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FDA Clarifies Use of Product Names in Advertising and Promotional Labeling

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The U.S. Food and Drug Administration recently published final guidance to clarify the requirements for the use of product names in promotional labeling and advertising for prescription drugs (including biological drug products). This newsletter provides a brief summary of the guidance and its implications.

On January 24, 2012, the U.S. Food and Drug Administration (FDA) posted final guidance entitled Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling. The final guidance, which modifies a draft guidance issued in January 1999, is intended to clarify the agency's interpretation of the requirements for product name placement, size, prominence and frequency in promotional labeling and advertising for prescription human drugs (including biological drug products) and prescription animal drugs. The recommendations provided in the final guidance apply to the use of product names in traditional print media, audio-visual (AV) promotional labeling (*e.g.*, videos shown in a doctor's office), broadcast media advertisements and electronic media (*e.g.*, internet, social media, e-mail). The guidance discusses requirements relating to single active ingredient products and products with two or more active ingredients.

The following topics are addressed in the sections of the final guidance that pertain to products with one active ingredient:

- When and how an established or proper (*i.e.*, non-proprietary) name must accompany a product's proprietary (*i.e.*, brand) name in labeling and advertising
- Relative size of proprietary and established names
- Relative prominence of proprietary and established names
- Frequency of disclosure of proprietary and established names

The final guidance also addresses the following issues with respect to products with two or more active ingredients:

- Juxtaposition of proprietary and established names
- Relative prominence of the proprietary and established names

Comparison of Final Guidance to 1999 Draft Guidance

In general, the substance of the final guidance is similar to that of the draft guidance. With respect to the to the applicability of these requirements to electronic and computer-based promotional labeling and advertisements, however, the final guidance illustrates a shift in the agency's position. The draft guidance gave sponsors the option of using any one of several approaches to comply with the requirements related to the frequency of disclosure of established and proprietary names. In the final guidance, however, the FDA takes a more prescriptive approach in its interpretation of the regulatory requirements:

- **If the proprietary name is *not* part of the running text**—the established name is required to accompany the proprietary name each time the proprietary name appears. The FDA interprets "running text" to mean the body of text in a piece, as distinct from a headline, tagline, logo, footnote, graph or picture.
- **If the proprietary name *is* part of the running text**—the established name must accompany the proprietary name at least once in the running text.
- **If the running text spans more than one screen**—the FDA recommends that the established name accompany the proprietary name at least once per screen.

Other changes reflected in the final guidance include:

- **Clarifying various concepts discussed in the draft guidance, including requirements regarding the size of proprietary and established names**—the FDA states the regulations require that when a proprietary name is presented outside the running text (*e.g.*, in a headline) or within the running text in larger size type than that of the surrounding running text, the established name is required to be printed in letters that are at least half as large as the letters of the proprietary name. In the final guidance, the FDA adds a recommendation that the smallest letter of the established name (upper or lower case) be printed in letters at least one half the actual size of the largest letter of the proprietary name (upper or lower case).
- **Adding a series of examples to illustrate principles laid out in the guidance (including appropriate juxtaposition and prominence of established and proprietary names)**—in addition, the final guidance now clearly states the FDA "does not intend" to prohibit sponsors from using trademark symbols associated with product names (*e.g.*, trademark, registered or controlled substances symbols).
- **Acknowledging differences in the regulatory requirements for prescription human drugs and biological products**—21 C.F.R. § 610.62 applies to the

position and prominence of the trade name and proper name of biological products on the "package label." To avoid user confusion, the FDA now recommends that the format described in that section also be applied to containers of biological products, such that the order of the proprietary name and the proper name on the package and container match.

- **Providing a definition of the term "running text"**—the regulations state that when an established name is required to accompany a proprietary name, both names must be presented in same type size in the "running text" of promotional labeling. Prior to issuance of the final guidance, the FDA had not indicated what it considered to be "running text."
- **Discussing the use of established and proprietary names in traditional print media that is presented in column format.**

Implications

Although the final guidance is substantively similar to the draft guidance, it makes enough changes and clarifications to the agency's position on the use of product names in promotional labeling and advertising that sponsors should review their promotional materials—particularly those used in an electronic forum—to determine if they comport with the FDA's current interpretation of the applicable regulations.

Moreover, both this guidance and the agency's recently released draft guidance regarding communication of off-label information (see FDA Issues Draft Guidance, Requests Public Comments on Communication of Off-Label Information for more information) address issues specific to the dissemination of information via the internet and social media. This development suggests the agency may be stepping up its efforts to ensure information provided via electronic avenues meets the same regulatory requirements as information provided via other, more traditional avenues.