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 allergic 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>
<thead>
<tr>
<th>Table 1—Workshop Schedule</th>
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<tr>
<td>Dates</td>
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<tr>
<td>September 14, 2011</td>
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<td>September 15, 2011</td>
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<td>September 16, 2011</td>
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<td>September 17, 2011</td>
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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, 301–287–3181, 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/
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 20077, 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=849f5996804743439bcc5be69d190051d.

Contact Person: Donald W. Juhn 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. 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 10:45 a.m. and 4:15 p.m.

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 which speakers for the scheduled open public hearing session. The contact person will notify interested persons.

The Web link will be available for approximately 6 months post-seminar.

Dated: July 19, 2011.

David Dorsey,
Acting Deputy Commissioner for Policy, Planning and Budget.