Center for Environmental Health and Injury Prevention (CCEHIP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

On October 10, 2008, President Bush signed S. 1382: ALS Registry Act which amended the Public Health Service Act to provide for the establishment of an Amyotrophic Lateral Sclerosis (ALS) Registry. The activities described are part of the effort to create the National ALS Registry. The purpose of the registry is to: (1) Better describe the incidence and prevalence of ALS in the United States; (2) examine appropriate factors, such as environmental and occupational, that might be associated with the disease; (3) better outline key demographic factors (such as age, race or ethnicity, gender, and family history) associated with the disease; and (4) better examine the connection between ALS and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS. The registry will collect personal health information that may provide a basis for further scientific studies of potential risks for developing ALS.

During a workshop held by The Agency for Toxic Substances and Disease Registry (ATSDR) in March 2006 to discuss surveillance of selected autoimmune and neurological diseases, it was decided to develop a proposal to build on work that had already been done and coordinate existing datasets to create a larger database, rather than to start from scratch with medical records review and physician reporting. Four pilot projects were funded to evaluate the accuracy and reliability of existing data from the Center for Medicare and Medicaid Services (CMS) and various datasets from the Veterans Administration. Preliminary results indicate that additional ways to identify cases of ALS will be necessary to increase completeness of the registry. Therefore, ATSDR developed a Web site where individuals will register and will also have the opportunity to provide additional information on such things as occupation, military service, and family history of ALS, which is not available in existing records.

The registration portion of the data collection will be limited to information that can be used to identify an individual to assure that there are not duplicate records for an individual. Avoiding duplication of registrants due to obtaining records from multiple sources is imperative to get accurate estimates of incidence and prevalence, as well as accurate information on demographic characteristics of the cases of ALS.

In addition to questions required for registration, there will be a series of short surveys to collect information on such things as military history, occupations, and family history that would not likely be available from other sources.

This project proposes to collect information on individuals with ALS which can be combined with information obtained from existing sources of information. This combined data will become the National ALS Registry and will be used to provide more accurate estimates of the incidence and prevalence of disease as well as the demographic characteristics of the cases. Information obtained from the surveys will be used to better characterize potential risk factors for ALS which will lead to further in-depth studies.

The existence of the Web site will be advertised by ATSDR and advocacy groups such as the Amyotrophic Lateral Sclerosis Association (ALSA) and the Muscular Dystrophy Association (MDA).

There will be approximately 30,000 individuals living with ALS when the National ALS Registry is initiated, and it is estimated that approximately 25% of those individuals will also participate. In addition, approximately 6,000 people are diagnosed with ALS each year and we expect about one-third of them will participate in the registry. Because an advantage to registration is participating in the surveys, we expect the one time surveys, and the twice yearly survey participation rate will be 50%.

There are no costs to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Data collection instruments/respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Validation questions (Screener) for suspected ALS cases	6,000	1	2/60	200
Registration Form of ALS cases	4,667	1	7/60	544
Cases of ALS completing 1-time surveys	2,334	6	5/60	1167
Cases of ALS completing twice yearly surveys	2,334	2	5/60	389
Total				2300

Dated: May 20, 2009.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E9–12397 Filed 5–27–09; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–09–0214]

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 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed project or to obtain a copy of data collection plans and instruments, call the CDC Reports Clearance Officer on 404–639–5960 or send comments to CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS D–74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov*.

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 the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

National Health Interview Survey (NHIS), (OMB No. 0920–0214)—Revision—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Section 306 of the Public Health Service (PHS) Act (42 U.S.C. 242k), as amended, authorizes that the Secretary of Health and Human Services (DHHS), acting through NCHS, shall collect statistics on the extent and nature of illness and disability of the population of the United States.

The annual National Health Interview Survey is a major source of general statistics on the health of the U.S. population and has been in the field continuously since 1957. Clearance is sought for three years, to collect data for 2010, 2011, and 2012. This voluntary household-based survey collects demographic and health-related information on a nationally representative sample of persons and households throughout the country. Information is collected using computer assisted personal interviews (CAPI). A core set of data is collected each year while sponsored supplements vary from year to year. For 2010, supplement information will be collected on cancer, occupational injury, epilepsy, and child mental health. The child mental health component includes a follow-up study to assess the validity of a short series of questions for measuring mental distress in children.

In accordance with the 1995 initiative to increase the integration of surveys within the Department of Health and Human Services, respondents to the NHIS serve as the sampling frame for the Medical Expenditure Panel Survey conducted by the Agency for Healthcare Research and Quality. The NHIS has long been used by government, university, and private researchers to evaluate both general health and specific issues, such as cancer, diabetes, and access to health care. It is a leading source of data for the Congressionally-mandated ''Health US'' and related publications, as well as the single most important source of statistics to track progress toward the National Health Promotion and Disease Prevention Objectives, ''Healthy People 2010.''

There is no cost to the respondents other than their time.

ANNUALIZED BURDEN TABLE

Questionnaire (respondent)	Number of respondents	Number of responses per respondent	Average burden per response in hours	Total burden in hours
Screener Questionnaire (adult family member)	10,000	1	5/60	833
Family Core (adult family member)	33,000	1	23/60	12,650
Adult Core (sample adult)	25,000	1	17/60	7,083
Child Core (adult family member)	10,000	1	9/60	1,500
Adult Cancer (sample adult)	25,000	1	19/60	7,917
Child Cancer (adult family member)	10,000	1	1/60	167
Adult Occupational Injury (sample adult)	25,000	1	2/60	833
Adult Epilepsy (sample adult)	25,000	1	1/60	417
Child Mental Health (adult family member)	10,000	1	2/60	333
Child Mental Health Follow-Up (parent)	430	1	40/60	287
Child Mental Health Follow-Up (child)	319	1	28/60	149
Re-interview Survey)	.....	1	5/60	250
Total Burden Hours	.....	.....	.....	32,419

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Office of the Chief Science Officer, Centers for Disease Control and Prevention.

[FR Doc. E9–12393 Filed 5–27–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0050]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Importer's Entry Notice

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 29, 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 0910–0046. Also include the FDA docket number found in brackets in the heading of this document.