



March 31, 2010

FDA Proposes to Amend Regulations Regarding the Presentation of Major Statement Information in Direct-to-Consumer Broadcast Advertisements

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On March 29, 2010, the Food and Drug Administration (FDA or “the Agency”) published a proposed rule to amend the regulations concerning the presentation of major statement information in direct-to-consumer advertisements (DTC ads) for prescription drugs (21 C.F.R. § 202.1).¹ The Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the Federal Food, Drug, and Cosmetic Act (FDCA) to require that the major statement in DTC television and radio ads relating to the side effects and contraindications of a prescription drug be presented in a “*clear, conspicuous, and neutral manner*,” effective March 25, 2008. As mandated by FDAAA, the proposed rule implements this new requirement and sets forth the standards for determining whether the major statement in an ad complies with this FDAAA requirement. FDA proposes that the standards in the final rule would become effective 90 days after its publication in the Federal Register.

This client alert addresses FDA’s regulation of risk information in DTC broadcast ads, key components of the proposed rule, and considerations that may have major implications for pharmaceutical manufacturers. Comments may be submitted to the docket by June 28, 2010.²

I. FDA’s Regulation of Risk Information in DTC Ads

Section 502(n) of the FDCA (21 U.S.C. § 352(n)) requires manufacturers, packers, and distributors who advertise prescription human and animal drugs, including biological products for use in humans, to disclose information about their product’s uses and risks. Ads for prescription drugs and biologics must contain a true statement that includes a brief summary of the product’s side effects, contraindications, and effectiveness. Ads that are broadcast through media, such as the television, radio, or telephone, must include a “*major statement*” that describes the major side effects and contraindications of the product. Print ads must include a “*brief summary*” of the risks in the product’s approved package labeling.³



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Under the current FDA regulations, the presentation of risk information in both broadcast and print ads must be “*comparable in prominence and readability*” to the presentation of effectiveness information in the ad. The failure to include this risk information, or the minimization of the risk information, can result in the misbranding of the product in violation of the FDCA.⁴

FDAAA § 901(d) amended FDCA § 502(n) to require that DTC television and radio ads that state the name of the prescription drug and its conditions of use must present the major statement relating to side effects and contraindications in a “*clear, conspicuous, and neutral*” manner, regardless of the manner in which the effectiveness information is represented by the DTC ad. Since this FDAAA amendment did not include telephone or electronic internet communications, FDA’s proposed rule is limited to television and radio ads.

II. FDA’s Proposed Standards for “Clear, Conspicuous, and Neutral” Major Statements

FDA proposes the following four-prong standard for determining whether a major statement is “*clear, conspicuous, and neutral*”:

1. “Information is presented in language that is readily understandable by consumers”;
 - The language used to convey risk should be particular and easily understandable to consumers, and the statement should accurately convey the frequency. For example, FDA suggests that if a drug’s prescribing information indicates that more than half of the patients experienced an adverse event, then the ad should accurately convey the frequency of this risk (e.g., more than half of patients) rather than presenting that “some patients” experienced the adverse event.
2. “Audio information is understandable in terms of the volume, articulation, and pacing used”;
 - FDA cites the example of risk information that is presented too quickly or quietly to be clear and conspicuous.
3. “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”;
 - FDA proposes that visual text major statement information must be placed in a manner that is easily read, such as parallel with the base of the ad, and in a manner regarding font size, style and background “*to highlight the risk information.*” The agency also observes that the presentation of visual risk information must be concurrent with audio information and paced so that the text remains on the screen for sufficient time “*to allow for consumers to identify and read and process the information.*”
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.”



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- FDA is particularly concerned when “*distracting representations*,” such as visuals, graphics or background music, sound effects or other noises, convey additional information about the product’s benefits such that risk information is not effectively communicated and a biased presentation heavily weighted toward benefit information is conveyed to the consumer.

In addition, FDA is requesting comments on the possible addition of a fifth element to require that the major statement in television ads be included in *both* the audio and visual parts of the broadcast presentation. (The Federal Trade Commission (FTC) has a similar requirement for disclosures in television ads.)

III. Considerations of potential interest to manufacturers

- **Absence of specific criteria for formatting a DTC broadcast ad.** According to FDA, the purpose of the proposed rule is to ensure the “*effective communication of risk information . . . so that consumers receive a fair and accurate impression of the drug being promoted.*” Towards that end, the Agency emphasizes that the purpose of the proposed standard is not “*to prescribe a set formula.*” The Agency considered and rejected specific requirements for the formatting of ads, *e.g.*, font sizes and placement of information. FDA explicitly recognizes that “*there is more than one way to achieve these standards.*” Although the absence of specific formatting criteria may afford more flexibility for manufacturers, it also potentially opens the door for disagreements between a company and FDA.
- **Potential for an increase in FDA enforcement and Congressional scrutiny.** The proposed standards may lead to increased FDA enforcement and congressional oversight once a final rule is promulgated, especially if companies attempt to apply previous internal company standards for acceptable content and formatting of DTC broadcast ads. In support of this concern, the preamble discusses that the Division of Drug Marketing, Advertising, and Communications (DDMAC) examined a random sample of 35 television and radio drug ads disseminated in 2009 with the aim of developing a baseline estimate of the percentage of DTC ads that could be judged to be in violation of a “*clear, conspicuous, and neutral standard.*” DDMAC found that approximately one-third of the broadcast ads in this sample could be judged in violation of this standard.
- **Definition of neutral.** In drafting the standards for the “*clear*” and “*conspicuous*” requirements, FDA examined similar standards used by other agencies, such as the FTC, Department of Treasury (DOT), Commodity Futures Trading Commission (CFTC), and Securities Exchange Commission (SEC). Creating a standard for the “*neutral*” requirement, however, proved more difficult. FDAAA is silent on this point, and FDA is not aware of any previous standards or regulations concerning the definition of “*neutral manner in the context of required disclosures.*” FDA is approaching “*neutral*” to mean in an “*unbiased manner.*” In addition, FDA is analyzing a research study it conducted on the impact of distraction, *e.g.*, visual images, on consumer comprehension of risk and benefit information in DTC prescription drug television ads. FDA plans to publish a report of its analysis in the docket and will provide an opportunity for public comment either during the comment period for the proposed rule or, if necessary, during a reopened comment period. When it is published, manufacturers may wish to examine this report



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closely regarding the utility and generalizability of FDA's findings regarding the standard of "neutral."

- **Date that the final rule would be effective.** FDA seeks public comment on its proposed 90 day effective date for any final rule that may issue based on this proposed rule. Manufacturers may wish to consider whether the 90 day effective date may pose an excessive burden if major changes in existing company processes and procedures, as well as removal or replacement of existing television and radio ads, are needed to ensure compliance.

King & Spalding will continue to monitor this important proposed rule and we will issue a follow-up client alert when FDA posts its upcoming research report in the docket on consumer comprehension of risk and benefit in DTC ads. We are happy to assist in the preparation of comments.

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This alert provides a general summary of recent legal developments. It is not intended to be and should not be relied upon as legal advice.

¹ 75 Fed. Reg. 15376 (Mar. 29, 2010). FDA Proposed Rule, *Direct-to-Consumer Prescription Drug Advertisements: Presentation of the Major Statement in Television and Radio Advertisements in a Clear, Conspicuous, and Neutral Manner*.

² Comments should be identified by Docket No. FDA-2009-N-0582 and/or RIN 0910-AG27. Comments may be submitted electronically to the Federal eRulemaking Portal: <http://www.regulations.gov>. Written comments may be submitted to Division of Dockets management (HFA-305), Food and Drug administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20851, or by FAX: 301-827-6870.

³ See 21 C.F.R. § 202.1(e).

⁴ See 21 U.S.C. §§ 321(n), 352(n).