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:** DR ROLANDO ENRIQUE D. DOMINGO, DBPODirector GeneralFood and Drug AdministrationDEPARTMENT 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:** DR. OSCAR G. GUTIERREZOfficer-in-ChargePolicy and Planning ServiceFood and Drug AdministrationDEPARTMENT OF HEALTHEmail: oggutierrez@fda.gov.ph; 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):** Health products under the DOH-Food and Drug Administration (e.g processed food, food supplements, food additives and ingredients, drugs or medicines, cosmetics, medical and health-related devices, including diagnostic kits and reagents, radiation emitting devices or equipment, household hazardous substances, including urban pesticides, cigarettes, toys and childcare articles, among other products as determined by the DOH-FDA) |
| **5.** | **Title, number of pages and language(s) of the notified document:** AO 2020-0017-Revised Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration Amending Administrative Order No. 2016-0003 (15 page(s), in English) |
| **6.** | **Description of content:** Consistent with Republic Act No. 9711 (Food and Drug Administration Act (FDA) Act of 2009)  and Republic Act No. 11032 (Ease of Doing Business (EODB) and Efficient Government Service Delivery (EGSD) Act of 2018) and the DOH-F1+ Strategic Goals, these guidelines are one of the continuing efforts of the FDA to streamline its processes and requirements and to automate and re-engineer its systems.  Main objectives of the issuance are to simplify the requirements and processes for initial, renewal and variation of  License to Operate (LTO) applications and to re-engineer FDA's system to comply with the maximum prescribed processing time depending on the complexity of transactions. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety; Reducing trade barriers and facilitating trade; Cost saving and productivity enhancement |
| **8.** | **Relevant documents:** RA 9711 (FDA Act of 2009) |
| **9.** | **Proposed date of adoption:** Not applicable**Proposed date of entry into force:** Not applicable |
| **10.** | **Final date for comments:** Not applicable  |
| **11.** | **Texts available from: National enquiry point [** **]** **or address, telephone and fax numbers and email and website addresses, if available, of other body:** DR. OSCAR G. GUTIERREZOfficer-in-ChargePolicy and Planning ServiceFood and Drug AdministrationDEPARTMENT OF HEALTHEmail: oggutierrez@fda.gov.ph; www.fda.gov.ph https://www.fda.gov.ph/administrative-order-no-2020-0017-revised-guidelines-on-the-unified-licensing-requirements-and-procedures-of-the-food-and-drug-administration-repealing-administrative-order-no-2016-0003/ |