

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Gastroenterology and Urology Devices Panel of the Medical Devices 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: Gastroenterology and Urology Devices Panel of the Medical Devices 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 June 8, 2005, from 9 a.m. to 5 p.m.

Location: Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Jeffrey Cooper, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1220, ext. 121, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512523. Please call the information Line for up-to-date information on this meeting.

Agenda: The committee will hear a presentation on the FDA Critical Path Initiative and a presentation by the Office of Surveillance and Biometrics in the Center for Devices and Radiological Health outlining their responsibility for the review of postmarket study design. The committee will also discuss and make recommendations regarding general issues related to the premarket requirements for the safe and effective use of hemodialysis equipment labeled for nocturnal hemodialysis therapies. Background information for the topics, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting, on the Internet at <http://www.fda.gov/cdrh/panelmtg.html>.

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 by May 25, 2005. Oral presentations from the public will be scheduled for approximately 30 minutes

at the beginning of committee deliberations and for approximately 30 minutes near the end of the deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person by May 25, 2005, 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.

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 AnnMarie Williams, Conference Management Staff, at 240-276-0450, ext. 113, at least 7 days in advance of the meeting.

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

Dated: April 28, 2005.

Sheila Dearybury Walcott,
Associate Commissioner for External Relations.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Tribal Management Grant Program; New Discretionary Funding Cycle for Fiscal Year 2006

Funding Opportunity Number: HHS-2006-IHS-TMP-0001.

CFDA Number: 93.228.

Key Dates: Training: May 23-27, 2005; June 15-16, 2005 June 29-30, 2005; and July 13-14, 2005.

Application Receipt Deadline: August 12, 2005.

Application Review Dates: October 3-7, 2005.

Application Notification: Second week of November 2005.

Anticipated Award Start Date: January 1, 2006.

Program Authority: Public Law 93-638, Sections 103(b)(2) and 103(e), Indian Self-Determination and Education Assistance Act, as amended.

I. Funding Opportunity Description

The Tribal Management Grant (TMG) Program is a national competitive

discretionary grant program established to assist Federally-recognized Tribes and Tribally-sanctioned Tribal organizations in assuming all or part of existing Indian Health Service (IHS) programs, services, functions, and activities (PSFA) through a Title I contract and to assist established Title I contractors and Title V compactors to further develop and improve their management capability. In addition, TMGs are available to Tribes/Tribal organizations under the authority of Public Law (Pub. L.) 93-638 section 103(e) for (1) obtaining technical assistance from providers designated by the Tribe/Tribal organization (including Tribes/Tribal organizations that operate mature contracts) for the purposes of program planning and evaluation, including the development of any management systems necessary for contract management and the development of cost allocation plans for indirect cost rates; and (2) planning, designing, and evaluating Federal health programs serving the Tribe/Tribal organization, including Federal administrative functions. These grants are established under the authority of section 103(b)(2) and section 103(e) of the Indian Self-Determination and Education Assistance Act, Pub. L. 93-638, as amended.

Funding Priorities: The IHS has established the following funding priorities for TMG awards. The funding of approved Priority I applicants will occur before the funding of approved Priority II applicants. Priority II applicants will be funded before approved Priority III applicant. Funds will be distributed until depleted.

- Priority I—Any Indian Tribe that has received Federal recognition (restored, untermiated, funded, or unfunded) within the past 5 years, specifically received during or after April 2000.
- Priority II—All other eligible Federally-recognized Indian Tribes or Tribally-sanctioned Tribal organizations submitting a competing continuation application or a new application with the sole purpose of addressing audit material weaknesses identified in Attachment A (Summary of Findings and Recommendations) and other attachments, if any, of the transmittal letter received from the Office of the Inspector General (OIG), National External Audit Review (NEAR) Center, Department of Health and Human Services (HHS). Please identify by underlining the weakness to be addressed on Attachment A. Please refer to Section III.3, "Other Requirements" for more information regarding Priority II participation.