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) [1916]**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 [****],** **5.7.1 [****], 3.2 [****], 7.2 [****],** **other****:**  |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Nonprescription drug product with an additional condition for nonprescription use (ACNU); Pharmaceutics (ICS code(s): 11.120); Domestic safety (ICS code(s): 13.120) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Nonprescription Drug Product With an Additional Condition for Nonprescription Use; (19 page(s), in English) |
| **6.** | **Description of content:** Proposed rule - The Food and Drug Administration (FDA, the Agency, or we) is proposing to establish requirements for a nonprescription drug product with an additional condition for nonprescription use (ACNU). The proposed rule, if finalized, would establish requirements for a nonprescription drug product that has an ACNU that an applicant must implement to ensure appropriate self-selection or appropriate actual use, or both, by consumers without the supervision of a healthcare practitioner. The proposed rule is intended to increase options for applicants to develop and market safe and effective nonprescription drug products, which could improve public health by broadening the types of nonprescription drug products available to consumers. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Consumer information, labelling; Cost saving and productivity enhancement |
| **8.** | **Relevant documents:** 87 Federal Register (FR) 38313, 28 June 2022; Title 21 Code of Federal Regulations (CFR) Parts 201 and 314:<https://www.govinfo.gov/content/pkg/FR-2022-06-28/html/2022-13309.htm><https://www.govinfo.gov/content/pkg/FR-2022-06-28/pdf/2022-13309.pdf>This proposed rule is identified by Docket Number FDA-2021-N-0862. The Docket Folder is available from Regulations.gov at <https://www.regulations.gov/docket/FDA-2021-N-0862/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. 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 26 October 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-0862/document) on Regulations.gov if received within the comment period. |
| **9.** | **Proposed date of adoption:** To be determined**Proposed date of entry into force:** To be determined |
| **10.** | **Final date for comments:** 26 October 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_4403_00_e.pdf> |