DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10697]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. 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 or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by October 13, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing*.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''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 publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment.

Information Collections

1. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Medicare Coverage of Items and Services for Coverage with Evidence Development; *Use:* This is a reinstatement package. In general, in order for an item or service to be covered under Medicare, it must meet the standard described in section 1862(a)(1)(A) of the Act—that is, it must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

When the available evidence is insufficient to demonstrate that the items and services are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member under section 1862(a)(1)(A) of the Act, CED has been used to support evidence development for certain items and services that are likely to show benefit for the Medicare population. CED relies primarily on the statutory exception in section 1862(a)(1)(E) of the Act, which effectively permits Medicare payment for items and services that are reasonable and necessary to carry out research conducted pursuant to section 1142 of the Act. Items and services that are not reasonable and necessary to carry out that research are excluded.

CED has been a pathway whereby, after a CMS and AHRQ review, Medicare covers items and services on the condition that they are furnished in the context of approved clinical studies or with the collection of additional clinical data. Any approved CED study submission should satisfy each of the criteria ''1 –17'' provided in the CMS Coverage with Evidence Development guidance document. *Form Number:* CMS–10697 (OMB control number 0938–1387); *Frequency:* Annually; *Affected Public:* Private sector—Not-for-profit institutions and Businesses or other for-profits; *Number of Respondents:* 15; *Total Annual Responses:* 15; *Total Annual Hours:* 1,500. (For policy questions regarding this collection, contact Lori Ashby at 410–786–6322.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1978–N–0018]

Amending Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use, and Related Information; Aminobenzoic Acid (PABA) and Trolamine Salicylate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability on its website of the final administrative order (final order) (OTC000008–1) titled ''Amending Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use, and Related Information; Aminobenzoic Acid (PABA) and Trolamine Salicylate.'' This final order amends ''Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use'' (Over-the-Counter (OTC) Monograph M020) to remove PABA and trolamine salicylate as sunscreen active ingredients. A sunscreen drug product containing PABA or trolamine salicylate is not generally recognized as safe and effective (GRASE).

DATES: The announcement of the availability on FDA's website of the final order is published in the **Federal Register** on September 11, 2026.

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.

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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