ADMINISTRATIVE ORDER
No. _____

SUBJECT: **Policies and Guidelines on the Regulation of Water Treatment Devices/Systems in the Philippines**

I. RATIONALE

The Revised Implementing Rules and Regulations of Chapter II- "Water Supply" of the Code on Sanitation of the Philippines (PD 856) provides that "Any person or entity, firm or company involved in the manufacture and sale of water purification equipment, gadgets and devices including household water filters and water purifiers and similar apparatus imported or locally made shall submit an application to the Department of Health through the Bureau of Health Devices and Technology, now the Food and Drug Administration - Center for Device Regulation, Radiation Health and Research (FDA-CDRRHR) for review, testing and certification before they could market the said equipment, gadgets or devices. To implement this provision, 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 and AO 2005-0003-C) were issued by the Department of Health (DOH).

The above policies cover only the issuance of the Certificate of Product Registration (CPR) for the above-mentioned health products and do not include the licensing of manufacturers, importers and other establishments involved in the distribution of water treatment devices/systems and provisions for donated water purification devices/systems.

Republic Act 9711, otherwise known as the "Food and Drug Administration (FDA) Act of 2009" through its Implementing Rules and Regulations (IRR) provides for the issuance of a License to Operate to concerned establishments under its jurisdiction. It also mandated the FDA to develop and/or issue policies, standards and authorizations that would cover establishments and health products to enhance and improve its health products regulatory system. To carry out these mandates and to effectively implement the regulation of water treatment devices/systems in the Philippines, there is a need to supplement and amend the provisions of the above-stated Administrative Orders (AOs). The DOH through the FDA – CDRRHR hereby issues these policies and guidelines revising and supplementing Administrative Order 2005-0003.

II. SCOPE

These guidelines shall apply to all 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, these guidelines shall 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.

III. OBJECTIVES

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:
    a. licensing of establishments covered by this AO
    b. registration of water purification devices/systems
    c. packaging and labelling requirements for registered water treatment devices/systems
    d. donated water purification devices/systems

IV. DEFINITION OF TERMS

The following are the definition of terms used in this AO:

1. **Applicant** – refers to a local or foreign establishment that seeks to secure a License to Operate or Certificate of Product Registration from FDA-CDRRHR

2. **Authorization –** means a permission embodied in a document granted by the FDA to a natural or juridical person who has submitted an application to implement the manufacture, importation, exportation, sale, offer for sale, distribution, transfer, and/or where appropriate, the use, testing, promotion, advertising, or sponsorship of health products. The authorization can take the form of a permit, a license, a certificate of registration, of accreditation, of compliance, or of exemption, or any similar document.

3. **Certificate of Product Registration** (CPR) – a certification issued by the Director of FDA-CDRRHR as authorized by the FDA Director-General, attesting the claims of the manufacturer, importer or distributor of the water treatment device/system. Claims can be found in the advertising material, label or manual of the product.

4. **Distributor/Importer/Exporter** – means any establishment that imports or exports raw materials, and/or finished products for its own use or for wholesale distribution to other establishments or outlets. If the distributor/importer/exporter sells to the general public, it shall be considered a retailer.

5. **Establishment** - means a sole proprietorship, a partnership, a corporation, an institution, an association, or an organization engaged in the manufacture, importation, exportation, sale, offer for sale, distribution, donation, transfer, use, promotion, advertising, or sponsorship of water treatment devices/systems, including the facilities and installation needed for its activities. It includes installer of water treatment devices/systems.

6. **Franchisee** - is a person, individual or a Corporation duly registered with the Department of Trade and Industry (DTI) or the Security Exchange Commission (SEC) granted by the franchisor (installer) the right to engage in the business of offering, selling, or distributing product water from a water refilling station under a marketing plan/system/concept, for a certain consideration. Unless otherwise provided, said right includes the use of a trademark, service mark, trade name / business name, know-how, logo-type advertising, or other commercial symbols associated with the franchisor's water refilling station business.

7. **Installer** – refers to an entity or a contractor providing installation, repair and/or maintenance services to operators of water refilling stations and other users of water treatment systems

8. **Label** - means a display of written, printed, or graphic matter on the immediate container, or other materials affixed thereto, of any article. Any word, statement or other information appearing on the label required under authority of the FDA Act of 2009 or other relevant laws shall be deemed complied with if such word, statement or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or easily legible through the outside container or wrapper.

9. **Licensing** - means the process of approval of an application to operate or establish an establishment prior to engaging in the manufacture, importation, sale, offer for sale, distribution, transfer, and where applicable the use, promotion, advertisement, and/or sponsorship of water treatment devices/systems

10. **Manufacturer** – refers to establishment engaged in any and all operations involved in the production, designing, assembly and/or installation of water treatment devices/systems including preparation, processing, filling, packaging, repackaging, altering, ornamenting, finishing and labelling with the end in view of its storage, sale or distribution

11. **Misbranding** - means, in addition to definitions provided in the Food , Drugs and Devices, and Cosmetics Act and in other relevant laws, giving unsubstantiated

claims, misinformation, or misleading information on the label or other information materials, including those contained in brand names or trademarks. It shall not refer to copyright, trademark, or other intellectual property-like instruments.

12. **Point-of-Use Water Treatment System –** A plumbed-in or faucet-mounted system used to treat the drinking water at a single tap or multiple taps but not used to treat the majority of water used for washing and flushing or other non-consumption purposes at a building or facility. Any batch system or device not connected to the plumbing system is considered a point-of-use system.

13. **Re-seller** – refers to any establishment, excluding distributor, importer and/or exporter of water treatment device/system, which sells or offers to sell such product directly to the general public

14. **Water System Components** - refers to materials or products that come in contact with drinking water, drinking water treatment chemicals, or both which include, but not limited, process media (carbon, sand, etc.), protective materials (coatings, linings, liners, etc), joining and sealing materials (solvent cement, welding materials, gaskets, etc.), devices used in storing and dispensing water (tanks, water dispenser, etc) and devices used in treatment/transmission/distribution systems (fittings, valves, chlorinators, separation members, etc)

15. **Water Treatment Devices** – equipment, apparatus, device or gadget whose purpose is to purify or treat water for drinking purposes

16. **Water Treatment System** – combination of water treatment devices and system components intended to purify or treat water for drinking purposes

V. GENERAL GUIDELINES

1. All manufacturers, importers, exporters, installers and distributors of water treatment device/system shall apply for a License to Operate (LTO) at the FDA in accordance with the pertinent provisions of DOH Administrative Order No. 2016-0003 entitled "Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration (FDA)".

2. All manufacturers, importers, installers, distributors and exporters of water treatment devices/system with valid LTO shall apply for a CPR for their products. Exporters are not required to secure a CPR for their device/system if such is sold abroad, however, if the product is sold or commercially distributed in the Philippines, exporters shall apply for a CPR for their water purification device/system. Manufacturers of water treatment devices that are sold directly to end users as replacement parts are also required to apply for a CPR. No water treatment device/system shall be imported, sold, offered for sale and/or distributed in the Philippines until and unless a CPR has been issued by the FDA.

VI. SPECIFIC GUIDELINES

A. Issuance of a License to Operate

1. The applicant shall submit the documentary requirements specified in DOH AO 2016-0003 when applying for a License to Operate and variations as applicable. In addition, the applicant shall submit the following documents when applying for initial LTO.
   a. List of all water treatment devices/systems;
   b. List of re-sellers (if applicable);
   c. List of branches/outlets and/or franchisees (if applicable);
   d. List of establishment installed with the applicant's water treatment system (if applicable). If system is installed in a water refilling station, specify if active (installed with maintenance contract with the installer) /inactive (installed but without maintenance contract with the installer);

2. Qualified person for establishments covered by this AO shall be a licensed Sanitary Engineer or an officer/personnel of the establishment who has attended a basic certification course as specified in the Supplemental Implementing Rules and Regulations of Chapter II-Water Supply of the Code on Sanitation of the Philippines (P.D. 856).

3. The LTO shall be issued and approved by the FDA-CDRRHR Director by authority of the Director General.

4. **LTO Exemption.** An operator of a water refilling station shall not be required to secure a License to Operate if he has imported a water treatment system or caused the installation of a locally manufactured water treatment system for exclusive use in his water refilling station. However, if the operator intends to open one or more water refilling stations with the same water treatment system or a different water treatment system whose design is for exclusive use in the said water refilling station(s); he shall be considered a manufacturer or importer and shall be required to apply for an LTO.

B. Issuance of a Certificate of Product Registration

1. Application for registration shall be applied on a per design for water treatment system/device, per product type and/or per brand except if the difference is in the size and/or capacity of the device.

2. Applicant shall submit the documentary requirements enumerated in Annex A when applying for a Certificate of Product Registration.

3. All water treatment devices/systems shall undergo product performance evaluation which shall be conducted by National Reference Laboratory (NRL) for Environmental and Occupational Health, Toxicology and Micronutrient Assay - East Avenue Medical Center or any FDA recognized testing laboratory upon the endorsement of FDA-CDRRHR for initial registration. NRL shall inform the FDA-CDRRHR of the action taken within thirty (30) days from receipt of the endorsement letter.

4. Approval of the applied CPR shall be based on compliance with the requirements set by the FDA-CDRRHR and the Philippine National Standards for Drinking Water (PNSDW) or other applicable Philippine National Standards for Drinking Water Treatment Units. Water treatment device/system shall be evaluated depending on the claims of the manufacturer, importer or distributor of the product. Approved claim shall be indicated on the advertising materials, in the operation manual or on the label affixed to the device/system.

5. The CPR shall be issued and approved by the FDA-CDRRHR Director by authority of the Director General.

6. FDA may recognize laboratories for testing procedures not prescribed in the PNSDW but are prescribed in other Philippine National Standards for Drinking Water Treatment Units.

7. For water refilling station wherein the installer of the water purification system has closed down his business, the operator shall apply for the renewal of the CPR.

8. **Grounds for Disapproval of CPR Application.** Any of the following or similar instances shall be ground for the disapproval of an application for a Certificate of Product Registration:
    a. The application requirements submitted show that the establishment does not meet the required technical requirements, PNSDW or other appropriate standards;
    b. The applicant made misrepresentations, false entries, or withheld any relevant data contrary to the provisions of the law, the R.A. 9711 Rules and Regulations, PNSDW or other appropriate standards;
    c. The applicant failed to comply with the requirements specified in the notice of deficiency within thirty (30) calendar days from receipt of the notice;
    d. Failure of the applicant to have its water purification device/system undergo product performance evaluation within 30 calendar days from receipt of notice from NRL-EAMC.
    e. Such other analogous grounds or causes as determined by the FDA.

9. **Grounds for Suspension, Revocation or Cancellation of issued CPR.** Any of the following or similar instances shall be ground for the suspension, revocation or cancellation of a License to Operate:
    a. The holder or owner has violated any of the terms and conditions of its authorization or registration;
    b. The label/claim of the water treatment device/system is false and misleading or does not conform with current labelling requirements;
    c. Any modification in the approved commercial presentation of the product; and
    d. Such other analogous grounds or causes as determined by the FDA.

10. **CPR Exemptions.** The following establishments/products shall be exempted from the CPR requirement based on the following conditions:
    a. Establishments that manufacture water treatment devices/systems for the purpose of selling or supplying to another establishment for further processing or assembly by the latter.
    b. Distributors of registered water treatment devices/systems
    c. Re-sellers of registered water treatment device/system.
    d. An operator of a water refilling station shall not be required to secure a Certificate of Product Registration if he has imported a water treatment system or caused the installation of a locally manufactured water treatment system for exclusive use in his water refilling station. However, if the operator intends to open one or more water refilling stations with the same water treatment system or a different water treatment system whose design is for exclusive use in the said water refilling station(s); he shall be considered a manufacturer or importer and shall be required to apply for CPR.
    e. Water purification devices/systems that are sold solely abroad or in other countries.

C. **Validity of LTO and CPR**

1. Initial LTO shall be valid for two (2) years from date of issuance and subject to renewal unless sooner suspended or revoked in accordance with the regulations of R.A. 9711. Renewed LTO shall be valid for three (3) years.

2. Initial CPR shall be valid for five (5) years from date of issuance and subject to renewal unless sooner suspended or revoked in accordance with the regulations of the FDA-CDRRHR. Renewed CPR shall be valid for five (5 years).

D. **Lost Copy of LTO and/or CPR.** Establishments who lost their original copy of LTO and/or CPR shall secure an authenticated copy of such, submit an affidavit of loss to and pay the prescribed fee at the FDA-CDRRHR.

E. **Late filing of application for renewal of LTO and/or CPR.** Late filing of application for renewal of LTO and/or CPR shall be subject to a surcharge or penalty

in accordance with the pertinent provisions of the Implementing Rules and Regulations of Republic Act 9711.

F. **Assignment and Transfer of Pending Applications, Existing LTO and/or CPR.** Requirements for assignment or transfer of a valid and unexpired LTO and/or CPR, or pending application for renewal thereof shall be in accordance with the pertinent provisions of the Implementing Rules and Regulations of R.A. 9711.

G. **Donated Water Treatment Devices/System.** Manufacturers, importers, distributors, exporters, private or public organizations, individuals or any entity intending to distribute water treatment devices/system through charities, donations, or promotional activities shall secure a CPR from FDA. In case of a disaster or an emergency wherein there is an urgent need to distribute imported and/or donated water purification devices/systems to the intended end users, the said products shall undergo product performance evaluation by the NRL and/or a DOH accredited water laboratory. The raw water to be collected and analyzed shall come from the source water where the said products will be used. The test report should show compliance of the product water to the PNSDW before the products can be given to the intended end-users. Clearance shall be secured by the concerned entity from the FDA or concerned FDA-Regional Field Office prior to its distribution. Non-functional, worn-out, broken or unsanitary imported donated water treatment devices/system shall be prohibited to enter the Philippines and shall be reshipped to the country of origin at the expense of the recipient, importer, and/or donor. Donated goods shall not be sold to the public.

H. **Issuance of Clearance for Conditional Release.** For imported water treatment devices/systems, a Clearance for Conditional Release shall be issued by the CDRRHR to facilitate the release of the water treatment device/system from the Customs custody pending the issuance of CPR. The importer, however shall not sell, distribute or transfer in whole or in part, the water treatment devices/systems to any place other than the address specified in the Conditional Release. Documentary requirements to be submitted when applying for a Clearance for Conditional Release are listed in Annex B. To ensure that no distribution, sale, use and/or transfer of the water treatment devices/systems, the importer shall allow authorized personnel of the FDA to conduct inspection/inventory of the import shipment anytime within official working hours.

I. All establishments shall abide with the guidelines of the FDA on electronic submission and processes of LTO and CPR applications into electronic format pursuant to Republic Act No. 8792 or the “Electronic Commerce Act of 2000”.

J. All applications and documents to be submitted shall be in English or in Filipino.

K. The licensed establishment shall apply for variation or amendment of CPR based on the applicable circumstances and documentary requirements as specified in Annex B of DOH AO 2016-0003.

L. Required fees shall be paid in accordance with the prescribed fees set by the FDA.

VII. LABELING AND PACKAGING REQUIREMENTS AND DISPLAY OF CPR

1. The FDA shall enforce mandatory labelling and packaging to enable the user to obtain accurate information as to the nature of the water treatment devices/system.

2. The following shall be included/indicated on the packaging of the water treatment devices/systems:
   a. Name and address of local manufacturer, importer or distributor or installer of the water treatment device/system
   b. LTO and CPR number issued by FDA.

3. All writings on the packaging shall be written/printed in English and/or Filipino.

4. For water refilling stations, local water districts and/or water service providers, CPR shall be displayed in a conspicuous place in the establishment.

VIII. ROLES AND RESPONSIBILITIES

A. FDA shall perform its mandates on the regulation of water treatment devices/systems in accordance with the provisions of RA 9711, its IRR and other pertinent laws and regulations.

B. **Re-sellers**

Re-sellers selling water treatment devices/systems in the Philippine market are required to:

1. Buy water treatment devices/system only from local manufacturers, importers and distributors with a valid LTO from FDA-CDRRHR;
2. Sell or offer for sale only water treatment devices/systems that were issued a CPR; and
3. Post in a conspicuous place the list of their water treatment device/system suppliers/distributors.

C. **Local Government Units**

1. The local government units through the local chief executives are enjoined to pass an ordinance in support of the implementation of the provisions of this AO.

2. The local chief executives are encouraged to require the prescribed LTO and/or CPR to the manufacturers, importers, exporters, installers and distributors of water treatment devices/system and to the operators of water refilling stations prior to the issuance of sanitary permit to the concerned establishments.

VII. PROHIBITED ACTS

1. The manufacture, importation, sale, offering for sale, distribution, transfer, or retail of any water treatment device/system by any natural or juridical person without a valid License to Operate from the FDA

2. The manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising or sponsorship of any water treatment device/system that is unregistered or misbranded

3. The adulteration or misbranding of any water treatment device/system

4. The refusal to permit entry or inspection of the office premises, warehouse by the FDA personnel as authorized by the Secretary of Health/FDA-Director-General/FDA Regional Director

5. The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labelling of, or the doing of any other act with respect to water treatment devices/systems if such act is done while such article is held for sale (whether or not the first sale) and results in such article being adulterated or misbranded.

6. The manufacture, importation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertisement, or sponsorship of any water treatment device/system which, although requiring registration, is not registered with FDA pursuant to this AO

7. Modification in the approved commercial presentation of the product without prior approval from the FDA-CDRRHR.

VIII. PENALTY CLAUSE

Sanctions over violations of any provisions of this Administrative Order shall follow the Rules of Administrative Procedure provided in the Implementing Rules and Regulations of Republic Act No. 9711.

IX. TRANSITORY PROVISION

Upon effectivity of this Order, all manufacturers, importers, exporters, installers and all other establishments within the scope of this Order that are already in operation shall be given six (6) months from the date of publication of this Order in leading

newspaper to comply with the provisions of this guideline. A certificate of pending application shall be given upon request of the company.

X. SEPARABILITY CLAUSE

In the event that any rule, section, paragraph, sentence, clause or words of this Administrative Order is declared invalid for any reason, the other provisions hereof shall not be affected.

XI. REPEALING CLAUSE

Administrative Order No. 2005-0003 and its amendments, rules and regulations and all other administrative issuances or parts thereof inconsistent with the provisions of this Administrative Order are hereby repealed or amended accordingly.

XII. EFFECTIVITY

This Administrative Order shall take effect after fifteen (15) days following the completion of its publication in a newspaper of general circulation and filing with the University of the Philippines - Office of the National Administrative Register (UP-ONAR).

FRANCISCO T. DUQUE III, MD, MSc
Secretary of Health

ANNEX A

REQUIREMENTS FOR CPR APPLICATION

A. INITIAL APPLICATION

1. Copy of LTO

2. For water treatment devices (filters, UV, etc.), pitcher type, point-of-use water treatment system (countertop water treatment system or under the sink water treatment system), and water treatment system installed in water dispensing machines:
   a. Duly accomplished application form;
   b. Label/labelling/product insert or manufacturer's performance claim;
   c. Description of the treatment process;
   d. Schematic layout of the device/system;
   e. Technical specification of the device/system (e.g. brandname, capacity, size, etc);
   f. Type of materials/chemicals/substances used as components of the water treatment device/system;
   g. Installation and maintenance manual;
   h. For water treatment device/system with special claims, data from scientific research that is published in a recognized scientific journal, and accredited laboratory analysis supporting and proving the claims of the manufacturer of the product; and
   i. Payment

3. For water treatment systems for water refilling stations and local water district/water service provider
   a. Duly accomplished application form;
   b. Description of the treatment process;
   c. Schematic layout of the water treatment system;
   d. Operation and maintenance manual;
   e. Technical specification of the water treatment system;
   f. Type of materials/chemicals/substances used as components of the water treatment system;
   g. For water treatment systems with special claims, data from scientific research and laboratory analysis supporting and proving the claims of the manufacturer of the product; and
   h. Payment

B. RENEWAL APPLICATION

1. Duly accomplished application form

2. Sworn statement indicating no change or variation whatsoever in the water treatment device/system being applied

3. Copy of previously issued original CPR

4. Valid test report from DOH accredited water laboratory for the required parameters. The DOH accredited water laboratory should not be affiliated with the applicant for the required parameters.

   For water treatment device/system for emergency use, test report shall comply the PNSDW limits for the parameters identified by FDA as recommended by NRL.

5. Payment

ANNEX B

REQUIREMENTS FOR APPLICATION FOR CLEARANCE FOR CONDITIONAL RELEASE

1. Duly accomplished application form;
2. LTO
3. Layout/picture of the device
4. Bill of lading/airway bill; and
5. Invoice or Packing List
6. Payment

Note: For establishment without LTO, the establishment shall apply for an LTO and a CPR first before he could apply for a Clearance for Conditional Release.