Contains Nonbinding Recommendations
Draft – Not for Implementation

Guidance for Industry

Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices

DRAFT GUIDANCE

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Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation Research (CBER)
Center for Veterinary Medicine (CVM)
Center for Devices and Radiological Health (CDRH)

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Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You may use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title pages of this guidance.

I. INTRODUCTION

This draft guidance is intended to describe the Food and Drug Administration's (FDA or Agency) current thinking about how manufacturers and distributors (firms) of prescription human and animal drug products (drugs) and medical devices (devices) can respond to unsolicited requests for information about unapproved or uncleared indications or conditions of use (off-label information) related to their FDA-approved or cleared products.[1,2] This draft guidance updates and clarifies FDA's policies on unsolicited requests for off-label information, including those that firms may encounter through emerging electronic media.

[1] This draft guidance has been prepared by the Office of Prescription Drug Products (OPDP) in the Center for Drug Evaluation and Research (CDER) in consultation with the Center for Biologics Evaluation Research (CBER), the Center for Devices and Radiological Health (CDRH), and the Center for Veterinary Medicine (CVM).

[2] The recommendations in this draft guidance also apply to biological products that are approved for marketing under section 351 of the Public Health Service Act (PHS Act). Because each biological product also meets the definition of "drug" or "device" under the Federal Food, Drug, and Cosmetic Act (FD&C Act), it is also subject to regulation under provisions of the FD&C Act applicable to drugs or devices, as well as the regulations implementing these provisions, except that a biological product licensed under section 351 of the PHS Act is not required to have an approved new drug application under section 505 of the FD&C Act. (See PHS Act section 351(j), 42 U.S.C. 262(j).)

In addition, the term "approved or cleared product" in this draft guidance encompasses devices that are legally marketed for a specific intended use without an individual product approval or substantial equivalence determination (clearance). This includes class I and class II devices marketed for uses that make them exempt from premarket notification, in accordance with sections 510(l) or (m) of the FD&C Act (21 U.S.C. 360(l) & (m)). As a result, with regard to such products, a request for "off-label information" refers to any request for information regarding a new use for which approval or clearance would be required. This draft guidance does not address devices solely intended for use in animals.

This draft guidance does not address requests for information about approved or cleared indications or conditions of use (on-label information) for FDA-regulated medical products. It also does not address requests for information about medical products that are not currently approved or cleared for any purpose.

FDA's guidance documents, including this draft guidance, do not establish legally enforceable rights or responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

The Federal Food, Drug, and Cosmetic Act (FD&C Act) and FDA's implementing regulations prohibit manufacturers and distributors (firms) from introducing new drugs, new animal drugs, and most Class III medical devices into interstate commerce for any intended use that FDA has not determined to be safe and effective. The FD&C Act and FDA's implementing regulations also prohibit device firms subject to premarket notification requirements under section 510(k), which includes most class II and some class I devices, from introducing such devices into interstate commerce for any intended use that is outside FDA's substantial equivalence determination (clearance) for such devices.[3] Statements that promote a drug or medical device for uses other than those approved or cleared by FDA may be used as evidence of a new intended use. Introducing a product into commerce for such a new intended use without FDA approval or clearance would, under these requirements, generally violate the law. However, once a drug or medical device has been approved or cleared by FDA, generally, health care professionals can lawfully use or prescribe that product for uses or treatment indications that are not included in the product's approved labeling[4] (or, in the case of a medical device cleared under the 510(k) process, in the product's statement of intended uses). FDA recognizes that these off-label uses or treatment regimens may be important therapeutic options and may even constitute a medically recognized standard of care.

Scientific or medical departments within drug or medical device firms often maintain a large body of information about their products. This information typically includes data and other information consistent with the approved or cleared indications or conditions of use for their products, but may also include off-label information for their products. As noted, although dissemination of off-label information can be used as evidence of new intended uses for products in distribution, such information may also be of use to individuals seeking information about a

[3] See e.g., sections 505(a), 501(a), 301(d), 501(f)(1)(B) and 502(o) of the FD&C Act; 21 U.S.C. 355(a), 351(a), 331(d), 351(f)(1)(B) and 352(o).

[4] See sections 512(a)(4) and (a)(5) of the FD&C Act and this Agency's regulations at 21 CFR part 530 for specific provisions related to the off-label (or extra-label) use of approved animal and human drugs in animals.

medical product for themselves, patients, family members, or friends. These individuals sometimes submit non-public requests for off-label information directly and privately to firms.

The rapid growth of the Internet, including social media tools and other emerging technologies, has made it easier for both consumers and health care professionals to quickly seek information about medical conditions and treatments.[5] Many firms have also used emerging electronic media to disseminate product information. As a result, firms may encounter requests for off-label information about their products through product websites, discussion boards, chat rooms, or other public electronic forums that they maintain and over which they have full control. In addition, 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) also may reveal questions about off-label uses of a firm's products. These questions about off-label uses are typically directed to users of the site at large, rather than directly and privately to firms. Such posted information is likely to be available to a much broader audience than just the original requester, especially because communication threads (i.e., questions and replies) are often available for an indefinite period of time.

This draft guidance provides FDA's recommendations to firms wishing to respond to unsolicited requests for off-label information, including both requests made directly and privately to firms and requests made in public forums, including through emerging electronic media. FDA recognizes that firms are capable of responding to requests about their own named products in a truthful, non-misleading, and accurate manner. Furthermore, as these firms are regulated by FDA and have robust and current information about their products, FDA recognizes that it can be in the best interest of public health for a firm to respond to unsolicited requests for information about off-label uses of the firm's products that are addressed to a public forum, as other participants in the forum who offer responses may not provide or have access to the most accurate and up-to-date information about the firm's products.

If a firm responds to unsolicited requests for off-label information in the manner described in this draft guidance, FDA does not intend to use such responses as evidence of the firm's intent that the product be used for an unapproved or uncleared use. Such responses would also not be expected to comply with the disclosure requirements related to promotional labeling and advertising. Firms may choose to respond to unsolicited requests for information about off-label uses of their approved or cleared products in a manner other than that recommended in this draft guidance. Such activity would not constitute a per se violation of the law, but could potentially be introduced as evidence of a new intended use.[6]

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[5] For example, the public is able to obtain information on certain clinical trial results from www.ClinicalTrials.gov. This may include information related to off-label uses. This information may generate questions directly to a firm.

[6] This draft guidance is not intended to suggest that receiving an unsolicited request is the only circumstance in which a firm can disseminate information about unapproved uses of its FDA-regulated products without such dissemination being used as evidence of the firm's intent that the product be used for an unapproved use. For example, FDA has developed separate guidance that addresses manufacturer-initiated distribution of reprints regarding off-label uses. See *Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference*

III. DETERMINING WHETHER A REQUEST IS UNSOLICITED OR SOLICITED

This draft guidance addresses how to respond to ***unsolicited requests*** for off-label information about drugs and medical devices. To illustrate the difference between unsolicited and solicited requests, this section describes these two categories of requests and presents a number of examples of both types of requests.

A. Unsolicited Requests

Unsolicited requests are those initiated by persons or entities that are completely independent of the relevant firm. (This may include many health care professionals, health care organizations, members of the academic community, and formulary committees, as well as consumers such as patients and caregivers). Requests that are prompted in any way by a manufacturer or its representatives are not unsolicited requests. Two types of unsolicited requests are addressed in this draft guidance: non-public unsolicited requests and public unsolicited requests. Responses to unsolicited requests can likewise be non-public (private) or public.

- Non-public unsolicited requests

A non-public unsolicited request is an unsolicited request that is directed privately to a firm using a one-on-one communication approach.

Example 1: An individual calls or e-mails the medical information staff at a firm seeking information about an off-label use. In this case, neither the request nor the response would be visible to the public.

- Public unsolicited requests

A public unsolicited request is an unsolicited request made in a public forum, whether directed to a firm specifically or to a forum at large.

Example 2: During a live presentation, an individual asks a question, directed to a firm's representative but heard by other attendees, regarding off-label use of a specific product. This request is a public request. Similarly, a response by the firm that is conveyed to the same audience as the original question would be considered a *public response*.

Example 3: An individual posts a question about off-label use of a specific product on a firm-controlled website (or a third-party discussion forum) that is visible to a broad audience. The request could be directed to a firm specifically or posed to users of a discussion forum at large.

Publications on Unapproved New Uses of Approved Drugs and Approved of Cleared Medical Devices, available at http://www.fda.gov/RegulatoryInformation/Guidances/ucm125126.htm.

This request is a public online request. Similarly, a response by the firm that is visible to the same audience as the original question would be considered a *public online response*.

B. Solicited Requests

FDA considers requests for off-label information that are prompted in any way by a manufacturer or its representatives to be solicited. Such solicited requests may be considered evidence of a firm's intent that a drug or medical device be used for a use other than that specifically approved or cleared by FDA. Although not exhaustive, the following examples illustrate what FDA generally considers to be solicited requests for off-label information[7]:

Example 4: If a firm's sales representative mentions a use of a product that is not reflected in the product's approved labeling and invites a health care professional to request more information, resulting requests would be considered solicited requests.

Example 5: If a representative of a firm, such as a medical science liaison or paid speaker (e.g., key opinion leader), presents off-label use data at a company-sponsored promotional event (e.g., a dinner) and attendees then ask or submit requests for more information, these requests would be considered solicited requests.

Example 6: If a firm issues to health care professionals business reply cards that are intended for use in requesting off-label information, presents statements or contact information in promotional pieces in a manner that solicits requests for off-label medical or scientific information (e.g., "Product X continues to be evaluated in more than 50 trials in a broad range of conditions and patients" and "Call 1-800-… for more information"), or displays a commercial exhibit panel suggesting a new indication (e.g., a sign that reads "Coming Soon, a new use for Product X"), requests made in response to these types of prompts would be considered solicited requests.

Example 7: If a firm provides a phone number, e-mail address, uniform resource locator (URL), or username that is a word, alpha phrase, or alpha representation implying the availability of off-label information for its product, requests using this phone number, e-mail address, URL, or username would be considered solicited requests.

Example 8: A firm asks or otherwise encourages users to post videos about their own uses of its product on third-party video-sharing sites (e.g., YouTube), which may result in video postings about an off-label use of its product. If the firm's initial request for posting of videos results in any questions about off-label uses, or if any off-label video posting made in response to the firm's encouragement of video postings results in questions about the product's off-label use, these questions would be considered solicited requests.

[7] The focus of this draft guidance is unsolicited requests for off-label information, not compliance with provisions of FDA's advertising and labeling regulations for drugs. We note, however, that in some of the following examples, a firm's activities that serve to solicit the requests for off-label information may themselves give rise to specific regulatory violations.

Example 9: If a firm sends out packets of information to known bloggers or online consumer reviewers and encourages them to write about an off-label use of its product on third-party sites and this then provokes a discussion about that off-label use, any requests inquiring about the product's off-label use as a result of these blogs, whether posted as comments to the third-party site or directed to the firm, would be considered solicited requests.

Example 10: If a firm announces results of a study via a microblogging service (e.g., Twitter) and suggests that an off-label use of its product is safe and effective, any comments and requests received as a result of the original message about the off-label use would be considered solicited requests.

Example 11: If a firm sets up a website that enables viewers to read prepared standard responses for the firm's products that are generated from prefixed pull-down menus naming various disease states, including any standard responses related to off-label uses for the firm's product, resulting requests for off-label information would be considered solicited. Moreover, if this website makes it possible to use search terms to generate standard responses that go beyond the scope of the product information being requested, including off-label use information, resulting requests for and responses to such a search would be considered solicited requests.

IV. OVERVIEW OF FDA'S POLICY ON RESPONDING TO UNSOLICITED REQUESTS FOR OFF-LABEL INFORMATION

FDA has long taken the position that firms can respond to unsolicited requests for information about FDA-regulated medical products by providing truthful, balanced, non-misleading, and non-promotional scientific or medical information that is responsive to the specific request, even if responding to the request requires a firm to provide information on unapproved or uncleared indications or conditions of use. If responses to unsolicited requests fall within these parameters, FDA has not expected those responses to meet regulatory requirements for promotional labeling or advertising and has not considered these responses as evidence of intended use. This draft guidance sets forth FDA's current thinking on this topic, consistent with the Agency's past policy statements about responding to unsolicited requests.[8,9] Regardless of whether the initial

[8] This policy was articulated in a letter to industry in 1982 and has been restated on many occasions. See *Position on the Concept of Solicited and Unsolicited Requests* (April 22, 1982) ("[T]he Division of Drug Advertising and Labeling will not regulate as labeling any and all unsolicited requests received from outside the company for information about a drug manufactured, distributed, or repacked by the company. These types of legitimate requests from scientists/individuals for drug information will be regarded and treated as a personal communication between the requestor and firm."); 59 Fed. Reg. 59820, 59823 (November 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"). FDA's current views (expressed in this draft guidance) remain consistent with these past policy statements.

[9] In addition, section 557(a) of the FD&C Act, which expired on September 30, 2006, provided that "nothing in section 551 [of the Act] shall be construed as prohibiting a manufacturer from disseminating information in response to an unsolicited request from a health care practitioner." 21 U.S.C.360aaa-6

unsolicited request for off-label information was made in a non-public or public forum, a firm that chooses to respond should provide the final response containing the requested off-label information about its product only to the specific individual who requested the information as a private, one-on-one communication.

Section V explains in detail FDA's recommendations for firms that choose to respond to non-public unsolicited requests for off-label information, and Section VI addresses FDA's recommendations for firms that choose to respond to public unsolicited requests for off-label information, including those that are encountered through emerging electronic media.

V. RESPONDING TO NON-PUBLIC UNSOLICITED REQUESTS FOR OFF-LABEL INFORMATION DIRECTED TO DRUG OR MEDICAL DEVICE FIRMS

This section of the draft guidance makes recommendations about responding to non-public unsolicited requests for off-label information about prescription human and animal drugs (drugs) and medical devices (devices) specifically directed to firms privately through one-on-one communications. For example, an individual might call or correspond directly with a firm concerning the use of its product for an unapproved or uncleared indication or condition of use. The firm could receive the request by mail, e-mail, telephone, or through a firm-controlled website that enables individuals to privately submit a request directly to the firm so that the request is *not* available to the public.

FDA makes the following recommendations to a firm that is responding to a ***non-public*** unsolicited request for off-label information about its product that was specifically directed to the firm privately through a one-on-one communication.

1. Information distributed in response to an unsolicited request should be provided only to the individual making the request directly to the firm as a private, one-on-one communication.

2. Information distributed in response to an unsolicited request should be tailored to answer only the specific question(s) asked.

A firm should ensure that all pertinent background data are obtained to be able to determine what information is being requested before providing a response. If an unsolicited question is broad in nature, the firm should appropriately narrow the question. In other words, the level of specificity of the question posed is important to ensure that the firm's response is tailored to the request.

Example 12: An individual requests information on the use of a drug or device for one particular disease or condition that is considered off-label for that drug or device (e.g., use of Drug X during pregnancy in patients with diabetes). Generally, a firm should provide information pertaining only to that disease or condition (i.e., the firm should provide a response tailored only to the use of Drug X during pregnancy in patients with diabetes).

However, if there is information about known or suspected *risks* associated with other diseases or conditions that is also relevant to the disease or condition for which information was requested, the firm should provide such information to ensure a complete and accurate presentation of the risk issues associated with the requested use (e.g., Drug X is known to cause fetal harm when used in pregnant patients with arthritis, and this risk information should be disclosed as part of the response about use of Drug X during pregnancy in patients with diabetes).

3. Information distributed in response to an unsolicited request should be truthful, non-misleading, accurate, and balanced.[10]

A response should provide non-biased information or data relating to the particular off-label use that is the subject of the request, including applicable data that are not supportive or that cast doubt on the safety or efficacy of that use. For example, when conclusions of articles or texts that are disseminated have been specifically called into question by other articles or texts, a firm should disseminate representative publications that reach contrary or different conclusions regarding the use at issue. The response should include complete copies of scientific reprints, technical literature, or other scientific and medical information responsive to the request, not just summary documents or abstracts prepared by the firm. The response can include unpublished data on file if they are responsive to the specific request (either supporting or casting doubt on the safety or efficacy of the off-label use). However, to the greatest extent possible, a firm should rely on published peer-reviewed journal articles, medical texts, or data derived from independent sources. To the extent the response consists of published reprints from journals, those reprints should be from journals that have a publicly stated policy, to which the organization adheres, of full disclosure of any conflict of interest or biases for all authors, contributors, or editors associated with the journal or organization.

4. Information distributed in response to an unsolicited request should be scientific in nature.

When responding to an unsolicited request for information, a firm should respond with material that is scientific in tone and presentation. The material should not be promotional in tone or presentation. Furthermore, the responsive material should not be distributed along with other material or information that is promotional in nature or tone.

5. Responses to unsolicited requests for information should be generated by medical or scientific personnel independent from sales or marketing departments.

FDA recommends that questions or requests about off-label uses be referred to the firm's medical or scientific representative or department. FDA recommends that medical or scientific personnel have specialized backgrounds in responding to unsolicited requests for information, including

[10] Evaluating evidence of intended use may also involve considering the context in which manufacturer communication about an off-label use occurs. For this reason, FDA's recommendations in this draft guidance for responding to unsolicited requests for information by third parties are not identical to its recommendations regarding the spontaneous manufacturer-initiated activity of distributing reprints, as addressed in other FDA guidance.

important training, such as appropriately narrowing questions, tailoring responses only to the specific questions being asked, providing unbiased responses, and properly documenting responses.

By contrast, because sales and marketing personnel are focused by training and experience on promoting a firm's products, FDA recommends that sales and marketing personnel have no input on the content of responses to unsolicited questions or requests for off-label information.

6. Information distributed in response to an unsolicited request should be accompanied by the following:

    - A copy of the FDA-required labeling, if any, for the product (e.g., FDA-approved package insert and, if the response is for a consumer, FDA-approved patient labeling or, for new animal drugs, FDA-approved client information sheet)
    - A prominent statement notifying the recipient that FDA has not approved or cleared the product as safe and effective for the use addressed in the materials provided
    - A prominent statement disclosing the indication(s) for which FDA has approved or cleared the product
    - A prominent statement providing all important safety information including, if applicable, any boxed warning for the product
    - A complete list of references for all of the information disseminated in the response (e.g., a bibliography of publications in peer-reviewed medical journals or in medical or scientific texts; citations for data on file, for summary documents, or for abstracts)

7. A firm should maintain the following records:

    - The nature of the request for information, including the name, address, and affiliation of the requestor
    - Records regarding the information provided to the requestor
    - Any follow-up inquiries or questions from the requestor

If a firm responds to non-public unsolicited requests for off-label information in the manner described above, FDA 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. Such responses also would not be expected to comply with the disclosure requirements related to promotional labeling and advertising.

VI. RESPONDING TO PUBLIC UNSOLICITED REQUESTS FOR OFF-LABEL INFORMATION, INCLUDING THOSE ENCOUNTERED THROUGH EMERGING ELECTRONIC MEDIA BY DRUG OR MEDICAL DEVICE FIRMS

This section of the draft guidance makes recommendations about responding to public unsolicited requests for off-label information about prescription human and animal drugs (drugs) and medical devices (devices), including those that are encountered through emerging electronic media.

The Internet has revolutionized communication, information-sharing, information exchange among systems, and collaboration, enabling consumers to become more proactive about their health and safety. Consequently, the Internet has become a widely used medium for manufacturers and distributors of FDA-regulated medical products to disseminate information. The Internet has also spawned a variety of social media tools that host online content primarily created and published by users other than the intellectual property owner or product manufacturer. In some cases, this online content may not be accurate. Because consumers increasingly use the Internet to search for information about medical conditions and treatments, firms may receive public requests for off-label information about their products through, for example, product websites, discussion boards, chat rooms, or other public electronic forums that they maintain and over which they have full control. Firms may also encounter requests for off-label information on 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). Questions about off-label use may be directed to the website users at large, rather than specifically to a firm.

As previously stated in Section II, FDA recognizes that firms are capable of responding to requests about their own named products in a truthful, non-misleading, and accurate manner. Moreover, because firms usually have robust and current information about their products, it can be in the best interest of public health for a firm to respond to unsolicited requests for information about off-label uses of the firm's products that are made in public forums, especially since other responders may not provide or have access to the most accurate and up-to-date medical product information.

However, because product information posted on websites and other public electronic forums is likely to be available to a broad audience and for an indefinite period of time, FDA is concerned that firms may post detailed public online responses to questions about off-label uses of their products in such a way that they are communicating unapproved or uncleared use information about FDA-regulated medical products to individuals who have not requested such information. In this circumstance, communications to persons who have not requested information may promote a product for a use or condition for which FDA has not approved or cleared. FDA is also concerned about the enduring nature of detailed public online responses to off-label questions because specific drug or device information may become outdated (e.g., new risk information may become available).

FDA makes the following recommendations to a firm that chooses to respond to ***public*** unsolicited requests for off-label information about its product(s), including those encountered through emerging electronic media.

1. If a firm chooses to respond to public unsolicited requests for off-label information, the firm should respond only when the request pertains specifically to its own named product (and is not solely about a competitor's product).

The level of specificity of the question posed in a public forum is important in determining the appropriateness of a firm responding to the unsolicited request.

Example 13: An individual poses the specific question "Can Drug/Device X be used for Condition Y" in a public forum (and this question is not prompted by or on behalf of the firm). It may be appropriate for the firm to respond as outlined below because the question is unsolicited and specific to the firm's named drug or device.

However, if an individual poses the non-specific question "What drug/device can be used for Condition Y" in a public communication thread and the firm manufactures or distributes Drug/Device X, which is not FDA-approved or cleared for Condition Y, the firm should not respond to the request because the question is ***not*** specific to Drug/Device X.

2. 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.

    - The firm's public response should convey that the question pertains to an unapproved or uncleared use of the product and state that individuals can contact the medical/scientific representative or medical affairs department with the specific unsolicited request to obtain more information.
    - The firm's public response should provide specific contact information for the medical or scientific personnel or department (e.g., e-mail address, telephone number, facsimile) so that individuals can follow up independently with the firm to obtain specific information about the off-label use of the product through a non-public, one-on-one communication.

After an individual has privately contacted a firm for more information regarding an off-label use of the firm's product, the firm should provide a detailed response and maintain records following the parameters outlined in Section V of this draft guidance. Therefore, any substantive communication about off-label uses for the product, in response to the original unsolicited off-label question, should occur solely between the firm and the individual who made the request. Regardless of the fact that the original, unsolicited off-label question may have been available to a very broad audience, the firm should not make its detailed response with off-label information publicly available within the same forum. For example, after the requestor has contacted the firm and provided a personal e-mail address to obtain an answer to the off-label question, the firm's

detailed off-label response, within the parameters outlined in Section V of this draft guidance, should be e-mailed to the requestor since this resulting communication will occur solely between the firm and the specific individual making the unsolicited request for the off-label information.

3. Representatives who provide public responses to unsolicited requests for off-label information should clearly disclose their involvement with a particular firm.

FDA recommends that a representative who responds to a public request clearly disclose in his/her public response that he/she is a particular firm's representative and inform the requestor of the name of the firm representative or department to contact should the individual choose to follow up directly with the firm in a non-public forum for detailed information about the unsolicited request for off-label information.

4. Public responses to public unsolicited requests for off-label information described in numbers 2 and 3 should not be promotional in nature or tone.

In addition to a firm's contact and disclosure information, a public response should include a mechanism for providing readily accessible current FDA-required labeling, if any, for the product (e.g., FDA-approved package insert and, if the response is for a consumer, FDA-approved patient labeling or, for new animal drugs, FDA-approved client information sheet). The public response should *not* provide any promotional information. For example, a public online response should include a direct link to the current FDA-required labeling, if any, but should *not* include links to any other information (e.g., product websites, product promotional materials, firm websites, third-party websites). Furthermore, the uniform resource locator (URL) or web address where viewers are directed to obtain the FDA-required labeling, if any, should *not* itself be promotional in tone or content (e.g., should not be www.bestcancercure.com).

If a firm responds to public unsolicited requests for off-label information, including those encountered through emerging electronic media, in the manner described above, FDA 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. Such responses also would not be expected to comply with the disclosure requirements related to promotional labeling and advertising.