



There Must Be Some Misunderstanding: FDA Issues New Guidance On Disclosing Risk Information In Consumer-Directed Print Advertisements And Promotional Labeling For Human Prescription Drugs

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The rock band Genesis sang in its 1980-released hit song, *“Misunderstanding,”* *“There must be some misunderstanding; there must be some kind of mistake.”* Someone at the Food and Drug Administration (FDA) must be a fan of the song, as the agency recently issued a revised draft guidance entitled, “Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisement and Promotional Labeling for Human Prescription Drugs.”¹ This guidance follows the agency’s 2004 draft after receiving industry feedback and conducting its own research. Comments are due 90 days from the date the guidance is issued in the Federal Register.

This Bulletin highlights the revised draft guidance. We will not describe here the basics of FDA’s regulation of prescription drugs labeling and advertisements, including the brief summary requirements.

Highlights

Main Policy Objectives

- FDA offers “alternative approaches” that companies may use to satisfy the brief summary requirements, some of those we will describe, which the agency refers to as the “consumer brief summary.”
- The agency makes clear that companies can use other approaches, not described in the draft guidance, if it complies with regulatory requirements.
- For a brief summary, FDA wants companies to focus on the most important risk information, rather than a laundry list of risks, but in a manner that consumers can understand.
 - FDA strongly recommends against the use of the traditional approach to fulfill the brief summary requirement in consumer-directed advertisements, an approach in which risk-related sections of the package insert (PI) are presented verbatim, often in small font.
- Because the full approved professional labeling can be lengthy and complex for consumers to understand, “FDA also strongly recommends against providing the full PI to satisfy the adequate directions for use requirement for consumer-directed print promotional labeling pieces for prescription drugs.”

Options for Disclosing Risk Information in Consumer-Directed Prescription Drug Print Advertisements and Promotional Labeling

- FDA states that it does not intend to object if a firm does not include “each specific side effect and contraindication from the PI in the brief summary in consumer-directed print advertisements . . . or does not supply the entire PI to fulfill the [regulatory] requirements . . . for consumer-directed print promotional labeling pieces, so long as the firm follows the recommendations and examples in this guidance.” The agency reminds the industry to use consumer-friendly language and notes a conversational tone might be useful.
- It is important for the consumer brief summary to be provided in a readable format, for example:

¹ See www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm069984.pdf.

- Signals, such as headlines and subheadings, and symbols, such as bullets;
- Layout of print information, including font size and type style, and double spacing between paragraphs and indentations (compared to plain box paragraphs).
- Regarding content, “FDA’s current thinking is that the consumer brief summary should provide clinically significant information on the most serious and the most common risks associated with the product and omit less pertinent information.”
 - FDA-approved patient labeling and Medication Guides, if applicable, are good places to start for content.
 - Looking at the Highlights section of Prescribing Information can help identify risk information to be presented, although more detail might be needed.
- FDA recommends that the consumer brief summary include the following information, as applicable:
 - Boxed Warning;
 - All contraindications;
 - Certain information regarding Warnings and Precautions:
 - The most clinically significant information from the Warnings and Precautions section(s) of the PI;
 - Information that would affect a decision to prescribe or take a drug;
 - Monitoring or laboratory tests that may be needed;
 - Special precautions not set forth in other parts of the PI;
 - Measures that can be taken to prevent or mitigate harm;
 - Most frequently occurring Adverse Reactions if a product has more than one indication, the most common adverse reactions for each indication being promoted should be included, if included in the PI, rather than pooled results for all indications (which could include indications that are not being promoted);
 - Adverse reactions should be listed in the same order as in the PI;
 - Other important Adverse Reactions, such as those that are serious or those that lead to discontinuation of the drug or dosage adjustment, should be included, unless they are repeated elsewhere in the PI (e.g., risks included in Warnings and Precautions).
 - Indication for the use being promoted, any clinically significant drug interactions, and information regarding topics or issues consumers should discuss with their health care providers (e.g., other drugs they are taking or pre-existing conditions).
- Not everything must be included in the consumer brief summary:
 - For example, dosage and administration, how the drug is supplied, clinical pharmacology, specific directions regarding use of the drug.
 - However, excluding information from the consumer brief summary does not mean one can omit from other parts of the promotional piece (e.g., information that a drug is administered via an injection versus orally might be material information that is required in the main body of the promotional piece, while detailed instructions for use may be omitted from the consumer brief summary).
- FDA recommends that the consumer brief summary include:
 - A statement that the information provided is not comprehensive;
 - A suggestion that consumers should speak to their doctor or pharmacist;
 - A toll-free telephone number or website address where an FDA-approved product labeling is provided.
- Concerning format, the agency acknowledges there are many types that might be acceptable, but recommends two formats in particular:
 - Prescription Drug Facts Box:
 - Information could appear within a box similar to the Over-the-Counter Drug Facts box with standardized headings, such as:
 - Uses
 - Do not use if
 - Warnings
 - Ask a health care provider before use if
 - When using this product, you may have

- The recommended content for this format is that described above.
- Question and Answer:
 - Information in the consumer brief summary could appear in columns or a similar layout and headings would be provided in the form of questions, such as:
 - What is [drug] used for?
 - When should I not take [drug]?
 - What Warnings should I know about [drug]?
 - What should I tell my health care provider?
 - What are the side effects of [drug]?
 - What other medications might interact with [drug]?
 - The recommended content for this format is that described above.

AGG Observations

- While the revised draft guidance is not legally binding, it represents FDA's current thinking.
- The agency offers recommendations; if a company chooses not to follow them, at least provide an alternative that addresses FDA's comments and concerns.
 - One might consider using a focus group to ensure consumer understanding, particularly if challenged by FDA or a competitor.
- The goal is to minimize "some misunderstanding" and "some kind of mistake" – who knew Genesis (the band) would be so relevant to FDA regulation?

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