

Regulatory Alert Responding to Unsolicited Requests via Social Media

January 5, 2012

Analyst: Dale Cooke

EXECUTIVE SUMMARY

On December 27, 2011, the Food and Drug Administration (FDA) released a draft Guidance to Industry: Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices. This guidance is the first of the so-called social media guidances that FDA has released. While this document does not address every issue associated with the use of social media, it does include numerous specific examples with direct bearing on communication channels widely employed in marketing prescription medicines and medical devices. Specifically, in light of this guidance, marketers have further information about the use of microblogging sites (such as Twitter) and patient testimonials.

In light of this guidance, companies should take the following actions:

1. Avoid using microblogging sites (such as Twitter) for announcing results of clinical trials related to unapproved uses of a medical product.
 2. Review all plans for soliciting information from consumers about their experiences with medical products (so-called "patient testimonials") in light of FDA's position on social media video postings.
 3. Ensure that all discussions of off-label information are handled by their medical affairs department, including social media discussions.
 4. Adopt a policy of directing discussions about off-label information away from public forums and instead use one-on-one communication (whether online or offline) with appropriate recordkeeping.
-

BACKGROUND

In November 2009, FDA held hearings about the promotion of FDA-regulated products using social media and the Internet. Following the hearings, FDA announced the intention to release draft guidance for industry in this area. From the start, FDA declared that the subject was too large and diverse for a single, comprehensive guidance. Instead, they declared their intention to provide a series of guidances on smaller areas of this broad topic. This guidance is the first in this series. We expect additional guidances to follow.

ITEMS OF NOTE

The examples in FDA guidances are always illustrative, and the examples provided here continue that trend. When discussing the question of whether a given request is solicited or unsolicited, two examples stand out for their wide ranging implications regarding social media and Internet promotion.

Microblogging

When discussing the crucial issue of whether a request for off-label information is solicited or unsolicited¹, the guidance discusses the use of Twitter.

Example 10: If a firm announces results of a study via a microblogging service (e.g., Twitter) and suggests that an off-label use of its product is safe and effective, any comments and requests

received as a result of the original message about the off-label use would be considered solicited requests. (Responding to Requests, p. 6)

This example merits careful consideration for a number of reasons. First, although much of the guidance mentions the importance of limiting discussions of off-label information to medical-science liaisons, this example does not take into account such nuances. Instead, it appears to set up a blanket prohibition on the use of microblogging services for announcing study results for off-label uses. No mention is made of what account is used. Would it matter if the account were @Company or @Company_MSL or @Company_Finances instead of @Brand? What if the Tweet itself didn't mention any product by name but instead merely mentioned that new study results were available and directed to a website hosting a press release?²

Perhaps the final guidance will resolve these finer details. For now, though, companies using microblogging services should be wary of releasing any information that is not on label.

Patient Testimonials

YouTube is the most popular location for viewing videos online, yet FDA-regulated products have little presence on YouTube.³ One of the examples presented by the FDA in this guidance could further inhibit forays into YouTube by FDA-regulated marketers.

Example 8: A firm asks or otherwise encourages users to post videos about their own uses of its product on third-party video-sharing sites (e.g., YouTube), which may result in video postings about an off-label use of its product. If the firm's initial request for posting of videos results in any questions about off-label uses, or if any off-label video posting made in response to the firm's encouragement of video postings results in questions about the product's off-label use, these questions would be considered solicited requests. (Responding to Requests, p. 5)

It is important to note what this example does NOT do. This example does not provide a blanket prohibition on the use of YouTube by FDA-regulated companies, nor does it completely prohibit the solicitation of video comments from patients.

But one of the major activities of people on YouTube—and one of the main appeals of this video-based social media site—is sharing personal experiences, and participating in the dialogue generated by that sharing. Marketers in other industries have been actively encouraging this behavior. FDA appears to be actively discouraging such behavior regarding prescription medicines and medical devices as doing so would entail a significant risk that someone might discuss or request information about off-label uses, a communication for which FDA would then hold the company accountable.

This is another area that would benefit from further clarification by the FDA. Makers of medical products would seem to be one of the primary actors with a motivation to encourage people to share their experiences. Such sharing can be extremely beneficial both for the individual patients and from a public health perspective because adverse reactions are more likely to come to light. By clearly stating an intention to hold companies accountable for any off-label presentations that result, FDA is setting up a barrier to uncovering such information.

In addition, the specific example of creating a video to share is one instance of a larger phenomenon called user-generated content (UGC). UGC can take many forms including blogging, posting videos, or creating online images and characters. Companies that make medical products regulated by the FDA have been slow

to venture into this arena, and most of their efforts are tightly restricted, precisely out of fear that users might go beyond the approved uses. FDA appears to be validating those fears.

Responding to Unsolicited Requests: One-on-One Communication is Preferred

FDA distinguishes public from non-public requests for information, and for non-public/private requests for off-label information, FDA sets out a clear procedure for responding:

1. Provide information “only to the individual making the request directly to the firm as a private, one-on-one communication.” (Responding to Requests, page 7)
2. Information provided “should be tailored to answer only the specific question(s) asked.” (Responding to Requests, page 7)
3. Information “should be truthful, non-misleading, accurate, and balanced.” (Responding to Requests, page 8)
4. Information “should be scientific in nature.” (Responding to Requests, page 8)
5. Information “should be generated by medical or scientific personnel independent from sales or marketing departments.” (Responding to Requests, page 8)
6. Provide in addition to the specific off-label information requested:
 - Current Labeling
 - “A prominent statement notifying the recipient that FDA has not approved or cleared the product as safe and effective for the use addressed in the materials provided” (Responding to Requests, page 9)
 - A “prominent statement” of the approved indication(s)
 - “A prominent statement providing all important safety information including, if applicable, any boxed warning for the product” (Responding to Requests, page 9)
 - Complete references for the off-label information
7. Maintain records of the request including:
 - “The nature of the request for information, including the name, address, and affiliation of the requestor” (Responding to Requests, page 9)
 - What information was provided
 - Any follow-up by the requestor

For public requests, FDA advises firms to take the conversation private. “A firm’s **public** response to public unsolicited requests for off-label information about its named product should be limited to providing the firm’s contact information and should **not** include any off-label information.” (Responding to Requests, page 11, emphasis in original) Publicly, the firm is advised to indicate that the request is for off-label information and provide contact information “for the medical or scientific personnel or department (e.g., e-mail address, telephone number, facsimile)” so requestors can follow up for a “non-public, one-on-one communication.” (Responding to Requests, page 11)

Note that FDA is NOT limiting the further communication to offline channels. Indeed, FDA mentions “e-mail address” as one of the means that further communication about off-label information can continue. So, it is consistent with this guidance to provide off-label information in response to specific requests online; however, doing so should be conducted via one-on-one communication, not by posting the information to an area that is accessible to the public. So, again, FDA’s guidance on how to respond to public requests for off-label information is to take the discussion private and follow the procedure outlined for a private request.

RECOMMENDATIONS

We should expect to hear more from the FDA about social media. Until then, this first guidance provides greater clarity on FDA's thinking about these issues, and gives marketers some much-needed guidance about how to proceed. Extracting from the procedures outlines above, companies should take the following actions:

1. Avoid using microblogging sites (such as Twitter) for announcing results of clinical trials related to unapproved uses of a medical product.
2. Review all plans for soliciting information from consumers about their experiences with medical products (so-called "patient testimonials") in light of FDA's position on social media video postings.
3. Ensure that all discussions of off-label information are handled by their medical affairs department, including social media discussions.
4. Adopt a policy of directing discussions about off-label away from public forums and into private, one-on-one communication channels.

ENDNOTES

- ¹ The distinction between solicited and unsolicited requests for information is crucial because it is impermissible to solicit such requests. The guidance spends two and a half pages on this distinction. Draft Guidance for Industry Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices ("Responding to Requests"), pages 4-6. Last accessed January 3, 2012, from <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm121568.htm>
- ² On some of the ways to use social media, see Digitas Health's "Online Sharing: What Pharma CAN Do," released on August 17, 2010, and available at <http://www.scribd.com/doc/36090621/Updated-Digitas-Health-Online-Sharing-POV>
- ³ In November 2011, comScore released rankings for online video in the US that showed Google (overwhelmingly dominated by YouTube) as having 152 million unique visitors. The next closest site was VEVO with 55 million. comScore's rankings also showed YouTube dominating in total videos viewed and minutes spent on the site. Last accessed January 3, 2012, from http://www.comscore.com/Press_Events/Press_Releases/2011/12/comScore_Releases_November_2011_U.S._Online_Video_Rankings