Annually, FDA projects about 29 focus group studies using 187 focus groups lasting an average of 1.71 hours each. FDA has allowed burden for unplanned focus groups to be completed so as not to restrict the agency's ability to gather information on public sentiment for its proposals in its regulatory as well as other programs.

Dated: May 14, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–13163 Filed 5–23–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pediatric Subcommittee of the Anti-Infective Drugs 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). The meeting will be open to the public.

Name of Committee: Pediatric Subcommittee of the Anti-Infective Drugs 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 June 11, 2002, from 8 a.m. to 6 p.m.

Location: Holiday Inn, Versailles Ballroom, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Thomas H. Perez, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, e-mail: perezt@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12530. Please call the Information Line for up-to-date information on this meeting.

Agenda: Beginning at 8 a.m., the subcommittee will discuss and receive comments on the ''written request template'' for the proton pump inhibitors in the treatment of gastroesophageal reflux disease in pediatric patients. Starting at 1 p.m., the subcommittee will discuss a ''preliminary priority list'' of drugs for which: (1) Additional studies are needed to assess the safety and effectiveness of the use of the drug in the pediatric population and (2) the drug has no remaining marketing exclusivity or patent protection. This list is mandated by the Best Pharmaceuticals for Children Act and the National Institutes of Health is the designated lead. At 4:30 p.m., representatives from Europe will provide information to the subcommittee on the ongoing pediatric initiatives in the European Union. Following this at 5 p.m., the agency will provide an update to the subcommittee on the pediatric labeling that has resulted from the exclusivity initiative under the FDA Modernization Act and the annual update on the pediatric rule, completed studies, deferrals, and waivers. The background material for this meeting will be posted on the Internet when available or one working day before the meeting on the Internet at www.fda.gov/ohrms/dockets/ac/menu.htm.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by June 3, 2002. Oral presentations from the public will be scheduled between approximately 9:15 a.m. and 9:45 a.m. and 2 p.m. and 2:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 3, 2002, 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.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please notify Thomas H. Perez at least 7 days in advance of the meeting.

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

Dated: May 20, 2002.

Linda A. Suydam,

Senior Associate Commissioner for Communications and Constituent Relations.

[FR Doc. 02–13106 Filed 5–23–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Process Analytical Technologies Subcommittee of the Advisory Committee for Pharmaceutical Science; 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). The meeting will be open to the public.

Name of Committee: Process Analytical Technologies Subcommittee of the Advisory Committee for Pharmaceutical Science.

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 June 12, 2002, from 8:30 a.m. to 5:30 p.m., and June 13, 2002, from 8 a.m. to 5 p.m.

Location: Hilton DC North—Gaithersburg, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Kathleen Reedy and Jayne Peterson, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, or e-mail: reedyk@cder.fda.gov, petersonj@cder.fda.gov or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12539. Please call the Information Line for up-to-date information on this meeting.

Agenda: On June 12, 2002, the subcommittee will: (1) Identify and define technology and regulatory uncertainties/hurdles, possible solutions, and strategies for the successful implementation of process analytical technologies (PATs) in pharmaceutical development and manufacturing; (2) discuss general principles for regulatory application of PATs including principles of method validation, specifications, and feasibility of the parametric release concept; and (3) discuss necessary general FDA