The draft guidance announces that FDA, in the exercise of its enforcement discretion, does not intend to object if a free clinic fails to comply with the requirements in § 203.39 while the agency studies the potential impact of this regulation on the ability of free clinics to receive and distribute prescription drug samples. For the purposes of the draft guidance, a ''free clinic'' is a charitable institution or organization under § 203.3(f) that actually provides health care services and relies in whole or part on drug donations and volunteer help to achieve its goals. Thus, charitable institutions that receive donated drug samples, but do not provide health care services, or that provide health care services, but do not rely at least in part on drug donations and volunteer help to provide those services, would not be considered free clinics and are expected to comply with § 203.39.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on enforcement of Prescription Drug Marketing Act Regulations for Donation of Prescription Drug Samples to Free Clinics. 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persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the draft guidance by September 25, 2002. 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 The draft guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.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 document at either *http://www.fda.gov/cder/guidance.index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: June 17, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–16160 Filed 6–26–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0475]

Guidance for Industry on Providing Regulatory Submissions in Electronic Format—ANDAs; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—ANDAs.'' This guidance provides information for applicants on how to submit abbreviated new drug applications (ANDAs) in electronic format.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this 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 guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. 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: Ruth A. Warzala, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–5845, e-mail: *ESUB__OGD@CDER.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—ANDAs.'' Traditionally, FDA has required that regulatory submissions, such as ANDAs and new drug applications, be submitted as paper documents. In the **Federal Register** of March 20, 1997 (62 FR 13430), FDA published the electronic records and electronic signatures regulation, which provided for the voluntary submission of parts or all of an application, as defined in the relevant regulations, in electronic format without an accompanying paper copy (21 CFR part 11). The agency also established public Docket No. 92S–0251 to provide a list of the agency units that are prepared to receive electronic submissions and the specific types of records and submissions that can be accepted in electronic format (62 FR 13430 at 13467). In the Prescription Drug User Fee Act as amended by the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115), the agency stated its plans to develop and update its information management capabilities to allow electronic submissions by 2002. In the **Federal Register** of January 28, 1999, the agency announced the availability of two guidances for industry entitled ''Providing Regulatory Submissions in Electronic Format—NDAs'' (64 FR 4432) and ''Providing Regulatory Submissions in Electronic Format—General Considerations'' (64 FR 4433). These guidances were the first two of a series of guidances for industry on making regulatory submissions in electronic format. This guidance should be used in conjunction with ''Providing Regulatory Submissions in Electronic Format—NDAs'' and ''Providing Regulatory Submissions in Electronic Format—General Considerations.''

The Center for Drug Evaluation and Research (CDER) has encouraged the electronic submission of some types of data on a voluntary basis since 1997. However, these electronic submissions could not previously be archived and could only be made in addition to a complete paper submission. In the **Federal Register** of November 16, 2001 (66 FR 57721), CDER announced the availability of a draft guidance entitled ''Providing Regulatory Submissions in Electronic Format—ANDAs.'' This guidance provided new information on submitting a complete archival copy of the ANDA in electronic format. The comment period closed on January 15, 2002, and the agency considered the received comments as it finalized this guidance. As in the past, applicants planning to make submissions in electronic format should consult public Docket No. 92S–0251 to determine which agency units are prepared to receive electronic submissions and the specific types of documents that can be submitted in electronic format.

This guidance is being issued consistent with FDA's good guidance practices (GGPs) regulation (21 CFR 10.115). The guidance represents the agency's current thinking on providing

regulatory submissions in electronic format for ANDAs. 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 or regulations.

II. Comments

Interested persons may, at any time, submit written or electronic comments on the guidance to the Dockets Management Branch (see **ADDRESSES**). 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 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

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: June 11, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–16163 Filed 6–26–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1532]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Final Guidances for Industry on ''Effectiveness of Anthelmintics: Specific Recommendations for Equine'' (VICH GL15), ''Effectiveness of Anthelmintics: Specific Recommendations for Porcine'' (VICH GL16), and ''Effectiveness of Anthelmintics: Specific Recommendations for Canine'' (VICH GL19); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of three final guidances for industry (Nos. 109, 110, and 111 respectively) entitled ''Effectiveness of Anthelmintics: Specific Recommendations for Equine'' (VICH GL15), ''Effectiveness of Anthelmintics: Specific Recommendations for Porcine'' (VICH GL16), and ''Effectiveness of Anthelmintics: Specific Recommendations for Canine'' (VICH GL19). These related guidance documents have been developed by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). They are intended to standardize and simplify methods used in the evaluation of new anthelmintics submitted for approval to the European Union, Japan, and the United States.

DATES: Submit written or electronic comments on the final guidance documents at any time.

ADDRESSES: Submit written requests for single copies of the final 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. *See* the **SUPPLEMENTARY INFORMATION** section for electronic access to the final guidance document.

Submit written comments on the final guidance documents to the Dockets Management Branch (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 final guidance and the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Thomas Letonja, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7576, e-mail: *tletonja@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 the differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonisation (ICH) of Technical Requirements for Registration 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 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; 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.

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 Conféderation Mondiale de L'Industrie de la Santé Animale (COMISA). A COMISA representative also participates in the VICH Steering Committee meetings.

II. Final Guidance on Effectiveness of Anthelmintics

In the **Federal Register** on October 19, 2000 (65 FR 62723), FDA published the notice of availability of these VICH draft guidances, giving interested persons until December 18, 2000, to submit comments. FDA received no comments. The final guidance was submitted to the VICH Steering Committee. At a meeting held on June 28, 2001, the VICH Steering Committee endorsed the three final guidances for industry, VICH GL15, VICH GL16, and VICH GL19.

The three final guidances VICH GL15, VICH GL16, and VICH GL19 should be read in conjunction with the ''Effectiveness of Anthelmintics: General Recommendations (EAGR)'' announced in the **Federal Register** on April 6, 2001 (66 FR 18257). The final