DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0156]

International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products; Final Guidance for Industry on Environmental Impact Assessments for Veterinary Medicinal Products—Phase II; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document for industry (#166) entitled ''Environmental Impact Assessments (EIA's) for Veterinary Medicinal Products (VMP's)—Phase II'' (VICH GL38). This guidance has been developed for veterinary use by the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This VICH guidance document provides recommendations for internationally harmonized test methods used to generate environmental fate and toxicity data.

DATES: Submit written or electronic comments at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7519 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 guidance document.

Submit written comments on the guidance to the Division of Dockets Management (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 guidance and the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Charles E. Eirkson, Center for Veterinary Medicine (HFV–145), 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 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 differences in technical requirements for drug development among regulatory agencies in different countries.

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; 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.

The following 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. Guidance on Environmental Impact Assessments

In the **Federal Register** of April 21, 2004 (69 FR 21552), FDA published the notice of availability of the VICH draft guidance, giving interested persons until May 21, 2004, to submit comments. After consideration of comments received, the draft guidance was changed in response to the comments and submitted to the VICH Steering Committee. At a meeting held on October 2004, the VICH Steering Committee endorsed the final guidance for industry (VICH GL38). The aim of the guidance is to assess the potential for VMPs to affect nontarget species in the environment, including both aquatic and terrestrial species. It is not possible to evaluate the effects of VMPs on every species in the environment that may be exposed to the VMP following its administration to the target species. The species tested are intended to serve as surrogates or indicators for the range of species present in the environment.

This Phase II guidance contains sections for each of the major branches: (1) Aquaculture; (2) intensively reared terrestrial animals; and (3) pasture animals, each containing decision trees pertaining to the branch. The document also contains a section listing the recommended tests for physical/chemical properties, environmental fate and environmental effects, as well as a recommendation of how to determine when tests may be relevant.

In the United States, the environmental impact of VMPs is determined under the requirements established by the National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.*) and its implementing regulations (40 CFR part 1500 and 21 CFR part 25) and under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(d)). Under NEPA, an environmental assessment (EA) is conducted to determine whether a VMP may have a significant environmental impact. A particular VMP may be categorically excluded from the requirement of an EA, or it may require an EA, an environmental impact statement, or both.

Information collection is covered under Office of Management and Budget control number 0910–0032.

III. Significance of Guidance

This 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.'' Because guidance

documents are not binding, mandatory words such as ''must,'' ''shall,'' and ''will'' in the original VICH document have been substituted with ''should.'' Similarly, words such as ''require'' or ''requirement'' have been replaced by ''recommend'' or ''recommendation'' as appropriate to the context.

This VICH guidance (#166) represents the agency's current thinking on the conduct of environmental impact assessments for veterinary medicinal products proposed for marketing in the European Union, Japan, and the United States. This guidance does not create or confer any rights for or on any person and will not operate to bind FDA or the public. You may use an alternative method as long as it satisfies the requirements of applicable statutes and regulations.

IV. Comments

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

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this 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.

V. Electronic Access

Copies of the guidance document entitled ''Environmental Impact Assessments (EIA's) for Veterinary Medicinal Products (VMP's)—Phase II'' (VICH GL38) may be obtained on the Internet from the CVM home page at *http://www.fda.gov/cvm*.

Dated: December 23, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–39 Filed 1–6–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Committee on Rural Health and Human Services; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), notice is hereby given that the following committee will convene its fifty-second meeting.

Name: National Advisory Committee on Rural Health and Human Services.

Dates and Times: January 29, 2006, 2 p.m.–5:15 p.m.; January 30, 2006, 8:45 a.m.–4:45 p.m.; January 31, 2006, 8:30 a.m.–11:15 a.m.

Place: Jurys Washington Hotel, 1500 New Hampshire Avenue, NW., Washington, DC 20036, Phone: 202–483–6000.

Status: The meeting will be open to the public.

Purpose: The National Advisory Committee on Rural Health and Human Services provides advice and recommendations to the Secretary with respect to the delivery, research, development and administration of health and human services in rural areas.

Agenda: Sunday afternoon, January 29, at 2 p.m., the Chairperson, the Honorable David Beasley, will open the meeting and welcome the Committee. The first session will open with a discussion of the Committee business and a review of the 2006 report to the Secretary. This will be followed by a session on the role of HHS in connecting the three 2007 report topics by Elizabeth M. Duke, Administrator of the Health Resources and Services Administration. Jack Kalavritinos, HHS Office of Intergovernmental Affairs has also been invited to speak on these three topics. The three topics for the 2007 report are as follows: Medicare Advantage, Substance Abuse and Head Start. The final two sessions of the day will be an overview of Medicare Advantage in rural communities and an overview of substance abuse in rural communities. The Sunday meeting will close at 5:15 p.m.

Monday morning, January 30, at 8:45 a.m. the meeting will begin with an overview of Head Start in rural communities. The next three sessions will look at the three topics from a research perspective. Speakers will include Keith Mueller from the Rural Policy Research Institute; Peggy Halpern and Ann McCormick from ASPE (Assistant Secretary for Planning and Evaluation, HHS); David Hartley with Maine Rural Health Research Center; and Maria Woolverton, Office of Planning, Research and Evaluation at the Administration for Children and Families. The final two sessions of the day will consist of an update on Washington by the National Rural Health Association and the appointment of Subcommittees for the 2007 report. The Monday meeting will close at 4:45 p.m.

The final session will be convened Tuesday morning, January 31, at 8:30 a.m. The Committee will break into Subcommittee format to discuss the chapter outlines and timelines. The meeting will conclude with a discussion of the June meeting. The meeting will be adjourned at 11:15 a.m.

FOR FURTHER INFORMATION CONTACT: Anyone requiring information regarding the Committee should contact Tom Morris, M.P.A., Executive Secretary, National Advisory Committee on Rural Health and Human Services, Health Resources and Services Administration, Parklawn Building, Room 9A–55, 5600 Fishers Lane, Rockville, MD 20857, telephone (301) 443–0835, Fax (301) 443–2803.

Persons interested in attending any portion of the meeting should contact Michele Pray-Gibson, Office of Rural Health Policy (ORHP), telephone (301) 443–0835. The Committee meeting agenda will be posted on ORHP's Web site *http://www.ruralhealth.hrsa.gov*.

Dated: December 29, 2005.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. E6–43 Filed 1–6–06; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant