

combination with work days of employment occurring within the parameters (excluding aggregate work day requirements) established for other classes of employees included in the SEC.

This designation will become effective on January 7, 2006, unless Congress provides otherwise prior to the effective date. After this effective date, HHS will publish a notice in the **Federal Register** reporting the addition of this class to the SEC or the result of any provision by Congress regarding the decision by HHS to add the class to the SEC.

**FOR FURTHER INFORMATION CONTACT:**

Larry Elliott, Director, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, MS C-46, Cincinnati, OH 45226, Telephone 513-533-6800 (this is not a toll-free number). Information requests can also be submitted by e-mail to [OCAS@CDC.GOV](mailto:OCAS@CDC.GOV).

Dated: December 20, 2005.

**John Howard,**

*Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.*

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**BILLING CODE 4163-17-P**

were employed for a number of work days aggregating at least 250 work days either solely under this employment or in combination with work days within the parameters (excluding aggregate work day requirements) established for other classes of employees included in the SEC.

This designation became effective on November 13, 2005, as provided for under 42 U.S.C. 7384(14)(C). Hence, beginning on November 13, 2005, members of this class of employees, defined as reported in this notice, became members of the Special Exposure Cohort.

**FOR FURTHER INFORMATION CONTACT:**

Larry Elliott, Director, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, MS C-46, Cincinnati, OH 45226, Telephone 513-533-6800 (this is not a toll-free number). Information requests can also be submitted by e-mail to [OCAS@CDC.GOV](mailto:OCAS@CDC.GOV).

Dated: December 20, 2005.

**John Howard,**

*Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.*

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not meet the statutory requirements for the SEC:

Physicists who worked in Building #2 at the National Bureau of Standards (NBS), Van Ness Street, Washington, DC, from 1943 through 1952.

This determination may be subject to an administrative review within HHS, pursuant to 42 CFR 83.16(b).

**FOR FURTHER INFORMATION CONTACT:**

Larry Elliott, Director, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, MS C-46, Cincinnati, OH 45226, Telephone 513-533-6800 (this is not a toll-free number). Information requests can also be submitted by e-mail to [OCAS@CDC.GOV](mailto:OCAS@CDC.GOV).

Dated: December 20, 2005.

**John Howard,**

*Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**National Center for Environmental Health/Agency for Toxic Substances and Disease Registry; Meetings**

The Health Department Subcommittee of the Board of Scientific Counselors (BSC), Centers for Disease Control and Prevention (CDC), National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (NCEH/ATSDR); Teleconference Meeting.

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), CDC, NCEH/ATSDR announces the following subcommittee teleconference meeting:

*Name:* Health Department Subcommittee (HDS).

*Times and Dates:* 1 p.m.-2:30 p.m., January 12, 2005

*Place:* Century Center, 1825 Century Boulevard, Atlanta, Georgia 30345.

*Status:* Open to the public, teleconference access limited only by availability of telephone ports.

*Purpose:* Under the charge of the Board of Scientific Counselors, NCEH/ATSDR the HDS will provide the BSC, NCEH/ATSDR with advice and recommendations on local and state health department issues and concerns that pertain to the mandates and mission of NCEH/ATSDR.

*Matters To Be Discussed:* The meeting agenda will include a review of the

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**Final Effect of Designation of a Class of Employees for Addition to the Special Exposure Cohort**

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Department of Health and Human Services (HHS) gives notice concerning the final effect of the HHS decision to designate a class of employees at the Mallinckrodt Chemical Works, Destrehan Street Facility, in St. Louis, Missouri, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000. On October 14, 2005, as provided for under 42 U.S.C. 7384q(b), the Secretary of HHS designated the following class of employees as an addition to the SEC:

Department of Energy (DOE) employees or DOE contractor or subcontractor employees who worked in the Uranium Division at the Destrehan Street Facility of Mallinckrodt Chemical Works from 1949 to 1957 and who

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**Employment and Training Administration Determination Concerning a Class of Employees Considered for Addition to the Special Exposure Cohort**

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Department of Health and Human Services (HHS) gives notice of a decision that a class of employees at the National Bureau of Standards, Van Ness Street, Washington, DC, do not meet the statutory criteria for addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA). On December 8, 2005, the Secretary of HHS determined, based on the decision by the Department of Energy to remove the site from the list of covered facilities, that the following class of employees do not meet the statutory requirements for covered employees under EEOICPA and thus do

Health Department Charge; a review of the Top Five Priority Issues of the HDS and how to proceed on the next top priority issues; a discussion on the formulation of recommendations on the Environmental Health Workforce; a discussion on issues the BSC would like addressed; and a discussion to establish the regularity and timing of the HDS face-to-face and teleconference meetings.

Items are subject to change as priorities dictate.

**SUPPLEMENTARY INFORMATION:** This teleconference meeting is scheduled to begin at 1 p.m. e.s.t. To participate during the Public Comment period (2–2:10 p.m.), dial (877) 315–6535, conference code 383520.

**FOR FURTHER INFORMATION CONTACT:** Individuals interested in attending the meeting, contact Sandra Malcom, Committee Management Specialist, NCEH/ATSDR, 1600 Clifton Road, M/S E–28, Atlanta, Georgia 30333; telephone 404/498–0003, fax 404/498–0059; e-mail: [smalcom@cdc.gov](mailto:smalcom@cdc.gov).

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the National Center for Environmental Health/Agency for Toxic Substances and Disease Registry.

Dated: December 27, 2005.

**Alvin Hall,**

*Director, Management Analysis and Services Office Centers for Disease Control and Prevention.*

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**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2005N–0350]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Reclassification Petitions for Medical Devices

**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 January 26, 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 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:** Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

**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.

#### Reclassification Petitions for Medical Devices—(OMB Control Number 0910–0138)—Extension

FDA has the responsibility under sections 513(e), 513(f), 514(b), 515(b), and 520(l) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(e), 360c(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 device from any one of the three classes (I, II, and III) to another class. The reclassification content regulation (§ 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.

Respondents are device manufacturers seeking reclassification.

In the **Federal Register** of September 14, 2005 (70 FR 54392), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
860.123	6	1	6	500	3,000

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.