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CLIENT ALERT

More of the Same: Recently Released FDA Social Media Guidance for the Life Sciences Industry

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On June 17, 2014, the U.S. Food and Drug Administration ("FDA") continued to outline its expectations for pharmaceutical and medical device manufacturer[1] use of social media platforms to promote manufacturers' products in two new draft guidance documents: "Internet/Social Media Platforms with Character Space Limitations—Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices"[2] ("Space Limitations Guidance") and "Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices"[3] ("Correcting Misinformation Guidance"). In these documents, which were eagerly awaited by manufacturers for the past four years, FDA addresses acceptable methods of promoting products on microblogging (e.g., Twitter) and other platforms, such as "sponsored links" (e.g., Google Sitelinks) with character limitations, and of correcting user-generated content ("UGC") on third-party websites. Despite the anticipation, however, FDA does not break substantial new ground in either guidance document.

Given FDA's recent increased attention to online promotion of prescription drugs and medical devices, as evidenced by recent enforcement actions,[4] manufacturers should pay careful attention to the recommendations in these guidances to avoid FDA scrutiny. However, the guidances raise questions about FDA enforcement of manufacturers' online activities that may benefit from further public dialogue. Manufacturers whose promotional

[1] The guidance applies to activities of pharmaceutical and medical device packers and distributors as well, but for the purposes of this alert, we will use "manufacturers" to encompass these entities.
[2] U.S. Food & Drug Admin., Draft Guidance for Industry on Internet/Social Media Platforms with Character Space Limitations—Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices (2014), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM401087.pdf.
[3] U.S. Food & Drug Admin., Draft Guidance for Industry on Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation about Prescription Drugs and Medical Devices (2014), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM401079.pdf.
[4] See Epstein Becker Green Client Alert: Recent FDA Social Media Marketing Enforcement Actions and the Likely Impact of Social Media Promotion Guidance, *available at* http://www.ebglaw.com/showclientalert.aspx?Show=18498.

activities are impacted by these guidances should consider submitting comments to both documents before their respective deadline.[5]

Social Media with Character Space Limitations

In the Space Limitations Guidance, FDA confirms that all current promotional labeling regulations apply to promotional statements on all social media platforms, even those with strict limitations on the amount of text that can appear in one post (e.g., Twitter or a sponsored link on an Internet search engine). In general, the Space Limitations Guidance applies current promotional labeling regulations for traditional media while making only limited allowances to work within social media's restricted space and format boundaries:

- Benefit information should be accurate and non-misleading and reveal material facts within each individual character-space-limited communication (e.g., each individual message or tweet).

- Benefit information should be accompanied by risk information within each individual character-space-limited communication.

- The content of risk information should, at a minimum, include the most serious risks associated with the product:

    - "Most serious risks" include boxed warnings, risks known to be life-threatening, and contraindications. However, if a prescription drug has none of these, the most significant warnings should be included.

- A direct link to comprehensive risk information about the product should be included in each communication:

    - The linked page should be entirely devoted to risk information and should not display any promotional content, and

    - Manufacturers may use URL shortening services to reduce the character count of the hyperlink.

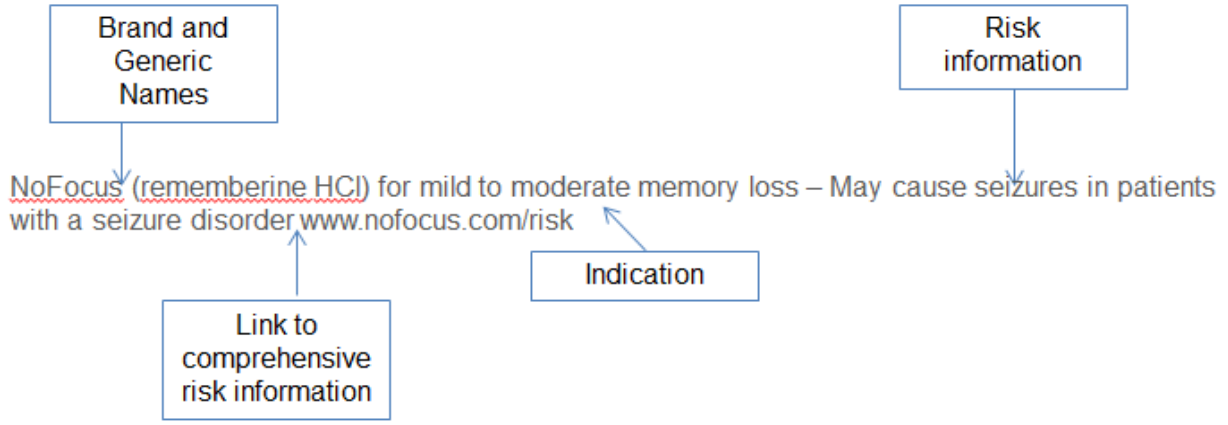
- The prominence of risk information should be comparable to the benefit information, taking into consideration any formatting capabilities available on the specific social media platform (e.g., the use of dashes).

- Both the brand name and the generic name of the product should appear within each character-space-limited communication and the linked risk information page:

    - Pharmaceutical manufacturers should also display at least one dosage form and quantitative ingredient information on the linked risk information page.

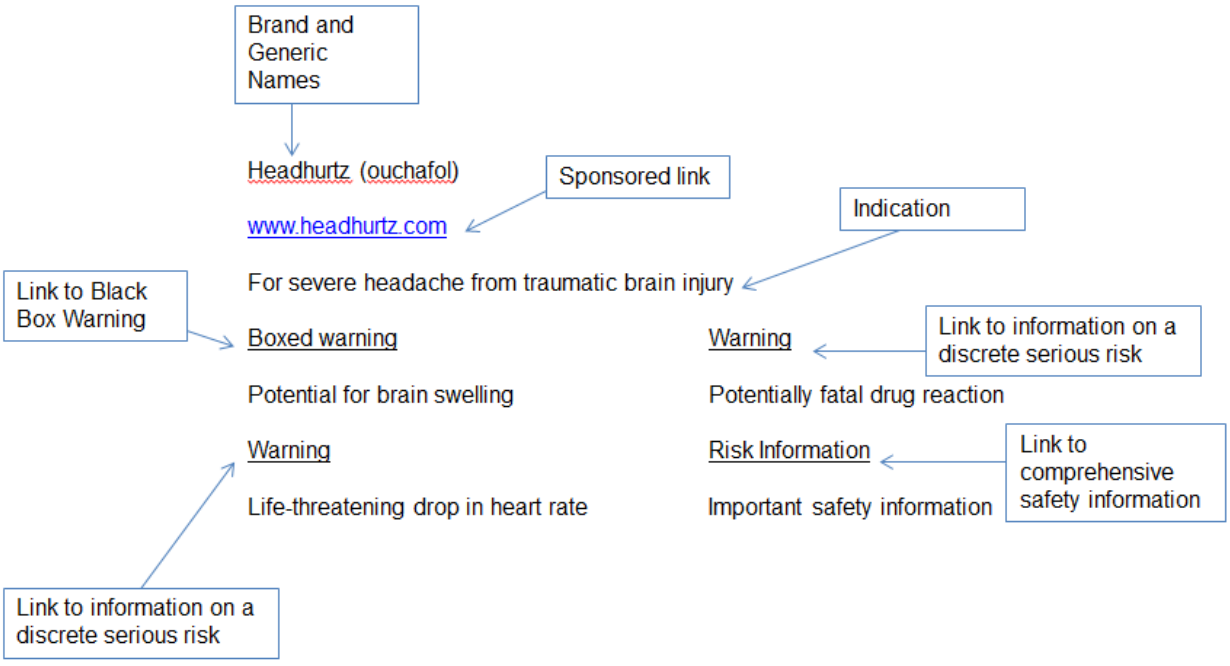
[5] Comments to the Draft Guidance on character-space-limited communications are due on September 16, 2014, and comments to the Draft Guidance on correcting independent third-party misinformation are due on August 18, 2014.

The Space Limitations Guidance offers the following example of a tweet that would satisfy these requirements and still remain within Twitter's character-space constraints:



Ultimately, however, FDA recommends that manufacturers consider carefully whether all of the required information can be adequately conveyed in a character-space-limited communication and, if it cannot, that manufacturers reconsider the use of social media as a promotional tool for that product. In light of the stringent requirements for risk and other information required for inclusion in each single tweet, in reality, it is likely that only a few products with very limited risk profiles will be susceptible to product-related tweets in a manner compliant with the guidance document.

Sponsored link services, such as Google Sitelinks, are significantly more useful for manufacturers because they are prominently displayed at the top of Internet search engine results, and they generally allow a greater number of characters. FDA also gives an example of an acceptable Google Sitelinks promotion:



Correcting Independent Third-Party Misinformation

The Correcting Misinformation Guidance establishes guidelines for manufacturers that choose to correct false or misleading information about their products. This draft guidance applies to information that appears in online posts on third-party websites from individuals unaffiliated with and not sponsored by the manufacturer or independent UGC. However, the draft guidance expressly provides that manufacturers are not obligated to seek out product misinformation on third-party websites. Manufacturers have long questioned FDA's authority to hold manufacturers responsible for communications by third parties who are not subject to the manufacturer's influence or control, and this draft guidance confirms that correcting third-party misinformation is voluntary, but only when the communication is free of *any* influence from the manufacturer.

In more welcome news for manufacturers, FDA makes a concession to traditional advertising and labeling requirements by allowing manufacturers to post corrective information without regard to fair balance as long as the information:

- Is relevant and responsive to the misinformation the manufacturer seeks to correct
- Is limited and tailored to the misinformation
- Is not promotional in nature, tone, and presentation
- Is accurate (i.e., not false or misleading)
- Is consistent with the FDA-required labeling for the product
- Is supported by sufficient evidence
- Either is posted in conjunction with the misinformation in the same area or forum, or references the misinformation with the intention of being posted in conjunction with the misinformation
- Discloses that the person providing the corrective information is affiliated with the manufacturer

However, since risk information is not required in such corrective postings, the draft guidance states that manufacturers should include a direct link to a non-promotional webpage with the complete FDA-required labeling for the product. In addition, the correction should clearly (a) identify the misinformation being addressed, (b) define the portion of the forum where the misinformation appears, and (c) address *all* misinformation appearing in that defined portion of the forum. While FDA does not require a manufacturer to seek out all product misinformation in a single forum, choosing to correct multiple posts may obligate the manufacturer to address all misinformation contained within the portion of the forum defined by the selected posts.

Once a manufacturer chooses to provide corrective information, it must not discriminate between positive and negative misinformation in independent UGC. For example, a

manufacturer may not correct misinformation that exaggerates product risk while ignoring misinformation in the same post that contains exaggerated efficacy claims.

Manufacturers have the option of posting corrections directly to the forum containing the misinformation or contacting the author of the offending post (or the forum administrator) to request (a) that corrective information be added to the post, (b) that the misinformation be removed, or (c) permission to post comments. FDA will not hold a manufacturer accountable if the author or forum administrator refuses to accommodate the manufacturer's request. The guidance document draws specific lines between corrections and promotional information, highlighting when the guidance will or will not apply. Those manufacturers must be sure that corrections do not cross over the line into "promotions." If they do, all promotional requirements, including fair balance, will apply to those communications.

Broader Implications

While more definitive social media guidance is welcome, these draft guidance documents do little to encourage or facilitate promotion of pharmaceuticals and medical devices in online forums. The Space Limitations Guidance reiterates the well-established promotional requirements that apply to other, more traditional, media platforms with only minor concessions for common abbreviations and shortened URLs to accommodate space restrictions found in many Internet platforms. In short, FDA's guidance simply confirms advice that drug and device companies have been hearing for some time: given the stringent space limitations, microblogging sites like Twitter, and to a lesser extent sponsored links, simply are not feasible for most promotional product communications. As a result, the release of these guidance documents is unlikely to have a substantial impact on a manufacturer's online promotional activities.

FDA did make some limited concessions for space-constrained media, such as allowing manufacturers to include a supplemental link to a product's full risk information in a character-space-limited communication. This is a break from FDA's former stance on online promotional labeling, which mandated the full disclosure of risks in any online promotion and disavowed the supposed "one-click" rule upon which some manufacturers relied for a time to support the practice of stating the benefits of a drug on one webpage and providing a direct link to pertinent risk information and FDA-required labeling. Nonetheless, even with permission to include a link to comprehensive risk information, the requirement to include the most serious risks or significant warnings will likely preclude promotional communications on character-space-limited platforms for most prescription drugs and devices.

Notably, the requirements for fair balance do not apply to reminder advertisements, which simply name the product without mentioning any suggested uses or benefits. Manufacturers may use reminder advertisements to call attention to their products without listing the associated risks. This could be the least risky and most impactful use of social media platforms, such as Twitter, for the pharmaceutical and medical devices industries because manufacturers need not include risk information that would threaten to exceed the character count.

The Correcting Misinformation Guidance reaffirms the commonly held understanding that FDA lacks authority to hold manufacturers responsible for communications by third parties who are not affiliated with the manufacturer. Similar to the Draft Guidance on Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics, released in March 2014, the recent guidances contemplate a broad but not well-defined scope of third parties whom FDA deems to be within a manufacturer's control. This ambiguity poses challenges for manufacturers assessing the range of product-related communications for which they are responsible. For example, a manufacturer will be responsible for content in a blog post on a third-party website if the manufacturer has prompted the communication in any way or has *any* form of influence over the post, even if the influence is limited in scope. Also, affirmatively endorsing an independent third-party statement will make a manufacturer responsible for that statement. Based on past FDA enforcement activity, it is possible that "liking" a Facebook post or "retweeting" will be deemed an affirmative endorsement by the manufacturer.

Despite the limited impact that these guidances are likely to have on manufacturer behavior, manufacturers with an interest in promoting their products in space-limited media or on correcting misinformation may wish to comment on the Space Limitations Guidance or the Correcting Misinformation Guidance to encourage FDA to expand the scope of exemptions from traditional promotional requirements to address the practical realities of many Internet platforms or to provide greater certainty around these activities.

Manufacturers should review current policies and procedures on promoting products and submitting marketing materials to FDA in light of the Space Limitations Guidance and the Correcting Misinformation Guidance and determine whether to provide comments and suggestions to FDA before the August 18 and September 16, 2014, deadlines. Epstein Becker Green is available to assist with drafting and submitting comments to FDA.

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