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FDA Law Update

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FDA Publishes Proposed Rule on Broadcast Direct-to-Consumer Prescription Drug Advertisement; the 4 New Standards

On March 29, 2010, FDA published a proposed rule setting forth how it would interpret the Congressionally mandated requirement that "major statements" in broadcast Director-to-Consumer ("DTC") advertisements for prescription drugs be presented in a "clear, conspicuous and neutral manner." See proposed 21 C.F.R. § 202.1(e), 75 Fed. Reg. 15376 (March 20, 2010).

Under current rules, each DTC broadcast (TV/Radio) advertisement for a prescription drug must contain a "major statement" of the "major side effects and contraindications" of the advertised prescription drug, along with identification of means to obtain the approved labeling for the advertised product (referred to as "adequate provision"). Under current regulations, the "major statement" is required to be "comparable in prominence and readability to the presentation of effectiveness information in the advertisement."

The Food and Drug Administration Amendments Act of 2007 ("FDAAA") amended Section 502(n) of the Federal Food Drug and Cosmetic Act by requiring that "[i]n the case of a prescription drug subject to section 503(b)(1) presented directly to consumers in television or radio format and stating the name of the drug and its conditions for use, the major statement relating to side effects and contraindications shall be presented in a clear, conspicuous and neutral manner." See Section 901(d)(3)(A) of FDAAA.

FDA has proposed four standards that it intends to use in interpreting the Congressional mandate. It will regard a broadcast DTC advertisement to meet the "clear, conspicuous, neutral" test if:

1. Information in the major statement is presented in language that is readily understandable by consumers;

2. Audio information in the major statement is understandable in terms of the volume, articulation, and pacing used;

3. The text of the major statement 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; and

4. 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 proposing these standards, FDA looked to rules of other agencies, including the Federal Trade Commission, the Securities and Exchange Commission and others who had previously interpreted "clear and conspicuous" in a similar fashion. As to defining a "neutral manner," the Agency noted it was unaware of similar regulatory precedent and determined that it would interpret "neutral" to mean "unbiased." To achieve a "neutral" and unbiased presentation, it said thatt "the major statement must not be presented in competition with other elements if these elements would arrest the attention and distract consumers from the presentation of the risk information."

Significantly, the Agency did not propose that the "major statement" be included in *both* audio and visual parts of the advertisement, even though it said it thought such a standard "could enhance the clarity, conspicuousness and neutrality" of the major statement. It is requesting public comment on whether major statements in TV advertisements should be in both the audio and visual parts of the advertisement. (Comments can be made on this issue and other issues raised by the proposed rule by June 28, 2010).

While to a great degree the Agency has already been utilizing similar criteria to determine whether a broadcast DTC advertisement is false and/or misleading, the new standards set forth in greater detail the approach FDA will utilize in reviewing broadcast DTC advertisement for prescription drugs. While it is not, as FDA says a "set formula," it does provide a roadmap as to how advertisers can satisfy FDA that their advertisements effectively communicate the overall message of a major statement.

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