comments, data, and information. Individuals submitting written information, or any individuals or entities submitting electronic comments, may submit one copy. Submissions are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by supporting information. Received submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Information submitted after the closing date will not be considered except by petition under 21 CFR 10.30.

### IV. Marketing Policy

Under § 330.14(h), any product containing the conditions for which data and information are requested may not be marketed as an OTC drug in the United States at this time unless it is the subject of an approved new drug application or abbreviated new drug application.

### V. Reference

The following reference is on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Comment No. EXT1.

Dated: May 12, 2004.

**William K. Hubbard,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. 04–11248 Filed 5–18–04; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2002D–0326]**

## International Cooperation on Harmonization of Technical Requirements for Approval of Veterinary Medicinal Products; Final Guidance for Industry on Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Testing; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; availability.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry (#149) entitled ''Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Testing'' (VICH GL33). This guidance has been developed by the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This guidance outlines a recommended testing approach to assure human food safety following the consumption of food products derived from animals treated with veterinary drugs.

**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, 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:** Louis T. Mulligan, Center for Veterinary Medicine (HFV–153), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6984, e-mail: *lmulliga@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; the 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: 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 General Testing

In the **Federal Register** of September 4, 2002 (67 FR 56570), FDA published the notice of availability of the VICH draft guidance, giving interested persons until October 4, 2002, 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 10 and 11, 2002, the VICH Steering Committee endorsed the final guidance for industry, VICH GL33.

Existing toxicological testing recommendations for veterinary drugs have evolved from the toxicological tests for human medicines, food additives, and pesticides. The following guidance was developed to include tests particularly relevant to the identification of a no-observable adverse effect level (NOAEL) for veterinary drugs. The scope of this guidance is to identify the following tests: (1) Basic tests recommended for all new animal drugs used in food-producing animals in order to assess the safety of drug residues present in human food; (2)

additional tests recommended based on specific toxicological concerns associated with the structure, class, mode of action, etc., of the drug; and (3) special tests that might be useful in the evaluation of the relevance or the interpretation of data obtained in the basic or additional tests.

**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, unless specifically supported by statute or regulation, mandatory words such as ''must,'' ''shall,'' and ''will'' in the original VICH documents have been substituted with ''should.''

This guidance document represents the agency's current thinking to establish the safety of veterinary drug residues in human food in a variety of toxicological evaluations. This guidance does 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.

**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 ''Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Testing'' (VICH GL33) may be obtained on the Internet from the CVM home page at *http://www.fda.gov/cvm*.

Dated: May 13, 2004.

**William K. Hubbard,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. 04–11254 Filed 5–18–04; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Proposed Collection: Comment Request; NIH Customer/Partner Satisfaction Survey of Modification in Procedures for Applications and Awards of Research Project Grants

**SUMMARY:** Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of Extramural Research, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. The proposed information collection was previously published in the **Federal Register** on May 23, 2002, page 36202. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The NIH may not conduct or sponsor, and the respondent is not required to respond to, any information that has been extended, revised or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

**Proposed Collection**

*Title:* NIH Customer/Partner Satisfaction Survey of Modification in procedures for Applications and Awards of Research Project Grants.

*Type of Information Collection Request:* New request.

*Need and Use of Information Collection:* The information collected in these surveys will be used by the Office of Extramural Research to evaluate the re-engineering initiative, including the Modular Grant Application Process and initiatives under the NIH Roadmap Initiative, intended to facilitate application and award of Federal assistance programs administered by the NIH Modular Applicant/Grant process has been in effect for two years. At the outset of its implementation, the community was advised that the process would reduce administrative burden by focusing the efforts of investigators, institutional officials, and National Institutes of Health (NIH) staff on the science of the application. The NIH now believes it is an appropriate time to determine if these objectives have been met.

*Frequency of Response:* On occasion.

*Affected Public:* Institutional Officials, Principal Investigators (PI's), Peer Reviewers, Program and Grants Management Staff, Institute Budget Officers.

The annual reporting burden is as follows:

*Estimated Number of Respondents:* 1,000.

*Estimated Number of Responses per Respondent:* 1.

*Average Burden Hours per Response:* .334.

*Estimated Total Burden Hours Requested:* 334. Each year we will repeat the same survey with different respondents. There are no Capital Costs, Operating Costs and/or Maintenance Costs to report.

*Request for Comments:* Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

*Direct Comments to OMB:* Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Anthony Demsey, OD, NIH, Building 1, Room 152, Bethesda, MD 20892–7974, or call non-toll-free number (301) 496–0232, or e-mail your request, including your address to: *Demseya@od.nih.gov.*

*Comment Due Date:* Comments regarding this information collection are best assured of having their full effect if