Guidance for Industry

Prescription Drug Marketing Act — Donation of Prescription Drug Samples to Free Clinics

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

March 2006
Compliance

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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 intends to propose revisions to § 203.39 to reduce the burden on free clinics while maintaining certain minimal requirements aimed at ensuring the integrity of the samples stored and dispensed by clinics. In the interim, FDA, in the exercise of its enforcement discretion, does not intend to object if a free clinic fails to comply with certain requirements in § 203.39.

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

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

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 by 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 § 203.39 of the final PDMA rule. "*Charitable institution* or *charitable organization*" is defined in § 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 § 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.

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 § 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 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 § 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 § 203.39, dated July 17, 2001, and August 17, 2001.

In response to the concerns expressed by free clinics, FDA commissioned a study to (1) determine the burden imposed on free clinics by the requirements in § 203.39, and (2) evaluate regulatory alternatives. In the interim, FDA issued a draft guidance[2] announcing that while the study was being conducted, the Agency would exercise its enforcement discretion and did not intend to object if a free clinic failed to comply with the requirements of § 203.39. FDA contracted with Eastern Research Group (ERG) to perform the study, which was completed in 2003. According to the ERG study report, implementing the requirements set forth in § 203.39 as written could impose a significant financial burden on free clinics. The requirements would be particularly burdensome for small free clinics having budgets of less than $200,000 per year.

In light of the information currently available to the Agency, FDA has decided to propose revisions to § 203.39 as applied to free clinics. In particular, FDA's decision is based on (1) the concerns expressed by free clinics, (2) the ERG report, (3) the fact that, to date, the Agency is unaware of any significant evidence of diversion of donated drug samples from free clinics, and (4) the Agency's appreciation that the donation of drug samples to free clinics serves an important public health role (i.e., providing health care to indigent, uninsured, and underinsured populations). While it works to develop proposed regulations, FDA has decided to finalize this guidance.

III. DISCUSSION

FDA recognizes the need to balance the goal of providing health care services to those in need against the objectives of the PDMA. To that end, FDA plans to propose revisions to § 203.39 to reduce the burden on free clinics while maintaining certain minimum requirements aimed at ensuring the integrity of samples stored and dispensed by the clinics. In the interim, FDA is announcing its intent to exercise its enforcement discretion in accordance with the following policy.

The term *free clinic* is not currently 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 § 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. As FDA works to revise § 203.39, it will welcome comment on the appropriateness of using this definition of *free clinic* in the regulation.

During the time necessary to engage in the rulemaking process, FDA intends to exercise its enforcement discretion with regard to certain provisions of § 203.39 as applied to free clinics. Specifically, FDA, in the exercise of its enforcement discretion, does not intend to object if a free clinic fails to comply with § 203.39(b), (d), (e), (f), and (g). For the most part, these subsections focus on recordkeeping requirements. FDA does, however, expect free clinics to comply with § 203.39(a), (c), (h), and (i). For the most part, these subsections focus on ensuring the integrity of samples stored and dispensed by clinics, and should not be too onerous for free clinics to comply

[2] In June 2002 (67 FR 43330), FDA made available a draft guidance document that is superseded by this guidance.

with and still operate effectively. Moreover, with regard to § 203.39(c), recognizing the limitations on the professional resources of free clinics, FDA does not intend to object if the required examination of donated samples is performed by any staff member designated to do so by a licensed practitioner or registered pharmacist affiliated with the free clinic.

The Agency wishes to clarify that its exercise of enforcement discretion with regard to certain requirements of § 203.39 will not extend to fraud or other illegal conduct with drug samples. 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, including violations of any and all applicable statutory and regulatory provisions. The Agency also notes that nothing in this guidance or its corresponding notice relieves any person or entity from the reporting, or other requirements, imposed by the U. S. Drug Enforcement Administration (DEA) with regard to controlled substances donated to free clinics.