

Five Things You Need To Know About the Recent FDA Guidance

At the very end of 2011, the FDA issued a draft guidance entitled “**Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices.**” While [this latest FDA response](#) is couched in the language of “guidance” and “recommendations,” a careful reading reveals some clear directives that firms would be wise to heed.

1. Firms should not actively solicit off-label questions.

“FDA considers requests for off-label information that are prompted in any way by a manufacturer or its representatives to be solicited. Such solicited requests may be considered evidence of a firm’s intent that a drug or medical device be used for a use other than that specifically approved or cleared by FDA.”

The new guidelines examine more than half a dozen tactics that firms have apparently been using to generate interest in off-label uses. These tactics rely on both digital and traditional communications channels.

For example,

“If a firm provides a phone number, e-mail address, uniform resource locator (URL), or username that is a word, alpha phrase, or alpha representation implying the availability of off-label information for its product, requests using this phone number, e-mail address, URL, or username would be considered solicited requests.”

Although not specifically stated, one can infer from the FDA’s numerous and detailed examples of soliciting off-label questions that this is an area that the Agency will be watching closely. While digital media may have raised some shades of grey about what constitutes solicitation of off-label use, the new guidelines are now very clear: If a firm does anything, in any channel, that drives off-label discussion—directly or indirectly—then the FDA will consider the resulting discussion as solicited, with the resulting patient questions being seen as potential evidence that the firm is deliberately expanding usage without clearance.

2. The FDA recognizes that legitimate, unsolicited off-label questions arise in both public and private communication. In both public and private channels, however, firms should respond in a private and non-promotional manner.

“FDA has long taken the position that firms can respond to unsolicited requests for information about FDA-regulated medical products by providing truthful, balanced, non-misleading, and non-promotional scientific or medical information that is responsive to the specific request, even if responding to the request requires a firm to provide information on unapproved or uncleared indications or conditions of use. If responses to unsolicited requests fall within these parameters, FDA has not expected those responses to meet regulatory requirements for promotional labeling or advertising and has not considered these responses as evidence of intended use.”

3. Marketing personnel should not be involved in responding to off-label questions.

“FDA recommends that questions or requests about off-label uses be referred to the firm’s medical or scientific representative or department. FDA recommends that medical or scientific personnel have specialized backgrounds in responding to unsolicited requests for information, including important training, such as appropriately narrowing questions, tailoring responses only to the specific questions being asked, providing unbiased responses, and properly documenting responses.”

4. In situations where off-label comments have been posted in public forums, firms are encouraged to provide accurate, non-promotional information.

The final section of the FDA document provides detailed guidance about responding to unsolicited public requests for off-label information that are received through emerging electronic media.

“...because firms usually have robust and current information about their products, it can be in the best interest of public health for a firm to respond to unsolicited requests for information about off-label uses of the firm’s products that are made in public forums, especially since other responders may not provide or have access to the most accurate and up-to-date medical product information.”

5. Individual representatives of a firm can now directly respond to public off-label comments, with certain restrictions.

Finally, the new guidelines address how representatives of a firm may interact and respond to public, off-label comments.

“FDA recommends that a representative who responds to a public request clearly disclose in his/her public response that he/she is a particular firm’s representative and inform the requestor of the name of the firm representative or department to contact should the individual choose to follow up directly with the firm in a non-public forum for detailed information about the unsolicited request for off-label information.”

“A public response should include a mechanism for providing readily accessible current FDA-required labeling, if any, for the product (e.g., FDA-approved package insert and, if the response is for a consumer, FDA-approved patient labeling or, for new animal drugs, FDA-approved client information sheet). The public response should not provide any promotional information. For example, a public online response should include a direct link to the current FDA-required labeling, if any, but should not include links to any other information (e.g., product websites, product promotional materials, firm websites, third-party websites). Furthermore, the uniform resource locator (URL) or web address where viewers are directed to obtain the FDA-required labeling, if any, should not itself be promotional in tone or content (e.g., should not be www.bestcancercure.com).”

Conclusion

While nothing in this FDA guidance is particularly groundbreaking, it does provide some welcome clarity about what industry should avoid—i.e., soliciting off-label comments even in an indirect fashion. It also provides new clarity on what to pursue—namely, active, measured response to off-label comments that occur in the online world. There is now a 90-day window for public response to this guidance, so it will be interesting to see what additional discussion and thinking may emerge on this topic. We’re hopeful that 2012 may see similar FDA guidance with regard to industry participation in online social communities.