

E-ALERT | Food & Drug

January 22, 2014

FDA ISSUES DRAFT GUIDANCE ON REQUIREMENTS FOR
POSTMARKETING SUBMISSIONS OF SOCIAL MEDIA

On January 13, 2014, FDA issued a draft guidance document entitled “[Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics](#)” (“the draft guidance”). The draft guidance addresses the procedural topic of submitting Forms FDA 2253 and 2301 when firms use social media such as blogs, microblogs, social networking sites, online communities, and podcasts to promote human and animal drugs. However, as discussed below, the draft guidance might provide at least a preview of FDA’s thinking on the wider issue of when it may consider firms responsible for promotional communications on social media platforms. At the same time, the draft guidance leaves several important open questions.

BACKGROUND

In 2009, FDA held a two-day public hearing on the “[Promotion of FDA-Regulated Medical Products Using the Internet and Social Media Tools](#).” Two years later, FDA took its first step in providing widely applicable guidance on promotional issues raised by the increasing use of social media in marketing. The guidance, entitled “[Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices](#),” provided FDA’s view of when certain online communications provide evidence of a new intended use or indicate that communications using social media are “soliciting” others to seek off-label information. As [we reported](#) at that time, and as FDA has stated, there would likely be many more guidance documents to come on issues raised by the increasing use of social media in advertising and promotion.

For the next two years, FDA did not publish any additional guidance documents on social media issues. Instead, it addressed social media issues on a case-by-case basis, sending various enforcement letters relating to online marketing and social media.¹ The latest guidance document, though ultimately speaking only to the circumstances in which Forms FDA 2253 and 2301 should be submitted by firms promoting human and animal drugs,² appears to be FDA’s largest step yet on addressing wider issues posed by the use of social media in marketing.

SUMMARY OF THE DRAFT GUIDANCE

The draft guidance is split into two sections as follows: the draft guidance initially explores the circumstances in which a firm is responsible for promotional content provided using social media,

¹ For a summary of these letters, please see our archive of e-alerts on advertising and promotion enforcement activities, available [here](#).

² For human drugs approved under an NDA, ANDA, or BLA, firms must generally submit any promotional labeling or advertising at the time of initial dissemination of the materials. Each submission is required to be accompanied by a completed Form FDA 2253. See 21 C.F.R. § 314.81(b)(3)(i) and 21 C.F.R. 601.12(f)(4). For approved prescription and over-the-counter new animal drugs, an applicant must submit promotional materials at the time of initial dissemination along with a completed Form FDA 2301. See 21 C.F.R. § 514.80(b)(5)(ii).

and next, the draft guidance describes the procedures a firm should follow in submitting Forms FDA 2253 or 2301 (if the firm is responsible for the content under the draft guidance). According to FDA, if a firm follows the recommendations in the draft guidance, it intends to “exercise enforcement discretion regarding the regulatory requirements for postmarketing submissions related to promotional labeling and advertising.”

When is a firm responsible for promotional content on social media?

The draft guidance provides the following three scenarios in which a firm is responsible for promotional content on social media:

1. “[P]romotional communications on sites that are owned, controlled, created, influenced, or operated by, or on behalf of, the firm”;
2. “Under certain circumstances . . . for promotion on third-party sites”; and
3. “For the content generated by an employee or agent who is acting on behalf of the firm.”

Under the first scenario, FDA states that “a firm is responsible if it exerts *influence* over a site in any particular, even if the influence is limited in scope” (emphasis added). FDA asserts that the requisite “influence” is present, for example, when a firm “collaborates on or has *editorial, preview, or review* privilege over the content provided” (emphasis added). However, a firm’s responsibility does not extend to independent user-generated content (“UGC”), as discussed further below.

FDA applies the “influence” test above in a similar fashion under the second scenario, in which a firm provides promotional material for third-party sites. Again, FDA states that influence on the third-party sites’ content (even if limited in scope), including editorial, preview, or review privilege of content, is sufficient to impose on the firm FDA’s postmarketing submission requirements with respect to the third-party site’s content. FDA also suggests that “influence” is present if a firm, for example, “direct[s] the placement of the promotion within [a third party] site.” If a firm directs placement of the promotional material within a site, the firm should submit not only the promotional piece it provided to the third-party, but “the surrounding pages [accompanying the promotion]” for FDA review.

Separately, FDA also states that merely providing financial support (e.g., through an unrestricted educational grant) does not meet its “influence” test. This statement appears consistent with long-standing principles separating largely unregulated “scientific exchange” from more heavily regulated “promotion” (though, as discussed below, the draft guidance does not expressly address the interplay of the new “influence” test with long-standing scientific exchange principles).

Finally, under the third scenario, FDA states that a firm is responsible for content generated by employees or agents, including bloggers, paid speakers, and medical science liaisons, if these individuals are “acting on behalf of the firm.”³ FDA clarifies that it will “not ordinarily view UGC as content on behalf of the firm as long as the user has no affiliation with the firm *and* the firm had *no influence* on the UGC” (emphasis added). Again, a firm’s “influence” would be key in determining its responsibility for the content.

³ The concept of extending responsibility to the firm for those “acting on behalf of the firm” also appears in FDA’s regulations regarding when materials constitute “labeling.” See 21 C.F.R. § 202.1(k).

What procedures should firms follow in submitting Forms FDA 2253 and 2301 for promotional social media?

The draft guidance provides detailed recommendations on the procedures firms should follow in submitting Forms FDA 2253 and 2301 for promotional content on social media. Noteworthy recommendations include:

- Providing for FDA review the entirety of all sites for which a firm is responsible, including the static website with the addition of interactive or real-time components at the time of initial dissemination.
- For third-party sites in which a firm's participation is limited to interactive or real-time communications, providing the home page of the third-party site along with the interactive page within the site and the firm's *first* communication.
- Once every *month*, submitting a new Form FDA 2253 or 2301 with an updated listing of sites for which the firm is responsible or in which it remains an active participant. Note that if a site is publicly accessible, screen shots of interactive or real-time communications need not be submitted. On the other hand, if the site is not publicly accessible, firms should submit all promotional content every month.

OUTSTANDING ISSUES

The draft guidance raises numerous issues firms might consider in assessing the regulatory risk of continuing or initiating the use of social media platforms, including the following:

- ***The scope of the "influence" test in practice.*** Questions remain about the practicality and breadth of the "influence" test, especially in the context of third-party sites. As discussed above, the draft guidance specifically states that by providing unrestricted grants to individuals or entities discussing their product, firms do not meet the "influence" test. But the draft guidance does not discuss the concept of "influence" in detail, raising questions about the types of contact that might constitute "influence." For example, if a firm provides promotional material to a third-party journal's site and has the informal ability to "preview" or "review" content on the site without the ability to affect such content, would FDA impose responsibility for the third-party content on the firm? Further, would specifying that promotional content appear prominently on a third-party site (for example, in a banner "at the top" of a site), cause a firm to be responsible for third-party content appearing in proximity to its promotional content, even without control over the substance of nearby content because the firm has directed the placement of the promotional content to some extent? Can third-party content adjacent to promotional material be treated as "labeling" (as suggested by the draft guidance), evidence of intended use only, or none of the above? Does FDA have jurisdiction to regulate such third-party content?
- ***When is someone considered to be "acting on behalf of" the firm?*** The answer to this question appears to rest on the same "influence" test, raising similar issues relating to breadth and practicality. What constitutes sufficient "influence" to render a firm responsible for UGC? Does a firm "influence" UGC by requesting comments on a certain issue? Would a firm be held responsible for content posted in response to a posting on a Facebook page without any particular invitation for others to comment?
- ***The role of scientific exchange.*** The draft guidance does not address the interplay between scientific exchange and the statements in the draft guidance on employees or agents or other content "influenced" by a firm. For example, the draft guidance states that "if an employee or agent of a firm, such as a medical science liaison or paid speaker (e.g., a key opinion leader)

acting on the firm's behalf, comments on a third-party site about the firm's product, the firm is responsible for the content its employee or agent provides." Does this statement extend to postings by a firm's scientific personnel on a non-commercial third-party scientific forum? Are statements previously thought to be scientific exchange subject to a different test because they are provided on a social media platform?

- ***Applicability to medical device promotion.*** The draft guidance was prepared by the Office of Prescription Drug Promotion (OPDP) in the Center for Drug Evaluation and Research (CDER) in consultation with the Center for Biologics Evaluation and Research (CBER) and the Center for Veterinary Medicine (CVM). Although the draft guidance focuses on submission of postmarketing reports for drugs and biologics, it addresses the broader principle of when firms are responsible for various types of social media communications. It remains to be seen whether the principles discussed in the draft guidance will be adopted by the Center for Devices and Radiological Health (CDRH) and applied to device promotion.

FDA has requested comments on the draft guidance by April 14, 2014. We will continue to apprise clients of developments relating to the guidance.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food & Drug Practice Group:

Michael Labson
Saurabh Anand

+1.202.662.5220
+1.202.662.5222

mlabson@cov.com
sanand@cov.com

This information is not intended as legal advice. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

Covington & Burling LLP, an international law firm, provides corporate, litigation and regulatory expertise to enable clients to achieve their goals. This communication is intended to bring relevant developments to our clients and other interested colleagues. Please send an email to unsubscribe@cov.com if you do not wish to receive future emails or electronic alerts.

© 2014 Covington & Burling LLP, 1201 Pennsylvania Avenue, NW, Washington, DC 20004-2401. All rights reserved.