

- Which audiences (*e.g.*, doctors, local health officials, researchers, etc.) receive their information from which CDC platforms?

- How often and with what purpose do they access CDC platforms?

- How satisfied are subscribers of the platforms with the content and delivery of information?

- Are there ways to enhance the platforms for the subscriber through improvements to current offerings or through new products / services?

- Who are our most critical target audiences, *i.e.*, what are our publication and dissemination priorities in service to our health impact goals?

The purpose of this project is to evaluate the content, processes, and

channels through which CDC communicates scientific information to partners and customers to ensure that health impact is maximized through the delivery of timely, effective, and credible information, which will result in optimal benefit for public health. The evaluation will help to ensure that these platforms meet subscriber and partner priorities, build CDC's brand, and contribute to health impact goals. Feedback from the subscriber base is necessary to fully evaluate the performance of CDC's platforms.

At this time, the scope of this project is limited to five communication platforms owned and managed by CDC which transmits information primarily

intended for scientific and professional audiences. However, future plans include adding additional publications as needed. The initial five communications platforms are: Emerging Infections Journal, MMWR, Epi-X, Preventing Chronic Diseases Journal, and Health Alert Network. We want to ensure that the timeliness, effectiveness, and credibility of this communication maximizes the health impact of that information, resulting in optimum benefit for public health. These channels include both print and electronic versions of the five platforms. There is no cost to respondents other than their time. The total estimated burden hours are 18,970.

ESTIMATES OF ANNUALIZED BURDEN HOURS

Form	Respondents	Responses per respondent	Hrs/response (in hrs)
MMWR	30,000	1	20/60
EID	12,750	1	20/60
PCD	10,500	1	20/60
Epi-X	1,650	1	20/60
HAN	2,000	1	20/60

Dated: August 18, 2005.

Joan F. Karr,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-05-05AF]

Proposed Data Collections Submitted for Public Comment and Recommendations

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 371-5983 or send an e-mail to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395-6974. Written comments should be received within 30 days of this notice.

Proposed Project

How Miners Modify Their Behavior In Response To Personal Dust Monitor Information—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Federal Mine Safety & Health Act of 1977, Section 501, and the Occupational Safety and Health Act of 1970, Public Law 91-256 enables CDC/NIOSH to carry out research relevant to the health and safety of workers in the mining industry. The objective of this project is to document how coal miners can use real-time information from their personal dust monitors (PDM) to reduce their exposure to respirable dust. The specific aims are to (1) identify several specific examples of how miners use PDM information to discover which parts of their jobs and/or which aspects of their work environment may be causing them to be overexposed to respirable dust, and (2) identify the types of changes that miners could make in order to try to reduce their exposure. Although the most recent data on the prevalence of Coal Workers' Pneumoconiosis (CWP) in the United States indicates that it is declining, substantial numbers of CWP cases continue to be diagnosed. In recent years, CWP has contributed to the

deaths of approximately 1,000 people in the U.S. each year.

A personal dust monitor (PDM) has recently been developed through a collaboration involving NIOSH, the Bituminous Coal Operators' Association, the United Mine Workers of America, the National Mining Association, and Rupprecht & Patashnick Co., Inc. This new device represents a major advance in the tools available for assessing coal miners' exposure to respirable dust levels. It will soon be field tested with coal miners throughout the U.S. As with the introduction of any new technology, it is very important to systematically document how workers react to it and make use of it. If miners know how to properly use the information PDMs are capable of providing, they should be able to make adjustments to their work place or work procedures that will reduce their exposure to respirable coal dust.

Various parties have speculated about the processes by which miners will use the information to reduce their exposure to respirable dust. There appears to be great potential. However, no one knows precisely how miners performing a wide variety of tasks and jobs are actually going to use this new information to reduce their exposure to dust. It is assumed that, once PDMs are introduced, miners will eventually find new ways to reduce their exposure to

dust. Once these discoveries are made, they need to be documented and shared throughout the industry.

The diffusion of this innovation will occur much more rapidly and efficiently if this proposed study takes place. Effective strategies for using PDM information will be well documented and quickly shared throughout the coal industry. The alternative is to wait for the miners at each of the 482 actively

producing coal mines in the U.S. to go through their own trial and error process of discovering how PDMs can and cannot be used to reduce dust exposure. The proposed study will help to significantly reduce the incidence of lung disease among coal miners, leading to improvements in their longevity and quality of life.

The information for this study will be collected by conducting one-on-one

structured interviews with approximately 20 miners at each of 5 mines located throughout the major coal producing regions of the U.S.

This survey will last 2 years. There will be no cost to respondents except their time to participate. The total estimated annualized burden hours are 25.

ESTIMATE OF ANNUALIZED BURDEN TABLE

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Coal Miners	50	1	30/60

Dated: August 18, 2005.

Joan F. Karr,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0296]

Agency Information Collection Activities; Proposed Collection; Comment Request; Financial Disclosure by Clinical Investigators

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information requiring the sponsor of any drug, biologic, or device marketing application to certify to the absence of clinical investigators and/or disclose those financial interests as required, when covered clinical studies are submitted to FDA in support of product marketing.

DATES: Submit written or electronic comments on the collection of information by October 24, 2005.

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether

the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Financial Disclosure by Clinical Investigators (OMB Control Number 0910-0396)—Extension

Respondents are sponsors of marketing applications that contain clinical data from studies covered by the regulations. These sponsors represent pharmaceutical, biologic and medical device firms. The applicant will incur reporting costs in order to comply with the final rule. Applicants will be required to submit, for example, the complete list of clinical investigators for each covered study, not employed by the applicant and/or sponsor of the covered study, and either certify to the absence of certain financial arrangements with clinical investigators or disclose the nature of those arrangements to FDA and the steps taken by the applicant or sponsor to minimize the potential for bias. The clinical investigator will have to supply information regarding financial interests or payments held in the sponsor of the covered study. FDA has said that it has no preference as to how this information is collected from investigators and that sponsors/applicants have the flexibility to collect the information in the most efficient and least burdensome manner that will be effective. FDA estimated