45 CFR section/IHS form	Number of respondents	Responses per respondent	Burden per response* (mins)	Total annual burden
Total Annual Burden		5		174,375

*For ease of understanding, burden hours are provided in actual minutes.

The total estimated burden for this collection of information is 174,375 hours.

There are no capital costs, operating costs and/or maintenance costs to respondents.

Request for Comments: Your written comments and/or suggestions are invited on one or more of the following points: (a) Whether the information collection activity is necessary to carry out an agency function; (b) whether the agency processes the information collected in a useful and timely fashion; (c) the accuracy of public burden estimate (the estimated amount of time needed for individual respondents to provide the requested information); (d) whether the methodology and assumptions used to determine the estimate are logical; (e) ways to enhance the quality, utility, and clarity of the information being collected; and (f) ways to minimize the public burden through the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Send Comments and Requests for Further Information: Send your written comments and requests for more information on the proposed collection or requests to obtain a copy of the data collection instrument(s) and instructions to: Ms. Betty Gould, Acting IHS Reports Clearance Officer, 801 Thompson Avenue, TMP, Suite 450, Rockville, MD 20852, call non-toll free (301) 443–7899, send via facsimile to (301) 443–9879, or send your e-mail requests, comments, and return address to: *betty.gould@ihs.gov*.

Comment Due Date: Your comments regarding this information collection are best assured of having full effect if received within 60 days of the date of this publication.

Dated: June 17, 2009.

Robert G. McSwain,

Deputy Director for Management Operations, Indian Health Service.

[FR Doc. E9–14841 Filed 6–23–09; 8:45 am]

BILLING CODE 4165–16–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–09–09BW]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–5960 and send comments to Maryam I. Daneshvar, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov.*

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Postural Analysis in Low-Seam Mines—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

NIOSH, under Public Law 91–596, sections 20 and 22 (section 20–22, Occupational Safety and Health Act of 1970) has the responsibility to conduct research relating to innovative methods, techniques, and approaches dealing with occupational safety and health problems.

According to the Mining Safety and Health Administration (MSHA) injury database, 227 knee injuries were reported in underground coal mining in 2007. With data from the National Institute for Occupational Safety and Health (NIOSH), it can be estimated that the financial burden of knee injuries was nearly three million dollars in 2007.

Typically, mine workers utilize kneepads to better distribute the pressures at the knee. The effectiveness of these kneepads is to be investigated in a study by NIOSH. Thus, NIOSH will be determining the forces, stresses, and moments at the knee while in postures associated with low-seam mining. At this time, the postures utilized by low-seam mine workers and their frequency of use are unknown. Therefore, before conducting this larger, experimental study, the proposed field study must be conducted.

The aim of the proposed field study is to determine the postures predominantly used by low-seam mine workers such that they may complete the various tasks associated with their job duties. A questionnaire was developed for each of the major job types seen in low-seam mines with continuous miners (continuous miner operator, roof bolter operator, shuttle car operator, mobile bridge operator, mechanic, beltman, maintenance shift worker, foreman). The questionnaire asks basic demographic information (*e.g.,* time in job type, years in mining, age). Additionally, a series of questions are asked such that it may be determined if a mine worker is likely to have a knee injury, even if it is undiagnosed. These questions were developed with the help of a physical therapist. A schematic of possible postures will then be presented to the mine workers and they will be asked to identify the primary two postures they utilize to complete their job duties. The questionnaire then asks mine workers to identify the primary postures they utilize to complete specific tasks (*e.g.,* hanging curtain, building stoppings) that are part of their job duties. Finally, mine workers are asked to identify those postures that are least and most comfortable/stressful. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Continuous Miner Operator	Continuous Miner Operator Form	5	1	10/60	1
Foreman	Foreman Form	5	1	10/60	1
Maintenance Shift Worker	Maintenance Shift Worker Form	10	1	10/60	2
Mobile Bridge Operator	Mobile Bridge Operator Form	10	1	10/60	2
Roof Bolter Operator	Roof Bolter Operator Form	14	1	10/60	2
Scoop Operator	Scoop Operator Form	6	1	10/60	1
Shuttle Car Operator	Shuttle Car Operator Form	6	1	10/60	1
Mechanic	Mechanic Form	6	1	10/60	1
Beltman	Beltman Form	2	1	10/60	0.5
Total					12

Dated: June 11, 2009.

Maryam I. Daneshvar,

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

[FR Doc. E9–14834 Filed 6–23–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0275]

Convener of Active Medical Product Surveillance Discussion (U13)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of a neutral, independent institution and/or organization that proposes appropriate methods and processes for convening a broad range of stakeholders with relevant expertise to manage and support conferences and meetings. The focus of the conferences and meetings is to explore and address methodological, data development, technical, and communication issues related to active medical product surveillance. The awardee would be expected to synthesize, summarize, and communicate findings from these conferences and meetings to a broad range of organizations and individuals who have the capability to use the information to further develop and create active medical product surveillance methods and systems.

DATES: The application due date is July 15, 2009. The earliest start date is in September 2009.

FOR FURTHER INFORMATION AND ADDITIONAL REQUIREMENTS CONTACT:

Programmatic/Peer Review Contact: Melissa Robb, Office of Critical Path Programs, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, rm. 14B–45, Rockville, MD 20857, 301–827–1516, e-mail: *melissa.robb@fda.hhs.gov*.

Financial or Grants Management Contact: Gladys M. Bohler, Office of Acquisitions and Grant Services, Food and Drug Administration, 5630 Fishers Lane, rm. 2105, Rockville, MD 20857, 301–827–7168, FAX: 301–827–7101, e-mail: *gladys.bohler@fda.hhs.gov*.

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at *http://www.fda.gov/Safety/FDAsSentinelInitiative/ucm149345.htm*.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

Request for Applications (RFA) Number: RFA–FD09–012

Catalog of Federal Domestic Assistance Number: 93.103

A. Background

In 2007, Congress enacted the Food and Drug Administration Amendments Act of 2007 (FDAAA). Section 905 of this statute calls for the Secretary of Health and Human Services (the Secretary) to develop methods to obtain access to disparate data sources and to establish an active postmarket risk identification and analysis system that links and analyzes safety data from multiple sources. The law sets a goal of access to data from 25 million patients by July 1, 2010, and 100 million patients by July 1, 2012. The law also requires FDA to work closely with partners from public, academic, and private entities.

In May 2008, the Secretary and the Commissioner of Food and Drugs announced the launch of the Sentinel Initiative, a long-term effort to create a national electronic system for monitoring regulated product safety. Once implemented, the Sentinel System is intended to augment FDA's existing postmarket (primarily passive) safety surveillance systems and to enable FDA to actively gather information about the postmarket safety and performance of its regulated products. FDA views its Sentinel Initiative as a mechanism through which some of the requirements mandated in FDAAA can be carried out.

As currently envisioned, the Sentinel System will enable FDA to capitalize on the capabilities of multiple, existing automated healthcare data systems (e.g. electronic health record systems, administrative claims databases, registries). The Sentinel System will enable queries of disparate data sources quickly and securely for relevant regulated product safety information. Data will continue to be managed by its owners, and only data of organizations who agree to participate in this system will be involved. FDA questions would be sent to appropriate, participating data holders, who would, in accordance with existing privacy and security safeguards, evaluate their data and send results summaries to FDA for review.

Following announcement of the Sentinel Initiative in May 2008, FDA's first step has been to create a broad public forum for discussion of issues related to developing and implementing the Sentinel System. During 2008, FDA sponsored a series of exploratory meetings with a broad variety of stakeholders to identify key issues that will need to be addressed before, during, and after implementation of the Sentinel System. Key questions include, for example, what level of collaboration between public and private entities would best ensure the success of the initiative; how a possible governance model could be identified and developed; what kind of methods and tools will be needed to facilitate the