OMB control number 0910–0452. The approval expires on March 31, 2007. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: April 15, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–9073 Filed 4–20–04; 8:45 am]

BILLING CODE 4160–01–S

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Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products; Draft Guidance for Industry on Environmental Impact Assessments for Veterinary Medicinal Products—Phase II; Request for Comments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for comments of a draft guidance document for industry (#166) entitled "Environmental Impact Assessments (EIA's) for Veterinary Medicinal Products (VMP's)—Phase II'' (VICH GL38). This draft guidance has been developed for veterinary use by the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal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

DATES: Submit written or electronic comments on the draft guidance by May 21, 2004, to ensure their adequate consideration in preparation of the final guidance document.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ADDRESSES: Submit written requests for single copies of the draft guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 Comments should be identified with the full title of the draft guidance and the docket number found in brackets in the heading of this document.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.

Four observers are eligible to participate in the VICH Steering Committee as follows: 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 Guidance on Environmental Impact Assessments

The VICH Steering Committee held a meeting in October 2003 and agreed that the draft guidance document entitled "Environmental Impact Assessments (EIA'S) For Veterinary Medicinal Products (VMP's)—Phase II'' (VICH GL38) should be made available for public comment. The aim of the guidance is to assess the potential for VMP's to affect nontarget species in the environment, including both aquatic and terrestrial species. It is not possible to evaluate the effects of VMP's 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 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.

FDA and the VICH Ecotoxicity/Environmental Impact Assessment Working Group will consider comments about the draft guidance document. Information collection is covered under the Office of Management and Budget control number 0910–0032.

III. Significance of Guidance

This draft 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.

The draft 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

This draft 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 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. A copy of the draft guidance and 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

Electronic comments may also be submitted electronically on the Internet at *http://www.fda.gov/dockets/ecomments*. Once on this Internet site, select [docket number] entitled "Environmental Impact Assessments (EIA's) for Veterinary Medicinal Products (VMP's)—Phase II'' (VICH GL38) and follow the directions.

Copies of the draft 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: April 13, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources And Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: The Division of Independent Review Grant Reviewer Recruitment Form—New

HRSA's Division of Independent Review (DIR) is responsible for carrying out the independent and objective review of all eligible applications submitted to HRSA. DIR ensures that the independent review process is efficient, effective, economical and complies with statutes, regulations and policies. The review of applications is performed by people knowledgeable in the field of endeavor for which support is requested and is advisory to individuals in HRSA responsible for making award decisions.

To streamline the collection, selection and assignment of grant reviewers to objective review committees, HRSA will utilize a web-based data collection form to gather critical reviewer information. The Grant Reviewer Recruitment Form will standardize pertinent categories of reviewer information, such as areas of expertise, occupation, work settings, reviewer experience, and allow maximum use of drop-down menus to simplify for the data collection process. All self-nominated reviewers will be channeled to the Grant Reviewer Recruitment Form; DIR anticipates a monthly volume of approximately 100 self-nominated responses. On a periodic basis, existing HRSA reviewers will be notified and directed to update their profile (via the Grant Reviewer Recruitment Form). HRSA maintains a pool of approximately 5,000 individuals that have previously served on HRSA objective review committees; DIR projects that approximately 3,700 individuals (or 75% of existing reviewers) would comply with instructions to update their profile on the web-based Recruitment Form.

For existing HRSA reviewers, the amount of time required to complete the Recruitment Form will be abbreviated since HRSA will fill-in the Form with previously collected personal information; existing reviewers will focus only on updating changes (*e.g.*, addresses, employer, expertise, occupation) to their profile.

The estimate of burden for the HRSA Grant Reviewer Recruitment Form is as follows:

Type of respondent*	Number of respondents	Responses per respondent	Total responses	Minutes per response (minutes)	Total burden hours
New reviewer	1,200	1	1,200	45	900