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) [1814]**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]:** [ 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), Domestic safety (ICS 13.120), Tobacco, tobacco products and related equipment (ICS 65.160) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Content and Format of Substantial Equivalence Reports; Food and Drug Administration Actions on Substantial Equivalence Reports (77 page(s), in English) |
| **6.** | **Description of content:** Final rule - The Food and Drug Administration (FDA, the Agency, or we) is issuing this final rule to provide additional information on the content and format of reports intended to demonstrate the substantial equivalence of a tobacco product (SE Reports). The final rule also establishes the general procedures FDA intends to follow when evaluating SE Reports, including procedures that address communications with the applicant and the confidentiality of data in an SE Report. The final rule will provide applicants with more certainty and clarity related to preparing and submitting SE Reports. |
| **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) 55224, 5 October 2021; Title 21 Code of Federal Regulations (CFR) Parts 16, 1100, 1107 et al.:<https://www.govinfo.gov/content/pkg/FR-2021-10-05/html/2021-21009.htm><https://www.govinfo.gov/content/pkg/FR-2021-10-05/pdf/2021-21009.pdf>This final rule is identified by Docket Number FDA-2016-N-3818. The Docket Folder is available on Regulations.gov at <https://www.regulations.gov/docket/FDA-2016-N-3818/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_6434_00_e.pdf> |