DIGITAS HEALTH

Regulatory Alert

2013 Product Name Placement & Prominence

November 18, 2013 **Analyst: Dale Cooke**

EXECUTIVE SUMMARY

On November 18, 2013, the Food and Drug Administration (FDA) released a draft Guidance to Industry: Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling[1]. This guidance was originally released as a draft in January 1999. A final version was presented in January 2012. The new draft guidance this week included some significant changes from the previous versions, and largely retracts many of the problematic aspects of the earlier versions.

In light of this guidance, companies should take the following actions[2]:

1. Ensure that new materials being developed take into account this new guidance.
2. Review existing materials as they expire for compliance with this guidance.
3. Revisit any internal guidelines for presentations of product name in electronic promotional items and television commercials, especially those that were developed or revised in light of the 2012 guidance on this topic.

BACKGROUND

According to the Code of Federal Regulations, "the established name [the generic name], if such there be, corresponding to such proprietary name or designation shall accompany such proprietary name or designation each time it is featured in the advertisement for the drug." (21 CFR 202.1(b)(1))

In addition, regulations require that "[o]n any page of an advertisement" if the brand name "is **not** featured but is used in the running text" (or body copy) of the advertisement, then the established name must accompany the brand name "at least once." (21 CFR 202.1(b)(1), emphasis added)

NEW GUIDANCE

The new draft guidance differs from the 2012 finalized guidance in three principal matters.

1) The FDA intends to exercise enforcement discretion regarding its expanded definition of what constitutes a featured use of a brand name, i.e. **FDA will not enforce the requirement to provide the generic name with every featured use of a brand name**.

2) The FDA intends to exercise enforcement **discretion "if the established [generic] name is not included in the audio portion"** of television commercials.[3]

3) The FDA has changed its understanding of the need for the generic name in electronic promotion from a requirement of "once per screen"[4] to a requirement that generic "name accompanies the proprietary name at least once per Web page **or** screen."[5] (emphasis added)

ENFORCEMENT DISCRETION

The phrase "enforcement discretion" is a technical term and can cause some confusion. When FDA states that it intends to exercise enforcement discretion in an area, it is asserting:

1. FDA has the legal authority to enforce legal and regulatory requirements in that area.
2. FDA will not use that authority.

In the context of this guidance, that means that FDA will not take enforcement actions based on the omission of the generic name from some featured uses of the brand name.[6] Instead, **FDA is accepting the standard industry practice of including the generic name "where the proprietary name most prominently appears on the page or spread."**[7] This largely returns industry to the practice that was standard prior to the 2012 guidance was issued and is in line with subsequent comments made by FDA representatives at industry events.[8]

RECOMMENDATIONS

In light of this newly finalized guidance, companies should take the following actions:

1. Ensure that new materials being developed take into account this new guidance.
2. Review existing materials as they expire for compliance with this guidance.
3. Revisit any internal guidelines for presentations of product name in electronic promotional items and television commercials, especially those that were developed or revised in light of the 2012 guidance on this topic.

ENDNOTES

[1] This guidance is herein referred to as "2013 Product Name Placement" and is available from the FDA website at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070076.pdf

[2] In this Regulatory Alert, I make no distinction between biologic products and drugs. The essential regulatory requirements for both are the same, and the descriptions and recommendations of this alert should be applied to both categories with only minor modifications.

[3] 2013 Product Name Placement, page 5.

[4] This requirement is taken from the 2012 finalized Guidance for Industry: *Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling*, page 5. This version of the guidance is no longer available on the FDA website.

[5] 2013 Product Name Placement, page 5.

[6] 2013 Product Name Placement, page 4.

[7] 2013 Product Name Placement, page 4.

[8] See for instance, Cooke, Dale, *Effective Review and Approval of Digital Promotional Tactics*, Appendix D, Food and Drug Law Institute, 2013.