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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[60Day-16-0041; Docket No. ATSDR-2016-0005]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS)

ACTION: Notice with comment period

SUMMARY: The Agency for Toxic Substances and Disease Registry (ATSDR), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on the "National Amyotrophic Lateral Sclerosis (ALS) Registry." The National ALS Registry collects information from persons with ALS to better describe the prevalence and potential risk factors for ALS.

DATES: Written comments must be received on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. ATSDR-2016-0005 by any of the following methods:

- Federal eRulemaking Portal: Regulation.gov. Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

Please note: All public comment should be submitted through the Federal eRulemaking portal (Regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (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. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

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; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

The National Amyotrophic Lateral Sclerosis (ALS) Registry (OMB Control No. 0923-0041, Expiration Date 09/30/2016) – 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 approved researchers and has added a respondent type. Researchers 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 collaborating with ALS service organizations to conduct outreach activities through their local chapters and districts as well as on a national level. They 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 1,986 hours.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Person with ALS	ALS Case Validation Questions	1,670	1	2/60	56
	ALS Case Registration Form	1,500	1	10/60	250
	Voluntary	750	1	80/60	1,000

	Survey Modules				
	Disease Progression Survey	750	3	5/60	188
	ALS Biorepository Specimen Processing Form	325	1	1	325
Researchers	ALS Registry Research Application Form	36	1	30/60	18
	Annual Update Form	24	1	15/60	6
ALS Service Organization	Chapter/District Outreach Reporting Form	135	12	5/60	135
	National Office Outreach Reporting Form	2	12	20/60	8
Total					1,986

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Leroy A. Richardson
Chief, Information Collection Review Office
Office of Scientific Integrity
Office of the Associate Director for Science
Office of the Director
Centers for Disease Control and Prevention

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