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FDA Requests Comments on Draft Guidance on Responding to Unsolicited Requests for Off-Label Information, and on Certain Other Policies Regarding Off-Label and Pre-Approval Promotion

In two separate announcements, the Food and Drug Administration ("FDA" or "Agency") is requesting (1) comments and suggestions regarding a draft guidance entitled *Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices* ("Draft Guidance") and (2) comments and information regarding scientific exchange related to both off-label promotion and pre-approval promotion of drugs and medical devices. The former document is slated for publication in the Federal Register on December 30, 2011, and comments will be due by March 29, 2012. The latter notice was published in the Federal Register on December 28, 2011, and comments are due by March 27, 2012.

Draft Guidance on Unsolicited Requests

FDA's Draft Guidance addresses two types of unsolicited requests for off-label information about drugs and medical devices: non-public unsolicited requests and public unsolicited requests. A "non-public unsolicited request" is described in the Draft Guidance as "an unsolicited request that is directed privately to a firm using a one-on-one communication approach." The Draft Guidance provides the following recommendations with respect to a firm's responses to such non-public requests:

1. Responses should be provided only to the individual making the request directly to the firm as a private, one-on-one communication.
2. The response should be tailored to answer only the specific question(s) asked.
3. Responses should be truthful, non-misleading, accurate and balanced.
4. The response should be scientific in nature.
5. Responses should be generated by medical or scientific personnel; sales or marketing personnel should have no input on the content of such responses.
6. Responses should be accompanied by the following:
    a. A copy of the FDA-approved labeling;
    b. A prominent statement that the FDA has not approved or cleared the product as safe and effective for the use at issue;
    c. A prominent statement disclosing the indication(s) for which the FDA has approved or cleared the product;
    d. A prominent statement providing all important product safety information including, if applicable, any boxed warning; and
    e. A complete list of references.
7. Certain types of records should be maintained.

A "public unsolicited request" is described in the Draft Guidance as "an unsolicited request made in a public forum, whether directed to a firm specifically or to a forum at large." The Draft Guidance makes the

following recommendations with respect to such public requests, "including those encountered through emerging electronic media":

1. The firm should respond only to requests that pertain specifically to its own product.
2. The firm's public response should be limited to its contact information and should not include any off-label information.
3. Representatives who provide responses should clearly disclose their affiliation.
4. Responses should not be promotional in nature or tone.

Interested parties may submit comments on the Draft Guidance by March 29, 2012.

Request for Comments on Scientific Information

FDA noted in its request for comments on scientific information that a citizen petition was submitted last July on behalf of seven manufacturers requesting clarification on certain of the Agency's policies relating to off-label and pre-approval promotion. Specifically, the petition requested clarification on FDA's policies on responses to unsolicited requests, scientific exchange, interactions with formulary committees and payors, and dissemination of third-party clinical practice guidelines.

The FDA's notice states that the Agency is requesting "detailed comment on all aspects of scientific exchange communications and activities related to off-label uses of marketed drugs, biologics, and devices and use of products that are not yet legally marketed." In addition, the Agency is particularly interested in responses to the following questions:

- How should FDA define scientific exchange?
- What types of activities fall under scientific exchange?
- What types of activities do not fall under scientific exchange?
- Are there particular types and quality of data that may indicate that an activity is, or is not, scientific exchange?
- In what types of forums does scientific exchange typically occur?
- What are the distinctions between scientific exchange and promotion?
- Who are the speakers involved in scientific exchange, and who is the audience for their communications?
- Should the identity of the participants be given particular significance in determining whether an activity is scientific exchange versus product promotion?
- How do companies generally separate scientific roles and promotional roles within their corporate structures?
- How should FDA treat scientific exchange concerning new uses under FDA-regulated investigation versus uses that are not under such regulation?
- How should the Agency treat scientific exchange concerning use of products that are not yet legally marketed?
- Should investigational drugs and investigational devices be treated the same with respect to scientific exchange?
- What actions, other than those specified in the regulations, indicate the commercialization of drugs and/or devices?

FDA's notice explains that it is seeking responses to these questions to assist with its evaluation of its policies on communications and activities related to off-label and pre-approval promotion. Interested stakeholders may submit comments by March 27, 2012.

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