FDA Stops Being Antisocial: Recent Social Media Guidance Breaks the Silence

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By law, FDA must give guidance by July 2014 describing the agency's policy regarding Internet promotion, including social media, of FDA-regulated medical products.[1] On January 13, FDA moved one step closer to meeting this mandate by issuing a draft guidance document, "Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics."[2] The Draft Guidance outlines FDA's expectations for when and how a company should submit such "interactive promotional media" (e.g., blogs, microblogs, online communities, live podcasts, and social networking sites) to the agency pursuant to postmarketing submission requirements.

While FDA has issued guidance that references social media, such as responding to requests for off-label information in certain venues, and has issued enforcement letters for promotional violations using social media, this guidance speaks directly on some (but not all) issues to consider.[3]

The guidance is specific to prescription drug and biologic companies. There are reasons for this distinction, as medical device and food companies do not have postmarketing submission requirements for promotional materials. However, we believe that medical device and food companies should review this document, as it offers some insights into FDA's view of social media promotion. Interested parties have 90 days to comment.

This Bulletin highlights some of the key points and our observations. We will not provide an overview of FDA's legal authority of labeling and advertising or the general post-marketing requirements, nor will we describe every FDA example in the guidance.

- A company is not responsible for "user generated content" that is truly independent of the company, even if it appears on a company website. FDA has left itself a window for enforcement if the company encouraged the comment or the comment is not "truly independent."

- FDA focuses on whether the company, or anyone acting on its behalf, is influencing or controlling the promotional activity or communication, not on who owns the website where the communication is posted.

- If a company exerts any influence on the content of third-party websites, "even if the influence is limited in scope," then the company is responsible for the website and should submit the pages surrounding its promotional materials on Form FDA 2253 (i.e., the form used to submit promotional materials to FDA on prescription drugs for human use at the time of initial dissemination or publication). The company has influence on the content if it "collaborates on or has editorial, preview, or review privilege over the content provided," such as influencing the placement of its promotional message on the independent third-party site. FDA recommends transparency in disclosing the company involvement.

1 Food and Drug Administration Safety and Innovation Act (FDASIA), Section 1121.

2 Available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/ Guidances/UCM381352.pdf.

3 See "Asked. Answered. Now Move On: FDA Issues Guidance on Responding to Unsolicited Requests for Off-label Information about Prescription Drugs and Medical Devices," Arnall Golden Gregory LLP, 01/04/2012, available at http://www.agg.com/Asked-Answered-Now-Move-On-FDA-Issues-Guidance-on-Responding-to-Unsolicited-Requests-for-Off-label-Information-about-Prescription-Drugs-and-Medical-Devices-01-04-2012/.

- However, if a company provides financial support but exerts no influence on a third-party site and places no content on the site, the company is not responsible for the content and is not required to make any submissions to FDA. For example, if a company only provides an unrestricted educational grant, it need not submit a 2253 form.

- Similarly, if a company does not have any control of information on an independent third-party site but promotes its product on that site (e.g., by providing specific promotional content for placement on the site), the company is only responsible for submitting the promotional content to the FDA. It is not responsible for the surrounding pages on the third-party website (but, in our opinion, companies should still pay attention to the surrounding areas).

- Companies are responsible for any content generated by an employee or agent acting on behalf of the company to promote the company's product and should submit the content to FDA.

- When a company initially displays a new website, it should submit the site in its entirety on a 2253 form. The initial submission should include annotations that describe the parts that are interactive and allow for real-time communications.

- For third-party sites on which the company's participation is limited to interactive or real-time communications, the firm should submit screenshots of the home page, the firm's interactive page on the website, and the firm's first communication on the website on a 2253 form.

- For non-restricted (i.e., not password-protected), third-party websites, companies do not need to submit each and every interactive posting (e.g., each Facebook post) to FDA. Instead, companies should submit a 2253 form once a month with an updated list of all non-restricted sites that include interactive or real-time communications for which it is responsible or in which it remains an active participant. For these monthly updates, the company is not required to submit screenshots. Screenshots should still be submitted at the time of the initial display and for any updates.

- For restricted (i.e., password-protected) websites, the company should submit all content related to the discussion that is necessary "to adequately provide context to facilitate the review." This may or may not include independent user generated content. Screenshots or other visual representations of interactive or real-time communications on these restricted websites should be submitted to FDA monthly.

- Whenever a company makes a 2253 submission, it should "take formatting factors (e.g., appearance, layout, visual impression) into consideration," so that FDA is able to view the communication as a whole.

AGG Observations

- FDA will issue more guidance in the future. Based on informal contacts with senior officials at FDA's Office of Prescription Drug Promotion, the agency expects to issue future guidance on other social media-related areas, such as space limitations, promotional venues, and correcting information on third-party websites. However, the timing is uncertain as there are a number of steps in the development and clearance process.

- The recently-issued guidance represents FDA's current thinking on such issues. In evaluating their social media content, we also recommend that companies consider non-FDA-related issues, such as product liability exposure and deceptive advertising competitor challenges, to name a few.

- Companies must train and monitor employees and agents (e.g., consultants, third-party vendors) acting on the company's behalf on company policies about social media usage and, for example, product-related postings. Similarly, company policies and procedures must be reviewed and, if needed, revised to consider FDA's

guidance. For instance, paid speaker or company representative postings or blogs must be reviewed internally by the company's Promotional Review Committee (or similar group) to ensure regulatory compliance and timely submission to FDA.

- We remind clients to carefully balance the commercial benefits of real-time, interactive discussions with the regulatory consequences and requirements that are associated with such use of social media.

- Remember, control and influence of the message is key. If FDA concludes the company is intimately involved in messaging, the company will be held responsible and accountable for regulatory compliance.

- It is not clear if and when any FDA enforcement actions will occur. The agency is aware of potential First Amendment free speech challenges. However, FDA has issued enforcement letters when it believed the product promotion through social media was unlawful. Speech that violates the law is not protected by the First Amendment. Based on our experience, the agency will identify an egregious case of violative messaging relating to interactive promotional media and issue a Notice of Violation or Warning Letter. Such correspondence will put industry on notice as to its enforcement policy.

For more information on the Draft Guidance, please contact Alan Minsk, Kelley Nduom, or Jordan Kearney.

In addition, please join AGG's Alan Minsk and Kelley Nduom, for a complimentary webinar on Thursday, January 23 from 2:30 – 3:30 pm ET. Please click here[4] to register.

4 https://event.on24.com/eventRegistration/EventLobbyServlet?target=registration.jsp&eventid=740437&sessionid=1&key=B6921BA8F6A83825C102EAD968DDC984&sourcepage=register

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