



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-2285]

Medical Product Communications That Are Consistent With the Food and Drug Administration-Required Labeling--Questions and Answers; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Medical Product Communications That Are Consistent With the FDA-Required Labeling--Questions and Answers.” This draft guidance provides information for manufacturers, packers, and distributors and their representatives (collectively “firms”) of drugs and medical devices for humans, including those that are licensed as biological products, and animal drugs (collectively “medical products”), about how FDA evaluates their medical product communications, including their promotional materials, that present information that is not contained in the FDA-required labeling for the product but that may be consistent with the FDA-required labeling for the product. The Agency is issuing this draft guidance to explain FDA’s current thinking on commonly asked questions regarding such communications in order to provide clarity for firms.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft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].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2016-D-2285 for “Medical Product Communications That Are Consistent With the FDA-Required Labeling-- Questions and Answers; Draft Guidance for Industry; Availability.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed

except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; 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; Division of Small Manufacturers, International and Consumer Assistance, Office of Communication, Education and Radiation Programs, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002; or to Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. 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.

FOR FURTHER INFORMATION CONTACT: Kristin Davis, Office of Policy, Office of the Commissioner, 10903 New Hampshire Ave., Bldg. 32, rm. 4252, Silver Spring, MD 20993-0002, 301-796-0418; or Catherine Gray, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 3203, Silver Spring, MD 20993-0002, 301-796-1200; or 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; or Angela Krueger, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1666, Silver Spring, MD 20993-0002, 301-796-6380; or Thomas Moskal, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl. (HFV-1), Rockville, MD 20855, 240-402-6251.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Medical Product Communications That Are Consistent With the FDA-Required Labeling--Questions and Answers.” This draft guidance provides information for firms about how FDA evaluates their medical product communications, including their promotional materials, that present information that is not contained in the FDA-required labeling¹ for the product but that may be consistent with the FDA-required labeling for the product.

FDA determines whether a medical product is safe and effective for use under the conditions prescribed, recommended, or suggested in the proposed labeling submitted to FDA

¹ As used in the draft guidance, the term FDA-required labeling includes the labeling reviewed and approved by FDA as part of the medical product marketing application review process. For products not subject to premarket approval, but instead subject to premarket notification requirements or exempt from premarket review, the term also includes the labeling relied on to provide adequate directions for use and other information required to appear on the label or in labeling.

with the product's marketing application or submission (and for devices, also during the classification process). In making this determination, FDA evaluates whether the conditions of use in the proposed labeling are supported by the required levels and types of evidence of safety and effectiveness and whether the benefits of using the product under those specific conditions of use outweigh the risks of the product. After FDA approves or clears a medical product, the FDA-required labeling sets forth the conditions of use under which the product has been shown to meet the relevant standard for marketing, and it provides directions and information on how to use the product safely and effectively under those conditions.

Medical product firms have expressed interest in communicating, including in promotional materials, data and information that are not contained in their products' FDA-required labeling but concern the approved/cleared uses of the products. We are aware that firms have questions about how FDA determines when such communications are consistent with the FDA-required labeling, and how they are viewed by FDA.

The draft guidance describes FDA's thinking on these topics. As explained in the draft guidance, a firm's communication of information that is not contained in the product's FDA-required labeling, but that is determined to be consistent with the FDA-required labeling, is not alone considered evidence of a new intended use. However, even if a communication is consistent with the FDA-required labeling, the representations or suggestions made about the product would misbrand the product and could subject firms to enforcement action if the representations or suggestions are false or misleading. Accordingly, the draft guidance both describes FDA's thinking on the types of information that are consistent with the FDA-required labeling and provides general recommendations for how this information can be conveyed in a truthful and non-misleading way. The draft guidance also provides some examples to illustrate

these concepts. The recommendations provided in the draft guidance to help ensure that communications are not false or misleading are specific to communications that are consistent with the FDA-required labeling; communication of information that is not consistent with the FDA-required labeling is outside the scope of these recommendations.

Elsewhere in this issue of the Federal Register, FDA is announcing the availability of a draft guidance for industry entitled “Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities--Questions and Answers.” This draft guidance provides answers to common questions regarding firms’ communications of health care economic information about their approved prescription drugs to payers and similar entities. This draft guidance also addresses common questions relating to firms’ dissemination of information about investigational products to payers before FDA approval or clearance of such products.

In addition, FDA is announcing in this issue of the Federal Register that it is reopening the comment period for the notice of public hearing that appeared in the Federal Register of September 1, 2016, concerning manufacturer communications regarding unapproved uses of approved or cleared medical products. The comment period will be reopened for 90 days, until [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. As announced in the notice of public hearing, FDA is engaged in a comprehensive review of its regulations and policies governing communications by firms about unapproved uses of approved or cleared medical products, and the comments it receives will inform FDA’s policy development in this area.

FDA will consider the feedback it receives in all three of these dockets as the Agency continues to review its policies on firm communications about medical products, and interested

persons may wish to review the documents FDA has issued in all three dockets before submitting comments to any of the relevant dockets.

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 current thinking of FDA on certain commonly asked questions regarding firms' communications for their medical products that may be consistent with the FDA-required labeling. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. 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 to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Recommended Content of Medical Product Communications That Are Consistent With the FDA-Required Labeling.

Description of Respondents: Respondents to the proposed collection of information are manufacturers, packers, and distributors and their representatives (firms) of human drugs and devices, including those licensed as biological products, and animal drugs.

Burden Estimate: The draft guidance includes Third-Party Disclosure recommendations regarding information that firms should include in communications that contain information not found in the FDA-required labeling for their medical products but that are consistent with the FDA-required labeling (as explained in the draft guidance) if they choose to publically disseminate such materials.

Specifically, FDA recommends that various aspects of study design and methodology for studies relied on in such communications be disclosed to provide material contextual information (e.g., type of study, study objectives, product dosage/use regimens, control(s) used, patient population studied), and that material limitations related to the study design, methodology, and results also be disclosed in a clear and prominent manner to help ensure that the communications are not false or misleading.

Furthermore, FDA recommends that firms accurately characterize and contextualize the relevant information about the product, including by disclosing unfavorable or inconsistent findings. FDA also recommends that firms disclose material contextual information from the

FDA-required labeling in these communications, such as data and information from studies in the FDA-required labeling that are relevant to the data or information presented in the communication (e.g., if a communication provides post-market information about the types and rates of occurrence of adverse events that have been observed in practice, the communication should also include information from the FDA-required labeling about the types and rates of occurrence of adverse reactions observed in clinical trials to provide context).

According to FDA data, approximately 162,000 FDA-regulated promotional materials are prepared by approximately 500 firms annually. Of these materials, we estimate approximately 5 percent contain unique presentations of information consistent with FDA-required labeling, as that term is described in the draft guidance, submitted by approximately 64 percent (or 324) of the firms. Anticipating the number of these FDA-regulated promotional materials will soon increase to 6 percent, we estimate the 324 firms will prepare and disseminate annually 9,720 FDA-regulated promotional materials that contain unique presentations of information that is consistent with FDA-required labeling, as that term is described in the draft guidance, and that therefore are recommended to include the proposed third party disclosures. Based on our experience reviewing FDA-regulated promotional materials for medical products, we estimate it will take respondents approximately 4 hours per unique presentation to prepare and incorporate the disclosures recommended in the draft guidance, if they choose to disseminate this information.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Third-Party Disclosure Burden¹

Type of Information	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Recommended information to be included when firms choose to disseminate communications that are consistent with the FDA-required labeling.	324	30	9,720	4	38,880

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

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>,

<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>,

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>,

<http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm>, or <https://www.regulations.gov>.

Dated: January 6, 2017.

Jeremy Sharp,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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