VII. Submission Requirements

The original and two copies of the completed Grant Application Form PHS 398 (Rev. 4/98 or Rev. 5/01) or the original and two copies of PHS 5161–1 (Rev. 7/00) for State and local governments, with copies of the appendices for each of the copies, should be delivered to Maura Stephanos (see **ADDRESSES**). State and local governments may choose to use the PHS 398 application form in lieu of PHS 5161–1. The application receipt date is July 29, 2002. No supplemental or addendum material will be accepted after the receipt date. The outside of the mailing package and item 2 of the application face page should be labeled: ''Response to RFA FDA CDRH–02–1.''

VIII. Method of Application

A. Submission Instructions

Applications will be accepted during normal business hours, 8 a.m. to 4:30 p.m., Monday through Friday, on or before the established receipt date. Applications will be considered received on time if sent or mailed on or before the receipt date as evidenced by a legible U.S. Postal Service dated postmark or a legible dated receipt from a commercial carrier, unless they arrive too late for orderly processing. Private metered postmarks shall not be acceptable as proof of timely mailing. Applications not received on time will not be considered for review and will be returned to the applicant. (Applicants should note that the U.S. Postal Service does not uniformly provide dated postmarks. Before relying on this method, applicants should check with their local post office.) Do not send applications to the Center for Scientific Research (CSR), NIH. Any application that is sent to NIH, and is then forwarded to FDA and not received in time for orderly processing will be deemed not responsive and returned to the applicant. Applications must be submitted via mail or hand delivered as stated above. FDA is unable to receive applications electronically. Applicants are advised that FDA does not adhere to the page limitations or the type size and line spacing requirements imposed by the NIH on its applications.

B. Format for Application

Submission of the application must be on Grant Application Form PHS 398 (Rev. 4/98 or Rev. 5/01) or on either form PHS 398 or PHS 5161–1 (Rev. 7/00) for State and local government applicants. All ''General Instructions'' and ''Specific Instructions'' in the application kit should be followed with the exception of the receipt dates and the mailing label address.

The face page of the application should reflect the request for applications number, RFA–FDA–CDRH–02–1. Data and information included in the application, if identified by the applicant as trade secret or confidential commercial information. Will be given confidential treatment to the extent permitted by the Freedom of Information Act (5 U.S.C. 552(b)(4)) and FDA's implementing regulations (21 CFR 20.61).

Information collection requirements requested on Form PHS 398 and the instructions have been submitted by PHS to the Office of Management and Budget (OMB) and were approved and assigned OMB control number 0925–0001. The requirements requested on Form PHS 5161–1 were approved and assigned OMB control number 0348–0043.

Dated: June 21, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–16293 Filed 6–26–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food And Drug Administration

[Docket No. 02D–0260]

Draft Guidance for Industry on Prescription Drug Marketing Act Regulations for Donation of Prescription Drug Samples to Free Clinics; 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 ''Prescription Drug Marketing Act Regulations for Donation of Prescription Drug Samples to Free Clinics.'' The draft guidance provides information for free clinics that receive donated prescription drug samples from licensed practitioners or other charitable institutions. The draft guidance discusses concerns that have been expressed by certain individuals regarding regulatory requirements of FDA's regulations for drug sample donations. 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 the regulations, while the agency studies the potential impact of its regulations on free clinics.

DATES: Submit written or electronic comments on the draft guidance by September 25, 2002. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to 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 (HFD–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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: Lee D. Korb, Office of Regulatory Policy (HFD–7), Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Prescription Drug Marketing Act Regulations for Donation of Prescription Drug Samples to Free Clinics.'' Section 203.39 (21 CFR 203.39) of the agency's regulations sets forth requirements for donation of prescription drug samples to charitable institutions. ''Charitable institution or charitable organization'' is defined in § 203.3(f) (21 CFR 203.3(f)) as ''a nonprofit hospital, health care entity, organization, institution, foundation, association, or corporation that has been granted an exemption under section 501(c)(3) of the Internal Revenue Code of 1954, as amended.'' Under § 203.39, a charitable institution may receive drug samples donated by a licensed practitioner or another charitable institution for dispensing to its patients, or may donate a drug sample to another charitable institution for dispensing to its patients, provided certain requirements are met. These requirements include, among other things, that a drug sample donated to a charitable institution must be inspected by a licensed practitioner or registered pharmacist, and that drug sample receipt and distribution records be maintained by the institution and retained for a minimum of 3 years.

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