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;

(3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Transmittal of Advertisements and Promotional Labeling for Drugs and Biologics for Human Use (Form FDA 2253)

Under § 314.81(b)(3)(i) (21 CFR 314.81(b)(3)(i)), sponsors of approved applications for marketed prescription drugs and antibiotic drugs for human use are required to submit specimens of promotional labeling and advertisements at the time of initial dissemination of the labeling and at the time of initial publication of the advertisement. Each submission is required to be accompanied by a completed transmittal Form FDA 2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use). Statutory authority for the collection of this information is provided by sections 505(a), (b), (j), and (k), 507(g), and 701(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a), (b), (j), and (k), 357(g), and 371(a)).

Similarly, under § 601.12(f)(4) (21 CFR 601.12(f)(4)) (62 FR 39890, July 24, 1997; effective October 7, 1997), manufacturers of licensed biological products are required to submit specimens of advertising and promotional labeling to FDA in accordance with § 314.81(b)(3)(i). Statutory authority for the collection of this information is provided by section 351 of the Public Health Service Act (42 U.S.C. 262), which gives FDA the responsibility to prescribe standards designed to ensure the safety, purity, potency, and effectiveness of biological products. In furtherance of this responsibility, FDA regulates advertising and labeling for biological products. Currently, specimens of advertising and promotional labeling are submitted to FDA with Form FDA 2567, a two-part transmittal form that is also used to transmit other forms of labeling (e.g., circulars, package labels, and container labels) for FDA review when a firm is requesting premarket approval of a product or proposing changes to product carton or container labeling.

FDA is revising Form FDA 2253 to enable it to be used to transmit specimens of promotional labeling and advertisements for biological products as well as for prescription drugs and antibiotics. The proposed revised form has the following major changes:

1. The revised, harmonized form will be used by sponsors of approved applications for marketed prescription drugs and antibiotic drugs regulated by CDER who must submit specimens of advertisements and promotional labeling to the agency, and may be used by manufacturers of licensed biological products regulated by CBER who submit draft and/or final copies of promotional labeling and advertisements to the agency. Revising and harmonizing Form FDA 2253 will eliminate the need for sponsors to use two different forms to transmit similar materials for submission to the agency; however, manufacturers of biological products may continue to use Form FDA 2567 to transmit advertisements and promotional labeling if they wish. The other uses of Form FDA 2567 will remain unchanged.

2. The revised, harmonized form updates the information about the types of promotional materials and the codes that are used to clarify the type of advertisement or labeling submitted; clarifies the intended audience for the advertisements or promotional labeling (e.g., consumers, professionals, news services); and helps ensure that the submission is complete.

3. Currently, when more than one prescription drug product is promoted in the promotional labeling or in an advertisement, sponsors submit specimens of the promotional labeling or advertisement to the approved application for each product promoted in the promotional labeling or advertisement. The revised form provides for sponsors to submit specimens of multi-product promotional labeling and advertisements to only two files; to the approved product application most frequently promoted, and to a company name file. This multi-product submission should cross-reference the other approved applications. The agency anticipates that the proposed revised form and revised submission procedures will save sponsors time and money by eliminating the need for making multiple submissions and for maintaining dual inventories of both forms and multiple processing capabilities.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

Form	No. of Respondents	Total Annual Responses	Hours per Response	Total Estimated Hours
FDA 2253	612	12,379	2	24,758

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

In FY 95, CDER received 10,879 submissions of advertising and promotional labeling under Form FDA 2253 from an estimated 512 manufacturers. In the same period of time, CBER received 1,034 submissions from 57 manufacturers that could have made use of revised Form FDA 2253. Prior to October 7, 1997, the submission of advertising and promotional labeling to CBER using Form FDA 2567 was a voluntary procedure. Under § 601.12(f)(4) (62 FR 39890), manufacturers of licensed biological products are required to submit specimens of advertising and promotional labeling to FDA in accordance with § 314.81(b)(3)(i). FDA estimates that under the new regulation, CBER will receive over 1,500 submissions from approximately 100 manufacturers that may use the revised Form FDA 2253. Thus, FDA estimates that there may be 12,379 submissions of advertising and promotional labeling to FDA under revised Form FDA 2253. Based on contacts with industry representatives, FDA estimates that 2 hours would be required for an industry regulatory affairs specialist to fill out the proposed form, collate the documentation, and send the submission to CDER or CBER. Manufacturers of biological products may use the revised Form FDA 2253 or may continue to use Form FDA 2567 for the submission of advertisements and promotional labeling to CBER.

Dated: October 17, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–28225 Filed 10–23–97; 8:45 am]

BILLING CODE 4160–01–F