NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** United States of America **If applicable, name of local government involved (Article 3.2 and 7.2):**  |
| **2.** | **Agency responsible:** Food and Drug Administration (FDA), Health and Human Services (HHS) [1490]**Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:** Please submit comments to: USA WTO TBT Enquiry Point, Email: usatbtep@nist.gov |
| **3.** | **Notified under Article 2.9.2 [****X],** **2.10.1 [ ],** **5.6.2 [****X],** **5.7.1 [ ],** **other:**  |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Mycoplasma; Quality (ICS 03.120), Laboratory medicine (ICS 11.100), Pharmaceutics (ICS 11.120) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Revocation of the Test for Mycoplasma (4 page(s), in English) |
| **6.** | **Description of content:** The Food and Drug Administration (FDA, Agency, or we) is proposing to amend the biologics regulations by removing the specified test for the presence of Mycoplasma for live virus vaccines and inactivated virus vaccines produced from in vitro living cell cultures. FDA is proposing this action because the existing test for Mycoplasma is 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 13771 and 13777. Under these Executive orders, 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. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety; Quality requirements |
| **8.** | **Relevant documents:** * 84 Federal Register (FR) 12534, 2 April 2019; Title 21 Code of Federal Regulations (CFR) Part 610. Will appear in the Federal Register when adopted.
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| **9.** | **Proposed date of adoption:** To be determined**Proposed date of entry into force:** To be determined |
| **10.** | **Final date for comments:** 17 June 2019 |
| **11.** | **Texts available from: National enquiry point [** **]** **or address, telephone and fax numbers and email and website addresses, if available, of other body:** <https://members.wto.org/crnattachments/2019/TBT/USA/19_2038_00_e.pdf> |