

Dated: March 15, 2007.

**James D. Seligman,**

*Chief Information Officer, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### National Institute for Occupational Safety and Health (NIOSH); Advisory Board on Radiation and Worker Health (ABRWH or Advisory Board), Subcommittee for Dose Reconstruction Reviews (SDRR)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention announces the following meeting of the aforementioned subcommittee:

*Subcommittee Meeting Time and Date:* 10 a.m.–5 p.m., April 11, 2007.

*Place:* Cincinnati Airport Marriott, 2395 Progress Drive, Hebron, KY 41018. Phone 859.334.4611, Fax 859.334.4619.

*Conference Call Access:* Phone 866.643.6504, Participant Pass Code 9448550.

*Status:* Open to the public.

*Background:* The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines that have been promulgated by the Department of Health and Human Services (HHS) as a final rule, advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule, advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program, and advice on petitions to add classes of workers to the Special Exposure Cohort.

In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to CDC. NIOSH implements this responsibility for CDC. The charter was issued on August 3, 2001, renewed at appropriate intervals, and will expire on August 3, 2007.

*Purpose:* The Advisory Board is charged with (a) Providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, providing advice to the

Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class.

*Matters To Be Discussed:* Need for Basic vs. Advanced Reviews; How to Conduct Blind Reviews; Status of Individual Dose Reconstruction Audits; Planning Future Dose Reconstruction Audits; and Assignment of Two Board Member Teams to Oversee Audit Process.

The agenda is subject to change as priorities dictate. There is no public comment period, however, written comments may be submitted. Any written comments received will be provided at the meeting and should be submitted to the contact person below well in advance of the meeting.

*Contact Person for Further Information:* Dr. Lewis V. Wade, Executive Secretary, NIOSH, CDC, 4676 Columbia Parkway, Cincinnati, OH 45226, Telephone 513.533.6825, Fax 513.533.6826.

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 Agency for Toxic Substances and Disease Registry.

**Elaine L. Baker,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention Announces the Following: Implementation of New Record Schedule

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

**ACTION:** Notice.

**SUMMARY:** NIOSH is implementing a new record schedule governing the retention of records transferred to the agency by employers pursuant to the regulations of the Occupational Safety and Health Administration (OSHA). Pursuant to this schedule, NIOSH will review these records to determine if they document exposures or medical conditions as required under the OSHA regulations and have research value. Those records that NIOSH determines meet the OSHA regulations and have a

research value will be retained for 30 years.

Those records that do not document exposure or medical condition and treatment or have no research value will not be retained.

**SUPPLEMENTARY INFORMATION:** The hazard-specific standards of the Occupational Safety and Health Administration (OSHA)(Title 29, Code of Federal Regulations [CFR], Parts 1910.1001 through 1910.1450) contain requirements stating that when a company closes and leaves no successor employer, it must transfer (or in some instances, offer to transfer) its employee's medical and exposure records to NIOSH. The OSHA carcinogens standards (29 CFR 1910.1003–1910.1016) also require that such records be transferred to NIOSH when an employee resigns, retires, or dies. The transfer of these records to NIOSH is intended to preserve them for research purposes.

NIOSH has amended its record schedule pertaining to these records, *Employee Exposure and Medical Records (NIOSH)*, (*NARA job Number N1-442-98-1, Item 2, Item 2-80 in the CDC Records Control Schedule (RCS) B-321*), to reduce the retention period of those records and permit the destruction of the records which do not serve any research purpose. Under the new schedule, those records that meet the requirements of the OSHA regulations and serve a research purpose will now be retained for 30 years, rather than 40 years (as under the previous record schedule). However, if upon review NIOSH determines that the records are not medical records or exposure records required to be transferred to NIOSH or were not systematically collected and will not serve a research purpose, the records will not be retained and will be destroyed.

On September 16, 2005, the National Archives and Records Administration (NARA) published in the **Federal Register** [70(179):54774–54776] a notice of availability of this proposed record schedule, *Employee Exposure and Medical Records (NIOSH)*, (*NARA job number N1-442-2005-1, Item 1*) and request for comments. Following receipt and review of comments, NARA approved this revised record schedule on December 16, 2005. This notice announces adoption of the revised schedule by NIOSH. A copy of the revised record schedule can be obtained from NIOSH.

**FOR FURTHER INFORMATION CONTACT:** Rodger Tatken, National Institute for Occupational Safety and Health, Robert A. Taft Laboratories, 4676 Columbia

Parkway, Cincinnati, OH 45226 (513) 533-8370.

Dated: March 14, 2007.

**James D. Seligman,**

*Chief Information Officer, Center for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2007N-0092]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Food and Drug Administration Rapid Response Surveys

**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 written or electronic comments on the collection of information by May 21, 2007.

**ADDRESSES:** Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. 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:**

Jonna Capezzuto, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**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.

#### Generic Food and Drug Administration Rapid Response Surveys (OMB Control Number 0910-0500)—Extension

Section 505 of the Federal Food, Drug, and Cosmetic Act (the 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 act (21 U.S.C. 372) authorizes investigational powers to FDA for enforcement of the act. Under section

519 of the 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 act (21 U.S.C. 360l) authorizes FDA to require manufacturers to conduct postmarket surveillance of medical devices. Section 705(b) of the 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 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 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 obtain quickly 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 estimates the burden of this collection of information as follows: