

risk behaviors, changes in behavior, and incidence of HIV infection.

In 1987, OMB approved the "Family of HIV Seroprevalence Surveys" (0920-0232). These surveys included seven seroprevalence surveys that involved interaction with individuals (non-blinded surveys). One of these surveys was the surveillance and evaluation of blood donors.

The objectives of this study are to: (1) Estimate the prevalence and incidence of HIV infection among blood donors at participating blood centers; (2) evaluate the characteristics of infected donors to strengthen the effectiveness of the donor

screening and deferral processes; (3) analyze the risk behavior characteristics of infected donors to assess distribution and trends of HIV; (4) monitor additional human immunodeficiency viruses, HIV genetic variation, and other infections relevant to the epidemiology of HIV among U.S. blood donors and seroconverted recipients; (5) estimate the risk of HIV transmission from screened blood; (6) and evaluate new tests to decrease transmission by window period donors.

In 1993 and 1996, OMB again approved for 3 years each, the surveillance and evaluation of blood

donors who test positive for Human Immunodeficiency Virus (HIV) Antibody and their needle-sharing and sexual partners (0920-0329). This request is for an additional 3-year approval. The CDC anticipates 125 positive donors will enroll annually in this study (based upon previous 3 year enrollment rates and epidemiological progress of the disease). The interview takes approximately 1 hour to complete for those who agree to the interview and 10 minutes to complete for those who refuse to enroll. The total cost to the respondent is \$8,206.19 over the 3-year period.

Respondents	Number of respondents	Number of responses/Respondent	Avg. burden response (in hours)	Total burden (in hours)
Blood donors (interviewed)	375	1	1.0	375
Blood donors (refuse interview)	275	1	0.16	44
Total	419.00

Dated: October 14, 1999.

Nancy Cheal,

Acting Associate Director for Policy, Planning, and Evaluation, Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY-00-04]

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) 639-7090. Send written comments to CDC, Desk Officer; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Project

Gene-Environment Interactions in Beryllium Sensitization and Disease Among Current and Former Beryllium Industry Workers—NEW—National Institute for Occupational Safety and Health (NIOSH). Beryllium is a light weight metal with wide application in

modern technology. The size of the U.S.A. Workforce at risk of beryllium exposure is estimated at approximately 30,000, with exposed workers in primary production, nuclear power and weapons, aerospace, scrap metal reclaiming, specialty ceramics, and electronics industries. Demand for beryllium is growing worldwide, which means that increasing numbers of workers are likely to be exposed. An acute pneumonitis due to occupational exposure to beryllium was common in the 1940s and 1950s, but has virtually disappeared with improvements in work-site control measures. Even with the improved controls, as many as 5% of currently-exposed workers will develop chronic beryllium disease (CBD).

CBD is a chronic granulomatous lung disease mediated through a poorly understood immunologic mechanism in workers who become sensitized. Sensitization can be detected using a blood test, that is used by the industry as a screening tool. The screening test for sensitization was first reported in 1989, but many questions remain about the natural history of sensitization and disease, as well as exposure risk factors. Sensitized workers, identified through workplace screening programs, undergo clinical diagnostic tests to determine whether they have CBD. The proportion of sensitized workers who have beryllium disease at initial clinical evaluation has varied from 41-100% in different workplaces. Sensitized workers often develop CBD with follow-up, but whether all sensitized workers will eventually develop beryllium

disease is unknown. Early diagnosis at the subclinical stage and careful follow-up seems prudent in that CBD usually responds to corticosteroid treatment. However, the efficacy of screening in preventing adverse outcomes of the disease has not yet been evaluated. While recent research has suggested that a genetic determinant of the immune response could be a susceptibility factor, this has not been well characterized.

The National Institute of Occupational Safety and Health (NIOSH) wants to determine how beryllium workers and former workers develop beryllium disease and how to prevent it. Through the proposed study, NIOSH has the opportunity to contribute to the scientific understanding of this disease in the context of environmental and genetic etiologic factors. The goals of this investigation are to: (1) determine the incidence of beryllium sensitization or disease over a 6-year period; (2) seek an association with exposure measurements; (3) identify a genetic determinant of susceptibility to CBD; and (4) characterize that genetic determinant to ascertain if it is associated with clinical impairment or progression of disease. Through a greater understanding of the environmental and genetic risk factors associated with the onset and progression of CBD, NIOSH will be able to develop strategies for both primary and secondary prevention applicable to beryllium-exposed workers. The total annual burden hours are 250.

Respondents	Number of respondents	Responses per respondent	Hours per response (in hrs.)
Former Workers	s60,175	1	0.5

Dated: October 13, 1999.

Nancy Cheal,

*Acting Associate Director for Policy,
Planning, and Evaluation, Centers for Disease
Control and Prevention (CDC)*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request Proposed Project.

Title: Federal Parent Locator Service.
OMB No.: 0970-0142.

Description: The Federal Parent Locator Service is a computerized national location network which provides address and social security number information to State and local child support enforcement agencies

upon request for purposes of locating parents to establish parentage or establish or enforcement a child support order and to assist authorized persons in resolving parental kidnapping and child custody and visitation issues. As such, the FPLS services as a conduct between child support enforcement offices and Federal and State agencies by conducting weekly, biweekly, or monthly matches of the collected information with various agencies and distributing the information back to the requesting State or local child support office.

Respondents: State, Local or Tribal Govt.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
FPLS	200	24	1	4,800

Estimated Total Annual Burden Hours: 4,800.

In Compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, 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.

The Department specifically requests comments 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) 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.

Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: October 15, 1999.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 99-27437 Filed 10-20-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-4202]

Agency Information Collection Activities; Proposed Collection; Comment Request; Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use—Form FDA 356h

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 the application form, Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use, Form FDA 356h, and a related regulation. This form applies to a wide range of products for human use that are regulated by both the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER) including drugs and biologics.

DATES: Submit written comments on the collection of information by December 20, 1999.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (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: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA-250), Food and Drug