GENERAL SERVICES ADMINISTRATION

Office of Communications; Cancellation of a Standard Form

AGENCY: General Services Administration.

ACTION: Notice.

SUMMARY: The following Standard Form is cancelled because of low usage: OF 68, Record of Travel Expense.

DATES: Effective upon publication in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Ms. Barbara Williams, General Services Administration, (202) 501–0581.

Dated: March 15, 2000.

Barbara M. Williams,

Deputy Standard and Optional Forms Management Office.

[FR Doc. 00–7725 Filed 3–28–00; 8:45 am]

BILLING CODE 6820–34–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control And Prevention

[60Day–00–30]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork reduction Act of 1995, the Centers for Disease Control and Prevention is providing opportunity for public comment on proposed data collection projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 639–7090.

Comments are invited 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) ways to enhance 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 for other forms of information technology. Send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Project

1. Hanford Community Health Project Survey—New—The Agency for Toxic Substances and Disease Registry (ATSDR) is mandated pursuant to the 1980 Comprehensive Environmental Response Compensation and Liability Act (CERCLA) and its 1986 Amendments, the Superfund Amendments and Re-authorization Act (SARA), to prevent or mitigate adverse human health effects and diminished quality of life resulting from the exposure to hazardous substances into the environment. These activities include conducting public health assessments at sites on the Environmental Protection Agency's (EPA) National Priorities List (NPL) to determine whether exposure to hazardous substances at these sites are harmful to human health.

The Hanford Nuclear Reservation, located in south central Washington State, is on EPA's National Priorities List. Between 1944 when it opened until its closing in 1972, an estimated 740,000 curies of radioactive Iodine were released to the air from chemical separation facilities used to produce plutonium for atomic weapons development. The Hanford Environmental Dose Reconstruction project (HEDR) estimates that the majority of releases of Iodine-131 occurred between 1944 and 1951. Radioactive Iodine accumulates in the thyroid gland. Studies indicate that exposure to radioactive Iodine is associated with an increased risk of developing thyroid cancers and other thyroid diseases. Children up to five years of age may be at higher risk than the general population of developing cancer after exposure.

The objective of this survey is to collect information on utilization of health care services, knowledge of and information needs related to radioactive Iodine releases from Hanford, health risk and exposure awareness, use of and interest in thyroid medical evaluations, and demographic information. This information will assist ATSDR staff in determining health education needs and planning effective health education activities for people exposed to radioactive Iodine and/or at risk for thyroid disease. This work may have applicability to other sites where exposure to radioactive Iodine has occurred. In previous ATSDR work (OMB No.0923–0006) approximately 6,000 people were located who were born between 1940 and 1951 in three counties (Benton, Franklin and Adams) nearest the Hanford site. For this proposed project, ATSDR plans to randomly select and complete 500 individual interviews from this cohort of 6,000 persons.

To reduce the amount of time required by the respondents, Computer Assisted Telephone Interviews (CATI) will be conducted. The information collected in this proposed survey will provide reliable baseline information for developing effective educational materials and outreach activities. Other than their time to participate, there are no costs to the respondents.

Respondents	Number of respondents per year	Number of responses per respondent	Avg. burden per response (in hrs.)	Total annual burden (in hrs.)
Individuals born near Hanford site	500	1	.25	125

Date: March 22, 2000.

Charles Gollmar,

Acting Associate Director for Policy, Planning, and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 00–7703 Filed 3–28–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1033]

Draft Guidance for Industry on Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Establishment of a Data Bank; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Establishment of a Data Bank.'' The draft guidance provides recommendations for sponsors of investigational new drug applications (IND's) on submitting information about clinical trials for serious or life-threatening diseases to a clinical trials data bank developed by the National Library of Medicine (NLM) at the National Institutes of Health (NIH). Section 113 of the Food and Drug Administration Modernization Act (Modernization Act) required the establishment of this data bank and specified what information was to be submitted for it.

DATES: Submit written comments on the draft guidance by May 30, 2000. The deadline for submission of comments on the information collection requirements is May 30, 2000. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/cber/guidelines.htm. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3844, FAX 888–CBERFAX. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance or on the collection of information requirements to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Theresa A. Toigo (HF–12), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4460.

SUPPLEMENTARY INFORMATION:

I. Description of Guidance

FDA is announcing the availability of a draft guidance for industry entitled ''Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Establishment of a Data Bank.'' The draft guidance is intended to provide recommendations for sponsors of IND's on submitting information about clinical trials for serious or life-threatening diseases to a clinical trials data bank developed by the NLM, NIH.

The Modernization Act (Public Law 105–115), enacted on November 21, 1997, amends section 402 of the Public Health Service Act (the PHS Act) (42 U.S.C. 282) and directs the Secretary of Health and Human Services (the Secretary), acting through the Director of NIH, to establish, maintain, and operate a data bank of information on clinical trials for drugs for serious or life-threatening diseases and conditions (hereafter referred to as the Clinical Trials Data Bank).

The Clinical Trials Data Bank is intended to be a central resource, providing current information on clinical trials to individuals with serious or life-threatening diseases, to other members of the public, and to health care providers and researchers. Specifically, the Clinical Trials Data Bank will contain information about both federally and privately funded studies of experimental treatments for patients with serious or life-threatening diseases conducted under FDA's IND regulations (part 312 (21 CFR part 312)). This Clinical Trials Data Bank expands upon currently available information on federally-sponsored trials in various data bases within NIH (e.g., NIH Intramural Clinical Center Studies, Physician's Data Query/National Cancer Institute) and information about federally and privately sponsored human immunodeficiency virus/acquired immune deficiency syndrome HIV/AIDS trials made available through the AIDS Clinical Trials Information Service (ACTIS).

The NLM is developing the Clinical Trials Data Bank and implementing it in a phased approach. The first version of the Clinical Trials Data Bank was made available to the public on February 29, 2000. The new data base can be reached at http://clinicaltrials.gov. It includes primarily NIH-sponsored trials. Later in 2000, data from other Federal agencies and the private sector will be incorporated.

The draft guidance provides recommendations for industry on the submission of protocol information to the Clinical Trials Data Bank. It includes information on the types of clinical trials for which submissions will be required under section 113 of the Modernization Act, as well as the types of information to be submitted. An implementation plan, addressing procedural issues, will be available later in 2000. The implementation plan will include information on how to submit protocols to the Clinical Trials Data Bank, and how to provide certification to the Secretary that disclosure of information for a particular protocol would substantially interfere with the timely enrollment of subjects in the clinical investigation. It will also discuss issues related to the voluntary submission of information not required by section 113 of the Modernization Act (e.g., study results, trials for non-serious or non-life-threatening diseases). Until the implementation guidance document is available, sponsors submitting clinical trials information for inclusion in the ACTIS data bank should continue to follow procedures currently in place. Non-NIH sponsors of clinical trials for other serious or life-threatening diseases need not provide clinical trials information to the data bank until after procedures are described in the implementation plan that will be available later this year. When the procedures are issued, we will establish a timeframe for submitting the information.

In developing a plan for making publicly available information from the Clinical Trials Data Bank, FDA and NIH considered comments submitted to Docket No. 98D–0293, ''Section 113 NIH Data Bank—Clinical Trials for Serious Diseases.'' A phased approach was used for developing guidance. This first document addresses general information on the scope of the data bank. The second guidance will be on implementation and will be developed