DIGITAS HEALTH

Regulatory Alert

2253 Filing Requirements for Social Media

January 13, 2014 **Analyst: Dale Cooke**

EXECUTIVE SUMMARY

On January 13, 2014, the Food and Drug Administration (FDA) released a draft Guidance to Industry: Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics[1]. This guidance is a direct outcome from the 2009 hearings on using the Internet and social media to promote prescription products. The guidance provided by FDA addresses how sponsors can meet their postmarketing submission requirements (i.e., the Form FDA 2253 or Form FDA 2301 filing) for promotional materials.

Sponsors of prescription products will welcome clarity from the FDA regarding what materials they will be required to submit and how to address the postmarketing submissions requirements in the context of real-time discussions. They will also likely be pleased to see FDA endorsing the view that "a firm generally is not responsible for UGC [User-generated content] that is truly independent of the firm" even if that content is posted to a venue that is wholly owned and controlled by the sponsor.[2] Some other aspects of this guidance will require additional clarification from the FDA, including the definition of when a sponsor is required to submit materials to meet its postmarketing obligations. Another area where this guidance requires further clarification is the nature of the responsibility of the sponsor for third-party content. The guidance presents a responsibility for sponsors under certain circumstances to submit third-party content as part of their postmarketing requirements but leaves unanswered whether the sponsor has any greater responsibility for that content.

In light of this guidance, Digitas Health recommends companies take the following actions[3]:

1. Review existing postmarketing submission filing procedures for compliance with the recommendations in the guidance, and update those procedures as needed.
2. Review corporate social media policies, and employee-generated content in owned social channels in light of this guidance and update as needed.
3. Review agreements with Key Opinion Leaders (KOLs), bloggers, agencies, and other agents of the company to ensure that postmarketing submission requirements are met.
4. Promulgate throughout the organization the expanded postmarketing filing requirements.

BACKGROUND

According to the Code of Federal Regulations, sponsors of prescription drugs, biologics, and veterinary medicines are required to "submit specimens of mailing pieces and any other labeling or advertising devised for promotion of the drug product at the time of initial dissemination…or publication." (Postmarketing Guidance, page 3) For offline materials, such as a printed brochure, or display ad in a printed magazine, sponsors have had little difficulty complying with this requirement; however, certain online promotional materials have created more difficulties. This draft guidance provides recommendations both for determining whether sponsors need to file materials with the FDA and recommendations on what to submit to meet the postmarketing filing requirements.

DETERMINING WHETHER TO SUBMIT

According to the draft guidance, a sponsor is responsible for submitting content on sites under three sets of circumstances. The first circumstance is for sites that "are owned, controlled, created, influenced, or operated by, or on behalf of, the firm…. even if the influence is limited."[4] Clearly, this applies to brand.com websites and firm-sponsored activities such as a Twitter account.[5] In addition, FDA makes clear that this applies to websites where firms have "editorial, preview, or review privilege over the content."[6] For example, if a sponsor were to review articles appearing on a health news website to determine whether the sponsor wanted to place its advertising and promotional material on the site, then the sponsor would have an obligation to submit all of the material posted on the site.[7]

The second set of circumstances makes clear that the sponsor is responsible not merely for the promotional materials it produces but could have an obligation to submit the content provided by the location where the firm's promotional materials appear. In the guidance the FDA exempts from postmarketing submission requirement any material on a site if "a firm provides only financial support (e.g., through an unrestricted educational grant) and has no other control or influence on that site" or "is merely providing promotional materials to a third-party site but does not direct the placement of the promotion within the site and has no other control or influence on that site."[8] In an example provided discussing this issue, FDA makes clear that if the sponsor "influenced the placement of its promotion within the third-party site, the firm is responsible for submitting to FDA the promotion, along with the surrounding pages, to adequately provide context to facilitate the review of the third-party site, in order to fulfill the postmarketing submission requirements."[9]

Applying this reasoning to the case of a banner ad placed on a website, it would appear that if a sponsor requested that its online banner ad appear in the fashion section of NYTimes.com, then the sponsor would be required not merely to submit the ad but also to submit the NYTimes.com fashion section to fulfill the postmarketing submission requirements because the sponsor had "influenced the placement of its promotion within the third-party website."[10]

The third set of circumstances where sponsors are required to submit materials to meet their postmarketing requirements are where agents or employees are "acting on behalf of the firm to promote the firm's product."[11] With regard to actions by such agents acting on behalf of the firm, FDA recommends that the relationship with be transparently disclosed on the site, such as via inclusion of the firm's logo.[12] In addition, any such content generated by the agent must be filed to meet the postmarketing submission requirement.

For example, if a sales representative or contracted KOL were to comment on a third-party site discussing the company's product, then the comment from the sales representative or KOL could be subject to the postmarketing submission requirement, even if the site itself has no connection to the firm, and even if no one at the firm is aware of the comment other than the sales representative or KOL making the comment. FDA does not clarify what it means to be "acting on behalf of the firm" and whether it is possible for an employee or someone contracted by the firm in some capacity to be acting independently in engaging in such actions.

WHAT TO SUBMIT

In addition to providing recommendations to determine whether to submit materials, this guidance also provides recommendations about what and how to submit interactive materials that display real-time information.

First, FDA recommends that for all static product websites for which a firm is responsible (as determined in the previous section), the firm should submit "the comprehensive static product website with the addition of

the interactive or real-time components."[13] The submission of such sites should include annotations to indicate which portions "are interactive and allow for real-time communications."[14] So long as the site is publicly accessible, FDA will not require that the every new information or real-time communication also be submitted. Instead, FDA intends to exercise enforcement discretion regarding such updates.[15]

Second, regarding third-party sites (such as Twitter or Facebook) on which a firm is engaging in real-time communication, FDA recommends submitting the home page of the third-party site and the interactive page where the firm's communications will appear with the first such communication.[16] For example, that would be the timeline page for a Facebook page or the profile page for a Twitter account. Presumably, sponsors should include all of the pages and descriptions that would appear as part of the interactive and static portions of the profile on such sites at the time of launching the profile.

Third, FDA recommends that sponsors provide an updated listing of all non-restricted (publicly accessible) sites for which it is responsible once every month.[17] That once-monthly listing does NOT have to include all of the updates and interactions that have taken place throughout the month. FDA explicitly states that "[f]irms need not submit screenshots…of the actual interactive or real-time communications with the monthly updates." Sponsors who were concerned that the postmarketing filing requirement would prevent their ability to engage in real-time dialogue, this should be a welcome development.

If, however, the site is not publicly accessible (because it is behind a log-in or is otherwise protected), then the sponsors should submit "screenshots…including the interactive or real-time communications…monthly."[18]

ENFORCEMENT DISCRETION

The phrase "enforcement discretion" is a technical term and can cause some confusion. When FDA states that it intends to exercise enforcement discretion in an area, it is asserting:

1. FDA has the legal authority to enforce legal and regulatory requirements in that area.
2. FDA will not use that authority.

In the context of this guidance, that means that FDA will not take enforcement actions based on the failure to submit all posts to social media and interactive online promotional media at the time of first use.[19] Instead, FDA is willing to accept from sponsors a monthly update of all interactive social media and online engagements. If the engagement is hosted in a publicly accessible location, then sponsors will also be able to avoid filing all of the real-time interactions themselves.[20] If the engagement is not publicly accessible because it requires a log-in or is password protected, then the real-time interactions (including the UGC not created by the sponsor) must be submitted once per month.[21]

RECOMMENDATIONS

In light of this guidance, Digitas Health recommends companies take the following actions[22]:

1. Review existing postmarketing submission filing procedures for compliance with the recommendations in the guidance, and update those procedures as needed.
2. Review corporate social media policies in light of this guidance and update as needed.
3. Review agreements with Key Opinion Leaders (KOLs), agencies, and other agents of the company to ensure that postmarketing submission requirements are met.
4. Promulgate throughout the organization the expanded postmarketing filing requirements.

ENDNOTES

[1] This guidance is herein referred to as "Postmarketing Guidance" and is available from the FDA website at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM381352.pdf
[2] Postmarketing Guidance, page 5.
[3] In this Regulatory Alert, I make no distinction between biologic products, human, and non-human animal drugs. The essential regulatory requirements for all are essentially the same, and the descriptions and recommendations of this alert should be applied to all categories with only minor modifications.
[4] Postmarketing Guidance, page 3.
[5] Postmarketing Guidance, page 3.
[6] Postmarketing Guidance, page 3.
[7] Postmarketing Guidance, page 3.
[8] Postmarketing Guidance, page 4.
[9] Postmarketing Guidance, page 4.
[10] Postmarketing Guidance, page 4.
[11] Postmarketing Guidance, page 4.
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[18] Postmarketing Guidance, page 7.
[19] Postmarketing Guidance, page 2.
[20] Postmarketing Guidance, page 6.
[21] Postmarketing Guidance, page 7.
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