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Client Alert

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FDA Revises Approach to Presentation of Risk Information in Brief Summary

FDA Recommends Using Consumer-Friendly Language and Replacing Package Insert with Drug Facts Box or Q&A

On February 6, 2015, the U.S. Food and Drug Administration (FDA) issued a revised draft guidance titled *Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Human Prescription Drugs.*[1] This revised guidance replaces a draft guidance issued by FDA in 2004.[2] In the revised draft guidance, FDA advises companies to stop using the full package insert (PI) to satisfy the "brief summary"[3] and "adequate directions for use"[4] requirements for prescription drug print advertisements and promotional labeling targeted to consumers. FDA urges firms to instead communicate important risk information in a more consumer–friendly format, such as a Drug Facts box format or question and answer format. FDA also recommends, among other things, that the consumer brief summary carry over elements of the main body of the ad (such as logos and branded colors) to establish a perceptual link between the consumer brief summary and promotional piece.

FDA is currently accepting comments to the docket on this revised draft guidance.[5] The deadline for submitting comments is May 11, 2015.

Package Insert is Too Technical for Many Consumers to Understand

In the revised draft guidance, FDA presents results from social science research and FDA's own investigations on consumer comprehension of risk information when presented in the form of the full PI. Research indicates that a large percentage of consumers rarely read the enclosed PI and those who do often fail to comprehend the technical language and highly scientific terms included in the PI.[6]

Given these findings, FDA suggests that a "consumer brief summary" should focus on "the most important risk information rather than an exhaustive list of risks" and suggests that the information be presented in consumer-friendly language and format.

FDA Recommends Drug Facts Box or Q&A Format

FDA suggests that a number of formats may be used to convey the information in the consumer brief summary for prescription drugs. However, FDA specifically recommends the following two formats in the revised draft guidance: (1) Drug Facts Box format (similar to the Drug Facts Box for over-the-counter drugs) and (2) Question & Answer format.

FDA recommends presenting the consumer brief summary for prescription drugs in the Drug Facts Box format based on the extremely positive consumer response to this format in a study testing various brief summary formats, as well as results from social sciences studies.[7] FDA also notes that consumers are already quite familiar with this format. The Agency suggests using standardized headings (such as "uses," "do not use if you," or "ask a health care provider before use if") to direct consumer attention to the appropriate information.

Alternatively, FDA recommends use of a question and answer format that simulates dialogue using personal pronouns. The use of personal pronouns is believed to increase consumer interest and therefore comprehension. In testing, this format did not perform any better or worse than the traditional full PI format with regard to risk recall or confidence in using the information, but consumers reported a marked preference for this format over the traditional format. FDA suggests that the information could be presented in columns or a similar layout, using consumer friendly language and phrasing headings in the form of questions, such as the following:

- 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]?

Language and Readability

FDA makes a number of suggestions regarding the tone and presentation of information in the consumer brief summary. The Agency suggests that technical language, scientific terms, and jargon be avoided. Firms should use a "conversational tone" or "language designed to engage the reader" to target a broad audience with various levels of literacy skills. Based on the social science findings cited, FDA makes the following recommendations:

- The consumer brief summary should carry over elements of the main body of the ad (such as logos and branded colors) to establish a perceptual link between the consumer brief summary and promotional piece.
- Font size and style should be selected or designed for readability.
- Double spacing should be used between paragraphs, and the first line of paragraphs should be indented in order to maximize white space.
- Information should be organized into textboxes with headings, and symbols such as bullets and capitalized words or phrases should be used in order to direct consumer attention.

Content

Under FDA's new policy, the consumer brief summary should provide clinically significant information on the most serious and most common risks associated with the product and omit less pertinent information that could be distracting or overwhelming. FDA notes that in formulating the consumer brief summary, the FDA-approved patient labeling or medication guide might provide a good starting point to identify appropriate risks. Information identified under the

2006 Physician Labeling Rule to include in the Highlights of Prescribing Information should be used by firms as an additional resource to identify the appropriate information and order of information to include in the consumer brief summary.[8] These resources should only form the starting point, however, as additional information may need to be included or excluded.

The following information should be addressed in the consumer brief summary:

- Boxed warning
- All contraindications
- Certain information regarding warnings and precautions: (a) the most clinically significant information from the Warnings and Precautions section(s) of the PI; (b) information that would affect a decision to prescribe or take a drug; (c) monitoring or laboratory tests that may be needed; (d) special precautions not set forth in other parts of the PI; and (e) measures that can be taken to prevent or mitigate harm.
- The most frequently occurring adverse reactions, as well as those that are serious or that would lead to discontinuation of the drug or dosage adjustment, should be included in the consumer brief summary and should be listed in the same order as they are in the PI. Adverse reactions should be listed by indication for each indication promoted, rather than "pooling" the adverse reactions for all indications.
- Information about the risks listed should include the severity of the risks (such as whether they are debilitating, life-threatening, irreversible, or whether stopping medication will alleviate or mitigate the risks), early warning signs of risks, the need for monitoring or testing during treatment, and any other relevant information depending on the drug and its risk profile.
- Indication for the use being promoted, any clinically significant drug interactions, and information regarding topics or issues consumers should discuss with their care providers.
- Information about special populations if they are of special concern based on the drug's known or potential safety profile.
- A statement that (a) reminds consumers that the information presented is not comprehensive, (b) suggests that consumers speak to their health care provider or pharmacist, and (c) contains a toll-free telephone number or website address where consumers can obtain the FDA-approved product labeling.

The following information can generally be excluded from the consumer brief summary (although it may be necessary to include it elsewhere in the promotional piece):

- Dosage and administration;
- How the drug is supplied;
- Clinical pharmacology;
- Specific directions regarding use of the drug; and
- How long the drug takes to work.

When the PI is revised, the consumer brief summary should be promptly revised as well.

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King & Spalding will continue to monitor any updates to FDA's policy on disclosing risk information in consumer-directed print advertisements and promotional labeling for human prescription drugs. Please contact us if you would like assistance in drafting comments on the revised draft guidance or in applying the newly revised draft guidance to your promotional material.

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[1] See http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm069984.pdf. The revised draft guidance was published in the Federal Register on February 9, 2015 (80 Fed. Reg. 6998).

[2] The revised draft guidance replaces the 2004 draft guidance, Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements.

[3] Section 502(n) of the Federal Food, Drug, and Cosmetic Act requires a print advertisement for a prescription drug to contain a true statement of the product's established name, quantitative composition, information in brief summary relating to side effects contraindications, and effectiveness, and, for published, direct-to-consumer advertisements, a statement encouraging consumers to report negative side effects to FDA. FDA further elaborates on these requirements in 21 C.F.R. § 202.1(e), requiring that the brief summary include warnings, precautions, and contraindications under headings such as "cautions," "special considerations," and "important notes" and states that the brief summary "shall disclose each specific side effect and contraindication… contained in required, approved, or permitted labeling for the advertised dosage forms." In the revised draft guidance, FDA refers to this information collectively as the "brief summary requirement." Prior to the issuance of FDA's revised draft guidance on February 9, 2015, firms had typically met the brief summary requirement by including all of the risk-related sections of the FDA-approved package insert (PI).

[4] In addition to advertising oversight, FDA has authority over labeling for prescription drugs, including both FDA-required labeling and promotional labeling. Although drug labeling is typically required to contain, "adequate directions for use," certain labeling may be exempt if, among other conditions, it bears "adequate information" for a recommended, prescribed or suggested dosage. "Adequate information for such use" includes "relevant warnings, hazards, contraindications, side effects, and precautions, under which practitioners licensed by law to administer the drug can use the drug safely and for purposes for which it is intended, including all conditions for which it is advertised or represented." 21 C.F.R. § 201.100(d)(1). As a general matter, the "adequate directions for use" requirement has been fulfilled by including the full, FDA-approved PI in all promotional labeling.

[5] Docket No. FDA-2004-D-0500.

[6] In an FDA-supported survey, "few respondents" reported reading even half of the brief summary when included as the complete PI. Over 40% reported that they generally do not read any of the brief summary in direct-to-consumer advertisements. (Revised Draft Guidance, p. 4, available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM069984.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery).

[7] Studies demonstrate that consumers reading information in the Drug Facts Box format demonstrate better recall of the information they have read, greater confidence in applying that information, and more positive feelings about reading the information in this format than in other formats tested. (Revised Draft Guidance, p. 9 – 10).

[8] Requirements on the Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922 (January 24, 2006).