NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

|  |  |
| --- | --- |
| **1.** | **Notifying Member:** Philippines  **If applicable, name of local government involved (Article 3.2 and 7.2):** |
| **2.** | **Agency responsible:**  ENGR. ANA TRINIDAD F. RIVERA  Director IV  Center for Cosmetics Regulation and Research (CCRR)  Food and Drug Administration  DEPARTMENT OF HEALTH  **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:**  MR. JEKEE BRYAN T. MIRAFLOR Center for Cosmetics Regulation and Research (CCRR)  Food and Drug Administration  DEPARTMENT OF HEALTH  Email: [jbtmiraflor@fda.gov.ph](mailto:jbtmiraflor@fda.gov.ph); [atfrivera@fda.gov.ph](mailto:atfrivera@fda.gov.ph)  [www.fda.gov.ph](http://www.fda.gov.ph) |
| **3.** | **Notified under Article 2.9.2 [****X],** **2.10.1 [****],** **5.6.2 [****],** **5.7.1 [****],** **other****:** |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Heated Tobacco Products (HTPs); Tobacco, tobacco products and related equipment (ICS 65.160) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Application Procedure for Product Marketing Authorizations through the FDA Electronic Portal (E-portal) System for Heated Tobacco Products (11 page(s), in English) |
| **6.** | **Description of content:** This Circular is being issued to provide the procedural guidelines and documentary requirements for the FDA Product Marketing Authorization application through the FDA e-Portal System covering all  manufacturers, traders, and importers of HTPs applying for product marketing authorizations under the Center for Cosmetics Regulation and Research. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety; Reducing trade barriers and facilitating trade |
| **8.** | **Relevant documents:**  Republic Act No. 9711 - FDA Act of 2009  Republic Act No. 11032 - Ease of Doing Business and Efficient and Government Service Delivery Act of 2018  Section 144 of Republic Act No. 11467, Section II of Executive Order No. 106  G/TBT/N/PHL/234 |
| **9.** | **Proposed date of adoption:** This Circular shall take effect 15 days after publication in a newspaper of general circulation and the Office of National Administrative Register of the UP Law Center.  **Proposed date of entry into force:** This Circular shall take effect 15 days after publication in a newspaper of general circulation and the Office of National Administrative Register of the UP Law Center. |
| **10.** | **Final date for comments:** 60 days from notification |
| **11.** | **Texts available from: National enquiry point [****X]** **or address, telephone and fax numbers and email and website addresses, if available, of other body:**  MR. NEIL P. CATAJAY Director Bureau of Philippine Standards Department of Trade and Industry 3F Trade and Industry Building 361 Sen. Gil Puyat Avenue Makati City Philippines 1200  (632) 7751 4700; (632) 7751 4706 [bps@dti.gov.ph](mailto:bps@dti.gov.ph) <http://www.bps.dti.gov.ph>  <https://members.wto.org/crnattachments/2020/TBT/PHL/20_5077_00_e.pdf> <https://members.wto.org/crnattachments/2020/TBT/PHL/20_5077_01_e.pdf> <https://members.wto.org/crnattachments/2020/TBT/PHL/20_5077_02_e.pdf> |