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.

PEI is an institution of the Federal Republic of Germany. PEI reports to the Bundesministerium für Gesundheit (Federal Ministry of Health). Most of its activities relate to provisions in German and European medicinal product legislation, such as the approval of clinical trials and the marketing authorization of particular groups of medicinal products. Since its foundation more than 100 years ago, PEI has concentrated on many biological medicinal products, including vaccines for humans and animals, medicinal products containing antibodies, allergens for therapy and diagnostics, blood and blood products, and more recently, tissue and medicinal products for gene therapy, somatic cell therapy, and xenogenic cell therapy.

DIA is a nonprofit, multidisciplinary, member-driven scientific association with a membership of over 22,000. These members are primarily from the regulatory Agencies, academia, contract service organizations, pharmaceutical, biological and device industry, and from other health care organizations. DIA provides a neutral global forum for the exchange and dissemination of knowledge on the discovery, development, evaluation, and utilization of medicines and related health care technologies. Through these activities, DIA provides development opportunities for its members.

The public workshop will feature presentations by FDA and regulators from Canada, China, Europe, and Mexico. The public workshop will begin with a keynote address by Harold S. Nelson and end with a closing address by N. Franklin Adkinson, Jr. During the public workshop, the following topics will be discussed:

- Standardization and characterization of natural allergenic products;
- Methods in product and study design of effective allergenic products for therapy;
- Standardization and characterization of modified and recombinant allergenic products;
- Immunological mechanisms of allergy immunotherapy;
- Immunotherapy with purified allergen components;
- Extrinsic adjuvants in the use of allergen immunotherapy;
- Immunomodulatory properties of allergens; and
- State-of-the-art of immunotherapy in different allergic diseases.

DIA will provide all seminar attendees with a Web link no later than 4 weeks post-seminar. The Web link will provide access to approved Portable Document Format (PDF) presentations. The Web link will be available for approximately 6 months postseminar.

Dated: July 19, 2011.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2011–18534 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]

Vaccines and Related Biological Products 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: Vaccines and Related Biological Products 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 September 20, 2011, from 8 a.m. to approximately 5:15 p.m.

Location: Hilton Hotel, Washington DC North/Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20977, 301–977–8900. For those unable to attend in person, the meeting will also be Web cast. The link for the Web cast is available at *http://fda.yorkcast.com/webcast/Viewer/?peid=84f95996804743439bcc5be69d1908051d.*

Contact Person: Donald W. Jehn or Denise Royster, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On September 20, 2011, the committee will meet in open session to hear an overview of the research program in the Laboratory of Enteric and Sexually Transmitted Diseases, Division of Bacterial, Parasitic and Allergenic Products, Office of Vaccines Research and Review, Center for Biologics Evaluation and Research, FDA. The committee will then discuss and make recommendations on the safety and immunogenicity (surrogate endpoint) of Pneumococcal 13-valent conjugate vaccine (Diphtheria CRM197 Protein) in adults aged 50 years and older using an accelerated approval regulatory pathway.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee link.

Procedure: On September 20, 2011, between approximately 8 a.m. and 10 a.m., and between approximately 10:45 a.m. and 5:15 p.m., the meeting is open to the public. 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 on or before September 13, 2011. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10 a.m. and between approximately 3:45 p.m. and 4:15 p.m. Those individuals interested in making formal oral presentations should notify the contact person 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 on or before September 1, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons