CLIENT UPDATE

FDA ISSUES PROPOSED GUIDANCE ON SOCIAL MEDIA AND INTERNET COMMUNICATIONS FOR PHARMACEUTICAL AND MEDICAL DEVICE MANUFACTURERS

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Last week, the FDA issued two draft Guidance for Industry documents which are the first in a series of long-anticipated guidance documents addressing prescription drug and medical device manufacturers' online product communications.

The first proposed Guidance, *Internet/Social Media Platforms with Character Space Limitations—Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices*, requires that manufacturers using social media services such as Twitter include information about product risks in addition to benefits in their product communications. The second proposed Guidance, *Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices*, establishes a safe harbor that permits manufacturers to correct misstatements posted on the Internet by independent third parties without triggering application of the FDA's full labeling and advertising regulations.

Although the Guidance documents are relatively narrow, manufacturers now have valuable new information to guide their use of Internet and social media platforms. However, the Guidance documents also raise some important issues that may warrant comment from the industry before they are finalized.

MANUFACTURERS MUST INCLUDE PRODUCT RISK INFORMATION EVEN IN LIMITED CHARACTER SOCIAL MEDIA AND INTERNET COMMUNICATIONS

Guidance for Industry *Internet/Social Media Platforms with Character Space Limitations—Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices* ("Limited Character Space Guidance") applies only to electronic and digital media platforms with limited character space, such as Twitter (which limits messages to 140 characters) and sponsored links. The Guidance requires that drug and device manufacturers using social media to communicate about FDA-regulated products include risk information in addition to statements about product benefits, regardless of character space constraints. Manufacturers must also include the brand and generic names of the medication, and a hyperlink to a full description of the product's risks.

The Guidance directs that benefits and risks be presented accurately and in a comparably prominent manner, and lists several factors to consider when determining what information to include.

- Benefit information should be accurate, non-misleading, and reveal material facts within the same communication.
- Benefits and risks must be presented within the same communication and risks must be presented as prominently as benefits.
- The content of the risk information must include at least the most serious risks associated with the product.

The Guidance advises that, when deciding whether to utilize social media, manufacturers should consider whether they can adequately include within the limited space provided accurate and non-misleading information about benefits, the most serious risks, and other required information. Where this is not possible – for example, where a product carries a black-box warning or has significant risks – the Guidance suggests that manufacturers refrain from using limited character communications to promote their products. The Guidance notes that reminder communications remain exempt from risk disclosure requirements.

MANUFACTURERS MAY CORRECT MISINFORMATION POSTED ON THIRD-PARTY WEBSITES WITHOUT ADHERING TO FULL LABELING AND ADVERTISING REGULATIONS

Guidance for Industry *Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices* ("Correction of Misinformation

Guidance") permits drug and medical device manufacturers to correct misstatements posted on the Internet by independent third parties without triggering the full panoply of FDA regulations relating to labeling and advertising, such as fair balance and full risk disclosure. To fit within the safe harbor, the correction must be accurate, narrowly tailored to address the misstatement, and accompanied by a link to a website or PDF containing the product's FDA-required labeling. Links to promotional websites may not be included, even if the website contains labeling information.

The Guidance is limited in scope to the correction of user-generated comments ("UGC") posted by independent third parties, not to communications created or controlled by a manufacturer.[1] An open forum hosted by a manufacturer will be considered independent as long as there is a clear and conspicuous statement that the manufacturer does not create or control the UGC. Manufacturers are permitted to define the scope of the information they are correcting, as long as they are explicit about the scope of the response and as long as the corrective communication addresses the comment in full. For example, a manufacturer can respond to one comment on a blog as long as the correction explicitly refers to that comment, without being held responsible for correcting every comment on the blog. Manufacturers also must be consistent – they cannot correct misinformation that portrays a product in a negative light while leaving unaddressed statements that overstate a product's benefits.

The Guidance proposes the following criteria for a communication to be considered an appropriate corrective action that meets the requirements of the safe harbor:

- Be relevant and responsive to the misinformation.
- Be limited and tailored to the misinformation.
- Be accurate.
- Be consistent with the FDA-required labeling for the product.
- Be supported by sufficient evidence, including substantial evidence, where appropriate, for prescription drugs.
- Either be posted in conjunction with the misinformation in the same area of the forum or reference the misinformation.
- Disclose that the person providing the corrective information is affiliated with the manufacturer or the product.

[1] Manufacturers are required to correct any misinformation within communications they create or control, and to ensure such communications are compliant with FDA labeling and advertising requirements.

The Guidance also provides manufacturers with other options for correcting misinformation, including contacting the author to request that he or she remove the misinformation or permit corrective comments to be posted.

FDA TAKES AGGRESSIVE VIEW OF MANUFACTURERS' RESPONSIBILITY FOR CONTENT

Another aspect of the Correction of Misinformation Guidance that warrants mention is the FDA's relatively aggressive stance on the scope of communications for which manufacturers will be held responsible (and which must therefore comply with all FDA requirements). The Guidance takes the position that manufacturers are responsible for the content of communications even if they merely "influence" them – a broad and undefined term that potentially could encompass a wide variety of relationships. For example, the Guidance suggests that if a manufacturer compensates a blogger for work unrelated to his or her blog, the manufacturer could be held responsible for communications posted by the blogger. This could impose a responsibility on manufacturers to monitor the communications of anyone with whom the manufacturer has a financial relationship to ensure that statements about the company's products are compliant with FDA labeling and advertising requirements. Not only would this impose an onerous burden, but a manufacturer's ability to effect modifications to third-party communications of this type is highly unlikely in many circumstances.

NEXT STEPS

Manufacturers have 90 days to submit written comments to the FDA. Members of industry should carefully review the Guidance documents and consider their potential impact on future communications. In addition to the FDA's broad view of manufacturers' responsibility for content reflected in the Correction of Misinformation Guidance, the requirements imposed by the Limited Character Space Guidance may well render communications of this type impracticable. Requiring inclusion of material benefit and risk information, in addition to the product brand name, generic name, and a hyperlink to a website all in the same communication, will likely make the use of limited character space communications difficult or impossible for a considerable number of drugs and devices.

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Please do not hesitate to contact us with any questions.

June 27, 2014