V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: July 1, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–15766 Filed 7–10–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Approaches to Reduce Risk of Transfusion-Transmitted Babesiosis in the United States; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Approaches to Reduce the Risk of Transfusion-Transmitted Babesiosis in the United States.'' The purpose of the public workshop is to discuss the risk and possible approaches to minimize the incidence of transfusion-transmitted babesiosis in the United States. We are convening this workshop at the present time because FDA has observed a recent increase in the number of reports of transfusion-transmitted babesiosis, thus warranting additional discussion to address this blood safety issue. The public workshop will feature presentations and roundtable discussions led by experts from academic institutions, government, and industry.

Date and Time: The public workshop will be held on September 12, 2008, from 7:30 a.m. to 5:30 p.m.

Location: The public workshop will be held at the Lister Hill Center Auditorium, Bldg. 38A, National Institutes of Health, 8800 Rockville Pike, Bethesda, MD 20894.

Contact Person: Rhonda Dawson, Center for Biologics Evaluation and Research (HFM–302), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6129, FAX: 301–827–2843, e-mail: *rhonda.dawson@fda.hhs.gov*.

Registration: Mail, fax or e-mail your registration information (including name, title, firm name, address, telephone and fax numbers) to the contact person by August 25, 2008. There is no registration fee for the public workshop. Early registration is recommended because seating is limited to 175 attendees. Registration on the day of the public workshop will be provided on a space available basis beginning at 7:30 a.m.

If you need special accommodations due to a disability, please contact Rhonda Dawson (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: Babesiosis is a malaria-like illness caused by infection of erythrocytes with protozoan parasites belonging to the genus *Babesia*. Transfusion-transmitted babesiosis is caused by transfusion of blood or blood components collected from donors infected with *Babesia* parasites. During the last 40 years, more than 60 cases of transfusion-transmitted babesiosis have been recognized in the United States. In fiscal years 2006 and 2007, FDA received a total of five reports of fatal transfusion-transmitted babesiosis (primary or contributory cause of death) in the United States.

The public workshop will facilitate a scientific discussion on approaches to reduce the risk of transfusion-transmitted babesiosis in the United States. Topics to be discussed include: (1) Biology, pathogenesis, transmission and epidemiology of babesiosis; (2) risk of *Babesia* infections through transfusion of blood and blood components; (3) laboratory testing to detect *Babesia* infections; and, (4) possible approaches, including donor testing and donor deferral, to reduce the risk of transfusion-transmitted babesiosis while maintaining blood availability and safety.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Transcripts: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page. A transcript of the public workshop will be available on the Internet at *http://www.fda.gov/cber/minutes/workshop-min.htm*.

Dated: July 2, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–15799 Filed 7–10–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Nominations for Voting Members on Public Advisory Committee, Food Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for voting members to serve on the Food Advisory Committee (FAC), Center for Food Safety and Applied Nutrition (CFSAN).

FDA has a special interest in ensuring that women, minority groups, and individuals with disabilities are adequately represented on advisory committees and, therefore, encourages nominations of qualified candidates from these groups.

DATES: Nominations received on or before August 11, 2008 will be given first consideration for membership on the Food Advisory Committee. Nominations received after August 11, 2008 will be considered for nomination to the committee should nominees still be needed.

ADDRESSES: All Nominations for membership should be sent electronically to *CV@FDA.HHS.GOV* or by mail to: Advisory Committee Oversight and Management Staff, 5600 Fisher Lane (HF–4), rm. 15A–12, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Regarding all nomination questions for membership, the primary contact is Carolyn Jeletic, Center for Food Safety and Applied Nutrition, 301–436–1913, FAX: 301–436–2633, e-mail:

Carolyn.Jeletic@fda.hhs.gov. Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's Web site by using the following link: *http://www.fda.gov/oc/advisory/default.htm*.

SUPPLEMENTARY INFORMATION: FDA is requesting nomination for voting members on the Food Advisory Committee.

I. Function of the Food Advisory Committee

The committee provides advice, primarily to the Commissioner of Food and Drugs and other appropriate officials, on emerging food safety, food science, nutrition, and other food-related health issues that the FDA considers of primary importance for its food and cosmetics programs. The committee may be charged with reviewing and evaluating available data and making recommendations on matters such as those relating to: (1) Broad scientific and technical food or cosmetic related issues, (2) the safety of new foods and food ingredients, (3) labeling of foods and cosmetics, (4) nutrient needs and nutritional adequacy, and (5) safe exposure limits for food contaminants. The committee may also be asked to provide advice and make recommendations on ways of communicating to the public the potential risks associated with these issues and on approaches that might be considered for addressing the issues.

II. Criteria for Voting Members

FDA is requesting nominations of voting members with appropriate expertise in the following specialties: Microbiology, food technology, and nutrition.

III. Nomination Procedures

Pursuant to 21 CFR 14.84(d), any interested person may nominate one or more qualified persons for membership on the advisory committee. Self-nominations are also accepted. Nominations shall include the name of the committee, a complete curriculum vitae of each nominee, and their current business address and telephone number and e-mail address if available. Each nomination shall state that the nominee is aware of the nomination, is willing to serve as a member, and appears to have no conflict of interest that would preclude membership. FDA will ask the potential candidates to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app.2) and 21 CFR part 14 relating to advisory committees.

Dated: July 3, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8–15839 Filed 7–10–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Tribal Self-Governance Program; Planning Cooperative Agreement

Announcement Type: New.

Funding Announcement Number: HHS–2008–IHS–TSGP–0002.

Catalog of Federal Domestic Assistance Number(s): 93.2 10.

Key Dates:

Application Deadline Date: August 15, 2008.

Review Date: August 25–26, 2008.

Earliest Anticipated Start Date: September 1, 2008.

I. Funding Opportunity Description

The purpose of the program is to award cooperative agreements that provide planning resources to Tribes interested in participating in the Tribal Self-Governance Program (TSGP) as authorized by Title V, Tribal Self-Governance Amendments of 2000 of the Indian Self-Determination and Education Assistance Act of Public Law (Pub. L.) 93–638, as amended. There is limited competition under this announcement because the authorizing legislation restricts eligibility to Tribes that meet specific criteria (Refer to Section III.1.A., Eligible Applicants in this announcement). The TSGP is designed to promote self-determination by allowing Tribes to assume more control of Indian Health Service (IHS) programs and services through compacts negotiated with the IHS. The Planning Cooperative Agreement allows a Tribe to gather information to determine the current types of Programs, Services, Functions, and Activities (PSFAs), and related funding available at the Service Unit, Area, and Headquarters levels and provide the opportunity to improve and enhance the healthcare delivery system to better meet the needs of the Tribal community. This program is described at 93.210 in the Catalog of Federal Domestic Assistance (CFDA).

II. Award Information

Type of Awards: Cooperative Agreement.

Estimated Funds Available: The total amount identified for Fiscal Year (FY) 2008 is $600,000 for approximately twelve (12) Tribes. Awards under this announcement are subject to the availability of funds.

Anticipated Number of Awards: The estimated number of awards to be funded is approximately 12.

Project Period: 12 months.

Award Amount: $50,000 per year.

Programmatic Involvement: TSGP funds will be awarded as cooperative agreements and will have substantial IHS programmatic involvement to establish a basic understanding of PSFAs and associated funding at the Service Unit, Area, and Headquarters levels.

The IHS roles and responsibilities will include:

- Providing a description of PSFAs and associated funding at all levels, including funding formulas and methodologies related to determining Tribal shares.
- Identifying IHS staff who will consult with applicants on methods currently used to manage and deliver health care.
- Providing applicants with statutes, regulations and policies that provide authority for administering IHS programs.

The grantee roles and responsibilities are critical to the success of the program and will include:

- Researching and analyzing the complex IHS budget, to gain a thorough understanding of funding distribution at all levels to determine which PSFAs the Tribe may elect to assume.
- Establishing a process by which Tribes can effectively approach the IHS to identify programs and associated funding which could be incorporated into their current programs.
- Determining the Tribe's share of each PSFA and evaluating the current level of health care services being provided to make an informed decision on new program assumption(s).

III. Eligibility Information

1. Eligible Applicants

To be eligible for a Planning Cooperative Agreement under this announcement, an applicant must meet all of the following criteria:

A. Be a federally-recognized Tribe as defined in Title V, Pub. L. 106–260, Tribal Self-Governance Amendments of 2000, of the Indian Self-Determination and Education Assistance Act (the Act), Pub. L. 93–638, as amended. However, Alaska Native Villages or Alaska Native Village Corporations are not eligible if they are located within the area served