organization or other affiliation, full address and phone, fax, and e-mail information or e-mail this information to FindYouthInfo@air.org. Additional identification documents may be required.

Dated: November 4, 2010.
Sherry Glied,
Assistant Secretary for Planning and Evaluation.


DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–10–10DE]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC), Agency for Toxic Substances and Disease Registry (ATSDR) publishes a list of information collection requests under review by the Office of management and Budget (OMB) in compliance with the Paperwork Reduction Act (33 U.S.C. chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer, at (404) 639–5960 or send an e-mail to omb@cdc.gov. Send written comments to ATSDR 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

Creation of State and Metropolitan Area-based Surveillance Projects for Amyotrophic Lateral Sclerosis (ALS)—Now—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 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 of individuals diagnosed 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.

This project purposes to collect information-specific data related to ALS. The objective of this project is to develop state-based and metropolitan area-based surveillance projects for ALS. The primary goal of the state-based and metropolitan area-based surveillance project is to use these data to evaluate the completeness of the National ALS Registry. The secondary goal of the surveillance project is to obtain reliable and timely information on the incidence and prevalence of ALS and to better describe the demographic characteristics (e.g., age, race, sex, and geographic location) of those with ALS.

Neurologists or their staff will complete an ALS Case Reporting Form on each of their ALS patients. This will be transmitted to the state or metropolitan health department. The contract surveillance staff assigned to the state and metropolitan area health departments will train medical personnel how to complete the ALS Case Reporting Form (Attachment 3) and assist with abstracting records as requested. An ALS Medical Record Verification Form will be collected on a subset of cases reported. Each medical provider reporting source should keep a line listing of individuals diagnosed with or thought to have ALS along with information on whether or not the case was reported and if not, the reason. Surveillance items to be collected include information to make sure that there are no duplicates. There are no costs to the respondents other than their time. The estimated annualized burden hours are 703.

ESTIMATED ANNUALIZED BURDEN HOURS

<table>
<thead>
<tr>
<th>Type of data collection instrument</th>
<th>Type of respondent</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden per response (in hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Training</td>
<td>Medical Personnel/Neurologist</td>
<td>243</td>
<td>1</td>
<td>30/60</td>
</tr>
<tr>
<td>ALS Case Reporting Form</td>
<td>Medical Personnel/Neurologist</td>
<td>2,250</td>
<td>1</td>
<td>5/60</td>
</tr>
<tr>
<td>ALS Medical Record Verification Form</td>
<td>Neurologist</td>
<td>450</td>
<td>1</td>
<td>20/60</td>
</tr>
<tr>
<td>Line Listing (record keeping)</td>
<td>Medical Personnel</td>
<td>243</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

Dated: November 4, 2010.

Carol E. Walker,
Acting Reports Clearance Officer, Centers for Disease Control and Prevention/Agency for Toxic Substances and Disease Registry.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; comment request; NCCAM Office of Communications and Public Liaison Communications Program Planning and Evaluation Research

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Center for Complementary and Alternative Medicine (NCCAM), the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the Federal Register on August 25, 2010 (Vol. 75, No. 164, p. 52349) and allowed 60-days for public comment. There was one public comments received during this time. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to
respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: NCCAM Office of Communications and Public Liaison Communications Program Planning and Evaluation Research. Type of Information Collection Request: Extension. Need and Use of Information Collection: To carry out NCCAM’s legislative mandate to educate and disseminate information about complementary and alternative medicine (CAM) to a wide variety of audiences and organizations, the NCCAM Office of Communications and Public Liaison (OCPL) requests clearance to carry out (1) formative and (2) evaluative research of a variety of print and online materials, outreach activities, and messages to maximize their impact and usefulness.

OCPL wishes to continue to carry out formative research to further understand the knowledge, attitudes, and behaviors of its core constituent groups: members of the general public, researchers, and providers of both conventional and CAM health care. In addition, it seeks to test newly formulated messages and identify barriers and impediments to the effective communication of those messages. With this formative audience research, OCPL test audience responses to NCCAM’s fact sheets, Web content, and other materials and messages.

Clearance is also requested to continue evaluative research on existing materials and messages, as part of OCPL’s ongoing effort to develop a comprehensive program of testing and evaluation of all of its communications strategies. This evaluative research will include pilot testing of recently developed messages and information products such as consumer fact sheets and brochures. It will address the need to evaluate the processes by which new materials and messages were developed, the effectiveness of an outreach activity or the extent to which behaviors were changed by the message, and the impact of a message on health knowledge and behaviors.

The tools to collect this information have been selected to minimize burden on NCCAM’s audiences, produce or refine messages that have the greatest potential to influence target audience attitudes and behavior in a positive manner, and to use Government resources efficiently. They may include individual in-depth interviews, focus group interviews, intercept interviews, self-administered questionnaires, gatekeeper reviews, and omnibus surveys.

The data will enhance OCPL’s understanding of the unique information needs and distinct health-information-seeking behaviors of its core constituencies, and the segments within these constituencies with special information needs (for example, among the general public these segments include cancer patients, the chronically ill, minority and ethnic populations, the elderly, users of dietary supplements, and patients integrating complementary therapies with conventional medical treatments).

Frequency of Response: On occasion.
Affected Public: Individuals and households; non-profit institutions; Federal Government; State, Local, or Tribal Government. Type of Respondents: Adult patients; members of the public; health care professionals; organizational representatives. The annual reporting burden is as follows: Estimated Number of Respondents: 2,500; Estimated Number of Responses per Respondent: 1; Average Burden Hours per Response: 0.58; and Estimated Total Burden Hours Requested: 2,109 for the 3-year clearance period (approximately 703 hours annually). The annualized cost to respondents is estimated at $18,123. There are no Capital Costs, Operating Costs, or Maintenance Costs to report.

Table 1—Annual Burden Hours

<table>
<thead>
<tr>
<th>Type of respondents</th>
<th>Estimated number of respondents</th>
<th>Estimated number of responses per respondent</th>
<th>Average burden hours per response</th>
<th>Estimated total burden hours requested</th>
</tr>
</thead>
<tbody>
<tr>
<td>In-depth interviews with general public</td>
<td>30</td>
<td>1</td>
<td>.75</td>
<td>23</td>
</tr>
<tr>
<td>Focus groups</td>
<td>20</td>
<td>1</td>
<td>1.5</td>
<td>30</td>
</tr>
<tr>
<td>Omnibus surveys</td>
<td>1,900</td>
<td>1</td>
<td>.25</td>
<td>475</td>
</tr>
<tr>
<td>Intercept interviews with public and healthcare professionals</td>
<td>300</td>
<td>1</td>
<td>.25</td>
<td>75</td>
</tr>
<tr>
<td>In-depth interviews health professionals</td>
<td>50</td>
<td>1</td>
<td>.50</td>
<td>25</td>
</tr>
<tr>
<td>Self-administered questionnaires with health professionals</td>
<td>200</td>
<td>1</td>
<td>.25</td>
<td>50</td>
</tr>
<tr>
<td>Total</td>
<td>2,500</td>
<td></td>
<td></td>
<td>678</td>
</tr>
</tbody>
</table>

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Attention: NIH Desk Officer, Office of Management and Budget, at OIRA_submission@omb.eop.gov or by fax to 202–395–6074. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Christy Thomsen, Director, Office of Communications and Public Liaison, NCCAM, 31 Center Drive, Room 2B11, Bethesda, MD 20892, or fax your request to 301–402–4741, or e-mail thomsenc@mail.nih.gov. Ms. Thomsen can be contacted by telephone at 301–451–8876.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Strengthening Communities Fund (SCF) Evaluation.

OMB No.: New Collection.

Description: This proposed information collection activity is to obtain information from participants in two Strengthening Communities Fund (SCF) programs: The Nonprofit Capacity Building Program and the State, Local, and Tribal Government Capacity Building Program. Both programs are designed to contribute to the economic recovery as authorized in the American Recovery and Reinvestment Act of 2009 (ARRA). The SCF evaluation is an important opportunity to examine outcomes achieved by the Strengthening Communities Fund and progress toward the objective of improving the capacity of organizations served by program grantees to address broad economic recovery issues in their communities.

ANNUAL BURDEN ESTIMATES

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden hours per response</th>
<th>Total burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>An on-line survey of SCF grantees</td>
<td>84</td>
<td>1</td>
<td>0.25</td>
<td>21</td>
</tr>
<tr>
<td>Telephone interview of SCF grantees</td>
<td>84</td>
<td>1</td>
<td>1.50</td>
<td>126</td>
</tr>
<tr>
<td>On-line survey of faith-based and community organizations (FBCOs) that received capacity building services from the SCF grantees</td>
<td>1,000</td>
<td>1</td>
<td>0.50</td>
<td>500</td>
</tr>
</tbody>
</table>

Estimated Total Annual Burden Hours: 647

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L’Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: infocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments 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) 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 or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: November 4, 2010.

Robert Sargis,
Reports Clearance Officer.

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Docket No. FDA–2009–P–0273]

Determination That Amphetamine Sulfate, 5 and 10 Milligram Tablets, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that Amphetamine sulfate, 5 and 10 milligram (mg) tablets, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for Amphetamine sulfate, 5 mg and 10 mg tablets, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Patrick Raulerson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6368, Silver Spring, MD 20993–0002, 301–796–3522.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the “listed drug,” which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.