WORLD TRADE ORGANIZATION

G/TBT/N/USA/1443/Add.5

11 June 2026

(26-4285)

Page: 1/2

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

Addendum

The following communication, dated 10 June 2026, is being circulated at the request of the delegation of the United States of America.

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

Reason for Addendum:	
[ ]	Comment period changed - date:
[ ]	Notified measure adopted - date:
[X]	Notified measure published - date: 10 June 2026
[X]	Notified measure enters into force - date: 10 June 2026
[X]	Text of final measure available from[1]: https://members.wto.org/crnattachments/2026/TBT/USA/final_measure/26_03055_00_e.pdf https://members.wto.org/crnattachments/2026/TBT/USA/final_measure/26_03055_01_e.pdf
[ ]	Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified:
[ ]	Content or scope of notified measure changed and text available from[1]: New deadline for comments (if applicable):
[ ]	Interpretive guidance issued and text available from[1]:
[ ]	Other:

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

[1] This information can be provided by including a website address, a pdf attachment, or other information on where the text of the final/modified measure and/or interpretive guidance can be obtained.

The announcement of the availability on FDA's website of the final order is published in the Federal Register on 10 June 2026.

91 Federal Register (FR) 35220, 10 June 2026:

https://www.govinfo.gov/content/pkg/FR-2026-06-10/html/2026-11578.htm

https://www.govinfo.gov/content/pkg/FR-2026-06-10/pdf/2026-11578.pdf

https://www.accessdata.fda.gov/drugsatfda_docs/omuf/order/supportDoc/OTC000039/Final_Administrative_Order.pdf

This notice of availability is identified by Docket Number FDA-2025-N-6494. The Docket Folder is available on Regulations.gov at https://www.regulations.gov/docket/FDA-2025-N-6494/document and provides access to primary documents as well as comments received. Documents are also accessible from Regulations.gov by searching the Docket Number.

Previous actions notified under the symbol G/TBT/N/USA/1443 are identified by Docket Numbers FDA-1978-N-0018 and FDA-2025-N-6494.