

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20814 (Telephone Conference Call).

Contact Person: Jeannette L. Johnson, Ph.D., Scientific Review Officer, National Institutes on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301-402-7705, JOHNSONJ9@NIA.NIH.GOV.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: August 17, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Organization, Functions, and Delegations of Authority

Part G, Indian Health Service, Proposed Functional Statement

Office of Direct Service and Contracting Tribes (ODSCT) (GABI)

(1) Provides Agency leadership and advocacy for Direct Service Tribes (DST) in the development of health policy, program management, budget formulation and resource allocation and advises the IHS Director and senior management on DST issues and concerns; (2) provides Agency leadership concerning policy development and Agency functions and responsibilities associated with self-determination contracting (Title I of the Indian Self-Determination and Education Assistance Act, Public Law 93-638, as amended), monitors Agency compliance with self-determination policies, administrative procedures and guidelines, and advises the Director, IHS, and senior management on activities and issues related to self-determination contracting; (3) provides Agency leadership in the development of contract support cost (CSC) policy, and fulfills national operational responsibilities, with respect to the CSC program administered by IHS; (4) provides Agency leadership with respect to policy development and issues concerning new Federally recognized/restored Tribes; (5) administers a national statutorily mandated grant program designed to assist Tribes and Tribal organizations in beginning and/or expanding self-

determination activities; (6) serves as the principal liaison with DST Tribal leaders, the Direct Service Tribes Advisory Committee (DSTAC), national Indian or Tribal organizations, inter-Tribal consortiums, Area health boards, and Service Unit health boards; (7) coordinates quarterly DSTAC and annual DST meetings to provide a forum for DST Tribal leaders to express their concerns and primary issues relating to direct health care delivery by the IHS; (8) coordinates and facilitates meetings between Direct Service and Title I contracting Tribal delegations and the Office of the Director at Headquarters, during national meetings and at other locations as required; (9) maintains a central database of contact information for Tribal leaders, health directors, health programs, etc.; (10) assures that Indian Tribes and Tribal organizations are informed regarding pertinent health policy and program management issues and that consultation, with participation by Indian Tribes and Tribal organizations, occurs during the development of IHS policies and Agency decision making; (11) provides technical assistance and support to IHS Area Offices and to Tribes in administering health programs; and (12) participates in cross-cutting issues and processes including but not limited to emergency preparedness/security, budget formulation, self-determination issues, Tribal shares computations, and resolution of audit findings as needed.

This reorganization shall be effective on August 14, 2009.

Dated: August 13, 2009.

Yvette Roubideaux,

Director, Indian Health Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0352]

Prescription Drug User Fee Act IV Information Technology Assessment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: In the last decade, the Food and Drug Administration (FDA) has achieved great success in reforming and modernizing its regulatory processes and responsibilities as a result of changes and improvements driven by the requirements of the Prescription Drug User Fee Act (PDUFA), the 1997

FDA Modernization Act (FDAMA), and other legislation. PDUFA was reauthorized by the Food and Drug Administration Amendments Act of 2007, Title I, Prescription Drug User Fee Amendments of 2007 (PDUFA IV). FDA plans to make even greater progress during the PDUFA IV timeframe (Fiscal Years 2008 through 2012), building on the foundation established in previous years. The additional resources provided by user fees, when combined with appropriations, have enabled the FDA to modernize its information technology infrastructure and begin a monumental transformation from a paper-based to an electronic work environment.

As part of the PDUFA IV commitment, FDA published the PDUFA IV Information Technology (IT) Plan for comment to allow the public to provide feedback as FDA moves towards a fully electronic standards-based submission and review environment. FDA reviewed the comments, updated the plan, and published the updated version in June 2008 (73 FR 36880; June 30, 2008).

Under the PDUFA IV IT Plan an assessment of progress against the plan is conducted on an annual basis. The most recent report, which is available at <http://www.fda.gov/oc/pdufa/>, reflects the current assessment of the PDUFA IV IT Plan. The report contains four columns. The first three columns were previously published as part of the original plan. The last column, labeled "Current Status" provides details of the activities for each project assessed. The next assessment will be published in November 2009.

More information on the PDUFA program is available at <http://www.fda.gov/oc/pdufa/>.

DATES: Submit written or electronic comments on the assessment at any time. These comments will be considered as the agency makes annual updates to the plan each fiscal year.

ADDRESSES: Submit written requests for single copies of the IT Assessment to the Office of the Chief Information Officer (HFA-080), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the IT Assessment to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the assessment.