SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Guidance for Industry on Formal Dispute Resolution; Appeals Above the Division Level'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 19, 1999 (64 FR 13587), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0430. The approval expires on December 31, 2002. A copy of the supporting statement for this information is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: February 14, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–4024 Filed 2–18–00; 8:45 am]

BILLING CODE 4160–01–F

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 regulatory issues.

Date and Time: The meeting will be held on March 24, 2000, 8:30 a.m. to 5:30 p.m.

Location: Marriott Washingtonian Center, Grand Ballroom, 9751 Washingtonian Blvd., Gaithersburg, MD.

Contact Person: Kimberly L. Topper, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001 or Topperk@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: The committee will discuss new drug applications (NDA) 21–130, Zyvox*L* (linezolid) tablets, NDA 21-131 Zyvox*L* for injection (linezolid injection), and NDA 21–132 Zyvox*L* Oral Suspension (linezolid oral suspension), Pharmacia & Upjohn Co., for treatment of community-acquired pneumonia, hospital-acquired pneumonia, complicated and uncomplicated skin and skin structure infections, and Vancomycin-resistant *Enterococcus faecalis* and *faecium* infections, including cases with concurrent bacteremia.

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 March 3, 2000. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 3, 2000, 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.

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

Dated: February 14, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–4027 Filed 2–18–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

General and Plastic Surgery Devices Panel of the Medical Devices 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: General and Plastic Surgery Devices Panel of the Medical Devices 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 March 1, 2, and 3, 2000, 8 a.m. to 5 p.m.

Location: Holiday Inn, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: David Krause, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090, ext. 141, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12519. Please call the Information Line or access the Internet address of http://www.fda.gov/cdrh/panelmtg.html for up-to-date information on this meeting.

Agenda: On March 1, 2000, there will be a brief FDA presentation on the least burdensome provisions of the FDA Modernization Act of 1997. Also, on March 1, 2000, the committee will discuss, make recommendations, and vote on a premarket approval application (PMA) for saline inflatable breast prostheses. On March 2, 2000, the committee will discuss, make recommendations, and vote on two PMA's for saline inflatable breast prostheses. These PMA's have been submitted in response to a call for PMA's under section 515(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 306e(b)), published in the **Federal Register** of August 19, 1999 (64 FR 45155). On March 3, 2000, the committee will discuss content, format, and consistency issues involving the labeling information provided to patients considering saline-filled breast prostheses. The document entitled ''Guidance on Medical Device Patient Labeling'' is the background information for the panel discussion and is available to the public on the Internet at http://www.fda.gov/cdrh/HumanFactors.html or CDRH Facts-on-Demand at 1–800–899–0381 or 301–827–0111, specify number 1128 when prompted for the document shelf number. As it becomes available, additional information specific to saline breast implants will be available to the public on FDA's website

at http://www.fda.gov/ohrms/dockets/ac/00mtbc.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 February 23, 2000. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 12 noon, and 3:45 p.m. and 4:15 p.m. on March 1, 2000; between approximately 8 a.m. and 8:30 a.m., 11:15 a.m. and 11:45 a.m., 1 p.m. and 1:30 p.m., and 4:15 p.m. and 4:45 p.m. on March 2, 2000; and between approximately 9:15 a.m. and 11:15 a.m., and 2:45 p.m. and 3:15 p.m. on March 3, 2000. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 23, 2000, 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.

FDA regrets that it was unable to publish this notice 15 days prior to the March 1, 2, and 3, 2000, General and Plastic Surgery Device Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the General and Plastic Surgery Device Panel of the Medical Devices Advisory Committee meeting were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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

Dated: February 14, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–4157 Filed 2–16–00; 4:19 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food and Drug Administration/Industry Exchange Workshop on Scale- Up and Postapproval Changes (SUPAC), Supplements, and Other Postapproval Changes; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of workshop.

SUMMARY: The Food and Drug Administration (FDA), Office of the Commissioner, Office of Regulatory Affairs, Center for Drug Evaluation and Research, and the Central Region Small Business Office, and the Northeast Region Small Business Office, in cooperation with the International Society for Pharmaceutical Engineering (ISPE) is announcing the following workshops: FDA/Industry Exchange Workshops on Scale-Up and Postapproval Changes (SUPAC), Supplements, and Other Postapproval Changes. The workshops are intended to review the scientific, regulatory, and quality basis of SUPAC; discuss current issues; and provide attendees with information on the impact of the SUPAC guidances that have been finalized, as well as future agency efforts in this area.

Date and Time: See Table 1 following the ''Location'' section of this document.

Location: See Table 1 below.

TABLE 1

Workshop Address	Date and Local Time	FDA Contact Person
Newark Airport Marriot, Newark International Airport, Newark, NJ 07114, 1–800–882–1037, FAX: 973–623–7618	Monday, March 20, 2000, from 9 a.m. to 5 p.m.	Marie T. Falcone
Chicago Marriott Schaumburg, 50 North Martingale Rd., Schaumburg, IL 60173, 847–240–0100, FAX: 847–240–2388	Monday, April 10, 2000, from 9 a.m. to 5 p.m.	Do.
Providence Marriott, One Ohms St., Providence, RI 02904, 1–800–937–7768, FAX: 401–861–3550	Thursday, May 4, 2000, from 9 a.m. to 5 p.m.	Do.

Persons needing hotel rooms should mention that they are attending the ISPE, FDA/SUPAC workshop.

Contact: Marie T. Falcone, Industry and Small Business Representative, FDA, rm. 900 U.S. Customhouse, Second and Chestnut Sts., Philadelphia, PA 19106, 215–597–2120, ext. 4003, e-mail: mfalcone@ora.fda.gov.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number), along with a $295 check (member) or $450 (nonmembers) (which will cover refreshments, lunch, and materials) made payable to ISPE, 3816 W. Linebaugh Ave., suite 412, Tampa, FL 33624, 813–960–2105, or visit the ISPE at the Internet at http://www.ispe.org. Registrations are due 1 week prior to the start of each course. Space is limited, therefore, interested parties are encouraged to register early. Limited on-site registration may be available. Please arrive early to ensure prompt registration. If you need special accommodations due to a disability, please contact ISPE at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The workshops further implement the FDA Plan for Statutory Compliance (developed under Section 406 of the FDA Modernization Act (21 U.S.C. 393)) by working more closely with stakeholders, maximizing the availability of, and clarifying information about the process for review and submissions, and ensuring access to needed scientific and technical expertise.

The topics to be discussed include the following: (1) The history of SUPAC development; (2) comparison of SUPAC immediate-release solid dosage forms, modified-release oral dosage forms, and semisolid-topical dosage forms; (3) bulk actives postapproval changes; (4) postapproval changes sterile aqueous solutions; (5) FDA field staff's involvement in SUPAC; (6) description