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February 8, 2012

FDA Releases Draft Guidance for Industry on Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices

RESOURCE LINKS

FDA Draft Guidance
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM285145.pdf

IMPORTANT DATES

Comments Due:
March 29, 2011

On December 27, 2011, the U.S. Food & Drug Administration ("FDA"), Office of Prescription Drug Promotion ("OPDP") (formerly the Division of Drug Marketing, Advertising, and Communications) released a new draft guidance document titled "Guidance for Industry on Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices" (the "Draft Guidance").[1] The OPDP will accept comments on the Draft Guidance through March 29, 2011.[2]

The FDA has a longstanding policy of permitting pharmaceutical manufacturers to respond to unsolicited requests for medical information about their products, even where such information pertains to unapproved products or uses.[3] However, there has been considerable debate over what constitutes "unsolicited" in this regard. In July 2011, a group of seven manufacturers filed a "citizen petition" with the FDA, requesting FDA clarification of the following issues: (1) Manufacturer Responses to Unsolicited Requests; (2) "Scientific Exchange"; (3) Interactions with Formulary Committees, Payors, and Similar Entities; and (4) Dissemination of Third-Party Clinical Practice Guidelines.[4]

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[1] Available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM285145.pdf.

[2] Submit electronic comments on the Draft Guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

[3] See 59 Fed. Reg. 59820, 59823 (Nov. 18, 1994) (stating that manufacturers may respond to unsolicited requests for information with "responsive, nonpromotional, balanced scientific information, which may include information on unapproved uses, without subjecting their products to regulation based on the information"). Additionally, under Section 401 of the Food and Drug Administration Modernization Act ("FDAMA"), 21 U.S.C. § 360aaa *et seq.*, Congress codified that the FDAMA provisions regarding disseminating written information about unapproved uses should not "be construed as prohibiting a manufacturer from disseminating information in response to an unsolicited request from a health care practitioner." However, FDAMA Section 401 ceased to be effective on September 30, 2006.

[4] *See* Citizen Petition on Behalf of Allergan, Inc.; Eli Lilly and Company; Johnson & Johnson; Novartis Pharmaceuticals Corporation; Novo Nordisk, Inc.; Pfizer, Inc.; and sanofi-aventis U.S. LLC (July 5, 2011).

The Draft Guidance relates only to the first of these requests. The Draft Guidance further states that it is not intended to address unsolicited requests for information about products that are not approved for any use.

Significantly, the Draft Guidance clarifies that the FDA continues to believe that appropriate responses to unsolicited requests for off-label information will not be cause for enforcement action. However, the FDA states that responding to "unsolicited requests" in a way other than as set forth in the Draft Guidance "would not constitute a per se violation of the law, but could potentially be introduced as evidence of a new intended use."

Among other things, the Draft Guidance attempts to clarify parameters regarding responding to requests for information through "emerging electronic media," which would include many so-called "social media" tools (with the FDA specifically citing examples, such as blogging, YouTube, and Twitter). The Draft Guidance also draws a distinction between "public" unsolicited requests for off-label information and "non-public" unsolicited requests for off-label information. A "non-public" request is "directed privately to a firm using a one-on-one communication approach." A "public" request is "made in a public forum, whether directed to a firm specifically or to a forum at large." Some examples of "public" forums cited in the Draft Guidance include product websites, discussion boards, chat rooms, or other public electronic forums that manufacturers maintain and over which they have full control. The Draft Guidance also contemplates manufacturer participation in "third-party sites (i.e., websites and other venues that are either entirely independent of a firm's control and influence or not fully controlled by a firm)" as "public" communication. In general, the Draft Guidance requires that 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."

Accordingly, manufacturers will want to carefully review the Draft Guidance in connection with the current policies and procedures, and should also consider whether to submit comments to the FDA. In this regard, the FDA specifically invites comments on the following:

> (1) Whether the proposed collection of information [for example, any requirement in the Draft Guidance to submit reports, keep records, or provide information to a third party] is necessary for the proper performance of the FDA's functions, including whether the information will have practical utility;
>
> (2) The accuracy of the FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
>
> (3) Ways to enhance the quality, utility, and clarity of the information collected; and
>
> (4) Ways to minimize the burden of information collected on the respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

In addition, however, manufacturers should evaluate whether there are more substantive concerns or clarifications needed regarding the Draft Guidance. Particular areas of comment may pertain to, for

example, social media implications of the "public" and "solicited" request guidance, website design parameters, speaker programs, and medical affairs issues.

While the Draft Guidance is significant in that it addresses certain "unsolicited request" forums that have not been expressly addressed by the FDA in previous guidance, the FDA's general position on unsolicited requests, as articulated in the Draft Guidance, does not represent a vast departure from its previous communications regarding unsolicited requests. The difference is the level of specificity provided in the Draft Guidance and the stringent parameters articulated regarding "public" responses to unsolicited requests.

Epstein Becker Green is available to assist with drafting and submitting comments to the Draft Guidance.

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For more information about this issue of *IMPLEMENTING HEALTH AND INSURANCE REFORM*, please contact one of the authors below or the member of the firm who normally handles your legal matters.

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