



Client Alert



Contact Attorneys Regarding
This Matter:

Alan G. Minsk
404.873.8690 - direct
404.873.8691 - fax
alan.minsk@agg.com

Kelley Coleman Nduom
404.870.5796 - direct
404.870.5797 - fax
kelley.nduom@agg.com

Arnall Golden Gregory LLP
Attorneys at Law

171 17th Street NW
Suite 2100
Atlanta, GA 30363-1031
404.873.8500

2001 Pennsylvania Avenue NW
Suite 250
Washington DC 20006
202.677.4030

www.agg.com

FDA Releases Final Guidance on Placement of Product Proprietary and Established Names in Advertising and Promotional Labeling

The Office of Prescription Drug Promotion (OPDP) in the Food and Drug Administration's (FDA) Center for Drug Evaluation and Research issued a final guidance document in January 2012 to clarify the regulations that specify requirements for the placement of a product's name, size, prominence and frequency in promotional labeling.¹ The regulations at issue, which appear at 21 C.F.R. §§ 201.10(g), (h) and 202.1(b), (c) and (d), apply to prescription drug products that contain one or more active ingredients. OPDP developed the guidance jointly with the Center for Biologics Evaluation and Research (CBER) and the Center for Veterinary Medicine (CVM). As such, the guidance applies to all prescription drugs, biologics and veterinary medicines. Notably, the guidance also addresses requirements pertaining to internet promotion and social media, an area in which FDA guidance has traditionally been less vocal. The guidance does not speak to requirements for over-the-counter drugs, medical devices, dietary supplements, or cosmetics. While the guidance is not legally binding, it represents the FDA's current thinking on this topic.

The guidance focuses on two main areas, based on the most frequent inquiries presented to the centers about the regulation's requirements: (1) the juxtaposition of proprietary and established names; and (2) the required size, prominence and frequency of disclosure of proprietary and established names. This Client Alert summarizes the guidance on each of these topics.

Juxtaposition

The guidance clarifies the requirement that the established name be placed "in direct conjunction" with the proprietary name. The FDA recommends the established name appear "either directly to the right of, or directly below the proprietary name" when the established name is required to accompany the proprietary name. This same direction applies to products with two or more active ingredients. Trademark or controlled substance symbols may be placed immediately after the proprietary name, but any other "intervening matter," such as logos, taglines or other graphics, are discouraged.

Size

The regulation requires that proprietary and established names be presented in the same type size when the established name must accompany the proprietary name in the running text of the promotional labeling or advertisement.

¹ *Guidance for Industry: Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling* (January 2012), available at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070076.pdf>.

The guidance clarifies the FDA's view that the "running text" means a body of text, excluding headlines, taglines, logos, footnotes, graphs or pictures. The guidance further states that when the proprietary name is presented outside of the running text (e.g., in a headline), or if it is presented in a larger-sized type than the surrounding running text, the established name must be printed in letters that are at least half as large as the letters of the proprietary name.

Prominence

The guidance specifies that type size, spacing and contrast, among other methods, can be used to provide emphasis. Whatever method is used to present the proprietary name, the established name must be presented "with commensurate emphasis and contrast."

Frequency

A significant portion of the guidance is devoted to clarifying how frequently the established name must accompany any mention of a product's proprietary name in various types of promotional materials. The chart below summarizes the guidance in each of these specific situations for various types of promotional media.

Traditional Print Labeling or Advertisement	
Presentation of Proprietary Name	FDA Guidance on Established Name
<ul style="list-style-type: none"> Proprietary name is part of the running text 	<ul style="list-style-type: none"> Established name must accompany the proprietary name at least once in the running text FDA recommends that the established name appear at least once per page if the running text spans more than one page
<ul style="list-style-type: none"> Proprietary name appears in more than one column of running text (but does not appear outside of the running text, above or below the column) FDA defines "column" to mean "one of two or more vertical sections of a printed page, separated by a rule or blank space" 	<ul style="list-style-type: none"> Established name should accompany proprietary name at least once per column FDA recommends that the established name accompany the proprietary name at least once per page if the column spans more than one page
<ul style="list-style-type: none"> Proprietary name is <i>not</i> part of the running text (e.g., proprietary name is in a headline, tagline, logo, footnote, graph, or picture) 	<ul style="list-style-type: none"> Established name is required to accompany the proprietary name each time the proprietary name appears

Audio-Visual Labeling or Advertisement (e.g., promotional video, television ad)	
Presentation of Proprietary Name	FDA Guidance on Established Name
<ul style="list-style-type: none"> Superimposed text where the proprietary name appears equivalent to a headline or tagline 	<ul style="list-style-type: none"> Established name should be placed “in direct conjunction with” (i.e., directly to the right of or directly below) the most prominent display of the proprietary name in the piece
<ul style="list-style-type: none"> Established name accompanies the proprietary name 	<ul style="list-style-type: none"> FDA recommends that the established name be displayed on the screen for the same amount of time as the proprietary name
<ul style="list-style-type: none"> Superimposed text that typically runs along the bottom of the screen 	<ul style="list-style-type: none"> Established name is not required to be included with the proprietary name Note: FDA recommends that established name be included in the audio portion with the most prominent display of the proprietary name
<ul style="list-style-type: none"> Radio and telephone advertisements 	<ul style="list-style-type: none"> Place established name in direct conjunction with the most prominent presentation of the proprietary name (often the first occurrence in the broadcast)

Electronic and Computer-Based Labeling or Advertisement	
Presentation of Proprietary Name	FDA Guidance on Established Name
<ul style="list-style-type: none"> Proprietary name is part of the running text 	<ul style="list-style-type: none"> Established name must accompany the proprietary name at least once in the running text FDA recommends that the established name appear at least once per screen if the running text spans more than one screen
<ul style="list-style-type: none"> Proprietary name is <i>not</i> part of the running text (e.g., proprietary name is in a headline, tagline, logo, footnote, graph, or picture) 	<ul style="list-style-type: none"> Established name is required to accompany the proprietary name each time the proprietary name appears

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