

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Draft Guidance for Industry on Prescription Drug Marketing Act Regulations for Donation of Prescription Drug Samples to Free Clinics; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Prescription Drug Marketing Act Regulations for Donation of Prescription Drug Samples to Free Clinics." The draft guidance provides information for free clinics that receive donated prescription drug samples from licensed practitioners or other charitable institutions. The draft guidance discusses concerns that have been expressed by certain individuals regarding regulatory requirements of FDA's regulations for drug sample donations. The draft guidance announces that FDA, in the exercise of its enforcement discretion, does not intend to object if a free clinic fails to comply with the requirements in the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DATES: Submit written or electronic comments on the draft guidance by [*insert date 90 days after date of publication in the Federal Register*]. 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ADDRESSES: Submit written requests for single copies of the draft guidance to Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 Submit written comments on the draft guidance to the Dockets Management Branch (HFD-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061,

cd0224

DMB

Display Date 6-26-02
Publication Date 6-27-02
Certifier G. Trenley

NAD-1

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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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FDA is announcing the availability of a draft guidance for industry entitled “Prescription Drug Marketing Act Regulations for Donation of Prescription Drug Samples to Free Clinics.”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.

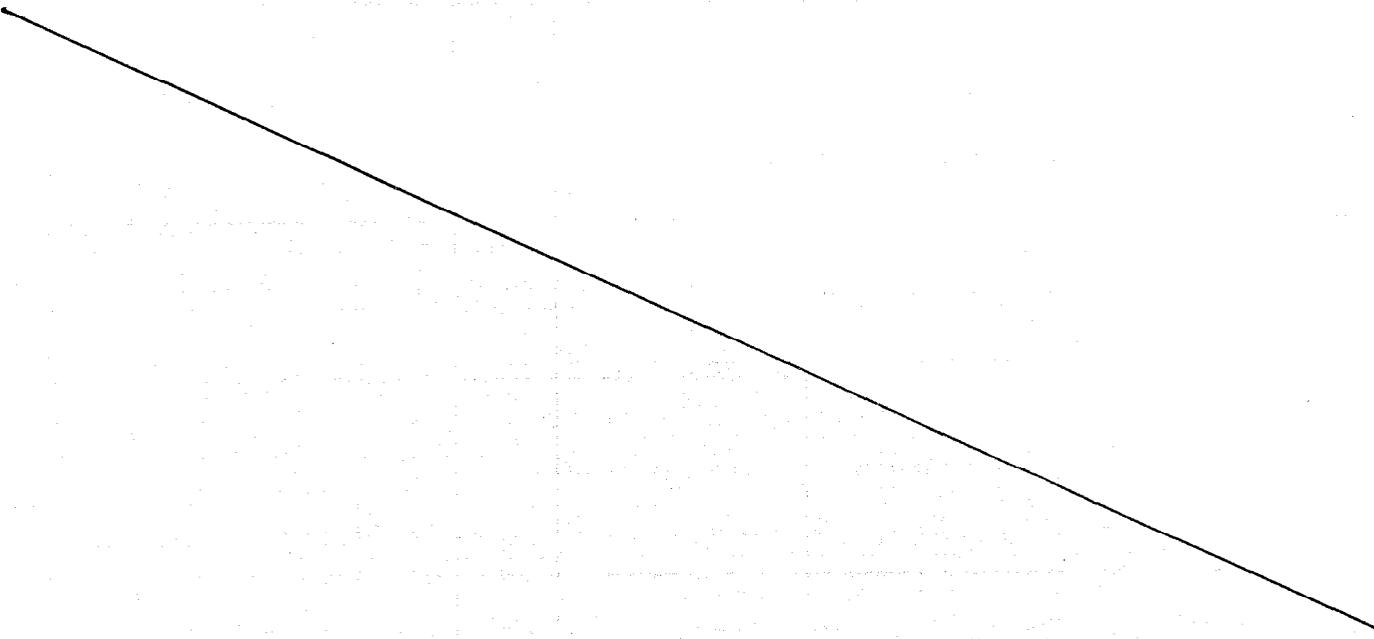
The draft guidance announces that FDA, in the exercise of its enforcement discretion, does not intend to object if a free clinic fails to comply with the requirements in § 203.39 while the agency studies the potential impact of this regulation on the ability of free clinics to receive and distribute 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

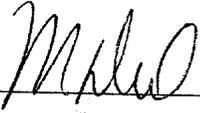
Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the draft guidance by [*insert date 90 days after date of publication in the Federal Register*]. Two copies of any comments are to be submitted, except that individuals may submit one 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: 6/17/02
June 17, 2002.



Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

BILLING CODE 4160-01-S

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

