WORLD TRADE ORGANIZATION

G/TBT/N/USA/1777/Add.1

23 April 2024

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Committee on Technical Barriers to Trade Original: English

NOTIFICATION

Addendum

The following communication, dated 22 April 2024, is being circulated at the request of the delegation of the United States of America.

Title: Poison Prevention Packaging Requirements; Proposed Exemption of Baloxavir Marboxil Tablets in Packages Containing Not More Than 80 mg of the Drug

Reason for Addendum:	
[ ]	Comment period changed - date:
[ ]	Notified measure adopted - date:
[X]	Notified measure published - date: 19 April 2024
[X]	Notified measure enters into force - date: 20 May 2024
[X]	Text of final measure available from[1]: 89 Federal Register (FR) 28604, Title 16 Code of Federal Regulations (CFR) Part 1700: https://www.govinfo.gov/content/pkg/FR-2024-04-19/html/2024-07651.htm https://www.govinfo.gov/content/pkg/FR-2024-04-19/pdf/2024-07651.pdf https://members.wto.org/crnattachments/2024/TBT/USA/final_measure/24_02740_00_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[ ]	Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified: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: The Consumer Product Safety Commission (Commission or CPSC) is amending the child-resistant packaging requirements of CPSC's regulation to exempt baloxavir marboxil tablets, currently marketed as XOFLUZATM, in packages containing not more than 80 mg of the drug, from the special packaging requirements. XOFLUZA is used to treat the flu, and the drug is taken in one dose within 48 hours of experiencing flu symptoms. The final rule exempts this prescription drug product on the basis that child-resistant packaging is not needed to protect young children from

[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.

serious injury or illness because the product is not acutely toxic and lacks adverse human experience associated with ingestion.

The rule is effective 20 May 2024.

Title 16 Code of Federal Regulations (CFR) Part 1700

This final rule and the notice of proposed rulemaking notified as G/TBT/N/USA/1777 are identified by Docket Number CPSC-2021-0027. The Docket Folder is available from Regulations.gov at https://www.regulations.gov/docket/CPSC-2021-0027/document and provides access to primary and supporting documents as well as comments received. Documents are also accessible from Regulations.gov by searching the Docket Number.