the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 601.12 have been approved under OMB Control No. 0910–0338; 21 CFR 640.63 have been approved under OMB Control No. 0910–0116.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: July 18 2011.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2011–18472 Filed 7–21–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0381]

Generic Drug User Fee; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

The Food and Drug Administration (FDA) is announcing a public meeting to provide a public update and to gather additional stakeholder input on the development of a generic drug user fee program. A user fee program could provide necessary supplemental funding, in addition to current Congressional appropriations, to facilitate the timely review of human generic drug applications by FDA. FDA has been in negotiations with the regulated industry aimed at providing a consensus proposal for Congressional consideration. In the interest of transparency, and to assure that all interested stakeholders' views are heard and considered, whether they are present at the negotiations or not, FDA is holding a fourth public meeting on this topic to provide an update and to gather additional input on such a program.

Date and Time: The public meeting will be held on August 25, 2011, from 2 to 3:30 p.m.

Location: The public meeting will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 1, Conference Rooms 4101, 4103, and 4105, Silver Spring, MD 20993–0002.

Contact Person: Mari Long, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4237, Silver Spring, MD 20993–0002, 301–796–7574, FAX 301–847–3541, *mari.long@fda.hhs.gov;* or

Peter C. Beckerman, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4238, Silver Spring, MD 20993–0002, 301–796–4830, FAX 301–847–3541, *peter.beckerman@fda.hhs.gov.*

Registration and Requests for Oral Presentations: If you wish to attend and/or present at the meeting, please e-mail your registration information to *GDUFA_Meeting3@fda.hhs.gov* by August 18, 2011. Your e-mail should contain complete contact information for each attendee, including name, title, affiliation, address, e-mail address, and telephone number. Registration is free and will be on a first-come, first-served basis. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization as well as the total number of participants, based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. We will try to accommodate all persons who wish to make a presentation. The time allotted for presentations may depend on the number of persons who wish to speak, and if the entire meeting time is not needed for presentations, FDA reserves the right to terminate the meeting early.

If you need special accommodations because of disability, please contact Mari Long or Peter Beckerman (see *Contact Person*) at least 7 days before the meeting.

Comments: Regardless of attendance at the public meeting, interested persons may submit either electronic or written comments regarding this document. To ensure consideration, all comments must be received by September 26, 2011. Submission of comments prior to the meeting is strongly encouraged. Submit any comments that you plan to present at the public meeting to the docket by the date of the public meeting, but note that either electronic or written comments generally may be submitted until September 26, 2011.

Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing its intention to hold a public meeting related to generic drug user fees. New legislation would be required for FDA to establish and collect user fees for generic drugs, and FDA has been engaged in negotiations with industry over aspects of a joint proposal for a generic drug user fee program, including fees and performance goals, for several months. The Agency has held three prior public meetings on the topic before and during this process. Because FDA can only negotiate with trade organizations, not individual companies, but remains interested in hearing from non-affiliated companies in addition to patient and consumer stakeholders, the Agency is holding an additional public meeting. The meeting will provide a status update and seek input from stakeholders on generic drug user fees. In addition, FDA continues to encourage all interested stakeholders to submit either electronic or written comments to the docket (see *Comments*).

II. What information should you know about the public meeting, when and where will the public meeting occur, and what format will FDA use?

Through this notice, we are announcing a public meeting to update stakeholders and hear stakeholder views on what features FDA should propose for a generic drug user fee program. We will conduct the meeting on August 25, 2011, from 2 to 3:30 p.m. at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 1, Conference Rooms 4101, 4103, and 4105, Silver Spring, MD 20993–0002. In general, the

meeting format will include a presentation by FDA and presentations by stakeholders and members of the public who have registered in advance to present at the meeting. The amount of time available for presentations will be determined by the number of people who register to make a presentation. We will also provide an opportunity for organizations and individuals to submit either electronic or written comments to the docket after the meeting (see *Comments*). FDA policy issues are beyond the scope of this initiative. Accordingly, the presentations should focus on process and funding issues, and not focus on policy.

Dated: July 19, 2011.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2011–18591 Filed 7–21–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Thirteenth International Paul-Ehrlich-Seminar: Allergen Products for Diagnosis and Therapy: Regulation and Science; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER), in cosponsorship with the Paul-Ehrlich-Institut (PEI), and the Drug Information Association (DIA), is announcing a public workshop entitled: ''13th International Paul-Ehrlich-Seminar: Allergen Products for Diagnosis and Therapy: Regulation and Science.'' The purpose of the public workshop is to bring together scientists, clinicians, and regulators from throughout the world to discuss the regulation of allergenic products with respect to their use for the diagnosis and treatment of allergenic diseases and asthma. The public workshop will provide a forum for scientists, clinicians, and regulators to discuss natural and modified allergens as they relate to the pathogenesis, diagnosis, and treatment of allergic diseases.

Dates and Times: See the following table 1.

TABLE 1—WORKSHOP SCHEDULE

Dates	Registration times	Public workshop hours
September 14, 2011	3 p.m. to 6 p.m	7:30 p.m. to 9 p.m. (keynote session).
September 15, 2011	7 a.m. to 8:30 a.m	8:30 a.m. to 5 p.m.
September 16, 2011	None	8:30 a.m. to 6 p.m.
September 17, 2011	None	8:45 a.m. to 12:30 p.m.

Location: The public workshop will be held at the Hyatt Regency Washington on Capitol Hill, 400 New Jersey Ave., NW., Washington, DC 20001. Overnight accommodations can be booked at the Hyatt Regency Washington on Capitol Hill, under group code ''DIA event''. Reduced rates are available until August 24, 2011. For the public workshop rate, call 1–800–243–2546 or go to the Web site at *http://washingtonregency.hyatt.com/hyatt/hotels/*. (FDA has verified the Web site addresses throughout this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Contact Person: Sandra Menzies, Center for Biologics Evaluation and Research (HFM–422), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–3181, FAX: 301–402–2776; e-mail: *Sandra.menzies@fda.hhs.gov* (in the subject line, type ''13th IPES''.)

Registration: Registration will be handled directly by DIA. Registration fees apply to all attendees. Registration will be accepted by mail, fax, or online. Register online at *http://www.diahome.org.* For mailing or faxing registration information, see the Web site at: *http://www.diahome.org/DIAHome/Education/FindEducationalOffering.aspx?productID=25839&eventType=Meeting.* Early registration is recommended because seating is limited. Registration at the public workshop will be provided on a space-available basis.

If you need special accommodations due to a disability, please contact DIA at least 15 days prior to the start of the public workshop at 215–293–5800; FAX: 215–442–6199; or e-mail *Constance.Burnett@diahome.org* or *JoAnn.Boileau@diahome.org.*

Continuing Education: This activity has been planned and implemented in accordance with the essential areas and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of Postgraduate Institute for Medicine (PIM) and the DIA. PIM is accredited by the ACCME to provide continuing medical education for physicians. PIM designates this educational activity for a maximum of 17.75 American Medical Association Physician's Recognition Ward (AMA PRA) Category 1 Credit(s).™ Physicians should only claim credit commensurate with the extent of their participation in the activity. DIA has been approved as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 8405 Greensboro Dr., suite 800, McLean, VA 22102; 703–506–3275. DIA is authorized by IACET to offer 1.8 continuing education units for this program.

SUPPLEMENTARY INFORMATION: For about 30 years, the International Paul-Ehrlich-Seminar has been a forum for regulators, scientists, and industry to discuss issues related to standardization and regulation of diagnostic and therapeutic allergenic products. The public workshop will consist of a series of seminars and discussions focused on standardization of allergens, including biochemical characterization, their mechanism of action as therapeutics, and ongoing and recently completed clinical trials as to safety and efficacy of a number of allergenic products as therapeutics.

FDA protects and advances the public health by approving biological products that it determines meets the requirements for safety, purity, and potency for the conditions for which the applicant is seeking approval, based on factors that include a review of data and, in some cases, taking into account recommendations and input from independent experts (*e.g.,* advisory committees), input from interested parties, and public comments.