

“What keeps you up at night?”

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FDA provides draft guidance to drug and medical-device manufacturers on presenting risk information

By Bruce D. Armon and Amy L. Piccola

On May 26, 2009, the FDA issued a draft guidance entitled, “Presenting Risk Information in Prescription Drug and Medical Device Promotion” (the “Guidance”). The Guidance describes factors FDA considers when evaluating the presentation of risk information to ensure compliance with the Federal Food, Drug and Cosmetic Act (the “Act”) and various federal regulations. The Act and the regulations generally require that promotional pieces not be false or misleading; must reveal material facts about the product being promoted; and present information regarding effectiveness and risk information in a balanced manner. The Guidance focuses primarily on the third factor.

It notes that FDA reviews specific risk-related statements and determines whether, based on the *net impression* of promotional and advertising material, the risk and benefit information provided is “accurate and non-misleading.” The Guidance recognizes the important role of social science research and the rationale adopted by other federal agencies, including the Federal Trade Commission. Importantly, it adopts a “reasonable consumer” standard to review claims in professional pieces.

The Guidance describes factors FDA considers when evaluating advertisements and promotional labeling for prescription drugs, advertisements for restricted medical devices and promotional labeling for all medical devices. It applies to promotional materials directed to both consumers and healthcare professionals. It does not apply to reminder promotions or over-the-counter drug promotional labeling.

When finalized, the Guidance will provide recommendations only. Manufacturers are welcome to use alternative approaches to presenting risk information as long as all requirements of the Act and its regulations are satisfied. The factors set-forth in the Guidance do, however, represent

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FDA’s “current thinking on this topic” and thus are meaningful considerations for ensuring promotional and advertising materials are compliant. The Guidance recognizes the release of PhRMA’s 15 guiding principles relating to DTC advertisements for prescription medicines — <http://www.phrma.org/files/DTCGuidingprinciples.pdf> — published in November 2005, but, as discussed above, it is focused on the role of the presentation of risk information.

FACTORS CONSIDERED BY FDA WHEN REVIEWING RISK COMMUNICATION

As part of its evaluation of advertisements and promotional materials, the FDA considers factors that relate to content and format.

General Considerations

Consistency and the signaling and framing of important information are key considerations in FDA evaluations of presentation of risk information. The following are the general factors highlighted in the Guidance:

- Consistent language should be used to describe benefits and risks. The language should also be appropriate for the target audience. For consumers, both benefit and risk information should be provided in clear, understandable and non-technical language.
- Signals, including headlines, graphics, and change in announcers in broadcast ads, must be consistent across benefit and risk information and must not act to minimize the risks of a product or mislead the audience.
- Risk information should be “framed,” or presented, in the same terms or with the same degree of specificity as benefit information and in a manner which accurately reflects their nature.
- The most important risk information should be placed or stated first, especially in print materials.

Considerations of Content

The Guidance specifically evaluates the content of risk presentations in determining whether a promotional piece is accurate and non-misleading. It states:

- Manufacturers should consider the space or time devoted to benefits and risk: benefits and risks should be presented in a comparable manner and in comparable amounts. As a whole, the communication should provide an accurate and non-misleading impression of the product.
- Material facts about risk, including the relevant properties of a product and for whom the product is appropriate, should be included in advertising and promotional materials. The Guidance describes material facts as those that influence reasonable consumers or health care professionals.
- Advertising and promotional pieces should ensure material risk information is provided.
- Package inserts are used by FDA in determining the materiality of risks.
- Accuracy and comprehensiveness of risk information is important.

Considerations of Format

The Guidance notes that certain formatting factors (e.g., shape, size and general layout of print promotional pieces and the organization) are considered by FDA when assessing promotional materials:

- In print promotions, risk information should be included in the main part of a piece and should generally appear in the same parts of the piece as the benefits. Risk information should not be placed in a manner to interfere with readers’ perceptions of the relative importance or utility of the information.
- There should not be substantial differences in font size between risk and benefit information and the presentation of risk information should not be in a

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difficult to read font size regardless of the font size of the benefit information.

- In both print and non-print promotions, the contrast between text and background should not highlight the benefit information more than the risk information.
- In non-print promotions, text that is superimposed on other images or visual components (e.g. graphics) should be reasonably visible and should appear on screen long enough to be read and understood.
- In non-print promotions, the visuals should not distract the audience from a statement of a product's risks. The audio portions of non-print promotions and ads should be consistent in both pace, volume and articulation for both risk and benefit information.

NEXT STEPS

Prescription drug and medical device manufacturers and those parties that assist these companies in developing and creating promotional materials should carefully review the Guidance. FDA is accepting comments with respect to it through August 25, 2009. While it is not binding, the Guidance provides important insights into how FDA will review promotional pieces and ensures consumers and health care professionals are presented with

effectiveness and risk information for products in a balanced manner. If you require assistance with providing comments to the Guidance or have other questions, please contact the authors or any other member of Saul Ewing's Life Sciences Practice Group.

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