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FDA ISSUES DRAFT GUIDANCE ON PROMOTION ON INTERNET AND SOCIAL MEDIA PLATFORMS

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On June 17, 2014, the FDA issued long-awaited draft guidance documents addressing two challenges related to use of social media to communicate about FDA regulated products: dissemination of information in character-limited forums and the correction of third-party misinformation. While helpful in certain respects, these draft guidance documents reveal a reluctance by the agency to modify existing policies to accommodate unique characteristics of social media.

Draft Guidance for Industry on Internet/Social Media Platforms with Character Space Limitations – Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices

This **draft guidance** addresses presentation of information on product risks and benefits in the context of electronic/digital platforms with character and space limitations. These include "microblog" platforms like Tweets and online sponsored links rather than to product websites or webpages on social networking platforms like Facebook, Twitter, or YouTube.

The agency makes clear that its general "fair balance" requirement with regard to risks and benefits applies in these settings, stating as follows:

Regardless of character space constraints that may be present on certain Internet/social media platforms, if a firm chooses to make a product benefit claim, the firm should also incorporate risk information within the same character-space-limited communication. The firm should also provide a mechanism to allow direct access to a more complete discussion of the risks associated with its product.

The draft guidance provides the following specific guidance for presenting risk and benefit information in these settings:

- Risk information should be presented together with benefit information within each individual character-space-limited communication; and
- The content of risk information presented within *each* individual character-space-limited communication should, at a minimum, include the most serious risks associated with the product (*i.e.*, all risk concepts from a boxed warning, all risks that are known to be fatal or life-threatening, and all contraindications from the approved product labeling).

The requirement of this scope of risk information may effectively eliminate character restricted platforms as a promotional tool for many medical products.

Draft Guidance for Industry Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices

This **draft guidance** addresses incorrect user-generated content ("UGC") that may appear in a firm-sponsored forum or independent forum. The specific concern of the draft guidance is third-party "misinformation," which it defines 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 promoted by the firm in any particular." (Emphasis added.) The draft guidance thus does not apply where a firm writes, collaborates on, or exerts control or influence over the third-party content and is held responsible for the information. This would include corrections of information in a forum that is monitored and edited by the firm.

The draft guidance provides that firms are generally not responsible for truly independent UGC about

their products even if the firm owns or operates the platform, but "might be responsible for UGC that they solicit or influence, regardless of the forum."

Where a firm wishes to correct misinformation about its products, the draft guidance states that the firm will not be held to the full array of requirements for promotional labeling and advertisements if the firm provides "appropriate corrective information" that is:

- Relevant and responsive to the misinformation;
- Limited and tailored to the misinformation;
- Non-promotional in nature, tone, and presentation;
- Accurate and not misleading;
- Consistent with the FDA-required labeling for the product; and
- Supported by sufficient evidence, including substantial evidence when appropriate, for prescription drugs.

The corrective information must be posted either in conjunction with the misinformation in the same area or forum, or references the misinformation and is intended to be posted in conjunction with the misinformation if provided to the forum operator or author. It must disclose that the person providing the corrective information is affiliated with the firm that manufactures, packs, or distributes the product and FDA-required labeling must be included or provided in a readily accessible format, such as a link to full labeling information.

The draft guidance further provides that a firm that corrects misinformation on one or more occurrence in one forum (*e.g.*, website) should correct all misinformation in the clearly defined portion of the forum it identifies, but it is not obligated to continually monitor the forum or communication. However, to the extent that a firm responds to misinformation by including information that goes beyond corrective information (*i.e.*, slogans, patient profiles, marketing campaign materials), such communications must comply with any FDA regulatory requirements related to labeling or advertising. Although firms need not submit their corrections to the agency, the draft guidance advises that they keep records to respond to agency questions regarding the firm's correction activities.

Comment Period

Companies have 90 days from the publication date, June 18, to submit comments and suggestions concerning these draft guidance documents. Companies marketing prescription drugs, biologics, and devices should review these draft guidance documents and consider whether to comment. Companies should also consider compliance during the interim. Although these are draft guidance documents that are not legally binding, they reflect the agency's current thinking.