office in processing your requests. 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Maureen Dewey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 5195, Silver Spring, MD 20993–0002, 301–796–0845.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Exocrine Pancreatic Insufficiency Drug Products—Submitting NDAs.'' On April 28, 2004 (69 FR 23410), FDA announced that all exocrine pancreatic insufficiency drug products are new drugs and that manufacturers who wish to continue to market these products must submit applications as required by section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) and 21 CFR part 314. The **Federal Register** announcement stated that FDA is prepared to accept NDAs for these products, including applications submitted under section 505(b)(2) of the act. This guidance is intended to assist manufacturers of currently marketed exocrine pancreatic insufficiency drug products in preparing and submitting documentation to meet NDA requirements for the drug products.

Also on April 28, 2004 (69 FR 23414), FDA announced the availability of the draft version of this guidance. A number of comments were received, and the agency considered them carefully as it finalized the guidance. Although the guidance has not changed substantially, the following changes are noteworthy: (1) In the Background section, the scope of the guidance was clarified; (2) in the Chemistry, Manufacturing, and Controls section, several items were further explained; (3) in the Nonclinical Pharmacology and Toxicology section, two points were additionally clarified; (4) in the Safety subsection, the recommended dosage was updated; and (5) in the References section, two additional references were added and one reference was deleted.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on submitting NDAs for exocrine pancreatic insufficiency drug products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

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.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: April 6, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–5528 Filed 4–13–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0139]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Draft Revised Guidance for Industry on Stability Testing of New Veterinary Drug Substances and Medicinal Products (Revision); Request for Comments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for comment of a draft revised guidance for industry (#73) entitled ''Stability Testing of New Veterinary Drug Substances and Medicinal Products (Revision)'' VICH GL3(R). This draft revised guidance, which updates a guidance on the same topic for which a notice of availability was published in the **Federal Register** of October 12, 1999 (64 FR 55293) (the 1999 guidance), has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This draft revised document is intended to provide guidance regarding the development of stability testing data new animal drug applications (referred to as registration applications in the guidance) submitted to the European Union (EU), Japan, and United States.

DATES: Submit written or electronic comments by May 15, 2006 to ensure their adequate consideration in preparation of the final 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 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 guidance and the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Dennis Bensley, Center for Veterinary Medicine, (HFV–143), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6956, e-mail: *dennis.bensley@fda.hhs.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 U.S. 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. Draft Revised Guidance on Stability Testing of New Veterinary Drug Substances and Medicinal Products

The draft revised guidance is entitled ''Stability Testing of New Veterinary Drug Substances and Medicinal Products (Revision)'' VICH GL3(R). It has been adapted for veterinary use by the VICH from guidances regarding pharmaceuticals for human use which were adopted by the ICH and for which notices of availability were published in the **Federal Register** of November 7, 2001 (66 FR 56332), June 14, 2002 (67 FR 40951), and November 21, 2003 (68 FR 65717).

In October 2005, the VICH steering committee agreed that a draft revised guidance entitled ''Stability Testing of New Veterinary Drug Substances and Medicinal Products (Revision)'' VICH GL3(R) should be made available for public comment. The draft revised guidance is a revision of a guidance on the same topic for which a notice of availability was published in the **Federal Register** of October 12, 1999. The draft revised guidance clarifies the 1999 guidance, adds information, and provides consistency with more recently published VICH guidances. The draft revised guidance seeks to exemplify the core stability data package to be included in registration applications for new veterinary drug substances and medicinal products. The draft revised guidance is the product of the Quality Expert Working Group of the VICH. Comments about this draft will be considered by FDA and the Quality Expert Working Group.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in section 2 of the guidance have been approved under OMB control number 0910–0032.

IV. Significance of Guidance

This draft revised 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.'' In addition, guidance documents must not include mandatory language such as ''shall,'' ''must,'' ''require,'' or ''requirement,'' unless FDA is using these words to describe a statutory or regulatory requirement.

The draft revised VICH guidance (GFI #73) is consistent with the agency's current thinking on the stability testing of new veterinary drug substances and medicinal products. This draft revised 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.

V. Comments

This draft revised 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 written 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 revised guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VI. Electronic Access

Electronic comments may also be submitted on the Internet at *http://www.fda.gov/dockets/ecomments*. Once on this Internet site, select Docket No. 1999D–2215, entitled ''Draft Revised Guidance for Industry on Stability Testing of New Veterinary Drug Substances and Medicinal Products (Revision)'' VICH GL3(R) and follow the directions.

Copies of the draft guidance document entitled ''Draft Revised Guidance for Industry on Stability Testing of New Veterinary Drug Substances and Medicinal Products (Revision)'' VICH GL3(R) may be obtained on the Internet from the CVM home page at *http://www.fda.gov/cvm*.

Dated: April 6, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–5525 Filed 4–13–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0138]

Draft Guidance for Industry: Recommended Study Design and Evaluation of Effectiveness Studies for Swine Respiratory Disease Claims; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (#178) entitled ''Recommended Study Design and Evaluation of Effectiveness Studies for Swine Respiratory Disease Claims.'' This draft guidance provides recommendations to industry relating to study design and describes the criteria that the Center for Veterinary Medicine (CVM) intends to use to evaluate effectiveness studies for swine respiratory disease (SRD) claims.

DATES: Submit written or electronic comments on this draft guidance by