regulatory submissions in electronic format for ANDAs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes or regulations.

II. Comments

Interested persons may, at any time, submit written or electronic comments on the guidance to the Dockets Management Branch (see **ADDRESSES**). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: June 11, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–16163 Filed 6–26–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1532]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Final Guidances for Industry on ''Effectiveness of Anthelmintics: Specific Recommendations for Equine'' (VICH GL15), ''Effectiveness of Anthelmintics: Specific Recommendations for Porcine'' (VICH GL16), and ''Effectiveness of Anthelmintics: Specific Recommendations for Canine'' (VICH GL19); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of three final guidances for industry (Nos. 109, 110, and 111 respectively) entitled ''Effectiveness of Anthelmintics: Specific Recommendations for Equine'' (VICH GL15), ''Effectiveness of Anthelmintics: Specific Recommendations for Porcine'' (VICH GL16), and ''Effectiveness of Anthelmintics: Specific Recommendations for Canine'' (VICH GL19). These related guidance documents have been developed by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). They are intended to standardize and simplify methods used in the evaluation of new anthelmintics submitted for approval to the European Union, Japan, and the United States.

DATES: Submit written or electronic comments on the final guidance documents at any time.

ADDRESSES: Submit written requests for single copies of the final guidance documents to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. *See* the **SUPPLEMENTARY INFORMATION** section for electronic access to the final guidance document.

Submit written comments on the final guidance documents to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Comments should be identified with the full title of the final guidance and the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Thomas Letonja, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7576, e-mail: *tletonja@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce the differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonisation (ICH) of Technical Requirements for Registration 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 recommendations 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.

Two observers are eligible to participate in the VICH Steering Committee: One representative from the Government of Australia/New Zealand and one representative from the industry in Australia/New Zealand. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the Conféderation Mondiale de L'Industrie de la Santé Animale (COMISA). A COMISA representative also participates in the VICH Steering Committee meetings.

II. Final Guidance on Effectiveness of Anthelmintics

In the **Federal Register** on October 19, 2000 (65 FR 62723), FDA published the notice of availability of these VICH draft guidances, giving interested persons until December 18, 2000, to submit comments. FDA received no comments. The final guidance was submitted to the VICH Steering Committee. At a meeting held on June 28, 2001, the VICH Steering Committee endorsed the three final guidances for industry, VICH GL15, VICH GL16, and VICH GL19.

The three final guidances VICH GL15, VICH GL16, and VICH GL19 should be read in conjunction with the ''Effectiveness of Anthelmintics: General Recommendations (EAGR)'' announced in the **Federal Register** on April 6, 2001 (66 FR 18257). The final

guidances for equine, porcine, and canine are part of the EAGR, and the aim of these three separate final guidances is to: (1) Be more specific for certain issues not discussed in the general guidance, (2) highlight differences with the EAGR on effectiveness data recommendations, and (3) give explanations for disparities between the EAGR and these documents.

These final level 1 guidance documents, developed under the VICH process, are consistent with FDA's good guidance practices regulation (21 CFR 10.115). These documents do 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. (Information collected is covered under OMB control number 0910–0032.)

III. Comments

As with all of FDA's guidances, the public is encouraged to submit written or electronic comments with new data or other new information pertinent to these guidances. FDA will periodically review the comments in the docket and, where appropriate, will amend the guidances. The agency will notify the public of any such amendments through a notice in the **Federal Register**.

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding these guidance documents at any time. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the final guidance documents and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Copies of the final guidance documents entitled ''Effectiveness of Anthelmintics: Specific Recommendations for Equine'' (VICH GL15), ''Effectiveness of Anthelmintics: Specific Recommendations for Porcine'' (VICH GL16), and ''Effectiveness of Anthelmintics: Specific Recommendations for Canine'' (VICH GL19) may be obtained on the Internet at http://www.fda.gov/cvm.

Dated: June 17, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–16292 Filed 6–26–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Single Source Cooperative Agreement Award to the Brigham and Women's Hospital, Harvard University, Boston, MA

AGENCY: Center for Mental Health Services (CMHS), Substance Abuse and Mental Health Services Administration (SAMHSA), HHS.

ACTION: Notice of intent to award a single source cooperative agreement to Brigham and Women's Hospital, Harvard University, to support a program expansion and extension for the PRISMe multisite study Coordinating Center.

SUMMARY: The Center for Mental Health Services (CMHS), Substance Abuse and Mental Health Services Administration (SAMHSA), is publishing this notice to provide information to the public concerning a planned single source cooperative agreement award in the amount of $500,000 in FY 2002, and $500,000 in FY 2003 for a project period of two years to the Brigham and Women's Hospital, Harvard University. This is not a formal request for applications. Assistance will be provided only to Brigham and Women's Hospital based on the receipt of a satisfactory application that is approved by an independent review group.

Authority/Justification: The grant will be made under the authority of Section 520A of the Public Health Service Act, as amended. The award is intended to complete data analyses and write-up of the PRISMe multisite study findings, to complete the program manuals for the PRISMe study findings, and to produce an archive of the study database suitable for public use at the end of the project period. This award is being made on a single source basis because Brigham and Women's Hospital has coordinated the design and implementation of the PRISMe multisite study from which the additional data analyses, write-ups of study findings, program manuals, and archived database will be drawn. Making the award to another entity would require additional start-up time and costs, significant loss of critical information, as well as duplication of previously completed work.

The Catalog of Federal Domestic Assistance (CFDA) number for this program is 93.243.

CONTACT: For more information about this program, contact: Betsy McDonel Herr, Ph.D., Government Project Officer, Community Support Branch, Division of Knowledge Development and Systems Change, Center for Mental Health Services (CMHS), SAMHSA, Room 11C–22 Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, (301) 594–2197, *bmcdonel@samhsa.gov.*

Dated: June 20, 2002.

Richard Kopanda,

Executive Officer, SAMHSA.

[FR Doc. 02–16322 Filed 6–25–02; 1:58 pm]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Single Source Grant Award to the National Families in Action, Inc., Atlanta, GA

AGENCY: Center for Substance Abuse Prevention (CSAP), Substance Abuse and Mental Health Services Administration (SAMHSA), HHS.

ACTION: Notice of intent to award a single source grant to National Families in Action, Inc. to support updating, pilot testing and adaptation for different target audiences of the Basic Training I module for the National Parent Drug Prevention Corps.

SUMMARY: The Center for Substance Abuse Prevention (CSAP), Substance Abuse and Mental Health Services Administration (SAMHSA), is publishing this notice to provide information to the public concerning a planned single source grant award in the amount of $100,000 in FY 2002 for a project period of one year to the National Families in Action (NFIA). This is not a formal request for applications. Assistance will be provided only to NFIA based on the receipt of a satisfactory application that is approved by an independent review group.

Authority/Justification: The grant will be made under the authority of section 516 of the Public Health Service Act, as amended. The award is intended to support updating, pilot testing, adaptation for different target audiences of the Basic Training I module that will be used in the National Parent Drug Prevention Corps activities that CSAP