



22 April 2016

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

Addendum

The following communication, dated 21 April 2016, is being circulated at the request of the delegation of the United States of America.

TITLE: Fixed-Combination and Co-Packaged Drugs: Applications for Approval and Combinations of Active Ingredients Under Consideration for Inclusion in an Over-the-Counter Monograph Proposed Rule; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS

ACTION: Proposed rule; reopening of the comment period

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the proposed rule, published in the Federal Register of 23 December 2015 (80 FR 79776), revising its regulations on prescription and nonprescription fixed-combination and co-packaged drugs and on combinations of active ingredients under consideration for inclusion in an over-the-counter monograph. FDA is reopening the comment period to permit time for additional comments.

DATES: Submit either electronic or written comments by 18 May 2016.

https://members.wto.org/crnattachments/2016/TBT/USA/16_1615_00_e.pdf
