U.S. Food and Drug Administration

Center for Drug Evaluation and Research

Office of New Drugs

Office of Nonprescription Drugs

Scientific Review Supporting Final Administrative Order

June 5, 2026

Order ID:	OTC000039
Order Title:	Amending Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use, and Related Information
OTC Monograph:	M020
Active Ingredient:	Bemotrizinol
Route of Administration:	Topical
Purpose of Review:	OTC Monograph Conditions - Dosage Forms

I. Introduction

This scientific review describes the additional findings supporting Final Administrative Order OTC000039 titled "Amending Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use, and Related Information."[1] OTC Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use (OTC Monograph M020) describes the conditions under which sunscreen drug products are generally recognized as safe and effective (GRASE).

[1] See also FDA's Scientific Review Supporting Proposed Administrative Order 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.

In this scientific review, FDA evaluated data to determine whether a sunscreen drug product containing bemotrizinol can be manufactured in an aerosol spray dosage form.[2]

II. Background

On September 23, 2024, DSM Nutritional Products LLC (DSM or the Requestor) submitted a Tier 1 OTC monograph order request (OMOR)[3] to add a new active ingredient, bemotrizinol, at concentrations up to 6 percent, for use as a sunscreen under the conditions described in OTC Monograph M020. Specifically, DSM requested, among other things, that bemotrizinol be allowed to be marketed in all dosage forms currently allowed under OTC Monograph M020.[4]

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."[5] FDA issued this proposed order pursuant to section 505G(b) of the FD&C Act (21 U.S.C. 355h(b)) 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.[6] 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.

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[2] Aerosols are dosage forms packaged under pressure and contain therapeutic agent(s) and propellant(s) that are released upon actuation of an appropriate valve system. Upon actuation of the valve system, the drug substance is released as a plume of fine particles or droplets. Only 1 dose is released from the preparation upon actuation of a metered valve. In the case of topical products and depending on the nature of the drug substance and the conditions being treated, actuation of the valve may result in a metered release of a controlled amount of the formulation or the continuous release of the formulation as long as the valve is depressed. Topical aerosols produce fine particles or droplets for application to the skin. See United States Pharmacopeia (USP) General Chapter <1151> Pharmaceutical Dosage Forms.

[3] An OTC monograph order request 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). A Tier 1 OTC monograph order requests means any OTC monograph order request not determined to be a Tier 2 OTC Monograph order request (see section 744L(8) of the FD&C Act). An OTC monograph order request requesting the addition of an active ingredient to an OTC monograph is not categorized as a Tier 2 OTC monograph order request and is therefore Tier 1.

[4] By operation of section 505G(m)(2) of the FD&C Act, sunscreen drug products under OTC Monograph M020 are currently permitted in the following dosage forms: oil, lotion, cream, gel, butter, paste, ointment, stick, spray, and powder.

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

[6] In accordance with section 505G(b)(1) of the FD&C Act, FDA proposed 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 (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.

Relevant to this review, 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 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). As part of the OMOR, the Requestor did not submit data demonstrating a drug product formulation combined with a propellant to support an aerosol spray dosage form. Additionally, the Requestor did not submit data to support a powder dosage form.[7] Accordingly, in the proposed order, FDA proposed that the data did not support a powder dosage form or drug product formulation directly combined with a propellant to create an aerosol spray dosage form.

In response to Proposed Administrative Order OTC000039, DSM submitted a public comment[8] providing additional data on drug product formulations directly combined with a propellant to support a sunscreen drug product containing bemotrizinol in an aerosol spray dosage form.

III. Scientific Review

This scientific review is FDA's evaluation of the data submitted in the Requestor's comment to support the use of sunscreen drug products containing bemotrizinol in aerosol spray dosage forms.

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[7] See Proposed Administrative Order OTC000039, Section IV.C.2. Drug Product Manufacturing, Including Dosage Form. See also FDA's Scientific Review Supporting Proposed Administrative Order, Section III.D.2. Drug Product and Allowed Dosage Forms 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.

[8] DSM Nutritional Products, LLC, Comment on Proposed Administrative Order (OTC000039) Amending Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use, FDA-2025-N-6494-0048 (January 28, 2026) available at https://www.regulations.gov/comment/FDA-2025-N-6494-0048.

A. Bemotrizinol Drug Product Formulations Containing Propellant

DSM prepared batches of market-image aerosol spray products designed to reflect typical commercial products. DSM developed market-image aerosol spray sunscreen products containing 6% PARSOL® Shield (bemotrizinol) with variation in the levels of ethanol (0%, 11%, 21%). DSM stated that the ethanol content could influence the performance and stability of an aerosol spray dosage form. DSM included other sunscreen active ingredients typically found in marketed formulations in addition to varying the levels of ethanol concentration to gain a better understanding of the impact of propellant on combination sunscreen drug formulations. DSM explained that a commonly used propellant for aerosol sunscreen sprays is a propane/butane blend at concentrations between 30% and 40%. DSM chose a final concentration of 36% propane/butane for the market image formulations. DSM also created high propellant concentration (80% propane/butane) products to determine the impact on product stability. The formulations are included in tables 3-5 in DSM's comment.[9]

DSM did not provide justification for the drug product formulations or support the market image formulations it chose with literature references. It is uncertain why ethanol may impact aerosol spray formulations, if ethanol is the only ingredient that may impact the formulations, and if the levels of ethanol included in the formulations were sufficient for product performance. Although propane/butane blends are the commonly used propellants in aerosol spray sunscreens, a concentration range of 30% to 40% propellant would depend on specific formulation and product characteristics. DSM did not provide justification for use of a concentration of 30% to 40% propellant in the final formulation. Additionally, only one propellant (propellant blend) was utilized, which raises concern that use of other propellants may not result in stable formulations or that the percent concentration of propellant may not be suitable for all bemotrizinol aerosol spray sunscreen products. Data on multiple propellants is needed to assure compatibility, stability, and consistent delivery of the drug product.

1. Preparation of Batches

DSM provided a brief explanation of how the drug product formulations were created and discussed the filling of the Pamasol Optical Aerosol Test Glass and the aluminum aerosol cans. The explanations provide few details. DSM did not provide any production (batch) records to support its discussion of the drug product or the filled containers. The stability specifications are shown in table 6 in DSM's comment.[10]

DSM did not include specifications for viscosity and microscopic appearance as they determined these specifications are not relevant for an aerosol spray dosage form to assess their stability. However, changes in these (viscosity, microscopic appearance) physical characteristics can be indicative of changes in the amount of product released when applied or in product breakdown. These changes may not be identified by the proposed specifications as visual appearance or smell may not capture physical changes to the formulation. In addition, DSM did not justify the absence of critical tests (e.g., spray patterns and delivery to assure uniformity of delivery,

[9] Id.

[10] Id.

internal pressure testing of the aerosol containing cans, valve function, degradation products; tests listed in USP <631> for Topical Aerosol) not performed during stability.

DSM also noted that recovery rate in aerosol sprays is lower as a consequence of the aerosol filling and degassing processes. They noted this is not just an issue for bemotrizinol as it was seen for the other sunscreen active ingredients in the test formulations.

2. Analytical Procedures

DSM provided a description of the analytical methods utilized for the aerosol spray sunscreen products. FDA determined that the analytical methods used were incomplete for the following reasons:

1. For the calibration and alignment standards, it is uncertain how much USP Bemotrizinol RS is weighed out or measured by volume.

2. For sample preparation, the method includes sonication of samples. The lack of method validation is concerning as some of the sunscreen active ingredients utilized in the market-image formulations may be impacted by extended sonication.[11]

3. The analytical method to assay bemotrizinol and the other sunscreen active ingredients was provided but was not accompanied by a method validation report. The calculation used to determine the assay results appeared suitable for bemotrizinol (see equation in DSM's comment).[12] However, standards for the other sunscreen active ingredients were not provided.

3. Release and Stability

DSM's stability study for the aerosol spray is not adequate for the reasons explained below.[13] DSM conducted stability testing including bulk samples, samples in a Pamasol Optical Aerosol Test Glass, and samples in aluminum containers. DSM utilized the Pamasol Optical Aerosol Test Glass because it allows for visual monitoring of final product/propellant formulations to determine if sediment or separation occurs over the stability program.

The stability conditions for aerosol spray product testing provided by DSM are included in Table 1.

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[11] Assay results of active ingredients at release were not conducted.

[12] See DSM Nutritional Products, LLC, Comment on Proposed Administrative Order (OTC000039) Amending Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use at page 9, footnote 7, FDA-2025-N-6494-0048 (January 28, 2026) available at https://www.regulations.gov/comment/FDA-2025-N-6494-0048.

[13] Information on stability testing can be found in *FDA Guidance for Industry: Q1A (R2) Stability Testing of New Drug Substances and Products.*

Table 1. Stability Storage Conditions and Testing Frequency for Aerosol Sprays Containing PARSOL® Shield

	0 weeks *(Nov 11, 2025)*	4 weeks *(Dec 11, 2025)*	10 weeks *(Jan 15, 2026)*
Bulk formulation (no propellant)			
23°C ± 2°C	✓	✓	✓
4°C ± 2°C	-	✓	✓*
40°C ± 2°C	-	✓	✓
Aerosol product (bulk formulation & Propellant) Pamasol Optical Aerosol Test Glass			
23°C ± 2°C	✓	✓	✓
Aerosol product (bulk formulation & Propellant), Stability in aluminum aerosol cans			
23°C ± 2°C	-	-	✓*
50°C ± 2°C	-	-	✓*

Relative humidity is not controlled as the samples are stored in closed and airtight containers.
✓: performed for tested batches
*: Identity, assay for tested batches
-: not applicable

Source: DSM Comments to FDA Proposed Administrative Order OTC000039 Amending Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use to Add Bemotrizinol as a Sunscreen Active Ingredient: docket number FDA-2025-N-6494 (Available at https://www.regulations.gov/comment/FDA-2025-N-6494-0048, page 3).

DSM stated that relative humidity was not controlled because the samples were stored in closed and airtight containers.[14] Long-term data from the stability studies could help support that the containers utilized in the stability program are impermeable. The standard lengths of a stability study for a drug product are 12 months long-term and 6 months intermediate and accelerated data.[15] However, DSM provided only 10 weeks of data. Thus, the length of the stability study is not adequate to support the stability of the market image formulations.

At the 10-week time point, only identity and assay were evaluated for product(s) packaged in aluminum aerosol cans (see stability results below). Accelerated stability was conducted at 50°C ± 2°C which, is 10 degrees higher than recommended.[16] As this is likely the type of packaging expected to be marketed, DSM should have provided full stability data at 10 weeks.

Table 2 shows the products evaluated in the stability program.

[14] Sensitivity to moisture or potential for solvent loss is not a concern for drug products packaged in impermeable containers that provide a permanent barrier to passage of moisture or solvent. Thus, stability studies for products stored in impermeable containers can be conducted under any controlled or ambient humidity condition. See Section 2.2.7.2 of *FDA Guidance for Industry: Q1A (R2) Stability Testing of New Drug Substances and Products.*

[15] See *FDA Guidance for Industry: Q1A (R2) Stability Testing of New Drug Substances and Products.*

[16] Id.

Table 2. Products on Which the Stability Program Has Been Initiated

	21% Ethanol			11% Ethanol			0% Ethanol		
Formula number	**RQA-007934 -01**	**RQA-007928-01**	**High dose compat-ibility test**	**RQA-007934 -02**	**RQA-007928-02**	**High dose compatibility test**	**RQA-007934 -03**	**RQA-007928-03**	**High dose compatibility test**
Product description	Bulk formulation	Aerosol product In cans & Pamasol Optical Aerosol Test Glass	Aerosol product Pamasol Optical Aerosol Test Glass	Bulk formulation	Aerosol product In cans & Pamasol Optical Aerosol Test Glass	Aerosol product Pamasol Optical Aerosol Test Glass	Bulk formulation	Aerosol product In cans & Pamasol Optical Aerosol Test Glass	Aerosol product Pamasol Optical Aerosol Test Glass
Production lot	001	001	001	001	001	001	001	001	001
Use of batch	Feasibility	Feasibility	Feasibility	Feasibility	Feasibility	Feasibility	Feasibility	Feasibility	Feasibility
Manufacturing date	07 November 2025	07 November 2025	07 November 2025	07 November 2025	07 November 2025	07 November 2025	07 November 2025	07 November 2025	07 November 2025
Study start date	07 November 2025	07 November 2025	07 November 2025	07 November 2025	07 November 2025	07 November 2025	07 November 2025	07 November 2025	07 November 2025

Source: DSM Comments to FDA Proposed Administrative Order OTC000039 Amending Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use to Add Bemotrizinol as a Sunscreen Active Ingredient: docket number FDA-2025-N-6494 (available at https://www.regulations.gov/comment/FDA-2025-N-6494-0048, page 3).

Table 3 shows the stability results for sunscreen bulk drug product containing 21% ethanol. Assay results for the 21% ethanol formulation RQA-007928-01 in bulk include assay results at 10 weeks for storage at 4°C but assay results were not provided from the start of the stability program nor at the 4-week timepoint. DSM provided results for storage at 4°C but not at 23°C and 50°C.

Table 3. Batch Analysis Results, RQA-007934-01 (Bulk Formulation, 21% Ethanol)

Parameters /Occurrence		Physical appearance	Color	Smell	Assay
Start	**RT**	Transparent	Yellow	characteristic	n.d.
	4°C	n.d.	n.d.	n.d.	n.d.
	40°C	n.d.	n.d.	n.d.	n.d.
4 weeks	**RT**	ok	ok	ok	n.d.
	4°C	ok	ok	ok	n.d.
	40°C	ok	ok	ok	n.d.
10 weeks	**RT**	ok	ok	ok	n.d.
	4°C	ok	ok	ok	6.01 %
	40°C	ok	ok	ok	n.d.

n.d.: not determined

Source: DSM Comments to FDA Proposed Administrative Order OTC000039 Amending Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use to Add Bemotrizinol as a Sunscreen Active Ingredient: docket number FDA-2025-N-6494 (Available at https://www.regulations.gov/comment/FDA-2025-N-6494-0048, page 11).

Table 4 provides stability data for the 21% ethanol sunscreen drug product formulation in Pamasol Optical Aerosol Test glass containers and/or cans. Assay results for the 21% ethanol formulation RQA-007928-01 in final packaging include assay results at 10 weeks for storage at 23°C and 50°C but not at the start of the stability program nor at the 4-week timepoint. This is not sufficient because assay results should have been provided for the start and at 10 weeks, at a minimum.[17]

[17] See the standard protocol requirements included in *FDA Guidance for Industry: Q1A (R2) Stability Testing of New Drug Substances and Products.*

Table 4. Batch Analysis Results, RQA-007928 -01 (Aerosol Spray Formulations, 21% Ethanol)

Parameters /Occurrence		Physical appearance	Color	Smell	Assay
Start	RT	ok	ok	n.a.	n.d.
	50˚C	n.a.	n.a.	n.a.	n.a.
4 weeks	RT	ok	ok	n.a.	n.d.
	50˚C	n.a.	n.a.	n.a.	n.a.
10 weeks	RT	ok	ok	ok	5.80 %
	50˚C	ok	ok	ok	5.73 %

n.d.: not determind
n.a.: not applicable

Source: DSM Comments to FDA Proposed Administrative Order OTC000039 Amending Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use to Add Bemotrizinol as a Sunscreen Active Ingredient: docket number FDA-2025-N-6494 (Available at https://www.regulations.gov/comment/FDA-2025-N-6494-0048, page 12).

Recovery of all active ingredients after 10 weeks was within established limits; however, recovery values for all sunscreen active ingredients were low. At 23°C, recovery values for all sunscreen active ingredients in the formulation were comfortably above the lower acceptable limit but under accelerated conditions, recovery values were much closer to the lower limit. (See Table 5). Assay recovery values for all ingredients were not provided for the product with high (80%) propellant levels. Similar results were observed for the 11% and 0% ethanol formulations. Recovery in the 0% formulations (see Table 6) was much lower at 23°C and 50°C than for the 21% and 11% ethanol formulations. Based on the performed incomplete stability study, it appears that the drug product would most likely not meet the proposed specifications at 3 or 6 months.[18] Similar statements can be made for the 21% and 11% ethanol formulations; however, sunscreen active ingredient recovery assay results for these two formulations were better than for the 0% ethanol formulation in over 10 weeks.

While FDA recognizes that the amount of stability data DSM could generate was limited due to time constraints, 10 weeks of data at 23°C and 50°C is insufficient to give a full picture of product stability. Had the recovery values been higher, the limited amount of data may not be so concerning. However, given the low recovery amounts at both 23°C and at 50°C for all three formulations, additional data, over time, are necessary to show the product is within specification when stored in long-term storage conditions. Therefore, a viable shelf-life for the drug product cannot be established based on the stability data provided.

[18] The assay ranges are tighter than what is often observed with assay recovery specifications. For many products, the commonly acceptable recovery specification is ±10% of target recovery.

Table 5. Analytical Assessment of RQA-007928-01 (Aerosol Product, 21% Ethanol) at 23°C +/- 2°C After 10 Weeks

Test	Specification	Bulk formulation
Identity of Bemotrizinol	Retention time	compliant
Assay of Bemotrizinol	6.0% (w/w) +/- 0.35% (w/w)	5.80 %
Assay of Avobenzone	3.0% (w/w) +/- 0.28% (w/w)	2.81 %
Assay of Octisalate	5.0% (w/w) +/- 0.30% (w/w)	4.81 %
Assay of Homosalate	15.0% (w/w) +/- 1.00% (w/w)	14.48 %
Assay of Octocrylene	10.0% (w/w) +/- 0.72% (w/w)	9.58 %

Analytical assessment of RQA-007928 -01 (aerosol product, 21% ethanol) at 50°C+/- 2°C after 10 weeks

Test	Specification	Bulk formulation
Identity of Bemotrizinol	Retention time	compliant
Assay of Bemotrizinol	6.0% (w/w) +/- 0.35% (w/w)	5.73 %
Assay of Avobenzone	3.0% (w/w) +/- 0.28% (w/w)	2.78 %
Assay of Octisalate	5.0% (w/w) +/- 0.30% (w/w)	4.76 %
Assay of Homosalate	15.0% (w/w) +/- 1.00% (w/w)	14.33 %
Assay of Octocrylene	10.0% (w/w) +/- 0.72% (w/w)	9.46 %

Source: DSM Comments to FDA Proposed Administrative Order OTC000039 Amending Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use to Add Bemotrizinol as a Sunscreen Active Ingredient: docket number FDA-2025-N-6494 (Available at https://www.regulations.gov/comment/FDA-2025-N-6494-0048, page 12).

Table 6. Analytical Assessment of RQA-007928-03 (Aerosol Product, 0% Ethanol) at 23°C +/- 2°C After 10 Weeks

RQA-007928 -03 (aerosol product, 0% ethanol) at 23°C+/- 2°C after 10 weeks

Test	Specification	Bulk formulation
Identity of Bemotrizinol	Retention time	compliant
Assay of Bemotrizinol	6.0% (w/w) +/- 0.35% (w/w)	5.65 %
Assay of Avobenzone	3.0% (w/w) +/- 0.28% (w/w)	2.72 %
Assay of Octisalate	5.0% (w/w) +/- 0.30% (w/w)	4.70 %
Assay of Homosalate	15.0% (w/w) +/- 1.00% (w/w)	14.03 %
Assay of Octocrylene	10.0% (w/w) +/- 0.72% (w/w)	9.28 %

Analytical assessment of RQA-007928 -03 (aerosol product, 0% ethanol) at 50°C+/- 2°C after 10 weeks

Test	Specification	Bulk formulation
Identity of Bemotrizinol	Retention time	compliant
Assay of Bemotrizinol	6.0% (w/w) +/- 0.35% (w/w)	5.68 %
Assay of Avobenzone	3.0% (w/w) +/- 0.28% (w/w)	2.73 %
Assay of Octisalate	5.0% (w/w) +/- 0.30% (w/w)	4.71 %
Assay of Homosalate	15.0% (w/w) +/- 1.00% (w/w)	14.06 %
Assay of Octocrylene	10.0% (w/w) +/- 0.72% (w/w)	9.30 %

Source: DSM Comments to FDA Proposed Administrative Order OTC000039 Amending Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use to Add Bemotrizinol as a Sunscreen Active Ingredient: docket number FDA-2025-N-6494 (Available at https://www.regulations.gov/comment/FDA-2025-N-6494-0048, pages 16-17).

IV. Conclusion Based on Scientific Review

Based on FDA's review of the data submitted in DSM's comment, FDA concludes that the data are not sufficient to support a sunscreen drug product containing bemotrizinol in an aerosol spray dosage form in which the propellant is combined directly with the drug product formulation.

Specifically, the data were insufficient for the following reasons:

1. The data to support the manufacturing and analytical methods used in these studies are incomplete.
2. The Requestor did not provide justification for the drug product formulations containing propellants developed for the included stability study.
3. The stability programs appear insufficient for the following reasons:
    a. Only ten weeks of data were presented.
    b. It is uncertain if the containers used are impermeable thus supporting storage conditions that did not include relative humidity.
    c. Limited data were provided across the stability program in general.
    d. 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.

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