WORLD TRADE ORGANIZATION

G/TBT/N/USA/2297

30 June 2026

(26-4710)

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Committee on Technical Barriers to Trade

Original: English

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 (Articles 3.2 and 7.2):**
2.	**Agency responsible:** Department of Health and Human Services (HHS), Food and Drug Administration (FDA) [2330]
3.	**Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], 3.2 [ ], 7.2 [ ], Other:**
4.	**Products covered (HS codes or national tariff lines. ICS numbers may be provided in addition, where applicable):** Tobacco products; Tobacco, tobacco products and related equipment (ICS code(s): 65.160)
5.	**Details of notified document(s) (title, number of pages and languages, means of access):** Establishment Registration and Product Listing for Tobacco Products; (36 page(s), in English) **Link to notified document(s) and/or contact details for agency or authority which can provide copies upon request:** https://members.wto.org/crnattachments/2026/TBT/USA/26_03376_00_e.pdf
6.	**Description of content:** Proposed rule - The Food and Drug Administration (FDA, the Agency, or we) is proposing regulations to prescribe the format, content, and procedures for establishment registration and tobacco product listing. Complete and accurate establishment registration and product listing information is important to accomplish statutory, regulatory, and public health objectives. Currently, only domestic owners and operators are required to register their establishments and list their tobacco products with FDA while foreign owners and operators are not subject to these requirements, creating significant gaps in Agency information. This action, if finalized, would extend registration and listing requirements to include owners and operators of foreign establishments.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety
8.	**Relevant documents:** 91 Federal Register (FR) 39168, 29 June 2026; Title 21 Code of Federal Regulations (CFR) Part 1108: https://www.govinfo.gov/content/pkg/FR-2026-06-29/html/2026-13047.htm https://www.govinfo.gov/content/pkg/FR-2026-06-29/pdf/2026-13047.pdf This proposed rule is identified by Docket Number FDA-2025-N-7130. The Docket Folder is available on Regulations.gov at https://www.regulations.gov/docket/FDA-2025-N-

	7130/document and provides access to primary documents as well as comments received. Documents are also accessible from Regulations.gov by searching the Docket Number.
9.	**Proposed date of adoption:** To be determined **Proposed date of entry into force:** To be determined
10.	**Provision of comments** **Final date for comments:** 14 September 2026 **[ ] 60 days from notification** WTO Members and their stakeholders are asked to submit comments to the USA TBT Enquiry Point by or before 4pm Eastern Time on 14 September 2026. Comments received by the USA TBT Enquiry Point from WTO Members and their stakeholders will be shared with the FDA and will also be submitted to the Docket on Regulations.gov if received within the comment period. **Contact details of agency or authority designated to handle comments regarding the notification:** Please submit comments to: USA WTO TBT Enquiry Point, Email: usatbtep@nist.gov