submit Form FDA 766. Although current instructions communicate that four copies be submitted (one copy to be returned to respondent), we plan to update the form to reduce this number.

Based on inquiries already received and processed by FDA, we anticipate 1,000 respondents will annually submit Form 5054 pertaining to general drug import information, as reflected in table 1, row 6.

As shown in table 1, row 7, we estimate 80 respondents to the PLAIR program annually, an increase of 10 since our last evaluation of the information collection. At the same time, we estimate one fewer submission per respondent to correspond with a decrease in submissions received by FDA.

Cumulatively these changes and adjustments result in an increase of 3,067,493 responses and 161,161 hours annually.

Dated: June 23, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–13729 Filed 6–27–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–2613]

Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer Promotional Labeling and Advertisements; 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 final guidance for industry entitled ''Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer (DTC) Promotional Labeling and Advertisements.'' This guidance provides recommendations for presenting quantitative efficacy and risk information in DTC promotional labeling and advertisements for prescription human drug and biological products and prescription animal drugs and in DTC promotional labeling for over-the-counter (OTC) animal drugs (collectively, ''promotional communications''). FDA is issuing this guidance to describe the Agency's recommendations for how manufacturers, distributors, and packers (collectively, ''firms'') that include quantitative efficacy or risk information about their drugs in DTC promotional communications can make the language and presentation more consumer-friendly. This guidance finalizes the draft guidance of the same title issued in October 2018.

DATES: The announcement of the guidance is published in the **Federal Register** on June 28, 2023.

ADDRESSES: 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–2018–D–2613 for ''Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer (DTC) Promotional Labeling and Advertisements.'' 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 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; 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; or the 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: Christine Bradshaw, 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, *CDER-OPDP-RPM@fda.hhs.gov;* Diane Maloney, 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 Kathryn Dennehy, Center for Veterinary Medicine (HFV–245), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–837–7554, *Kathryn.Dennehy@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer (DTC) Promotional Labeling and Advertisements.'' This guidance describes recommendations for how firms including quantitative efficacy or risk information about their drugs [1] in DTC promotional communications can make the language and presentation more consumer-friendly. While this guidance focuses on quantitative presentations of efficacy and risk information, firms may wish to refer to these principles and recommendations for quantitative presentations of other product benefits (keeping in mind that any such presentation of other product benefits must comply with applicable statutory and regulatory requirements).

When describing efficacy and risk information about a drug in promotional communications, firms generally have flexibility regarding how they present this information as long as the presentation is not false or misleading and complies with other applicable statutory and regulatory requirements. FDA understands that firms may experience challenges when determining how to present quantitative efficacy or risk information in their DTC promotional communications so that consumers have an opportunity to attend to, understand, and use the information to form accurate perceptions about their drugs. Therefore, FDA is issuing this guidance to provide recommendations for presenting quantitative efficacy and risk information in DTC promotional communications and to encourage firms to follow these recommendations when including such information in their DTC promotional communications.

The guidance covers the following topics for presenting quantitative efficacy and risk information in DTC promotional communications, based on current research findings related to communicating health information:

- Providing quantitative efficacy or risk information for the control group, when applicable;
- Presenting probability information in terms of absolute frequencies, percentages, and relative frequencies;
- Formatting quantitative efficacy or risk information; and
- Using visual aids to illustrate quantitative efficacy or risk information.

This guidance finalizes the draft guidance entitled ''Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer Promotional Labeling and Advertisements'' issued on October 17, 2018 (83 FR 52484). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include clarifying considerations for quantitative efficacy or risk presentations across various media types and providing additional explanations regarding specific concepts and examples that were included in the draft guidance. In addition, editorial and organizational changes were made to improve clarity.

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 ''Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer Promotional Labeling and Advertisements.'' 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

This guidance document recommends information collection activity subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). Burden that may be attributable to recommendations for presenting quantitative efficacy and risk information in direct-to-consumer promotional labeling and advertisements as discussed in Section III of the guidance document is approved under OMB control number 0910–0686. The guidance document also refers to previously approved FDA collections of information. The collections of information in 21 CFR 202.1 have been approved under OMB control number 0910–0686.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov*.

Dated: June 23, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–13775 Filed 6–27–23; 8:45 am]

BILLING CODE 4164–01–P

[1] The term ''drugs'' in the guidance refers to prescription human drug and biological products and to prescription and OTC animal drugs.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–2370]

Patient-Matched Guides to Orthopedic Implants; Draft Guidance for Industry and Food and Drug Administration Staff; 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 the draft guidance entitled ''Patient-Matched Guides to Orthopedic Implants.'' This draft guidance document provides recommendations regarding information that should be included in regulatory submissions for patient-matched guides to orthopedic implants. This draft guidance also provides recommendations that manufacturers should consider when developing their design process for these device types.