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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[30Day-16-0041]

Agency Forms Undergoing Paperwork Reduction Act Review

The Agency for Toxic Substances and Disease Registry (ATSDR) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond,

including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

National Amyotrophic Lateral Sclerosis (ALS) Registry – Revision – Agency for Toxic Substances and Disease Registry (ATSDR).

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 ongoing effort to maintain the National ALS Registry.

First approved in 2010 for self-registration, the primary goal of the surveillance system/registry remains to obtain reliable information on the incidence and prevalence of ALS and to better describe the demographic characteristics (age, race, sex, and geographic location) of persons with ALS (PALS). Those interested in participating in the National ALS Registry must answer a series of validation questions and if determined to be eligible they can register.

The secondary goal of the surveillance system/registry is to collect additional information on potential risk factors for ALS, including, but not limited to, family history of ALS, smoking history, military service, residential history, life-time occupational exposure, home pesticide use, hobbies, hormonal and reproductive history (women only), caffeine use, trauma, health insurance, open-ended supplemental questions, and clinical signs and symptoms. After registration, participants complete as many as 16 voluntary survey modules, each taking five minutes (maximum 80 minutes). In addition, in Year 1, a disease progression survey for new registrants is completed at 0, 3, and 6 months. In Years 2 and 3, the disease progression survey is repeated at the yearly anniversary and at 6 months. For burden estimation, the number of disease progression survey responses per year has been rounded up to 3 times.

A biorepository component is being added to increase the value of the National ALS Registry to researchers. As part of registration the participant can request additional information about the biorepository and provide additional contact information. A geographically representative sample will be selected to provide specimens. There are two types of specimen collections, in-home and postmortem. The in-home collection includes blood, urine, hair and nails. The postmortem collection includes the brain, spinal cord, cerebral spinal fluid (CSF), bone, muscle, and skin.

In addition to fulfilling the two-part Congressional mandate, the Registry is designed to be a tool for ALS researchers. Now that the Registry has matured, ATSDR will make data and specimens available to researchers. They can request access to specimens, data, or both collected by the National ALS Registry for their research projects. ATSDR will review applications for scientific validity and human subjects protection and make data/specimens available to approved researchers.

ATSDR is also collaborating with ALS service organizations to conduct outreach activities through their local chapters and districts as well as on a national level. They will provide

ATSDR with information on their outreach efforts in support of the Registry on a monthly basis.

There are no costs to the respondents other than their time. The total number of burden hours requested is 1,824 hours.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)
Person with ALS	ALS Case Validation Questions	1,670	1	2/60
	ALS Case Registration Form	1,500	1	10/60
	Voluntary Survey Modules	750	1	80/60
	Disease Progression Survey	750	3	5/60
	ALS Biorepository Specimen Processing Form	325	1	30/60
Researchers	ALS Registry Research Application Form	36	1	30/60
	Annual Update	24	1	15/60
ALS Service Organization	Chapter/District Outreach Reporting Form	135	12	5/60
	National Office Outreach Reporting Form	2	12	20/60

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