

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.

[FR Doc. E9-20156 Filed 8-20-09; 8:45 am]

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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.

[FR Doc. E9-20056 Filed 8-20-09; 8:45 am]

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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.

FOR FURTHER INFORMATION CONTACT: Gina Kiang, Office of the Chief Information Officer, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-255-6702

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of the IT Assessment entitled "Prescription Drug User Fee Act (PDUFA) IV Information Technology Assessment." This Assessment is intended to provide regulated industry and other stakeholders with information on FDA's progress toward the goals set out in the PDUFA IV IT Plan. As referenced in that plan published in May 2008, Section 7.2, B. Communications and Technical Interactions, 3.b., "FDA will conduct an annual assessment of progress against the IT plan and publish on the FDA Web site a summary of the assessment within 2 months after the close of each fiscal year."

II. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.regulations.gov> and at <http://www.fda.gov/oc/pdufa>.

III. 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: August 12, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9-20083 Filed 8-20-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number NIOSH-174]

Recent Coal Dust Particle Size Surveys and the Implications for Mine Explosions

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of draft publication available for public comment.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces the following draft Publication available for public comment entitled "Recent Coal Dust Particle Size Surveys and the Implications for Mine Explosions." The document and instructions for submitting comments can be found at <http://www.cdc.gov/niosh/review/public/174/default.html>.

Public Comment Period: Comment period from August 31, 2009 to September 30, 2009.

ADDRESSES: Written comments may be submitted to the NIOSH Docket Office, Robert A. Taft Laboratories, 4676 Columbia Parkway, MS-C34, Cincinnati, Ohio 45226. All material submitted to the NIOSH should reference docket number NIOSH-174 and must be submitted by September 30, 2009 to be considered by the Agency. All electronic comments should be formatted as Microsoft Word. In addition, comments may be sent via e-mail to nioshdocket@cdc.gov or by facsimile to (513) 533-8285. A complete electronic docket containing all comments submitted will be available on the NIOSH Web page at <http://www.cdc.gov/niosh/docket>, and comments will be available in writing by request. NIOSH includes all comments received without change in the electronic docket, including any personal information. All information received in response to this notice will be available for public examination and copying at the NIOSH Docket Office, Room 111, 4676 Columbia Parkway, Cincinnati, Ohio 45226, telephone (513) 533-8611.

Background: Spreading rock dust in bituminous coal mines is the primary means of reducing the explosion potential of coal dust that collects

during the normal workings of an active coal mine. Accordingly, guidelines have been established by the Mine Safety and Health Administration (MSHA) about the relative proportion of rock dust that needs to be present in both intake and return airways. Specifically, current MSHA regulations require that intake airways contain at least 65% incombustible content and return airways contain at least 80%. The higher limit for return airways was set in large part because fine "float" coal dust (100% < 200 mesh or 75 µm) tends to collect in these airways. MSHA inspectors routinely monitor rock dust inerting efforts by collecting dust samples and measuring the percentage of total incombustible content (TIC). These regulations were based on two important findings: a survey of coal dust particle size that was performed in the 1920s and large-scale explosion tests conducted in the U.S. Bureau of Mines' Bruceton Experimental Mine (BEM) using dust particles of that size range to determine the amount of inerting material required to prevent explosion propagation.

Mining technology and practices have changed considerably since the 1920s when the original coal dust particle survey was performed. Also, it has been shown conclusively that as the average size of coal dust particles decreases, the explosion hazard increases. Given these factors, the National Institute for Occupational Safety and Health (NIOSH) and MSHA conducted a joint survey to determine the range of coal particle sizes found in dust samples collected from intake and return airways of U.S. coal mines. Results from this survey show that the coal dust found in mines today is much finer than in mines of the 1920s, presumably due to increased automation and a greater reliance on mining machinery.

In light of this recent comprehensive dust survey, NIOSH conducted additional large-scale explosion tests at the Lake Lynn Experimental Mine (LLEM) to determine the degree of rock dusting necessary to abate explosions using Pittsburgh seam coal dust blended as 38% < 200 mesh and referred to as medium-sized dust. Explosion tests indicate that medium-sized coal dust required 76.4% TIC to prevent explosion propagation. Even the coarse coal dust (20% < 200 mesh or 75 µm) representative of samples obtained from mines in the 1920s required approximately 68% TIC to be rendered inert, a level higher than the current regulation of 65% TIC. In return airways, the particle size survey revealed that the average dust particle size is roughly the same as float coal