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Bioscience Alert

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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Recently, the Food and Drug Administration (FDA) released draft guidance addressing how pharmaceutical and medical device manufacturers and distributors (firms) should respond to unsolicited requests for off-label information about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.

Questions?
If you have any questions about this alert, please contact:

David M. Mack
Partner
dmack@goodwin.com
(860) 251-5058

Alex J. Hwang
Associate
ahwang@goodwin.com
(860) 251-5334

Non-Public Unsolicited Requests

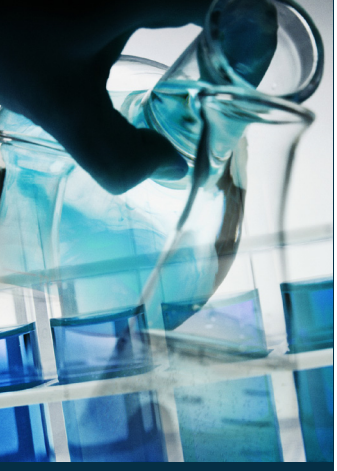
A non-public unsolicited request is a request that is directed privately to a firm using a one-on-one communication method. For example, a consumer may directly call, mail, or email a firm and privately submit a request for off-label information. The important aspect about such requests is that their 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.

One Constitution Plaza
Hartford, CT 06103-1919
860-251-5000

300 Atlantic Street
Stamford, CT 06901-3522
203-324-8100

1133 Connecticut Avenue NW
Washington, DC 20036-4305
202-469-7750

289 Greenwich Avenue
Greenwich, CT 06830-6595
203-869-5600

12 Porter Street
Lakeville, CT 06039-1809
860-435-2539

www.shipmangoodwin.com

BIOSCIENCE CLIENT TEAM

If you have questions about this alert, you may contact any member of our Bioscience client team below.

David Mack
860.251.5058
dmack@goodwin.com

Donna Brooks
860.251.5917
dbrooks@goodwin.com

Patrick Fahey
860.251.5824
pfahey@goodwin.com

Joan Feldman
860.251.5104
jfeldman@goodwin.com

Alex Hwang
860.251.5334
ahwang@goodwin.com

Catherine Intravia
860.251.5805
cintravia@goodwin.com

Gabriel Jiran
860.251.5520
gjiran@goodwin.com

Lina Estrada McKinney
860.251.5660
lmckinney@goodwin.com

Matthew Monteith
860.251.5784
mmonteith@goodwin.com

William Roberts
860.251.5051
wroberts@goodwin.com

James Schulwolf
860.251.5949
jschulwolf@goodwin.com

J. Dormer Stephen
860.251.5938
dstephen@goodwin.com

Marcus Wilkinson
860.251.5937
mwilkinson@goodwin.com

SHIPMAN & GOODWIN LLP®
COUNSELORS AT LAW