of the information collection described above. You can obtain copies of the proposed collection of information and submit comments by emailing *infocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: OTIP's NHTTAC delivers training and technical assistance (T/TA) to inform and deliver a public health response to trafficking. In applying a public health approach, NHTTAC builds the capacity of professionals, organizations, and communities to identify and respond to the complex needs of all individuals who have experienced trafficking or who have increased risk for trafficking and address the root causes that put individuals, families, and communities at risk of trafficking. These efforts ultimately help improve the availability and delivery of coordinated and trauma-informed services before, during, and after an individual's trafficking exploitation.

NHTTAC provides a variety of services, programs, and facilitated T/TA sessions to improve service provision to people who have experienced trafficking or who have increased risk factors for trafficking, including the Stop, Observe, Ask, and Respond (SOAR) to Health and Wellness training; specialized T/TA; NHTTAC Customer Support; and information through resources and materials about trafficking. This information collection is intended to collect feedback from participants to assess T/TA provided by NHTTAC. Revisions have been made in order to reduce respondent burden where applicable. Additionally, since this collection was last renewed, the SOAR Demonstration Grant Program went into effect. The program's goal is to fund the implementation of SOAR trainings and related capacity building efforts to identify, treat, and respond to clients who have experienced human trafficking in healthcare settings. Feedback from SOAR Demonstration Grant Program recipients who participate in NHTTAC SOAR offerings is obtained through instruments approved within this NHTTAC Evaluation Package (0970–0519). Burden estimates have been adjusted to account for these SOAR Demonstration Grant Program participants where applicable.

Respondents: NHTTAC T/TA participants include OTIP grant recipients, including SOAR Demonstration Grant program recipients, individuals with lived experience, professionals who interact with and provide services to individuals who have experienced trafficking or are at risk of trafficking, including healthcare, behavioral health, public health, and human service practitioners, organizations, and communities.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Universal T/TA Participant Feedback Long Version (full form)	1,500	1	0.43	645	215
Short Version (partial form)	225,000	1	0.10	22,500	7,500
Intensive T/TA Participant Feedback	600	1	1.17	702	234
Follow-Up Feedback	8,000	1	0.50	4,000	1,333
Qualitative Guide	2,000	1	1.50	3,000	1,000
Network Survey	600	1	1.00	600	200
Client Satisfaction Survey	1,000	1	0.08	80	27
Resources Feedback	500	1	0.08	40	13
Requester Feedback	200	1	0.12	24	8
Estimated Total Annual Burden Hours					10,530

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 22 U.S.C. 7104 and 22 U.S.C. 7105(c)(4).

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2026–09048 Filed 5–6–26; 8:45 am]

BILLING CODE 4184–47–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–2370]

Patient-Matched Guides for Orthopedic Implants; 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 a final guidance titled ''Patient-Matched Guides for Orthopedic Implants.'' This guidance document provides recommendations regarding information that should be included in regulatory submissions for patient-matched guides for orthopedic implants. This guidance also provides recommendations that manufacturers should consider when developing their design process for these device types. This 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.

DATES: The announcement of the guidance is published in the **Federal Register** on May 7, 2026.

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–2023–D–2370 for ''Patient-Matched Guides for 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 guidance document titled ''Patient-Matched Guides for Orthopedic Implants'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5441, 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 guidance for industry and FDA staff titled ''Patient-Matched Guides for 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 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 guidance provides recommended best practices regarding certain elements of the design process.

This 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.

A notice of availability of the draft guidance appeared in the **Federal Register** of June 28, 2023 (88 FR 41967). FDA considered comments received and revised the guidance as appropriate in response to the comments, including clarification of recommendations that are technical in nature (*e.g.,* device description, cadaveric testing), as well as clarification of certain modifications that FDA would consider likely to require submission of a new 510(k) submission.

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 ''Patient-Matched Guides for 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 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 for 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. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR part	Topic	OMB Control No.
807, subpart E	Premarket notification	0910–0120
820	Current Good Manufacturing Practice (CGMP); Quality Management Systems Regulation (QMSR).	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

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–09023 Filed 5–6–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–P–7054]

Determination That MICARDIS (Telmisartan), Tablets, 20 Milligrams and 80 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) has determined that MICARDIS (telmisartan), tablets, 20 milligrams (mg) and 80 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to these products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Sungjoon Chi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6216, Silver Spring, MD 20993–0002, 240–402–9674, *Sungjoon.Chi@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161). FDA may not approve an ANDA that does not refer to a listed drug.

MICARDIS (telmisartan), tablets, 20 mg and 80 mg, are the subject of NDA 020850, held by Boehringer Ingelheim. NDA 020850 was initially approved on November 10, 1998. MICARDIS is indicated for the treatment of hypertension, to lower blood pressure and for cardiovascular risk reduction in patients unable to take ACE inhibitors.

MICARDIS (telmisartan), tablets, 20 mg and 80 mg, are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Unichem Pharmaceuticals (USA), Inc. submitted a citizen petition dated December 12, 2025 (Docket No. FDA–2025–P–7054), under 21 CFR 10.30, requesting that the Agency determine whether MICARDIS (telmisartan), tablets, 20 mg and 80 mg, were voluntarily withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that MICARDIS (telmisartan), tablets, 20 mg and 80 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that these drug products were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of MICARDIS (telmisartan), tablets, 20 mg and 80 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was