A Roadmap to Meaningful Use: FDA Releases More Social Media Guidance

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On June 17, 2014, the U.S. Food and Drug Administration (FDA) provided the long-sought-after additional elements of the comprehensive social media guidance with the release of two Draft Guidance documents, “Internet/Social Media Platforms With Character Space Limitations—Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices” (the “Space Limitations Draft Guidance”)¹ and “Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices” (the “Correcting Misinformation Draft Guidance”).² These two Draft Guidance documents complement a third Draft Guidance, “Fulfilling Regulatory Requirements for Postmarketing Sub-


missions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics” (the “Postmarketing Submission Draft Guidance”) released earlier in 2014³ (collectively, the “Social Media Guidelines”).

For years, technological advances in electronic media have far outpaced the FDA’s ability to develop clear guidance. Recently, the FDA attempted to address this gap with the release of draft guidance related to advertising and promotion using social media. The most recent draft guidance documents were issued jointly by the Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), Center for Veterinary Medicine (CVM) and the Center for Devices and Radiological Health (CDRH). The Space Limitations Draft Guidance describes the FDA’s current thinking regarding the presentation of balanced risk and benefit information in advertising and promotional materials on social media platforms with character space limitations. While Twitter, with its 140-character limit, is the most obvious example, the Space Limitations Draft Guidance also applies to online paid searches (e.g., sponsored links on Google or Yahoo search engines) and other similar electronic platforms. The Correcting Misinformation Draft Guidance, meanwhile, addresses how companies may voluntarily correct inaccurate information about their products that appear on social media platforms. Together, the Social Media Guidelines seem to reflect a pragmatic approach

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in regulating industry use of social media platforms and a recognition of the increasing importance of these platforms in disseminating information.

I. Space Limitations Draft Guidance

Social media platforms with character space limitations or other space restrictions create challenges for regulated industry, making it difficult to post promotional materials that present adequate benefit and risk information. While the Space Limitations Draft Guidance provides greater clarity about the use of such social media platforms, the strict limitations described in the Draft Guidance suggest that the widespread use of platforms with character space limitations for promotional activity is unlikely. We note that the Draft Guidance covers popular platforms such as Twitter and sponsored links (e.g., Google or Yahoo banners), but it is does not apply to product promotion on product websites or social media platforms such as Facebook, where no character space limitations are imposed. Thus, it seems that expanded use of social media platforms for promotional activity is far more likely to occur through the use of those websites or platforms that do not impose rigid space limitations.

A. Existing Requirements

Under the Federal Food, Drug, and Cosmetic Act (FDCA) and related FDA regulations, a drug or device is misbranded if the promotional labeling contains representations about the use of a product but fails to disclose certain risk information. In addition to being truthful and not misleading, promotional labeling must include certain required information, such as indications or intended uses, as well as the risks associated with use of the prescription drug or device. Section 502 of the FDCA also includes requirements about the prominence, conspicuousness and placement of such information. Many of these requirements obligate companies to include a balanced presentation of benefit and risk information, a requirement the FDA acknowledges may pose challenges to companies on sites such as Twitter, which limits content to 140 characters.

B. Presenting Risk and Benefit Information

The Draft Guidance makes clear that an accurate and balanced presentation is not possible, these platforms should not be used. Rather than reject the use of platforms with strict space limitations outright, however, the FDA provides recommendations that could enable industry to develop promotional materials that comply with applicable regulatory requirements.

The Space Limitations Draft Guidance provides specific factors to consider in the communication of a fair balance of risk and benefit information, both in terms of content and format. Benefit information must be accurate and not misleading and must include material facts about use of the product, such as limitations to an indication or relevant patient population information. Moreover, benefit information should not be conveyed unless there is adequate space to convey appropriate risk information.

The Space Limitations Draft Guidance also contains specific recommendations regarding the disclosure of risk information. In addition to the overarching principle that benefit information must be accompanied by appropriate risk information, the FDA states that a firm must provide a direct link that allows the user to access a more complete description of product risks. As a general principle, presentation of risk information must be comparable in scope to the presentation of benefit information, and the FDA will assess the disclosure of risks using two factors: (1) whether the risk information qualifies any representations made about the product, and (2) whether the prominence and readability of the risk information is comparable to benefit information.

Given the constraints imposed by the FDCA, the FDA is careful to remind industry of the challenges in balancing benefit and risk information. Some of the specific requirements for conveying risk information set forth in the Draft Guidance include:

- The risk information must include, at a minimum, the most serious risks associated with the product.
- For prescription drugs, the risk information must include all risks that are known to be fatal or life threatening and all contraindications, or in the absence of such risks, the most significant warnings or precautions.
- For animal drugs, the risk information must include any risks to human handlers and animal patients as well as the risk of drug residues entering the human food chain.
- For devices, the risk information must include any risks associated with a particular identifiable use or population.
- The risk information must include a hyperlink that allows direct access to more complete risk information.
- The hyperlink must be a direct hyperlink to information “devoted exclusively to the communication of risk information about the product.”
- The hyperlink must not link to a product homepage or other webpage that includes only benefit information or other promotion claims and graphics.
- The hyperlink may be shortened into a URL, but the URL or web address themselves must not be promotional in content or tone.
- The risk information must be displayed prominently, comparable to the benefit information (e.g., the risk information cannot appear as fine print).
- Formatting (e.g., highlighting, bold, underline) should not be used to emphasize benefit information over risk information, but may be used to highlight significant risk information.

The Space Limitations Draft Guidance also includes recommendations for other product information and explains that the FDA will not object to additional product information included in character-space-limited social media platforms if presented in accordance with the agency’s recommendations.
The Space Limitations Draft Guidance contains examples of acceptable promotional tweets and other character-space-limited communications for hypothetical “approved” drug products. We have summarized one of the examples below:

**NoFocus**

This hypothetical product is indicated for memory loss that is mild to moderate. The Draft Guidance states that the following tweet, “NoFocus for mild to moderate memory loss [40/140],” provides accurate and not misleading information about the product indication, but does not provide risk information or other required information, which would need to be presented in the remaining 100 character spaces. The Draft Guidance assumes that the hypothetical product has no boxed warnings or known risks that are fatal or life-threatening. The most serious risk is the potential for seizures in patients with a seizure disorder. The Draft Guidance indicates that the following tweet would convey benefit and risk information in a manner that is accurate and non-misleading: “NoFocus for mild to moderate memory loss; may cause seizures in patients with a seizure disorder [117/140].” The Draft Guidance states that by including a URL that is a landing page devoted entirely to presenting comprehensive risk information about NoFocus, a company would be able to develop promotional material within the confines of a tweet that complies with the statutory requirements established in the FDCA.

By providing this level of detail regarding tweets and other sponsored links, the FDA provides a relatively well defined roadmap for the use of limited character space social media platforms for advertising and promotion. The Draft Guidance provides greater clarity about the FDA’s current thinking, but it remains to be seen how companies will be able to follow this roadmap in practice.

**II. Correcting Misinformation Draft Guidance**

The FDA also released a second Draft Guidance that describes the agency’s thinking regarding how firms should respond, if they choose to respond, to misinformation about a firm’s products that are created or disseminated by third parties. The Draft Guidance does not apply to firm-controlled communications or any other communication where the firm is responsible for the product communication containing misinformation. It applies only where the firm is not responsible for the third-party communication, which is consistent with the agency’s longstanding view that firms are generally not responsible for third-party user-generated content about their products that is truly independent of the firm.\(^8\) Second, the correction of misinformation is voluntary, but the Draft Guidance imposes mandatory requirements if a firm elects to engage in the voluntary correction of information.

Misinformation is defined in the Draft Guidance as “positive or negative incorrect representations or implications about a firm’s product created or disseminated by independent third parties who are not under the firm’s control or influence and that is not produced by, or on behalf of, or prompted by the firm in any particular.”\(^9\) The FDA will not object to corrective information voluntarily provided by a firm so long as it is truthful and not misleading and is presented in accordance with the requirements set forth in the Draft Guidance, even if the firm does not satisfy other applicable regulatory requirements regarding labeling or advertising.

Once a firm elects to correct misinformation posted by a third party about prescription drugs and medical devices, the requirements in the Draft Guidance take effect and firms are obligated to include appropriate corrective information that is relevant and responsive, limited and narrowly tailored, nonpromotional in nature, tone and presentation accurate and not misleading, consistent with FDA-required labeling and supported by scientific evidence. This information must also be posted either in conjunction with the misinformation in the same area or forum (if posted directly) or intended to be posted in conjunction with the misinformation (if provided to the author). Finally, the corrective information must include a disclosure that the firm is the source of the information.

As with the Space Limitations Draft Guidance, the Correcting Misinformation Draft Guidance also emphasizes the importance of including FDA-required labeling, since risk information is not necessarily part of corrective information. Therefore, the FDA recommends that the firm provide a direct link to the FDA-required labeling with the caveat that such a hyperlink cannot itself be promotional in content or tone. Although the FDA states that the corrective information must be “relevant and responsive” and “limited and tailored to the communication,” clearly the agency believes that risk information falls within the scope of these requirements.

Any firm seeking to correct misinformation must also consider the scope and quantity of information that should be corrected. It may be difficult for a firm to correct all misinformation about its products in a single forum, which may contain a vast amount of information or may have operated over a long period of time. Therefore, a firm is not obligated to correct all instances of misinformation. However, the firm must:

- Clearly identify the misinformation it is correcting;
- Correct all misinformation appearing in a clearly defined portion of the forum;
- Describe the location or nature of the misinformation;
- Provide a date the corrective information is posted; and
- Not selectively correct misinformation so as to only address misinformation that portrays a product in a negative light, while not addressing misinformation, for example, overstating a product’s efficacy.

In addition to the “what” firms may correct if they voluntarily elect to correct misinformation, the Draft Guidance also address “how” firms can do so by providing four approaches:

- A firm may correct information directly on a forum;

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\(^9\) See Correcting Misinformation Draft Guidance at 3.
A firm may provide corrective information directly to the independent third-party author for the author to correct;

- A firm may request that the misinformation be removed by the author or alternatively, allow that comments be posted in response to the misinformation posted by the author; or

- A firm may request that the site administrator remove the misinformation or alternatively, allow that comments be posted in response to the misinformation posted by the author.

The FDA recognizes that there may be instances in which an author or site administrator refuses to comply with a request to correct misinformation. Therefore, importantly, firms will not be held accountable for any subsequent actions taken by the third party, including a failure to correct the misinformation, since a firm cannot control whether an independent third party complies with the request or refuses to do so. There is also no obligation to continue to monitor websites or communications containing misinformation once a firm elects to voluntarily correct misinformation. This is an especially important allowance given the large volume of information that exists on social media and other websites.

The Draft Guidance cautions, however, that if firms go beyond the correction of misinformation to include full-blown advertising (e.g., slogans or examples of patient profiles from its marketing campaign), then the firm’s corrective information communication falls outside the scope of the Draft Guidance and instead must comply with all applicable regulatory requirements for labeling and advertising. Although the FDA will not require firms to submit corrections to the agency when correcting information, the FDA also advises firms to keep records in order to have answers to any questions that may come from the agency.

III. Considerations for Industry

Companies seeking to expand their social media presence should consider the following:

A. Use the Roadmap

While the Social Media Guidances seem to clarify how and when firms can use social media and provide more clear direction for their use, the parameters that have been set are stringent, and there appears to be little room for error. Nevertheless, there is still a clear roadmap for firms to follow if firms seek to expand their social media presence. Firms must tread carefully, however, because there are several ways to overstep the bounds of the Social Media Guidances and risk FDA enforcement action. For example, the Space Limitations Draft Guidance requires extensive risk information to be included in a tweet that is comparable to the type and quantity of information that appears in the fine print in magazine ads. Likewise, the Correcting Misinformation Draft Guidance strikes a delicate balance between the scope and quantity of misinformation that a company chooses to correct. Thus, while industry has finally been given a roadmap to the social media realm, there are twists, turns and most likely uncharted territory. While the roadmap provides some direction, firms should proceed with caution before proceeding with new and innovative social media campaigns.

B. Be Careful When You Click

Character-space-limited communications and corrections of misinformation are required to communicate very specific information, as illustrated in the two June Draft Guidance documents, but they must also include a direct link to a page that is devoted exclusively to the communication or risk information (e.g., for tweets) or FDA-required labeling (for correcting misinformation) that is available with a single click of a mouse in a non-promotional, easily accessible format. Enabling users to bypass the link to risk information, or encouraging them to click to a page that does not contain risk information, is one click too many. As the FDA cautions in the Draft Guidance documents, a product website that contains non-risk information is too promotional in nature. Even the name of a shortened URL can be construed as being promotional. In order to avoid becoming an enforcement test case in the social media area, companies should be careful when directing internet traffic.

C. Be Transparent

In the Postmarketing Submission Draft Guidance, the FDA recommends that firms be transparent in disclosing their involvement on third-party sites by clearly identifying the content and communications of their employees or agents. Similarly, in the Correcting Misinformation Draft Guidance, FDA requires an “overarching clear and conspicuous statement” that the firm did not create or control user generated content that may appear on a firm site. This would seem to be a complicated issue for a Facebook page, for example, which may be controlled by a firm but can feature both user generated and firm-controlled content.

IV. Conclusion

Whether firms seek to quickly expand their presence on social media platforms remains to be seen, but one thing is clear: the FDA has finally provided industry with the roadmap it needs to move forward. Comments regarding the two June 2014 Draft Guidances were due on September 16, 2014. The FDA will continue to refine and expand the Social Media Guidances as they become finalized, but companies must continue to proceed with caution when using social media platforms.