

one or more other classes of employees in the Special Exposure Cohort.

This designation became effective on January 9, 2010, as provided for under 42 U.S.C. 7384l(14)(C). Hence, beginning on January 9, 2010, members of this class of employees, defined as reported in this notice, became members of the Special Exposure Cohort.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Interim 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.

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2010-1088 Filed 1-20-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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: 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 Metals and Controls Corp. in Attleboro, Massachusetts, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000. On December 10, 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 Employees who worked at Metals and Controls Corp. in Attleboro, MA, from January 1, 1952 to December 31, 1967, 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 SEC.

This designation became effective on January 9, 2010, as provided for under 42 U.S.C. 7384l(14)(C). Hence,

beginning on January 9, 2010, members of this class of employees, defined as reported in this notice, became members of the Special Exposure Cohort.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Interim 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.

John Howard,

Director, National Institute for Occupational Safety and Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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: 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 Brookhaven National Laboratory in Upton, New York, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000. On December 10, 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 employees of the Department of Energy, its predecessor agencies, and its contractors and subcontractors who worked at the Brookhaven National Laboratory in Upton, New York, from January 1, 1947 to December 31, 1979, 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 Special Exposure Cohort.

This designation became effective on January 9, 2010, as provided for under 42 U.S.C. 7384l(14)(C). Hence, beginning on January 9, 2010, members of this class of employees, defined as reported in this notice, became members of the Special Exposure Cohort.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Interim 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.

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2010-1090 Filed 1-20-10; 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: Tribal Child Support Enforcement Direct Funding Request: 45 CFR 309—Plan Form OCSE 34A; Statistical Reporting.

OMB No.: 0970-0218.

Description: The final rule within 45 CFR part 309, published in the **Federal Register** on March 30, 2004, contains a regulatory reporting requirement that, in order to receive funding for a Tribal IV-D program a Tribe or Tribal organization must submit a plan describing how the Tribe or Tribal organization meets or plans to meet the objectives of section 455(f) of the Social Security Act, including establishing paternity, establishing, modifying, and enforcing support orders, and locating noncustodial parents. The plan is required for all Tribes requesting funding; however, once a Tribe has met the requirements to operate a comprehensive program, a new plan is not required annually unless a Tribe makes changes to its title IV-D program. Tribes and Tribal organizations must respond if they wish to operate a fully funded program. In addition, any Tribe or Tribal organization participating in the program will be required to submit form OCSE 34A. This paperwork collection activity is set to expire in September, 2010.

Respondents: Tribes and Tribal Organizations.

Annual Burden Estimates

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
45 CFR 309—Plan	33	1	480	15,840
Form OCSE 34A	49	4	8	1,568
Estimated total burdenhours				17,408

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: infocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments 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) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: January 14, 2010.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2010-963 Filed 1-20-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-D-0470]

International Conference on Harmonisation; Guidance on M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled "M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals." The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance, which is a revision of an existing guidance, discusses the types of nonclinical studies, their scope and duration, and their relation to the conduct of human clinical trials and marketing authorization for pharmaceuticals. The guidance is intended to facilitate the timely conduct of clinical trials and reduce the unnecessary use of animals and other drug development resources.

DATES: Submit written or electronic comments on agency guidance at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002, or the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. Send two self-addressed adhesive labels to

assist the office in processing your requests.

Submit electronic comments to <http://www.regulations.gov>. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Abigail Jacobs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 22, rm. 6484, Silver Spring, MD 20993-0002, 301-796-0174; or Martin D. Green, Center for Biologics Evaluation and Research (HFM-475), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-3070.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4480.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three