at 301–468–1100 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, October 23, 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 5 p.m.; closed committee deliberations, October 24, 1995, 7:30 a.m. to 8:30 a.m.; open public hearing, 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 5 p.m.; Alfred W. Montgomery, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1180, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area) Obstetrics and Gynecology Devices Panel, code 12524.

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 October 4, 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 October 23, 1995, the committee will consider a list of devices used for in vitro fertilization and other assisted reproduction technologies. The committee will provide expert advice on these devices that will be used to develop 510(k) guidance. On October 24, 1995, the committee will consider a draft guidance document on the preparation of an investigational device exemption for thermal endometrial ablation devices. Single copies of the list of in vitro fertilization devices and the guidance document for thermal endometrial ablation devices are available to the public after October 1, 1995, by contacting the Division of

Small Manufacturers Assistance, 1350 Piccard Dr., Rockville, MD 20851, 1–800–638–2041.

Closed committee deliberations. On October 24, 1995, FDA staff will present to the committee trade secret and/or confidential commercial information regarding various medical devices used in obstetrics and gynecology that are currently being evaluated by FDA. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

## Vaccines and Related Biological Products Advisory Committee

Date, time, and place. October 26 and 27, 1995, 8 a.m., Parklawn Bldg., conference rooms D and E, 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Open committee discussion, October 26, 1995, 8 a.m. to 8:15 a.m.; open public hearing, 8:15 a.m. to 8:45 a.m., unless public participation does not last that long; open committee discussion, 8:45 a.m. to 1:30 p.m.; closed committee deliberations, 1:30 p.m. to 2:30 p.m.; open committee discussion, 2:30 p.m. to 6 p.m.; closed committee deliberations, October 27, 1995, 8 a.m. to 12:30 p.m.; open public hearing, 12:30 p.m. to 1 p.m., unless public participation does not last that long; open committee discussion, 1 p.m. to 5:15 p.m.; Nancy T. Cherry or Sandy M. Salins, Center for **Biologics Evaluation and Research** (HFM-21), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0314, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Vaccines and Related Biological Products Advisory Committee, code 12388.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of vaccines intended for use in the diagnosis, prevention, or treatment of human diseases.

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 October 18, 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 October 26, 1995, the committee will

hear presentations on recent acellular pertussis trials sponsored by the Public Health Service, and on a new strategic plan for the year 2004 developed by the Center for Biologics Evaluation and Research. The committee will also consider whether a single formulation for pneumococcal conjugate vaccines should be adopted for children in the United States. On October 27, 1995, the committee will discuss a draft Points to Consider document addressing the evaluation of combination vaccines. Copies of the document will be available at the meeting.

Closed committee deliberations. On October 26 and 27, 1995, the committee will review trade secret and/or confidential commercial information relevant to pending investigational new drug applications or product licensing applications. These portions of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

## Medical Imaging Drugs Advisory Committee

Date, time, and place. October 26 and 27, 1995, 8 a.m., Holiday Inn, Plaza Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Type of meeting and contact person. Open public hearing, October 26, 1995, 8 a.m. to 9 a.m., unless public participation does not last that long; closed committee deliberations, 9 a.m. to 11 a.m.; open committee discussion, 11 a.m. to 4 p.m.; open committee discussion, October 27, 1995, 8 a.m. to 4 p.m.; Leander B. Madoo (HFD-9), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4695, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Medical Imaging Drugs Advisory Committee, code 12540.

General function of committee. The committee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in diagnostic and therapeutic procedures using radioactive pharmaceuticals and contrast media used in diagnostic radiology.

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 October 12, 1995, and submit a brief statement of the general nature of the evidence or