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 In the afternoon, the Committee will hear an update on the ''Food and Drug Administration Draft Guidance for Industry on Regulation of Genetically Engineered Animals Containing Heritable Recombinant Deoxynucleic Acid Constructs.''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

promotion and chronic disease prevention approaches at the local, regional, and national levels.

The HP/DP competitive grant was established in 2005 to encourage Tribal and urban Indian programs to fully engage their local schools, communities, health care providers, health centers, faith-based/spiritual communities, senior centers, youth programs, local governments, academia, non-profit organizations, and many other community sectors to work together to enhance and promote health and prevent chronic disease in their communities. Thirty-three Tribal/urban Indian organizations and programs were awarded competitive grants to expand and enhance health promotion and disease prevention to address health disparities among AI/AN populations.

To conduct a thorough evaluation of the grant program, 29 telephone and four face-to-face interviews will be conducted to collect information to complete a quantitative and qualitative evaluation of the HP/DP grant program. The teleconference interviews may include one staff member per site. Each of the Tribal/urban organization/programs will determine the number of their staff members that will participate in the interview. The evaluation will include an assessment of whether HP/DP grantees achieve measurable health outcomes, synthesize the evaluation findings, and include a written report with recommendations to enhance program effectiveness. The information gathered will be used to prepare a final report for OMB.

Affected Public: Individuals.

Type of Respondents: Tribal/urban organizations program staff.

The table below provides: Types of data collection instruments, estimated number of respondents, number of responses per respondent, average burden hour per response, and total annual burden hour(s).

ESTIMATED BURDEN HOURS

Data collection instrument	Estimated number of respondents	Responses per respondent	Average burden hour per response	Total annual burden hours
HP/DP Grantees Telephone and Face-to-Face Interview Survey	231	1	1	231
Total	231			231

There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

Request for Comments: Your written comments and/or suggestions are invited on one or more of the following points: (a) Whether the information collection activity is necessary to carry out an agency function; (b) whether the agency processes the information collected in a useful and timely fashion; (c) the accuracy of the public burden estimate (the estimated amount of time needed for individual respondents to provide the requested information); (d) whether the methodology and assumptions used to determine the estimates are logical; (e) ways to enhance the quality, utility, and clarity of the information being collected; and (f) ways to minimize the public burden through the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Send your written comments and suggestions regarding the proposed information collection contained in this notice, especially regarding the estimated public burden and associated response time to: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for IHS.

To request more information on the proposed collection or to obtain a copy of the data collection instrument(s) and/or instruction(s) contact: Ms. Janet Ingersoll, Freedom of Information Act Coordinator, 801 Thompson Avenue, TMP Suite 450, Rockville, MD 20852–1601; call non-toll free (301) 443–1116; send via facsimile to (301) 443–9879; or send your e-mail requests, comments, and return address to: *Janet.Ingersoll@ihs.gov*.

Comment Due Date: Comments regarding this information collection are best assured of having full effect if received within 30 days of the date of this publication.

Dated: December 2, 2008.

Robert G. McSwain,

Director, Indian Health Service.

[FR Doc. E8–28922 Filed 12–8–08; 8:45 am]

BILLING CODE 4160–16–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; MOSS Continuous Receipt.

Date: December 18, 2008.

Time: 2 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Daniel F. McDonald, PhD, Scientific Review Officer, Chief, MOSS IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814,Bethesda, MD 20892, (301) 435–1215, *mcdonald@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Oncological Sciences Integrated Review Group; Cancer Molecular Pathobiology Study Section.

Date: January 15–16, 2009.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Delfina, 530 West Pico Boulevard, Santa Monica, CA 90405.

Contact Person: Elaine Sierra-Rivera, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health,6701 Rockledge Drive, Room 6184, MSC 7804, Bethesda, MD 20892, 301–435–1779, *riverase@csr.nih.gov*.

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group; Psychosocial Risk and Disease Prevention Study Section.