NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** Philippines  **If applicable, name of local government involved (Article 3.2 and 7.2):** |
| **2.** | **Agency responsible:**  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:**  JESUSA JOYCE N. CIRUNAY, RPh  Director IV  Center for Drug Regulation and Research Email: [cdrr.od@fda.gov.ph](mailto:cdrr.od@fda.gov.ph) Website: [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):** Human blood; animal blood prepared for therapeutic, prophylactic or diagnostic uses; antisera and other blood fractions and immunological products, whether or not modified or obtained by means of biotechnological processes; vaccines, toxins, cultures of micro-organisms (excl. yeasts) and similar products (HS 3002); Pharmaceutics (ICS 11.120) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Implementation of Abridged and Verification Review Pathways for New Drug, Initial Registration and Post-Approval Changes Applications of Drug Products, including Vaccines and Biologicals (6 page(s), in English) |
| **6.** | **Description of content:** The proposed issuance aims to provide the implementing guidelines on facilitated registration pathways (FRPs) through abridged review or verification review of drug products, including vaccines and biologicals as per Administrative Order No. 2020-0045. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Streamlining its regulatory review to accelerate the registration process for medicines, by leveraging against product regulatory assessments made by reference drug regulatory authorities (RDRAs), especially during the pandemic.; Protection of human health or safety; Reducing trade barriers and facilitating trade |
| **8.** | **Relevant documents:**   * Republic Act No. 9711, "Food and Drug Administration Act of 2009" * Republic Act No. 11032, "Ease of Doing Business and Efficient Government Service Delivery Act of 2018" * Administrative Order (AO) No. 2020-0045, "Establishing Facilitated Registration Pathways for Drug Products, including Vaccines and Biologicals" |
| **9.** | **Proposed date of adoption:** This Circular shall take effect fifteen (15) days following its publication in a newspaper of general circulation and upon filing to the University of the Philippines Law Center – Office of the National Administrative Register.  **Proposed date of entry into force:** Upon effectivity |
| **10.** | **Final date for comments:** 5 October 2021 |
| **11.** | **Texts available from: National enquiry point [****X]** **or address, telephone and fax numbers and email and website addresses, if available, of other body:**  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> Head of Organization  <https://www.fda.gov.ph/draft-for-comments-implementation-of-abridged-and-verification-review-pathways-for-new-drug-initial-registration-and-post-approval-changes-applications-of-drug-products-including-vaccines-and-bio/> |