FDA Releases Guidance on Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices

Recently, the Food and Drug Administration (FDA) released draft guidance addressing how pharmaceutical and medical device manufacturers and distributors (firms) should respond to unsolicited requests for off-label information about their FDA-approved products. The guidance was issued in response to industry feedback from 2009 hearings regarding social media marketing. It is the first of multiple planned policy recommendations by FDA on marketing practices and emerging electronic media.

Background

In general, firms cannot promote a drug or a medical device for uses other than those approved or cleared by FDA. However, once FDA approval has been attained, products may be used by healthcare professionals for purposes that are not included in FDA approved labeling or statement of intended uses. FDA permits such “off-label” uses because it recognizes that “off-label uses or treatment regimens may be important therapeutic options and may even constitute a medically recognized standard of care.”

The rapid growth of the internet, along with social media tools and other emerging technologies, has made it easier for consumers and healthcare professionals to seek and obtain information about medical treatments and conditions. As a result, FDA acknowledges that firms may encounter requests for off-label information about their products at an increasing rate and in manners that were not available previously, especially through social media.

The guidance focuses on unsolicited requests for off-label information. Unsolicited requests are those initiated by persons or entities that are independent of a firm. In the guidance, FDA divides unsolicited requests for off-label information into two categories: (i) non-public unsolicited requests and (ii) public unsolicited requests. While firms may choose to respond to unsolicited requests for off-label information, they are not required to do so. It is only when a firm voluntarily decides to respond to unsolicited requests that FDA recommendations should be observed.
Non-Public Unsolicited Requests

A non-public unsolicited request is a request that is directed privately to a firm using a one-on-one communication method. For example, a consumer may directly call, mail, or email a firm and privately submit a request for off-label information. The important aspect about such requests is that their content or nature is not available to the general public. When responding to non-public unsolicited requests, FDA recommends that:

1. Responses should be limited to the requestor and treated as a private, one-on-one communication.
2. Responses should be tailored to answer only the specific question asked.
3. Responses should be “truthful, non-misleading, accurate, and balanced.”
4. Responses should be scientific in nature.
5. Responses should be generated “by medical or scientific personnel independent from sales or marketing departments.”
6. Responses should be accompanied by several documents, including, but not limited to, a copy of the FDA-required labeling, if any, for the product, a statement notifying the recipient that FDA has not approved the product for the specific off-label use, and a statement providing all important safety information.
7. The responding firm should maintain records, including, but not limited to, information on the nature of the request, the name, address and affiliation of the requestor, and any follow-up inquiries from the requestor.

Public Unsolicited Requests

In contrast, a public unsolicited request is one made in a public forum, whether directed to a firm specifically or to a forum at large, including those encountered through emerging electronic media. Public unsolicited requests may occur where a consumer posts a request for off-label information on the message board of a third party website, or through the use of social networking channels such as Twitter or YouTube. When responding to public unsolicited requests for off-label information, FDA recommends that:

1. A firm should respond only to a request about its own named product, not one solely about a competitor’s product.
2. A firm’s public response “should be limited to providing its contact information and should not include any off-label information.”
3. Representatives that respond on behalf of a firm should clearly disclose their involvement with the firm.
4. Responses “should not be promotional in nature or tone.”
Implications

According to FDA, if a firm responds to unsolicited requests for off-label information in the manner described in the guidance, it does not intend to use such responses as evidence of the firm’s intent that its product be used for an unapproved or uncleared use. In addition, such responses would not be expected to comply with the disclosure requirements usually associated with promotional labeling and advertising.

Adhering to the recommendations in the guidance will likely require firms to train employees and representatives on the appropriate manner to respond to unsolicited requests. Moreover, firms will likely have to monitor social media use by employees and representatives. Firms should also develop record keeping systems to track requests for and responses to unsolicited requests and implement a process to funnel requests to the appropriate medical or scientific personnel.

This communication is being circulated to Shipman & Goodwin LLP clients and friends and does not constitute an attorney client relationship. The contents are intended for informational purposes only and are not intended and should not be construed as legal advice. This may be deemed advertising under certain state laws. © 2012 Shipman & Goodwin LLP.