DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0038]

Blood 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: Blood 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 January 9, 2009, from 8 a.m. to 6 p.m.

Location: Hilton Hotel, Washington, D.C./Rockville Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: William Freas or Pearline K. Muckelvene, 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 3014519516. 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 the morning of January 9, 2009, the Committee will discuss CSL Behring's Biologics License Application for plasma-derived fibrinogen concentrate for treatment of bleeding in congenital fibrinogen deficiency. In the afternoon, the Committee will hear an update on the ''Food and Drug Administration Draft Guidance for Industry on Regulation of Genetically Engineered Animals Containing Heritable Recombinant Deoxynucleic Acid Constructs.'' Following this update, the Committee will discuss GTC Biotherapeutics' Biologics License Application for recombinant Antithrombin III derived from genetically engineered goats for treatment of patients with hereditary Antithrombin III deficiency to prevent thrombosis during high risk situations like surgery and obstetrical procedures.

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/ohrms/dockets/ac/acmenu.htm*, click on the year 2009 and 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 December 30, 2008. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 11 a.m. and between approximately 4 p.m. and 5 p.m. on January 9, 2009. 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 December 19, 2008. 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 December 22, 2008.

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 William Freas or Pearline K. Muckelvene 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/oc/advisory/default.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: December 1, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8–29105 Filed 12–8–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 30-Day Proposed Information Collection: Indian Health Service Health Promotion/Disease Prevention Grantee Survey

AGENCY: Indian Health Service, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 which requires 30 days for public comment on proposed information collection projects, the Indian Health Service (IHS) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection project was previously published in the **Federal Register** (73 FR 23254) on August 25, 2008 and allowed 60 days for public comment. No public comment was received in response to the notice. The purpose of this notice is to allow 30 days for public comment to be submitted directly to OMB.

Proposed Collection: Title: 0917–NEW, ''Indian Health Service Health Promotion/Disease Prevention Grantee Survey.''

Type of Information Collection Request: This is a one-time survey to fulfill an OMB request for an independent external evaluation collection, 0917–NEW, ''Indian Health Service Health Promotional Disease Prevention (HP/DP) Grantee Survey.''

Form Number(s): None.

Need and Use of Information Collection: The IHS goal is to raise the health status of the American Indian and Alaska Native (AI/AN) people to the highest possible level by providing comprehensive health care and preventive health services. HP/DP is one of the three IHS Director's initiatives to reduce health disparities among AI/AN populations through a coordinated and systematic approach to enhance health