NOTIFICATION

Addendum

The following communication, dated 23 November 2021, is being circulated at the request of the delegation of the United States of America.

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**Title:** Sunscreen Drug Products for Over-the-Counter Human Use

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| **Reason for Addendum:** | |
| [X] | Comment period changed - date: 27 December 2021; FDA is extending the comment period on the Proposed Order issued on 24 September 2021 (86 FR 53322). |
| [  ] | Notified measure adopted - date: |
| [  ] | Notified measure published - date: |
| [  ] | Notified measure enters into force - date: |
| [  ] | Text of final measure available from[[1]](#footnote-1): |
| [  ] | Notified measure withdrawn or revoked - date:  Relevant symbol if measure re-notified: |
| [  ] | Content or scope of notified measure changed and text available from1:  New deadline for comments (if applicable): |
| [  ] | Interpretive guidance issued and text available from1: |
| [X] | Other: <https://www.govinfo.gov/content/pkg/FR-2021-11-22/html/2021-25371.htm>  <https://www.govinfo.gov/content/pkg/FR-2021-11-22/pdf/2021-25371.pdf>  <https://members.wto.org/crnattachments/2021/TBT/USA/21_7289_00_e.pdf> |

**Description:** TITLE: Amending Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-The-Counter Human Use; Over-The-Counter Monograph Proposed Order (OTC 000008) Extension of Comment Period  
  
AGENCY: Food and Drug Administration, HHS  
  
ACTION: Proposed order; extension of comment period.  
  
SUMMARY: The Food and Drug Administration (FDA or Agency) has extended the comment period for the over-the-counter (OTC) monograph proposed order (order ID OTC000008) entitled "Amending Over-the-Counter (OTC) Monograph M020: Sunscreen Drug Products for OTC Human Use" (Proposed Order), which was issued on 24 September 2021. A notice of availability for the [Proposed Order appeared in the Federal Register of 27 September 2021](https://www.govinfo.gov/content/pkg/FR-2021-09-27/html/2021-20780.htm). FDA issued the Proposed Order to amend and revise the deemed final administrative order concerning non-prescription sunscreen drug products (Deemed Final Order) established by the enactment of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). The Proposed Order, if finalized, would replace the Deemed Final Order in its entirety with new conditions under which non-prescription sunscreen drug products would be determined to be generally recognized as safe and effective (GRASE) under the Federal Food, Drug, and Cosmetic Act (FD&C Act). It would also set forth certain characteristics that would establish that a sunscreen drug product is not GRASE. FDA has extended the comment period for the Proposed Order in response to a request for an extension to allow interested persons additional time to submit comments.  
  
DATES: FDA is extending the comment period on the Proposed Order issued on 24 September 2021 (86 FR 53322) to 27 December 2021.

This extension of comment period and previous actions notified under the symbol [G/TBT/N/USA/1443](http://tbtims.wto.org/en/Notifications/Search?ProductsCoveredHSCodes=&ProductsCoveredICSCodes=&DoSearch=True&ExpandSearchMoreFields=False&NotifyingMember=United+States+of+America&DocumentSymbol=1443&DistributionDateFrom=&DistributionDateTo=&SearchTerm=&ProductsCovered=&DescriptionOfContent=&CommentPeriod=&FinalDateForCommentsFrom=&FinalDateForCommentsTo=&ProposedDateOfAdoptionFrom=&ProposedDateOfAdoptionTo=&ProposedDateOfEntryIntoForceFrom=&ProposedDateOfEntryIntoForceTo=&ReasonForAddendum=) are identified by Docket Number FDA-1978-N-0018. The Docket Folder is available on [Regulations.gov](https://www.regulations.gov/) at <https://www.regulations.gov/docket/FDA-1978-N-0018/document> and provides access to primary and supporting documents as well as comments received. Documents are also accessible from [Regulations.gov](https://www.regulations.gov/) by searching the Docket Number.   
WTO Members and their stakeholders are asked to submit comments to the [USA WTO TBT Enquiry Point](mailto:usatbtep@nist.gov) by 4:00 p.m. [Eastern Standard Time (EST)](https://www.timeanddate.com/time/zones/est) at the end of 27 December 2021. Comments received by the [USA WTO TBT Enquiry Point](mailto:usatbtep@nist.gov) from WTO Members and their stakeholders will be shared with the regulator and will also be submitted to the [Docket](https://www.regulations.gov/docket/FDA-1978-N-0018/document) on [Regulations.gov](https://www.regulations.gov/) if received within the comment period.

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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. [↑](#footnote-ref-1)