

ALERTS

Food, Drug & Device Law Alert - FDA Gives An Inch, But Only An Inch, On Use Of Social Media To Promote Drugs And Devices

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The FDA recently issued a draft guidance document on using certain social media platforms for advertising and promotion of both drugs and medical devices. More specifically, the draft guidance addresses how to present both benefit and risk information within character space limitations such as those imposed by Twitter and by sponsored links on Google and Yahoo. With one notable exception, the FDA's advice boils down to: if you cannot present full benefit and risk within the character space limits, then you should not use that outlet for advertising and promotion.

The background section of the draft guidance articulates several familiar principles applicable to drug and medical device advertising and promotion. The FDA wastes little time presenting its primary recommendation, concluding this section as follows:

For some products, particularly those with complex indications or extensive serious risks, character space limitations imposed by platform providers may not enable meaningful presentations of both benefit and risk.... If an accurate and balanced presentation of both risks and benefits of a specific product is not possible within the constraints of the platform, then the firm should reconsider using that platform for the intended promotional message (other than for permitted reminder promotion).

This admonition carries even more weight when coupled with the FDA's assertions that benefit information must be accurate and reveal material facts within each character space limit and that risk information, including at least the most serious risks, must accompany benefit information within each character space limit. In other words, each tweet for example must contain accurate benefit and risk information. A firm cannot send out a series of tweets and present some of the information in each.

The news is not all bad, however, for firms that would like to consider using these types of social media platforms. In its biggest concession to the use of such platforms, FDA states:

The Agency believes that a concise disclosure of specific risk information may be presented together with benefit information within the confines of character-space-limited Internet/social media platforms if supplemented by a prominent reference to the presence and location elsewhere of a more complete discussion of the risks associated with the product (or for restricted-device advertising, a "brief statement" of intended use and relevant risk information) and that this is consistent with requirements of the FD&C Act and FDA's implementing regulations....

Further, FDA will allow use of shortened URLs to link to the complete

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discussion of risk, saving valuable characters.

The draft guidance also notes several times that “reminder” promotions, which call attention to the name of a product but do not make any representations or suggestions about the product, are exempt from many of the labeling and advertising disclosure requirements.

The draft guidance is [available here](#).

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