropriate accommodations cannot be assured unless prior written notification is received.

Type of meeting and contact person. Open public hearing, August 21, 1995, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 1:30 p.m.; closed presentation of data, 1:30 p.m. to 4:30 p.m.; open public hearing, August 22, 1995, 9 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 4:30 p.m.; Ramiah Subramanian, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8320, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Circulatory System Devices Panel, code 12625.

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 August 15, 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. On August 21, 1995, the committee will discuss general issues related to a premarket approval application (PMA) for an automatic cardiac defibrillator. On August 22, 1995, the committee will review and recommend: (1) The reclassification status for human heart valve allografts; and (2) the reclassification status of nonroller type cardiopulmonary bypass blood pumps (i.e., centrifugal pump) for short-term (6 hours or less) use.

Closed presentation of data. On August 21, 1995, FDA staff will present to the committee trade secret and/or confidential commercial information relevant to investigational device exemption applications and PMA's for cardiovascular system devices. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).