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.