

Surgeon General, Director, Division of Health Assessment and Consultation, Agency for Toxic Substances and Disease Registry, 1600 Clifton Road, NE., Mailstop E-32, Atlanta, Georgia 30333, telephone (404) 639-0610.

SUPPLEMENTARY INFORMATION: The most recent list of completed public health assessments was published in the **Federal Register** on June 21, 1999 (64 FR 33090). This announcement is the responsibility of ATSDR under the regulation, Public Health Assessments and Health Effects Studies of Hazardous Substances Releases and Facilities (42 CFR part 90). This rule sets forth ATSDR's procedures for the conduct of public health assessments under section 104(i) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), as amended by the Superfund Amendments and Reauthorization Act (SARA) (42 U.S.C. 9604(i)).

Availability

The completed public health assessments and addenda are available for public inspection at the Division of Health Assessment and Consultation, Agency for Toxic Substances and Disease Registry, Building 33, Executive Park Drive, Atlanta, Georgia (not a mailing address), between 8 a.m. and 4:30 p.m., Monday through Friday except legal holidays. The completed public health assessments are also available by mail through the U.S. Department of Commerce, National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, Virginia 22161, or by telephone at (703) 605-6000. NTIS charges for copies of public health assessments and addenda. The NTIS order numbers are listed in parentheses following the site names.

Public Health Assessments Completed or Issued

Between April 1 and June 30, 1999, public health assessments were issued for the sites listed below:

NPL Sites

California

Sherwin Williams—Emeryville—(PB99-155590)

Union Pacific (a/k/a Union Pacific Railroad Yard)—Sacramento—(PB99-155608)

Florida

Normandy Park Apartments—Temple Terrace—(PB99-140956)

Georgia

USAF Robins Air Force (Landfill/Sludge LA) (a/k/a USAF Robins Air Force

Base)—Warner Robins—(PB99-152738)

Illinois

Byron Salvage Yard (a/k/a Byron Johnson)—Byron—(PB99-149239)

National Lead Industries/Taracorp Lead Smelt Site—Granite City—(PB99-155343)

Sandoval Zinc Company—Sandoval—(PB99-155616)

Sangamo Electric Dump/Crab Orchard National Refuge (a/k/a Crab Orchard National Refuge)—Cartersville—(PB99-149205)

Louisiana

Agriculture Street Landfill—New Orleans—(PB99-152282)

Massachusetts

Re-Solve, Incorporated—Dartmouth—(PB99-151490)

New Jersey

LCP Chemicals Incorporated—Linden—(PB99-155335)

New York

General Motors (Central Foundry Division)—Massena—(PB99-140949)

Pennsylvania

Sharon Steel Corporation (Farrell Works)—Farrell—(PB99-149197)

Tennessee

Ross Metals Incorporated—Rossville—(PB99-156622)

Wisconsin

US Army Badger Army Ammunition Plant—Baraboo—(PB99-151532)

Non NPL Petitioned Sites

Mississippi

Mayfair/New Haven Subdivision—Natchez—(PB99-163305)

New York

Underground Storage Tanks—Jacksonville—(PB99-156630)

Rhode Island

Smithfield Chemical Industrial Dump—Smithfield—(PB99-163321)

Dated: September 13, 1999.

Georgi Jones,

Director, Office of Policy and External Affairs, Agency for Toxic Substances and Disease Registry.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[INFO-99-39]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 639-7090.

Comments are invited 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) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) and ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques for other forms of information technology. Send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Project

1. Studies of Adverse Reproductive Outcomes in Female Occupation Groups (0920-0367)—EXTENSION—National Institute for Occupational Safety and Health (NIOSH). An estimated 50,000 to 60,000 chemicals are in common use throughout society today and hundreds of new chemicals are introduced each year. Yet the list of environmental chemicals and agents that have been investigated to determine whether they have adverse effects on reproductive health is still limited. With the growing number of women in the work force, it is becoming increasingly important to evaluate the potential female reproductive health effects of occupational and physical agents.

This study will examine reproductive disorders among female flight attendants. Approximately 66,000 flight attendants are currently employed by

U.S. commercial airlines and are potentially exposed to ionizing radiation and disruption of circadian rhythms, two exposures that may adversely affect reproductive function. Teachers will be enrolled as an external comparison group for this study.

Data from company personnel records containing demographic and work

history information will be used to estimate workplace exposures. Each woman will be asked to complete a telephone questionnaire on reproductive history and other factors (such as cigarette smoking) that may influence reproductive function. Each questionnaire will take approximately 60 minutes to complete. Medical

records will be requested to confirm adverse reproductive outcomes reported by the participants. The risk of adverse reproductive outcomes between the two groups of women will then be compared.

The total cost to respondents to estimated at \$102,000.

Respondents	Number of respondents	Number of responses respondent	Avg. burden per response	Total burden
Workers	6,200	1	1.0	6,200
Medical providers	1,200	1	0.5	600
Total				6,800

Dated: September 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

Food and Drug Administration

[Docket No. 99N-0407]

Agency Information Collection Activities: Proposed Collection; Comment Request; Reclassification Petitions for Medical Devices

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 information collection, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for Reclassification Petitions for Medical Devices.

DATES: Submit written comments on the collection of information by November 16, 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: Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

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, including each proposed extension of an existing 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 set forth 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.

Reclassification Petitions for Medical Devices; 21 CFR 860.123 (OMB Control Number 0910-0138—Extension)

FDA has the responsibility under sections 513(e) and (f), 514(b), 515(b), and 520(l) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(e) and (f), 360d(b), 360e(b), and 360j(l)) and part 860 (21 CFR part 860), subpart C, to collect data and information contained in reclassification petitions. The reclassification provisions of the act allow any person to petition for reclassification of a medical device from any one of three classes (I, II, and III) to another class. The reclassification procedures (§ 860.123) requires the submission of sufficient, valid scientific evidence demonstrating that the proposed classification will provide a reasonable assurance of safety and effectiveness of the device for its intended use. The reclassification provisions of the act serve primarily as a vehicle for manufacturers to seek reclassification from a higher to a lower class, thereby reducing the regulatory requirements applicable to a particular device. The reclassification petitions requesting classification from class III to class II or class I, if approved, provide an alternative route to the market in lieu of premarket approval for class III devices.

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