above, ZOLOFT Tablets, 150 mg and 200 mg, were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list ZOLOFT Tablets, 150 mg and 200 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to ZOLOFT Tablets, 150 mg and/or 200 mg, may be approved by the agency.

Dated: September 10, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–21022 Filed 9–16–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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: 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 October 14, 2004, from 8 a.m. to 4:30 p.m.

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

Contact Person: Shalini Jain, 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, FAX: 301–827–6776, e-mail: *jains@cder.fda.gov* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512530. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss the following topics: (1) Issues related to clinical trial design and analysis in studying catheter-related bacteremia and (2) issues related to clinical trial design and analysis in studying bacteremia due to staphylococcus aureus. Background materials for this meeting will be posted on the Internet 1 business day before the meeting at: *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by October 4, 2004. Oral presentations from the public will be scheduled between approximately 1 p.m. to 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 4, 2004, 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 contact Shalini Jain 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: September 9, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 04–20935 Filed 9–16–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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: 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 October 19 and 20, 2004, from 8:30 a.m. to 5 p.m.

Location: Food and Drug Administration, Center for Drug Evaluation and Research Advisory Committee conference rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Hilda Scharen, 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, FAX: 301–827–6776, e-mail: SCHARENH@cder.fda.gov, or FDAAdvisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512539. Please call the Information Line for up-to-date information on this meeting.

Agenda: On October 19, 2004, the committee will do the following: (1) receive updates pertaining to the Manufacturing Subcommittee, the Parametric Tolerance Interval Test (PTIT) Workgroup, and the Good Manufacturing Practices (GMPs) for the 21st Century Initiative, and (2) review and discuss research opportunities under the Critical Path Initiative. On October 20, 2004, the committee will do the following: (1) review and discuss the Office of Pharmaceutical Science (OPS) plans and activities designed to take the organization towards the ''desired state'' of science and risk-based regulatory policies and practices as articulated under the GMPs for the 21st Century Initiative, and (2) review and discuss specific topics related to pharmaceutical equivalence and bioequivalence of generic drugs.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by October 12, 2004. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on both days. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 12, 2004, 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.