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Client Alert 09-181

June 2009

reedsmith.com

Prescription Drug and Medical Device Promotion – New FDA Draft Guidance on Presenting Risk Information

On May 27, 2009, the Food and Drug Administration ("FDA") announced the availability of a draft guidance titled *Presenting Risk Information in Prescription Drug and Medical Device Promotion ("Draft Guidance")*.[1] The *Draft Guidance* sets forth the standards FDA intends to consider when evaluating promotional pieces to determine whether they effectively communicate risk information in a non-misleading manner. Under the Food, Drug & Cosmetic Act ("FDCA") and FDA's implementing regulations, promotional pieces making claims about a product are deemed misleading if they fail to disclose certain information about the product's risks. Although FDA will accept comments on the *Draft Guidance* at any time, comments should be submitted to FDA by Aug. 25, 2009, to be considered before FDA finalizes the document. This Client Alert provides a brief outline of the *Draft Guidance* and identifies issues for possible comment to FDA.

I. Summary of New Draft Guidance

The *Draft Guidance* conveys FDA's current thinking about risk communication in evaluating advertisements (ads) and labeling (together referred to as "promotional materials") for prescription drugs, ads for restricted medical devices, and labeling for all medical devices. It does not address over-the-counter (OTC) drug ads. Along with factors to be considered, FDA sets forth the standard it will apply when reviewing promotional materials and specific examples. Although FDA has found promotional materials false and misleading for other reasons, the *Draft Guidance* suggests that adequate and accurate risk information is the most important element of any promotional material.

A. Standard for Review: The Reasonable Consumer

FDA proposes to assess promotional material using a "reasonable consumer" standard. In other words, FDA will examine materials from the perspective of a consumer "acting reasonably in the circumstances." If a material is directed primarily to a particular group (e.g., practitioners), then FDA will consider the group's perspective and level of expertise in determining reasonableness. The reasonableness standard does not preclude multiple interpretations of a claim, so long as each interpretation is reasonable. However, when a representation could convey more than one meaning, one of which is untrue or inaccurate for the reasonable person in the target audience, FDA will consider the material to be false and misleading.

B. Net Impression

The *Draft Guidance* states that when evaluating risk information in drug and device promotion, FDA looks not just at specific risk-related statements, but at the net impression of each piece (i.e., the collective message communicated by all elements of the piece). For example, even if specific individual claims or presentations are not misleading, FDA may find a promotional communication that conveys a deceptive net impression to be misleading.

C. Factors Considered in the Review of Risk Communication

The *Draft Guidance* sets forth factors that FDA will consider when determining whether risk information is communicated in a fashion consistent with the FDCA's and FDA's implementing regulations. The factors that FDA will evaluate include the following:

1. General Considerations

- **Consistent Use of Language Appropriate for Target Audience:** Both benefit and risk information should be presented in clear, understandable, and non-technical language for the intended audience.

- **Use of Signals:** Signaling is the use of structure or emphasis on aspects of the content without altering the information in the text. Headlines and subheads should be consistent and true for both benefit and risk information. Signals should not frame subsequent risk information in ways that minimize its importance.
- **Framing of Risk Information:** Framing refers to how a piece of information is stated or conveyed. Risk information should be presented in the same terms and with the same degree of specificity as benefit information.
- **Hierarchy of Risk Information:** FDA will consider how risks are ordered within a presentation. If a product's most important risks are in the middle of a list of less important risks, the most important risks may not be effectively communicated. The order of risk information should also not suggest that certain risks apply only to certain populations or only under certain conditions, when this is not the case.

2. Considerations of Content

- **Quantity:** The quantity and treatment of risk information in each piece should be comparable to the quantity and treatment of benefit information, including how it is conveyed. A promotional piece, however, does not have to convey an identical number of benefits and risks, and a given drug or device may have few or many risks. The *Draft Guidance* lists numerous factors that it will consider when determining the net impression of a promotional piece.
- **Materiality:** FDA may consider a promotional piece that omits material information (i.e., information that is objectively important, relevant, or substantial to the target audience) about a product's risks to be misleading, even if the piece devotes similar space or time to other risk and effectiveness presentations. The *Draft Guidance* lists the factors that FDA will use to determine if a fact is material.
- **Comprehensiveness:** Consumer and professional audiences expect that certain information will be present in promotions. FDA believes it is important for promotional materials to be comprehensive enough to meet these expectations, and will assess the quality as well as the quantity of the risk information in any given promotion.

3. Considerations of Format

- **Overall Location of Risk Information (Print and Non-Print Promotion):** Risk information should not just be presented in one location in a piece, but should, like benefit information, appear as an integral part of the main piece. Further, FDA will consider whether the placement of risk information interferes with readers' perceptions of the relative importance or utility of the information.
- **Font Size and Style (Print and Non-Print Promotion):** Font size and style should be similar and comparable. Although minor differences in font size might be acceptable, substantial differences in size or promotional pieces that present risk information in a difficult to read font size (irrespective of the font size of benefit information) may be problematic from FDA's perspective because of the potential impact on readability and comprehension.
- **Contrast (Print and Non-Print Promotion):** Contrast between text and background (e.g., color, superimposed photos) should not highlight the benefit information more than the risk information. Risk information should always be easy to read.
- **White Space (Print and Non-Print Promotion):** White space (i.e., background space between and around letters) influences the prominence and readability of text and will be considered by FDA when it evaluates the communication of risk information. The white space for benefit information should be comparable to the white space for risk information.
- **Textual, Audio, and Visual Elements (Non-Print Promotion):** Broadcast advertisements must present major product risks in the audio or audio and visual parts of the advertisements. If claims need to be qualified, FDA recommends that the qualifiers be vocalized, presented through visual images, or placed in a prominent superimposed text that runs concurrently with the claim. The *Draft Guidance* lists numerous issues that manufacturers should keep in mind when developing superimposed text and inserting audio and visual clips for non-print promotions.

D. Draft Guidance Attachment: Statutory and Regulatory Requirements for Labeling and Advertising

The attachment to the *Draft Guidance* document reviews the applicable FDA statutory and regulatory requirements for labeling and advertising of drugs and devices, and it notes the need to comply with

the First Amendment, but does not provide a detailed discussion on freedom-of-speech issues. The attachment also includes FDA's broad definition of the term "labeling," which generally encompasses Internet promotion and advertising.

II. Omissions

The *Draft Guidance* document provides some useful clarification regarding the factors FDA considers when evaluating the presentation of risk information in drug and device promotional materials. Although the document mentions the Internet in some places, it fails to substantively address promotional activities on the Internet, an increasingly important and relevant marketing venue for drug and device companies.

More than a decade has passed since 1996, when FDA held public hearings on Internet issues involving advertising and promotion.[2] Since that date, the agency has repeatedly stated its intention to issue guidance on Internet advertising and labeling. To date, however, it has failed, missing the opportunity to address this import subject in this *Draft Guidance*. Public statements by FDA officials and untitled/warning letters issued in connection with industry websites are all that can be used to infer FDA's current thinking on Internet promotional activities.

The *Draft Guidance* does include a few general references to the Internet. Footnote nine, at page 3 of the *Draft Guidance*, states that when used in the guidance, the terms "promotional pieces, promotional materials, and promotional communications" refer generally to both advertising and promotional labeling, "regardless of format" – including "internet web sites." The Draft Guidance also references an Internet website in an example to highlight the need for promotional pieces to disclose material risk information. In these references, FDA acknowledges that Internet promotional materials will be subject to agency scrutiny with regard to the presentation of risk information, but fails to address issues that are unique to the Internet. FDA does not describe how it will determine the "net impression" of an Internet site. It is unclear whether risk information should be presented on each web page or whether it should be placed on the relevant subsets of a web page. Previous Warning Letters have evaluated only the product pages of a company's web page, suggesting that subsets can be carved out. FDA also does not mention whether it would look at blogs or chat rooms, which arguably could fall within the protected zone of Free Speech.

Formal guidance from FDA can better address Internet promotional issues than case-by-case enforcement actions. Sometimes such enforcement actions conflict with previous agency positions. For example, FDA's recent issuance of untitled letters to 14 companies[3] concerning Google banner advertisements for their failure to include risk information in the banner conflicted with previous agency action (or inaction) that suggested risk information could be located one click away on another web page (i.e., the one-click policy). The untitled letters first revealed the agency's new thinking on the matter, but left many unanswered questions.

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1 http://www.fda.gov/cder/guidance/7427dft.pdf

2 *See* Promotion of FDA-Regulated Medical Products on the Internet; Notice of Public Meeting, 61 Fed. Reg. 48,707 (Sept. 16, 1996).

3 On April 3, 2009, FDA issued untitled letters to (1) Bayer Healthcare Pharmaceuticals, Inc.; (2) Biogen Idec; (3) Boehringer Ingelheim Pharmaceuticals, Inc.; (4) Cephalon, Inc.; (5) Eli Lilly and Co.; (6) Forest Laboratories, Inc.; (7) Genentech, Inc.; (8) GlaxoSmithKline; (9) Hoffman-LaRoche, Inc.; (10) Johnson & Johnson Pharmaceutical Services LLC; (11) Merck & Co., Inc.; (12) Novartis Pharmaceuticals Corp.; (13) Pfizer, Inc.; and (14) Sanofi Aventis, U.S. LLC.

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