DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0447]

Addressing Misinformation About Medical Devices and Prescription Drugs: Questions and Answers; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a revised draft guidance for industry entitled ''Addressing Misinformation About Medical Devices and Prescription Drugs: Questions and Answers.'' This revised draft guidance, when finalized, will describe FDA's current thinking on common questions firms may have when voluntarily addressing misinformation about or related to their approved/cleared medical products. This guidance revises and replaces the draft guidance for industry entitled ''Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices'' issued in June 2014. This revised draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by September 9, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance. Submit electronic or written comments on the proposed collection of information in the draft guidance by September 9, 2024.

ADDRESSES: You may submit comments on any guidance 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–2014–D–0447 for ''Addressing Misinformation About Medical Devices and Prescription Drugs: Questions and Answers.'' 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, 240–402–7500.

- 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.govinfo.gov/content/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, 240–402–7500.

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

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; 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; the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002; or the Policy and Regulations Staff, 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 request or include a Fax number to which the draft guidance may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: *With regard to the draft guidance:* Samantha Bryant, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Room 3203, Silver Spring, MD 20993–0002, 301–796–1200; James Myers, 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; Stephanie Philbin, Center for Devices and Radiological Health, Food and Drug Administration,

10903 New Hampshire Ave., Bldg. 66, Rm. 5456, Silver Spring, MD 20993–0002, 301–837–7151; Kathryn Dennehy, Center for Veterinary Medicine (HFV–245), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–7082, *Kathryn.Dennehy@fda.hhs.gov;* or Julie Finegan, Office of Policy, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4252, Silver Spring, MD 20993–0002, 301–827–4830.

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

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised draft guidance for industry entitled ''Addressing Misinformation About Medical Devices and Prescription Drugs: Questions and Answers.'' In addition to describing already existing avenues for communications by firms, the guidance sets out an enforcement policy for certain kinds of internet-based communications that firms might choose to use to address internet-based misinformation about or related to the firm's approved/cleared medical product when that misinformation is created or disseminated by an independent third party. This guidance is not intended to address a firm's correction of its own false or misleading representations about its medical products. For the purposes of this guidance, the term firms refers to the persons or entities legally responsible for the labeling of approved/cleared medical products, which includes applicants, sponsors, manufacturers, packers, distributors, and any persons communicating on behalf of these entities. The term medical product refers to a medical device for human use (including one that is a biological product), a prescription human drug (including one that is a biological product), or a prescription animal drug. The term approved/cleared medical product refers to medical products (as that term is defined in this guidance) that may be introduced into interstate commerce for at least one use under the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Public Health Service Act, and their implementing regulations (collectively, the FDA Authorities) as a result of having satisfied applicable premarket requirements. For ease of reference, when approval and clearance (and similar terms) are used in discussing devices, the terms refer to FDA permitting the marketing of a device via the premarket approval, premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)), De Novo classification, or Humanitarian Device Exemption pathways and to devices that are exempt from premarket notification.

For the purposes of this guidance and as further described in section II of the guidance, the term misinformation refers to implicit or explicit false, inaccurate, or misleading representations of fact about or related to the firm's approved/cleared medical product.

Misinformation about a firm's approved/cleared medical product can cause harm to both individuals and the public health in general. Basing medical decisions on misinformation can lead patients and healthcare providers to choose treatments that are not safe and effective, or forgo treatments that are, which can have adverse consequences. While misinformation can appear in many forms of communication and be shared in many different ways, internet-based forms of communication have enabled misinformation to travel quickly and reach more people who otherwise might not be exposed to that misinformation. Additionally, misinformation about or related to medical products that treat or prevent serious or life-threatening diseases is especially concerning and represents a significant public health concern.

This guidance revises and replaces the draft guidance for industry entitled ''Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices,'' issued in June 2014 (2014 draft guidance). The revised draft guidance reflects the Agency's consideration of feedback from interested parties, including comments received on the 2014 draft guidance. Changes include a revised title, a question-and-answer format, and certain changes in scope. For example, the enforcement policy now extends to a firm's voluntary ''tailored responsive communications'' that address misinformation that suggests that the firm's cleared/approved medical product be used for an unapproved use. Additionally, new content has been added to reflect changes in technology and functionality of internet-based platforms, as well as changes in the way information is shared online to help a firm to have greater flexibility and control over the timing of the firm's communication when the firm chooses to address certain internet-based third-party misinformation with ''tailored responsive communications.'' This guidance also now includes a subsection on ''general medical product communications'' that describes many existing avenues available to firms for communicating information about or related to their approved/cleared medical products. New examples were also added to illustrate the new considerations and recommendations outlined in the guidance and to provide additional clarity to firms.

This revised draft guidance, when finalized, is intended to advance FDA's mission to help members of the public get the accurate, up-to-date, science-based information they need to inform their decisions about medical products to maintain and improve their health. More specifically, the guidance describes two categories of communications firms might choose to use to address misinformation: tailored responsive communications and general medical product communications.

As described in the guidance, a ''tailored responsive communication'' is a firm's voluntary, internet-based communication that identifies and addresses internet-based misinformation about or related to the firm's approved/cleared medical product when that misinformation is created or disseminated by an independent third party.

For the purposes of this guidance, communications through existing avenues are collectively referred to as ''general medical product communications.'' Unlike the tailored responsive communications described in the guidance, general medical product communications are not necessarily internet-based or prompted by or tailored to address specific identified internet-based misinformation. General medical product communications can include, among other things, content and messaging that address misinformation about a firm's approved/cleared medical product. Inclusion in a general medical product communication of content that addresses misinformation creates no special considerations regarding the application of the FDA Authorities or other FDA enforcement policies.

FDA recognizes that misinformation about or related to medical products authorized for emergency use is a public health concern. The Agency continues to evaluate the unique considerations that can apply to communications by firms addressing misinformation about or related to such products. As such, this revised draft guidance does not apply to communications by firms that address misinformation about or related

to an emergency use authorized for the firm's medical product under section 564 of the FD&C Act (21 U.S.C. 360bbb-3), whether that be an emergency use authorized for an ''unapproved use of an approved product'', or an emergency use authorized for an ''unapproved product'', as those terms are used in section 564(a) of the FD&C Act. See section 564 of the FD&C Act for more information on the authorities for emergency use authorizations.

This revised draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The revised draft guidance, when finalized, will represent the current thinking of FDA on ''Addressing Misinformation About Medical Devices and Prescription Drugs: Questions and Answers.'' 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 (PRA) (44 U.S.C. 3501–3521), 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.

Disclosures for Tailored Responsive Communications Addressing Misinformation About Medical Devices and Prescription Drugs

OMB Control Number 0910–NEW

The revised draft guidance document, ''Addressing Misinformation About Medical Devices and Prescription Drugs: Questions and Answers,'' describes two categories of communications firms might choose to use to address misinformation: tailored responsive communications and general medical product communications. As explained in the guidance, general medical product communications are already existing avenues for communication and are subject to approved information collections, summarized below. The revised draft guidance recommends that a firm's tailored responsive communication clearly identify both the specific misinformation that the firm is addressing and a specific internet-based, independent third-party communication in which that misinformation appears. Additionally, the revised draft guidance discusses disclosures that we recommend firms include when choosing to share tailored responsive communications.

Specifically, the guidance recommends that firms include (1) a mechanism for obtaining a copy of the current FDA-required labeling (including FDA-approved patient labeling, if any), (2) the date the firm's tailored responsive communication is posted (if a date is not automatically generated), and (3) a disclosure that the tailored responsive communication is being shared by the medical product firm or that the person addressing the misinformation is affiliated with the firm and is authorized to provide information on behalf of the firm about the medical product. The guidance also provides recommendations for firms that wish to use a tailored responsive communication to address misinformation about or related to an unapproved use of the firm's approved/cleared medical product. Specifically, the guidance recommends including an additional disclosure identifying the unapproved use and noting that the unapproved use of the medical product has not been approved by FDA and that the safety and effectiveness of the medical product for the unapproved use has not been established.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Recommended disclosure activity; guidance section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Clearly identify both the specific misinformation that the firm is addressing and a specific internet-based, independent third-party communication in which that misinformation appears; Section IV.A. Q3.	958	50	47,900	0.4 (24 minutes)	19,160
A mechanism for obtaining a copy of the current FDA-required labeling (including FDA-approved patient labeling, if any); Section IV.A. Q5.	958	50	47,900	0.1 (6 minutes)	4,790
The date the firm's tailored responsive communication is posted (if a date is not automatically generated); Section IV.A. Q5.	958	50	47,900	0.05 (3 minutes)	2,395
A disclosure that the tailored responsive communication is being shared by the medical product firm or that the person addressing the misinformation is affiliated with the firm and is authorized to provide information on behalf of the firm about the medical product; Section IV.A. Q5.	958	50	47,900	0.1 (6 minutes)	4,790
In the case of a tailored responsive communication that addresses misinformation about an unapproved use of the firm's approved/cleared medical product, a disclosure identifying the unapproved use and noting that the unapproved use of the medical product has not been approved by FDA and that the safety and effectiveness of the medical product for the unapproved use has not been established; Section IV.A. Q5.	958	5	4,790	0.1 (6 minutes)	479
Total	.....	.....	196,390	.....	31,614

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

Based on data currently available to FDA on the number of firms disseminating promotional communications about prescription drugs (697) combined with an estimated number of device firms marketing products (261), we assume that approximately 958 firms (''number of respondents'' in table 1) might each choose to disseminate 50 tailored responsive communications annually. Our estimate of the burden per disclosure reflects what we believe is the average burden based on the number and content and complexity of disclosures as recommended in the guidance.

This draft guidance also refers to previously approved FDA collections of information. The collections of information in 21 CFR part 314 are approved under OMB control number 0910–0001. The collections of information in 21 CFR part 201 regarding content and format of labeling for human drug and biological products are approved under OMB control number 0910–0572. The collections of information in 21 CFR part 801 are approved under OMB control number 0910–0485. The collections of information in 21 CFR 202.1 regarding prescription drug advertising are approved under OMB control number 0910–0686. The collections of information in 21 CFR part 601 regarding marketing approval of biological products are approved under OMB control number 0910–0338; and the collections of information regarding marketing approval of animal drug products in 21 CFR part 514 are approved under OMB control number 0910–0032.

III. Electronic Access

Persons with access to the internet may obtain an electronic version of the draft guidance at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm, https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry, https://www.fda.gov/regulatory-information/search-fda-guidance-documents*, or *https://www.regulations.gov.*

Dated: July 3, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–15009 Filed 7–8–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2844]

Agency Information Collection Activities; Proposed Collection; Comment Request; Reclassification Petitions for Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with reclassification of medical devices.

DATES: Either electronic or written comments on the collection of information must be submitted by September 9, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 9, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–2024–N–2844 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Reclassification Petitions for Medical Devices.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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, 240–402–7500.

- 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