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.

This draft guidance is intended to promote clarity and transparency as to expectations regarding submission recommendations for orthopedic patient-matched guides. Following such recommendations may increase efficiency and consistency in review. This draft guidance is not final nor is it for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by August 28, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

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–2023–D–2370 for ''Patient-Matched Guides to Orthopedic Implants.'' 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)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Patient-Matched Guides to Orthopedic Implants'' to 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. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Michel Janda, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4428, Silver Spring, MD 20993–0002, 301–796–6395.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry and FDA staff entitled ''Patient-Matched Guides to Orthopedic Implants.'' FDA has developed this guidance document for members of industry who submit and FDA staff who review premarket submissions for patient-matched guides for orthopedic implants. Patient-matched guides are intended to assist in the execution of a pre-surgical plan concurred upon by the patient's healthcare professional to position an orthopedic implant in a way consistent with the implant's indicated use. This draft guidance is intended to promote clarity and transparency as to expectations regarding submission recommendations for orthopedic patient-matched guides. Following such recommendations may increase efficiency and consistency in review. Additionally, this draft guidance provides recommended best practices regarding certain elements of the design process.

This draft guidance was part of the 2015 initiative to incorporate stakeholder feedback during guidance development (80 FR 1424, January 9, 2015) available at *https://www.federalregister.gov/documents/2015/01/09/2015-00115/medical-device-user-fee-and-modernization-act-notice-to-public-of-website-location-of-fiscal-year.* Specific questions were posed to solicit input into the context of the guidance and comments were collected through Docket No. FDA–2012–N–1021.

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 ''Patient-Matched Guides to Orthopedic Implants.'' 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. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov* or *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Patient-Matched Guides to Orthopedic Implants'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI01400006 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations, guidance, and forms have been approved by OMB as listed in the following table:

21 CFR Part	Topic	OMB Control No.
807, subpart E	Premarket notification	0910–0120
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation	0910–0073
812	Investigational Device Exemption	0910–0078
814, subparts A through E	Premarket approval	0910–0231
800, 801, and 809	Medical Device Labeling Regulations	0910–0485

Dated: June 22, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–13730 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–2023–D–0939]

Prohibition on Wholesaling Under Section 503B of the Federal Food, Drug, and Cosmetic Act; 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 ''Prohibition on Wholesaling Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' This draft guidance describes FDA's interpretation of, and policies concerning, the statutory prohibition on wholesaling for certain compounded drugs. This draft guidance also describes examples of how FDA intends to apply the statutory wholesaling provision.

DATES: Submit either electronic or written comments on the draft guidance on or before August 28, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before August 28, 2023. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 28, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2023–D–0939 for ''Prohibition on Wholesaling Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' 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