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  **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:**  Engr. Bayani C. San Juan, Director IV  Center for Device Regulation, Radiation Health, and Research (CDRRHR)  Civic Drive, Filinvest Corporate City, Alabang 1781 Muntinlupa, Philippines  +632.857.1900 loc 8301  [info@fda.gov.ph](mailto:info@fda.gov.ph) / [eppayas@fda.gov.ph](mailto:eppayas@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):** Water treatment devices/systems which product water is for drinking purposes; Water quality (ICS 13.060) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Draft Administrative Order No. \_\_\_ : Policies and Guidelines on the Regulation of Water Treatment Devices/ Systems in the Philippines (14 page(s), in English) |
| **6.** | **Description of content:** The proposed policy covers the manufactures, exporters, importers and distributors including establishments that assemble, repackage and re-label water treatment systems or devices for the purpose of donation, promotion, giving free of charge, selling or commercial distribution in the Philippines. Furthermore, the guidelines also cover establishments that sell, install and/or provide repair and maintenance of water treatment system for local water district/water service provider, water refilling station, household, institution, food establishment, office and other commercial establishments.  Water treatment systems used in the production of bottled water are not covered by these guidelines.  The proposed policy is an amendment of the Department of Health Administrative Order 2005- 0003 entitled "Guidelines on the Issuance of Certificate of Product Registration for Water Purification Equipment and Devices" and its subsequent amendments (AO 2005-0003-A, AO 2005-0003-B, AO 2005-0003-C).  The regulatory agency that will implement the proposed policy is the Department of Health – Food and Drug Administration. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** This Administrative Order is promulgated to innovate and improve the regulation of water treatment devices/systems in the Philippines. Specifically, this AO aims to:  1. Align and harmonize the regulation of water treatment devices/systems with the regulation of other health products under the jurisdiction of the FDA.  2. Establish rules and regulations for:  licensing of establishments covered by this AO  registration of water purification devices/systems  packaging and labelling requirements for registered water treatment devices/systems  donated water purification devices/systems;  Consumer information, labelling; Prevention of deceptive practices and consumer protection; Protection of human health or safety |
| **8.** | **Relevant documents:**   * PD 856 - Code on Sanitation of the Philippines * Administrative Order 2005-0003 - Guidelines on the Issuance of Certificate of Product Registration for Water Purification Equipment and Devices * Administrative Order 2005-0003-A * Administrative Order 2005-0003-B * Administrative Order 2005-0003-C * Republic Act 9711 - "Food and Drug Administration (FDA) Act of 2009" |
| **9.** | **Proposed date of adoption:** This Order shall take effect 15 days after its publication in a national newspaper of general circulation.  **Proposed date of entry into force:** This Order shall take effect 15 days after its publication in a national newspaper of general circulation. |
| **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:**  Center for Device Regulation, Radiation Health, and Research (CDRRHR)  Civic Drive, Filinvest Corporate City, Alabang 1781 Muntinlupa, Philippines  +632.857.1900 loc 8301  [info@fda.gov.ph](mailto:info@fda.gov.ph) / [eppayas@fda.gov.ph](mailto:eppayas@fda.gov.ph)  [www.fda.gov.ph](http://www.fda.gov.ph)  <https://members.wto.org/crnattachments/2019/TBT/PHL/19_1875_00_e.pdf> |