

Ongoing information collections	Annual number of respondents	Total number of responses per respondent	Average burden hours per response	Annual burden hours
2026 Native Communities Home Visiting Meeting	580	1	0.210	122
Tribal Maternal, Infant, and Early Childhood Home Visiting (TMIECHV) Kickoff Meeting Registration	20	1	0.100	2
Fiscal Responsibility Act Outcomes Working Group Interest Form	50	1	0.080	4
Child Care Quality and Business Support Center, Events Registration Questions	7360	1	0.032	242
Office of Child Care Events Registration and Post-Event Survey	4500	1.75	0.064	506
Office of Child Care National Tribal Conference Registration Questions	400	1	0.083	33
Office of Child Care Regional Meeting Registration Questions	330	1	0.082	27
Office of Child Care State and Territory Administrator’s Meeting Registration Questions	400	1	0.082	33
Office of Child Care Tribal Child Care and Development Fund (CCDF) Plan Training	630	1	0.084	53
Office of Child Care Tribal Cluster Meeting Registration Questions	190	1	0.084	16
Registration for National Center on Subsidy Innovation and Accountability Events	1000	1	0.033	33
Community Economic Development Grant Recipient Conference	200	1	0.229	96
Head Start Registration Form Questions	34,000	1	0.017	567
Sum Totals:	59,945	2,315

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.

Mary B. Jones,
ACF/OPRE Certifying Officer.
 [FR Doc. 2026–11558 Filed 6–9–26; 8:45 am]
BILLING CODE 4184–79–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–6494]

Amending Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use, and Related Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: In response to an over-the-counter (OTC) monograph order request (OMOR), the Food and Drug

Administration (FDA) is announcing the availability on its website of the final administrative order (final order) (OTC000039) titled “Amending Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use, and Related Information.” This final order amends “Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use” (OTC Monograph M020) to add bemotrizinol at concentrations up to 6 percent as a sunscreen active ingredient. A sunscreen drug product containing bemotrizinol is generally recognized as safe and effective (GRASE) if it meets the conditions described in OTC Monograph M020 as amended by this final order.

DATES: The announcement of the availability on FDA’s website of the final order is published in the **Federal Register** on June 10, 2026.

ADDRESSES: For access to final order OTC000039, 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 OTC000039 to amend the requirements for sunscreen drug products for OTC human use, as described in OTC Monograph M020, to add bemotrizinol for use as a sunscreen active ingredient at concentrations up to 6 percent. 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 OTC000006, as deemed by sections 505G(b)(8) and 505G(k)(2)(B) of the FD&C Act, and was effective upon enactment of the Coronavirus Aid, Relief, and Economic Security Act (Pub. L. 116–136) on March 27, 2020. 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.

On September 23, 2024, DSM Nutritional Products LLC submitted a Tier 1 OMOR requesting FDA issue an administrative order finding that a sunscreen drug product containing bemotrizinol as an active ingredient is GRASE under the conditions described in OTC Monograph M020.

Final order OTC000039 amends the conditions described in OTC Monograph M020, as set forth in final order OTC000006, to add bemotrizinol at concentrations up to 6 percent as a sunscreen active ingredient. The final

order establishes that for a sunscreen drug product containing bemotrizinol as a sunscreen active ingredient to be legally marketed without an approved application under section 505 of the FD&C Act (21 U.S.C. 355), among other requirements, it must conform to certain conditions that address the concentration of bemotrizinol in the sunscreen drug product, permitted combinations of bemotrizinol with other sunscreen active ingredients and with skin protectant active ingredients, and permitted dosage forms. Specific to dosage forms, the final order permits sunscreen drug products containing bemotrizinol to be in the following dosage forms: oil, lotion, cream, gel, butter, paste, ointment, stick, and spray, provided that the sunscreen drug product in spray dosage form is manufactured and packaged with no propellant or is manufactured and packaged in a spray delivery system where all propellant is isolated from the drug product formulation within the container closure system, and there is no contact between the propellant and the drug product formulation.

Final order OTC000039 also includes minor stylistic and formatting changes to improve the readability, clarity, and presentation of OTC Monograph M020.

A notice of availability of the proposed order titled “Amending Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use” was announced in the **Federal Register** on December 12, 2025 (90 FR 57765). FDA considered timely submitted comments on the proposal to amend OTC Monograph M020 to add bemotrizinol as a sunscreen active ingredient. After considering comments, FDA did not make changes to the final order.

II. Paperwork Reduction Act of 1995

Final order OTC000039 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 (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 Paperwork Reduction Act of 1995 is not required for collections of information, if any, in a final order issued under section 505G.

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

HHS Request for Comment on Chronic Disease of Addiction

AGENCY: US Department of Health and Human Services (HHS or the Department).

ACTION: Notice of Request for Information (RFI) regarding substance research, policy, and strategies to improve the prevention, treatment, recovery of chronic disease of addiction and mental illness and how to promote the Great American Recovery Initiative.

SUMMARY: Thanks to President Trump’s leadership, since 2017, the country has made significant progress in addressing mental health and substance use. However, President Trump and HHS Secretary Kennedy realize that the Department and country have more work to do. To facilitate this effort, HHS invites public comment in response to this RFI on the research, development, programs, and policies that have been most successful in improving availability of and access to effective prevention, treatment, and recovery interventions for addiction, mental illness, and co-occurring substance use and mental disorders. The purpose of this RFI is to identify research, programs, and policies that have been successful and recommend novel policy ideas and gaps in research that could be addressed and implemented to further the Great American Recovery using existing funding.

DATES: Comments on this notice must be received by July 5, 2026.

ADDRESSES: Interested parties may submit comments electronically to

REPORTSCLEARANCEOFFICER@ahrq.hhs.gov with the subject line ‘Great American Recovery.’

FOR FURTHER INFORMATION CONTACT:

Erica Moshtahedian, Agency for Healthcare Research and Quality (AHRQ) Chief of Staff, Department of Health and Human Services (HHS), Erica.Moshtahedian@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION: HHS is dedicated to promoting the health and well-being of the American people. To advance this goal, HHS is implementing President Trump’s Executive Order (E.O.) 14379 of January 29, 2026: *Addressing Addiction Through the Great American Recovery Initiative* and E.O. 14321 of July 24, 2025: *Ending Crime and Disorder on America’s Streets* that will bring back safety and trust to America’s communities.

This initiative represents a critical new step to strengthen federal guidance and grants to support the nation’s recovery, with a focus on prevention, treatment, and long-term resilience. It consists of:

Guidance

1. Strengthening Agency Collaboration

The Centers for Medicare & Medicaid Services (CMS), the Substance Abuse and Mental Health Services Administration (SAMHSA), and the Administration for Children and Families (ACF) issued joint guidance to improve coordination between state Medicaid, substance abuse, mental health, and child welfare agencies, with a focus on youth mental health, substance use prevention, and early intervention.¹ SAMHSA and CMS also recently issued guidance concerning best practices for implementing behavioral health crisis services through Medicaid and CHIP.²

2. Engaging Faith-Based Providers

States receiving SAMHSA and ACF block grants and large formula grants were issued new guidance and best practices on how to include faith-based organizations as part of their provider networks. This includes SAMHSA’s State Opioid Response (SOR) grants and the Mental Health and Substance Use Block Grants.³

3. Development of Non-Opioid Options

The Food and Drug Administration (FDA) issued guidance in September 2025 to help expand non-opioid options

¹ <https://www.samhsa.gov/sites/default/files/dear-colleague-letter-moud.pdf>.

² <https://www.medicaid.gov/federal-policy-guidance/downloads/sho25004.pdf>.

³ <https://www.samhsa.gov/sites/default/files/dear-colleague-letter-faith-based-organizations.pdf>.