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FDA's First New Sunscreen Active Ingredient in Decades: Regulatory Exclusivity and Commercial Implications

On June 10, 2026, just in time for summer's high ultraviolet rays, the U.S. Food and Drug Administration (FDA) issued Final Administrative Order OTC000039, adding bemotrizinol to the list of permitted active ingredients in the over-the-counter (OTC) Sunscreen Monograph (M020). The order marks the first addition of a new active ingredient to FDA's sunscreen monograph in almost three decades, and the first ingredient added through the administrative order process established by the Coronavirus Aid, Relief, and Economic Security Act. The order becomes effective on August 9, 2026. Bemotrizinol itself is not a new ingredient; it has been marketed safely in Europe and other countries for decades.

DSM Nutritional Products LLC initiated the process by submitting a Tier 1 OTC Monograph Order Request (OMOR) on September 23, 2024. FDA issued a proposed order on December 12, 2025, and finalized it roughly six months later. In addition to expanding the range of UV filters available for use in OTC sunscreen products, the order grants DSM an 18-month period of marketing exclusivity.

The Statutory Basis for Exclusivity

The exclusivity arises under Section 505G(b)(5)(C)(i) of the Federal Food, Drug, and Cosmetic Act. Under that provision, when FDA issues a final order permitting an active ingredient not previously included in a monograph, the requestor receives the exclusive right to market products incorporating that ingredient for 18 months.

The exclusivity clock runs for 18 months from the order's effective date of August 9, 2026, when DSM becomes legally entitled to market a compliant product. The

exclusivity also extends beyond DSM itself to its licensees, assignees, and successors in interest.

How this Exclusivity Differs from Drug Approval Exclusivities

The bemotrizinol exclusivity attaches to a successful OMOR, not to an approved drug application. That distinguishes it from the exclusivity regimes such as new chemical entity (NCE) or orphan drug exclusivity, both of which are tied to FDA approval of a drug through the sponsor's own clinical and regulatory pathway. It is also distinct from the three-year exclusivity available for a prescription-to-OTC switch, which similarly applies in the nonprescription space but still requires the sponsor to support the switch through a new drug application containing new clinical data rather than through an OMOR. An OMOR offers a faster, less data-intensive route to the OTC market, but it currently provides a shorter period of exclusivity than the traditional prescription-to-OTC switch.

The exclusivity period is also considerably shorter than most of these regimes. The 18-month exclusivity available for successful OMOR is substantially less than the five-year exclusivity available for NCE drugs and the seven-year exclusivity available for orphan drugs. The shorter term may reflect a narrower policy objective: encouraging companies to seek monograph orders for ingredients with established safety records abroad, rather than rewarding the extensive investment associated with developing and obtaining approval for a new drug.

Conditions for Use

The final order also sets specific conditions for bemotrizinol's use. It is permitted at concentrations up to 6%, with a minimum finished product SPF of 2. It may be combined with any other permitted sunscreen active ingredient except aminobenzoic acid or trolamine salicylate, which FDA found unsafe and ineffective in combination with bemotrizinol. Permitted dosage forms include oil, lotion, cream, gel, butter, paste, ointment, and stick, along with sprays that use no propellant or that isolate the propellant from the formulation. Propellant-based aerosol sprays and powder form are not permitted; FDA found DSM's stability data for an aerosol formulation insufficient during the comment period.

What to Watch

Apart from the exclusivity question, FDA's broader sunscreen rulemaking remains pending. Proposed Administrative Order OTC000008, which would establish additional Generally Recognized as Safe and Effective conditions applicable to all sunscreen products marketed under OTC Monograph M020, has not yet been finalized. Once finalized, that order would apply to bemotrizinol-containing products as well. We will continue to monitor that rulemaking, along with any additional OMORs seeking to add other internationally marketed UV filters to the U.S. sunscreen monograph.

This blog was drafted by Sadaf Deedar and Brian Malkin, attorneys on the Spencer Fane FDA Pharmaceutical and Biologics Market Team. For more information, visit spencerfane.com.

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