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The FDA Gets Social: Interpreting Its Draft Social Media Guidance

Sharon R. Klein | kleins@pepperlaw.com
Melissa L. Nuñez | nunezm@pepperlaw.com

The U.S. Food and Drug Administration (FDA) recently released draft guidance that paves the way for regulated companies to harness the power of social media.[1] This draft guidance addresses how FDA-regulated manufacturers, packers and distributors of prescription human and animal drugs and biologics ("regulated firms") can comply with regulatory requirements for postmarketing submissions of interactive promotional materials. Regulated firms have been shut out of real-time communications via social networking sites due to restrictions on promotional activities. The new guidance, while not yet finalized, indicates that regulated firms may jump into this market in the coming months. The FDA has requested comments on the draft guidance by April 14, 2014.

Background

Generally, regulated firms are required to submit all promotional labeling and advertising materials to the FDA at the time of their initial dissemination or publication. In the case of real-time social media (think: blogs, Facebook updates, tweets, podcasts and online communities), submission at the time of initial dissemination would be all but impossible. Now, the FDA has issued guidance for submission of most materials after-the-fact.

What Is 'Interactive Promotional Media'?

"Interactive promotional media" is the term the FDA is using to refer to real-time social media promotions by regulated firms. The key guidance relating to determining whether a regulated firm is responsible for interactive promotional media is as follows:

1. Regulated firms are responsible for promotional communications on sites that are owned, controlled, created, influenced or operated by or on behalf of the firm.

What This Means: Promotional content posted to company-sponsored sites is clearly covered and must be submitted to the FDA. The trickier issue is whether a regulated firm influences or has control over a site owned by a third party. The FDA's threshold is very low; the FDA states that a firm is responsible for promotion on a third-party site if it has "*any* control or influence" (emphasis added) on the third-party site. Indeed, the influence can be limited in scope and still trigger responsibility; editorial, preview or review privileges will suffice. Notably, financial support alone does not trigger responsibility, so long as it is not coupled with other influence.

If a regulated firm does not have influence over a third-party site, it need only submit to the FDA the promotional content it provided that site but not everything on the third-party site. If a regulated firm does have such influence, it will be responsible for submitting the promotion, along with the surrounding pages, to the FDA and otherwise meet the new postmarketing submission requirements.

Pepper Point: To reduce submission burdens to the FDA, regulated firms should not request previews of third-party Web sites or direct the particular placement of promotional materials on third-party Web sites.

2. Regulated firms may be responsible for content on third-party sites if it is generated by their employees or agents or if the regulated firm has control over or influence on the site.

What This Means: Comments by employees and other agents acting on a regulated firm's behalf and made on third-party Web sites about the regulated firm's products are attributed to the regulated firm for purposes of FDA submission. For example, if a paid speaker makes a comment on a third-party site, that material should be submitted to the FDA.

Pepper Point: Regulated firms should consider training employees so they understand the possible consequences of their online activity when acting on behalf of the regulated firm. Additionally, regulated firms should take steps to distance themselves from online content not under their control.

3. Regulated firms are responsible for content generated by employees and agents acting on their behalf to promote the regulated firm's products.

What This Means: Content placed online by employees and agents that promotes a regulated firm's products must be submitted to the FDA pursuant to the new postmarketing guidance. The FDA has also recommended that regulated firms clearly identify content generated by such employees and agents. Notably, the FDA will not "ordinarily" hold regulated firms responsible for user-generated content on firm-owned or controlled venues as long as the user has no affiliation with the regulated firm and the regulated firm had no influence on the user-generated content.

Pepper Point: Regulated firms should strictly police the content its employees and agents put on the Internet on their behalf and consider including a unique identifier, such as a logo, to clearly identify sponsored content. Consider including a pre-approval requirement for social media advertising in all contracts with advertisers.

Submission of 'Interactive Promotional Media' to the FDA

1. Regulated firms must submit sponsored sites to the FDA at the time of initial display.

What This Means: If a regulated firm creates or sponsors a Web site that will include interactive promotional media, it must submit a comprehensive static product Web site with the real-time or interactive components to the FDA at the time of initial display. The submission will include information that will allow the FDA to review the content and features of the site. Any changes to the site must be resubmitted to the FDA.

Pepper Point: Regulated firms should limit changes to Web sites or make multiple changes at one time to limit resubmissions to the FDA.

2. Regulated firms must submit the home page, the interactive or real-time communications and the regulated firm's first communication for any third-party sites that contain regulated interactive promotional media.

What This Means: If a regulated firm's participation in a third-party site is limited to interactive or real-time communications, it must submit to the FDA: (1) the homepage of the third-party site, (2) the interactive page(s) of the site, and (3) the regulated firm's first communication. The submission process for continued participation of regulated firms on such sites is streamlined in the case of "unrestricted" sites (sites that are publicly viewable and do not require a password or subscription).

3. Regulated firms must submit monthly updates to the FDA for all non-restricted sites.

What This Means: Regulated firms must make a monthly filing with the FDA to disclose all non-restricted sites that contain interactive or real-time communications. The filing will include, for each site: (1) the name, (2) URL, (3) date range, and (4) a cross-reference to the date of the most recent submission of the site. Notification is also required when a regulated firm ceases activity on a site.

Pepper Point: The FDA is allowing one filing per month for all sponsored sites, rather than a filing for each such site, which cuts down on paperwork.

4. Regulated firms must submit more detailed information for restricted sites.

What This Means: If sites with interactive promotional material are restricted (*i.e.*, require a password or subscription) and are therefore not easily monitored by the FDA, regulated firms must submit more detailed information in their monthly filings. This includes all content related to the discussion, which may include independent user-generated content, to adequately provide context to facilitate the FDA's review. Screenshots and other visual representations of the actual site, including the real-time communications, must also be submitted. Additionally, the FDA has recommended that regulated firms take formatting factors into account when submitting materials in order to facilitate the FDA's review. Such factors include appearance, layout and visual impression.

Pepper Point: Regulated firms should take the greater disclosure burden into account in determining whether to utilize restricted sites for promotional materials.

Endnote

1. "Guidance for Industry: Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics" can be found at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM381352.pdf.