

ADVERTISING, MARKETING & PROMOTIONS

>> ALERT

FDA PROPOSES TO AMEND ITS REGULATIONS CONCERNING DIRECT-TO-CONSUMER (DTC) PRESCRIPTION DRUGS

On March 29, 2010, the Food and Drug Administration (FDA) issued a notice proposing to amend its regulations concerning DTC prescription drug advertisements by implementing standards that the FDA would consider in determining whether the major statement in these advertisements is presented in a manner that is clear, conspicuous and neutral as required by the Federal Food, Drug and Cosmetics Act (the Act) as amended by the Food and Drug Administration Amendments Act of 2007 (the FDAAA).

BACKGROUND

The Act states that a prescription drug will be deemed misbranded unless all DTC advertisements for the drug contain a brief summary relating to side effects, contraindications, and effectiveness of the drug. This requirement is referred to as the “brief summary.” In a print advertisement the brief summary is readily recognizable as the full page of disclosures that always follows a prescription drug advertisement.

In acknowledgment of the fundamental differences between print and broadcast advertising media, the FDA does not require the full brief summary to be disclosed in the audio or video portion of a broadcast advertisement. Many experts, including the FDA, agreed that disclosing so much information in such a brief period of time would likely result in the inadequate disclosure of important information. Instead, as part of the information disclosures required for broadcast

advertisements, the FDA requires information about the drug’s major side effects, warnings, contraindications, special considerations and other important information in the audio or the audio and video portions of the advertisement to be disclosed. This requirement is termed the “major statement.” The FDA will find a prescription drug to be misbranded when a broadcast advertisement for a drug lacks the major statement or contains a deficient major statement.

Pursuant to the FDAAA, the Act now further requires the major statement to be presented in a clear, conspicuous and neutral manner. The FDAAA also instructed the FDA to establish by regulation standards for determining whether the major statement is presented in such a manner.

In an effort to fulfill its obligations under the FDAAA, on March 29th, the FDA issued a notice proposing to define the requirement.

THE BOTTOM LINE

Once the FDA’s proposal is finalized, standards will dictate how the major statement must be disclosed in DTC prescription drug advertisements. The only way to have a say in the proposed standards is to submit comments before the June 28, 2010 deadline. Now is the time to write in to ensure that your point of view is considered.

THE PROPOSAL

As proposed by the FDA, a major statement is clear, conspicuous and neutral if:

- >> Information is presented in language that is readily understandable by consumers.
- >> Audio information is understandable in terms of the volume, articulation, and pacing used.

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- >> Textual information is placed appropriately and is presented against a contrasting background for sufficient duration and in a size and style of font that allows the information to be read easily.
 - >> The advertisement does not include distracting representations (including statements, text, images, or sounds or any combination thereof) that detract from the communication of the major statement.
- In developing the above-mentioned proposed standards, the FDA considered other Federal agency's standards, including:
- >> The FTC enforcement policy statement issued in 1970 for determining whether an affirmative disclosure in a television commercial is "clear and conspicuous."
 - >> The factors the FTC takes into account in determining whether audio messages, such as radio ads, are "clear and conspicuous," as published in the Federal Register of May 6, 1998.
 - >> The FTC regulations under the Telephone Disclosure Act requiring disclosures in the advertising of pay-per-call services be made "clearly and conspicuously."
 - >> Relevant provisions of the FTC guides for environmental marketing claims.

- >> Standards for "clear and conspicuous" set forth by Congress in House Report 102-839, written to accompany the National Waste Reduction, Recycling and Management Act.
- >> "a number of [other] Federal regulations [that] provide similar standards in contexts other than advertising for disclosures that are required to be presented in a "clear and conspicuous" manner to consumers. For example, a number of Federal agencies, including FTC, SEC, DOT and CFTC, provided standards for "clear and conspicuous" disclosures in regulations that were implemented as a result of the privacy provisions of the Gramm-Leach-Bliley Act."

The FDA stated that it is not aware of any standards or regulations concerning the definition of "neutral manner" in the context of required disclosures but considers it to mean "unbiased manner" and proposed the above-mentioned standards accordingly.

As always, interested parties are being given the opportunity to send comments relating to the proposed rule to the FDA. The FDA is specifically soliciting comments on standards to establish "neutral." In addition, the FDA considered adding a fifth standard that would require the major statement in a television advertisement to be

included in both the audio and video portions of the presentation. While such a standard did not make it into the proposed rule, the FDA is also specifically soliciting comments on whether the final rule should contain such a standard.

Comments on the FDA proposed rule must be submitted by June 28, 2010. Please contact us if you would like any help or advice in connection with drafting or submitting comments to the FDA on the proposed rule.

FOR MORE INFORMATION

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