

Recent FDA Social Media Marketing Enforcement Actions and the Likely Impact of Social Media Promotion Guidance

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In recent years, guidance by the U.S. Food and Drug Administration ("FDA" or "Agency") for industry on the use of social media has continued to evolve in incremental steps, but the pharmaceutical and medical device industries continue to await more comprehensive guidance regarding the use of social media for drug, biologic, and medical device product communications. Beginning with the "sponsored link" warning letters to 14 pharmaceutical manufacturers in April 2009 and through the most recent untitled letter involving social media promotion sent to Swiss drug manufacturer Institut Biochimique SA ("IBSA") in February 2014, much of FDA's guidance on the use of social media for product communications has come in the form of untitled and warning letters to manufacturers. These letters demonstrate, in particular, that FDA has been independently scrutinizing social media outlets, including Facebook,[1] Twitter,[2] and YouTube,[3] and offer a window into FDA's nascent social media policies.

While it is clear that FDA has held social media promotions to the same standards as traditional prescription drug promotional media (e.g., balance of therapeutic benefits and potential risks, and stating only FDA-approved indications), drug and medical device manufacturers are still uncertain about the boundaries on using social media to promote products and interact in real time with customers and about how to submit such materials to FDA for approval. Though recently issued guidance documents shed some light on the manner in which companies may utilize social media platforms to communicate regarding their products, FDA has not yet provided the more extensive guidance anticipated by industry in advance of the July 2014 deadline for FDA to issue social media guidance established by Section 1121 of the Food and Drug Administration Safety and Innovation Act ("FDASIA"). In the absence of comprehensive guidance, an increasing number of manufacturers are forging ahead to promote their products through social media.

FDA's Latest Facebook Enforcement Action

FDA's Office of Prescription Drug Promotion ("OPDP") recently sent an untitled letter to IBSA and its U.S. agent, Akrimax Pharmaceuticals, LLC, warning IBSA that its Facebook site for a prescription drug, Tirosint, violates FDA's promotional labeling requirements.[4] The letter stated that IBSA had

failed to disclose any risks associated with Tirosint, whose label contains a Boxed Warning and other specific Warnings and Precautions, and did not include material information about the drug's FDA-approved indications that limit its therapeutic uses. OPDP stated that the Facebook post was misleading because it "suggests that Tirosint is safer than has been demonstrated" and failed to convey the limited extent of the FDA-approved indications.

As with some previous enforcement actions involving social media,[5] FDA became aware of the violation through its internal monitoring and surveillance program, meaning that FDA continues to monitor manufacturers' social media sites, as well as traditional static websites, for statements that violate promotional labeling rules. This enforcement action highlights why manufacturers must pay close attention to information about their products posted on social media outlets, and should carefully consider the recently released Draft Guidance (discussed below) on submitting social media promotional materials for FDA review.

Draft Social Media Guidance

On January 13, 2014, FDA released a significant piece of the social media guidance that manufacturers have been seeking. The document, "Draft Guidance: Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics" ("Draft Guidance"),[6] sets out the Agency's expectations for submitting prescription drug promotional materials to be posted on social media sites. The Draft Guidance states that FDA intends to exercise its enforcement discretion regarding regulatory requirements for postmarketing submissions of interactive promotional media under "certain circumstances." In its determination of whether a drug or medical device manufacturer is responsible for submitting specimens of interactive promotional media, FDA will consider the following criteria:

- A firm is responsible for product promotional communications of sites that are owned, controlled, created, influenced, or operated by, or on behalf of, the firm, including any site to which the firm posts materials, such as Facebook, Twitter, firm blogs, and any other site over which the firm exerts influence, even if the influence is limited in scope.
- Under certain circumstances, a firm is responsible for promotion on third-party sites. This includes third-party sites over which the firm has control or influence, including editorial, preview, or review privileges or any sort of collaboration, even if the influence is limited in scope. However, this does not include circumstances in which the firm provides only financial support to the third party.
- A firm is responsible for the interactive promotional content generated by an employee or agent who is acting on behalf of the firm to promote the firm's product. This includes postings on Facebook, Twitter, or a blog, or responses to consumer questions on an

electronic forum or discussion board. Notably, however, FDA will not hold manufacturers accountable for third-party user-generated content posted to a site that it controls.

The Draft Guidance recommends that manufacturers submit interactive promotional media using the following possible approaches:

- At the time of initial display, a firm should submit, in its entirety, each site for which it is responsible on Form FDA 2253 or Form FDA 2301. For example, the firm should submit the comprehensive static product website with the addition of the interactive or real-time components, including annotations to indicate the interactive portions.
- For third-party sites on which a firm's participation is limited to interactive or real-time communications (e.g., a public electronic forum or discussion board), a firm should submit the home page of the third-party site, along with the interactive page within the third-party site and the firm's first communication, on Form FDA 2253 or Form FDA 2301 at the time of initial display.
- Once every month, a firm should submit an updated listing of all non-restricted sites for which it is responsible or in which it remains an active participant and that include interactive or real-time communications, but the firm need not include screenshots of the actual communications.
- If a site has restricted access, a firm should submit all user-generated content related to the discussion, as well as screenshots or other visual representations of the site and communications, to provide context to facilitate FDA review.
- When submitting the site, FDA recommends that a firm take formatting factors (e.g., appearance, layout, and visual impression) into consideration to enable the Agency to view the communications as a whole.

FDA specifies that the Draft Guidance applies only to interactive promotional media rather than traditional static webpages (e.g., a product webpage without interactive elements).

Broader Implications

While the Draft Guidance answers some basic questions about how companies may submit interactive promotional media to FDA, the guidance does not address all aspects of social media use for product communications. FDA is expected to provide additional guidance covering other aspects of social media promotion in the near future.

One particularly notable example of the Draft Guidance's incompleteness is the absence of any mention of the "like" function on Facebook or any similar function on other social media sites allowing one to "endorse" another's post. FDA warning letters have addressed the use of the "like"

function,[7] indicating that the Agency considers such use a promotional activity; however, the Draft Guidance does not clarify whether "liking" or "re-tweeting" someone else's post gives a manufacturer "control or influence" over a third-party site.

FDA's recommended approaches for submitting interactive promotional media clarify that manufacturers need not report all real-time communications in separate submissions. Instead, a manufacturer must initially submit (1) its own entire interactive or social media website, or (2) the home page of a third-party site on which the manufacturer posts along with the first communication on that site. Otherwise, a manufacturer must submit monthly reports listing sites on which the manufacturer is an active participant. This implies that FDA will independently monitor manufacturers' real-time promotional communications by periodically reviewing the listed sites. We expect that the interactive media submission requirements will continue to evolve as FDA begins regular surveillance of reported websites. Given the greater visibility resulting from required submissions, the industry will likely continue to see FDA enforcement in this area.

Compliance Considerations

Although the Draft Guidance is not yet final, it represents FDA's current thinking on enforcing manufacturer compliance regarding interactive, real-time promotion of prescription drug products on social media outlets. Manufacturers should review current policies and procedures on product promotion and submitting marketing materials to FDA in light of the Draft Guidance and determine whether to take advantage of the comment period to provide comments and suggestions to FDA before the April 14, 2014, deadline. FDA has stated that it will provide clarification on the Draft Guidance in July 2014.

In light of the recommendations offered by FDA in the Draft Guidance, manufacturers should consider the following questions:

- Does the manufacturer currently have a mechanism for tracking websites on which its employees and agents post messages or statements about its products so that it may submit all representative interactive promotional materials to FDA?
- Does the manufacturer have the capability to track its employees' and agents' product-related posts on social media sites to ensure that it may efficiently locate a post that becomes the subject of an FDA enforcement action?
- Will the manufacturer's current policies and procedures for company and employee posting of product-related statements on social media websites and submitting such materials to FDA need to change in order to comply with FDA's recommended submission methods?
- Will the manufacturer use website functions to endorse third-party posts, such as the "like" or "re-tweet" functions? How will the manufacturer ensure that these uses conform to the Draft Guidance?

- Will the manufacturer implement internal monitoring or auditing of social media promotions—e.g., by requiring a review of social media activities and/or postings by a promotional review committee and an annual review by audit and monitoring committees?

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*This Client Alert was authored by **Natasha F. Thoren** and **Benjamin M. Zegarelli**. For additional information about the issues discussed in this Client Alert, please contact one of the authors or the Epstein Becker Green attorney who regularly handles your legal matters.*

ENDNOTES

[1] See, e.g., U.S. Food & Drug Admin. Warning Letter to Quincy Bioscience Manufacturing Inc. (Oct. 12, 2012), available at <http://www.fda.gov/iceci/enforcementactions/warningletters/2012/ucm324557.htm> (citing promotional claims on the company's Facebook page); U.S. Food & Drug Admin., Warning Letter to Novartis Pharmaceutical Corp. (July 29, 2010), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM221325.pdf> (citing the lack of risk information on the content the company posted to a "Facebook Share" widget).

[2] U.S. Food & Drug Admin. Warning Letter to Oasis Consumer Healthcare, LLC (Feb. 11, 2013), available at <http://www.fda.gov/iceci/enforcementactions/warningletters/2013/ucm339773.htm> (citing unauthorized health claims on the company's Twitter account); U.S. Food & Drug Admin. Warning Letter to Nenningers Naturals, LLC (Dec. 14, 2011), available at <http://www.fda.gov/iceci/enforcementactions/warningletters/2011/ucm283764.htm> (same).

[3] U.S. Food & Drug Admin. Warning Letter to Big Mountain Drugs (Feb 4, 2013), available at <http://www.fda.gov/iceci/enforcementactions/warningletters/2013/ucm340264.htm>.

[4] U.S. Food & Drug Admin. Untitled Letter to Institut Biochimique SA & Akrimax Pharmaceuticals, LLC (Feb. 24, 2014), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM388800.pdf>.

[5] See, e.g., U.S. Food & Drug Admin. Warning Letter to Novartis Pharmaceutical Corp., *supra* note 1.

[6] U.S. Food & Drug Admin., Draft Guidance: Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics (2014), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM381352.pdf>.

[7] U.S. Food & Drug Admin. Warning Letter to AMARC Enterprises, Inc. (Dec. 11, 2012), *available at* <http://www.fda.gov/iceci/enforcementactions/warningletters/2012/ucm340266.htm>.

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