Republic of the Philippines
DEPARTMENT OF HEALTH
Office of the Secretary
San Lazaro Compound., Sta. Cruz, Manila
Tel# 743-83-01

January 11, 2005

ADMINISTRATIVE ORDER
No. 2005-0003

SUBJECT: Guidelines on the Issuance of Certificate of Product Registration for Water Purification Equipment and Device

I. RATIONALE

Pursuant to the provisions of the Revised Implementing Rules and Regulations of Chapter II – "Water Supply" of the Sanitation Code of the Philippines (P.D. 856), the Department of Health through the Bureau of Health Devices and Technology is hereby mandated to implement these guidelines on the issuance of Certificate of Product Registration for water purification equipment, and devices including household water filters and water purifiers.

II. SCOPE/COVERAGE

These guidelines shall apply to local manufacturers, importers and distributors, including establishments that repackage and re-label water purification equipment, and devices including household water filters and water purifiers for the purpose of selling or commercial distribution in the local market.

III. DEFINITION OF TERMS

As used in this set of guidelines, the terms below shall be defined as follows:

- **APPLICANT** – refers to a local or foreign establishment that seeks to include its health related device in the BHDT list of registered water purification devices.

- **BHDT** – refers to the Bureau of Health Devices and Technology (BHDT) of the Department of Health.

- **CERTIFICATE OF PRODUCT REGISTRATION** – a certification issued by the Secretary of Health or his duly authorized representative, the Director of BHDT, attesting the claims of the manufacturer, importer or distributor on the product. Claims can be found in the label and the manual of the product.

- **DISTRIBUTOR** – refers to any person or establishment to whom or where a water purification device product is delivered or sold for purposes of distribution in commerce, except that such term does not include a manufacturer or retailer of such product.

- **HRDRD** – refers to the Health Related Device Regulation Division of the Bureau of Health Devices and Technology of the Department of Health.

- **IMPORTER** – refers to any person or business establishment that receives water purification devices from foreign manufacturers for the purpose of offering them for sale and/or distribution in the Philippines.

- **LABELING** – display of written, printed or graphic matter, printed or graphic matter on any water purification device product, its immediate container, tag, literature or other suitable material affixed thereto for the purpose of giving information as to the identity, components, attributes, directions for use, specifications and such other information as may be required by law or regulations.

- **MANUFACTURER** – refers to any person who manufactures, assembles or processes water purification devices, except that if such products are manufactured, assembles or processed for another person who attaches his own brand name to the product, the latter shall be deemed the manufacturer. In case of imported products, the manufacturer's representative or, in his absence, the importer shall be deemed the manufacturer.

- **WATER SYSTEM COMPONENTS** – materials or products that come in contact with drinking water, drinking water treatment chemicals, or both which include, but are not limited to, 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.).

- **WATER PURIFICATION DEVICES** – equipment, apparatus, device or gadget whose purpose is to purify or treat water, either for household, commercial or other uses.

- **WATER PURIFICATION SYSTEM** – combination of water purification devices and water system components intended to purify or treat water for drinking purposes.

IV. GENERAL REQUIREMENTS

A. All local manufacturers, importers and distributors, including establishments that repackage and re-label water purification equipment, and devices including household water filters and water purifiers shall apply for Certificate of Product Registration to the Department of Health through the Bureau of Health Devices and Technology that fall under any of the following conditions:

1. Water purification devices and water purification system that are already in the market prior to the publication of this guideline.

2. When introducing a device or a system into commercial distribution for the first time.

3. When proposing an additional use for the device that is already in the market. Additional use is indicated in the new label/labeling of the device.

4. When there is a change or modification of a device or a system the manufacturer already markets, if that change could significantly affect its safety or effectiveness.

B. The following shall be exempted from registration requirements:

1. Manufacturers that sell unfinished devices to another firm for further processing, including components to be used in the assembling of devices by other firms. However, if the components are to be sold directly to end users as replacement parts, the manufacturer of such components shall apply for a CPR.

2. Manufacturers of water purification devices that are not being marketed or commercially distributed in the Philippines.

3. Distributors of locally manufactured water purification devices that have already been issued a BHDT CPR for their product.

4. Importers of water purification devices whose foreign manufacturer or his representative in the Philippines has already been issued a BHDT Certificate of Product Registration.

V. POLICIES AND PROCEDURE FOR CERTIFICATE OF PRODUCT REGISTRATION

A. Documentary Requirements

1. Properly filled-up application form

2. Copy of DTI Certificate of Registration/ SEC Articles of Incorporation (to present original)

3. Copy of Mayor's Permit (to present original)

4. Copy of the Operational Manual (to present the original copy)

5. Layout of Devices

6. Result of Analysis (ROA) of the Device/Product Water done by a Laboratory accredited by Department of Health (DOH) for all claims listed in the label and manual

B. Specific Procedures

1. Applicant shall submit properly filled up application form per device/system to HRDRD Secretariat.

2. The Secretariat shall receive and indicate the time and date the documents were received.

3. The Secretariat shall issue the Order of Payment for the application fee. The applicant goes to the Cashier Section, DOH for payment, then submits photocopy of the receipt to the Secretariat for further processing of the application.

4. The Secretariat forwards the documents to the BHDT-HRDRD evaluator for review. If there are no deficiencies an ocular inspection shall be undertaken. He/She then, shall submit a report to the HRDRD Division Chief, who shall recommend approval/disapproval of the application

   4.1 The product water which shall be used for drinking purposes shall pass the Philippine National Standards for Drinking Water and other applicable standards, if applicable.
   4.2 Completeness of documents and Results of Laboratory Analysis (ROLA) will be the basis of the CPR issuance.
   4.3 Applicants whose documents have deficiencies shall be notified and shall be given one-month abeyance period to correct the deficiencies; otherwise, the application shall be discarded and destroyed.
   4.4 Issued CPR shall not be used for advertisement purposes by the manufacturer, distributor and importer of the device.
   4.5 A failed ROLA will be a major ground for non-issuance of the CPR.

C. Validity/Expiration

The Certificate of Product Registration to be issued by the BHDT Director shall be valid for three (3) years from the date of issuance.

D. Fees And Charges

All fees shall be payable to the Department of Health in accordance with the following schedule

1. One Thousand Pesos (PHP 1,000.00) per system

2. Five Hundred Pesos (PHP 500.00) per device

3. Fees and charges are subject to change as may be deemed necessary

E. Renewal Of Certificate Of Product Registration

1. Filing for renewal of Certificate of Product Registration shall be made at least two (2) months before the expiration date.

2. A penalty of fifty percent (50%) of the registration fee shall be paid by the applicant for late renewal of CPR.

F. Grounds For Disapproval/Revocation Of CPR

The following shall be grounds for disapproval/revocation of CPR.

1. Material misrepresentation or concealment of significant data or information about the product sought for certification.

2. Submission of falsified documents by the applicant.

3. Failure of device after monitoring.

G. Investigation Of Charges And Complaints

1. The Health Related Devices Regulation Division (HRDRD) of BHDT shall recommend imposition of sanctions. The decision shall be issued by the BHDT Director

2. The party affected by the decision may file a motion for reconsideration with the Office of the Secretary of Health within fifteen (15) days from receipt thereof. The BHDT shall issue the appropriate order therefore.

3. The aggrieved party may appeal the decision on its original appeal within fifteen (15) days from receipt thereof to the Secretary of Health. The decision of the Secretary of Health shall be final and executory.

VI. REPEALING CLAUSE

All administrative orders, rules and regulations and administrative issuances or parts thereof inconsistent with the provisions of this guideline are hereby repealed or amended accordingly.

VII. EFFECTIVITY

This order shall take effect fifteen (15) days after its publication in an official gazette or in a newspaper of general circulation.

MANUEL M. DAYRIT, M.D.
Secretary of Health