construction, repair, and alteration or lease contracts.

**DATES:** December 23, 1997.

**ADDRESSES:** Send comments to Edward Springer, GSA Desk Officer, Room 3235, NEOB, Washington, DC 20503, and to Marjorie Ashby, General Services Administration (MVP), 18th and F Streets, NW, Washington, DC 20405.

*Annual Reporting Burden:* Respondents: 1350; annual responses: 1; average hours per response: 12; burden hours: 16,200.

**FOR FURTHER INFORMATION CONTACT:** Al Matera, Office of GSA Acquisition Policy (202) 501–1224.

*Copy of Proposal:* A copy of this proposal may be obtained from the GSA Acquisition Policy Division (MVP), Room 4011, GSA Building, 18th and F Streets NW, Washington, DC 20405, or by telephoning (202) 501–3822, or by faxing your request to (202) 501–3341.

Dated: October 15, 1997.

**Edward C. Loeb,**

*Acting Deputy Association Administrator, Office of Acquisition Policy.*

[FR Doc. 97–28236 Filed 10–23–97; 8:45 am]

**BILLING CODE 6820–61–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

### National Institute for Occupational Safety and Health; Occupational Exposure to Inorganic Lead: Request for Comments and Information; Republication

This notice is being republished because the µ symbol was missing throughout the original document published in the **Federal Register** on October 7, 1997 (62 FR 52343).

**AGENCY:** National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS).

**ACTION:** Request for comments and information relevant to occupational exposure to inorganic lead.

**SUMMARY:** NIOSH is reviewing its recommendations contained in the document *Criteria for a Recommended Standard....Occupational Exposure to Inorganic Lead, Revised Criteria—1978* [NIOSH 1978]. The evaluation of recent literature indicates that the NIOSH recommended exposure limit (REL) of 100 µg/m$^3$ as an 8-hour time-weighted average (TWA) in that document does not sufficiently protect workers from the adverse effects of exposure to inorganic lead. NIOSH is requesting comments and information relevant to the evaluation of the potential health risks associated with occupational exposure to inorganic lead, as well as case reports or other data that demonstrate adverse health effects in workers exposed to inorganic lead at or below the OSHA permissible exposure limit (PEL) of 50 µg/m$^3$ as an 8-hour TWA and any information pertinent to evaluating the technical feasibility of establishing a more protective REL for inorganic lead. NIOSH is also soliciting information on worker blood lead levels (BLLs) including data on methodologies used in measuring BLLs in the workplace and information that can be used for comparing airborne inorganic lead concentrations to observed BLLs.

NIOSH intends to analyze the feasibility of developing preventive measures including an REL that would provide better protection for workers. In the interim, NIOSH plans to adopt the more protective current OSHA PEL as its REL.

**DATES:** Written comments to this notice should be submitted to Diane Manning, NIOSH Docket Office, 4676 Columbia Parkway, M/S C–34, Cincinnati, Ohio 45226, on or before December 23, 1997. Comments may also be faxed to Diane Manning at (513) 533–8285 or submitted by email to dmm2@cdc.gov as WordPerfect 6.0/6.1 files.

**FOR FURTHER INFORMATION CONTACT:** Technical information may be obtained from Dr. Henryka Nagy, NIOSH, CDC, 4676 Columbia Parkway, M/S C–32, Cincinnati, Ohio 45226, telephone (513) 533–8369.

**SUPPLEMENTARY INFORMATION:** NIOSH has conducted a literature review of the health effects data on inorganic lead exposure and finds evidence that some adverse effects on the adult reproductive, cardiovascular, and hematologic systems, and on the development of children of exposed workers can occur at BLLs as low as 10 µg/dl with no apparent threshold. At BLLs below 40 µg/dl, many of the health effects associated with lead exposure would not necessarily be evident by routine physical examinations, but represent early stages in a continuum of disease development. The risk of developing adverse health effects appears to increase as BLLs rise above 40 µg/dl.

In the NIOSH 1978 criteria document entitled *Occupational Exposure to Inorganic Lead* [NIOSH 1978], NIOSH recommended that exposure to inorganic lead be limited to 100 µg/m$^3$ as an 8-hour TWA. This exposure limit was expected to maintain BLLs below 60 µg/dl and to prevent clinical health effects to the hematologic system, the central and peripheral nervous systems, the reproductive system, and the kidneys. NIOSH also expressed concern about possible health effects that may occur below 60 µg/dl: ''In adhering to the 60 µg/dl figure, NIOSH has not relinquished its concerns for possible effects that may occur below 60 µg/dl. Adherence to this 60 µg/dl figure should not be interpreted as a firm NIOSH opposition to establishing a lower blood lead standard. In fact, NIOSH endorses a lower blood lead standard as a future goal to provide greater assurance of safety.''

In 1978, the Occupational Safety and Health Administration (OSHA) promulgated an occupational inorganic lead standard for general industry that incorporates a PEL of 50 µg/m$^3$ which is intended to maintain worker BLLs below 40 µg/dl. OSHA also included provisions for reducing the PEL for work shifts that exceed 8 hours, medical monitoring of workers exposed to airborne inorganic lead concentrations at or above the action level of 30 µg/m$^3$, and medical removal of workers with BLLs greater than 50 µg/dl. Workers are permitted to return to jobs involving inorganic lead exposure only after their BLLs have declined to 40 µg/dl.

OSHA concluded in 1978 that a PEL of 50 µg/m$^3$ represented the lowest level for which there was evidence of feasibility in most industries. OSHA also acknowledged that, based on the scientific data, the PEL of 50 µg/m$^3$ did not provide protection from all adverse health effects of inorganic lead toxicity because the hematologic system, the nervous system, the kidneys, and the fetus can be adversely affected by exposures to inorganic lead resulting in BLLs below 40 µg/dl [43 FR 52952, November 14, 1978]. In May 1993, OSHA published the Interim Final Lead in Construction Standard [58 FR 26590, May 4, 1993]. This standard extended the general industry standard for inorganic lead to include workers in the construction industry. No additional analysis of the health data was performed by OSHA in adopting this standard for the construction industry.

NIOSH seeks to obtain materials, including reports and research findings, to evaluate the health risks of occupational exposure to inorganic lead. Examples of requested information include, but are not limited to, the following:

1. Occupational (environmental) exposure data.

2. Data on the effectiveness of engineering controls, work practices,

training, personal protective equipment and other activities used to limit workers' exposure.

3. Identification of industries or occupations where intermittent or low concentrations of inorganic lead may occur.

4. Descriptions of work practices and engineering controls used to reduce workplace exposure.

5. Case reports or other health data that demonstrate adverse health effects in workers exposed to inorganic lead at or below the OSHA PEL and any information pertinent to evaluating the feasibility of establishing a more protective exposure limit. Case reports and health data should be submitted without personal identifiers.

6. Information regarding methods for BLL determination that could be used routinely in the workplace (e.g., determination of BLLs using portable equipment). NIOSH is evaluating whether the routine biological monitoring of inorganic lead exposed workers (through BLLs) may be a more appropriate measure than airborne concentrations for estimating the potential for developing adverse health effects.

This information will be used by NIOSH to determine the need for developing new recommendations for lowering the occupational exposure to inorganic lead and improving strategies for monitoring inorganic lead exposure.

All information received in response to this notice will be available for public examination and copying at the NIOSH Docket Office, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

**References**

43 FR 52952, November 14, 1978. Chapter XVII—Occupational Safety and Health Administration, Department of Labor; Part 1910—Occupational safety and health standards: occupational exposure to lead.

58 FR 26590, May 4, 1993. Occupational Safety and Health Administration: lead exposure in construction; interim final rule. (To be codified at 29 CFR 1926.)

NIOSH [1978]. Criteria for a recommended standard * * * occupational exposure to inorganic lead, revised criteria. Rockville, MD: U.S. Department of Health, Education, and Welfare, Public Health Service, Center for Disease Control, National Institute for Occupational Safety and Health, DHEW (NIOSH) Publication No. 78–158.

Dated: October 20, 1997.

**Linda Rosenstock,**

*Director, National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).*

[FR Doc. 97–28219 Filed 10–23–97; 8:45 am]

BILLING CODE 4163–19–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 97N–0424]**

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on a proposed revision of the form for the 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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on a revised, harmonized transmittal form, ''Transmittal of Advertisements and Promotional Labeling for Drugs and Biologics for Human Use'' (Form FDA 2253). This revised and harmonized form will be used for the submission of advertisements and promotional labeling for prescription drugs, antibiotics, and biological products that are regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER).

**DATES:** Submit written comments on the collection of information by December 23, 1997.

**ADDRESSES:**

*CDER Information*: Submit written requests for single copies of the revised, harmonized transmittal form, Form FDA 2253, to the Drug Information Branch (HFD–210), Division of Communications Management, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–1012. Send one self-addressed adhesive label to assist that office in processing your requests. The form may also be obtained by calling the CDER Fax–on–Demand System at 1–800–342–2722 or 1–301–827–0577.

*CBER Information*: Submit written requests for single copies of the revised, harmonized transmittal form, Form FDA 2253, to the Office of Communications, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The form may also be obtained by calling the CBER Voice Information System at 1–800–835–4709.

Submit written comments on the revised, harmonized transmittal form, Form FDA 2253, and its proposed use in collection of information, to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Two copies of any comments are to be submitted except that individuals may submit one copy. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the revised, harmonized transmittal form, Form FDA 2253, and received comments are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

**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 before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (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;