strategies, objectives, and priorities, and reviews progress toward injury prevention and control. The Committee provides advice on the appropriate balance of intramural and extramural research, and also provides guidance on the needs, structure, progress and performance of intramural programs, and on extramural scientific program matters. The Committee provides second-level scientific and programmatic review for applications for research grants, cooperative agreements, and training grants related to injury control and violence prevention, and recommends approval of projects that merit further consideration for funding support. The Committee also recommends areas of research to be supported by contracts and cooperative agreements and provides concept review of program proposals and announcements.

Matters to be Discussed: The meeting will convene in open session from 8:30 a.m. to 4:25 p.m. on March 28, 2001. Following the NCIPC Director's update, the Committee will discuss the role of ACIPC; NCIPC growth areas, including presentations on fire-related injury prevention and child maltreatment prevention research; NCIPC budget; and current spending plan in violence against women. The Committee will also discuss reports from a March 12, 2001, conference call meeting of the Subcommittee on Family and Intimate Violence Prevention and the March 28, 2001, meeting of the Science and Program Review Subcommittee. Other topics include patient safety as an injury prevention and control issue, and small business innovative research.

Name: ACIPC Science and Program Review Subcommittee.

Times and Dates: 11:30 a.m.—12:30 p.m., March 28, 2001.

Place: DoubleTree Hotel Atlanta-Buckhead, 3342 Peachtree Road, N.E., Atlanta, Georgia 30326.

Status: Open to the public, limited only by the space available.

Purpose: The Subcommittee provides advice on the needs, structure, progress and performance of NCIPC programs. The Subcommittee provides second-level scientific and programmatic review for applications for research grants, cooperative agreements, and training grants related to injury control and violence prevention, and recommends approval of projects that merit further consideration for funding support. The Subcommittee also advises on priorities for research to be supported by contracts, grants, and cooperative agreements and provides concept review of program proposals and announcements.

Matters to be Discussed: The meeting will convene in open session from 11:30 a.m. to 12:30 p.m. on March 28, 2001. The Subcommittee will discuss an update on NCIPC's evaluation and planning.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Mr. Thomas E. Blakeney, Acting Executive Secretary, ACIPC, NCIPC, CDC, 4770 Buford Highway, NE, M/S K61, Atlanta, Georgia 30341–3724, telephone 770/488–1481.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: March 7, 2001.

Carolyn J. Russell,

Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 01–6130 Filed 3–12–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Peripheral and Central Nervous System Drugs Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of a meeting of the Peripheral and Central Nervous System Drugs Advisory Committee. This meeting was announced in the **Federal Register** of February 14, 2001 (66 FR 10304). The amendment is being made to cancel the entire session on March 15, 2001. This meeting is open to the public. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Sandra L. Titus, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301–827–7001, e–mail: tituss@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area) code 12543. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 14, 2001 (66 FR 10304), FDA announced that a meeting of the Peripheral and Central Nervous System Drugs Advisory Committee would be held on March 13, 14, and 15, 2001. On page 10304, beginning in the last column, the *Date and Time*, *Agenda*, and *Procedure* portions of this meeting are amended to read as follows:

Date and Time: The meeting will be held on March 13 and 14, 2001, 8 a.m. to 5 p.m.

Location: Holiday Inn, The Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Agenda: On March 13, 2001, the committee will discuss drug development for individuals with mild cognitive impairment (MCI). In the recent literature there has been a discussion of an entity referred to as MCI. While MCI is considered by some to be a distinct clinical entity, others consider that the majority of patients diagnosed with MCI have an early form of Alzheimer's Disease. It is critical for regulatory purposes that the issues surrounding this diagnosis are fully explored. Toward that end the committee will listen to speakers and discuss the following and other related questions:

1. Can MCI be clearly defined in a clinical setting?

2. Are there valid criteria for the diagnosis of MCI?

3. Can MCI be distinguished from Alzheimer's Disease and other causes of dementia?

4. What outcome measures are appropriate to use in clinical drug trials conducted in MCI?

5. Should clinical drug trials in MCI incorporate any special features in their design?

On March 14, 2001, the committee will discuss drug development for individuals with vascular dementia. While vascular dementia is considered by some to be a distinct entity others do not agree that it can be easily distinguished from Alzheimer's Disease and/or other dementias. It is critical for regulatory purposes that the issues surrounding this diagnosis are fully explored. Toward that end the committee will listen to presentations and then discuss the following and other related questions:

1. Can vascular dementia be clearly defined in a clinical setting?

2. Are there valid criteria for the diagnosis of vascular dementia?

3. Can vascular dementia be distinguished from Alzheimer's Disease and other causes of dementia?

4. What outcome measures are appropriate to use in clinical drug trials conducted in vascular dementia?

5. Should clinical drug trials in vascular dementia incorporate any special features in their design?

FDA will provide a background position paper on MCI and on vascular dementia prior to each meeting. When the background material becomes available, it will be posted under the Peripheral and Central Nervous System Drugs Advisory Committee Docket site at http://www.fda.gov/ohrms/dockets/ac/acmenu.htm. (Click on the year 2001 and scroll down to the Peripheral and Central Nervous System Drugs meetings.)

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by March 1, 2001. On March 13 and 14, 2001, oral presentations from the public will be scheduled between approximately 10:30 a.m. and 12:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 1, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 7, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–6241 Filed 3–8–01; 4:21 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2975]

International Cooperation on Harmonisation of Technical Requirements for Approval of Veterinary Medicinal Products (VICH); Final Guidance on ''Environmental Impact Assessments (EIA's) for Veterinary Medicinal Products (VMP's)–Phase I'' (VICH GL6); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance for industry (No. 89) entitled ''Environmental Impact Assessments (EIA's) for Veterinary Medicinal Products (VMP's)–Phase I'' (VICH GL6). This final guidance document has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Approval of Veterinary Medicinal Products (VICH). It is intended to assist in developing harmonized guidance for conducting environmental assessments for VMP's in the European Union, Japan, and the United States.

DATES: Submit written comments at any time.

ADDRESSES: Copies of the final guidance documents entitled ''Environmental Impact Assessments (EIA's) for Veterinary Medicinal Products (VMP's)–Phase I '' (VICH GL6) may be obtained on the Internet from the CVM home page at http://www.fda.gov/cvm/fda/mappgs/vich.html. Persons without Internet access may submit written requests for a single copy of the final guidance 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 request.

Submit written comments on the final guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Charles E. Eirkson (HFV–145), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6958, e–mail: ceirkson@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 recommendations. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical recommendations for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce the differences in technical recommendations for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use for several years to develop harmonized technical recommendations 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 VMP's. The VICH is concerned with developing harmonized technical recommendations for the VMP's 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; U.S. FDA; U.S. Department of Agriculture; Animal Health Institute; Japanese Veterinary Pharmaceutical Association; 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 Confédération Mondiale de L'Industrie de la Santé Animale (COMISA). A COMISA representative also participates in the VICH Steering Committee meetings.

II. Guidance on Assessing Environmental Impacts of VMP's Other Than Veterinary Biological Products

In the **Federal Register** of September 17, 1999 (64 FR 50519), FDA published the notice of availability of the VICH GL6 guidance entitled ''Environmental Impact Assessments (EIA's) for Veterinary Medicinal Products (VMP's)–Phase I'' giving interested persons until October 18, 1999, to submit comments. In response to the **Federal Register** notice, the agency received one comment that endorsed adoption of the Phase I document. The European Union and Japan also published this guidance in their respective countries and requested comments. The comments were evaluated at the November 12 through 16, 1999, VICH Ecotoxicity/ Environmental Impact Assessment Working Group meeting in Brussels, Belgium. In response to the comments from the European Union and Japan, the working group revised the wording in questions 2, 6, 7, 8, 11, 14, 15, 16, and 17 to clarify the questions, the issues covered by questions or the information to be provided in response to questions. The working group also added questions 18 and 19 to the Phase I document. Questions 18 and 19 were added to account for regional laws that can alter environmental introductions of VMP's. Specifically in the European Union, certain member countries have legal requirements for a minimum manure storage period. Others have legal restrictions on the amount of manure that may be spread in a given area. These legal requirements will modify variables in the predicted