

All employees of the Department of Energy, its predecessor agencies, and their contractors and subcontractors who worked in any area at the Sandia National Laboratories-Livermore in Livermore, California, from October 1, 1957, through December 31, 1994, 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 included in the Special Exposure Cohort.

This designation will become effective on January 6, 2014, 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:**

Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, NIOSH, 4676 Columbia Parkway, MS C-46, Cincinnati, OH 45226, Telephone 1-877-222-7570. Information requests can also be submitted by email to [DCAS@CDC.GOV](mailto:DCAS@CDC.GOV).

**John Howard,**

*Director, National Institute for Occupational Safety and Health.*

[FR Doc. 2013-30581 Filed 12-23-13; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

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

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

**ACTION:** Notice.

**SUMMARY:** HHS gives notice of a decision to designate a class of employees from the Rocky Flats Plant in Golden, Colorado, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000. On December 7, 2013, the Secretary of HHS designated the following class of employees as an addition to the SEC:

All employees of the Department of Energy, its predecessor agencies, and their contractors and subcontractors who worked at the Rocky Flats Plant in Golden, Colorado, from April 1, 1952, through December 31, 1983, 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 included in the Special Exposure Cohort.

This designation will become effective on January 6, 2014, 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:**

Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, NIOSH, 4676 Columbia Parkway, MS C-46, Cincinnati, OH 45226, Telephone 1-877-222-7570. Information requests can also be submitted by email to [DCAS@CDC.GOV](mailto:DCAS@CDC.GOV).

**John Howard,**

*Director, National Institute for Occupational Safety and Health.*

[FR Doc. 2013-30584 Filed 12-23-13; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2013-N-1496]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Food and Drug Administration Rapid Response Surveys (Generic Clearance)**

**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 collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the use of rapid response surveys to obtain data on safety information to support quick turnaround decisionmaking about potential safety problems or risk management solutions from health care professionals, hospitals, and other user facilities (e.g., nursing homes, etc.); consumers;

manufacturers of biologics, drugs, and medical devices; distributors; and importers, when FDA must quickly determine whether or not a problem with a biologic, drug, or medical device impacts the public health.

**DATES:** Submit either electronic or written comments on the collection of information by February 24, 2014.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (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:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**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 in this document.

With respect to the following collection of information, FDA invites comments on these topics: (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.

**FDA Rapid Response Surveys (Generic Clearance)—(OMB Control Number 0910-0500)—Extension**

Section 505 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355), requires that important safety information relating to all human prescription drug products be made available to FDA so that it can take appropriate action to protect the public health when necessary. Section 702 of the FD&C Act (21 U.S.C. 372) authorizes investigational powers to FDA for enforcement of the FD&C Act. Under section 519 of the FD&C Act (21 U.S.C. 360i), FDA is authorized to require manufacturers to report medical device-related deaths, serious injuries, and malfunctions to FDA; to require user facilities to report device-related deaths directly to FDA and to manufacturers; and to report serious injuries to the manufacturer. Section 522 of the FD&C Act (21 U.S.C. 360j) authorizes FDA to require manufacturers to conduct postmarket surveillance of medical devices. Section 705(b) of the FD&C Act (21 U.S.C. 375(b)) authorizes FDA to collect and disseminate information

regarding medical products or cosmetics in situations involving imminent danger to health or gross deception of the consumer. Section 903(d)(2) of the FD&C Act (21 U.S.C. 393(d)(2)) authorizes the Commissioner of Food and Drugs to implement general powers (including conducting research) to carry out effectively the mission of FDA. These sections of the FD&C Act enable FDA to enhance consumer protection from risks associated with medical products usage that are not foreseen or apparent during the premarket notification and review process. FDA's regulations governing application for Agency approval to market a new drug (21 CFR part 314) and regulations governing biological products (21 CFR part 600) implement these statutory provisions. Currently, FDA monitors medical product related postmarket adverse events via both the mandatory and voluntary MedWatch reporting systems using FDA Forms 3500 and 3500A (OMB control number 0910-0291) and the vaccine adverse event reporting system.

FDA is seeking OMB clearance to collect vital information via a series of rapid response surveys. Participation in these surveys will be voluntary. This request covers rapid response surveys

for community based health care professionals, general type medical facilities, specialized medical facilities (those known for cardiac surgery, obstetrics/gynecology services, pediatric services, etc.), other health care professionals, patients, consumers, and risk managers working in medical facilities. FDA will use the information gathered from these surveys to quickly obtain vital information about medical product risks and interventions to reduce risks so the Agency may take appropriate public health or regulatory action including dissemination of this information as necessary and appropriate.

FDA projects six emergency risk related surveys per year with a sample of between 50 and 10,000 respondents per survey. FDA also projects a response time of 0.5 hours per response. These estimates are based on the maximum sample size per questionnaire that FDA may be able to obtain by working with health care professional organizations. The annual number of surveys was determined by the maximum number of surveys per year FDA has ever conducted under this collection.

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

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

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
FDA Rapid Response Survey .....	10,000	6	60,000	0.5	30,000

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

Dated: December 18, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013-30630 Filed 12-23-13; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2013-N-0001]

**Science Advisory Board to the National Center for Toxicological Research; Notice of Meeting**

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

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

*Name of Committee:* Science Advisory Board (SAB) to the National Center for Toxicological Research (NCTR).

*General Function of the Committee:* To provide advice and recommendations to the Agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on January 29, 2014, from 8:45 a.m. to 5:30 p.m. and on January 30, 2014, from 8 a.m. to 2 p.m.

*Location:* NCTR SAB Conference Room B-12, 3900 NCTR Rd., Jefferson, AR 72079.

*Contact Person:* Margaret Miller, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 2208, Silver Spring, MD 20993-0002, 301-796-8890, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), to find out further information regarding FDA advisory committee information. A notice in the **Federal**

**Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

*Agenda:* On January 29, 2014, the NCTR Director will welcome the participants and provide a Center-wide update on scientific initiatives and accomplishments during the past year. The SAB will be presented with an overview of the Division of Microbiology Subcommittee and the Subcommittee Site Visit Report. Following the public session, the SAB will hear an update from each of NCTR's research Division's the Office of