FDA has actively participated in the International Conference on Harmonization of Technical Requirements for Approval of Pharmaceuticals for Human Use for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH steering committee is composed of member representatives from the European Commission; European Medicines Evaluation Agency; European Federation of Animal Health; Committee on Veterinary Medicinal Products; the U.S. FDA; the U.S. Department of Agriculture; the Animal Health Institute; the Japanese Veterinary Pharmaceutical Association; the Japanese Association of Veterinary Biologics; and the Japanese Ministry of Agriculture, Forestry and Fisheries.

Four observers are eligible to participate in the VICH steering committee: One representative from the government of Australia/New Zealand, one representative from the industry in Australia/New Zealand, one representative from the government of Canada, and one representative from the industry of Canada. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation for Animal Health (IFAH). An IFAH representative also participates in the VICH steering committee meetings.

II. Draft Revised Guidance on Stability Testing of New Veterinary Drug Substances and Medicinal Products

The draft revised guidance is entitled ''Stability Testing of New Veterinary Drug Substances and Medicinal Products (Revision)'' VICH GL3(R). It has been adapted for veterinary use by the VICH from guidances regarding pharmaceuticals for human use which were adopted by the ICH and for which notices of availability were published in the **Federal Register** of November 7, 2001 (66 FR 56332), June 14, 2002 (67 FR 40951), and November 21, 2003 (68 FR 65717).

In October 2005, the VICH steering committee agreed that a draft revised guidance entitled ''Stability Testing of New Veterinary Drug Substances and Medicinal Products (Revision)'' VICH GL3(R) should be made available for public comment. The draft revised guidance is a revision of a guidance on the same topic for which a notice of availability was published in the **Federal Register** of October 12, 1999. The draft revised guidance clarifies the 1999 guidance, adds information, and provides consistency with more recently published VICH guidances. The draft revised guidance seeks to exemplify the core stability data package to be included in registration applications for new veterinary drug substances and medicinal products. The draft revised guidance is the product of the Quality Expert Working Group of the VICH. Comments about this draft will be considered by FDA and the Quality Expert Working Group.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in section 2 of the guidance have been approved under OMB control number 0910–0032.

IV. Significance of Guidance

This draft revised document, developed under the VICH process, has been revised to conform to FDA's good guidance practices regulation (21 CFR 10.115). For example, the document has been designated ''guidance'' rather than ''guideline.'' In addition, guidance documents must not include mandatory language such as ''shall,'' ''must,'' ''require,'' or ''requirement,'' unless FDA is using these words to describe a statutory or regulatory requirement.

The draft revised VICH guidance (GFI #73) is consistent with the agency's current thinking on the stability testing of new veterinary drug substances and medicinal products. This draft revised guidance does not create or confer any rights for or on any person and will not operate to bind FDA or the public. An alternative method may be used as long as it satisfies the requirements of applicable statutes and regulations.

V. Comments

This draft revised guidance document 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 written 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. A copy of the draft revised guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VI. Electronic Access

Electronic comments may also be submitted on the Internet at *http://www.fda.gov/dockets/ecomments*. Once on this Internet site, select Docket No. 1999D–2215, entitled ''Draft Revised Guidance for Industry on Stability Testing of New Veterinary Drug Substances and Medicinal Products (Revision)'' VICH GL3(R) and follow the directions.

Copies of the draft guidance document entitled ''Draft Revised Guidance for Industry on Stability Testing of New Veterinary Drug Substances and Medicinal Products (Revision)'' VICH GL3(R) may be obtained on the Internet from the CVM home page at *http://www.fda.gov/cvm*.

Dated: April 6, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–5525 Filed 4–13–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0138]

Draft Guidance for Industry: Recommended Study Design and Evaluation of Effectiveness Studies for Swine Respiratory Disease Claims; 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 (#178) entitled ''Recommended Study Design and Evaluation of Effectiveness Studies for Swine Respiratory Disease Claims.'' This draft guidance provides recommendations to industry relating to study design and describes the criteria that the Center for Veterinary Medicine (CVM) intends to use to evaluate effectiveness studies for swine respiratory disease (SRD) claims.

DATES: Submit written or electronic comments on this draft guidance by

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*.

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.

[FR Doc. E6–5527 Filed 4–13–06; 8:45 am]

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