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>>ALERT

FDA ISSUES DRAFT GUIDANCE ON RESPONDING TO UNSOLICITED REQUESTS FOR OFF-LABEL INFORMATION

On December 27, 2011, the Food and Drug Administration (FDA) released its draft "Guidance for Industry on Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices," the first of multiple planned draft guidances responding to testimony and comments from 2009 hearings addressing social media marketing by manufacturers and distributors (companies) of prescription human and animal drug products and medical devices.

This first draft Guidance recommends how companies should respond to unsolicited requests for off-label information about their drugs and devices, including requests received through social media. The draft Guidance limits its recommendations to unsolicited requests, which are non-public or public requests initiated by persons or entities that are completely independent of the relevant companies (i.e., requests made by healthcare professionals, academics, patients, and caregivers) about off-label information, which excludes information about approved or cleared indications or conditions of use, for drugs and devices. Requests for off-label information prompted in any way by a company or its representatives are solicited requests outside the scope of this draft Guidance. The FDA's draft Guidance generally advises that companies may respond to unsolicited requests for off-label information about drugs and devices by providing "truthful, balanced, non-misleading, and non-promotional scientific or medical information that is responsive to the specific request," providing specific examples and direction depending on whether the request was made publicly or privately.

NON-PUBLIC UNSOLICITED REQUESTS

Non-public unsolicited requests for off-label information may be received by mail, e-mail, telephone, or through a firm-controlled website (for example, an individual making a request directly to the company as a private, one-on-one communication). The FDA recommends that a company's response to a non-public unsolicited request should be provided only to the individual making the request, and information distributed in response to an unsolicited request should be tailored to answer only the specific question or questions asked.

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THE BOTTOM LINE

Although not as expansive as the healthcare marketing industry had anticipated, the draft Guidance nonetheless provides a helpful framework for companies to follow when responding to unsolicited requests for off-label information, especially when received via social media channels. Manufacturers and distributors of prescription drug products and medical devices should familiarize themselves with the FDA's draft Guidance to ensure their responses to unsolicited requests for off-label information are in line with the FDA's recommendations and examples, so that these responses do not convey a company's intent that a drug or device be used for a new unapproved or unclear use.

PUBLIC UNSOLICITED REQUESTS

Public unsolicited requests for off-label information may be received via a company's websites, discussion boards, chat rooms, or other public electronic forums maintained by and/or under the control of the company (for example, an individual posting a question on a company's Facebook page). A company may also encounter public requests for off-label information on third-party sites, including where questions are directed to website users at large.

In situations involving public requests, the draft Guidance's recommendations include the following:

- a company should respond only when the request pertains specifically to its own named drug or device (and is not solely about a competitor's drug or device);
- information about a company's named drug or device should be limited to providing the company's contact information and should not include any off-label information;
- a response should convey that the question pertains to an unapproved or un-cleared use of the drug or device and state that individuals can contact the medical/scientific representative or medical affairs department with the specific unsolicited request to obtain more information;
- representatives who provide public responses to unsolicited requests for off-label information should clearly disclose their involvement with a particular company;
- a response should include a mechanism for providing readily accessible current FDA-required labeling, if any, for the product; and
- a response should not provide any promotional information.

Companies should look out for further updates as this draft Guidance is finalized and the related draft guidances addressing social media marketing for the healthcare industry are released.

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