



Client Alert

Contact Attorneys Regarding
This Matter:

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

Diana Rusk Cohen
404.873.8108 - direct
404.873.8109 - fax
diana.cohen@agg.com

Arnall Golden Gregory LLP
Attorneys at Law
171 17th Street NW
Suite 2100
Atlanta, GA 30363-1031
404.873.8500
www.agg.com

Good Things Come to Those Who Wait? FDA Delays Draft Guidance on Use of Social Media in Product Promotion

*Anticipation, anticipation
Is makin' me late
Is keepin' me waitin'*

Singer/songwriter Carly Simon wasn't singing in 1971 about the Food and Drug Administration's (FDA's) draft guidance on social media, but the lyrics ring true today as the FDA-regulated industry anxiously await for the now-delayed (again) guidance.¹

The FDA has indicated that it plans to issue a draft guidance on how companies can use social media platforms, such as *Facebook* and *Twitter*, in product communications and promotions. However, despite the recent promise that such guidance would be available by March 31, 2011, the agency has continued to delay release of formal guidelines, and has not indicated a new release date. The industry will have to continue to wait patiently, and exercise caution when using social media, until the FDA's much-anticipated guidance is finally available.

The question is whether good things come to those who wait. Will the FDA's guidance document result in more flexibility for companies that wish to use powerful social media tools, or will the guidance restrict meaningful use of these tools? While the exact tenor of the eventual draft guidance is unknown, companies might look to current FDA product labeling and promotional rules to understand the agency's likely approach to social media. The FDA has stated publicly that the same laws and regulations that apply to traditional product promotion apply equally to new media promotion.

As we reported in an article for the *Regulatory Rapporteur*,² FDA enforcement action related to new marketing platforms has been brewing for several years. The agency's Division of Drug Marketing, Advertising, and Communications (DDMAC) issued Untitled Letters to fourteen pharmaceutical companies in early 2009 for unlawful promotion using sponsored links on internet search engines, such as *Google*. The letters expressed concern that the sponsored

¹ Ms. Simon has stated that the lyrics were inspired as she was waiting to meet Cat Stevens for the first time.

² Alan Minsk published an article entitled "Face the Strange... Ch-ch-changes: Potential FDA Regulation of Social Media" in the October 2010 issue of the *Regulatory Rapporteur*, which provides further analysis of social media promotional issues. The article can be found at <http://www.agg.com/media/interior/publications/Minsk-RegulatoryRapporteur-October2010.pdf>.



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links tended to identify the product, its use, and a website, but failed to provide required product risk information. Similarly, in a 2008 Warning Letter to another company, the FDA stated that the company's celebrity endorsement video on *YouTube* overstated the relevant drug product's efficacy, omitted important risk information, and advertised uses beyond the approved indication.

These enforcement letters demonstrate that the FDA tends to view social media through the same lens that it views traditional promotions and seems disinclined to allow new promotional platforms to command a substantially different regulatory regime. Consequently, companies that currently use social media or plan to do so in the near future should follow the same promotional principles that apply to other forms of advertising and communications. For example, companies should not promote any claims that are not in the product's FDA-approved labeling, and risk information should be clearly communicated, not buried at the end of an ad or provided in a completely separate area from the indication or claims (e.g., by requiring a separate click for more risk information).

When the FDA finally issues the draft guidance on social media, companies will have a better sense of the agency's particular concerns and recommendations. The FDA recognizes that the appropriate application of promotional rules to social media is complicated, but at the same time, the agency understands that social media will continue to play an increasing role in the marketing and promotion of FDA-regulated products. Indeed, officials have been working on the draft guidance for more than a year but are reportedly still struggling with ways to develop rules that will not become outdated as social media continues to evolve. For now, companies should continue to watch and wait and should ensure that all product communications, regardless of venue, follow the FDA's well-established labeling and promotional rules.

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