

June 28, 2006 to ensure their adequate consideration in preparation of the final document. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Comments should be identified with the full title of the guidance and the docket number found in brackets in the heading of this document. Submit electronic comments on the guidance via the Internet at <http://www.fda.gov/dockets/ecomments>.

See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Michelle L. Stull, Center for Veterinary Medicine (HFV-133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-5058, e-mail: [michelle.stull@fda.hhs.gov](mailto:michelle.stull@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

The purpose of this draft guidance is to provide the Center for Veterinary Medicine's current thinking regarding the recommended design and evaluation of effectiveness studies for SRD claims. This guidance identifies specific detailed recommendations for sponsors of new animal drug applications to consider when designing and writing protocols for SRD effectiveness studies.

##### **II. Significance of Guidance**

This Level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance represents the agency's current thinking on the topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate method may be used as long as it satisfies the requirements of applicable statutes and regulations.

##### **III. Comments**

This draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this draft

guidance document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

#### **IV. Electronic Access**

Electronic comments may be submitted on the Internet at <http://www.fda.gov/dockets/ecomments>. Copies of the guidance document entitled "Recommended Study Design and Evaluation of Effectiveness Studies for Swine Respiratory Disease Claims" may be obtained from the CVM Home Page (<http://www.fda.gov/cvm>) and from the Division of Dockets Management Web site (<http://www.fda.gov/ohrms/dockets/default.htm>).

Dated: April 6, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**BILLING CODE 4160-01-S**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **The National Institutes of Health**

#### **Submission for OMB Review; Comment Request; Child/Parent Evaluation and Satisfaction Surveys; Brain Train4Kids: New Delivery of the Brain Power! Program**

*Summary:* In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute on Drug Abuse (NIDA), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval. The proposed information collection was previously published in the **Federal Register** on December 8, 2004, page 71060 and allowed 60 days for public comment. No public comments were received. 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:* BrainTrain4Kids: New Delivery of the Brain Power Program. *Type of information Collection Request:* NEW. *Need and Use of Information Collection:* This research will evaluate the effects of *BrainTrain4Kids.com*, an online program for students (Grades 2 and 3), on: (1) Students' knowledge of scientific inquiry, the human nervous system, the effects of alcohol and tobacco on the brain, and the differences between helpful and harmful drugs; (2) students' attitudes toward science in general; and (3) students' attitudes toward substance abuse. The secondary goals of the summative evaluation are to determine if changes in knowledge and attitudes are retained over follow-up period as well as to determine if parents and second- and third-grade students will report a high degree of satisfaction with the online program. The online program is a new delivery of a National Institute on Drug Abuse science education curriculum for second- and third-grade teachers (*Brain Power! The NIDA Junior Scientist Club*) adapted for the Internet and for use by children at home under the guidance of their parents. If the new program is successful, the public will have access to an evidence-based program via the Internet that contributes to scientific literacy and provides a basis of knowledge upon which to build future substance abuse prevention. In order to evaluate the effectiveness of the program, information will be collected from students before (pretest) and after (post-test) exposure to the Web site and again 6 weeks after the program has been completed (follow-up). Parents will be asked to complete usage logs at six points during their use of the *BrainTrain4Kids* Web site with their children. Prior to the evaluation study, the knowledge and attitude assessment instruments will be pilot-tested with a small sample of students to determine validity and reliability. All data collection will occur online. *Frequency of Response:* On occasion. *Affected Public:* Second- and third-grade children and their parents. *Type of Respondents:* Second- and third-grade children and their parents. The reporting burden is as follows: *Estimated Number of Respondents:* 308; *Estimated Number of Responses per Respondents:* One for two key cohorts, three for one key cohort, and seven for one key cohort; *Average Burden Hours per Response:* 0.378; and *Estimated Total Annual Burden Hours Requested:* 479.50. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report. The

estimated annualized burden is summarized below.

Type of respondents	Number of respondents	Frequency of responses	Average time per response	Annual hour burden
Children (Assessment Instrument Pilot Test) .....	34	1	0.75	25.5
Parents (Assessment Instrument Pilot Test) .....	34	1	1	34.0
Children (Evaluation) .....	120	3	0.5	180.0
Parents (Evaluation: 1 Satisfaction Scale/6 Usage Logs) .....	120	1	0.5	240.0
		6	0.25	
Total .....	308	.....	.....	479.50

**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 the 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: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, room 1-235, Washington, DC 20503, 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](mailto:csasek@nida.nih.gov).

**Comments Due Date**

Comments regarding this information are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: April 10, 2006.  
**Laura Rosenthal,**  
*Executive Officer, National Institute on Drug Abuse.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Public Health Service**

**National Institutes of Health**

**Submission for OMB Review; Comment Request; National Survey of Primary Care Physicians' Recommendations and Practice for Breast, Cervical, Colorectal, and Lung Cancer Screening**

**SUMMARY:** Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH), National Cancer Institute (NCI), has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on January 20, 2006, page 3309 and allowed 60-days for public comment. No public comments were received. 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:* National Survey of Primary Care Physicians' Recommendations and Practice for Breast, Cervical, Colorectal, and Lung Cancer Screening. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* This study will obtain current, national data on primary care physicians' knowledge, attitudes, recommendations, and practices related to screening for breast, cervical, colorectal, and lung cancer. There have been substantial changes in guidelines and/or technologies for these types of cancer screening in recent years. The data collected in this study will support and further NCI work in monitoring and evaluating providers' cancer control knowledge, attitudes, and practices and their impact on population health, as well as enable monitoring of progress toward major cancer control goals. Two questionnaires, one covering breast and cervical cancer screening and the other colorectal and lung cancer screening, will be administered by mail or telephone to a randomly-selected national sample of primary care physicians. *Frequency of Response:* One Time. *Affected Public:* Medical practices, clinics, or other health care organizations. *Type of Respondents:* Primary Care Physicians. *Burden estimates* are as follows:

Questionnaire	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours
Breast & cervical cancer screening .....	1250	1	0.333	416.25
Colorectal & lung cancer screening .....	1250	1	0.333	416.25
Total .....	.....	.....	.....	832.5