instrumentation for use in the mining industry. NIOSH worked with industry, labor, and the Mine Safety and Health Administration (MSHA) to develop and test a new type of instrument known as the Personal Dust Monitor (PDM). The PDM is designed to be an integral part of the cap lamp that miners normally carry to work and provides continuous information about the amount of respirable coal mine dust in the breathing zone of that individual. Laboratory testing was conducted to verify the instruments' accuracy, as received from the manufacturer, and after a period of underground use of the instruments. Under the broad range of test conditions the PDM provided equal or better functioning than the current coal mine dust sampler in terms of availability for use, accuracy, precision, and miner acceptance; while also providing real-time data to miners wearing the units.

We are seeking comment on the draft document, ''Laboratory and Field Performance of a Respirable Personal Dust Monitor,'' which is available at: *http://www.cdc.gov/niosh/review/public/dustmonitor/*.

If you would prefer to have a hard copy rather than electronic, please contact NIOSH at the address shown below and we will mail or fax a copy to you. Please submit your comment on this document to *nioshdocket@cdc.gov* or mail them to: NIOSH Mailstop: C–34, Robert A. Taft Lab., 4676 Columbia Parkway, Cincinnati, Ohio 45226.

The draft report will remain available for public comment until June 30, 2006. After that date, NIOSH will post the public comments received on the NIOSH Web site. NIOSH will review all of the comments submitted and make appropriate revisions to the draft document before the document is finalized.

FOR FURTHER INFORMATION CONTACT: Jon C. Volkwein, CDC/NIOSH, Respiratory Hazards Control Branch, 626 Cochrans Mill Rd., Pittsburgh, PA 15236. 412–386–6689.

Information requests can also be submitted by e-mail to *pdmcomments@cdc.gov*.

Dated: May 26, 2006.

John Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. E6–8652 Filed 6–2–06; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0183]

Guidance for Industry on Antiviral Product Development—Conducting and Submitting Virology Studies to the Agency; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Antiviral Product Development—Conducting and Submitting Virology Studies to the Agency.'' The purpose of this guidance is to assist sponsors in developing and submitting nonclinical and clinical virology data, which are important to support clinical trials of antiviral products. Nonclinical and clinical virology reports are essential components in the review of investigational antiviral products. The information in this guidance will facilitate the development of antiviral products.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, 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 guidance 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.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Lisa K. Naeger, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6367, Silver Spring, MD 20993–0002, 301–796–1500, or Julian O'Rear, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6368, Silver Spring, MD 20993–0002, 301–796–1500.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Antiviral Product Development—Conducting and Submitting Virology Studies to the Agency.'' The purpose of this guidance is to assist sponsors in the development of antiviral products and to serve as a starting point for understanding the nonclinical and clinical virology data important to support clinical trials of antiviral products. This guidance focuses on nonclinical and clinical virology studies, which are essential components in the review of investigational antiviral products. Topics in this guidance include studies defining the mechanism of action, establishing specific antiviral activity of the investigational product, assessing the potential for antagonism of other antiviral products that might be used in combination with the investigational product, providing data on the development of viral resistance to the investigational product, and providing data that identify cross-resistance to approved products having the same target.

The guidance announced in this document finalizes the draft guidance entitled ''Antiviral Drug Development—Conducting Virology Studies and Submitting the Data to the Agency'' that was announced in the **Federal Register** of May 25, 2005 (70 FR 30127). The sample formats that were included as appendixes in the draft guidance have been removed from the guidance and are now included as stand-alone documents. A fourth format for assisting sponsors in the submission of influenza data has been added. These sample formats will be updated as needed, and additional formats for other viruses may be provided.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on conducting virology studies and submitting the data and reports to the agency. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–

3520). The collections of information have been approved under OMB control number 0910–0014.

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. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: May 23, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–8635 Filed 6–2–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Office of Clinical and Preventive Services; Dental Preventive and Clinical Support Centers Program

Announcement Type: New Grant.

Funding Announcement Number: HHS–2006–IHS–TDCP–0001.

Catalog of Federal Domestic Assistance Numbers: 93.933.

Key Dates: Application Deadline Date: July 17, 2006, 5 p.m. EST;

Review Date: July 24, 2006;

Anticipated Award Announcement Date: July 31, 2006;

Anticipated Start Date: August 1, 2006.

I. Funding Opportunity Description

The Indian Health Service (IHS) Division of Oral Health (DOH) requests competitive applications for funding of Dental Preventive and Clinical Support Centers (DPCSC) through a grant process. This program is authorized under the authority of the 25 U.S.C. 13, Snyder Act, and the 25 U.S.C. 1602(B) (21–26), Indian Health Care Improvement Act, and Public Health Service Act, section 301 (a), as amended. This program is described at 93.933 in the Catalog of Federal Domestic Assistance.

Support centers will combine existing resources and infrastructure with IHS Headquarters (HQ) and IHS Area resources in order to address the broad challenges and opportunities associated with IHS preventive and clinical dental programs.

1. Centers will provide technical assistance and resources for local and Area clinic-based and community-based oral health promotion/disease prevention (HP/DP) initiatives.

2. Centers are strongly encouraged to provide technical assistance and resources for local and Area clinical programs.

3. Centers are encouraged to provide technical assistance and resources for regional and national preventive and clinical initiatives.

4. Centers will send one or more representatives to national support centers project meetings convened by IHS HQ DOH. Such meetings will be held no more than annually. All centers are expected to reserve sufficient funds in annual budgets to send a representative to these meetings.

5. Centers will promote the coordination of research, demonstration projects, and studies relating to the causes, diagnosis, treatment, control, and prevention of oral disease. This will be addressed through the collection, analysis, and dissemination of data, or other basic research methodology deemed appropriate by the grantee and the IHS.

II. Award Information

Type of Award: Grant.

Estimated Funds Available: The total amount to be awarded for the project period is a maximum of $750,000 for four years.

Anticipated Number of Awards: 3 or less.

Anticipated Project Period: August 1, 2006—July 31, 2010.

Award Amount: Maximum $250,000 per year, for each award. This amount is inclusive of direct and indirect costs. Awards under this announcement are subject to the availability of funds. Continuation awards will be issued annually based on satisfactory performance, availability of funding, and continuing needs of the IHS. Requests for funding greater than $250,000 per year will not be considered, and will not be entered into the review process. Applicants will be notified if the application does not meet the submission requirements.

The DOH through its Project Officer will:

1. Provide information pertinent to program planning, program evaluation, and the evolving needs of the IHS DOH upon request.

2. Provide feedback concerning biannual reports and performance.

3. Provide a template for biannual reports.

III. Eligibility Information

1. Eligible Applicants

A. Federally-recognized Indian Tribe;

B. Urban Indian Organizations as defined by 25 U.S.C. 1603(h); and

C. Tribal organizations as defined by 25 U.S.C. 1603(e).

All non-profit Tribal organizations must provide proof of non-profit status with the application. See IV.2 for additional information.

Eligible applicants must be located within the following Areas: Aberdeen, Bemidji, Billings, California, Navajo, Oklahoma, Phoenix, and Tucson. Existing support centers that do not terminate prior to 1 August 2006 are not eligible to apply for funding under this announcement.

While multiple submissions from the same Area or region will be reviewed, only one award will be made to any one Area or region. Organizations in the same Area are encouraged to share resources in order to produce one strong proposal, rather than competing with each other.

2. Cost Sharing or Matching

The Support Centers Project does not require matching funds or cost sharing.

IV. Application and Submission Information

1. Web Address for Application Package

Application package (HHS–2006–IHS–TDCP–0001) may be found in Grants.gov.

Information regarding the electronic application process may be obtained from the following person: Michelle G. Bulls, Grants Policy Officer, Grants Policy Staff, Office of Management Support. (301) 443–6528, Direct line. (301) 443–2510, Fax. *E-mail: michelle.bulls@ihs.gov.*

Information regarding the Support Centers project may be obtained from the Project Official: Dr. Patrick Blahut, Division of Oral Health, HIS, 801 Thompson Ave, Suite 300, Rockville, MD, 20852. (301) 443–4323.

2. Content and Form of Application Submission if Prior Approval was Obtained for Paper Submission

A. Single spaced.

B. Typewritten.

C. Consecutively numbered pages.