DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

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 November 16, 2010, from 9 a.m. to approximately 4 p.m. and on November 17, 2010, from 8:30 a.m. to approximately 1:15 p.m.

Location: Hilton Silver Spring Hotel, Maryland Ballroom, 8727 Colesville Rd., Silver Spring, MD 20910.

Contact Person: Donald W. Jehn or Denise Royster, Food and Drug Administration, 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), code 3014512391. 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 November 16, 2010, the committee will meet in open session to review and discuss the pathway to licensure for protective antigen-based anthrax vaccines for a post-exposure prophylaxis indication using the animal rule. On November 17, 2010, the committee will meet in open session to review and discuss the effectiveness of vaccinating males and females with Gardasil manufactured by Merck & Co. for the prevention of anal dysplasia and anal cancer.

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 November 16, 2010, from 9 a.m. until approximately 11:45 a.m. and from 2 p.m. until approximately 4 p.m. and on November 17, 2010, 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 November 10, 2010. Oral presentations from the public will be scheduled between approximately 2:15 p.m. and 2:45 p.m. on November 16, 2010, and between approximately 11:45 a.m. and 12:15 p.m. on November 17, 2010. Those desiring to make 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 November 2, 2010. 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 November 3, 2010.

Closed Committee Deliberations: On November 16, 2010, between 12 p.m. and approximately 2 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)). The committee will hear firms discuss protocols they propose to use for the pathway to licensure for protective antigen-based anthrax vaccines for a post-exposure prophylaxis indication using the animal rule.

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: September 23, 2010.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 10–????? Filed ??–??–10; 8:45 am]

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