

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D-0260] (formerly Docket No. 02D-0260)

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Guidance for Industry on Prescription Drug Marketing Act—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 guidance for industry entitled "Prescription Drug Marketing Act—Donation of Prescription Drug Samples to Free Clinics." The guidance provides information for free clinics that receive donated prescription drug samples from licensed practitioners or other charitable institutions. The guidance discusses concerns that have been expressed by certain individuals regarding regulatory requirements for drug sample donations. The guidance announces that FDA, after reviewing an independent study report analyzing the potential effects of the regulations on free clinics, has decided to propose revisions to those regulations. In the interim, FDA intends to exercise its enforcement discretion and does not intend to object if a free clinic fails to comply with certain regulatory requirements for drug sample donations.

DATES: General comments on agency guidance documents are welcome 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 Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. 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: Meredith S. Francis, 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 guidance for industry entitled “Prescription Drug Marketing Act—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) 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.

In the **Federal Register** of June 27, 2002 (67 FR 43330), FDA announced the availability of a draft guidance entitled "Prescription Drug Marketing Act Regulations for Donation of Prescription Drug Samples to Free Clinics." The draft guidance announced that FDA, in the exercise of its enforcement discretion, did not intend to object if a free clinic failed to comply with the requirements in § 203.39. The draft guidance defined the term "free clinic," which is not otherwise defined in the Federal Food, Drug, and Cosmetic Act or regulations, as 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. According to the draft guidance, FDA intended to exercise enforcement discretion while the agency studied the potential impact of the regulation on the ability of free clinics to receive and distribute prescription drug samples. Interested persons were given the opportunity to submit comments on the draft guidance by September 25, 2002.

Since issuing the draft guidance, FDA has received a completed study report from Eastern Research Group (ERG) analyzing the burden imposed on free clinics by the requirements in § 203.39 and the potential regulatory alternatives. According to the ERG study report, implementing § 203.39 as written could impose a significant financial burden on free clinics. Based in part on the study report's conclusions, FDA is announcing today that it intends

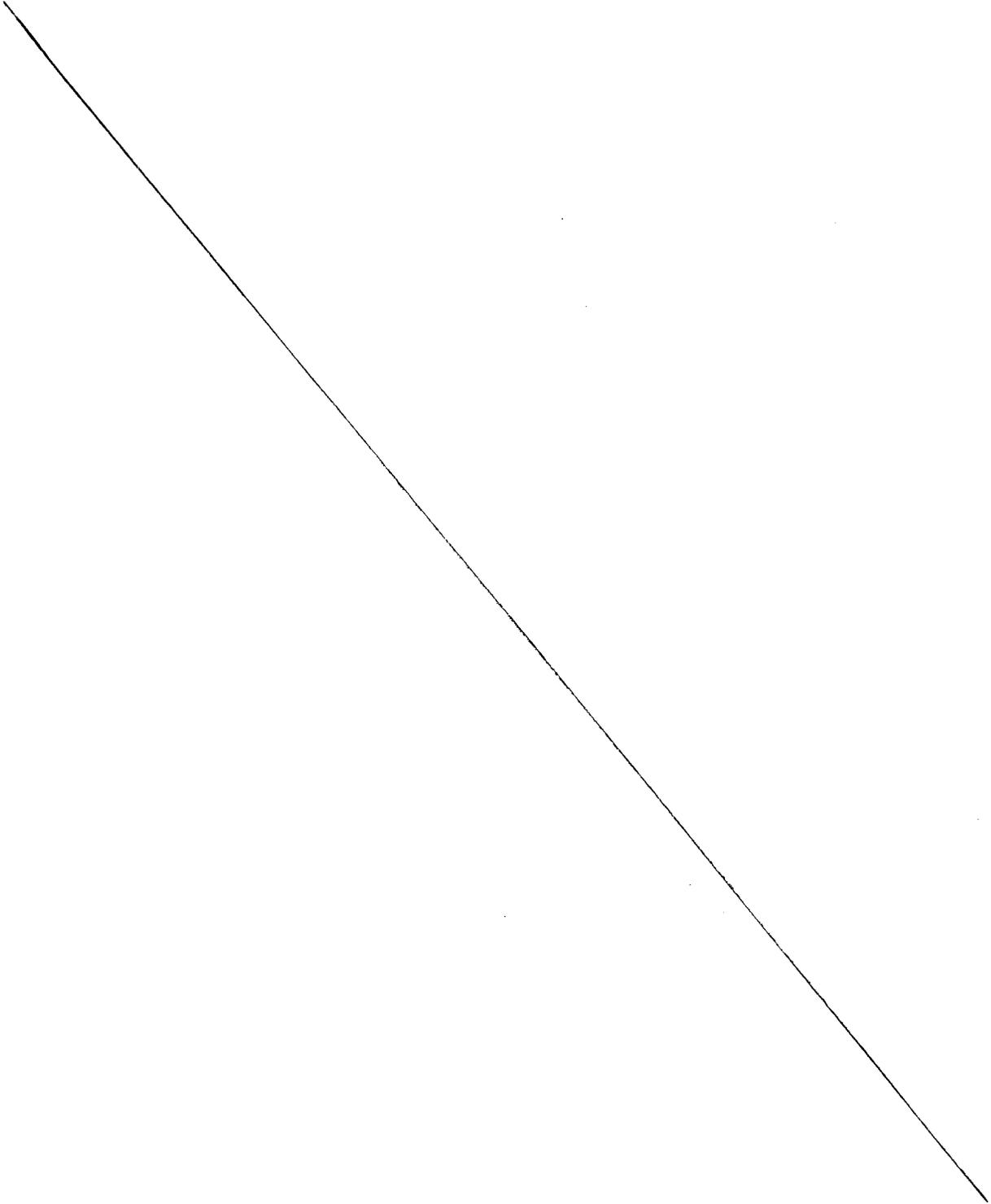
to exercise enforcement discretion while the agency proposes revisions to § 203.39 as applied to free clinics. Specifically, as FDA works to propose regulatory revisions, the agency does not intend to object if a free clinic fails to comply with certain parts of the regulation. The guidance clarifies that the agency's exercise of enforcement discretion with regard to certain requirements of § 203.39 will not extend to fraud or other illegal conduct involving drug samples, and that the agency could, at its discretion, initiate enforcement action for violations of any and all applicable statutory and regulatory provisions implicated by fraudulent or illegal activity. We note also that neither this notice, nor its corresponding guidance, affects or alters any requirements imposed by the U.S. Drug Enforcement Administration (DEA) on any free clinic, person, or other entity with regard to controlled substances donated to those entities. All DEA requirements relating to controlled substances remain fully in effect.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). It 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 submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of

this document. Received comments may be seen in the Division of Dockets Management 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>.

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Jeffrey Shuren,
Assistant Commissioner for Policy.

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