KING & SPALDING

Client Alert

FDA & Life Sciences Practice Group

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FDA Issues Draft Guidances Regarding Social Media: *Handling Misinformation and Character Space Limits*

On June 17, 2014, the U.S. Food and Drug Administration (FDA) issued two draft guidance documents concerning the use of social media and internet platforms for advertising and promotion: *Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices* ("Internet/Social Media: Correcting Misinformation Draft Guidance")[1] and *Internet/Social Media Platforms with Character Space Limitations—Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices* ("Internet/Social Media: Character Limitations Draft Guidance").[2] The Office of Prescription Drug Promotion (OPDP) in the Center for Drug Evaluation and Research (CDER) prepared both draft guidances, in consultation with the Center for Biologics Evaluation and Research (CBER), the Center for Devices and Radiological Health (CDRH), and the Center for Veterinary Medicine (CVM). Although the draft guidances do not present binding rules or requirements, they nevertheless provide critical insight into FDA's views on social media communications. Written comments on the draft guidances are due by September 16, 2014.[3]

Internet/Social Media: Correcting Misinformation Draft Guidance

The Internet/Social Media: Correcting Misinformation Draft Guidance sets forth guidelines for when and how manufacturers, packers, and distributors (collectively, "firms") can address incorrect information about their products that is disseminated by third parties on the internet or social media. If a firm voluntarily corrects misinformation in a truthful and non-misleading manner and as described in the draft guidance, FDA will not object if the corrective information otherwise does not satisfy FDA's other labeling or advertising regulatory requirements.

Scope of the Draft Guidance

The draft guidance applies only to misinformation generated by third parties, *i.e.*, user-generated content ("UGC"), that is not controlled, influenced, endorsed, solicited, or adopted by the correcting firm. The draft guidance narrowly defines "misinformation" as "positive or negative incorrect representations or implications about a firm's product created or disseminated by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

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prompted by the firm in any particular."[4] The draft guidance does not apply "if a firm writes, collaborates on, or exerts control or influence on product-specific content provided by a third party, to the extent that responsibility for the development of the content is imputable to the firm."[5]

FDA notes that even when a firm owns or otherwise operates a social media or internet platform on which third parties post misinformation, "[f]irms are generally not responsible for third-party UGC about their products when the UGC is truly independent of the firm (*e.g.*, is not produced by, or on behalf of, or prompted by the firm in any particular)."[6] To ensure that third-party UGC misinformation is not attributed to the firm, FDA suggests that the social media or internet forum contain "an overarching clear and conspicuous statement that the firm did not create or control the UGC."[7] With such a disclaimer, FDA would not hold a firm responsible for subsequent UGC posted on a firm-hosted online discussion about on-label uses.

Appropriate Corrective Information

When there is inaccurate information about a firm's product(s) that meets the definition of third-party UGC misinformation, a firm may respond with truthful and non-misleading corrective information in the same internet or social media platform in which the misinformation appears. Alternately, the firm can direct users to a reputable source from which to obtain correct information (*e.g.*, the firm's Medical Information department). If the firm chooses to respond with truthful and non-misleading corrective information, such information should be:

- Relevant and responsive to the misinformation;
- Limited and tailored to the misinformation – the correction should not be used as an opportunity to introduce unrelated information about the product;
- Non-promotional in nature, tone, and presentation;
- Accurate;
- Consistent with the product's label;
- Supported by "sufficient evidence, including substantial evidence, when appropriate, for prescription drugs"[8];
- Posted in the same area or forum in conjunction with the misinformation, or supplied to the forum operator or author with an intent that it be posted in conjunction with the specific misinformation; and
- Disclose the affiliation of the person/firm providing the corrective information.

Because the corrective information may not necessarily include risk information, the response should include or provide easy access (*e.g.*, a direct hyperlink) to the FDA-required labeling for the product (*e.g.*, Prescribing Information, Instructions for Use) in a format that does not contain promotional content.

Correcting a Clearly Defined Portion of a Forum

When a firm chooses to make multiple corrections in one forum[9], it can do so in the aggregate by: (1) clearly identifying the misinformation that is being corrected, (2) defining the portion of the forum being corrected, (3) correcting *all* misinformation that appears in the *defined portion* of the forum, and (4) providing the date that the correction is posted or provided.

Once the firm decides to respond in the aggregate to correct multiple instances of misinformation in a defined portion of a forum, it should not select only certain misinformation to correct; rather, in this situation, the firm should correct all misinformation in the defined portion of the forum. For example, if a firm corrects negative misinformation about its product, then it also should correct misinformation that overstates the benefits of the product that appears in the same defined portion of the forum. In short, firms should not "cherry pick" the misinformation that it chooses to correct when there are multiple instances of misinformation within a defined forum. The draft guidance does not provide details on how to determine what is considered a defined portion of a forum (*e.g.*, a section of a message board devoted to one topic but with multiple threads, a single message board thread).

Additional Guidelines Regarding Correcting Misinformation

- After misinformation has been corrected, FDA does not expect firms to continue monitoring the forum or original communication.
- FDA does not expect firms to submit the corrective information to the Agency for review, but firms should keep records about the original misinformation and the corrective communication.
- FDA will not hold firms responsible for the failure of the owner of a forum or author of misinformation to correct the misinformation upon the firm's request.

Internet/Social Media: Character Limitations Draft Guidance

The Internet/Social Media: Character Limitation Draft Guidance applies to promotional communications that include benefit information on an internet or social media platform that has character space limitations. The draft guidance provides two specific examples: tweets on Twitter (limited to 140 characters) and online paid search links (*e.g.*, sponsored links Google and Yahoo). The draft guidance specifically excludes a variety of other internet communications—*e.g.*, general product websites, online web banners, and individual product pages on Twitter and other social media platforms—because they "do not impose the same character space constraints as online microblog messaging and online paid search."[10]

For character-limited communications about a product's benefits, FDA's longstanding expectations apply: (1) information should be accurate, non-misleading, and reveal material facts (*e.g.*, limits on the indication or relevant patient population), and (2) the benefit information should be accompanied by pertinent risk information. The draft guidance is thus consistent with the guidelines FDA informally set forth in the fourteen Untitled Letters issued on April 2, 2009 in connection with the use of sponsored links for paid search results.[11]

As described below, the draft guidance provides some flexibility in the precise language used to communicate benefits and risks in a character-limited platform. FDA counsels, however, that if sufficient characters do not remain to communicate risk or indication information, then the firm should "reconsider" using the specific platform for the desired message. The draft guidance notes that character-limited platforms may not be "a viable promotional tool" for discussing benefit information about products with "complex indications or extensive serious risks"[12]; a reminder ad (*i.e.*, mentioning the product name only), however, may be more appropriate where otherwise permissible.

Communication of Risk Information

The draft guidance recommends the following structure for character-limited communications:

1. *Present risk information within each character-limited communication*:
    - Risk information should be presented with benefit information in each character-limited communication. In other words, rather than issuing a series of tweets, some containing benefit information and others containing risk information, FDA suggests that each tweet that contains benefit information also should contain balancing risk information.
2. *Identify the most serious risks*:
    - For prescription drugs and biologics, the most serious risks are risks contained in boxed warnings, risks that are life-threatening or fatal, and contraindications (except for hypersensitivities). If the relevant Prescribing Information does not contain any of these risks, the most significant warnings or precautions should be included in the communication. For devices, FDA expects the inclusion of any specific risks that are associated with particular uses or populations. For animal drugs, the most serious risks are those with potential for injury to human handlers or animal patients and the risk of drug residues entering the human food chain.
3. *Provide a mechanism, e.g., hyperlink, to allow direct access to the full safety/risk information*:
    - FDA suggests that character-limited communications contain a direct hyperlink to a website, PDF, or similar electronic resource that is devoted *exclusively* to the communication of risk information and does not contain any promotional material. Although FDA prefers that the URL itself makes clear that the link leads to a page with risk information (*e.g.*, www.product.com/risk), the draft guidance states that FDA will not object to the use of URL-shortening services (*e.g.*, TinyURL, Google URL Shortener, Bitly). The URL, however, should not be promotional in content or tone.
4. *Ensure comparable prominence of benefit and risk information, taking into account any formatting capabilities available on the platform*:
    - For example, FDA suggests highlighting significant risk information, *e.g.*, boxed warnings, by bolding the text, if possible. If benefits are bolded, then firms should also consider bolding the risks.

Communication of Other Product Information Required by FDA Regulations

To communicate established names, dosage form, and quantitative ingredient information, FDA suggests the following:

- Include both the proprietary (*i.e.*, trade or brand) name and established name (*e.g.*, generic name for a drug) within the character-limited communication. The generic name should be listed directly to the right of, or directly below, the brand name.
- On the landing page of each hyperlink provided in the character-limited communication, state again both the brand and established names. For prescription drugs, firms also should prominently display at least one dosage form and quantitative ingredient information in direct conjunction with the brand and established names; FDA does not suggest that the dosage form and quantitative ingredient information should appear within the character-limited communication itself.

FDA also acknowledges that, in communicating required information, "common abbreviations (including scientific and medical abbreviations), punctuations [sic] marks, and other symbols may, in many cases, reasonably be used to help address character space constraints."[13]

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King & Spalding will continue to monitor FDA's draft and final guidances on social media and other advertising and promotion topics. If you have any questions about how to apply these new guidelines to your advertising and promotional practices, please let us know.

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[1] *Available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM401079.pdf.
[2] *Available at* http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm401087.pdf.
[3] Comments can be submitted electronically at www.regulations.gov or by mail to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be filed by docket number: FDA-2014-D-0397 for the Internet/Social Media: Correcting Misinformation Draft Guidance and FDA-2014-D-0447 for the Internet/Social Media: Character Limitations Draft Guidance.
[4] Internet/Social Media: Correcting Misinformation Draft Guidance at 3.
[5] *Id.* at 4.
[6] *Id.* at 4.
[7] *Id.* at 5.
[8] *Id.* at 6.
[9] Note that FDA repeatedly refers to forums in the draft guidance but does not define the term. It appears that FDA is using the term in a generic sense to refer to whatever internet or social media platform, service, site, or community is at issue. It is unclear whether the term applies broadly (*e.g.* all of Facebook as one forum) or narrowly (*e.g.*, the Facebook page for a particular drug product).
[10] Internet/Social Media: Character Limitations Draft Guidance at 2.
[11] These Untitled Letters are available on FDA's website at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM055773.
[12] Internet/Social Media: Character Limitations Draft Guidance at 5.
[13] *Id.* at 14.