DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review;
Comment Request; Brain Power! The NIDA Junior Scientist Program and the Companion Program, Brain Power! Challenge Information Collection

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute on Drug Abuse (NIDA), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. 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. The proposed information collection was previously published in the Federal Register on June 28, 2010 Volume 75, No. 123, pages 36659–36660, and allowed 60-days for public comment. No comments were received on this notice.

Proposed Collection: Title: Brain Power! The NIDA Junior Scientist Program, for grades K–5, and the companion program for Middle School, the Brain Power! Challenge.

Type of Information Collection Request: NEW. The previous OMB approval was discontinued on March 31, 2009 (OMB Control number 0925–0542 that was obtained in 2005), and the new submission is requested until July 31, 2011.

Need and Use of Information Collection: This is a request for clearance to evaluate the effectiveness of the Brain Power! Program’s ability to:
- Increase students’ knowledge about the biology of the brain and the neurobiology of drug addiction;
- Increase positive attitudes toward science, careers in science, and science as an enjoyable endeavor, and stimulating interest in scientific careers; and
- Promote more balanced perceptions and attitudes of scientists as being of many races, ages, and genders

The secondary goal is to determine the influence or change of attitudes toward and intentions about drug use. The findings will provide valuable information concerning the goals of NIDA’s Science Education Program of increasing scientific literacy and stimulating interest in scientific careers. In order to test the effectiveness of the evaluation, information will be collected from students before and after exposure to the curriculum with pre- and post-test self-report measures. Surveys will also be administered to teachers after the completion of the program to examine ease and fidelity of implementation, as well as impact in knowledge and understanding of the neurobiology of addiction. Surveys will be administered to parents to obtain parental reaction and opinion on the materials and the degree to which parents find the curriculum informative and appropriate.

Frequency of Response: On occasion.
Affected Public: Elementary and middle school students, teachers, and parents.

Type of Respondents: Students, Teachers, and Parents. The reporting burden is as follows:

Estimated Number of Respondents: 1,260.

Estimated Number of Responses per Respondent: Students: 2, Parents: .5, and Teachers: 1.

Average Burden Hours per Response: Students: .5, Parents: .5, and Teachers: .5.

Estimated Total Annual Burden Hours Requested: 892.5. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report. The estimated annualized burden is summarized below.

<table>
<thead>
<tr>
<th>Types of respondents</th>
<th>Number of respondents</th>
<th>Frequency of response</th>
<th>Average time per response</th>
<th>Annual hour burden</th>
</tr>
</thead>
<tbody>
<tr>
<td>Students (K-grade 5)</td>
<td>375</td>
<td>2</td>
<td>.5</td>
<td>375</td>
</tr>
<tr>
<td>Students (grades 6–9)</td>
<td>375</td>
<td>2</td>
<td>.5</td>
<td>375</td>
</tr>
<tr>
<td>Parents (survey) (K-grade 5)</td>
<td>25</td>
<td>1</td>
<td>.25</td>
<td>6.25</td>
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<tr>
<td>Parents (survey) (grades 6–9)</td>
<td>25</td>
<td>1</td>
<td>.25</td>
<td>6.25</td>
</tr>
<tr>
<td>Parents (postcard) (K-grade 5)</td>
<td>200</td>
<td>1</td>
<td>.25</td>
<td>50</td>
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<tr>
<td>Parents (postcard) (grades 6–9)</td>
<td>200</td>
<td>1</td>
<td>.25</td>
<td>50</td>
</tr>
<tr>
<td>Teachers (evaluation)</td>
<td>30</td>
<td>1</td>
<td>.5</td>
<td>15</td>
</tr>
<tr>
<td>Teachers (online survey)</td>
<td>30</td>
<td>1</td>
<td>.5</td>
<td>15</td>
</tr>
<tr>
<td>Total</td>
<td>1,260</td>
<td></td>
<td></td>
<td>892.50</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 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: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202–395–6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Cathrine Sasek, Coordinator, Science Education Program, Office of Science Policy and Communications, National Institute on Drug Abuse, 6001 Executive Blvd, Room 5237, Bethesda, MD 20892, or call non-toll-free number (301) 443–6071; fax (301) 443–6277; or by e-mail to csasek@nida.nih.gov.

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.


Mary Affeldt, Executive Officer, (OM Director, NIDA).

[FR Doc. 2010–24400 Filed 9–28–10; 8:45 am]

BILLING CODE 4140–01–P

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>
</table>

Estimated Total Annual Burden Hours: 0

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.


Robert Sargis, Reports Clearance Officer.

[FR Doc. 2010–24212 Filed 9–28–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0482]

Draft Guidance for Industry and Investigators on Safety Reporting Requirements for Investigational New Drug Applications and Bioavailability/ Bioequivalence Studies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry and investigators entitled “Safety Reporting Requirements for INDs and BA/BE Studies.” This draft guidance is intended to help sponsors and investigators comply with the new requirements in the final rule entitled “Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety