4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0447]

Draft Guidance for Industry on Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices." This draft guidance responds to (among other things) stakeholder requests for specific guidance and describes FDA's current thinking on how manufacturers, packers, and distributors (firms) of prescription human and animal drugs (drugs) and medical devices for human use (devices), including biological products, 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. This draft guidance updates and clarifies FDA's policies on the correction of misinformation created or disseminated by independent third parties on the Internet or through social media platforms, regardless of whether that misinformation appears on a firm's own forum or an independent third-party forum or Web site. The draft guidance represents FDA's current thinking on specific aspects of FDA's evolving consideration of social media platforms and other Internet-related matters. FDA continues actively to review, analyze, and develop approaches to a variety of topics related to the labeling and advertising of

medical products, including the development of this and other guidance addressing the use of social media platforms and the Internet.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submit written comments on the proposed collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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; to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002; to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855; or to the 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. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

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.

FOR FURTHER INFORMATION CONTACT:

Regarding human prescription drugs: Julie Chronis, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD 20993-0002, 301-796-1200.

Regarding human prescription biological products: Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

Regarding animal prescription drugs: Thomas Moskal, Center for Veterinary Medicine (HFV-216), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9300.

Regarding medical devices for human use: Deborah Wolf, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3414, Silver Spring, MD 20993-0002, 301-796-5732.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices." On November 12-13, 2009, FDA held a public hearing entitled "Promotion of Food and Drug Administration-Regulated Medical Products Using the Internet and Social Media Tools" to provide an opportunity for broad public

participation and comment on the following questions that relate specifically to promotional issues:

1. For what online communications are manufacturers, packers, or distributors accountable?
2. How can manufacturers, packers, or distributors fulfill regulatory requirements (e.g., fair balance, disclosure of indication and risk information, and postmarketing submission requirements) in their Internet and social media promotion, particularly when using tools that are associated with space limitations and tools that allow for real-time communications (e.g., microblogs and mobile technology)?
3. What parameters should apply to the posting of corrective information on Web sites controlled by third parties?
4. When is the use of links appropriate?

Subsequent to the live testimony heard at the public hearing, FDA received 72 comments to the docket.

This draft guidance provides FDA's recommendations regarding how manufacturers, packers, and distributors of prescription human and animal drugs and medical devices for human use, including biological products, should respond, if they choose to respond, to misinformation created or disseminated by independent third parties related to a firm's own FDA-approved or cleared products on the Internet or through social media platforms.

This draft guidance provides FDA's recommendations to firms that voluntarily choose to correct misinformation that appears on the Internet or through social media platforms. This draft guidance discusses the type of information that is considered misinformation, recommends parameters for corrective information, and recommends approaches to correcting

misinformation. It refers only to misinformation that is created or disseminated by an independent third party and that is not produced by, or on behalf of, or prompted by the firm in any particular. When a firm chooses to correct misinformation in a truthful and non-misleading manner and according to the recommendations 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.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on correcting misinformation created or disseminated by independent third parties. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to

provide a 60-day notice in the Federal Register concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of 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.

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

Description of Respondents: Respondents to this collection of information are manufacturers, packers, and distributors (firms) of prescription human and animal drugs and medical devices for human use, including biological products.

Burden Estimate: The draft guidance pertains to the correction of misinformation created or disseminated by independent third parties related to a firm's own FDA-approved or -cleared products on the Internet or through social media platforms.

The draft guidance explains FDA's current policy position that a firm may voluntarily correct misinformation about its own FDA-approved or -cleared products that is created or disseminated by independent third parties who are not under the firm's control or influence. If a

firm does so in a truthful and non-misleading manner and in accordance with the recommendations in the draft guidance, FDA does not intend to object if the corrective information voluntarily provided by the firm does not satisfy otherwise applicable regulatory requirements related to labeling and advertising, if any.

Because the draft guidance recommends that a firm disclose certain information to others when correcting misinformation created or disseminated by independent third parties, this "third-party disclosure" constitutes a "collection of information" under the PRA. In addition, the PRA is triggered because the draft guidance also recommends that a firm maintain certain records related to this disclosure--the content of the misinformation, where the misinformation appeared, the date the misinformation appeared or was located, the corrective information that was provided, and the date the corrective information was provided.

Specifically, the draft guidance recommends that firms provide appropriate truthful and non-misleading corrective information, or alternatively, it may provide a reputable source from which to obtain the correct information. For the purposes of the 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;
- 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); and
- Disclose that the person providing the corrective information is affiliated with the firm that manufactures, packs, or distributes the product.

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 draft guidance also recommends that a firm correct all the misinformation in one clearly defined portion of a forum, but it is not expected to correct each occurrence of independent third-party misinformation throughout an entire forum. When a firm decides to correct all the misinformation in one clearly defined portion of a forum, the firm should clearly identify the misinformation it is correcting, define the portion of the forum it is correcting, describe the location or the nature of the misinformation that was corrected, and provide a date the correction is made.

A firm may provide the correct information to the independent author for the author to incorporate or request the author remove the misinformation or allow comments to be posted. The firm may request that the site administrator remove the misinformation or allow comments to be posted.

FDA estimates that approximately 400 firms annually undertake correcting 50 pieces of misinformation created or disseminated by independent third parties on the Internet or through

social media. FDA estimates that it will take firms approximately 3 hours to correct misinformation as recommended in the draft guidance.

FDA also estimates that approximately 20,000 records will be maintained by firms that have chosen to correct misinformation created or disseminated by independent third parties on the Internet or through social media and that each record will take approximately 30 minutes to prepare and maintain.

Table 1.--Estimated Annual Recordkeeping Burden[1]

Draft Guidance on Correcting Independent Third-Party Misinformation	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Hours per Record	Total Hours
Records related to the correction of independent third-party misinformation	400	50	20,000	0.5 (30 minutes)	10,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2.--Estimated Annual Third-Party Disclosure Burden[1]

Draft Guidance on Correcting Independent Third-Party Misinformation	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Hours per Disclosure	Total Hours
Corrections of independent third-party misinformation	400	50	20,000	3	60,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

III. Comments

In addition to general comments, FDA specifically requests comments on the following issue: The draft guidance recommends that a firm should identify the misinformation or define the portion of the forum it is correcting and should correct all the misinformation that appears in that clearly defined portion. Is this an appropriate and effective way for firms to correct misinformation without correcting all misinformation that might appear in a forum? When or under what conditions should a sponsor choose a specific portion of a forum to correct? What factors, such as the platform(s) or technology(ies) that can be used to view the forum, the relative location of pieces of misinformation the firm chooses to correct, the nature of the forum, the

quantity of information, and the length of time the forum encompasses, should be taken into account in choosing the portion of a forum to correct?

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

IV. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm, http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm, or http://www.regulations.gov.

Dated: June 13, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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