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E-ALERT | Food & Drug

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FDA ISSUES TWO DRAFT GUIDANCE DOCUMENTS CONCERNING INTERNET/SOCIAL MEDIA PLATFORMS

On June 17, 2014, the United States Food and Drug Administration ("FDA")[1] released two, long-awaited draft guidance documents pertaining to the internet and social media platforms:

- *Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices*; and
- *Internet/Social Media Platforms with Character Space Limitations--Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices*.

FDA has attempted to address the issue of internet and social media promotion of FDA-regulated medical products for many years. In 2009, FDA held a two-day public workshop to discuss this topic. However, it was the 2012 Food and Drug Administration Safety and Innovation Act ("FDASIA") that required the Secretary of Health and Human Services to finally issue guidance by July 2014 that "describes [FDA] policy regarding the promotion, using the internet (including social media), of medical products that are regulated by such Administration."[2]

FDA released an earlier internet guidance on January 14 of this year, entitled *Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics* ("January 2014 Guidance").[3] Our analysis of the January 2014 Guidance is available here.

Comments and suggestions regarding the two newly-published draft guidance documents should be submitted by September 15, 2014.

"Correcting Independent Third-Party Misinformation" Guidance

Summary of Guidance

This draft guidance outlines FDA's current thinking concerning how manufacturers, packers, and distributors ("firms") of drugs, biological products, and medical devices should respond to misinformation about their products when placed on the internet/social media by third parties. FDA recognizes that information created by third parties is not always accurate and may be "dangerous

[1] The Office of Prescription Drug Promotion ("OPDP") in the Center for Drug Evaluation and Research ("CDER") prepared these guidance documents in consultation with the Center for Biologics Evaluation and Research ("CBER"), the Center for Veterinary Medicine ("CVM"), and the Center for Devices and Radiological Health ("CDRH").

[2] 21 U.S.C. 379d-5. Based on *FDA's Guidance Agenda: New & Revised Draft Guidance CDER is Planning to Publish During Calendar Year 2014*, another draft guidance concerning the Internet and social media, *Internet/Social Media Advertising and Promotional Labeling of Prescription Drugs and Medical Devices--Use of Links*, will be published later this year.

[3] The January 2014 Guidance, unlike the two guidance documents issued in June, was not prepared in consultation with CDRH, and was not expressly applicable to device firms.

or harmful to public health." Therefore, the guidance provides firms various methods to correct such misinformation.

Under the guidance, a firm may choose to correct misinformation in certain circumstances, though it is not necessarily required to do so. If a firm corrects the misinformation in the manner recommended, FDA does not intend "to object if the corrective information voluntarily provided by the firm does not satisfy otherwise applicable regulatory requirements regarding labeling or advertising." If a firm corrects the misinformation in a manner inconsistent with the guidance or responds using non-truthful or misleading information, FDA may object if the information provided by the firm does not comply with applicable regulatory requirements related to labeling or advertising.

The draft guidance is not applicable when the firm is responsible for the product communication containing misinformation. According to FDA, a firm "is responsible for communications that are owned, controlled, created, or influenced, or affirmatively adopted or endorsed, by, or on behalf of, the firm." Therefore, a firm would be responsible for promotional communications made by its employees or any agents acting on behalf of the firm. Additionally, this draft guidance does not apply to a firm that "writes, collaborates on, or exerts control or influence on product-specific content provided by a third party."[4]

In contrast, the misinformation draft guidance does apply to firms not responsible for third-party user-generated content ("UGC") when the UGC is "truly independent of the firm…regardless of whether the firm owns or operates the platform on which the communication appears."[5]

Correcting Misinformation

In responding to misinformation, a firm can provide either appropriate truthful and non-misleading corrective information directly on the applicable internet/social media site, or can cite a reputable source that contains the corrective information, such as the contact information for a firm's Medical Affairs Department. As previously highlighted, a firm may decide not to respond to the misinformation at all. Under the guidance, in order for corrective information to be considered "appropriate," FDA recommends that a firm's communication should be:

- relevant and responsive to the misinformation;
- limited and tailored to the misinformation;
- non-promotional in nature, tone, and presentation;
- accurate;
- consistent with FDA-required labeling for the product;
- supported by sufficient evidence (including substantial evidence for prescription drugs);
- posted in conjunction with, or reference, the misinformation; and
- disclose that the person providing the corrective information is affiliated with the firm that manufactures, packages, or distributes the product.

Furthermore, corrective information should be accompanied by the FDA-approved labeling for the product (*e.g.*, the package insert). Such labeling should be provided in a "readily accessible format,"

[4] These two circumstances echo the "influence test" we previously discussed in our client alert addressing the January 2014 Guidance.

[5] However, if the firm owns, operates, or creates the platform on which UGC appears, FDA recommends that the firm should include an "overarching clear and conspicuous statement that the firm did not create or control the UCG."

such as a direct link to the labeling or a link to a PDF containing the labeling. It should not be provided via a link to a promotional website. If the firm provides any additional information outside these outlined corrective actions, then those communications must comply with any applicable FDA labeling or advertising regulatory requirements.

Based on these requirements, it is uncertain how a firm should treat misinformation concerning an "off-label" use of product, since the corrective information must be "consistent with the FDA-required labeling." All the misinformation examples provided in the guidance relate to FDA-approved indications of the product.

FDA acknowledges the vast amount of information located on the internet and social media. As such, even if a firm corrects one instance of misinformation, it is not required to correct every piece of similar misinformation. Yet, FDA recommends that a firm should always:

- clearly identify the particular piece of misinformation it is correcting;
- define the portion of the forum it is correcting;
- correct all misinformation that appears in that defined portion; and
- provide the date the correction was made.

When a firm is defining the portion of the forum it intends to correct, FDA warns that a firm cannot intentionally select only negative misinformation and fail to correct "readily accessible and visible positive information."

Instead of correcting misinformation directly on a forum, a firm may also provide corrective information to the author of the misinformation or the site administrator. FDA does not intend to hold a firm accountable for the failure of a third party to take action in correcting this misinformation. A firm is not required to continuously monitor a site or forum once it has corrected misinformation. Furthermore, the firm does not need to submit information to FDA when correcting misinformation. It is recommended, however, that the firm maintain certain records relating to corrections of misinformation.

"Character Space Limitations" Guidance

Summary of Guidance

This second draft guidance provides FDA's current thinking concerning the presentation of benefit and risk information on electronic/digital platforms that have character space limitations.

FDA's guidance provides examples of platforms to which the guidance applies, such as "tweets" on Twitter and "sponsored links" on search engines, like Google and Yahoo. This guidance does not cover promotion on product websites, webpages on social media networking platforms (*i.e.*, Facebook, YouTube), or online web banners, since FDA has concluded that these forums "do not impose the same character space constraints as online microblog messaging and online paid search." Furthermore, the guidance does not apply to reminder promotions that are exempted from the requirements under the Federal Food, Drug, and Cosmetic Act ("FDCA") for the disclosure of risk information.[6]

FDA recognizes that character space limitations may present hurdles for firms with certain products, like those with complex indications or extensive serious risks. Thus, for these particular products, FDA recommends that the character space limitations imposed by platform providers "may not

[6] *See* 21 C.F.R. §§ 200.200, 201.100(f), 201.105(d)(2), 202.1(e)(2)(i), 801.109(d).

enable meaningful presentations of both benefit and risk…[and] the firm should reconsider using that platform for the intended promotional message."

Stating Both Benefits and Risks

Promotional communications must contain claims about product benefits and risks and must be accurate, non-misleading, and contain material facts (such as limitations to an indication or relevant patient population). Further, the benefits and the risks must be presented in a comparably prominent manner.

The FDA will review two key factors in determining whether risk information is comparable in scope to benefit information: 1) whether the risk information qualifies any representations made about the product, and 2) whether the risk information is presented with a prominence and readability comparable to the benefit claims about the product. In character-space-limited contexts, FDA recommends that the risk information be presented together with the benefit information within each specific individual communication. For example, benefit information could not be one tweet followed by a second tweet containing the risk information. Also, if the internet platform permits different formatting options, FDA recommends that the firm use differences in formatting to underscore significant risk information.

The guidance also provides recommendations of minimum safety information that should be included in character-space-limited internet contexts. Given the space limitations in certain internet forums, FDA's guidance recommends that a firm should at a minimum list the following "most serious risks" associated with a given product:

Prescription human drugs	All risk concepts from a boxed warning, all risks known to be fatal or life-threatening, and all contraindications from the approved product labeling; if a prescription human drug does not have any of these types of risks, then the most significant warnings or precautions should be listed.
Animal drugs	Potential injury to human handlers/animal patients and risk of drug residues entering the human food chain.
Medical Devices	Any particular risk associated with an identifiable use or population.

In any of these instances, a mechanism--like a hyperlink--should be provided with the communication to allow for direct access to a "more complete discussion of risk information about the product." This link should connect to a landing page that is "devoted ***exclusively*** to the communication of risk information about the product" (emphasis added).

Finally, in addition to risk/benefit information and in accordance with the FDCA[7], FDA recommends that firms should communicate both the proprietary (trade/brand) name and the established name in these types of communication. The generic name should be listed to the right or below of the brand name. Furthermore, on the landing page of each listed hyperlink, firms should list both the brand and established names. For prescription drugs, firms should prominently display at least one dosage form and quantitative ingredient information. And, in order to meet the character-limit requirements on these forums, firms can use common abbreviations, including scientific and medical abbreviations.

[7] Sections 502(e), (n), and (r). *See also* 21 C.F.R 201.10(g)(1) and 202.1(b)(1).

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