NOTIFICATION

Addendum

The following communication, dated 24 August 2020, is being circulated at the request of the delegation of the United States of America.

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**Title:** Revocation of the Test for Mycoplasma

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| **Reason for Addendum:** | |
| [  ] | Comment period changed - date: |
| [X] | Notified measure adopted - date: 21 August 2020 |
| [  ] | Notified measure published - date: |
| [X] | Notified measure enters into force - date: 21 September 2020 |
| [X] | Text of final measure available from[[1]](#footnote-1):  <https://www.govinfo.gov/content/pkg/FR-2020-08-21/html/2020-17085.htm>  <https://www.govinfo.gov/content/pkg/FR-2020-08-21/pdf/2020-17085.pdf>  <https://members.wto.org/crnattachments/2020/TBT/USA/final_measure/20_5060_00_e.pdf> |
| [  ] | Notified measure withdrawn or revoked - date:  Relevant symbol if measure re-notified: |
| [  ] | Content or scope of notified measure changed  New deadline for comments (if applicable): |
| [  ] | Interpretive guidance issued and text available from1: |
| [  ] | Other: |

**Description:** AGENCY: Food and Drug Administration, HHS

ACTION: Final rule

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule to remove the specified test for the presence of Mycoplasma for live virus vaccines and inactivated virus vaccines produced from in vitro living cell cultures. The rule is being finalized because the existing test for Mycoplasma is overly restrictive in that it identifies only one test method in detail to be used even though other methods also may be appropriate. More sensitive and specific methods exist and are currently being practiced, and removal of the specific method to test for Mycoplasma provides flexibility for accommodating new and evolving technology and capabilities without diminishing public health protections. This action is part of FDA's implementation of Executive Orders under which FDA is comprehensively reviewing existing regulations to identify opportunities for repeal, replacement, or modification that will result in meaningful burden reduction, while allowing the Agency to achieve our public health mission and fulfill statutory obligations.

This rule is effective 21 September 2020.

This final rule and the proposed rule notified as [G/TBT/N/USA/1462](http://tbtims.wto.org/en/Notifications/Search?ProductsCoveredHSCodes=&ProductsCoveredICSCodes=&DoSearch=True&ExpandSearchMoreFields=False&NotifyingMember=&DocumentSymbol=USA%2F1462&DistributionDateFrom=&DistributionDateTo=&SearchTerm=&ProductsCovered=&DescriptionOfContent=&CommentPeriod=&FinalDateForCommentsFrom=&FinalDateForCommentsTo=&ProposedDateOfAdoptionFrom=&ProposedDateOfAdoptionTo=&ProposedDateOfEntryIntoForceFrom=&ProposedDateOfEntryIntoForceTo=) are identified by Docket Number FDA-2018-N-4757. The Docket Folder is available on [Regulations.gov](http://www.regulations.gov) at <https://www.regulations.gov/docket?D=FDA-2018-N-4757>, 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.

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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 measure and/or interpretive guidance can be obtained. [↑](#footnote-ref-1)