

ADDRESSES: For access to final order OTC000008–1, go to the OTC Monographs@FDA portal at <https://www.accessdata.fda.gov/scripts/cder/omuf/index.cfm>. See the **SUPPLEMENTARY INFORMATION** section for more information on electronic access to the final order.

FOR FURTHER INFORMATION CONTACT: Shannon Liu, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 240–402–2484, Shannon.Liu@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is issuing final order OTC000008–1 to amend the requirements for sunscreen drug products for OTC human use, as described in OTC Monograph M020, to remove PABA and trolamine salicylate as sunscreen active ingredients. FDA is issuing the final order pursuant to section 505G(b)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355h(b)(1)).

OTC Monograph M020 describes the conditions under which OTC sunscreen drug products are GRASE under section 201(p)(1) of the FD&C Act (21 U.S.C. 321(p)(1)). OTC Monograph M020 was previously set forth in final order OTC000039, issued on June 10, 2026. The conditions described in OTC Monograph M020 may be amended, revoked, or otherwise modified in accordance with the procedures of section 505G(b) of the FD&C Act.

Final order OTC000008–1 amends the conditions described in OTC Monograph M020, as set forth in final order OTC000039, to remove PABA and trolamine salicylate as sunscreen active ingredients. FDA has determined that there are no conditions under which a drug product containing PABA or trolamine salicylate as a sunscreen active ingredient is GRASE under section 201(p)(1) of the FD&C Act because FDA's review of the available safety data for PABA and trolamine salicylate shows that the risks associated with use of these active ingredients in sunscreen drug products outweigh the benefits.

A notice of availability of the proposed order OTC000008 titled “Amending Over-the-Counter (OTC) Monograph M020: Sunscreen Drug Products for OTC Human Use” was announced in the **Federal Register** on September 27, 2021 (86 FR 53322) (comment period extended November 22, 2021 (86 FR 66318)). FDA proposed to establish certain new conditions

under which nonprescription sunscreen drug products would be determined to be GRASE. Relevant to this final order, FDA proposed to amend OTC Monograph M020 to remove PABA and trolamine salicylate as sunscreen active ingredients because FDA's review of the available safety data for PABA and trolamine salicylate shows that the risks associated with use of these active ingredients in sunscreen drug products outweigh their benefits. FDA considered timely submitted comments on the proposal to amend OTC Monograph M020 to remove PABA and trolamine salicylate as sunscreen active ingredients, and after considering comments, FDA in this final order OTC000008–1 finalizes its proposed determinations regarding sunscreen drug products containing PABA and trolamine salicylate without change. FDA will address the other aspects of proposed order OTC000008 in a future order or orders.

II. Paperwork Reduction Act of 1995

Final order OTC000008–1 is issued under section 505G(b)(1) of the FD&C Act. Under section 505G(o) of the FD&C Act, the Paperwork Reduction Act of 1995 (PRA) (Chapter 35 of title 44, United States Code) does not apply to collections of information made under section 505G of the FD&C Act. Therefore, clearance by the Office of Management and Budget under the PRA is not required for collections of information, if any, in a final order issued under section 505G of the FD&C Act.

III. Electronic Access

The final order can be accessed on the OTC Monographs@FDA portal at <https://www.accessdata.fda.gov/scripts/cder/omuf/index.cfm>. Under the “Administrative Orders” banner, click on the desired link under the “Order ID” heading and follow the prompts. FDA established this information technology system with a web portal that can be accessed through FDA's website. The OTC Monographs@FDA portal provides a resource for the public to view administrative orders (proposed, final, and interim final orders), as well as related supporting documents, for OTC Monograph Drugs and view OTC Monographs. In the future, the OTC Monographs@FDA portal will facilitate the public's ability to submit, search,

and view comments and data for proposed and interim final orders.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–18551 Filed 9–10–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–9350]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device Tracking

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 requirements for the tracking of medical devices.

DATES: Either electronic or written comments on the collection of information must be submitted by November 10, 2026.

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 November 10, 2026. 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-2026-N-9350 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device Tracking." 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 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.

FOR FURTHER INFORMATION CONTACT:

Amber Barrett, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the 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, including each proposed extension of an existing 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.

Medical Device Tracking—21 CFR Part 821

OMB Control Number 0910-0442—Extension

Section 519(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(e)(1)) provides that FDA may require by order that a manufacturer adopt a method for tracking a class II or III medical device, if the device meets one of the three following criteria: (1) the failure of the device would be reasonably likely to have serious adverse health consequences, (2) the device is intended to be implanted in the human body for more than 1 year (referred to as a "tracked implant"), or (3) the device is life-sustaining or life-supporting (referred to as a "tracked l/s-l/s device") and is used outside a device user facility. Tracked device information is collected to facilitate identifying the current location of medical devices and patients possessing those devices, to the extent that patients permit the collection of identifying information. Manufacturers and FDA (where necessary) use the data to: (1) expedite the recall of distributed medical devices that are dangerous or defective and (2) facilitate the timely notification of patients or licensed practitioners of the risks associated with the medical device. In addition, applicable regulations in 21 CFR part 821 (21 CFR 821.1 through 821.60) include provisions for: (1) exemptions and variances; (2) system and content requirements for tracking; (3) obligations of persons other than device manufacturers, e.g., distributors; (4) records and inspection requirements; (5) confidentiality; and (6) record retention requirements.

Respondents to the collection of information are medical device manufacturers, importers, and distributors of tracked implants or tracked l/s-l/s devices used outside a device user facility. Distributors include multiple and final distributors, including hospitals. We currently estimate 22,000 potential respondents.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

Activity/21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Discontinuation of business—821.1(d)	1	1	1	1	1
Exemption or variance—821.2 and 821.30(e)	1	1	1	1	1
Notification of failure to comply—821.25(d)	2	2	4	1	4
Multiple distributor data—821.30(c)(2)	1	1	1	1	1
Total					7

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Tracking information—821.25(a)	13	1	13	76	988
Record of tracking data—821.25(b)	13	46,260	601,380	1	601,380
Standard operating procedures—821.25(c) ¹	13	1	13	63	819
Manufacturer data audit—821.25(c)(3)	13	1,124	14,612	1	14,612
Multiple distributor data and distributor tracking records—821.30(c)(2) and (d)	22,000	1	22,000	1	22,000
Total					639,799

¹ One-time burden.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN

Activity/21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Acquisition of tracked devices and final distributor data—821.30(a) and (b)	22,000	1	22,000	1	22,000
Multiple distributor data and distributor tracking records—821.30(c)(2) and (d)	1,100	1	1,100	1	1,100
Total					23,100

Our estimated burden for the information collection reflects an overall increase of 47,526 hours and a corresponding increase of 47,389 responses/records. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–18529 Filed 9–10–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–2917]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Generic Clearance for Qualitative Data To Support Social and Behavioral Research for Food, Dietary Supplements, Cosmetics, and Animal Food and Feed

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is 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: Submit written comments (including recommendations) on the

collection of information by October 13, 2026.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910–0891. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Christopher Colburn, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8758, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed