are to be submitted except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 7, 2001.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 01–12093 Filed 5–14–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0192]

Draft Guidance for Industry on Forms for Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Forms for Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution.'' The draft guidance is intended to assist establishments that are required to register (''registrants'') and submit listing information for drugs and biological products in obtaining and submitting the necessary forms to meet registration and listing requirements; this draft guidance will also assist those private label distributors that are not required to register, but elect to submit designated information directly to FDA. FDA proposes to make available through the Internet, rather than through conventional mail, the following registration and listing forms: Form FDA 2656 (Registration of Drug Establishment), Form FDA 2656e (Annual Update of Drug Establishment), Form FDA 2657 (Drug Product Listing), and Form FDA 2658 (Registered Establishments' Report of Private Label Distributors).

DATES: Submit written comments on this draft guidance document by July 16, 2001. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of this draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

For human drugs: Kathy Smith, Center for Drug Evaluation and Research (HFD–90), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–1086.

For biological drugs: Robert A. Yetter, Center for Biologics Evaluation and Research (HFM–10), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0373, yetter@cber.fda.gov.

For veterinary drugs: Lowell Fried, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0165, lfried@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Under part 207 (21 CFR part 207), as authorized and required by section 510 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360) and sections 351 and 361 of the Public Health Service Act (PHS Act) (42 U.S.C. 262 amd 264), establishments (e.g. manufacturers, repackers, and relabelers) engaged in the manufacture, preparation, propagation, compounding, or processing of human drugs, veterinary drugs, and biological products, with certain exceptions, are required to register and submit listing information.

Under part 207, these ''registrants'' use Form FDA 2656 to submit establishment registration information and to submit annual re-registration information (FDA had also used Form FDA 2656e for annual re-registration, but this form will no longer be necessary); private label distributors use Form FDA 2656 to obtain a labeler code; registrants and, in some cases, private label distributors use Form FDA 2657 to submit listing information for drugs and biological products and to update listing information; and registrants use Form FDA 2658 to submit listing information for private label distributors (FDA has also used the compliance verification report for updating listing information). Registrants will use new Form FDA 3356 to submit establishment and listing information for those human cells, tissues, and cellular and tissue-based products regulated as drugs and/or biological products under the act and section 351 of the PHS Act beginning January 21, 2003.

If a registrant or private label distributor prefers to receive any of these forms through conventional mail, they may direct such requests to the designated agency contacts. Under the draft guidance, information previously submitted on Form FDA 2656e would be submitted on Form FDA 2656. Distribution of these forms through the Internet will reduce administrative costs to the agency. The draft guidance also contains registration information applicable to human cells, tissue, and cellular and tissue-based product establishments.

The draft guidance explains that, unless specifically requested otherwise, FDA is discontinuing the conventional mailing of these forms to registrants and private label distributors. These forms are available on the Internet. Registrants, and if appropriate, private label distributors must continue to submit completed forms to FDA in accordance with the registration and listing requirements in part 207. The draft guidance explains where to obtain the forms on the Internet, how to make changes to information, and where to submit completed forms.

Internet availability of these forms (instead of availability by conventional mail) is part of an agency initiative to use modern technology to facilitate the submission of establishment registration and listing information. FDA is developing software to make possible the electronic submission of the requisite registration and listing information for drugs and biological products. The agency plans to propose rulemaking that would revise the requirements for registration and listing and would require registrants to submit this information electronically.

This Level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). This draft guidance represents the agency's current thinking on this topic. 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, at any time, submit written or electronic comments regarding the draft guidance. Written comments should be submitted to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance 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

Comments may also be submitted electronically on the Internet at http://www.fda.gov/dockets/ecomments. Once on this Internet site, select the relevant ''docket number'' and follow the directions. Copies of this draft guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm.

Dated: May 7, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–12179 Filed 5–14–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2406]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Final Guidance for Industry entitled ''Good Clinical Practice'' (VICH GL9); 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. 85) entitled ''Good Clinical Practice'' (VICH GL9). This guidance document has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). The final VICH guidance is intended to provide a unified standard for designing, conducting, monitoring, recording, and reporting studies used in registration applications for approval of veterinary products submitted to the European Union, Japan, and the United States.

DATES: Submit written comments at any time. This guidance will be implemented July 1, 2001.

ADDRESSES: 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 requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the final guidance document.

Submit written comments at any time on the final guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852,— e-mail: *fdadockets@oc.fda.gov*.

FOR FURTHER INFORMATION CONTACT: Herman M. Schoenemann (HFV–120), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0220, e-mail: *3hschoene@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 veterinary medicinal products. The VICH is concerned with developing harmonized technical recommendations 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; the European Medicines Evaluation Agency; the European Federation of Animal Health; 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.

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 Good Clinical Practice

In the **Federal Register** of August 3, 1999 (64 FR 42135), FDA published the notice of availability of the draft guidance entitled ''Good Clinical Practices'' (VICH GL9), giving interested persons until September 2, 1999 to submit comments. After considering the comments received, FDA made principally editorial changes. The final guidance was submitted to the VICH Steering Committee. At a meeting held on June 14 through 16, 2000, the VICH Steering Committee endorsed the final guidance for industry, VICH GL9.

The guidance is intended to be an international ethical and scientific quality standard for designing, conducting, monitoring, recording, auditing, analyzing, and reporting clinical studies evaluating veterinary products. This final guidance document is intended to be consistent with the laws of the European Union, Japan, and the United States.

VICH GL9 is a revision of and will replace CVM guidance No. 58 entitled ''Good Target Animal Studies Practices: Investigators and Monitors.'' In addition, there are some minor conflicts between this guidance and recent CVM guidance No. 56 entitled ''Protocol Development Guideline for Clinical Effectiveness and Target Animal Safety Trials,'' and No. 104 entitled ''Guidance for Industry: Content and Format of Effectiveness and Target Animal Safety Technical Sections and Final Study Reports for Submission to the Division of Therapeutic Drugs for Non-Food Animals.'' Until the center revises these guidances, sponsors should follow the