NOTIFICATION

Corrigendum

The following communication, dated 6 April 2021, is being circulated at the request of the delegation of the United States of America.

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Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs

TITLE: Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs; Corrections

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS)

ACTION: Final rule; correcting amendments

SUMMARY: On 31 August 2016, the Food and Drug Administration (FDA or Agency) published an amended final rule that listed inaccurate cross- references to FDA's drug establishment registration and drug listing regulations. This document corrects the inaccurate cross-references used in the final regulations.

This rule is effective 1 April 2021.

This final rule; correcting amendments and previous actions notified under the symbol [G/TBT/N/USA/214](http://tbtims.wto.org/en/Notifications/Search?ProductsCoveredHSCodes=&ProductsCoveredICSCodes=&DoSearch=True&ExpandSearchMoreFields=False&NotifyingMember=&DocumentSymbol=usa%2F214&DistributionDateFrom=&DistributionDateTo=&SearchTerm=&ProductsCovered=&DescriptionOfContent=&CommentPeriod=&FinalDateForCommentsFrom=&FinalDateForCommentsTo=&ProposedDateOfAdoptionFrom=&ProposedDateOfAdoptionTo=&ProposedDateOfEntryIntoForceFrom=&ProposedDateOfEntryIntoForceTo=&ReasonForAddendum=) are identified by Docket Number FDA-2005-N-0464. The Docket Folder is available on Regulations.gov at <https://www.regulations.gov/docket/FDA-2005-N-0464/document> and provides access to primary and supporting documents as well as comments received. Documents are also accessible from [Regulations.gov](http://www.regulations.gov) by searching the Docket Number.

<https://www.govinfo.gov/content/pkg/FR-2021-04-01/html/2021-06677.htm> <https://www.govinfo.gov/content/pkg/FR-2021-04-01/pdf/2021-06677.pdf> <https://members.wto.org/crnattachments/2021/TBT/USA/21_2445_00_e.pdf>

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