Guidance for Industry

Prescription Drug Marketing Act Regulations for Donation of Prescription Drug Samples to Free Clinics

DRAFT GUIDANCE

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For questions regarding this document contact Lee Korb at 301-594-2041.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
June 2002
Enforcement Policy

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If you plan to submit comments on this draft guidance, to expedite FDA review of your comments, please:

- Clearly explain each issue/concern and, when appropriate, include a proposed revision and the rationale/justification for the proposed change.

- Identify specific comments by line number(s); use the PDF version of the document, whenever possible.

I. INTRODUCTION

This 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 in 21 CFR 203.39 for drug sample donations. The 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 section 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.

II. BACKGROUND

The Prescription Drug Marketing Act (PDMA) (Public Law 100-293) was enacted on April 22, 1988, and was modified by the Prescription Drug Amendments (PDA) (Public Law 102-353, 106 Stat. 941) on August 26, 1992. The PDMA, as modified by the PDA, amended sections 301, 303, 503, and 801 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 331, 333, 353, 381) to, among other things, establish requirements for distribution of prescription drug samples. Section 503(d) of the Act prohibits the distribution of a drug sample except by the manufacturer or an authorized distributor of record. For the purposes of section 503(d), "distribute" does not include the provision of a drug sample to a patient by a licensed practitioner, a health care professional acting at the direction and under the supervision of a

[1] This guidance has been prepared by the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration.

licensed practitioner, or a hospital or health care entity pharmacy acting at the direction of a licensed practitioner.

On December 3, 1999, the Agency published final regulations in part 203 (21 CFR part 203) implementing the PDMA. The regulations set forth various requirements for the distribution of prescription drug samples from manufacturers and authorized distributors of record to practitioners licensed to prescribe such samples. In addition, the regulations addressed the practice whereby licensed practitioners donate unused prescription drug samples to charitable institutions such as free clinics, nursing homes, and other charitable health care entities for dispensing to patients, or for further donation to another charity for dispensing to its patients. The Agency recognized the importance of this practice and concluded that charitable donation of drug samples is permissible under PDMA, provided that a system of controls is in place to provide accountability and oversight for such donations and to minimize the potential for drug diversion.

The requirements for donation of drug samples to charitable institutions are set forth in section 203.39 of the final PDMA rule. "Charitable institution or charitable organization" is defined in section 203.3(f) of the final rule 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 section 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 must be kept by the institution for a minimum of 3 years.

III. DISCUSSION

On October 23, 2000, FDA received a letter submitted on behalf of the North Carolina Association of Free Clinics asserting that the recordkeeping requirements in section 203.39 are unnecessarily burdensome and would force many small and underfunded free clinics to discontinue dispensing donated drug samples to their patients. The letter requested, among other things, that the relevant provisions of the final rule be stayed indefinitely until such time as alternative, less-burdensome regulatory provisions are adopted by FDA. In response to the concerns expressed in the letter, FDA sent a reply on December 7, 2000, indicating that in the exercise of its enforcement discretion the Agency did not intend to object if free clinics did not comply with certain specified portions of the regulations. For example, FDA stated that to conserve professional resources the Agency did not intend to object if the inspection of incoming drug samples required under section 203.39(c) was conducted by a person authorized by a licensed practitioner affiliated with the free clinic, rather than a licensed practitioner. However, FDA stated that it would expect compliance with certain other basic requirements.

On June 22, 2001, FDA met with representatives of several free clinics to discuss their concerns about the requirements noted in the December 7, 2000, letter. They said that despite the

Agency's attempt to reduce burdens on free clinics, some clinics would be forced to close their doors if the recordkeeping provisions and certain other requirements were imposed. FDA and the Department of Health and Human Services received further correspondence relating to the requirements in section 203.39, dated July 17, 2001, and August 17, 2001.

Although the term "free clinic" is not defined in the Act or regulations, for the purposes of this guidance the Agency considers a free clinic to be a charitable institution or organization under section 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. FDA encourages interested persons to comment on the appropriateness of this definition.

The Agency recognizes that the donation of drug samples to charitable institutions such as free clinics serves an important public health objective: providing health care to indigent, uninsured, and underinsured populations. Although some free clinics may find compliance with section 203.39 to be unduly burdensome, others are apparently already in compliance with the recordkeeping portions of it. Furthermore, the objective of providing health care services to those in need must be balanced against the intent of PDMA to provide accountability for drug sample distribution to ensure that drug samples are not diverted.

The Agency is currently considering whether regulatory changes or other actions may be appropriate in light of the concerns expressed. At this time, the Agency does not believe it has adequate information to determine the extent of the burden on free clinics and the public health consequences if FDA were to enforce the requirements in section 203.39. FDA has decided that it needs more information about the potential burdens on free clinics as well as the risks from diversion if free clinics were to be relieved of some or all of the recordkeeping or other requirements in section 203.39. FDA intends to conduct a study to obtain enough information to make an informed regulatory judgment on this matter. However, while FDA is conducting this study and considering the issues involved, the Agency believes that it is appropriate to permit free clinics to continue to receive prescription drug samples and perform important public health functions. Therefore, this 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 section 203.39.

The Agency wishes to clarify, however, that its exercise of enforcement discretion will not extend to fraud or other illegal conduct with drug samples that does not involve the requirements in section 203.39. Thus, if a free clinic or its employees were found to be selling prescription drug samples or to be otherwise illegally diverting them, the Agency could at its discretion initiate enforcement action against the clinic or the employees for the misconduct.