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

environmental concentration in soil PEC_{soil} calculation and the resulting PEC_{soil}, as described in question 17. Therefore, it is important to consider them in the Phase I EIA. At a meeting held June 14 through 16, 2000, the VICH Steering Committee endorsed the final VICH GL6 guidance that incorporates these changes.

VICH GL6 offers guidance on how to assess the environmental impact of VMP's other than veterinary biological products.

In the United States, the environmental impact of VMP's 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 (EIS), or both.

This final guidance document is intended to be consistent with the laws of the European Union, Japan, and the United States. In an effort to harmonize the different recommendations in each of these areas for assessing the environmental impact of VMP's, this final guidance document adopts the terminology ''Phase I EIA's'' and ''Phase II EIA's.'' Using the terminology of the final guidance document, a Phase I EIA is equivalent under NEPA to either a categorical exclusion or an EA that addresses only environmental exposures (40 CFR 1508.4 and 1508.9). A Phase II EIA is equivalent to an EA with more extensive data than would be necessary under the U.S. equivalent of a Phase I EIA. A Phase II EIA may lead to a finding of no significant impact or preparation of an EIS under NEPA.

This final Level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). This final guidance document represents a portion of FDA's current thinking on the conduct of ecological risk assessment for veterinary medicinal products proposed for marketing in the European Union, Japan, and the United States. 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.

Information collected is covered under OMB control number 0910–0332.

III. Comments

As with all of FDA's guidances, the public is encouraged to submit written comments with new data or other new information pertinent to this final 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, at any time, submit written comments to the Dockets Management Branch (address above) regarding this guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 5, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–6116 Filed 3–12–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0079]

Acceptance of Foreign Clinical Studies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance entitled ''Acceptance of Foreign Clinical Studies.'' This final guidance is intended to clarify the ethical principles with which a sponsor must comply before FDA would accept a foreign clinical study not conducted under an investigational new drug application (IND) or investigational device exemption (IDE) in support of a marketing approval application.

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

ADDRESSES: Submit written requests for single copies of the final guidance entitled ''Acceptance of Foreign Clinical Studies'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1601, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the final guidance.

FOR FURTHER INFORMATION CONTACT: David A. Lepay, Office for Science Coordination and Communication (HF–34), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4000.

SUPPLEMENTARY INFORMATION:

I. Background

FDA regulations allow for the acceptance of foreign clinical studies not performed under an IND or IDE in support of a marketing approval application for a drug, biological product, or device if certain conditions are met. Under these regulations, the study must conform to the ethical principles contained in the Declaration of Helsinki (the Declaration) or with the laws and regulations of the country in which the research was conducted, whichever provides greater protection of the human subjects. In October 2000, the World Medical Association approved a fifth revision of the Declaration. FDA is making this guidance available to clarify which version of the Declaration was incorporated into the drug regulations, and which version of the Declaration was incorporated into the device regulations, and, therefore, which version of the Declaration is applicable to foreign studies conducted without an IND or IDE. FDA will also review any other guidance documents on this subject, and modify them, if necessary, to conform to the clarification expressed in this guidance.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The guidance represents the agency's current thinking on the ethical principles with which a sponsor must comply before FDA would accept a foreign clinical study not conducted under an IND or IDE in support of a marketing approval application. It does not create or confer