DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

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 July 20, 2009, from 8 a.m. to 6 p.m. and on July 21, 2009, from 9 a.m. to 12 noon.

Location: Hilton Washington DC North/Gaithersburg, Grand Ballroom, 620 Perry Pkwy., Gaithersburg, MD 20877, 301–977–8900.

Contact Person: William Freas or Pearline K. Muckelvene, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike (HFM–71), 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 July 20, 2009, in the morning, the committee will review proposed strategies to demonstrate the effectiveness of new coral snake antivenoms. In the afternoon, the committee will discuss alternative clinical and surrogate endpoints for evaluating efficacy of Alpha-1 Proteinase Inhibitor (Human) augmentation therapy in Alpha-1 antitrypsin deficiency. Alpha-1 antitrypsin deficiency is a genetic condition associated with decreased circulating levels of alpha-1 antitrypsin that significantly increases the risk of serious lung disease (i.e. emphysemia) in adults. On July 21, 2009, the committee will hear updates on the following topics: The April 30 to May 1, 2009, meeting of the Department of Health and Human Services Advisory Committee on Blood Safety and Availability (*http://www.hhs.gov/ophs/bloodsafety/index.html*); the June 12, 2009, meeting of the FDA Transmissible Spongiform Encephalopathies Advisory Committee (*http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/TransmissibleSpongiformEncephalopathiesAdvisoryCommittee/ucm129559.htm*); and an overview of the epidemiology and virology of the 2009 A/H1N1 influenza virus and its impact on the U.S. blood system. The committee will also hear informational presentations on recent public and private hemovigilance efforts, including the pilot hemovigilance module in the National Healthcare Safety Network.

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 July 15, 2009. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 11 a.m. and between approximately 3:45 p.m. and 5 p.m. on July 20, 2009, and between approximately 11:30 a.m. and 12 noon on July 21, 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 July 13, 2009. 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 July 8, 2009.

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/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

FDA regrets that it was unable to publish this notice 15 days prior to the July 20, 2009, Blood Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Blood Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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

Dated: June 29, 2009.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E9–16101 Filed 7–7–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Advisory Committee for Pharmaceutical Science and Clinical Pharmacology; 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: Advisory Committee for Pharmaceutical Science and Clinical Pharmacology.

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 August 5, 2009, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC/Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD. The hotel telephone number is 301–589–5200.

Contact Person: Paul Tran, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *paul.tran@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572) in the Washington, DC area), code 3014512539. 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: The committee will: (1) Receive a status update from the Office of Generic Drugs (OGD) on bioequivalence for highly variable drugs (highly variable means that the rate and amount of the drug entering blood varies significantly from one administration to another); (2) receive presentations from the Office of Pharmaceutical Science (OPS) on the scientific and regulatory challenges of Transdermal Drug Delivery Systems (TDDS); (3) receive presentations from OPS and discuss current thinking on ''Classifying Pre-Surgical Preparations as Sterile Products'' in consideration of how these products are used; and (4) be updated by OPS on the current status of the International Conference on Harmonization (ICH) Quality Topics [i.e., those relating to chemical and pharmaceutical quality assurance (stability testing, impurity testing, etc.)], and outline the role of the ICH Implementation Work Group (Q IWG), its future activities, and any remaining gaps and challenges.

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*, 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 July 21, 2009. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 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 July 13, 2009. 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 July 14, 2009.

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 Paul Tran 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: June 29, 2009.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E9–16136 Filed 7–7–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Office of Clinical and Preventive Services; Division of Behavioral Health; the Methamphetamine & Suicide Prevention Initiative for American Indian and Alaska Native Urban Programs

Announcement Type: New.

Funding Announcement Number: HHS–2009–IHS–METHU–0002.

Catalog of Federal Domestic Assistance Number(s): 93.933.

Key Dates: Application Deadline Date: July 31, 2009.

Review Date: August 6–7, 2009.

Earliest Anticipated Start Date: August 14, 2009.

Table of Contents

I. Funding Opportunity
II. Award Information
III. Eligibility
IV. Application & Submission Information
V. Application Review Information
VI. Award Administration Information
VII. Agency Contacts
VIII. Other Information

I. Funding Opportunity Description

The Indian Health Service (IHS) announces competitive grant applications for the Methamphetamine & Suicide Prevention Initiative (MSPI) for American Indian and Alaska Native (AI/AN) Urban Program communities. This program is authorized under the Snyder Act, 25 U.S.C. 13, and 25 U.S.C. 1602(a)(b)(9)(11)(12) of the Indian Health Care Improvement Act (IHCIA), as amended. This program is described at 93.933 in the Catalog of Federal Domestic Assistance. The purpose of the MSPI–U is to expand community-level access to effective, Urban AI/AN methamphetamine and/or suicide prevention and treatment programs. Resources will enhance evidence-based or practice-based methamphetamine and/or suicide prevention or treatment programs and/or community mobilization programs. The methamphetamine and suicide prevention or treatment funding will be used to:

- Provide community-focused responses that enhance evidence-based or practice based methamphetamine and/or suicide prevention or treatment services or education programming;