



4164-01-P

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; 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 guidance for industry entitled “Medical Product Communications That Are Consistent With the FDA-Required Labeling--Questions and Answers.” This 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 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 guidance to explain FDA’s current thinking on commonly asked questions regarding such communications to provide clarity for firms. FDA is also announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Submit written comments on the

collection of information by [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-NEW and title “Recommended Content of Medical Product Communications That Are Consistent With the FDA-Required Labeling--Questions and Answers; Guidance for Industry.” Also include the FDA docket number found in brackets in the heading of this document.

You may submit either electronic or written comments on Agency guidances at any time 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): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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; 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 Dockets Management Staff 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 Dockets Management Staff. 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: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this 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 Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7500 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 guidance document.

FOR FURTHER INFORMATION CONTACT: *Regarding the guidance:* 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 Elizabeth Pepinsky, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3248, 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 Ana Loloie Marsal, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5452, Silver Spring, MD 20993-0002, 301-796-8774; or Thomas Moskal, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl. (HFV-216), Rockville, MD 20855, 240-402-6251.

Regarding the information collection: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 11601 Landsdown St., 10A-12M, North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Medical Product Communications That Are Consistent With the FDA-Required Labeling--Questions and Answers.” This guidance provides information for firms about how FDA evaluates their medical product communications (that fall within the scope of FDA’s regulatory authority) 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 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, clears, or licenses 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 told FDA that they are interested in communicating, including in their promotional materials, data and information about the approved/cleared/licensed uses of their products that are not contained in their products’ FDA-

¹ As used in the 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 (510(k)) requirements or exempt from premarket review, the term FDA-required labeling includes the labeling that provides adequate directions for use and other information required to appear on the label or in labeling.

required labeling. We are aware that firms have questions about how FDA determines whether such communications are consistent with the FDA-required labeling.

The guidance describes FDA's thinking when examining the consistency of a firm's product communications with that product's own FDA-required labeling. As explained in the guidance, if a firm communicates information that is not contained in its product's FDA-required labeling but that is determined to be consistent with the FDA-required labeling, FDA does not intend to rely on that communication to establish a new intended use, different from the use(s) for which the product is legally marketed. Establishing a product's intended uses is an element in establishing certain violations under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and Public Health Service Act. However, firms' communications about their products that are consistent with the products' FDA-required labeling but that are false or misleading may subject a firm to enforcement action under the FD&C Act. Thus, the guidance not only describes FDA's thinking on communications that are consistent with the FDA-required labeling, but also provides general recommendations intended to aid firms in complying with requirements in the FD&C Act and FDA's implementing regulations for conveying information that is consistent with the FDA-required labeling in a truthful and non-misleading way. The general recommendations provided in the guidance for conveying information in a truthful and non-misleading way are applicable only to drug and device labeling and prescription drug and restricted device advertising 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.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on 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. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection for OMB review and clearance.

Title: Recommended Content of Medical Product Communications That Are Consistent With the FDA-Required Labeling; OMB Control No. 0910-NEW

The 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 guidance) if they choose to publicly disseminate such materials. The guidance 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. Additionally, the guidance recommends that firms accurately characterize and contextualize the relevant information about the product, including by disclosing unfavorable or inconsistent findings. Finally, the guidance 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).

In the *Federal Register* of January 19, 2017 (82 FR 6575), we published a notice announcing the availability of the draft guidance document and included an analysis under the PRA of the information collection burden associated with our recommendations. No comments were received in response to the four information collection topics solicited in the notice.

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 described in the guidance, submitted by approximately 64 percent (or 324) of the firms. Anticipating that 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 the FDA-required labeling, as described in the 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 guidance, if they choose to disseminate this information.

We therefore estimate the burden of the information collection 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.

FDA is issuing this final guidance subject to OMB approval of the collection of information. Before implementing the information collection provisions of the guidance, FDA will publish a notice in the *Federal Register* announcing OMB's decision to approve, modify, or disapprove the collection of information, including OMB control number(s) for newly approved collections.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>, <https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm>, or <https://www.regulations.gov>.

Dated: June 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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