

## FDA Accepting Comments On A Proposed Rule For Direct-To-Consumer (“DTC”) Advertisements

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On March 29, 2010, the U.S. Food and Drug Administration (“FDA”) published a proposed rule titled *Direct-to-Consumer Prescription Drug Advertisements; Presentation of the Major Statement in Television and Radio Advertisements in a Clear, Conspicuous, and Neutral Manner* (“**Proposed Rule**”).<sup>1</sup> The Proposed Rule would require direct-to-consumer (“DTC”) television and radio advertisements to present the mandated “Major Statement” for major side effects and contraindications “in a clear, conspicuous, and neutral manner.” ***The FDA is accepting written comments on the Proposed Rule until June 28, 2010.***

This Client Alert provides an overview of the Proposed Rule’s impact on the current regulatory requirements for DTC advertisements and highlights several key considerations for manufacturers. Manufacturers should consider addressing comments to the FDA on this Proposed Rule.

### OVERVIEW OF THE PROPOSED RULE

#### ***Summary of Key Regulatory Framework Currently***

Currently, 21 U.S.C. § 352(n) requires DTC advertisements of prescription drugs to include “a true statement of: 1) the established name; 2) the formula; and 3) information relating to side effects, contraindications and effectiveness.”<sup>2</sup> In addition, FDA requirements set forth in 21 C.F.R. § 202.1 require broadcast DTC advertisements to “include information relating to the major side effects and contraindications of the advertised drugs in the audio or audio and visual parts of the presentation...”,<sup>3</sup> otherwise known as the Major Statement requirement. DTC advertisements also must provide fair balance between the presentation of the drug’s benefits and risks.<sup>4</sup> Therefore, under the current regulatory structure, “[i]f an advertisement presents effectiveness information in

a clear and conspicuous manner, risk information is required to be presented in a comparable manner.”<sup>5</sup>

### ***FDA’s Proposed Rule***

Section 901(d)(3)(A) of the Food and Drug Administration Amendments Act of 2007 (“**FDAAA**”) amended § 502(n) of the Federal Food, Drug, and Cosmetic Act (“**FDCA**”) to require the Major Statement to be presented in a “clear, conspicuous, and neutral manner.”<sup>6</sup> In other words, fair balance between the presentation of the drug’s benefits and risks is no longer the applicable standard. Rather, the Major Statement must satisfy the “clear, conspicuous, and neutral” standard “regardless of the manner in which effectiveness information is presented in the advertisement.”<sup>7</sup> Consequently, once this regulation becomes final, manufacturers using DTC advertising in radio and television will be required to present the product’s major side effects and contraindications in the audio or audio and visual presentation regardless of the manner in which the advertisement presents the product’s benefits.

The FDA reviewed similar standards developed by several federal regulatory agencies including the Federal Trade Commission (“**FTC**”) in developing the standard set forth in the Proposed Rule. Specifically, the FDA would consider a Major Statement as satisfying the “clear, conspicuous, and neutral” standard if the following **four** requirements are satisfied:

1. Information must be presented in language that is readily understandable by consumers. For example, DTC advertisements should avoid using medical terms and vague references.
2. Audio information must be understandable in terms of the volume, articulation, and pacing used in the DTC advertisement.
3. Textual information must be placed appropriately and presented against a contrasting background for sufficient duration and in a size and style of font that allows the information to be read easily. Such information should be concurrent with related audio information.
4. The DTC advertisement may not include distracting representations that detract from the communication of the major statement. This includes, by way of example, statements, text, images, visuals, graphics, sound effects and background music.

The FDA noted that these standards are consistent with the factors set forth in its Draft Guidance titled *Presenting Risk Information in Prescription Drug and Medical Device Promotion*.<sup>8</sup>

### **KEY CONSIDERATIONS**

The FDA’s Proposed Rule intends to provide manufacturers with additional guidance on satisfying regulatory requirements for DTC advertisements. Manufacturers should

review this Proposed Rule carefully and consider submitting comments to the FDA, including comments on the following:

- Whether the FDA’s four proposed elements for the “clear, conspicuous, and neutral” standard are reasonable and practical. Consider providing specific examples to demonstrate how the elements may be applied in practice.
- Whether the FDA’s final rule should include a fifth element similar to the FTC standard that would require the Major Statement to be included in both the audio and visual portions of the DTC advertisement. The FDA considered adding this fifth element to enhance the “clear, conspicuous and neutral” standard. Although it is not part of the Proposed Rule, the FDA specifically requested comments as to whether the FDA should add this fifth element.
- The reasonableness of the FDA’s proposed timeline that the effective date be 90 days after publication of a final rule. The effective date would be applicable to any DTC advertisements that air on or after that date.

EpsteinBeckerGreen encourages interested parties to submit written comments responsive to these questions.

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*This Client Alert was authored by Sarah Giesting and Lee Rosebush. For additional information about the issues discussed in this Client Alert, please contact one of the authors or contributors or the EpsteinBeckerGreen attorney who regularly handles your legal matters.*

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<sup>1</sup> 75 Fed. Reg. 15,376 (March 29, 2010).

<sup>2</sup> 21 U.S.C. 352(n).

<sup>3</sup> *Id.*

<sup>4</sup> 21 CFR 202.1(e)(5)(ii).

<sup>5</sup> 75 Fed. Reg. 15,377.

<sup>6</sup> FDAAA required the FDA to implement the “clear, conspicuous and neutral” standard within thirty months of the enactment of FDAAA (September 27, 2007).

<sup>7</sup> *Id.*

<sup>8</sup> 74 Fed. Reg. 25,245 (May 27, 2009).