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:**  Department of Health  Food and Drug Administration  Center For Food Regulation and Research  **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:**  DR. ROLANDO ENRIQUE D. DOMINGO Director-General  JESUSA JOYCE N. CIRUNAY, RpH  Director,  Center for Food Regulation and Research  Email: [jjncirunay@fda.gov.ph](mailto:jjncirunay@fda.gov.ph) ; [cdrr.od@fda.gov.ph](mailto:cdrr.od@fda.gov.ph); [rmvmorante@fda.gov.ph](mailto:rmvmorante@fda.gov.ph); [pps@fda.gov.ph](mailto:pps@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):** Pharmaceutical products; Pharmaceutics (ICS 11.120) |
| **5.** | **Title, number of pages and language(s) of the notified document:** FDA Circular No.\_\_\_\_\_: Interim Guidelines on the Renewal of Current Good Manufacturing Practice (cGMP) Clearance of Foreign Drug Manufacturers (3 page(s), in English) |
| **6.** | **Description of content:** Considering the COVID-19 pandemic and consistent with the spirit and continuing policy of the government manifested in the pertinent objectives and the declared COVID-19 response and recovery interventions provided under Republic Act No. 11494 or the "Bayanihan to Recover As One Act", this Circular is being issued to provide the interim guidelines on the renewal of cGMP clearance of foreign drug manufacturers. |
| **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:**   * Administrative Order (AO) No. 2013-0022 "Guidelines for Current Good Manufacturing Practice (cGMP) Clearance and Inspection of Foreign Drug Manufacturers" * FDA Circular No. 2014-016 Implementing Guidelines * FDA Circular No. 2020-020 "Interim Guidelines Governing the Issuance of a Permit to Register to Drug Importers for Foreign Drug Manufacturers" * FDA Circular No. 2020-024 "Updated Guidelines for Application of Authorizations at the Food and Drug Administration in Light of the Community Quarantine Declarations" |
| **9.** | **Proposed date of adoption:** 10 June 2021  **Proposed date of entry into force:** 10 June 2021 |
| **10.** | **Final date for comments:** N/A |
| **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) 751 4700; (632) 7913128 [bps@dti.gov.ph](mailto:bps@dti.gov.ph) <http://www.bps.dti.gov.ph> Head of Organization  <https://www.fda.gov.ph/wp-content/uploads/2021/05/Draft-FDA-Circular-on-Interim-Guidelines-for-cGMP-Clearance_for-posting.docx.pdf>  <https://members.wto.org/crnattachments/2021/TBT/PHL/21_3797_00_e.pdf> |