field of activity of the committee. The particular needs at this time for each committee are shown in the first paragraph of the **SUPPLEMENTARY INFORMATION** section of this document. The term of office is up to 4 years, depending on the appointment date.

Nomination Procedures

Any interested person may nominate one or more qualified persons for membership on one or more of the advisory committees. Self-nominations are also accepted. Nominations shall include the name of the committee, a complete curriculum vitae of each nominee, current business address and telephone number, and shall state that the nominee is aware of the nomination, is willing to serve as a member (name of committee(s) must be specified), and appears to have no conflict of interest that would preclude membership. FDA will ask the potential candidates to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest.

Consumer Representatives

Any interested person may nominate one or more qualified persons for membership on one or more of the advisory committees to represent consumer interests. Self-nominations are also accepted. To be eligible for selection, the applicant's experience and/or education will be evaluated against Federal civil service criteria for the position to which the person will be appointed.

Selection of members representing consumer interests is conducted through procedures that include use of a group of consumer organizations that has the responsibility for recommending candidates for the agency's selection. Candidates should possess appropriate qualifications to understand and contribute to the committee's work.

Nominations shall include a complete curriculum vita of each nominee, current address and telephone numbers, and shall state that the nominee is aware of the nomination, is willing to serve as a member, and appears to have no conflict of interest that would preclude membership. FDA will ask the potential candidates to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest. The nomination should state whether the nominee is interested only in a particular advisory committee or in any advisory committee. The term of office is up to 4 years, depending on the appointment date.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14 relating to advisory committees.

Dated: June 24, 2002.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 02–16692 Filed 7–2–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02P–0043]

Determination That Piperacillan for Injection USP, 40–Gram Pharmacy Bulk Package, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that piperacillan for injection USP (PIPRACIL), 40-gram (g) pharmacy bulk package, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for piperacillan for injection USP, 40-g pharmacy bulk package.

FOR FURTHER INFORMATION CONTACT: Nicole Mueller, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is typically a version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

Piperacillan for injection USP, 40-g pharmacy bulk package, is the subject of approved NDA 50–545 held by Lederle (part of Wyeth-Ayerst Pharmaceuticals) under the trade name PIPRACIL. Piperacillan for injection USP, 40-g pharmacy bulk package, is a broad-spectrum penicillin indicated for the treatment of serious infections and for prophylactic use in surgery. According to information from Wyeth-Ayerst submitted in 2001, production of the 40-g pharmacy bulk package was discontinued. On January 17, 2002, Mr. Michael Lisjak submitted a citizen petition (Docket No. 02P–0043) under 21 CFR 10.30 and 314.122, requesting that the agency determine whether piperacillan for injection USP, 40-g pharmacy bulk package, was withdrawn from sale for reasons of safety or effectiveness. The petitioner seeks this determination in preparation for filing an ANDA for piperacillan for injection USP, 40-g pharmacy bulk package.

The agency has determined that Wyeth-Ayerst's piperacillan for injection USP, 40-g pharmacy bulk package, was not withdrawn from sale for reasons of safety or effectiveness. Two grounds support the agency's finding. First, Wyeth-Ayerst continues to market PIPRACIL in 2-, 3-, and 4-g vials. The 40-g pharmacy bulk package is a larger package of the same product; it contains up to 20 doses of piperacillan for injection USP. Second, the petitioner identified no data or other information suggesting that PIPRACIL (piperacillan for injection USP, 40-g pharmacy bulk package) was withdrawn

from sale as a result of safety or effectiveness concerns. FDA has independently evaluated relevant literature and data for possible postmarketing adverse event reports, but has found no information that would indicate this product was withdrawn for reasons of safety or effectiveness.

After considering the citizen petition and reviewing its records, FDA determines that, for the reasons outlined previously, Wyeth-Ayerst's piperacillan for injection USP, 40-g pharmacy bulk package, was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list piperacillan for injection USP, 40-g pharmacy bulk package, 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 piperacillan for injection USP, 40-g pharmacy bulk package, may be approved by the agency.

Dated: June 24, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–16668 Filed 7–2–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food and Drug Administration/Industry Exchange Workshops on Food Security and Recalls; Public Workshops

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshops.

SUMMARY: The Food and Drug Administration (FDA) and the Pacific Region Small Business Office, in cooperation with the Western Association of Food and Drug Officials (WAFDO), is announcing a series of workshops on food security and recalls. Topics for discussion include: Food safety and security guidance and procedures, preparing for and conducting a food recall, the use of tamper-evident packaging to avoid product counterfeiting, and the introduction of adulterants. These 1-day workshops for the food industry target food manufacturers, repackers, growers, and transporters. The workshops will include both industry and FDA perspectives.

Date and Time: The public workshops are scheduled as follows:

1. Thursday, July 25, 2002, 8:30 a.m. to 4:30 p.m., Oakland, CA.

2. Wednesday, August 28, 2002, 8:30 a.m. to 4:30 p.m., Los Angeles, CA.

3. Tuesday, September 24, 2002, 8:30 a.m. to 4:30 p.m., Seattle, WA.

Location: The public workshops will be held at the following locations:

1. Oakland—Ronald V. Dellums Federal Building Auditorium and Conference Center, 1301 Clay St., Oakland, CA.

2. Los Angeles—Ronald Reagan State Building Auditorium, 300 South Spring St., Los Angeles, CA.

3. Seattle, WA—Seattle Center, Lopez Room, 300 First Ave. North, corner of Republican Street, Seattle, WA.

Contact: Marcia Madrigal, Industry and Small Business Representative, Food and Drug Administration, Oakland Federal Building, 1301 Clay St., suite 1180N, Oakland, CA 94612, 510–637–3980, FAX 510–637–3977, or e-mail: mmadriga@ora.fda.gov.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) and registration fee to Chuck Henry at WAFDO, 14344 East Caley Ave., Aurora, CO 80016, FAX 303–753–6809, or e-mail: chuck.henry@state.co.us.

The registration fee will be used to offset the expenses of hosting the conferences, including meals, refreshments, meeting rooms, and materials. Space is limited, therefore interested parties are encouraged to register early. Limited onsite registration may be available. Please arrive early to ensure prompt registration.

If you need special accommodations due to a disability, please contact Marcia Madrigal at least 7 days in advance of the workshop.

SUPPLEMENTARY INFORMATION: The ''Food Security and Recalls'' workshops help fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health by preventing and countering terrorism related to the nation's food supply. FDA has made providing security guidance and information to the food industry a high priority.

The workshop helps to implement the objectives of section 406 of the FDA Modernization Act (21 U.S.C. 393) and the FDA Plan for Statutory Compliance, which includes working more closely with stakeholders and ensuring access to needed scientific and technical expertise. The workshop also furthers the goals of the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121) by providing outreach activities by Government agencies directed to small businesses.

Dated: June 26, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–16667 Filed 7–2–02; 8:45 am]

BILLING CODE 4160–01–S

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). At least one portion of the meeting will be closed 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 July 8, 2002, from 1 p.m. to 5 p.m., and July 9, 2002, from 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 July 8, 2002, the committee will discuss and make recommendations on the classification of a preamendment device, the silicone elastomer for scar management. The committee will also discuss and make recommendations on the reclassification of a transitional class III device, the absorbable hemostatic agent and dressing device intended for hemostasis during surgical procedures. On July 9, 2002, FDA and two manufacturers of approved saline inflatable breast implant devices will present postmarket