regulations, ACF requests extension of the ACF–800. With this extension, ACF is proposing several changes and clarifications to the reporting requirements and instructions.

Respondents: States, the District of Columbia, and Territories including Puerto Rico, Guam, the Virgin Islands, American Samoa, and the Northern Marianna Islands.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF–800	56	1	40	2,240

Estimated Total Annual Burden Hours: 2,240

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, *Fax:* 202–395–7245, Attn: Desk Officer for the Administration for Children and Families.

Dated: September 1, 2009.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. E9–21410 Filed 9–3–09; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0098]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Evaluation of Potential Data Sources for the Sentinel Initiative

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by October 5, 2009.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–NEW and title, ''Evaluation of Potential Data Sources for the Sentinel Initiative.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794, *JonnaLynn.Capezzuto@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Evaluation of Potential Data Sources for the Sentinel Initiative

In September 2005, the Secretary of Health and Human Services (the Secretary) asked FDA to expand its current system for monitoring medical product performance. The Secretary asked FDA to explore the possibility of working in collaboration with multiple healthcare data systems to augment FDA's capability of identifying and evaluating product safety information beyond its existing voluntary reporting systems. Such a step would strengthen FDA's ability, ultimately, to monitor the performance of a product after marketing approval. The Secretary recommended that FDA explore creating a public-private collaboration as a framework for such an effort leveraging increasingly available large, electronic healthcare databases and taking advantage of emerging technologies and building on existing systems and efforts, rather than creating new systems.

In 2006, the Institute of Medicine (IOM) issued a report entitled ''The Future of Drug Safety—Promoting and Protecting the Health of the Public.''[1] Among other suggestions, this IOM report recommended FDA identify ways to access other health-related databases and create a public-private partnership to support safety and efficacy studies.

In 2007, Congress enacted the Food and Drug Administration Amendments Act of 2007[2] (FDAAA). Section 905 of FDAAA calls for 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 healthcare 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. FDA views the Sentinel Initiative as a mechanism through which this mandate can be carried out.

Consistent with FDA's mission to protect and promote the public health, FDA is embarking on the Sentinel Initiative to create a national, electronic distributed system, strengthening FDA's ability to monitor the post-market performance of a product. As currently envisioned, the Sentinel Initiative will enable FDA to capitalize on the capabilities of multiple, existing data systems (e.g. electronic health record systems and medical claims databases)

[1] Institute of Medicine, ''The Future of Drug Safety—Promoting and Protecting the Health of the Public,'' September 22, 2006, *http://www.iom.edu/* . (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

[2] Food and Drug Administration Amendments Act of 2007, Public Law 110–85, was signed into law in September 2007. See Title IX, Section 905.

to augment the agency's current surveillance capabilities. The proposed system will enable queries of distributed data sources quickly and securely for relevant 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 included. Operations will adhere to strict privacy and security safeguards.

The success of this Initiative will depend largely on the content, quality, searchability, and responsiveness of participating data sources and/or data environments. It is essential that FDA understand the strengths and limitations of potential data sources that might be included in the Sentinel Initiative. This survey will be used to collect information from potentially participating data sources and/or environments. The data we are seeking will describe the characteristics of the data available, not personally identifiable information. The findings will help FDA plan for this proposed system and for future work related to the Sentinel Initiative.

This survey will collect information on the scope, content, structure, quality, and timeliness of data; patient population(s), duration of followup, and capture of care across all settings; availability, experience, and interest of investigators with knowledge of the data in using it for post-market product safety surveillance as well as plans for further data source enhancements; availability, experience, and interest of investigators with knowledge of the data in participating in a distributed data system; and barriers that exist to including each data source in the Sentinel Initiative.

In the **Federal Register** of March 9, 2009 (74 FR 10053), FDA published a 60-day notice requesting public comment on the information collection provisions to which one comment was received but was outside the scope of the PRA.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Data Source and/or Environment Survey	250	1	250	24.5	6,125

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates that approximately 250 respondents will participate in this voluntary survey. These respondents will consist mostly of other Federal agencies, health plan data sources, health information exchanges, large multi-specialty medical groups and academic medical centers, large hospital systems, pharmacies, medical societies, consumer-oriented Web sites, commercial data sets, research networks, lab data, and registries.

Each respondent will extend approximately 24.5 hours to complete one survey for a total of 6,125 hours (250 x 1 x 24.5 = 6,125).

Dated: August 27, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–21364 Filed 9–3–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–09–09BW]

Agency Forms Undergoing Paperwork Reduction Act Review

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) 639–5960 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) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Postural Analysis in Low-Seam Mines—Existing collection without an OMB control number—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 existing collection without an OMB control number was required.

The aim of the field study described in this document was 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 asked basic demographic information (*e.g.*, time in job type, years in mining, age). Additionally, a series of questions were asked such that it could 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 was then presented to the mine workers and they were asked to identify the primary two postures they utilize to complete their job duties. The questionnaire then asked 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,