Guidance for Industry

Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments 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. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (CDER) Julie Chronis at 301-796-1200; (CBER) Office of Communication, Outreach and Development at 800-835-4709 or 240-402-7800; (CVM) Thomas Moskal at 240-276-9300; or (CDRH) Deborah Wolf at 301-796-5732.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Veterinary Medicine (CVM)
Center for Devices and Radiological Health (CDRH)

June 2014
Advertising

Guidance for Industry

Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices

Additional copies are available from:

Office of Communications, Division of Drug Information
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, rm. 2201
Silver Spring, MD 20993-0002
Tel: 301-796-3400; Fax: 301-847-8714;
E-mail: druginfo@fda.hhs.gov
http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm

Communications Staff (CVM)
Center for Veterinary Medicine
Food and Drug Administration
7519 Standish Place, HFV-12
Rockville, MD 20855
Tel: 240-276-9300;
E-mail: AskCVM@fda.hhs.gov
http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm

Office of Communication, Outreach and Development
Center for Biologics Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave., WO71, Room 3128
Silver Spring, MD 20993
Tel: 800-835-4709 or 240-402-7800;
E-mail: ocod@fda.hhs.gov
http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm

Office of the Center Director
Guidance and Policy Development
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 66, rm. 5431
Silver Spring, MD 20993-0002
Tel: 301-796-5900;
E-mail: CDRH-Guidance@fda.hhs.gov
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Veterinary Medicine (CVM)
Center for Devices and Radiological Health (CDRH)

June 2014
Advertising

TABLE OF CONTENTS

Guidance for Industry[1]

Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's or Agency's) 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 can 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 page of this guidance.

I. INTRODUCTION

This draft guidance is intended to describe FDA's current thinking about how manufacturers, packers, and distributors (firms) of prescription human and animal drugs (drugs) and medical devices for human use (devices)[2] should respond, if they choose to respond, to misinformation related to a firm's own FDA-approved or -cleared products when that information is created or disseminated by independent third parties on the Internet or through social media or other technological venues (Internet/social media), regardless of whether that misinformation appears on a firm's own forum or an independent third-party forum or website. This draft guidance responds to (among other things) stakeholder requests for specific guidance regarding a firm's voluntary correction of misinformation when that misinformation is created or disseminated by an independent third party.

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

[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 (21 U.S.C. 355). See PHS Act section 351(j) (42 U.S.C. 262(j)). References to "drugs" and "devices" in this guidance therefore also include biological products that fall within each of those definitions. The recommendations in this draft guidance do not apply to veterinary biological products regulated under the Virus-Serum-Toxin Act (21 U.S.C. 151, et seq.) by the U.S. Department of Agriculture. This draft guidance does not address devices solely intended for use in animals.

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

Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Agency has responsibility for regulating the manufacture, sale, and distribution of drugs and medical devices in the United States. This authority includes oversight of the labeling of drugs and medical devices (21 U.S.C. 352(a)) and the advertising of prescription drugs and restricted medical devices (21 U.S.C. 352(n), (q), and (r)). [3]

Section 201(m) of the FD&C Act defines *labeling* as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article" (21 U.S.C. 321(m)).[4] The U.S. Supreme Court has explained that the language "accompanying such article" in the "labeling" definition is interpreted broadly, to include materials that supplement or explain an article. No physical attachment between the materials and the article is necessary; rather, it is the textual relationship between the items that is significant (*Kordel v. United States*, 335 U.S. 345, 350 (1948)). FDA generally recognizes two types of labeling: (1) FDA-required labeling[5] and (2) promotional labeling. Promotional labeling is generally any labeling, other than the FDA-required labeling, that is devised for promotion of the product. Examples of materials that may be considered promotional labeling pieces for prescription drugs are described in 21 CFR 202.1(l)(2). The scope of labeling requirements for prescription medical devices is described in 21 CFR 801.109.

The FD&C Act does not define what constitutes an "advertisement," but FDA regulations provide several examples, including "advertisements in published journals, magazines, other

[3] Devices may become restricted by regulation issued under section 520(e) of the FD&C Act (21 U.S.C. 360j(e)), by performance standard issued pursuant to section 514(a)(2)(B)(v) (21 U.S.C. 360d(a)(2)(B)(v)), or by order approving an application for premarket approval (i.e., a PMA) pursuant to section 515(d)(1)(B)(ii) (21 U.S.C. 360e(d)(1)(B)(ii)).

[4] See also 21 CFR 1.3(a).

[5] Much FDA-required labeling is subject to FDA review and approval. For example, after drafting by the manufacturer, labeling is reviewed and approved by FDA as part of the new drug application (NDA), new animal drug application (NADA), biologics license application (BLA) or premarket approval application (PMA) review (see 21 CFR 314.50(c)(2), 514.1(b)(3), 601.2(a), 814.20(b)(10), and 814.44(d)). For devices that are subject to premarket notification (510(k)) requirements, the 510(k) must contain the proposed labeling sufficient to describe the device, its intended use, and the directions for its use (21 CFR 807.87(e)). All devices, including those exempt from premarket review, are subject to the requirements of applicable labeling regulations, including requirements for adequate directions for use (see 21 CFR Part 801). For a prescription drug or prescription device to be exempted from the FD&C Act's requirement of adequate directions for use (21 U.S.C. 352(f)(1)), its FDA-required labeling must contain, among other information, information addressing product hazards and other risk information, as specified in FDA regulations (21 CFR 201.100(d)(1), (3), 201.105(c)(1), and 801.109).

periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems" (21 CFR 202.1(l)(1)).

The Internet and Internet-based technologies have made it easier for third parties who are independent of firms to disseminate information about drugs and devices. Information created by third parties (which for purposes of this guidance is *user-generated content* (UGC)) might appear on an interactive portion of a firm-controlled website or other interactive Internet/social media platform, or information might appear on a website or other Internet/social media platform that is independent of, or not under the control or influence of, a firm. Many Internet/social media platforms allow for real-time and continuous communications and interactions (e.g., blogs, microblogs, social networks, online communities, and live podcasts) while other platforms do not provide a means for interactive content to be posted. Whether a forum is interactive may affect the means by which a firm is able to respond to information.

Although the Internet has facilitated the transmission of information, allowing patients and other interested parties the opportunity to share experiences as well as to communicate with others about drugs and devices, UGC might not always be accurate and may be dangerous or harmful to the public health. For the purposes of this draft guidance, *misinformation* is defined as positive or negative incorrect representations or implications about a firm's product created or disseminated by independent third parties who are not under the firm's control or influence and that is not produced by, or on behalf of, or prompted by the firm in any particular. FDA has determined it may benefit the public health for firms to correct misinformation about their products (including, for example, situations in which a firm is aware of misinformation that may be dangerous or harmful to the public health).

If a firm voluntarily corrects misinformation in a truthful and non-misleading manner and as described in this draft guidance, FDA does not intend to object if the corrective information voluntarily provided by the firm does not satisfy otherwise applicable regulatory requirements regarding labeling or advertising, if any. If a firm chooses to respond to misinformation about its products using non-truthful or misleading information or in a manner other than that recommended in this draft guidance, however, FDA may object if the information provided by the firm does not comply with applicable regulatory requirements related to labeling or advertising, if any.

III. DETERMINING WHETHER THIS DRAFT GUIDANCE APPLIES

This draft guidance does not apply when a firm *is* responsible for the product communication that contains misinformation. A firm is responsible for communications that are owned, controlled, created, or influenced, or affirmatively adopted or endorsed, by, or on behalf of, the firm. A firm is thus responsible for communications on the Internet and Internet-based platforms, such as social media, made by its employees or any agents acting on behalf of the firm

to promote the firm's product, and these communications must comply with any applicable regulatory requirements.[6] Firms should not use this guidance in these situations.

> ***Example 1*:** As part of a marketing campaign, a member of a firm's marketing department posts incorrect statements about a product's safety or efficacy compared to the efficacy of a competitor's product on a discussion board hosted by an independent third party. The firm is responsible for the content of the communication because the member of the firm's marketing department is acting on behalf of the firm. Thus, this draft guidance would not apply.

Additionally, if a firm writes, collaborates on, or exerts control or influence on product-specific content provided by a third party, to the extent that responsibility for the development of the content is imputable to the firm, the recommendations set forth in this guidance do not apply. Accordingly, as a general matter, the firm must comply with all applicable regulatory requirements related to labeling or advertising for that content.

> ***Example 2*:** A firm hosts a discussion group on its own website, monitors the discussion for content that does not speak positively about its product, then removes or edits postings that portray its product in a negative light, and adds positive postings about the product. This firm is exerting control over the UGC and is responsible for the resulting content. Thus, the firm's actions would not fall under the scope of this guidance.

In contrast, this draft guidance applies when a firm is *not* responsible for a product-related communication that appears on the firm's own forum, an independent third-party website, or through social media, and the firm chooses to correct misinformation about its own product contained in that communication. In such cases, we recommend that the firm do so as described in this draft guidance.

Firms are generally not responsible for third-party UGC about their products when the UGC is truly independent of the firm (e.g., is not produced by, or on behalf of, or prompted by the firm in any particular) regardless of whether the firm owns or operates the platform on which the communication appears.[7] If the firm owns or operates the platform or created or initiated the

---

[6] For example, with respect to prescription drugs and biologics, firms should consult the draft guidance for industry *Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics* for recommendations regarding how firms can fulfill regulatory requirements for postmarketing submissions of interactive promotional media (e.g., blog, message board, or chat room) for their FDA-approved products. When final, this guidance will represent the FDA's current thinking on this topic. For the most recent version of a guidance, check the FDA Drugs guidance webpage at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

[7] *Cf.* 47 U.S.C. 230(c)(1) ("no provider or user of an interactive computer service shall be treated as the publisher or speaker of any information provided by another information content provider"). The Communications Decency Act further defines "information content provider" as someone "responsible, in whole or in part, for the creation or development of information provided through the Internet or any other interactive computer service" (47 U.S.C. 230(f)(3)).

forum on which such UGC appears, the firm should include an overarching clear and conspicuous statement that the firm did not create or control the UGC.

> ***Example 3:*** A firm becomes aware of a blogger who is posting inaccurate information about the firm's product. The blogger does not have a relationship with the firm and the firm does not compensate the blogger for the blog or for any other activity. The firm is not responsible for the content of the blog. The firm may decide to attempt to correct the misinformation, but it is not obligated to attempt to correct it.
>
> ***Example 4*****:** A firm hosts a discussion forum about its drug's or device's FDA-approved use on its corporate website and does not participate in the discussion, but it does monitor the forum for profanity and obscenity. The forum includes an overarching clear and conspicuous statement that the firm did not create the content of the forum. The firm is not responsible for the information that is posted by independent third parties and can, if it so chooses, correct misinformation according to this guidance.

However, a firm's control over, involvement with, or influence over a product-related communication, even when generated by a third party, may result in the firm being responsible for the information as a promotional communication. Thus, firms might be responsible for UGC that they solicit or influence, regardless of the forum.

IV. RECOMMENDATIONS FOR THE CORRECTION OF MISINFORMATION ABOUT PRESCRIPTION DRUGS AND MEDICAL DEVICES

A. Appropriate Corrective Information

This draft guidance sets forth approaches a firm may use once it decides to voluntarily correct misinformation about its own product that is created or disseminated by an independent third party who is not under the firm's control or influence. In accordance with the approaches discussed below, a firm may choose to provide appropriate truthful and non-misleading corrective information or, alternatively, it may provide a reputable source from which to obtain the correct information, such as the firm's contact information.[8] For purposes of this draft guidance, to be considered "appropriate corrective information," a firm's communication should:

- Be relevant and responsive to the misinformation;
- Be limited and tailored to the misinformation;
- Be non-promotional in nature, tone, and presentation;
- Be accurate;

[8] For example, a firm may choose to provide contact information for the firm's Medical Affairs Department.

- Be consistent with the FDA-required labeling for the product;

- Be supported by sufficient evidence, including substantial evidence, when appropriate, for prescription drugs;

- Either be posted in conjunction with the misinformation in the same area or forum (if posted directly to the forum by the firm), or should reference the misinformation and be intended to be posted in conjunction with the misinformation (if provided to the forum operator or author) (see section IV.B); and

- Disclose that the person providing the corrective information is affiliated with the firm that manufactures, packs, or distributes the product.

Because risk and other information about the product are not necessarily part of corrective information, the FDA-required labeling should be included or provided in a readily accessible format. As two examples, a firm may provide a link that goes directly to the FDA-required labeling or may provide a link that opens a new window to a portable document format (PDF) file. The information should not be provided by including a link to a promotional website even if the information is available on the promotional website. Please note that if the uniform resource locator (URL), web address, or link where viewers are directed to obtain the respective FDA-required labeling is promotional in content or tone, FDA would not consider the corrective information to fall within the scope of this draft guidance.

> ***Example 5*:** A firm discovers a chat room where participants are discussing the firm's product for one of its approved indications—diabetes. The firm finds misinformation posted by an independent third party about the diabetes indication that the firm would like to correct according to this draft guidance. Although the product has multiple approved indications, the firm should limit its corrective information to the relevant diabetes indication being discussed.
>
> ***Example 6*:** An independent third party writes an online post stating that one reason he likes taking a prescription drug (or using a device) is that it has no food restrictions, which is inconsistent with information from the required labeling regarding the need to avoid taking the drug with fatty foods (or to avoid using the device in a certain way). The firm decides to correct the misinformation according to this draft guidance. The firm's representative identifies herself as being affiliated with the firm and posts the corrective information from the required labeling. She also includes a direct link to the FDA-required labeling.

B. Correcting a Clearly Defined Portion of a Forum

FDA recognizes that the Internet, social media, and other technological venues contain a vast amount of information and even one particular forum might have a large quantity of information. It may be difficult for a firm to correct all misinformation about its products in one forum depending on the nature of the forum, the quantity of information, and the length of time the forum encompasses. Furthermore, technologies or platforms that may be used to view the forum

affect what information will simultaneously be displayed to users. In light of these considerations, if a firm corrects one or more occurrences of misinformation, it is *not* expected to correct each piece of misinformation in an entire forum. However, a firm should clearly identify the misinformation it is correcting, define the portion of the forum it is correcting, and should correct all the misinformation that appears in that clearly defined portion. A firm should describe the location or the nature of the misinformation that was corrected and should provide a date the correction is made to ensure that parties reading the information do not assume the firm has responded to the entire forum.

> ***Example 7*:** A firm decides to correct misinformation posted by an independent third party on one page of an interactive website. The misinformation consists of three consecutive sentences about the firm's product. The firm should correct all three sentences. It should provide a statement that the firm is responding only to the specified information on that one page and provide the date the change was made. The firm is not expected to correct misinformation that appears on other webpages of the website.
>
> ***Example 8*:** A firm decides to correct misinformation posted by an independent third party who has commented on a blog that allows comments. The firm should correct each piece of misinformation in the particular comment to which it is responding. The firm should provide a statement that it is responding only to one particular comment along with the date the correction is provided. The firm is not expected to correct misinformation that appears in other comments.

A firm should correct all misinformation in the clearly defined portion of the forum it identifies. For example, if a firm chooses to correct only misinformation that portrays its product in a negative light in a third-party communication but does not address misinformation that overstates the benefits of its product in that same clearly defined portion of the communication, the firm's actions do not meet the recommendations in this draft guidance. Additionally, if a firm chooses to correct more than one piece of misinformation in a forum, the portion of the forum that the firm is expected to correct may be defined, in part, by the locations of the pieces of misinformation the firm corrects and the location of additional pieces of misinformation.

> ***Example 9*:** A firm decides to correct misinformation posted on a blog that allows comments. The firm corrects misinformation in several blog postings that provide incorrect risk information associated with the product and makes clear it is only correcting those pieces of misinformation, but the firm does not address exaggerated efficacy claims in favor of the firm's product in other postings that appear to readers between the postings it is correcting. Even if the firm corrects the misinformation in the limited posts it chose, the firm's actions are not in accord with this guidance because it has intentionally selected only negative information about its product to correct while readily accessible and visible positive misinformation was not corrected.

C. Approaches to Correcting Misinformation

If a firm chooses to correct misinformation, it may do so by correcting misinformation directly on the forum. Alternatively, the firm may provide the corrective information to the independent

author for the author to incorporate; the firm may request that the author remove the misinformation or allow comments to be posted; or the firm may request that the site administrator remove the misinformation or allow comments to be posted. The following are examples of approaches that FDA considers to be within the scope of this draft guidance and that firms may take to correct misinformation.

> ***Example 10*:** A firm encounters misinformation posted by an independent third party about its product on a website sponsored by a patient group. The website allows comments to be posted by viewers. The firm may post corrective information directly on the website.
>
> ***Example 11*:** A firm finds a webpage about its product that was written by an independent third party on an Internet-based, interactive, collaboratively edited encyclopedia. The firm may choose to contact the author of the webpage and provide corrective information to the author.
>
> ***Example 12*:** An independent third party posts a video on a video hosting website about a firm's product. It is not possible for viewers, such as a firm, to post comments about the video. The firm may contact the entity that administers the website and ask that entity to allow comments about the video to be posted so that the firm may post corrective information.

FDA recognizes that a firm cannot control whether an independent third party refuses to correct the misinformation, or corrects only a portion of the misinformation even though the firm provided complete corrective information, or declines to include the respective required labeling, or declines to remove misinformation, or does not correct all the misinformation in one clearly defined part (if the firm sought to correct more than one piece of misinformation). Accordingly, FDA will not hold a firm accountable for an independent third party's subsequent actions or lack thereof.

> ***Example 13*:** A firm finds a webpage about its product that was written by an independent third party on an interactive reference website. The firm contacts the author of the webpage and provides corrective information to the author. The firm is not accountable for the author's subsequent actions or lack thereof.

D. Communications That Fall Outside the Scope of This Guidance

Once a firm undertakes the correction of misinformation, FDA does not expect the firm to continue to monitor the website or communication that previously included UGC containing misinformation. However, when a communication by or on behalf of the firm to the UGC author, site administrator, or the forum goes beyond the correction of misinformation, the communication falls outside the scope of this draft guidance.

> ***Example 14*:** A firm decides to correct misinformation found in a blog entry where the blogger is not affiliated with the firm. The firm is not obligated to continue to monitor the blog although it may choose to do so. The blogger responds to the firm's correction,

disputes the corrective information, and also brings up another facet of the product's adverse event profile. The firm replies with additional corrective information that is consistent with the original corrective information and that corrects the new misinformation about the product's adverse event profile. The blogger replies again and now disputes the effectiveness of the product. The firm responds again with slogans and examples of patient profiles from its marketing campaign. The slogans and patient profiles go beyond providing corrective information. The firm's communications now must comply with any applicable regulatory requirements related to labeling or advertising.

***Example 15*:** An independent third party downplays a labeled contraindication on an email distribution list. A firm provides, to the distribution list recipients, the corrective information regarding the contraindication, and additionally provides information unrelated to the contraindication comparing the safety profile of its product to a competitor's product. The firm's communication goes beyond providing corrective information with respect to the third party's statements about the product's contraindication and, therefore, is not considered to be a correction of misinformation within the scope of this draft guidance.

E. The Consequences of Correcting Misinformation

When a firm voluntarily undertakes the correction of misinformation in a truthful and non-misleading manner pursuant to the recommendations in this draft guidance, FDA does not intend to object if these voluntary corrections do not satisfy otherwise applicable regulatory requirements, if any. If a firm chooses to provide information outside the scope of this draft guidance, the firm should ensure the information it provides complies with any applicable requirements related to labeling or advertising. Information considered to be outside the scope of this guidance includes information that does not meet criteria listed above.

FDA does not expect firms to submit corrections to the Agency when correcting misinformation pursuant to this draft guidance; however, FDA recommends that firms keep records to assist in responding to questions that may come from the Agency. The records should include, for example, the content of the misinformation, where it appeared, the date it appeared or was located, the corrective information that was provided, and the date the corrective information was provided.