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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-06-0463]

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) 639-4766 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

Longitudinal Surveillance for Beryllium Disease Prevention—0920-0463—Extension—National Institute for Occupational Safety and Health (NIOSH)—Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The mission of the National Institute for Occupational Safety and Health (NIOSH) is to promote safety and health at work for all people through research and prevention. The Occupational

Safety and Health Act, Public Law 91-596 (section 20[a][1]) authorizes the National Institute for Occupational Safety and Health (NIOSH) to conduct research to advance the health and safety of workers. NIOSH is conducting a study of beryllium workers. Beryllium is a lightweight metal with many applications. Exposed workers may be found in the primary production, nuclear power and weapons, aerospace, scrap metal reclamation, specialty ceramics, and electronics industries, among others. The size of the U.S. workforce at risk of chronic beryllium disease (CBD), from either current or past work-related exposure to the metal, may be as high as one million. Demand for beryllium is growing worldwide, which means that increasing numbers of workers are likely to be exposed.

CBD is a chronic granulomatous lung disease mediated through an immunologic mechanism in workers who become sensitized to the metal. Sensitization can be detected with a blood test called the beryllium lymphocyte proliferation test (BeLPT), which is used by the industry as a surveillance tool. Use of this test for surveillance was first reported in 1989. Sensitized workers, identified through workplace surveillance programs, undergo clinical diagnostic tests to determine whether they have CBD. Research has indicated certain genetic determinants in the risk of CBD; follow-up studies will be invaluable for further characterizing the genetic contribution to sensitization and disease.

NIOSH is in a unique position to accomplish this research for a number of reasons: (a) It has a successful collaboration with the leading manufacturer of beryllium in the US. This has allowed us to establish well-characterized worker cohorts within the

beryllium industry. (b) It is conducting industrial hygiene research that should significantly improve workplace-based exposure assessment methods. This research will allow characterization of jobs and tasks by physicochemical characteristics, leading to an estimation of dose rather than mass concentration-based exposure. (c) It has pioneered the evaluation of the dermal exposure route in the beryllium sensitization process. (d) It has developed and improved genetic research that will contribute to the understanding of risk variability in sensitization and disease, as well as discerning the underlying mechanisms. (e) NIOSH has the institutional stability to continue longitudinal evaluations of health outcomes in relation to exposure and genetic risk factors.

NIOSH has been conducting this survey of beryllium workers for three years and this extension will allow for completion of the data collection on former workers. Workers are asked to complete an interviewer administered medical and work history questionnaire and to give a blood sample. Without medical and work history data on former workers, NIOSH staff will be unable to conduct the necessary research to make recommendations for preventing beryllium sensitization and disease. Follow-up on this cohort will provide invaluable information on the natural history of disease, gene-gene, and gene-environment interactions, which can become the basis for prevention policy at both company and government levels.

There are no costs to the respondents other than their time. The only change to this previously approved project is a decrease in the burden hours because the proposed data collection is almost complete. The total estimated annualized burden hours are 50.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Former Workers	100	1	30/60

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0443]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Focus Groups as Used by the Food and Drug Administration

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 March 29, 2006.

ADDRESSES: OMB is still experiencing significant delays in the regular mail,

including first class and express mail, and messenger deliveries are not being accepted. 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: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

FOR FURTHER INFORMATION CONTACT:

Jonna Capezzuto, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

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.

Focus Groups as Used by the Food and Drug Administration—(OMB Control Number 0910-0497)—Extension

FDA will collect and use information gathered through the focus group vehicle. This information will be used to develop programmatic proposals, and as such, compliments other important research findings to develop these proposals. Focus groups do provide an important role in gathering information because they allow for a more in-depth understanding of consumers' attitudes, beliefs, motivations, and feelings than do quantitative studies.

Also, information from these focus groups will be used to develop policy

and redirect resources, when necessary, to our constituents. If this information is not collected, a vital link in information gathering by FDA to develop policy and programmatic proposals will be missed causing further delays in policy and program development.

In the **Federal Register** of November 25, 2005 (FR 70 71165), FDA published a 60-day notice requesting public comment on the information collection provisions. FDA received one comment, however it was not related to the information collection.

Annually, FDA projects about 28 focus group studies using 286 focus groups lasting an average of 1.78 hours each. FDA has allowed burden for unplanned focus groups to be completed so as not to restrict the agency's ability to gather information on public sentiment for its proposals in its regulatory as well as other programs. To arrive at each center's estimated burden we multiplied the number of focus groups per study by the number of participants per group. (e.g., Center for Biologics Evaluation and Research (CBER): 5x9=45). We multiplied that total by the hours of duration for each group to arrive at the total burden hours. (e.g., CBER: 45x1.58=71.1).

The total annual estimated burden imposed by this collection of information is 4,252 hours annually.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

FDA Center	Subject	No. of Focus Groups per Study	No. of Focus Groups Sessions Conducted Annually	No. of Participants per Group	Hours of Duration for Each Group (Includes Screening)	Total Hours
Center for Biologics Evaluation and Research	May use focus groups when appropriate	1	5	9	1.58	71
Center for Drug Evaluation and Research	Varies (e.g., direct-to-consumer Rx drug promotion, physician labeling of Rx drugs, medication guides, over-the-counter drug labeling, risk communication)	10	200	9	1.58	2,844
Center for Devices and Radiological Health	Varies (e.g., FDA Seal of Approval, patient labeling, tampons, on-line sales of medical products, latex gloves)	4	16	9	2.08	300
Center for Food Safety and Applied Nutrition	Varies (e.g., food safety, nutrition, dietary supplements, and consumer education)	8	40	9	1.58	569
Center for Veterinary Medicine	Varies (e.g., animal nutrition, supplements, labeling of animal Rx)	5	25	9	2.08	468