For years, industry has been awaiting useful guidance from the FDA regarding social media-based drug promotion. The authors write that draft guidance released earlier this year by the agency is narrowly tailored and does not provide the comprehensive social media guidance that industry needs. However, the draft guidance does offer the FDA’s current thinking regarding the use of social media outlets and third-party websites.

**FDA’s Latest Social Media Draft Guidance: Proceed with Caution**

By Cathy L. Burgess, Julie K. Tibbets and Brendan M. Carroll

On Jan. 14, 2014, the Food and Drug Administration (FDA) continued its piecemeal approach toward regulation of social media with the release of a new draft guidance, “Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human Drugs and Animal Drugs and Biologics” (the “2014 draft guidance”).1 For years, industry has been awaiting useful guidance from the FDA regarding social media-based drug promotion. The 2014 draft guidance is narrowly tailored and does not provide the comprehensive social media guidance that industry needs, but it does offer the FDA’s current thinking regarding the use of social media outlets and third-party websites.

I. Background

For years, the FDA has struggled to articulate its views on social media. Part of the challenge has been

---

that advances in Web-based technologies have far out-paced the agency’s ability to formulate cogent policies. At a November 2009 FDA Public Hearing, “Promotion of Food and Drug Administration-Regulated Medical Products Using the Internet and Social Media Tools,” The FDA opened the debate to industry in an attempt to address the types of communications for which manufacturers, packers and distributors are accountable. Apparently, this effort simply raised more questions for the agency. Between November 2009 and January 2014, the FDA more or less left the social media sphere untouched.

A December 2011 draft guidance, “Responding to Unsolicited Requests for Off-Label Information About Prescription Medical Devices” (the “2011 draft guidance”), provided very limited guidance on the use of social media, focusing narrowly on how FDA-regulated entities should respond to unsolicited requests for off-label use information. Despite the fact that the preamble suggested it would address “emerging electronic media,” the 2011 draft guidance fell short of providing any broader guidelines for the use of social media.

For example, the 2011 draft guidance never mentioned Facebook, the most popular social media service on the Internet, as of mid-2011, had over 1 billion users. This was particularly troubling because, despite the lack of guidance on social media, the FDA had already issued a Notice of Violation letter to a drug company in 2010, mentioning a feature for sharing content to Facebook, and also been issuing Warning Letters to companies in 2011 citing improper promotional activities posted on, or involving, Facebook and other social media communications. At the time, with the 2011 draft guidance limited to unsolicited requests for off-label information, the FDA enforcement activity provided the only “guidance” regarding the agency’s latest thinking.

In 2012, as part of a broader legislative package on FDA reform, Congress signaled to the agency that it could no longer delay issuing guidance on social media. Section 1121 of the Food and Drug Administration Reform and Innovation Act (FDARA), signed into law by President Barack Obama on July 9, 2012, mandated that the FDA issue guidance on social media no later than two years after enactment of the act—i.e., by July 9, 2014.

II. Newest Social Media Guidance

The 2014 draft guidance, issued jointly by the Office of Prescription Drug Promotion (OPDP) in the Center for Drug Evaluation and Research (CDER) with the Center for Biologics Evaluation and Research (CBER) and the Center for Veterinary Medicine (CVM), describes the FDA’s current thinking on what the agency considers to be “interactive promotional material” and outlines when, and how, these technologies are subject to the FDA’s postmarketing submission requirements.

Specifically, the FDA defines “interactive promotional media” to include “modern tools and technologies that often allow for real-time communications and interactions (e.g., blogs, microblogs, social networking sites, online communities and live broadcasts) that firms use to promote their drugs.” Unlike certain traditional promotional media (e.g., television and print ads), such interactive technologies possess novel presentation and content features that present challenges not associated with postmarketing reporting requirements for traditional media.

The federal Food, Drug and Cosmetic Act (FDCA) and FDA regulations require firms to submit all promotional labeling and advertising pieces at the time of initial dissemination of the labeling and at the time of initial publication of the advertisement for a drug. The 2014 draft guidance addresses the challenges of submitting promotional materials using “interactive promotional media” that display real-time information “at the time of initial dissemination.” For example, applying existing law, a firm would be required to send real-time submissions to the FDA for every Facebook or Twitter post at the time of publication, or posting, and each time the interactive content (e.g., new comments or postings) changes.

The 2014 draft guidance, recognizing that such a requirement would invite a deluge of information and overwhelm the agency, states that “FDA intends to exercise its enforcement discretion under certain circumstances due to the high volume of information that may be posted within short periods of time using interactive promotional media that allow for real-time communications.” Note that the FDA retains the right to enforce the postmarketing submission requirements, as applied to interactive promotional material, but will not take action to enforce these regulations if companies submit interactive promotional media in the manner described below.

A. When to Submit Interactive Promotional Media

The 2014 draft guidance discusses the timing of postmarketing reporting related to promotional activities carried out by the firm itself, conducted on behalf of the firm or in other instances “prompted” by the firm. Regardless of whether the promotional activity occurs on firm-sponsored or third-party websites, manufacturers and marketers subject to the FDA’s postmarketing submission requirements are generally responsible and accountable for any website or social media content that “they maintain and over which they have full control.”

---

2 The FDA has constructed a Web page dedicated to this meeting that includes the transcripts from the two-day meeting, available at http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm184250.htm.


6 See 2014 draft guidance, supra note 1, at 1.

7 See 21 C.F.R. § 314.81(b)(3)(i); 21 C.F.R. § 601.12(f)(4); 21 C.F.R. § 514.80(b)(5)(ii).

8 See 2014 draft guidance, supra note 1, at 2 (emphasis added).
This is consistent with the thinking expressed in, among other things, the 2011 draft guidance.\(^9\) In the 2011 draft guidance, the FDA first addressed the different types of websites that consumers might encounter: (1) company websites that firms maintain and over which they have full control; (2) website and other venues that are entirely independent of a firm’s control and influence; and (3) websites not fully controlled by a firm. In the 2014 draft guidance, the FDA went one step further to sharpen these differences and explain what factors the agency considers in determining a firm’s responsibility for submitting interactive promotional material to the FDA. As discussed in the 2014 draft guidance, firms are subject to postmarketing submission requirements under the following circumstances:

- Any website that is owned, controlled, created, influenced or operated by (in whole or in part), or on behalf of, the firm. This includes social media sites such as Twitter and Facebook and any other sites under the control or influence of the firm, even if the influence is limited in scope.

- Third-party sites, if the firm has any control or influence, even if limited in scope (e.g., editorial or review privileges). This does not include situations where firms provide only financial support (but maintain no other control or influence over the site) or promotional materials to the third-party site (but do not direct placement of the promotion within that site).

- Any content generated by an employee or agent who is acting on behalf of the firm to promote the firm’s product. This includes medical science liaisons, paid speakers, sales representatives and even bloggers, if the blogger is asking on behalf of the firm.\(^10\)

While the FDA has been consistent in its position that firms are responsible for any site that they maintain and over which they have full control, and not responsible for websites and other venues that are entirely independent of a firm’s control, the 2014 draft guidance clarifies that materials posted to a social media site controlled either directly or indirectly by the firm (e.g., under the influence or control of the firm) must submit materials to the FDA, even if that influence is limited in scope.\(^11\)

### B. When and How to Submit Interactive Promotional Media

As previously discussed, the FDA intends to exercise its enforcement discretion if companies comply with the recommendations in the 2014 draft guidance, which apply to the submission of interactive promotional media that display real-time communications. Specifically, the FDA makes important distinctions between firm-generated content and user-generated content (UGC). For the purposes of these submissions, companies are required to utilize Form FDA-2253 (human drugs and biologics)\(^12\) and Form FDA-2301 (animal drugs).\(^13\)

At the initial time of display, a company is required to submit all websites for which it is responsible, which includes the static product website, as well as interactive or real-time components, on Form FDA-2253 or Form FDA-2301. With regard to third-party sites on which a company’s participation is limited to interactive or real-time communications, at the time of initial display, companies must submit on Form FDA-2253 or Form FDA-2301 the home page of the third-party site, the interactive page and the firm’s first communication. In both instances, the submission must include annotations describing the components that are interactive, or that allow for real-time communications. Also, in both instances, if the site is publicly accessible (e.g., nonrestricted), the FDA will not object, so long as the company submits a Form FDA-2253 or Form FD-2301 containing an updated listing of all nonrestricted sites on a monthly basis. These submissions need not contain screenshots or other visual representations of the actual or real-time communications.

If the site has restricted access and is therefore not publicly accessible by the FDA or others, however, companies must submit all UGC content related to the discussion, which may include independent UGC that provides context to facilitate the review. As opposed to nonrestricted sites, companies must submit screenshots and other visual representations of the actual sites, including the interactive or real-time communications. Firms also have a responsibility to notify the FDA on the first day the firm ceases to be active on any site.

The FDA’s intention to exercise its enforcement discretion under these circumstances signifies the agency’s understanding that full enforcement of traditional postmarketing submission requirements is virtually impossible, due to the sheer volume of submissions and filings that would flood it.

Industry has until April 14, 2014, to comment on the 2014 draft guidance. Additional guidance related to social media is expected from the FDA, but timing is uncertain. There have been reports that by issuing the 2014 draft guidance, the FDA intends to comply with the requirements established under Section 1121 of FDASIA.\(^14\) If that is the case, then without additional pressure from Congress, industry has no option but to monitor the guidance agendas published by the FDA’s

---

\(^9\) See 2011 draft guidance, supra note 3, at 3.
\(^10\) See 2014 draft guidance, supra note 1, at 3-5.
\(^11\) See id. at 4 (emphasis added).
\(^12\) Form FDA 2253, Transmittal of Advertisements and Promotional Labeling for Drugs and Biologics for Human Use (Revised November 2013), available at http://www.fda.gov/
centers, as well as the Unified Regulatory Agenda, for official pronouncements of additional forthcoming guidance, and hope that in the meantime, the agency will exercise enforcement discretion with respect to issues not addressed by the regulations or the 2014 draft guidance. If the FDA does intend to meet the July 9, 2014, deadline, industry should expect to see guidance documents addressing issues with character space limitations, links (and appropriate use thereof) and sponsor responsibility regarding the correction of misinformation about products disseminated by third parties.

III. Considerations for Industry

Companies seeking to increase their digital engagement can begin to inventory current social media and third-party promotional engagements (or desired engagements) and examine whether current company policies and procedures adequately account for the FDA’s recommendations and considerations in this latest social media guidance. Companies would be prudent to observe the agency’s recommendations and considerations to the greatest extent possible in order to avail themselves of the FDA’s enforcement discretion and avoid becoming an enforcement story test case in this area.

A. Content Generated by Employees or Other Agents

One of the messages in the 2014 draft guidance is that companies are responsible for “the content generated by an employee or agent who is acting on behalf of the firm to promote the firm’s product.” For this reason, it is imperative that companies review promotional content and clarify any limitations or prohibitions with respect to content on social media and websites. While this may drive some companies to be more restrictive in terms of the types of speech or promotion employees or paid speakers are permitted to make regarding company products—in fact, it may deter speakers from engaging in promotional activity on behalf of the company—developing clear expectations and guidelines for appropriate content will benefit the company in the long run. Ensuring that restrictions are embedded in contracts with third parties reduces the likelihood that third-party conduct will trigger unanticipated postmarketing submission requirements.

Although the 2014 draft guidance seems clear cut with regard to paid speakers in terms of UGC, it is much more ambiguous with regard to how and when the FDA will view employees or agents as acting on behalf of the company. The 2014 draft guidance is silent with regard to social media training and compliance expectations for employees, but it is clearly in a company’s best interests to clarify when, in the company’s view, an employee or agent is allowed to act on the company’s behalf and when the person is not allowed to do so.

B. To Prompt or Not to Prompt

The 2014 draft guidance is vague regarding what constitutes “prompting” of UGC by the company. In light of the fact that UGC represents a large percentage of the information that can be found online, the lack of clarity on this point is a shortcoming of the guidance. For example, it is not clear whether the FDA believes that merely providing an interactive functionality for users to provide comments triggers promotional filing requirements with the FDA. Also, it is not clear whether offering interactive commenting functionality in conjunction with a statement such as “Tell us about your experience with our product” could trigger such a requirement. This leaves companies to wonder whether to delete inappropriate UGC postings and determine which postings could remain, and whether such editorial influence would be sufficient for the FDA to consider the UGC as promotional and under the company’s control. For the time being, the burden will be on industry not only to prove whether it has influence on UGC but also to define what company “influence” means.

C. Adequately Presenting Risk in Social Media

The 2014 draft guidance is also silent regarding the duty of companies to adequately present risk information in the context of social media platforms. Under the FDCA, advertising claims about a product are deemed misleading if they fail to disclose certain information about a product’s risks, including balanced information about the effectiveness and risks of a product.15 This has been a particularly thorny issue for social media outlets when space is finite (e.g., Twitter has a 140-character limit). For the time being, the FDA’s 2009 draft guidance, “Presenting Risk Information for Prescription Drug and Medical Device Promotion,”16 along with what industry can glean from enforcement action letters, are the only guidelines for industry on how to ensure adequate presentation of risk information. It remains to be seen whether the FDA will inflexibly apply these principles to social media or find an acceptable means for meeting its requirements—particularly in space-limiting social media outlets. This is one of the many questions industry hopes the FDA will answer in its future guidance.

D. Adverse Event Monitoring for UGC and Third-Party Sites

Another area where the FDA thus far has failed to weigh in relates to adverse event (AE) monitoring responsibilities with respect to both UGC and information on third-party sites. In the 2014 draft guidance, the FDA provided no insight into when a company’s social media presence changes its responsibilities with respect to AE monitoring and reporting. For example, it is unclear how the FDA’s distinctions in the 2014 draft guidance regarding levels of control or influence over placement of promotional content on a third-party site could oblige a company to monitor for AEs elsewhere on the third-party’s site. This remains an area where industry needs further guidance from the FDA.

E. Monthly Submission Burden

The good news is that under the 2014 draft guidance, submissions do not need to occur with every tweet or posting on a social media website. This is a pragmatic approach because a strict reading of the existing postmarketing reporting requirements would have caused the FDA to be flooded

with information. Although the monthly submission requirement signifies the FDA’s understanding of the sheer volume of information in cyberspace, industry is left with a burdensome reporting requirement to monitor and track all social media and third-party sites on a monthly basis for potential resubmission to the FDA. The FDA may find that the monthly submission requirement is still untenable in terms of volume and later change its approach, particularly if more companies begin using social media.

IV. Conclusion

While many in the industry expected the FDA to issue guidance on a broader range of social media uses, this is a small step forward. Though the agency has officially begun the conversation on social media for prescription drugs, biologics and animal drugs, there are a number of lingering and open questions, with considerable room for FDA interpretation. Therefore, it would be prudent for companies to proceed with caution and await additional guidance in this area before substantially changing their approaches to interactive social media and third-party site engagement. Up until now, most companies have dealt with the lack of guidance from the FDA in the social media arena by minimizing their engagement on the interactive front, and this is a trend that is likely to continue.

Given that the only clear-cut guidelines in the 2014 draft guidance relate to situations in which companies exercise complete control over promotional content, companies are likely to continue focusing their promotional efforts in media where they can maintain control over content and minimize exposure to the unknown regulatory risks that lie within UGC and other interactive functionalities. Finally, we note that the FDA’s Center for Devices and Radiological Health (CDRH) did not join in issuing this draft guidance. Thus, medical device companies are left with only the minimal guidance provided in the 2011 draft guidance and without any guidance as to the CDRH’s likely direction and view as to engagement in interactive promotional media. In order for the FDA to provide meaningful guidance to industry as mandated by Congress, and not claim to have satisfied its statutory obligation by issuing a narrowly tailored guidance that leaves many questions unanswered, the 2014 draft guidance should be only the first in a comprehensive series of guidance documents that will address the evolving complexities of regulatory compliance in online product promotion.
NEW RULES OF ENGAGEMENT

SOCIAL MEDIA LAW & POLICY REPORT

Corporate use of social media is skyrocketing, and so are the legal risks to your clients and their organizations. Now, staying up to date on the latest legal implications just got easier.

Introducing Social Media Law & Policy Report™ — the only resource that integrates timely news, real-world analysis, full-text case law, primary sources, reference tools, checklists, and sample policies to help you advise clients with confidence.

START YOUR FREE TRIAL — CALL 800.372.1033
OR GO TO www.bna.com/smlr-article