DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institute for Occupational Safety and Health

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

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice concerning the final effect of the HHS decision to designate a class of employees at Westinghouse Atomic Power Development Plant in East Pittsburgh, Pennsylvania, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000. On March 31, 2009, 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:

All Atomic Weapons Employer employees who worked at Westinghouse Atomic Power Development Plant in East Pittsburgh, Pennsylvania, from August 13, 1942 through December 31, 1944, for a number of work days aggregating at least 250 work days, occurring either solely under this employment or in combination with work days within the parameters established for one or more other classes of employees in the SEC.

This designation became effective on April 30, 2009, as provided for under 42 U.S.C. 7384l(14)(C). Hence, beginning on April 30, 2009, 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 (NIOSH), 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*.

Christine M. Branche,

Acting Director, National Institute for Occupational Safety and Health.

[FR Doc. E9–10829 Filed 5–7–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institute for Occupational Safety and Health

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

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice concerning the final effect of the HHS decision to designate a class of employees at Tyson Valley Powder Farm near Eureka, Missouri, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000. On March 31, 2009, 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:

All Atomic Weapons Employer (AWE) employees who worked at Tyson Valley Powder Farm near Eureka, Missouri, from February 13, 1946 through June 30, 1948, for a number of work days aggregating at least 250 work days, occurring either solely under this employment or in combination with work days within the parameters established for one or more other classes of employees in the SEC.

This designation became effective on April 30, 2009, as provided for under 42 U.S.C. 7384l(14)(C). Hence, beginning on April 30, 2009, 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 (NIOSH), 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*.

Christine M. Branche,

Acting Director, National Institute for Occupational Safety and Health.

[FR Doc. E9–10830 Filed 5–7–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0635]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Emergency Shortages Data Collection System (formerly ''Emergency Medical Device Shortages Program Survey'')

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 June 8, 2009.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0491. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3793.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA published a 30-day notice in the **Federal Register** of March 16, 2009 (74 FR 11116), that: (1) Responded to comments on the information collection provisions received in response to a 60-day notice that published in the **Federal Register** of December 19, 2008 (73 FR 77718), and (2) announced submission of the proposed collection of information to OMB for review and clearance. In response to a request by OMB, FDA is republishing the 30-day notice of the proposed collection of information set forth in this document.

Emergency Shortages Data Collection System (formerly ''Emergency Medical Device Shortages Program Survey'')—Section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (OMB Control Number 0910–0491)—Extension

Under section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 393(d)(2)), the FDA Commissioner is authorized to implement general powers (including conducting research) to carry out effectively the mission of FDA. Subsequent to the events of September 11, 2001, and as part of broader counter-terrorism and emergency preparedness activities, FDA's Center for Devices and Radiological Health (CDRH) began developing operational plans and interventions that would enable CDRH to anticipate and respond to medical device shortages that might arise in the context of federally-declared disasters/emergencies or regulatory actions. In particular, CDRH identified the need to acquire and maintain detailed data on domestic inventory, manufacturing capabilities, distribution plans and raw material constraints for medical devices that would be in high demand, and/or would be vulnerable to shortages in specific disaster/emergency situations, or following specific regulatory actions. Such data could support prospective risk assessment, help inform risk mitigation strategies, and support real-time decisionmaking by the Department of Health and Human Services during actual emergencies or emergency preparedness exercises.

''The Emergency Medical Device Shortages Program Survey'' was developed in 2002 to support the acquisition of such data from medical device manufacturers. In 2004, CDRH changed the process for the data collection, and the electronic database in which the data were stored and was formally renamed the ''Emergency Shortages Data Collection System'' (ESDCS). Recognizing that some of the data collected may be commercially confidential, access to ESDCS is restricted to members of the FDA Emergency Shortage Team (EST) and senior management with a need-to-know. At this time, the need-to-know senior management personnel are limited to 5 senior managers. Further, the data are used by this defined group only for decisionmaking and planning in the context of a federally-declared disaster/emergency, an official emergency preparedness exercise, or a potential public health risk posed by non-disaster-related device shortage.

The data procurement process consists of an initial scripted telephone call to a regulatory officer at a registered manufacturer of one or more key medical devices being tracked in the emergency shortages data collection system. In this initial call, the intent and goals of the data collection effort are described, and the specific data request is made. After the initial call, one or more additional followup calls and/or electronic mail correspondence may be required to verify/validate data sent from the manufacturer, confirm receipt and/or request additional detail. Although the regulatory officer is the agent who is initially contacted, they may designate an alternate representative within their organization to correspond subsequently with the CDRH EST member who is collecting or verifying/validating the data.

Because of the dynamic nature of the medical device industry, particularly with respect to specific product lines, manufacturing capabilities and raw material/subcomponent sourcing, it is necessary to update the data in the ESDCS at regular intervals. This is done on a weekly basis, but efforts are made to limit the frequency of outreach to a specific manufacturer to no more than every 4 months.

The ESDCS will only include those medical devices for which there will likely be high demand during a specific emergency/disaster, or for which there are sufficiently small numbers of manufacturers such that disruption of manufacture or loss of one or more of these manufacturers would create a shortage.

In the **Federal Register** of December 19, 2008 (73 FR 77718), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section of the Act	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
903(d)(2)	125	3	375	0.5	188

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

FDA based the burden estimates in Table 1 of this document on past experience with direct contact with the medical device manufacturers, and anticipated changes in the medical device manufacturing patterns for the specific devices being monitored. FDA estimates that approximately 125 manufacturers would be contacted by telephone and/or electronic mail 3 times per year to either obtain primary data or to verify/validate data. Because the data being requested represent data elements that are monitored or tracked by manufacturers as part of routine inventory management activities, it is anticipated that for most manufacturers, the estimated time required of manufacturers to complete the data request will not exceed 30 minutes per request cycle.

Dated: May 4, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–10816 Filed 5–7–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Title IV–E Foster Care Eligibility Review and Child and Family Service Reviews; Final Rule.

OMB No.: 0970–0214.

Description: The following five separate activities are associated with this information collection: Foster Care Eligibility Review (FCER) Program Improvement Plan; Child and Family Services Reviews (CFSR) State agency