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Life Sciences Health Industry Alert

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FDA Issues Proposed Rule Governing Major Statements in Television and Radio Advertisements

The Food and Drug Administration ("FDA") released a proposed rule that would amend the Agency's prescription drug advertising regulation governing direct-to-consumer ("DTC") advertising, and establish criteria for determining whether a major statement in DTC advertising is presented in a clear, conspicuous, and neutral manner.[1] This action was mandated by the Food and Drug Administration Amendments Act of 2007 ("FDAAA") (Public Law No. 118-05).[2]

The standards set forth in the Proposed Rule are unlikely to significantly alter the enforcement landscape for DTC advertising. Rather than articulating new principles for application in this area, the standards contain more specific language from which practitioners may draw from to articulate FDA's approach towards whether a particular DTC advertisement meets the "clear, conspicuous and neutral" standard. That is, it's unclear whether any given DTC advertisement's presentation of information regarding the side effects and contraindications of a product would be viewed differently under the proposed standards compared the current "fair balance" requirement.

Background

FDA regulations currently require that advertisements for prescription drugs include information about both the uses and risks associated with the product. Print advertisements are required to include a brief summary of the information relating to side effects, contraindications, and effectiveness.[3] Because of limitations inherent to radio and broadcast advertisements, FDA only requires such advertisements to include a "major statement," which must include the major side effects and contraindications associated with the product. To comply with the regulations, the major statement (1) must not be false or misleading; (2) must present a fair balance between information on risks and contraindications and the effectiveness of the product; and (3) must reveal material information vis-à-vis the representations in the advertisement or consequences flowing from use of the drug.[4] Current FDA regulations require that this information be provided "with a prominence and readability reasonably comparable to the presentation of information relating to the effectiveness of the drug."[5]

Proposed Rule

The Proposed Rule clarifies that radio and television advertisements "must present the major statement in a clear, conspicuous, and neutral manner." Notably, the fair balance requirement for DTC regulations already contemplates that risk information be placed in a clear and conspicuous manner. Currently, to ensure "fair balance," product information relating to risk must be presented in a manner equivalent to the presentation of benefits. However, the current approach is relative in that the description of risks is directly linked to the description of benefits. The Proposed Rule would impose an absolute requirement separate from the "fair balance" requirement that closely tracks the express language under FDAAA that all such advertisements present risk information in a clear, conspicuous and neutral manner.

More important are the four standards FDA has proposed for major statements, which are considerably more specific than the DTC standards under the current regulations (i.e., not false and misleading, fair balance, and failure to reveal material information). Under the Proposed Rule, a major statement is clear, conspicuous, and neutral if the following four standards are satisfied:

- **Understandable language.** The rule would require information to be "presented in language that is readily understandable by consumers." In other words, the language used to communicate risks in the major statement must be comprehensible to the intended audience of the advertisement. The major statement should avoid vague terms or explanations that are readily subject to different interpretation.
- **Understandable audio.** The rule would require audio information to be "understandable in terms of the volume, articulation, and pacing used." Markedly reducing volume or delivering the major

statement in an inarticulate manner hinders the audience's comprehension of the risks being presented. The rule would also require attention to pacing, a risk information presentation to allow the audience to hear and process it.

- **Appropriate text appearance.** The rule would require that 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." When information from the major statement is conveyed in the visual as well as the audio portion of the television advertisement, the rule would require this information be placed in a manner that allows it to be easily read (e.g., parallel with the base of the advertisement), and appear concurrently with any directly related audio information. In addition, the rule would require sufficient contrast between visually presented text and the background to highlight the risk information, and sufficient screen time to allow consumers to identify, read, and process the information.
- **No distracting representations.** The rule would also prohibit "distracting representations (including statements, text, images, or sounds or any combination thereof) that detract from the communication of the major statement." The major statement could not be presented in competition with other elements if those elements would arrest the attention and distract consumers from the presentation of the risk information. FDA notes that examples of such distracting elements may include visuals, images, graphics, background music, sound effects, or other noises. Importantly, FDA notes that this is of particular concern when distracting elements convey additional benefit information that results in the risk information not being effectively communicated.

The Agency does not intend for these standards to prescribe a set formula for clear, conspicuous, and natural statements, as there is more than one way to achieve this purpose. However, FDA cautions manufacturers that this flexible approach does not negate the requirement to comply with the standards set forth in the Proposed Rule. Note that although the Proposed Rule is largely consistent with prior FDA guidance and enforcement,[6] manufacturers that engage or plan to engage in DTC advertising should consider whether these more specific standards would present practical issues for the development of DTC advertisements for their products.

Comments on the Proposed Rule must be filed with the FDA no later than June 28, 2010. In addition to requesting general comments about the Proposed Rule itself, FDA has specifically requested comments on whether it should add a standard requiring that the major statement in television advertisements be included in both the audio and visual parts of the presentation. FDA believes this approach, which is similar to the standard used by the Federal Trade Commission for over-the-counter drug and certain medical device[7] advertisements, could enhance the clarity, conspicuousness, and neutrality of the major statement.

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1 75 Fed. Reg. 15376 (March 29, 2010).

2 21 U.S.C. § 352(n) ("In the case of an advertisement for a drug subject to section 353(b)(1) of this title presented directly to consumers in television or radio format and stating the name of the drug and its conditions of use, the major statement relating to side effects and contraindications shall be presented in a clear, conspicuous, and neutral manner.").

3 21 C.F.R. § 202.1(e)(1).

4 21 C.F.R. § 202.1(e)(5).

5 21 C.F.R. § 202.1(e)(7)(viii).

6 *See* FDA Guidance, *Consumer Directed Broadcast Advertisements, Questions and Answers* (August 1999) (stating that the Agency has sent letters to manufacturers warning against the practice of including distracting visual representations during the major statement).

7 FDA spent significant effort in the Proposed Rule explaining how other federal agencies have established standards for compliance with the "clear and conspicuous" language in other legislation. Presumably, these efforts seek to demonstrate that the Agency is proceeding rationally in the development of standards, and that the standards in the Proposed Rule are based on a reasonable and mutual interpretation of the statute.

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