“NIOSH Safety and Health Topic: Chest Radiography”

Notice: The National Institute for Occupational Safety and Health (NIOSH), acting on behalf of the Secretary of Health and Human Services (HHS), is responsible for prescribing the manner in which radiographs are read and classified for the chest x-ray program available to coal miners under the Federal Mine Safety and Health Act, 30 U.S.C. 843; 42 CFR part 37. In carrying out this responsibility, NIOSH issues B Reader certifications to physicians who demonstrate proficiency in the classification of chest radiographs for the pneumoconioses using the International Labour Office (ILO) Classification System. NIOSH uses these B Reader certifications to classify chest radiographs for the presence and severity of pulmonary parenchymal and pleural changes potentially caused by exposure to dusts such as asbestos, silica, and coal mine dust. NIOSH requested comments on its previous draft Web pages: “Recommendations for Applying the International Labour Office (ILO) International Classification of Radiographs of Pneumoconioses in Medical Diagnosis, Research and Population Surveillance, Worker Health Monitoring, Government Program Eligibility, and Compensation Settings” and “Ethical Considerations for B Readers” [Federal Register, Vol. 70, No. 221 (Thursday, November 17, 2005/Notices at 69765–6)]. Based on the comments it received, NIOSH has developed a revised and expanded Web site that includes materials from those web pages and provides more information about radiographic reading and the ILO system, including recommendations for use of the ILO system in different settings. We are specifically seeking public comment for the draft revised Web site:

“NIOSH Safety and Health Topic: Chest Radiography”

We are particularly interested in receiving public comment on the following Web page and associated pages located within the larger Web site: “Recommended Practices for Reliable Classification of Chest Radiographs by B Readers.”

The Web site “NIOSH Safety and Health Topic: Chest Radiography” can be found at http://www.cdc.gov/niosh/topics/chestradiography/.

Please review and submit your comments on this document to nioshdocket@cdc.gov. If you would prefer to have a hard copy rather than electronic, please contact NIOSH at this same e-mail address, and we will be happy to fax or mail copies of the documents to you.

The documents will remain available for comment until October 1, 2006. After that date, NIOSH will consider all the comments submitted and make appropriate revisions to the document before posting a final version on its Web site.

FOR FURTHER INFORMATION CONTACT:
David N. Weissman, MD, CDC/NIOSH, Division of Respiratory Disease Studies, Mailstop H—2900, 1095 Willowdale Road, Morgantown, WV 26505, 304–285–5749.

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


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

[FR Doc. E6–8653 Filed 6–2–06; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Public Input Opportunity

AGENCY: Centers for Disease Control and Prevention (CDC). Department of Health and Human Services (HHS).

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces the following:

Availability of opportunity for the Public to Provide Input on a proposed Web based document:

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The documents will remain available for comment until October 1, 2006. After that date, NIOSH will consider all the comments submitted and make appropriate revisions to the document before posting a final version on its Web site.

FOR FURTHER INFORMATION CONTACT:
David N. Weissman, MD, CDC/NIOSH, Division of Respiratory Disease Studies, Mailstop H—2900, 1095 Willowdale Road, Morgantown, WV 26505, 304–285–5749.

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

[FR Doc. E6–8653 Filed 6–2–06; 8:45 am]

BILLING CODE 4163–19–P
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 below. Please submit your comments to NIOSH at the address shown below and we will mail or fax a copy to you. Submit written comments on the draft 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 Cochran 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]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
[Notice 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, 5600 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.


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 appendices 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–