NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

|  |  |
| --- | --- |
| **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) [1965]**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 [****],** **2.10.1 [****],** **5.6.2 [****],** **5.7.1 [****], 3.2 [****], 7.2 [****],** **other****[X]:** To allow FDA to better protect the public health by preventing re-importation and deterring future shipments of refused medical devices subject to administrative destruction. |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Medical devices: Instruments and appliances used in medical, surgical, dental or veterinary sciences, including scintigraphic apparatus, other electro-medical apparatus and sight-testing instruments (HS code(s): 9018); Medical equipment (ICS code(s): 11.040); Domestic safety (ICS code(s): 13.120) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Medical Devices Subject to Administrative Destruction; (9 page(s), in English) |
| **6.** | **Description of content:** Notice of Proposed Rulemaking - The Food and Drug Administration (FDA, Agency, or we) is proposing a regulation to implement its new authority to destroy a device valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation), that has been refused admission into the United States under the Federal Food, Drug, and Cosmetic Act (FD&C Act [21 USC Ch. 9](https://www.govinfo.gov/content/pkg/USCODE-2011-title21/html/USCODE-2011-title21-chap9.htm)), by providing to the owner or consignee notice and an opportunity to appear and introduce testimony prior to the destruction. Once finalized, this regulation will allow FDA to better protect the public health by preventing re-importation and deterring future shipments of refused devices subject to administrative destruction. We also discuss in this Notice of Proposed Rulemaking our intent to change FDA's procedures for administrative destruction of drugs and, if this proposed rule is finalized, these procedures will also include devices subject to administrative destruction. We described our current procedures in the proposed and final rules entitled "Administrative Destruction of Certain Drugs Refused Admission to the United States." |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety |
| **8.** | **Relevant documents:** 87 Federal Register (FR) 60947, 7 October 2022; Title 21 Code of Federal Regulations (CFR) Part 1:<https://www.govinfo.gov/content/pkg/FR-2022-10-07/html/2022-21809.htm><https://www.govinfo.gov/content/pkg/FR-2022-10-07/pdf/2022-21809.pdf>This notice of proposed rulemaking is identified by Docket Number FDA-2021-N-1348. The Docket Folder is available on Regulations.gov at <https://www.regulations.gov/docket/FDA-2021-N-1348/document> and provides access to primary documents as well as comments received. Documents are also accessible from [Regulations.gov](http://www.regulations.gov/) by searching the Docket Number. WTO Members and their stakeholders are asked to submit comments to the USA TBT Enquiry Point by or before [4pm](http://time-time.net/times/time-zones/usa-canada/current-eastern-time-est.php) [Eastern Time](https://24timezones.com/time-zone/et) on 6 December 2022. Comments received by the USA TBT Enquiry Point 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-2021-N-1348/document) on Regulations.gov if received within the comment period.FDA Administrative Destruction of Certain Drugs Refused Admission to the United States; Proposed and Final Rules (Primary Documents), Comments, Supporting Materials are available from [Regulations.gov](https://www.regulations.gov/): [FDA-2014-N-0504](https://www.regulations.gov/docket/FDA-2014-N-0504/document). |
| **9.** | **Proposed date of adoption:** To be determined**Proposed date of entry into force:** To be determined |
| **10.** | **Final date for comments:** 6 December 2022 |
| **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/2022/TBT/USA/22_7094_00_e.pdf> |