Manufacturers'' (CP 7382.830). This draft document provides guidance to the FDA field staff for the enforcement of the quality system regulation (part 820 (21 CFR part 820)). This draft is a revision to the document first made available in May 1995, in accordance with the amendments to part 820, effective June 1, 1997.

This guidance document represents the agency's current thinking on inspection of medical device manufacturers. 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 applicable statute, regulations, or both.

The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This draft guidance document is issued as a Level 1 guidance consistent with GGP's.

II. Electronic Access

In order to receive the ''Draft Compliance Program Guidance Manual: Inspection of Medical Device Manufacturers'' (CP 7382.830) via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (487) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Web. Updated on a regular basis, the CDRH home page includes the ''Draft Compliance Program Guidance Manual: Inspection of Medical Device Manufacturers'' (CP 7382.830), device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at ''http://www.fda.gov/cdrh''. The ''Draft Compliance Program Guidance Manual: Inspection of Medical Device Manufacturers'' (CP 7382.830) will be available at ''http://www.fda.gov/cdrh/ochome.html''.

A text-only version of the CDRH Web site is also available from a computer or VT–100 compatible terminal by dialing 800–222–0185 (terminal settings are 8/1/N). Once the modem answers, press Enter several times and then select menu choice 1: FDA BULLETIN BOARD SERVICE. From there follow instructions for logging in, and at the BBS TOPICS PAGE, arrow down to the FDA home page (do not select the first CDRH entry). Then select Medical Devices and Radiological Health. From there select CENTER FOR DEVICES AND RADIOLOGICAL HEALTH for general information, or arrow down for specific topics.

II. Comments

This draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to Dockets Management Branch (address above) written comments regarding this draft guidance document. Written comments may be submitted at any time, however, comments should be submitted by October 28, 1998, to ensure adequate consideration in preparation of the final 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 brackets in the heading of this document. A copy of the document and received comments are available for examination in the the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 17, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–20305 Filed 7–29–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0566]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Draft Guidance on Stability Testing of New Animal Drug Substances and Products (#73), Stability Testing for New Dosage Forms of New Animal Drugs (#74), and Stability Testing: Photostability Testing of New Animal Drug Substances and Products (#75); Availability; Request for Comments

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 three draft guidance for industry documents entitled ''Stability Testing of New Animal Drug Substances and Products,'' ''Stability Testing for New Drug Dosage Forms of New Animal Drugs,''and ''Stability Testing: Photostability Testing of New Animal Drug Substances and Products.'' These related draft guidance documents have been adapted for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) from guidelines that were adopted by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guidance is intended to provide guidance on stability testing of new drug substances and products and new dosage forms included as part of registration applications for approval of veterinary medicinal products submitted to the European Union, Japan, and the United States.

DATES: Written comments should be submitted by August 31, 1998.

Note: FDA will accept comments after the deadline, but to assure consideration at the next VICH Committee meeting, we must receive them by August 31, 1998.

ADDRESSES: Submit written requests for single copies of these draft guidance documents 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 requests. Submit written comments to the Dockets Management Branch (HFA–

305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the full title of the draft guidance document and the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section of this document for electronic access to the draft guidance documents.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance documents: William G. Marnane, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–0678, e-mail ''wmarnane@bangate.fda.gov''.

Regarding VICH: Sharon Thompson, Center for Veterinary Medicine (HFV–3), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1798, e-mail ''sthompso@bangate.fda.gov''.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities, industry associations, and individual sponsors to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seeking scientifically based harmonized technical requirements for the development of pharmaceutical products. One of the goals of harmonization is to identify and reduce the differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the ICH for several years to develop harmonized technical requirements for the registration of human pharmaceutical 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 registration of veterinary medicinal products in the European Union, Japan, and the United States, and it includes input from both regulatory and industry representatives.

The VICH meetings are held under the auspices of the Office International des Épizooties (OIE). The VICH Steering Committee is composed of member representatives from the European Commission, the European Medicines Evaluation Agency, the European Federation of Animal Health, the U.S. Food and Drug Administration, the U.S. Department of Agriculture, the Animal Health Institute, the Japanese Veterinary Pharmaceutical Association, 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 MERCOSUR (Argentina, Brazil, Uruguay, and Paraguay), and one representative from Federacion Latino-Americana de la Industria para la Salud Animal. 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 participates in the VICH Steering Committee meetings.

At a meeting held on February 26 and 27, l998, the VICH Steering Committee agreed that the draft guidance documents entitled ''Stability Testing of New Animal Drug Substances and Products,'' ''Stability Testing for New Dosage Forms of New Animal Drugs,'' and ''Stability Testing: Photostability Testing of New Animal Drug Substances and Products'' should be made available for public comment. These draft guidance documents were prepared by the VICH Quality Working Group and are based on ICH Guidelines that have already been adopted by FDA for human pharmaceuticals.

The draft guidance entitled ''Stability Testing of New Animal Drug Substances and Products'' addresses the generation of stability information that should be included in submissions for applications for registration or approval of new molecular entities and associated drug products in the European Union, Japan, and the United States. In this guidance's discussion of ''stress testing'' for both new drug substances and drug products, the comment states that ''light testing'' should be an integral part of stress testing and will be considered in a separate annexed VICH document. That separate draft document is entitled ''Stability Testing: Photostability Testing of New Animal Drug Substances and Products,'' and sets out a basic testing protocol for photostability. The third draft guidance entitled ''Stability Testing for New Dosage Forms of New Animal Drugs'' is also an annex to ''Stability Testing of New Animal Drug Substances and Products.'' It addresses the generation of stability information for new dosage forms for submission by the owner of the original application for registration, after the original application for new drug substances and products has been submitted. Comments about these draft guidance documents will be considered by FDA and the VICH Quality Working Group. Ultimately, FDA intends to adopt the VICH Steering Committee's final guidance and to publish as future guidance documents.

These draft guidance documents, developed under the VICH process, have been revised to conform to FDA's Good Guidance Practices (62 FR 8961, February 27, l997) . For example, the documents have been designated ''guidance'' rather than ''guideline.'' Since guidance documents are not binding, mandatory words such as ''must,'' ''shall,'' and ''will'' in the original VICH documents have been substituted with ''should.''

These draft guidance documents represent current FDA thinking on stability testing of new animal drug substances and products and new dosage forms of new animal drugs. The documents do not create or confer any rights for or on any person and will not operate to bind FDA or the public. Alternate approaches may be used if they satisfy the requirements of applicable statutes, regulations, or both.

II. Comments

Interested persons may, on or before August 31, 1998, submit to the Dockets Management Branch (address above) written comments regarding the guidance documents. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the guidance documents and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the guidance documents using the World Wide Web (WWW). For WWW access, connect to CVM at ''http://www.fda.gov/cvm''.

Dated: July 23, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–20310 Filed 7–29–98; 8:45 am]

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