Type of meeting and contact person. Open public hearing, July 13, 1995, 8:30 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 5 p.m.; open committee discussion, July 14, 1995, 8:30 a.m. to 11:30 a.m.; open public hearing, 11:30 a.m. to 12 m., unless public participation does not last that long; closed committee deliberations, 12 m. to 1 p.m.; open committee discussion, 1 p.m. to 4 p.m.; Lee L. Zwanziger or Liz Ortuzar, Center for Drug Evaluation and Research (HFD–9), 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), Nonprescription Drugs Advisory Committee, code 12541.

General functions of the committees. The Nonprescription Drugs Advisory Committee reviews and evaluates available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products for use in the treatment of a broad spectrum of human symptoms and diseases. The Gastrointestinal Drugs Advisory Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in gastrointestinal diseases. The Arthritis Advisory Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in arthritic conditions.

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 July 7, 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 July 13, 1995, the Nonprescription Drugs Advisory Committee and the Gastrointestinal Drugs Advisory Committee will discuss data relevant to NDA 20–520 to switch Zantac® 75 (ranitidine hydrochloride tablets) (Glaxo, Inc.) from prescription to over-the-counter status for the treatment of heartburn. On July 14, 1995, the Nonprescription Drugs Advisory Committee and the Arthritis Advisory Committee will discuss data relevant to NDA 20–499 (Bayer Corp.,) and NDA 20–429 (Whitehall-Robins Healthcare). Both NDA's are to switch ketoprofen (12.5 milligrams tablet/caplet) from prescription to over-the-counter status for the temporary relief of minor aches and pains associated with the common cold, toothache, muscular aches, backache, for the minor pain of arthritis, for the pain of menstrual cramps, and for reduction of fever.

Closed committee deliberations. On July 14, 1995, the committees will discuss trade secret and/or confidential commercial information relevant to pending IND's. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. July 17, 1995, 4:30 p.m., and July 18, 1995, 8 a.m., Holiday Inn—Gaithersburg, Ballroom, 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 and reference the FDA Panel meeting block. Reservations may 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 notification is received.

Type of meeting and contact person. Closed committee deliberations, July 17, 1995, 4:30 p.m. to 5:30 p.m.; open public hearing, July 18, 1995, 8 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.; Janet L. Scudiero, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1287, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), General Hospital and Personal Use Devices Panel, code 12520.

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 July 10, 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 July 18, 1995, the committee will discuss the classification of general purpose disinfectants and sterilants, and as time permits, will discuss the classification of Apgar timers, infusion stands, and lice detectors and removers.

Closed committee deliberations. On July 17, 1995, FDA staff will present to the committee trade secret and/or confidential commercial information regarding present and future FDA issues. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. July 19, 1995, 8 a.m., Holiday Inn— Gaithersburg, Whetstone Room, 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 and reference the FDA Panel meeting block. Reservations will be confirmed at the group rate based on availability.

Type of meeting and contact person. Open public hearing, 8 a.m. to 10 a.m., unless public participation does not last that long; open committee discussion, 10 a.m. to 3 p.m.; closed committee deliberations, 3 p.m. to 5 p.m.; Daniel Schultz, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1307, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in Washington, DC area), General and Plastic Surgery Devices Panel, code 12519.

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 July 1, 1995, and submit a brief statement of the general