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) [1815]**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 [****],** **other** **[X]:**  |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Tobacco products; TOBACCO AND MANUFACTURED TOBACCO SUBSTITUTES (HS 24); Information sciences. Publishing (ICS 01.140), Tobacco, tobacco products and related equipment (ICS 65.160) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Premarket Tobacco Product Applications and Recordkeeping Requirements (140 page(s), in English) |
| **6.** | **Description of content:** Final rule - The Food and Drug Administration (FDA, the Agency, us, or we) is issuing a final rule that sets forth requirements for premarket tobacco product applications (PMTAs) and requires manufacturers to maintain records establishing that their tobacco products are legally marketed. The rule will help ensure that PMTAs contain sufficient information for FDA to determine whether a marketing granted order should be issued for a new tobacco product. The rule codifies the general procedures FDA will follow when evaluating PMTAs and creates postmarket reporting requirements for applicants that receive marketing granted orders. The rule also requires tobacco product manufacturers to keep records establishing that their tobacco products are legally marketed, such as documents showing that a tobacco product is not required to undergo premarket review or has received premarket authorization.  |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Prevention of deceptive practices and consumer protection; Protection of human health or safety |
| **8.** | **Relevant documents:** 86 Federal Register (FR) 52300, 5 October 2021; Title 21 Code of Federal Regulations (CFR) Parts 1100, 1107 and 1114:<https://www.govinfo.gov/content/pkg/FR-2021-10-05/html/2021-21011.htm><https://www.govinfo.gov/content/pkg/FR-2021-10-05/pdf/2021-21011.pdf>This final rule is identified by Docket Number FDA-2019-N-2854. The Docket Folder is available on Regulations.gov at <https://www.regulations.gov/docket/FDA-2019-N-2854/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. |
| **9.** | **Proposed date of adoption:** 5 October 2021**Proposed date of entry into force:** 4 November 2021 |
| **10.** | **Final date for comments:** None |
| **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/2021/TBT/USA/21_6435_00_e.pdf> |