U.S. Food and Drug Administration

Final Administrative Order (OTC000039)

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

(Issued June 10, 2026, corrected August 10, 2026)*

Pursuant to section 505G(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355h(b)), the U.S. Food and Drug Administration (FDA or the Agency) is issuing Final Administrative Order OTC000039, as set forth in Section IX of this document. This document also contains additional information related to the final administrative order (final order), including the statement of reasons for issuance of the final order (Section IV), and sections addressing exclusivity, the effective date of Final Administrative Order OTC000039, and an environmental assessment.

I. Introduction

FDA is issuing this final order to amend the requirements for sunscreen drug products for over-the-counter (OTC) human use in Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use (OTC Monograph M020).[1] On September 23, 2024, DSM Nutritional Products LLC (DSM or Requestor) submitted a Tier 1 OTC monograph order request

---

* On August 10, 2026, FDA corrected minor typographical errors.

[1] OTC Monograph M020 was initially set forth in Final Administrative Order OTC000006 Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use, available via the OTC Monographs@FDA portal at https://www.accessdata.fda.gov/scripts/cder/omuf/. On September 24, 2021, FDA issued Proposed Administrative Order OTC000008 Amending Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use, available via the OTC Monographs@FDA portal at https://www.accessdata.fda.gov/scripts/cder/omuf/. The final order contained in this document does not address Proposed Administrative Order OTC000008 which, if finalized, would amend and revise OTC Monograph M020 to establish certain new conditions under which nonprescription sunscreen drug products would be determined to be generally recognized as safe and effective (GRASE). If Proposed Administrative Order OTC000008 is finalized, all sunscreen drug products marketed under OTC Monograph M020, including products containing bemotrizinol as a sunscreen active ingredient, would be required to meet the conditions described in OTC Monograph M020, as amended by OTC000008.

(OMOR)[2] to add bemotrizinol, at concentrations up to 6 percent,[3] to OTC Monograph M020 for use as a sunscreen active ingredient.

This final order amends OTC Monograph M020, as initially set forth in Final Administrative Order OTC000006, to add bemotrizinol as a sunscreen active ingredient.[4] This final order establishes that for a 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 drug product, permitted combinations of bemotrizinol with other sunscreen active ingredients and with skin protectant active ingredients, and permitted dosage forms.[5]

II. Addresses

- For access to the preceding proposed administrative order (proposed order) and supporting documents, go to the OTC Monographs@FDA portal at https://www.accessdata.fda.gov/scripts/cder/omuf/ and go to Proposed Order ID OTC000039.

- For access to the docket to read comments received on the proposed order, go to the Federal eRulemaking Portal at https://www.regulations.gov and insert the docket number FDA-2025-N-6494 into the "Search" box and follow the prompts.

---

[2] An OMOR means a request for an order submitted under section 505G(b)(5) of the FD&C Act (see section 744L(7) of the FD&C Act (21 U.S.C. 379j-71(7)). A Tier 1 OMOR means any OMOR not determined to be a Tier 2 OMOR (see section 744L(8) of the FD&C Act (21 U.S.C. 379j-71(8)). An OMOR requesting the addition of an active ingredient to an OTC monograph is not categorized as a Tier 2 OMOR and is, therefore, a Tier 1 OMOR.

[3] For the purposes of OTC Monograph M020, FDA interprets a concentration up to 6 percent to mean up to and including 6 percent.

[4] In accordance with section 505G(b)(1) of the FD&C Act, FDA determined that there are conditions under which a sunscreen drug product containing bemotrizinol as a sunscreen active ingredient is GRASE under section 201(p) of the FD&C Act (21 U.S.C. 321(p)(1)) and not subject to section 503(b)(1) of the FD&C Act (21 U.S.C. 353(b)(1)), including certain conditions specific to the use of bemotrizinol as an active ingredient.

[5] See section 505G(b)(1)(B) of the FD&C Act.

- Confidential Information in Comments: FDA reviewed comments submitted on Proposed Administrative Order OTC000039 to determine whether they contained information that, pursuant to section 505G(d) of the FD&C Act and any other applicable disclosure law, would not be made public. If applicable, FDA redacted such information prior to the comment being publicly viewable. Under section 505G(d) of the FD&C Act (21 U.S.C. 355h(d)), FDA must make any information submitted by any person with respect to this order available to the public upon submission, with limited exceptions. FDA will not make public information pertaining to pharmaceutical quality unless such information is necessary to establish standards under which a drug is generally recognized as safe and effective under section 201(p)(1) of the FD&C Act (21 U.S.C. 321(p)(1)) (see section 505G(d)(2)(B) of the FD&C Act). FDA will also not make public information that is of the type contained in raw datasets (see section 505G(d)(2)(B) of the FD&C Act).

- For further information, contact Shannon Liu, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 240-402-2484, shannon.liu@fda.hhs.gov.

III. Background

An OTC Monograph describes conditions under which an OTC drug product is generally recognized as safe and effective (GRASE). To be deemed GRASE under section 201(p)(1) of the FD&C Act (21 U.S.C. 321(p)(1)), not a new drug under section 201(p) of the FD&C Act, and not subject to section 503(b)(1) of the FD&C Act (21 U.S.C. 353(b)(1)), a drug product marketed without an application approved under section 505 of the FD&C Act must be in conformity with an OTC Monograph, among other requirements.[6]

OTC Monograph M020 was initially set forth in Final Administrative Order OTC000006, which is a final order as deemed by sections 505G(b)(8) and 505G(k)(2)(B) of the FD&C Act (21 U.S.C. 355h(b)(8) and 355h(k)(2)(B)), effective upon enactment of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Public Law 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 (21 U.S.C. 355h(b)). Either FDA or a requestor[7] can initiate the administrative order process in section 505G(b). A requestor can initiate the order process by submitting an OMOR with respect to certain drugs, classes of drugs, or combination of drugs.[8] The OMOR may request that the

---

[6] See section 505G(a)(1) and (2) of the FD&C Act (21 U.S.C. 355h(a)(1) and (2)). Among other things, a sunscreen drug product marketed without an application approved under section 505 of the FD&C Act must also conform to the general requirements for nonprescription drugs. See section 505G(a)(1) and section 505G(b)(6). With the exception of bemotrizinol in § M020.10(c) of OTC Monograph M020, by operation of section 505G(m)(2) of the FD&C Act, sunscreen active ingredients included in § M020.10(a)-(b) and (d)-(q) are currently permitted in the following dosage forms: oil, lotion, cream, gel, butter, paste, ointment, stick, spray, and powder, See Final Administrative Order OTC000006 at page 2, footnote 7.

[7] Under section 505G(q)(3) of the FD&C Act (21 U.S.C. 355h(q)), the term *requestor* refers to any person or group of persons marketing, manufacturing, processing, or developing an OTC monograph drug.

[8] See section 505G(b)(5) of the FD&C Act.

Agency issue an order determining: (1) whether a drug is GRASE; or (2) whether a change to a condition of use is GRASE.[9]

FDA is issuing this final order pursuant to section 505G(b)(1) of the FD&C Act (21 U.S.C. 355h(b)(1)).

On December 12, 2025, FDA issued Proposed Administrative Order (OTC000039) titled "Amending Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use."[10] FDA issued this proposed order pursuant to section 505G(b) of the FD&C Act in response to DSM's submission of an OMOR. In the proposed order, FDA proposed to amend OTC Monograph M020 to add bemotrizinol as a sunscreen active ingredient. FDA proposed to establish that for a 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 drug product, permitted combinations of bemotrizinol with other sunscreen active ingredients and with skin protectant active ingredients, and permitted dosage forms. The proposed order also included minor stylistic, formatting, and technical changes to OTC Monograph M020 to improve the readability, clarity, and presentation of OTC Monograph M020. For more information on the background and statement of reasons for issuance of the proposed order, see Proposed Administrative Order OTC000039.

IV. Statement of Reasons for Issuance of Final Order

A. Summary

FDA is amending OTC Monograph M020 to add bemotrizinol as a sunscreen active ingredient. FDA has determined that there are conditions under which a sunscreen drug product containing bemotrizinol as a sunscreen active ingredient is GRASE under section 201(p)(1) of the FD&C Act and not subject to section 503(b)(1) of the FD&C Act, among other requirements.[11] FDA evaluated the safety and efficacy of bemotrizinol at concentrations up to 6 percent as a sunscreen active ingredient and considered whether there were specific bemotrizinol-related conditions necessary to find that a sunscreen drug product containing bemotrizinol as an active ingredient is GRASE.

FDA conducted a scientific review of the available data on the safety and efficacy of bemotrizinol, including human clinical and nonclinical studies as well as other related information submitted by the Requestor in the OMOR, and data from independent literature

---

[9] See section 505G(b)(5)(B) of the FD&C Act.

[10] FDA's Proposed Administrative Order OTC000039 is available via the OTC Monographs@FDA portal at https://www.accessdata.fda.gov/scripts/cder/omuf/.

[11] Supra footnote 1 and 6.

reviews.[12] Consistent with the Agency's proposed findings based on this review,[13] FDA concludes: (1) that there is adequate evidence from two independent human clinical efficacy studies to support the efficacy of bemotrizinol, at concentrations up to 6 percent, for use as a sunscreen active ingredient intended for use in adults and children 6 months of age and older; and (2) that, based on a review of nonclinical, clinical pharmacology, and clinical safety studies and information, there is adequate evidence of the safety of bemotrizinol at concentrations up to 6 percent for use as an active ingredient in sunscreen drug products intended for use in adults and children 6 months of age and older.

To inform consideration of potential OTC monograph conditions needed specifically to help assure that sunscreen drug products that contain bemotrizinol are GRASE, FDA conducted a review to determine whether: (1) bemotrizinol can be manufactured as a drug substance and the identified impurity levels are supported by sufficient data; (2) bemotrizinol can be manufactured into a drug product, including the different types of dosage forms; (3) a single drug product may combine bemotrizinol with other permitted sunscreen active ingredients in § M020.10 of OTC Monograph M020; (4) a single drug product may combine bemotrizinol alone or in an allowed combination with other sunscreen active ingredients, with one or more skin protectant active ingredients identified in § M016.10 of OTC Monograph M016: Skin Protectant Drug Products for Over-the-Counter Human Use (OTC Monograph M016);[14] and (5) a drug product containing bemotrizinol as a sunscreen active ingredient would need different labeling from other sunscreen drug products.[15]

Based on a review of data submitted by the Requestor in the OMOR, data from literature reviews,[16] and data submitted in comments on the proposed order,[17] FDA concludes that specific bemotrizinol-related conditions are needed that address the concentration of bemotrizinol in the drug product, permitted combinations of bemotrizinol with other sunscreen active ingredients and with skin protectant active ingredients, and permitted dosage forms.

---

[12] FDA's Scientific Review Supporting Proposed Administrative Order is available via the OTC Monographs@FDA portal at https://www.accessdata.fda.gov/scripts/cder/omuf/ under the supporting documents for the Proposed Administrative Order OTC000039. See also the Proposed Administrative Order OTC000039, Section IV. Statement of Reasons for Issuance of Proposed Order.

[13] Ibid.

[14] OTC Monograph M016 is set forth in Final Administrative Order OTC000005 Over-the-Counter Monograph M016: Skin Protectant Drug Products for Over-the-Counter Human Use, available via the OTC Monographs@FDA portal at https://www.accessdata.fda.gov/scripts/cder/omuf/.

[15] FDA's Scientific Review Supporting Proposed Administrative Order is available via the OTC Monographs@FDA portal at https://www.accessdata.fda.gov/scripts/cder/omuf/ under the supporting documents for the Proposed Administrative Order OTC000039. See also the Proposed Administrative Order (OTC000039), Section IV. Statement of Reasons for Issuance of Proposed Order.

[16] Ibid.

[17] See FDA's Scientific Review Supporting Final Administrative Order available via the OTC Monographs@FDA portal at https://www.accessdata.fda.gov/scripts/cder/omuf/ under the supporting documents for the Final Administrative Order OTC000039. See also FDA Response 3 in Section IV.B.2.c Comments on Dosage Forms of Bemotrizinol and FDA Responses.

The specific bemotrizinol-related conditions are:

- Bemotrizinol is present in the drug product in a concentration up to 6 percent, and the finished drug product provides a minimum sun protection factor (SPF) value of not less than 2.[18]

- A single drug product may combine bemotrizinol with any single sunscreen active ingredient identified in § M020.10 of OTC Monograph M020 except for aminobenzoic acid (PABA) or trolamine salicylate or may combine bemotrizinol with any combination of sunscreen active ingredients identified in § M020.20(a) of OTC Monograph M020 that does not include PABA or trolamine salicylate, provided that certain other conditions are met.

- A single drug product may combine certain skin protectant active ingredients identified in OTC Monograph M016 with bemotrizinol in any combination with other sunscreen active ingredients identified in § M020.20 of OTC Monograph M020 that does not include PABA or trolamine salicylate, provided that certain other conditions are met.

- A drug product containing bemotrizinol is in one of the following dosage forms: oil, lotion, cream, gel, butter, paste, ointment, stick, or spray (provided that certain spray-specific conditions are met).

Because of the noted safety concerns with PABA and trolamine salicylate, FDA concludes that sunscreen drug products containing bemotrizinol in combination with PABA and/or trolamine salicylate are not GRASE.[19] In addition, as discussed in more detail in this final order, FDA concludes that a sunscreen drug product containing bemotrizinol is limited to the following dosage forms: oil, lotion, cream, gel, butter, paste, ointment, stick, and spray, provided that the product in spray dosage form is manufactured and packaged with no propellant (e.g., a pump spray) 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 (e.g., a bag-on-valve spray). FDA concludes that the data do not support a drug product formulation directly combined with a propellant to create an aerosol spray dosage form (e.g., a propellant-based sunscreen) or a powder dosage form.

FDA also concludes that there are no safety or efficacy concerns that would necessitate amending the labeling requirements in § M020.50 of OTC Monograph M020 specifically for sunscreen drug products containing bemotrizinol.

---

[18] In addition, a finished drug product containing bemotrizinol as a sunscreen active ingredient must also provide a minimum SPF of not less than 2 as measured by the testing procedures established in § M020.80 of OTC Monograph M020.

[19] See Proposed Administrative Order OTC000008 at pages 32-37.

B. Comments on the Proposed Administrative Order and FDA Responses

1. Introduction

FDA received approximately 50 timely submitted comments in response to Proposed Administrative Order OTC000039 by the end of the comment period, each addressing one or more issues. FDA received comments from entities and individuals including the Requestor, individual consumers, consumer groups, trade organizations, pharmaceutical industry firms, public advocacy groups, and healthcare professional organizations.

FDA describes and responds to the comments in this section.

FDA has numbered each comment to help distinguish between different comments. FDA has grouped similar comments together under the same number and, where needed, FDA has separated out different issues discussed in the same comment and considered them as distinct comments for purposes of FDA's responses. The number assigned to each comment topic is purely for organizational purposes and does not signify the comment's value or importance or the order in which the comments were received.

2. Description of Comments and FDA Responses

FDA received comments on different topics including:

- General support for the proposed order
- Safety of bemotrizinol
- Dosage forms of bemotrizinol
- Labeling of sunscreen drug products including bemotrizinol
- Miscellaneous

FDA considered all timely submitted comments received on the proposed order, and FDA is finalizing the order as proposed.

a. Description of General Comments and FDA Responses

FDA received general comments supporting the reasons for issuance of the proposed order. In the following paragraphs, FDA discusses and responds to these general comments. FDA did not make any changes to the final order based on consideration of these general comments.

(Comment 1) Nearly all the comments support the proposed order to add bemotrizinol to OTC Monograph M020 as a sunscreen active ingredient. Many comments urge FDA to make bemotrizinol available in the United States, citing bemotrizinol's broad spectrum protection, photostability, low systemic absorption, and favorable safety profile. Many comments discuss the potential benefits of bemotrizinol's inclusion as a sunscreen active ingredient, such as improved public health outcomes due to increased protection from skin cancer. Some comments characterize the addition of bemotrizinol as a sunscreen active ingredient under OTC Monograph M020 as bringing sunscreen innovation in the United States. These comments also state that bemotrizinol has been used safely for decades in numerous other countries and express frustration with how long it has taken the FDA to make bemotrizinol available in the United

States. One comment explains that this proposed order is a milestone and is a direct result of the landmark OTC monograph reform provisions enacted as part of the CARES Act.

(Response 1) FDA appreciates the broad support for adding bemotrizinol as a sunscreen active ingredient to OTC Monograph M020. Based on FDA's comprehensive review of data submitted in the OMOR, available data from independent literature reviews, and data submitted in comments on the proposed order, FDA concludes that bemotrizinol is GRASE for use as an active ingredient in OTC sunscreen drug products under the conditions set forth in Section IX of this document, and other applicable requirements. FDA agrees that the inclusion of bemotrizinol as a sunscreen active ingredient may help improve public health given the recognized public health benefits of sunscreen use when sunscreen drug products are used as directed.

While FDA recognizes that bemotrizinol has been available in sunscreen products internationally for many years and understands the frustration of some American consumers, there is a fundamental difference in how sunscreens are regulated in the United States compared to many other countries. In the United States, sunscreens are regulated as drugs. Section 201(g)(1)(B) of the FD&C Act (21 U.S.C. 321(g)(1)(B)) defines the term "drug" as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals." The intended use of sunscreen drug products is to help prevent sunburn (see § M020.50(c)(1) of OTC Monograph M020). Additionally, when used as directed with other skin protection, sunscreen drug products with broad spectrum SPF value of 15 or higher are intended to decrease the risk of skin cancer and early skin aging caused by the sun (see § M020.50(c)(2) of OTC Monograph M020). Therefore, because of their intended use, sunscreen drug products are drugs under United States law.[20] The United States classification of sunscreens as drugs is in contrast to other countries, where sunscreens are regulated as cosmetics. Unlike cosmetics, all drug products, including sunscreens, are subject to the safety and efficacy requirements for drug products as set out in the FD&C Act.

b. Comments on Safety of Bemotrizinol and FDA Responses

Based on FDA's review of the nonclinical, clinical pharmacology, and clinical safety studies and related information submitted in the OMOR, FDA proposed to conclude that there is adequate evidence of the safety of bemotrizinol at concentrations up to 6 percent for use as an active ingredient in nonprescription sunscreen drug products intended for use in adults and children 6 months of age and older.[21] After consideration of the public comments discussing bemotrizinol's safety, FDA did not make any changes to the final order based on these comments.

(Comment 2) FDA received several comments emphasizing the need for postmarketing surveillance of sunscreen drug products containing bemotrizinol. One comment explains that there is a need for continued monitoring for adverse events especially in the pediatric population

[20] Further, under section 503(h)(1) of the FD&C Act (21 U.S.C. 353(h)(1)), any OTC monograph drug is deemed to be a drug under section 201(g).

[21] See Proposed Administrative Order OTC000039, Section IV.B. Safety.

due to concerns that there are data gaps such as an absence of information on bemotrizinol in human breast milk and limited long-term pediatric data.

(Response 2) While FDA agrees on the importance of postmarketing surveillance, FDA disagrees that there is a safety information gap for bemotrizinol. The clinical pharmacology data submitted in the OMOR demonstrated that bemotrizinol is not readily absorbed through human skin, even with repeat application. In addition, as explained in the Scientific Review Supporting Proposed Administrative Order,[22] while the pediatric data for bemotrizinol are limited, the clinical human safety data submitted by the Requestor demonstrated that bemotrizinol at concentrations up to 6 percent is safe for use as an active ingredient in nonprescription sunscreen drug products intended for use in adults and children ages 6 months and older. Because the data demonstrated low overall absorption of bemotrizinol and no instances of irritation, phototoxicity, or photoallergenicity in the dermal studies, FDA did not consider similar studies in the pediatric population to be necessary. While the postmarketing safety reports in children were very few, the types of adverse events reported were similar to those in adults.

FDA also monitors adverse events and safety issues related to drug products, which would include any sunscreen drug products containing bemotrizinol that are marketed in the United States. FDA Adverse Event Monitoring System (AEMS)[23] is the database currently designed to support FDA's postmarketing safety surveillance programs. Under section 760 of the FD&C Act (21 U.S.C. 379aa), manufacturers, packers, or distributors of nonprescription drug products, including sunscreen drug products, must report serious adverse events associated with the use of such a nonprescription drug in the United States to FDA. Additionally, FDA has robust reporting systems for the public to report adverse drug experiences, complaints, or other issues with FDA regulated products, including nonprescription drug products. MedWatch is FDA's program for the public to report serious adverse drug experiences, product quality problems, therapeutic inequivalence/failure, and product use errors with human medical products.[24] FDA's SmartHub is designed to help the public navigate the appropriate form or resources to report a problem with an FDA-regulated human or animal product, adverse health experience, or facility issue.[25] FDA encourages consumers and healthcare professionals to submit any relevant reports to FDA.

c. Comments on Dosage Forms of Bemotrizinol and FDA Responses

In determining conditions under which a sunscreen drug product containing bemotrizinol as a sunscreen active ingredient is GRASE, FDA considered permitted dosage forms. Specifically, FDA proposed that OTC monograph conditions for drug products containing bemotrizinol as a sunscreen active ingredient include conditions that limit such products to the following dosage

---

[22] See Scientific Review Supporting Proposed Administrative Order, Section III.C.4. Proposal Based on Clinical Safety Data.

[23] AEMS (formerly FDA Adverse Event Reporting System) is a database designed to support the FDA's postmarketing safety surveillance program. For more information, see FDA's Adverse Event Monitoring System (AEMS) available at https://www.fda.gov/drugs/surveillance/fda-adverse-event-monitoring-system-aems.

[24] For more information, see MedWatch: The FDA Safety Information and Adverse Event Reporting Program is available at https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program.

[25] FDA's SmartHub is available at https://www.safetyreporting.hhs.gov/smarthub#/.

forms: oil, lotion, cream, gel, butter, paste, ointment, stick, and spray; provided that the product in spray dosage form is manufactured and packaged with no propellant (e.g., a pump spray) 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 (e.g., a bag-on-valve spray).[26] As part of the OMOR, the Requestor did not submit data demonstrating a sunscreen drug product formulation directly combined with a propellant to support an aerosol spray dosage form. Additionally, the Requestor did not submit data to support a powder dosage form.[27] Accordingly, in the proposed order, FDA proposed that the data for bemotrizinol did not support a powder dosage form or a drug product formulation directly combined with a propellant to create an aerosol spray dosage form.

After consideration of the comment FDA received on permitted dosage forms, FDA did not make any changes to the final order based on this comment.

(Comment 3) FDA received one comment from the Requestor providing additional data intended to support the use of sunscreen drug products containing bemotrizinol in an aerosol spray dosage form. The Requestor developed market-image aerosol spray sunscreen products containing bemotrizinol at a concentration of 6 percent and variations in the levels of ethanol (0%, 11%, 21%) and using propane/butane 36 percent as the propellant. The Requestor also included other sunscreen active ingredients typically found in market formulations to gain an understanding of the impact of propellants on combination sunscreen drug formulations. The Requestor conducted a 10-week stability study on aerosol spray formulations that reflect typical commercial aerosol sunscreens. The comment includes the 10-week stability study data. The Requestor asserted that bemotrizinol is physically and chemically stable in an aerosol spray dosage form across solvent systems, propellant levels, temperatures, and packaging formats. The Requestor asserted that there were no qualitative indicators of instability for any of the formulations or conditions evaluated during the study period. Similarly, the Requestor asserted that quantitative data on the

[26] With the exception of bemotrizinol, newly added as § M020.10(c) of OTC Monograph M020, by operation of section 505G(m)(2) of the FD&C Act, sunscreen active ingredients in §§ M020.10(a)-(b) and (d)-(q) are currently permitted in the following dosage forms: oil, lotion, cream, gel, butter, paste, ointment, stick, spray, and powder, See Final Administrative Order OTC000006, page 2, footnote 7.

[27] See Proposed Administrative Order OTC000039, Section IV.C.2. Drug Product Manufacturing, Including Dosage Forms.

recovery of bemotrizinol from an aerosol spray dosage form are consistent with the patterns seen for other sunscreen active ingredients evaluated in aerosol spray recovery assays.

(Response 3) Based on FDA's analysis of the data submitted in the OMOR and the Requestor's comment,[28] FDA concludes that the data are not sufficient to support bemotrizinol in an aerosol spray dosage form in which the propellant is combined directly with the drug product formulation. The data to support the manufacturing and analytical methods used in the market-image aerosol spray study were incomplete. The Requestor did not provide justification for the drug product formulations developed for this study. Further, the stability program appears insufficient for the following reasons: (1) only 10 weeks of data were presented; (2) it is uncertain if the containers used are impermeable and therefore support storage conditions that did not include relative humidity; (3) limited data were provided across the stability program in general; and (4) assay results were provided at 10 weeks but results at release were not provided. The assay results at 10 weeks were close to the lower limit of acceptance and it is not possible to determine if this is due to degradation of the drug product or because recovery at release was less than the theoretical values provided in the stability program.

FDA did not receive additional data to support a sunscreen drug product containing bemotrizinol in a powder dosage form. Accordingly, sunscreen drug products containing bemotrizinol are limited to the following dosage forms: oil, lotion, cream, gel, butter, paste, ointment, stick, and spray, provided that the product in spray dosage form is manufactured and packaged with no propellant (e.g., a pump spray) 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 (e.g., a bag-on-valve spray).

d. Comments on Labeling of Bemotrizinol and FDA Responses

Consistent with FDA's review of the safety and efficacy data for bemotrizinol, FDA did not propose any distinct labeling as an OTC monograph condition for drug products that contain bemotrizinol as a sunscreen active ingredient.[29]

After consideration of the comment on labeling for bemotrizinol, FDA did not make any changes to the final order based on this comment.

---

[28] See FDA's Scientific Review Supporting Final Administrative Order for a complete review of the data submitted in the Requestor's comment.

[29] See Proposed Administrative Order OTC000039, Section IV.C.5. Labeling Requirements.

(Comment 4) FDA received one comment requesting that sunscreen drug products containing bemotrizinol intended for daily use in children over the age of 6 months include clear ingestion warning language such as "keep out of reach of children."

(Response 4) Nonprescription drug products marketed without an approved application under section 505 of the FD&C Act, including sunscreen drug products containing bemotrizinol, must be labeled with a warning to keep the drug product out of reach of children.[30] Additionally, the label for all nonprescription drugs must include a warning about accidental overdose/ingestion.[31] For topical drug products, including sunscreen drug products, the labeling must state "Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away."[32]

e. Miscellaneous Comments and FDA Responses

FDA received other general comments that were not specific to the proposed OTC monograph determination.

After consideration of these comments, FDA did not make any changes to the final order based on these comments.

(Comment 5) FDA received one comment requesting that FDA promptly notify the national poison control network once this final order is posted. The comment recommends ensuring that poison control centers and toxicology laboratories can detect bemotrizinol and other sunscreen active ingredients in toxicology screens.

(Response 5) As part of the issuance of FDA's final orders, FDA has a robust communications plan that includes press releases and email messages to interested parties on FDA mailing lists. While outside of FDA's jurisdiction, FDA encourages the development of assays to detect bemotrizinol and other sunscreen active ingredients in toxicology screenings. Additionally, as explained in Response 2, FDA has robust reporting systems for the public to report adverse drug experiences, complaints, or other issues with FDA regulated products, including sunscreen drug products. FDA encourages consumers and healthcare professionals to submit any relevant reports to FDA.

(Comment 6) FDA received multiple additional comments, including comments requesting FDA evaluate other specific sunscreen active ingredients for inclusion in OTC Monograph M020, explaining the need for broader reforms to the requirements for marketing OTC sunscreen drug products, requesting the use of nonclinical testing alternatives to animal testing and use of real-world evidence, or requesting FDA evaluate the safety and efficacy of sunscreen active ingredients currently allowed under OTC Monograph M020.

(Response 6) Proposed Administrative Order OTC000039 proposed to amend the requirements for sunscreen drug products for OTC human use to add a new sunscreen active ingredient,

---

[30] See 21 CFR 330.1(g).

[31] See 21 CFR 201.66(c)(5)(x).

[32] See 21 CFR 330.1(g).

bemotrizinol, at concentrations up to 6 percent, to OTC Monograph M020, and Final Administrative Order OTC000039 finalizes FDA's proposal. Therefore, these comments are outside the scope of the order.

3. Conclusion

Based on FDA's scientific review of available data, including data submitted in the OMOR, available data from independent literature reviews, and data submitted in comments on the proposed order, FDA concludes that bemotrizinol is GRASE under the conditions described in the final order, Section IX of this document. Among these conditions are conditions specific to the use of bemotrizinol as an active ingredient in sunscreen drug products, including a concentration up to 6 percent,[33] permitted combinations of bemotrizinol with other sunscreen active ingredients and with skin protectant active ingredients, and permitted dosage forms. Therefore, FDA is amending the conditions described in OTC Monograph M020 to include bemotrizinol as a sunscreen active ingredient. As such, drug products containing bemotrizinol as a sunscreen active ingredient are GRASE under section 201(p)(1) of the FD&C Act and not subject to section 503(b)(1) of the FD&C Act, if they conform with the conditions in this final order, among other applicable requirements.

FDA is also including in the final order minor stylistic and formatting changes to improve the readability, clarity, and presentation of OTC Monograph M020.

V. Exclusivity

As described in Section IV (Statement of Reasons for Issuance of Final Order) and elsewhere in this document, Final Administrative Order OTC000039 amends OTC Monograph M020 to provide for a nonprescription sunscreen drug product to contain bemotrizinol under specified conditions. Section 505G(b)(5)(C)(i) of the Act establishes that this final order shall have the effect of authorizing solely DSM Nutritional Products LLC (or the licensees, assignees, or successors in interest of DSM with respect to the subject of this final order) to market drugs incorporating changes described in section 505G(b)(5)(C)(ii)(I) subject to this order. The statute provides that this exclusivity shall last for a period of 18 months following the effective date of this final order and beginning on the date DSM may lawfully market drugs pursuant to this order.

VI. Effective Date

This final order shall take effect—

(a) August 9, 2026; or

(b) if the final order is disputed under section 505G(b) of the FD&C Act, in accordance with section 505G(b)(2)(A)(iv)(I) of such Act.

---

[33] In addition, a finished drug product containing bemotrizinol as a sunscreen active ingredient must also provide a minimum SPF of not less than 2 as measured by the testing procedures established in § M020.80 of OTC Monograph M020.

VII. Analysis of Environmental Impact

The Agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The Agency's finding of no significant impact along with the supporting environmental assessment and scientific review may be accessed in the Additional Information section for Final Administrative Order OTC000039.[34]

VIII. References

For references cited in this document, see Supporting Documents for the final order available in OTC Monographs@FDA at https://www.accessdata.fda.gov/scripts/cder/omuf/.

IX. Final Administrative Order (OTC000039)

Pursuant to section 505G(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355h(b)), it is hereby ordered as follows:

[34] See the OTC Monographs@FDA portal at https://www.accessdata.fda.gov/scripts/cder/omuf/ under the Additional Information section for the Final Administrative Order OTC000039.

A. OTC Monograph Determinations[35]

FDA has determined that the following conditions are necessary, but not alone sufficient,[36] for a sunscreen drug product containing bemotrizinol as an active ingredient to be GRASE under section 201(p)(1) of the FD&C Act and not subject to FD&C Act section 503(b)(1):

- Bemotrizinol is present in the drug product in a concentration up to 6 percent, and the finished drug product provides a minimum SPF value of not less than 2 as measured by the testing procedures established in § M020.80 of OTC Monograph M020;

- The composition of a single drug product may combine bemotrizinol with any single active ingredient identified in § M020.10 of OTC Monograph M020, except for PABA or trolamine salicylate, or may combine bemotrizinol with any combination of sunscreen active ingredients identified in § M020.20(a) of OTC Monograph M020 that does not include PABA or trolamine salicylate, provided that the following additional conditions are met: (1) each active ingredient is used in the concentration established for it in § M020.10 of OTC Monograph M020; (2) the concentration of each active ingredient is sufficient to contribute a minimum SPF of not less than 2 to the finished product; (3) the finished product must have a minimum SPF of not less than the number of sunscreen active ingredients used in the combination, multiplied by 2; and (4) the SPF of the product is measured by the testing procedures established in § M020.80 of OTC Monograph M020;

- The composition of a single drug product may combine any one (two when required to be in combination) or more of the skin protectant active ingredients identified in § M016.10(a), (d), (e), (g), (h), (i), (k), (l), (m), and (r) of OTC Monograph M016 with bemotrizinol as a single sunscreen active ingredient provided that the drug product meets the conditions for a drug product that contains bemotrizinol in OTC Monograph M020; and is labeled according to § M016.60(b)(3) of OTC Monograph M016;

---

[35] For information about other sunscreen orders, see footnote 1, supra.

[36] To be GRASE under section 201(p)(1) of the FD&C Act, a sunscreen drug product containing bemotrizinol must also conform to other applicable conditions in final orders under 505G(b) of the FD&C Act. In addition, to be legally marketed without an approved application under section 505 of the FD&C Act, such a drug product must meet other requirements including the general requirements for nonprescription drugs. See 505G(b)(1)(B) of the FD&C Act and Section III, Background of this document.

- The composition of a single drug product may combine any one (two when required to be in combination) or more of the skin protectant active ingredients identified in § M016.10(a), (d), (e), (g), (h), (i), (k), (l), (m), and (r) of OTC Monograph M016 with bemotrizinol in any combination with other sunscreen active ingredients identified in § M020.20 of OTC Monograph M020 that does not include PABA or trolamine salicylate; provided the drug product meets the conditions for a drug product that contains bemotrizinol in OTC Monograph M020; and is labeled according to § M016.60(b)(3) of OTC Monograph M016;

- The drug product containing bemotrizinol as a sunscreen active ingredient is in one of the following dosage forms and meets additional conditions specified: oil, lotion, cream, gel, butter, paste, ointment, stick, or spray, provided that the spray product 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.

FDA also finds that a drug product containing bemotrizinol as a sunscreen active ingredient is not GRASE if it includes bemotrizinol in combination with PABA and/or trolamine salicylate.

Thus, FDA is issuing this final order to amend OTC Monograph M020 including technical amendments as follows:

1. Amend the heading of Part B of OTC Monograph M020 to read as follows:

   Part B—Active Ingredients, Route of Administration, and Dosage Forms

2. Amend § M020.10 to redesignate paragraphs (c), (d), (e), (f), (g), (h), (i), (j), (k), (l), (m), (n), (o), and (p) as (d), (e), (f), (g), (h), (i), (j), (k), (l), (m), (n), (o), (p), and (q), respectively.

3. Amend § M020.10(c) to add new paragraph (c) to read as follows:

   (c) Bemotrizinol up to 6 percent.

4. Amend § M020.20(a)(1) to read as follows:

   (1) Two or more sunscreen active ingredients identified in §§ M020.10(a), (d), (e), (f), and (g) through (q) may be combined with each other in a single product when used in the concentrations established for each ingredient in § M020.10. The concentration of each active ingredient must be sufficient to contribute a minimum SPF of not less than 2 to the finished product. The finished product must have a minimum SPF of not less than the number of sunscreen active ingredients used in the combination multiplied by 2.

5. Amend § M020.20(a)(2) to read as follows:

   (2) Two or more sunscreen active ingredients identified in §§ M020.10(b), (d), (e), (g), (i) through (l), (n), and (p) may be combined with each other in a single product when used in the concentrations established for each ingredient in § M020.10. The concentration of each active ingredient must be sufficient to contribute a minimum SPF of not less than 2 to the

finished product. The finished product must have a minimum SPF of not less than the number of sunscreen active ingredients used in the combination multiplied by 2.

6. Amend § M020.20 to include subparagraph (a)(3) to read as follows:

(3) The sunscreen active ingredient identified in § M020.10(c) may be combined with any one active ingredient identified in §§ M020.10(b), (d) through (o), and (q) in a single product when used in the concentrations established for each ingredient in § M020.10. The sunscreen active ingredient identified in § M020.10(c) may be combined with one or more active ingredients identified in §§ M020.10(b), (d), (e), (g), (i) through (l), and (n) in a single product when used in the concentrations established for each ingredient in § M020.10. The sunscreen active ingredient identified in § M020.10(c) may be combined with one or more active ingredients identified in §§ M020.10(d), (e), (f), (g) through (o), and (q) when used in the concentrations established for each ingredient in § M020.10. The concentration of each active ingredient must be sufficient to contribute a minimum SPF of not less than 2 to the finished product. The finished product must have a minimum SPF of not less than the number of sunscreen active ingredients used in the combination multiplied by 2.

7. Add § M020.40 under Part B with the heading "Dosage forms" to read as follows:

The product is in one of the following dosage forms and meets any additional conditions specified, as applicable:

(a) If it contains skin protectant active ingredient(s) identified in § M016.20(e) of OTC Monograph M016 it complies with applicable dosage form conditions in § M020.40.

(b) If it contains the sunscreen active ingredient identified in § M020.10(c),

(1) oil

(2) lotion

(3) cream

(4) gel

(5) butter

(6) paste

(7) ointment

(8) stick

(9) spray, provided that the product is manufactured and packaged

(i) with no propellant; or

(ii) 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 propellant and the drug product formulation.

8. Amend § M020.50(h) to read as follows:

(h) Labeling of products containing a combination of sunscreen and skin protectant active ingredients identified in § M016.20(e) of OTC Monograph M016. Statements of identity, indications, warnings, and directions for use, respectively, applicable to each ingredient in the product may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable. Labeling provisions in § M016.50(e) of OTC Monograph M016 shall not apply to these products.

B. Revision: Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use

Upon the effective date of this order, as a reflection of the cumulative product of Final Administrative Order OTC000006 and this order, OTC Monograph M020 will read, in its entirety, as follows:

U.S. Food and Drug Administration

Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use

Part A—General Provisions

Sec.

M020.1 Scope

Part B—Active Ingredients, Route of Administration, and Dosage Forms

M020.10 Sunscreen active ingredients

M020.20 Permitted combinations of active ingredients

M020.40 Dosage forms

Part C—Labeling

M020.50 Labeling of sunscreen drug products

Part D—Testing Procedures

M020.80 Sun protection factor (SPF) test procedure

M020.90 Broad spectrum test procedure

Part A—General Provisions

§ M020.1 Scope

An over-the-counter (OTC) sunscreen drug product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this OTC monograph and each general condition established in 21 CFR 330.1.

Part B—Active Ingredients, Route of Administration, and Dosage Forms

§ M020.10 Sunscreen active ingredients

The active ingredient of the product consists of any of the following, within the concentration specified for each ingredient, and the finished product provides a minimum sun protection factor (SPF) value of not less than 2 as measured by the testing procedures established in § M020.80:

(a) Aminobenzoic acid (PABA) up to 15 percent.

(b) Avobenzone up to 3 percent.

(c) Bemotrizinol up to 6 percent.

(d) Cinoxate up to 3 percent.

(e) Dioxybenzone up to 3 percent.

(f) Ensulizole up to 4 percent.

(g) Homosalate up to 15 percent.

(h) Meradimate up to 5 percent.

(i) Octinoxate up to 7.5 percent.

(j) Octisalate up to 5 percent.

(k) Octocrylene up to 10 percent.

(l) Oxybenzone up to 6 percent.

(m) Padimate O up to 8 percent.

(n) Sulisobenzone up to 10 percent.

(o) Titanium dioxide up to 25 percent.

(p) Trolamine salicylate up to 12 percent.

(q) Zinc oxide up to 25 percent.

§ M020.20 Permitted combinations of active ingredients

The SPF of any combination product is measured by the testing procedures established in § M020.80.

(a) Combinations of sunscreen active ingredients.

(1) Two or more sunscreen active ingredients identified in §§ M020.10(a), (d), (e), (f), and (g) through (q) may be combined with each other in a single product when used in the concentrations established for each ingredient in § M020.10. The concentration of each active ingredient must be sufficient to contribute a minimum SPF of not less than 2 to the finished product. The finished product must have a minimum SPF of not less than the number of sunscreen active ingredients used in the combination multiplied by 2.

(2) Two or more sunscreen active ingredients identified in §§ M020.10(b), (d), (e), (g), (i) through (l), (n), and (p) may be combined with each other in a single product when used in the concentrations established for each ingredient in § M020.10. The concentration of each active ingredient must be sufficient to contribute a minimum SPF of not less than 2 to the finished product. The finished product must have a minimum SPF of not less than the number of sunscreen active ingredients used in the combination multiplied by 2.

(3) The sunscreen active ingredient identified in § M020.10(c) may be combined with any one active ingredient identified in §§ M020.10(b), (d) through (o), and (q) in a single product when used in the concentrations established for each ingredient in § M020.10. The sunscreen active ingredient identified in § M020.10(c) may be combined with one or more active ingredients identified in §§ M020.10(b), (d), (e), (g), (i) through (l), and (n) in a single product when used in the concentrations established for each ingredient in § M020.10. The sunscreen active ingredient identified in § M020.10(c) may be combined with one or more active ingredients identified in §§ M020.10(d), (e), (f), (g) through (o), and (q) when used in the concentrations established for each ingredient in § M020.10. The concentration of each active ingredient must be sufficient to contribute a minimum SPF of not less than 2 to the finished product. The finished product must have a minimum SPF of not less than the number of sunscreen active ingredients used in the combination multiplied by 2.

§ M020.40 Dosage forms

The product is in one of the following dosage forms and meets any additional conditions specified, as applicable:

(a) If it contains skin protectant active ingredient(s) identified in § M016.20(e) of OTC Monograph M016, it complies with applicable dosage form conditions in § M020.40.

(b) If it contains the sunscreen active ingredient identified in § M020.10(c),

(1) oil

(2) lotion

(3) cream

(4) gel

(5) butter

(6) paste

(7) ointment

(8) stick

(9) spray, provided that the product is manufactured and packaged

(i) with no propellant; or

(ii) 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 propellant and the drug product formulation.

Part C—Labeling

§ M020.50 Labeling of sunscreen drug products

(a) Principal display panel. In addition to the statement of identity in § M020.50(b), the following labeling shall be prominently placed on the principal display panel:

(1) Effectiveness claim

(i) For products that pass the broad spectrum test in § M020.90.

(A) The labeling states “Broad Spectrum SPF [insert numerical SPF value resulting from testing under § M020.80]”.

(B) Prominence. The Broad Spectrum SPF statement shall appear as continuous text with no intervening text or graphic. The entire text shall appear in the same font style, size, and color with the same background color.

(ii) For sunscreen products that do not pass the broad spectrum test in § M020.90. The labeling states “SPF [insert numerical SPF value resulting from testing under § M020.80]”. The entire text shall appear in the same font style, size, and color with the same background color.

(2) Water resistance statements

(i) For products that provide 40 minutes of water resistance according to the test in § M020.80(g)(1). The labeling states "Water Resistant (40 minutes)".

(ii) For products that provide 80 minutes of water resistance according to the test in § M020.80(g)(2). The labeling states "Water Resistant (80 minutes)".

(b) Statement of identity. The labeling of the product contains the established name of the drug, if any, and identifies the drug as a "sunscreen."

(c) Indications. The labeling of the product states, under the heading "Uses," the phrases listed in § M020.50(c), as appropriate. Other truthful and nonmisleading statements, describing only the uses that have been established and listed in § M020.50(c), may also be used, as provided in 21 CFR 330.1(c)(2), subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 352) relating to misbranding and the prohibition in section 301(d) of the FD&C Act (21 U.S.C. 331(d)) against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the FD&C Act (21 U.S.C. 355(a)).

(1) For all sunscreen products, the following indication statement must be included under the heading "Uses": "[Bullet][37] helps prevent sunburn".

(2) For sunscreen products with a Broad Spectrum SPF value of 15 or higher according to the tests in §§ M020.80 and M020.90, the labeling may include the following statement in addition to the indication in § M020.50(c)(1): "[Bullet] if used as directed with other sun protection measures (see Directions [in bold italic font]), decreases the risk of skin cancer and early skin aging caused by the sun".

(3) Any labeling or promotional materials that suggest or imply that the use, alone, of any sunscreen reduces the risk of or prevents skin cancer or early skin aging will cause the product to be misbranded under section 502 of the FD&C Act.

(d) Warnings. The labeling of the product contains the following warnings under the heading "Warnings".

(1) For all sunscreen products.

(i) The labeling states "Do not use [bullet] on damaged or broken skin".

(ii) The labeling states "When using this product [bullet] keep out of eyes. Rinse with water to remove."

(iii) The labeling states "Stop use and ask a doctor if [bullet] rash occurs".

---

[37] See 21 CFR 201.66(b)(4).

(2) For sunscreen products that are broad spectrum with SPF values of at least 2 but less than 15 according to the SPF test in § M020.80 or that do not pass the broad spectrum test in § M020.90. The first statement under the heading "Warnings" states "Skin Cancer/Skin Aging Alert [in bold font]: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not [in bold font] skin cancer or early skin aging."

(e) Directions. The labeling of the product contains the following statements, as appropriate, under the heading "Directions." More detailed directions applicable to a particular product formulation may also be included.

(1) For all sunscreen products.

(i) As an option, the labeling may state "For sunscreen use:".

(ii) The labeling states "[bullet] apply [select one of the following: 'Liberally' or 'generously'] [and, as an option: 'And evenly'] 15 minutes before sun exposure".

(iii) As an option, the labeling may state "[bullet] apply to all skin exposed to the sun".

(iv) The labeling states "[bullet] children under 6 months of age: Ask a doctor".

(2) For sunscreen products with a Broad Spectrum SPF value of 15 or higher according to the tests in §§ M020.80 and M020.90. The labeling states "[bullet] Sun Protection Measures. [in bold font] Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including: [Bullet] limit time in the sun, especially from 10 a.m.-2 p.m. [bullet] wear long-sleeved shirts, pants, hats, and sunglasses".

(3) For products that satisfy the water resistance test in § M020.80(g). The labeling states "[bullet] reapply: [Bullet] after [select one of the following determined by water resistance test: '40 minutes of' or '80 minutes of'] swimming or sweating [bullet] immediately after towel drying [bullet] at least every 2 hours".

(4) For products that do not satisfy the water resistance test in § M020.80(g). The labeling states "[bullet] reapply at least every 2 hours [bullet] use a water resistant sunscreen if swimming or sweating".

(f) Other information. The labeling of the product contains the following statement under the heading "Other information:" "[bullet] protect the product in this container from excessive heat and direct sun".

(g) False and misleading claims. There are claims that would be false and/or misleading on sunscreen products. These claims include but are not limited to the following: “Sunblock,” “sweatproof,” and “waterproof.” These or similar claims will cause the product to be misbranded under section 502 of the FD&C Act.

(h) Labeling of products containing a combination of sunscreen and skin protectant active ingredients identified in § M016.20(e) of OTC Monograph M016. Statements of identity, indications, warnings, and directions for use, respectively, applicable to each ingredient in the product may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable. Labeling provisions in § M016.50(e) of OTC Monograph M016 shall not apply to these products.

Part D—Testing Procedures

§ M020.80 Sun protection factor (SPF) test procedure

(a) UV source (solar simulator).

(1) Emission spectrum. A single port or multiport solar simulator should be filtered so that it provides a continuous emission spectrum from 290 to 400 nanometers (nm) with a limit of 1,500 Watts per square meter (W/m2) on total irradiance for all wavelengths between 250 and 1,400 nm.

(i) The solar simulator should have the following percentage of erythema-effective radiation in each specified range of wavelengths:

Solar Simulator Emission Spectrum

Wavelength range (nm)	**Percent erythemal contribution [1]**
<290	<0.1
290-300	1.0-8.0
290-310	49.0-65.0
290-320	85.0-90.0
290-330	91.5-95.5
290-340	94.0-97.0
290-400	99.9-100.0

[1]Calculation of erythema action spectrum described in § M020.80(a)(2).

(ii) In addition, UVA II (320-340 nm) irradiance should equal or exceed 20 percent of the total UV (290-400 nm) irradiance. UVA I (340-400 nm) irradiance should equal or exceed 60 percent of the total UV irradiance.

(2) Erythema action spectrum.

(i) Calculate the erythema action spectrum weighting factor (Vi) at each wavelength λ:

(A) $Vi\ (\lambda) = 1.0\ (250 < \lambda \leq 298\ nm)$

(B) $Vi\ (\lambda) = 10^{0.094*(298-\lambda)}\ (298 < \lambda \leq 328\ nm)$

(C) $Vi\ (\lambda) = 10^{0.015*(140-\lambda)}\ (328 < \lambda \leq 400\ nm)$

(ii) Calculate the erythema-effective UV dose (E) delivered by a solar simulator as follows:

$$E = \sum_{250}^{400} V_i(\lambda) * I(\lambda) * t$$

Where $Vi(\lambda)$ = erythema action spectrum weighting factor at each wavelength λ

$I\ (\lambda)$ = irradiance (Watts per square meter) at each wavelength λ

t = exposure time (seconds)

Erythema-effective dose (E) is expressed as effective Joules per square meter (J/m^2-eff).

(iii) The emission spectrum must be determined using a handheld radiometer with a response weighted to match the spectrum in ISO 17166 CIE S 007/E entitled "Erythemal reference action spectrum and standard erythema dose," dated 1999 (First edition, 1999-12-15; corrected and reprinted 2000-11-15), which is incorporated by reference and is available for inspection at FDA. For further information about inspecting incorporated materials, see https://www.fda.gov. Copies may also be available from the publisher/ISO Copyright Office. The solar simulator output should be measured before and after each phototest or, at a minimum, at the beginning and end of each test day. This radiometer should be calibrated using side-by-side comparison with the spectroradiometer (using the weighting factors determined according to § M020.80(a)(2)(i)) at the time of the annual spectroradiometric measurement of the solar simulator as described in § M020.80(a)(4).

(3) Operation. A solar simulator should have no significant time-related fluctuations (within 20 percent) in radiation emissions after an appropriate warm-up time and demonstrate good beam uniformity (within 20 percent) in the exposure plane. The delivered dose to the UV exposure site must be within 10 percent of the expected dose.

(4) Periodic measurement. To ensure that the solar simulator delivers the appropriate spectrum of UV radiation, the emission spectrum of the solar simulator should be measured at least annually with an appropriate and accurately calibrated spectroradiometer system (results should be traceable to the National Institute for Standards and Technology). In addition, the solar simulator must be recalibrated if there is any change in the lamp bulb or the optical filtering components (i.e., filters, mirrors, lenses, collimating devices, or focusing devices). Daily solar simulator radiation intensity should be monitored with a broadband radiometer with a response weighted to match the erythema action spectrum in ISO 17166 CIE S 007/E entitled "Erythemal reference action spectrum and standard erythema dose," which is incorporated by reference in § M020.80(a)(2)(iii). If a lamp must be replaced due to failure or aging during a phototest, broadband device readings consistent with those obtained for the original calibrated lamp will suffice until measurements can be performed with the spectroradiometer at the earliest possible opportunity.

(b) SPF standard

(1) Preparation. The SPF standard should be a formulation containing 7-percent padimate O and 3-percent oxybenzone.

Composition of the Padimate O/ oxybenzone SPF Standard

Ingredients	Percent by weight
Part A:	
Lanolin	4.50
Cocoa butter	2.00
Glyceryl monostearate	3.00
Stearic acid	2.00
Padimate O	7.00
Oxybenzone	3.00
Part B:	
Purified water USP	71.60
Sorbitol solution	5.00
Triethanolamine, 99 percent	1.00
Methylparaben	0.30
Propylparaben	0.10
Part C:	
Benzyl alcohol	0.50
Part D:	
Purified water USP	QS [1]

[1] Quantity sufficient to make 100 grams.

Step 1. Add the ingredients of Part A into a suitable stainless-steel kettle equipped with a propeller agitator. Mix at 77 to 82 °C until uniform.

Step 2. Add the water of Part B into a suitable stainless-steel kettle equipped with a propeller agitator and begin mixing at 77 to 82 °C. Add the remaining ingredients of Part B and mix until uniform.

Step 3. Add the batch of Step 1 to the batch of Step 2 and mix at 77 to 82 °C until smooth and uniform. Slowly cool the batch to 49 to 54 °C.

Step 4. Add the benzyl alcohol of Part C to the batch of Step 3 at 49 to 54 °C. Mix until uniform. Continue to cool batch to 35 to 41 °C.

Step 5. Add sufficient water of Part D to the batch of Step 4 at 35 to 41 °C to obtain 100 grams of SPF standard. Mix until uniform. Cool batch to 27 to 32 °C.

(2) High-performance liquid chromatography (HPLC) assay. Use the HPLC procedure to verify the concentrations of padimate O and oxybenzone in the SPF standard:

(i) Instrumentation.

(A) Equilibrate a suitable liquid chromatograph to the following or equivalent conditions:

(1) Column	C-18, 250 millimeters (mm) length, 4.6 mm inner diameter (5 microns)
(2) Mobile Phase	85:15:0.5 methanol: water: acetic acid
(3) Flow Rate	1.5 milliliters (mL) per minute
(4) Temperature	Ambient
(5) Detector	UV spectrophotometer at 308 nanometers
(6) Attenuation	As needed

(B) Use HPLC grade reagents for mobile phase.

(ii) Preparation of the HPLC reference standard.

(A) Weigh 0.50 gram (g) of oxybenzone USP reference standard into a 250-mL volumetric flask. Dissolve and dilute to volume with isopropanol. Mix well.

(B) Weigh 0.50 g of padimate O USP reference standard into a 250-mL volumetric flask. Dissolve and dilute to volume with isopropanol. Mix well.

(C) Pipet 3.0 mL of the oxybenzone solution and 7.0 mL of the padimate O solution into a 100-mL volumetric flask. Dilute to volume with isopropanol and mix well.

(iii) HPLC system suitability.

(A) Make three replicate 10-microliter injections of the HPLC reference standard (described in § M020.80(b)(2)(ii)). The relative standard deviation in peak areas should not be more than 2.0 percent for either oxybenzone or padimate O.

(B) Calculate the resolution (R) between the oxybenzone and padimate O peaks from one chromatogram as follows:

$$R = \frac{2 * (t_o - t_p)}{W_o + W_p}$$

Where t_o = retention time for oxybenzone

t_p = retention time for padimate O

W_o = oxybenzone peak width at baseline

W_p = padimate O peak width at baseline

If the resolution (R) is less than 3.0, adjust the mobile phase or replace the column.

(iv) SPF standard assay

(A) The SPF standard is diluted to the same concentration as the HPLC reference standard according to the following steps:

(1) Step 1. Weigh 1.0 g of the SPF standard (described in § M020.80(b)(1)) into a 50-mL volumetric flask.

(2) Step 2. Add approximately 30 mL of isopropanol and heat with swirling until contents are evenly dispersed.

(3) Step 3. Cool to room temperature (15 to 30 °C) and dilute to volume with isopropanol. Mix well.

(4) Step 4. Pipet 5.0 mL of the preparation into a 50-mL volumetric flask and dilute to volume with isopropanol. Mix well.

(B) Inject 10-microliter of diluted SPF standard from paragraph § M020.80(b)(2)(iv)(A) and calculate the amount of oxybenzone and padimate O as follows:

$$\text{Percent Oxybenzone} = \frac{\text{Peak area of oxybenzone in sunscreen standard}}{\text{Peak area of oxybenzone in HPLC reference standard}} * 100$$

$$\text{Percent Padimate O} = \frac{\text{Peak area of padimate O in sunscreen standard}}{\text{Peak area of padimate O in HPLC reference standard}} * 100$$

The percent of oxybenzone and padimate O in the SPF standard should be between 95 and 105.

(c) Test subjects

(1) Number of subjects. A test panel should include enough subjects to produce a minimum of 10 valid test results. A maximum of three subjects may be rejected from this panel based on § M020.80(e)(5).

(2) Medical history.

(i) Obtain a medical history from each subject with emphasis on the effects of sunlight on the subject's skin. Determine that each subject is in good general health with skin type 1, 2, or 3 as follows:

(1) Always burns easily; never tans (sensitive).

(2) Always burns easily; tans minimally (sensitive).

(3) Burns moderately; tans gradually (light brown) (normal).

(4) Burns minimally; always tans well (moderate brown) (normal).

(5) Rarely burns; tans profusely (dark brown) (insensitive).

(6) Never burns; deeply pigmented (insensitive).

(ii) Skin type is based on first 30 to 45 minutes of sun exposure after a winter season of no sun exposure. Determine that each subject is not taking topical or systemic medication that is known to alter responses to UV radiation. Determine that each subject has no history of sensitivities to topical products and/or abnormal responses to sunlight, such as a phototoxic or photoallergic response.

(3) Physical examination. Conduct a physical examination to determine the presence of sunburn, suntan, scars, active dermal lesions, and uneven skin tones on the areas of the back to be tested. A suitable source of low power UVA, such as a Woods lamp, is helpful in this process. If any of these conditions are present, the subject is not qualified to participate in the study. The presence of nevi, blemishes, or moles will be acceptable if, in the physician's judgment, they will neither compromise the study nor jeopardize a subject's safety. Subjects with dysplastic nevi should not be enrolled. Excess hair on the back is acceptable if the hair is clipped. Shaving is unacceptable because it may remove a significant portion of the stratum corneum and temporarily alter the skin's response to UV radiation.

(4) Informed consent. Obtain legally effective written informed consent from all test subjects.

(d) Sunscreen application.

(1) Test site. Test sites are locations on each subject's back, between the beltline and the shoulder blades (scapulae) and lateral to the midline, where skin responses to UV radiation are determined. Responses on unprotected skin (no test material applied) and protected skin (sunscreen test product(s) or SPF standard applied) are determined at separate unprotected and protected test sites, respectively. Test sites should be randomly located in a blinded manner. Each test site should be a minimum of 30 square centimeters and outlined with indelible ink.

(2) Test subsite. Test subsites are the locations to which UV radiation is administered within a test site. At least five test subsites should receive UV doses within each test site. Test subsites should be at least 0.5 square centimeters (cm^2) in area and should be separated from each other by at least 0.8 cm. Each test subsite should be outlined with indelible ink.

(3) Applying test materials. Apply the sunscreen test product and the SPF standard at 2 milligrams per square centimeter (mg/cm^2) to their respective test sites. Use a finger cot compatible with the sunscreen to spread the product as evenly as possible.

(4) Waiting period. Wait at least 15 minutes after applying a sunscreen product before exposing the test sites to UV radiation as described in § M020.80(e). For water resistant sunscreen products, proceed with the water resistance testing procedure described in § M020.80(g) after waiting at least 15 minutes.

(e) UV exposure

(1) Definition of minimal erythema dose. The minimal erythema dose (MED) is the smallest UV dose that produces perceptible redness of the skin (erythema) with clearly defined borders at 16 to 24 hours after UV exposure. The MED for unprotected skin (MEDu) is determined on a test site that does not have sunscreen applied. The MED for protected skin (MEDp) is determined on a test site that has sunscreen applied. An MEDp is determined for the SPF standard (ssMEDp). An MEDp is determined for the sunscreen test product (tpMEDp).

(2) UV exposure for initial MEDu. For each test subject, administer a series of UV radiation doses expressed as J/m^2-eff (as determined according to § M020.80(a)(2)(ii)) to the test subsites within an unprotected test site using an accurately calibrated solar simulator. Select doses that are a geometric series represented by 1.25^n (i.e., each dose is 25 percent greater than the previous dose).

(3) UV exposure for final MEDu, ssMEDp, and tpMEDp. For each subject, determine the final MEDu, ssMEDp, and tpMEDp by administering a series of five UV doses to the appropriate test sites. The middle dose (X) in each of these dose series (i.e., the third dose) should equal the initial MEDu times the expected SPF. Note that the expected SPF equals 1 and 16.3 for the final MEDu and ssMEDp, respectively. The remaining UV doses in the series depend upon the expected SPF value of the sunscreen test product(s).

For products with an expected SPF less than 8, administer UV doses that increase by 25 percent with each successive dose (i.e., 0.64X, 0.80X, 1.00X, 1.25X, and 1.56X). For products with an expected SPF from 8 to 15, administer UV doses that increase by 20 percent with each successive dose (i.e., 0.69X, 0.83X, 1.00X, 1.20X, and 1.44X). For products with an expected SPF higher than 15, administer UV doses that increase by 15 percent with each successive dose (i.e., 0.76X, 0.87X, 1.00X, 1.15X, and 1.32X).

(4) Evaluation of test subsites. In order that the person who evaluates the test subsites is not biased, he/she should not be the same person who applied the sunscreen drug product to the test site or administered the UV doses. After UV doses are administered, all immediate responses should be recorded. These may include an immediate darkening or tanning, typically grayish or purplish in color, which fades in 30 to 60 minutes; an immediate reddening at the subsite, due to heating of the skin, which fades rapidly; and an immediate generalized heat response, spreading beyond the subsite, which fades in 30 to 60 minutes. After the immediate responses are noted, each subject should shield the exposed area from further UV radiation until the MED is determined. Determine the MED 16 to 24 hours after UV exposure. Because erythema is evaluated 16 to 24 hours after UV exposure, the final MEDu, ssMEDp, and tpMEDp are typically determined the day following determination of the initial MEDu. Evaluate the erythema responses of each test subsite using either tungsten or warm white fluorescent lighting that provides at least 450 lux of illumination at the test site. For the evaluation, the test subject should be in the same position as when the test site was irradiated.

(5) Invalid test data. Reject test data for a test subject if erythema is not present on either the unprotected or protected test sites; or erythema is present at all subsites; or the responses are inconsistent with the series of UV doses administered; or the subject was noncompliant (e.g., the subject withdraws from the test due to illness or work conflicts or does not shield the exposed testing sites from further UV radiation until the MED is determined).

(f) Determination of SPF.

(1) Calculate an SPF value for each test subject (SPFi) as follows:

$$\mathrm{SPFi} = \frac{\mathrm{MEDp}}{\mathrm{MEDu}}$$

(2) Calculate the mean:

$$\mathrm{SPF} = \left(\overline{\mathrm{SPF}}\right)$$

and the standard deviation (s) from the SPFi values. Calculate the standard error (SE), which equals s/√n (where n equals the number of subjects who provided valid test results). Obtain the t value from Student's t distribution table corresponding to the upper 5-percent point with n-1 degrees of freedom. Determine the labeled SPF value, which equals the largest whole number less than:

$$\overline{\mathrm{SPF}} - (\mathrm{t} * \mathrm{SE})$$

In order for the SPF determination of a test product to be considered valid, the SPF value of the SPF standard should fall within the standard deviation range of the expected SPF (i.e., 16.3 ± 3.43).

(g) Determination of water resistance.

The following procedure should be performed in an indoor fresh water pool, whirlpool, and/or hot tub maintained at 23 to 32 °C. Fresh water is clean drinking water that meets the standards in 40 CFR part 141. The pool and air temperature and the relative humidity should be recorded.

(1) Water resistance (40 minutes). The labeled SPF should be determined after 40 minutes of water immersion using the following procedure:

(i) Step 1: Apply the sunscreen as described in § M020.80(d).

(ii) Step 2: Perform moderate activity in water for 20 minutes.

(iii) Step 3: Rest out of water for 15 minutes. Do not towel test site(s).

(iv) Step 4: Perform moderate activity in water for 20 minutes.

(v) Step 5: Allow test sites to dry completely without toweling.

(vi) Step 6: Apply the SPF standard as described in § M020.80(d).

(vii) Step 7. Expose test sites to UV doses as described in § M020.80(e).

(2) Water resistance (80 minutes). The labeled SPF should be determined after 80 minutes of water immersion using the following procedure:

(i) Step 1: Apply the sunscreen as described in § M020.80(d).

(ii) Step 2: Perform moderate activity in water for 20 minutes.

(iii) Step 3: Rest out of water for 15 minutes. Do not towel test site(s).

(iv) Step 4: Perform moderate activity in water for 20 minutes.

(v) Step 5: Rest out of water for 15 minutes. Do not towel test site(s).

(vi) Step 6: Perform moderate activity in water for 20 minutes.

(vii) Step 7: Rest out of water for 15 minutes. Do not towel test site(s).

(viii) Step 8: Perform moderate activity in water for 20 minutes.

(ix) Step 9: Allow test sites to dry completely without toweling.

(x) Step 10: Apply the SPF standard as described in § M020.80(d).

(xi) Step 11: Expose test sites to UV doses as described in § M020.80(e).

§ M020.90 Broad spectrum test procedure

(a) UV Spectrometry.

(1) Plate. Use optical-grade polymethylmethacrylate (PMMA) plates suitable for UV transmittance measurements. The plate should be roughened on one side to a three dimensional surface topography measure (Sa) between 2 and 7 micrometers and must have a rectangular application area of at least 16 square centimeters (with no side shorter than 4 cm).

(2) Sample holder. The sample holder should hold the PMMA plate in a horizontal position to avoid flowing of the sunscreen drug product from one edge of the PMMA plate to the other. It should be mounted as close as possible to the input optics of the spectrometer to maximize capture of forward scattered radiation. The sample holder should be a thin, flat plate with a suitable aperture through which UV radiation can pass. The PMMA plate should be placed on the upper surface of the sample holder with the roughened side facing up.

(3) Light source. The light source should produce a continuous spectral distribution of UV radiation from 290 to 400 nanometers.

(4) Input optics. Unless the spectrometer is equipped with an integrating sphere, an ultraviolet radiation diffuser should be placed between the sample and the input optics of the spectrometer. The diffuser will be constructed from any UV radiation transparent material (e.g., Teflon ® or quartz). The diffuser ensures that the radiation received by the spectrometer is not collimated. The spectrometer input slits should be set to provide a bandwidth that is less than or equal to 1 nanometer.

(5) Dynamic range of the spectrometer. The dynamic range of the spectrometer should be sufficient to measure transmittance accurately through a highly absorbing sunscreen product at all terrestrial solar UV wavelengths (290 to 400 nm).

(b) Sunscreen product application to PMMA plate. The accuracy of the test depends upon the application of a precisely controlled amount of sunscreen product with a uniform distribution over the PMMA plate. The product is applied at 0.75 mg per square centimeter to the roughened side of the PMMA plate. The sunscreen product should be applied in a series of small dots over the entire PMMA plate and then spread evenly using a gloved finger. Spreading should be done with a very light spreading action for approximately 30 seconds followed by spreading with greater pressure for approximately 30 seconds. The plate should then be allowed to equilibrate for 15 minutes in the dark before the pre-irradiation described in § M020.90(c).

(c) Sunscreen product pre-irradiation. To account for lack of photostability, apply the sunscreen product to the PMMA plate as described in § M020.90(b) and then irradiate with a solar simulator described in § M020.80(a). The irradiation dose should be 4 MEDs which is equivalent to an erythemal effective dose of 800 J/m^2 (i.e., 800 J/m^2-eff).

(d) Calculation of mean transmittance values. After pre-irradiation described in § M020.90(c), mean transmittance values should be determined for each wavelength λ over the full UV spectrum (290 to 400 nanometers). The transmittance values should be measured at 1 nanometer intervals. Measurements of spectral irradiance transmitted for each wavelength λ through control PMMA plates coated with 15 microliters of glycerin (no sunscreen product) should be obtained from at least 5 different locations on the PMMA plate [C1(λ), C2(λ), C3(λ), C4(λ), and C5(λ)]. In addition, a minimum of 5 measurements of spectral irradiance transmitted for each wavelength λ through the PMMA plate covered with the sunscreen product will be similarly obtained after pre-irradiation of the sunscreen product [P1(λ), P2(λ), P3(λ), P4(λ), and P5(λ)].

The mean transmittance for each wavelength,

$$\overline{T(\lambda)}$$

is the ratio of the mean of the C(λ) values to the mean of the P(λ) values, as follows:

$$\overline{T(\lambda)} = \frac{\sum_1^n P(\lambda)/n}{\sum_1^n C(\lambda)/n}$$

Where n ≥5

(e) Calculation of mean absorbance values.

(1) Mean transmittance values,

$$\overline{T(\lambda)}$$

are converted into mean absorbance values,

$$\overline{A(\lambda)}$$

at each wavelength by taking the negative logarithm of the mean transmittance value as follows:

$$\overline{A(\lambda)} = -\log\overline{T(\lambda)}$$

(2) The calculation yields 111 monochromatic absorbance values in 1 nanometer increments from 290 to 400 nanometers.

(f) Number of plates. For each sunscreen product, mean absorbance values should be determined from at least three individual PMMA plates. Because § M020.90(d) requires at least 5 measurements per plate, there should be a total of at least 15 measurements.

(g) Calculation of the critical wavelength. The critical wavelength is identified as the wavelength at which the integral of the spectral absorbance curve reaches 90 percent of the integral over the UV spectrum from 290 to 400 nm. The following equation defines the critical wavelength:

$$\int_{290}^{\lambda c} A(\lambda)d\lambda = 0.9 \int_{290}^{400} A(\lambda)d\lambda$$

Where λc = critical wavelength

$A(\lambda)$ = mean absorbance at each wavelength

$d\lambda$ = wavelength interval between measurements

A mean critical wavelength of 370 nm or greater is classified as broad spectrum protection.

KAREN M. MURRY -S

Digitally signed by KAREN M. MURRY -S
Date: 2026.08.10 08:54:41 -05'00'

Corrected:
Karen Murry, MD
Director, Office of Nonprescription Drugs
Office of New Drugs
Center for Drug Evaluation and Research
August 10, 2026