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

regarding their request to speak by September 2, 2011.

Closed Committee Deliberations: On September 20, 2011, between approximately 10:15 a.m. and 10:45 a.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss the report of the intramural research programs and make recommendations regarding personnel staffing decisions.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Donald W. Jehn or Denise Royster at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

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

Dated: July 18, 2011.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2011–18506 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]

Risk Communication 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: Risk Communication 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 August 15, 2011, from 8 a.m. to 5 p.m. and August 16, 2011, from 8 a.m. to 2 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You'', click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Lee L. Zwanziger, Office of Policy, Planning and Budget, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 3278, Silver Spring, MD 20993, 301–796–9151, FAX: 301–847–8611, *e-mail: RCAC@fda.hhs.gov,* 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 August 15, 2011, the Committee will discuss challenges of communicating about evolving methodology in the attribution of foodborne illness. Estimating the number of illnesses, hospitalizations, and deaths caused by major pathogens is the first step in the development of disease prevention strategies. Estimating the proportions of these illnesses due to specific food sources (food source attribution) is a necessary second step towards identifying the sources that cause substantial preventable human illness and measuring progress toward public health goals resulting from public health interventions applied to those food sources. Consequently, FDA, the Centers for Disease Control and Prevention, and the U.S. Department of Agriculture/Food Safety Inspection Service have begun a joint initiative, called the Interagency Food Safety Analytics Collaboration (IFSAC), to improve our collective understanding of source attribution of infections to specific foods and settings. While the IFSAC works to improve methodology, we are also committed to keeping stakeholders informed and engaged, and are seeking advice about how to communicate most effectively. On August 16, 2011, the Committee will present ''Communicating Risks and Benefits: An Evidence-Based User's Guide.'' This volume is the result of work, as discussed in previous meetings, by current and former members of the Risk Communication Advisory Committee.

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: 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 August 10, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on August 15, 2011, and 10:30 a.m. and 11:30 a.m. on August 16, 2011. 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 August 2, 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 regarding their request to speak by August 3, 2011. Interested persons can also log on to *https://collaboration.fda.gov/rcac/* to hear and see the proceedings.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical