

ENFORCEMENT CORNER



FDA Given New Enforcement Authority under FDAAA

by John R. Fleder

On Sep. 27, 2007, President Bush signed into law the Food and Drug Administration Amendments Act of 2007 (FDAAA).¹ While the user fee sections have perhaps received the most attention, there are also important enforcement provisions in FDAAA.

This article focuses on the three new civil money penalty provisions added to the Federal Food, Drug, and Cosmetic Act (FDCA) by FDAAA. These provisions add teeth to some of the major changes made by FDAAA: 1) the dramatic expansion of information that is required to be submitted to the government concerning clinical trials for inclusion in a clinical trials “registry and results data bank,” 2) FDA’s authority to pre-review television advertisements, and 3) the new provisions concerning risk evaluation and mitigation strategies and postmarketing studies.

Registry and Results Data Bank Penalty Provision

A new subsection has been added to Section 301 of the FDCA that now deems the following to be prohibited acts: submitting false or misleading information to the registry and results data bank; failing to submit a required certification (or filing a false certification) to FDA; and failing to submit the required clinical trial information to the registry and results data bank.² Correspondingly, Section 303, the civil money penalties provision, has been amended so that a clinical trial violation of Section 301 is now punishable by a civil penalty of up to \$10,000.³ If the violation is not corrected within 30 days, the responsible party is also liable for an additional \$10,000 per day until the violation is corrected, with no statutory cap.⁴

There is also a provision that requires government publication in the registry and results data bank of:

- A notice that the responsible party has violated the law by failing to submit required clinical trial information or has

submitted false or misleading clinical trial information;

- The penalties imposed for the violation; and
- Whether the responsible party has corrected the incorrect or missing clinical trial information in the registry and results data bank.⁵

This publication could well damage the reputation of a firm whose “misdeeds” are publicly disclosed under these provisions. Indeed, there is a requirement in FDAAA that the data base be made searchable for entries containing these disclosure notices.⁶

DTC Ads Targeted

The Federal Trade Commission Act prohibits the dissemination of any false advertisement involving the purchase of foods, drugs, devices and cosmetics.⁷ However, until the passage of FDAAA there was no specific enforcement authority in the FDCA concerning false advertisements.⁸ FDAAA adds a new section to the FDCA that specifically authorizes FDA to impose civil penalties on a person who disseminates or causes to be disseminated a direct-to-consumer (DTC) advertisement that is false or misleading.⁹

While the clinical trial penalties can only potentially grow enormous if violations continue, the starting penalty faced by those found liable for disseminating or causing another person to disseminate a false or misleading DTC advertisement is already there: up to \$250,000 for the first violation in a three year period.¹⁰ Each subsequent violation in that period cannot exceed \$500,000.¹¹ The new provision explains how the FDA is to calculate the number of violations, and the factors that FDA shall consider when imposing a penalty.¹²

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Also included in FDAAA, however, is the possibility of complete insulation from liability under certain circumstances.¹³ If and when the agency so requires, DTC television ads will need to be submitted to FDA at least 45 days before the advertisement is disseminated on television, thereby allowing the agency an opportunity to comment (but not generally order changes) with regard to the proposed advertisement.¹⁴ Thus, FDAAA does not generally require that the advertiser adopt comments provided by FDA. However, FDAAA does state that FDA may not impose a penalty if the company has submitted an advertisement for FDA's review (whether because FDA required the submission, or the sponsor made a voluntary submission) and has subsequently incorporated each FDA comment about the advertisement.¹⁵

Risk Evaluation and Mitigation Strategy Penalty Provision

There is also a third civil penalty provision that applies in several other situations. FDA can determine that a risk evaluation and mitigation strategy is necessary to ensure that the benefits of a drug outweigh the risks of the drug. In those instances, once informed by the agency, the person must submit a proposed strategy, get it approved, and maintain compliance with the approved strategy.¹⁶ In addition, a person is prohibited from introducing a drug into interstate commerce when FDA has required the submission of certain post approval or post marketing studies or post approval clinical trials and the person has failed to conduct such studies or trials,¹⁷ or fails to submit a supplement to a drug application with proposed labeling changes if an FDA order to make labeling changes is issued to address new safety information.¹⁸

Any person who violates these requirements is subject to a civil penalty of not more than \$250,000 per violation, not to exceed \$1,000,000 for all violations adjudicated in a single proceeding. If the responsible party continues the violation after FDA has provided written notice of the violation to that person, then the responsible party becomes liable for up to an additional \$250,000 for any portion of that first month in which the violation continues, to be doubled to \$500,000 for the second month, and \$1,000,000 for each month thereafter, with a cap of \$10,000,000 in a given proceeding.¹⁹

Other New Provisions

In addition to the provisions mentioned above, the following are other enforcement-related provisions in FDAAA:

- The FDA can require a manufacturer to conduct postmarket surveillance for certain class II and III devices;²⁰

- It is also now a violation to sell a food to which has been added an approved drug or biological product, or a drug or biological product for which substantial clinical trials have commenced and been made public, unless: 1) the drug or biological product was marketed in food prior to such approval or before institution of substantial clinical trials; 2) FDA has approved use of the drug or biological product in food; 3) use of the drug or biological product is permitted to enhance the safety of a food based on a food additive approval, a GRAS affirmation, listing or notification, or a food contact substance notification; 4) the drug or biological product was marketed for smoking cessation prior to FDAAA; or 5) the drug is an approved animal drug.²¹
- The agency has been ordered to “expand and enhance” its resources and facilities involving regulatory and criminal enforcement of the FDCA to protect the drug supply chain against counterfeit, diverted, subpotent and adulterated, misbranded and expired drugs and biological products (including active pharmaceutical ingredients), and undertake enhanced joint enforcement activities with other federal and state agencies to further that goal.²²
- It is now a prohibited act under the FDCA to fail to submit a required food safety report or notification (involving situations where there is a reasonable probability that use of, or exposure to, the food will cause serious adverse health consequences), or to submit a false report or notification in that area.²³

Finally, a number of new provisions state that certain actions now render a product misbranded under the FDCA:

- Failing to agree to a FDA-requested labeling change regarding pediatric use within 30 days of the request;²⁴
- Failing to comply with an approved risk evaluation and mitigation strategy;²⁵ and
- Failing to comply with a post market study or clinical trials requirement.²⁶ ▲

Gwendolyn McKee, an Associate with the law firm of Hyman, Phelps & McNamara, P.C., Washington, DC., assisted in writing this article.

1 Public Law 110-85, 121 Stat. 823-978.

2 121 Stat. 920.

3 121 Stat. 920.

4 121 Stat. 920.

5 121 Stat. 919.

6 121 Stat. 920.

- 7 15 U.S.C. §§ 52-55.
- 8 Instead, the FDCA, until passage of FDAAA, deemed the dissemination of a false advertisement to render a drug to be misbranded, thereby subjecting the drug to the general enforcement provisions of the FDCA.
- 9 121 Stat. 940.
- 10 121 Stat. 940.
- 11 121 Stat. 940.
- 12 121 Stat. 940-41.
- 13 121 Stat. 941.
- 14 121 Stat. 939.
- 15 121 Stat. 939, 941 (except that FDA can mandate changes for disclosures regarding a serious risk).
- 16 121 Stat. 926.
- 17 121 Stat. 922-26.
- 18 121 Stat. 925.
- 19 121 Stat. 943.
- 20 121 Stat. 865.
- 21 121 Stat. 951.
- 22 121 Stat. 953.
- 23 121 Stat. 968-69.
- 24 121 Stat. 873, 882, 888-89.
- 25 121 Stat. 943.
- 26 121 Stat. 943.

U.S. Sentencing Commission Considering Amending the FDA Sentencing Guidelines

On Sept. 11, 2007, the U.S. Sentencing Commission published a notice in the Federal Register that one of its current priorities will be to consider amending the current federal Sentencing Guidelines relating to "counterfeit controlled substances, human growth hormones (HGH), Prescription Drug Marketing Act ... [offenses], and other food and drug violations."

The federal Sentencing Guidelines govern the sentences that federal judges impose on individuals and corporations that are convicted (either through a plea or a trial) of federal crimes. There are currently a number of applicable Guidelines in this area, but Guideline 2N2.1 is the most explicit guideline for food and drug offenses. Corporations convicted of food and drug offenses are sentenced under a different sentencing scheme as set forth in Section 8 of the Guidelines.

In 1996, the Sentencing Commission proposed deleting Guideline 2N2.1, in favor of having all persons convicted of FDA-related offenses sentenced under the harsher guidelines applicable to fraud cases. The Commission ultimately withdrew that proposal after a number of organizations filed comments objecting to the proposal. The Sentencing Commission and its staff have not made any public statement as what they are considering as possible amendments to the Guidelines. The Commission is likely to announce its actual proposal in this area in January 2008, have a short period during which people can comment, and then issue any applicable changes to the Guidelines before May 1, 2008.

— John Fleder

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