

TABLE 1—INFORMATION ON PARTICIPATION IN THE MEETING AND ON SUBMITTING COMMENTS TO THE DOCKET—  
Continued

	Dates	Electronic addresses	Addresses	Other information
Submit electronic or written comments.	Submit comments by May 26, 2015.	Federal eRulemaking Portal: <a href="http://www.regulations.gov">http://www.regulations.gov</a> . Follow the instructions for submitting comments.	Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.	Identify your comments with the docket number listed in brackets in the heading of this document. We encourage you to submit electronic comments by using the Federal eRulemaking Portal.

<sup>1</sup> You may also register via email, mail, or fax. Please include your name, title, firm name, address, and phone and fax numbers in your registration information and send to: Courtney Treece, Planning Professionals Ltd., 1210 West McDermott Dr., suite 111, Allen, TX 75013, 704-258-4983, FAX: 469-854-6992, email: [ctreece@planningprofessionals.com](mailto:ctreece@planningprofessionals.com).

#### IV. Comments, Transcripts, and Recorded Video

Regardless of attendance at the public meeting, interested persons may submit to FDA's Division of Dockets Management (see Addresses in table 1 of this document) either electronic or written comments on FSMA implementation issues. You only need to send one set of comments. Identify the comments with the docket number listed in brackets in the heading of this document. However, we will not use any information or data submitted during the public meeting or through the docket to inform any FSMA rulemakings where the comment periods have closed.

With respect to transcripts, please be advised that as soon as a transcript is available it will be accessible at <http://www.regulations.gov> and at FDA's FSMA Web site at <http://www.fda.gov/FSMA>. You may also view the transcript at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Send written requests to the Division of Freedom of Information (ELEM-1029), 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Additionally, we will be video recording the public meeting. Once the recorded video is available, it will be accessible at FDA's FSMA Web site at <http://www.fda.gov/FSMA>.

Dated: March 18, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015-06656 Filed 3-23-15; 8:45 am]

**BILLING CODE 4164-01-P**

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Centers for Disease Control and Prevention

##### Interagency Committee on Smoking and Health: Notice of Charter Renewal

This gives notice under the Federal Advisory Committee Act (Pub. L. 92-463) of October 6, 1972, that the Interagency Committee on Smoking and Health, Department of Health and Human Services, has been renewed for a 2-year period through March 20, 2017.

For information, contact Simon McNabb, Designated Federal Officer, Interagency Committee on Smoking and Health, Centers for Disease Control and Prevention, Department of Health and Human Services, Patriot's Plaza, 395 E Street SW., M/S P06, Washington, DC 20201, telephone 202/245-0550 or fax 202/245-0599, Email: [BOL1@cdc.gov](mailto:BOL1@cdc.gov).

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 2015-06649 Filed 3-23-15; 8:45 am]

**BILLING CODE 4163-18-P**

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Agency for Toxic Substances and Disease Registry

[60Day-15-15TG; Docket No. CDC-2015-0009]

##### Proposed Data Collection Submitted for Public Comment and Recommendations

**AGENCY:** Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control and Prevention (CDC).

**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 Promotion of the National Amyotrophic Lateral Sclerosis (ALS) Registry to Non-referral Centers.

**DATES:** Written comments must be received on or before May 26, 2015.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2015-0009 by any of the following methods:

- **Federal eRulemaking Portal:** *Regulations.gov*. Follow the instructions for submitting comments.
- **Mail:** Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., 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 NE., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; Email: *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

Promotion of the National Amyotrophic Lateral Sclerosis (ALS) Registry to Non-referral Centers—New—Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention (CDC).

#### Background and Brief Description

The Agency for Toxic Substances and Disease Registry (ATSDR) is requesting a two-year Office of Management and Budget (OMB) information collection clearance for the project entitled "Promotion of the National ALS Registry to Non-referral Centers". ATSDR is authorized by the Public Health Law No: 110-373, ALS Registry Act to (1) develop a system to collect data on amyotrophic lateral sclerosis (ALS) and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, or progress to ALS; and (2) establish a national registry for the collection and storage of such data to develop a population-based registry of cases.

The primary goal of the National ALS surveillance system/registry is to obtain more complete information on the likely prevalence of ALS and to better describe the demographic characteristics (age, race, sex, and geographic location) of those with ALS. The secondary goal of the registry is to collect additional information on potential risk factors for ALS including, but not limited to, family history of ALS, smoking history, and military service. The proposed project is a new component to be added to the existing Registry and ALS Surveillance Projects to increase self-enrollment rates of those with ALS.

ATSDR implemented the National ALS Registry (Registry) in 2009 using an algorithm applied to national administrative databases. A self-registration component was launched in October 2010. The Registry's case ascertainment methodology required validation; therefore, ATSDR established State and Metropolitan ALS Surveillance Projects (Surveillance Projects). In order to avoid biasing results from the Surveillance Projects' evaluation of the Registry's completeness, staff received instruction to not promote the Registry during the surveillance period.

According to the Morbidity and Mortality Weekly Report (MMWR) published in 2014, the proportion of cases identified via self-registration was

lower than those identified in the administrative data for the period October 2010–December 2011. On-going self-registration is critical because not all persons with ALS can be identified through the algorithm, and only self-registering persons with ALS can complete the risk-factor surveys. Therefore, efforts to increase Registry awareness among non-referral center neurology practices/neurologists is needed to increase self-enrollment of persons with ALS.

This new information collection request is a result of the need to promote the Registry among neurologists who do not work at major ALS referral centers. The following objectives are set for this project:

- To implement a pilot project to conduct educational and promotional outreach activities at non-referral center neurology practices in the U.S., to inform neurologists and their staff about the Registry;
- To encourage neurologists to inform their patients about the Registry, and to increase persons with ALS self-enrollment in the Registry through the web portal via the use of existing Registry brochures, pamphlets, and factsheets; and
- To examine the effectiveness of educational and promotional outreach activities by reviewing persons with ALS self-enrollment rates before, during, and after the project period.

The increase in self-enrollment rates will allow ATSDR to produce more accurate estimates of prevalence of ALS, and collect risk-factor survey data from a more representative sample of persons with ALS nationwide. Additionally, self-enrollment of people with ALS provides them with opportunities to be informed about the disease risk factors, learn more about beneficial therapies and a cure for the disease. In due course, these activities will also allow ATSDR to fulfill its congressional mandate under the ALS Registry Act.

To achieve the above mentioned objectives, a four group educational and promotional outreach study has been designed. Three groups (Group 1, Group 2 and Group 3), with two states in each group, will receive various educational and promotional components, and a fourth group (Group 4) consisting of the remaining 44 states, will serve as a comparison (will not receive any intervention). This project will implement a methodology similar to that used during previous ALS Surveillance Projects to identify all non-referral center neurologists in Groups 1, 2, and 3. Neurologists who do or would diagnose and/or care for ALS patients in Groups 1 and 2 and all neurologists in

Group 3 will receive a mailing about the registry, whereas Group 4 the comparison group will not receive any outreach component. To analyze the change in ALS registry self-enrollment, ATSDR will compare, on a monthly basis, enrollment rates between Groups 1, 2, and 3, and 4, as well as with the 44-state Group 4.

Study activities include, but are not limited to, initial and follow-up phone calls, mailings, train-the-trainer sessions, and key informant interviews. The initial phone call will: (1) determine if the neurologist(s) diagnose/care for patients with ALS; (2) determine how many ALS patients are seen on an annual basis, and (3) confirm contact information for neurologists.

Providers who do or would diagnose/care for patients with ALS will receive a targeted mailing about the registry. Follow-up phone calls and faxes, as needed, will confirm the receipt of mailings (including posters, provider guide pamphlet, Persons with ALS Quick Start Guide etc.). Key informant interviews with neurologists will allow for better understanding of their knowledge, attitudes, and beliefs about the Registry, and for gathering additional information about the currently deployed Registry materials. As neurologists may not be familiar with the self-enrollment process of the Registry, the project includes train-the-trainer site visits that will provide neurologists and staff (if requested to

attend by the neurologist) with information to educate persons with ALS about the National ALS Registry self-enrollment process. The train-the-trainer module activities do not involve information collections.

Participation is voluntary. For the duration (2 years), the project staff will conduct 3,800 initial phone calls, 1,900 follow-up #1 calls at one week post-mailing, 1,900 follow-up #2 calls at three months post-mailing, 30 train-the-trainer presentations, and 32 key-informant interviews.

There are no costs to respondents other than their time. The estimated annualized burden hours for this data collection activity are 326.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Neurologist Support Staff .....	Initial Phone Call Checklist .....	1,900	1	6/60	190
Neurologist Support Staff .....	Fax to Determine Provider Status ...	380	1	1/60	6
Neurologist Support Staff .....	Follow-up Phone Call #1 (One Week Post-Mailing).	950	1	3/60	48
Neurologist Support Staff .....	Follow-up Phone Call #2 (Three Months Post-Mailing).	950	1	3/60	48
Neurologist Support Staff .....	Fax to Determine if Mailing Was Received.	190	1	1/60	3
Neurologist .....	Train-the-Trainer .....	15	1	1	15
Neurologist .....	Key Informant Interview .....	16	1	1	16
<b>Total .....</b>	.....	.....	.....	.....	<b>326</b>

**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.*

[FR Doc. 2015-06654 Filed 3-23-15; 8:45 am]

**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Heart, Lung, and Blood Institute; Notice of Closed Meetings**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning

individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Heart, Lung, and Blood Institute Special Emphasis Panel; Basic Research in HIV-Related Heart, Lung and Blood Diseases.

*Time:* April 16, 2015.

*Time:* 8:00 a.m. to 11:00 a.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Renaissance Washington, DC Dupont Circle Hotel, 1143 New Hampshire Avenue NW., Washington, DC 20037.

*Contact Person:* Susan Wohler Sunnarborg, Ph.D. Scientific Review Officer, Office of Scientific Review/DERA National, Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7182, Bethesda, MD 20892, sunnarborgsw@nhlbi.nih.gov.

*Name of Committee:* National Heart, Lung, and Blood Institute Special Emphasis Panel; Translational Programs in Lung Diseases.

*Date:* April 16, 2015.

*Time:* 8:30 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Crystal City Marriott, 1999 Jefferson Davis Highway, Arlington, VA 22202.

*Contact Person:* William J. Johnson, Ph.D., Scientific Review Officer, Office of Scientific

Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7178, Bethesda, MD 20892-7924, 301-435-0725, johnsonwj@nhlbi.nih.gov.

*Name of Committee:* National Heart, Lung, and Blood Institute Special Emphasis Panel; Basic Research in HIV-Related Heart, Lung and Blood Diseases (R21).

*Date:* April 16, 2015.

*Time:* 11:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Renaissance Washington, DC Dupont Circle Hotel, 1143 New Hampshire Avenue NW., Washington, DC 20037.

*Contact Person:* Susan Wohler Sunnarborg, Ph.D. Scientific Review Officer, Office of Scientific Review/DERA National, Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7182, Bethesda, MD 20892, sunnarborgsw@nhlbi.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)