

Social Media Draft Guidance Webinar Q&A's (July 10, 2014)

Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics

Q1: Is a firm responsible for User Generated Content (UGC) that is independent of the firm?

A1: A firm generally is not responsible for UGC that is truly independent of the firm (i.e., is not produced by, or on behalf of, or prompted by the firm in any particular). FDA will not ordinarily view UGC on firm-owned or firm-controlled venues, such as blogs, message boards, and chat rooms, as promotional content on behalf of the firm as long as the user has no affiliation with the firm and the firm had no influence on the UGC.

Q2: Have the requirements changed for the submission of static promotional materials?

A2: FDA's expectations remain unchanged for submitting static promotional materials (e.g., sites that do not allow for real-time communications and emails with predetermined content) that are substantially similar to traditional promotional materials in presentation and content.

Internet/Social Media Platforms with Character Space Limitations—Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices

Q1. Does this draft guidance apply to space limitations imposed by mobile devices?

A1: This draft guidance does not address technology-specific layout features that may result in product promotion presentations that differ depending on the technology used to view them (e.g., mobile devices, desktop computer monitors, and tablets). The scope of this draft guidance is specific to Internet/social media platforms that impose *character* space limitations.

Q2: When will this draft guidance be finalized?

A2: The draft guidance is open for comment at any time, but FDA particularly encourages interested parties to submit comments within the first 90 days, to ensure that those comments are considered during the development of final guidance. FDA will consider the comments it receives during this initial period before the draft guidance is finalized. As a reminder, we encourage you to submit comments to both the character space limitations and correcting misinformation draft guidances by September 16, 2014.

Q3: Does this draft guidance apply to reminder promotions?

A3: No, this draft guidance does not apply to those reminder promotions (labeling or advertising that calls attention to the name of a drug or device but does not include indications, dosage recommendations, or other information) that are exempted by regulation from the requirements under the Federal Food, Drug, and Cosmetic Act for the disclosure of risk information.

Q4: Is it really necessary to require firms to include risk information when space is so limited? Will consumers really benefit from this information?

A4: Regardless of the platform chosen by product manufacturers and their representatives to put forth product information, truthful, accurate, non-misleading, and balanced communications about medical products best serve the public health. The character space limitations addressed in this draft guidance are imposed by the private platform providers (e.g., by Twitter or Google). If manufacturers choose to use these platforms, the draft guidance provides recommendations to help manufacturers who choose to make benefit claims to also provide risk information. The examples in the draft guidance demonstrate that it is feasible to do so for certain products. However, for some products, particularly those with complex indications or extensive serious risks, character space limitations imposed by platform providers may not enable meaningful presentations of both benefit and risk (although they may be sufficient for “reminder” promotions). If an accurate and balanced presentation of both risks and benefits of a specific product is not possible within the constraints of the platform, then the firm should reconsider using that particular platform for the intended promotional message (other than for permitted reminder promotion).

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

Q1: Is it really appropriate for companies to correct misinformation by third parties? Is this corrective information subject to labeling and advertising requirements?

A1: While the correction of misinformation is a voluntary activity, it may benefit the public health for companies to correct misinformation about their products (including, for example, situations in which a company is aware of misinformation that may be dangerous or harmful to the public health). When a company voluntarily undertakes the correction of misinformation in a truthful and non-misleading manner pursuant to the recommendations in this draft guidance, FDA does not intend to object if these voluntary corrections do not satisfy otherwise applicable regulatory requirements, if any. If a company chooses to provide information outside the scope of this draft guidance, the company should ensure the information it provides complies with any applicable requirements related to labeling or advertising.

To clarify, this means that if companies choose to correct misinformation and do so as set forth per the specific recommendations in this draft guidance, FDA does not intend to object if the company’s voluntary correction of misinformation does not meet otherwise applicable regulatory requirements, if any.

Q2: Will FDA actively monitor the Internet/social media to ensure manufacturers are correcting misinformation according to FDA’s draft guidance?

A2: FDA’s guidance does not establish legal requirements, but monitoring for compliance with underlying statutory and regulatory requirements, where applicable, is one component of FDA’s multi-faceted program for the oversight of prescription drugs and medical devices. Manufacturers are not obligated to correct misinformation. If manufacturers choose to correct information, and do so in accordance with the recommendations of the draft guidance, FDA does not intend to object if the company’s voluntary correction of misinformation does not meet otherwise applicable regulatory requirements, if any.

In general, monitoring compliance with underlying statutory and regulatory requirements, where applicable, is an important part of our efforts to encourage voluntary compliance by industry, which also includes our work on guidances, advisory comments on draft promotional materials, and outreach to our stakeholders; in some cases, we may also pursue enforcement action. FDA’s top priorities in this area are policy and guidance development, labeling reviews, core launch reviews and TV ad reviews, enforcement, and training and communications. We use a risk based approach to carefully allocate our resources among these activities to have the greatest beneficial public health impact.