nor an environmental impact statement is required.

Dated: March 17, 2010.

Mitchell A. Cheezeman,
Acting Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

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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). The meeting will be open 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 May 7, 2010, from 8 a.m. to approximately 4:30 p.m.

Location: Hilton Hotel Washington DC North/Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20877.

Contact Person: Christine Walsh 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, 1–800–741–0318 (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 May 7, 2010, in the morning, the committee will review and discuss available data regarding the unexpected finding of DNA originating from porcine circovirus type 1 (PCV 1) in Rotarix, a U.S. licensed vaccine manufactured by GlaxoSmithKline and indicated for the prevention of rotavirus gastroenteritis in infants. The committee will discuss what additional steps should be considered to address this finding. In the afternoon, the committee will discuss and make recommendations on the use of advanced analytical detection methods not currently applied for the characterization of cell substrates, viral seeds, and other biological materials used in the production of viral vaccines for human use.

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 May 4, 2010. Oral presentations from the public will be scheduled between approximately 10:50 a.m. and 11:20 a.m. and 2:45 p.m. and 3:15 p.m. 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 April 29, 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 April 30, 2010.

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 on FDA’s Web site at http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm. Scroll down to the appropriate advisory committee link.

Secretary’s Advisory Committee on Heritable Disorders in Newborns and Children; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Secretary’s Advisory Committee on Heritable Disorders in Newborns and Children.

Dates and Times: May 13, 2010, 8:30 a.m. to 5 p.m. May 14, 2010, 8:30 a.m. to 3:30 p.m.

Place: Renaissance Washington, DC Dupont Circle Hotel, 1143 New Hampshire Avenue, NW, Washington, DC 20037.

Status: The meeting will be open to the public with attendance limited to space availability. Participants are asked to register for the meeting by going to the registration Web site at http://events.SignUp4.com/ACHDNCO0510. The registration deadline is Tuesday, May 11, 2010. Individuals who need special assistance, such as sign language interpretation or other reasonable accommodations should indicate their needs on the registration Web site. The deadline for special accommodation requests is Friday, May 7, 2010. If there are technical problems gaining access to the Web site, please contact Maureen Ball, Meetings Coordinator, at conferences@alturum.org.

Purpose: The Secretary’s Advisory Committee on Heritable Disorders in Newborns and Children (Advisory Committee) was established to advise