Guidance for Industry and FDA Staff

Reduction of Civil Money Penalties for Small Entities

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This document supersedes the Draft Civil Money Penalty Reduction Policy for Small Entities released on May 18, and June 15, 1999.

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
Office of Enforcement
Division of Compliance Policy

Preface

Public Comment:

Comments and suggestions regarding this document may be submitted at any time for agency consideration to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments may not be acted upon by the agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance, contact Jeffrey Governale at 301-827-0411.

Additional Copies:

Submit written requests for a paper copy of the guidance to the Division of Compliance Policy (HFC-230), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or FAX your request to 301-827-0482. A copy of the guidance may also be downloaded to a personal computer with access to the Internet. The Office of Regulatory Affairs' (ORA) home page includes the guidance and may be accessed at "http://www.fda.gov/ora". The guidance is available under "Compliance References."

Reduction of Civil Money Penalties for Small Entities

This guidance document represents the agency's current thinking on the reduction of civil money penalties for small entities. 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 statute, regulations, or both.

I. Background

The Food and Drug Administration (FDA) is issuing this final guidance for the reduction of civil money penalties (CMPs) for small entities (penalty reduction guidance) as mandated by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (Public Law 104-121) and the Presidential Memorandum of April 21, 1995 (60 FR 20621, April 26, 1995).

FDA currently enforces the following amendments to the Federal Food, Drug, and Cosmetic Act (21 U.S.C.) and the Public Health Service Act (42 U.S.C.), which authorize CMPs under the referenced sections:

Radiation Control for Health and Safety Act of 1968 (21 U.S.C. 360pp)

Safe Medical Devices Act of 1990 (21 U.S.C. 333(f))

Mammography Quality Standards Act of 1992 and the Mammography Quality Standards Reauthorization Act of 1998 (42 U.S.C. 263b(h))

National Childhood Vaccine Injury Act of 1986 (42 U.S.C. 262(d)(2) and 42 U.S.C. 300aa-28)

Prescription Drug Marketing Act of 1988 (21 U.S.C. 333(b))

Generic Drug Enforcement Act of 1992 (21 U.S.C. 335b)

Food Quality Protection Act of 1996 (21 U.S.C. 333(f))

SBREFA was enacted on March 29, 1996, and seeks to improve the regulatory climate for small entities by, among other things, requiring agencies to establish small entity penalty reduction policies as follows:

Sec. 223--Rights of Small Entities in Enforcement Actions

(a) In General--Each agency regulating the activities of small entities shall establish a policy * * * to provide for the reduction, and under appropriate circumstances for the waiver, of civil penalties for violations of a statutory or regulatory requirement by a small entity. Under appropriate circumstances, an agency may consider ability to pay in determining penalty assessments on small businesses.

(b) Conditions and Exclusions--Subject to the requirements or limitations of other statutes, policies or programs established under this section shall contain conditions or exclusions which may include, but not be limited to--

(1) requiring the small entity to correct the violation within a reasonable correction period;

(2) limiting the applicability to violations discovered through participation by the small entity in a compliance assistance or audit program operated or supported by the agency or a State;

(3) excluding small entities that have been subject to multiple enforcement actions by the agency;

(4) excluding violations involving willful or criminal conduct;

(5) excluding violations that pose serious health, safety or environmental threats; and

(6) requiring a good faith effort to comply with the law.

A statement entered into the Congressional Record (142 Congressional Record S3242, daily ed. March 29, 1996) after enactment of SBREFA explains that agencies have "flexibility to tailor their specific programs to their missions and charters" and instructs agencies "to develop the boundaries of their program and the specific circumstances for providing for a waiver or reduction of penalties"(id. at S3244). To that end, SBREFA specifies that a penalty reduction guidance adopted by an agency may be subject to the requirements or limitations of other applicable statutes. SBREFA also lists six possible exclusions or conditions (see section 223 of SBREFA as quoted previously in this document) that an agency may incorporate in its guidance.

The Presidential Memorandum of April 21, 1995, directs agencies to use their discretion to modify the penalties for small businesses in certain situations. Specifically, it states:

> 1. Authority to Waive Penalties. (a) To the extent permitted by law, each agency shall use its discretion to modify the penalties for small businesses in the following situations. Agencies shall exercise their enforcement discretion to waive the imposition of all or a portion of a penalty when the violation is corrected within a time period appropriate to the violation in question. For those violations that may take longer to correct than the period set by the agency, the agency shall use its enforcement discretion to waive up to 100 percent of the financial penalties if the amounts waived are used to bring the entity into compliance. The provisions in paragraph 1(a) of this memorandum shall apply only where there has been a good faith effort to comply with applicable regulations and the violation does not involve criminal wrongdoing or significant threat to health, safety, or the environment.

On May 18, and June 15, 1999, FDA issued a draft civil money penalty reduction policy for small entities in the *Federal Register* (64 FR 26984 and 64 FR 32059).

In developing this final guidance, FDA has reviewed: (1) The Federal statutes it enforces which authorize CMPs, (2) its current practices used to assess CMPs on small entities, (3) SBREFA, (4) the April 21, 1995 Presidential Memorandum, and (5) comments submitted to the 1999 draft civil money penalty reduction policy. On the basis of that review, this document is FDA's final penalty reduction guidance for small entities.

II. Guidance for Reduction of Civil Money Penalties for Small Entities

FDA will consider on a case-by-case basis whether to reduce or waive CMPs against a small entity. In determining whether to reduce or waive CMPs against a specific small entity, the following considerations should apply:

A. Except as provided in paragraph C below, penalty reduction or waiver may not be available for any small entity if:

1. The small entity was subject to an enforcement action[1] (e.g. seizure, injunction or prosecution) by FDA within the last 5 years, and is still owned or managed by the same persons;

2. Any of the small entity's violations involve willful conduct;

3. The small entity does not make a good faith effort to comply with the law; or

4. Any of the small entity's violations pose serious health, safety or environmental threats.

B. In considering whether FDA should reduce or waive a CMP, FDA may consider:

1. The egregiousness of the violations;

2. The isolated or repeated nature of the violations;

3. The small entity's history (if any) of violations;

4. The amount of harm caused by the violations;

5. The degree to which a CMP may deter the small entity or others from committing future violations;

6. The extent to which the small entity cooperated during the investigation;

7. Whether the small entity corrected the violations within a reasonable time period;

8. Whether the small entity has engaged in subsequent significant remedial efforts to mitigate the effects of the violations and to prevent future violations;

9. Whether the small entity voluntarily reported the violations to FDA promptly after discovering them; and

10. The small entity's efforts to determine and meet its legal obligations.

C. FDA may also consider whether to reduce or waive a CMP against a small entity, including a small entity otherwise excluded from this guidance under paragraph A above, if the small entity can demonstrate to the FDA's

[1] "Enforcement action" does not include a Warning Letter or any judicially reversed enforcement action.

satisfaction that it is financially unable to pay the penalty, immediately or over a reasonable period of time, in whole or in part.

D. If a small entity corrects the violative conditions within a reasonable time period, FDA may reduce the amount of any CMP that may be imposed for the violations, up to the amount spent by the small entity for corrective action. FDA may take into account the time in which the small entity took corrective action and any difficulties the small entity encountered when doing so.

Penalties Eligible for Reduction

The penalty reduction guidance applies to judicial and administrative CMPs.

Exclusions from the Penalty Reduction Guidance

The penalty reduction guidance does not apply to any remedy that may be sought by FDA other than CMPs.

SBREFA also permits an agency to apply penalty reduction to violations discovered through a small entity's participation in a compliance assistance or audit program operated or supported by the agency or state. Although various units within FDA provide regulatory guidance to small entities, FDA does not operate a formal compliance assistance or audit program. Because FDA does not have a compliance program of the type described in SBREFA, this condition is not included in the penalty reduction guidance.

If a small entity is eligible for CMP reduction, but has obtained an economic benefit from the violations such that it may have obtained an economic advantage over its competitors, FDA may seek the full amount of the penalty. FDA retains this discretion to ensure that small entities that comply with public health laws enforced by the agency are not disadvantaged by those who have not complied.

FDA has determined that all CMPs assessed under the authority of the Generic Drug Enforcement Act (GDEA) and the Prescription Drug Marketing Act (PDMA) should be excluded from the penalty reduction guidance. Because of the level of scienter required to assess a CMP under GDEA or PDMA, FDA believes it is not appropriate to consider reduction or waiver of penalties in such cases. Under GDEA, CMPs may be assessed for a variety of intentional or "knowing" conduct related to abbreviated new drug applications (21 U.S.C. 335b(a)). Also, GDEA permits CMPs for debarred individuals who provide services in any capacity to persons who have approved or pending drug product applications (id). In accordance with the PDMA, CMPs may be assessed on a firm following conviction of that firm's representative for a violation of section 503(c)(1) of the Federal Food, Drug, and Cosmetic Act or any state law prohibiting the sale, purchase, or trade, or the offer to sell, purchase, or trade of a prescription drug sample. CMPs may also be assessed on a firm if that firm fails to report the conviction of that firm's representative to the FDA. Such conviction is a prerequisite for imposition of CMPs under the PDMA, and the "knowingly" standard must be met for conviction.

The National Childhood Vaccine Injury Act (NCVIA) also has a provision for CMPs, for which intentional or knowing conduct is a requirement for

assessment of penalties. Section 2128(b) of the Public Health Service Act (42 U.S.C. 300aa-28) states that a CMP may be assessed when a vaccine manufacturer intentionally destroys, alters, falsifies, or conceals records associated with the manufacture of vaccines. Accordingly, FDA believes it is not appropriate to consider reduction or waiver of CMPs in cases involving this provision of the NCVIA.

Definition of "Small Entity"

Section 211(1) of SBREFA defines the term "small entity" as having the same meaning as in section 601 of the United States Code (5 U.S.C. 601). Section 601 defines "small entity" as "small business," "small organization" and "small governmental jurisdiction."

Under section 601(3) of 5 U.S.C., a "small business" has the same meaning as "small business concern" under section 3 of the Small Business Act (15 U.S.C. 632(a)), unless an agency, after consultation with the Office of Advocacy of the Small Business Administration (SBA) and after opportunity for public comment, establishes its own definition.

Section 632(a)(1) of 15 U.S.C. defines a "small business concern" as an enterprise "which is independently owned and operated and which is not dominant in its field of operation" (15 U.S.C. 632(a)(1)). The SBA has further defined "small business concern" for a number of specific industries based on the sizes of the enterprises and their affiliations (see 13 CFR part 121 and the SBA Table of Size Standards).

When SBA determines whether an enterprise is a small business, it generally counts the enterprise's affiliations (see 13 CFR 121.103). Family enterprises or enterprises in which the same individual or individuals have a controlling interest are aggregated for this purpose. If the aggregate total of the affiliated enterprises exceeds the size requirement for small businesses, none of the affiliated enterprises is considered a small business.

Federal law defines "small organization" as a not-for-profit enterprise which is independently owned and operated and not dominant in its field (5 U.S.C. 601(4)). The U.S. Code defines a "small governmental jurisdiction" as a governmental entity with a population of less than 50,000 (5 U.S.C. 601(5)). The definitions of "small organization" and "small governmental jurisdiction" may be changed by agencies after an opportunity for public comment.

FDA intends to use the "small entity" definition, in reference to CMPs, as described in the above statutes, regulations, and SBA Table of Size Standards. The small business definitions within the nutritional food labeling exemptions (21 CFR 101.9(j) and 101.36(h)) are not applicable to CMPs.

Statutory and Regulatory Requirements

This penalty reduction guidance shall not supersede or negate any applicable statutory or regulatory requirements. For example, in device and food cases, in determining the amount of a CMP and any modification, the agency shall comply with 21 U.S.C. 333(f). Subsequently, this penalty reduction guidance would be applied to small entities.