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AMENDMENT TO ADMINISTRATIVE ORDER NO. 2005-0003 DATED JANUARY 11, 2005, RE: GUIDELINES ON THE ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION FOR WATER PURIFICATION EQUIPMENT AN...

DOH ADMINISTRATIVE ORDER NO. 2005-0003-A, June 06, 2005

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Administrative Order No. 2005-0003 dated January 11, 2005 is hereby amended with the following changes:

1. Section II - Scope/Coverage

> From: 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.

> To: These guidelines shall apply to local and foreign 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. Further, these guidelines shall also cover companies or individuals that sell water purification system for water refilling station, household, food establishment, institution and office use.

2. Section III - DEFINITION OF TERMS

> From: 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.

> 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 identity, components, attributes, directions for use, specifications and such other information as may be required by law or regulations.

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

> To: APPLICANT - refers to a local or foreign establishment including individuals that seek to include its water purification devices and water purification system for water refilling station, household, food establishment,

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institution and office use in the BHDT list of registered devices.

LABELING - display of written, 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 identify components attributes, directions for use, specifications and such other information as may be required by law or regulations.

WATER PURIFICATION SYSTEM - combination of water purification devices and water system components intended to purify or treat water for drinking purposes for water refilling station, household, food establishment, institution and office use.

3. Section V - A.6. POLICIES AND PROCEDURES FOR CERTIFICATE OF PRODUCT REGISTRATION - Documentary Requirements

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

To: Result of Laboratory Analysis (ROLA) of the Device/Product Water done by Department of Health (DOH) laboratory or National Reference Laboratory for Environmental and Occupational Health Toxicology and Micronutrient Assay - East Avenue Medical Center (NRL-EAMC) for all claims listed in the label and manual. In case NRL-EAMC cannot perform the laboratory analysis due to unavoidable circumstances, BHDT may allow DOH-accredited laboratories to conduct the said test according to the standard method adopted or prescribed by the DOH/NRL-EAMC

4. Section V - A. POLICIES AND PROCEDURES FOR CERTIFICATE OF PRODUCT REGISTRATION - Documentary Requirements

In addition thereto, the following documents shall be submitted by the applicant to BHDT for evaluation prior to the issuance of CPR.

7. List of raw materials used as components of the water purification device
8. Label/labeling/product insert or manufacturer's performance claim.
9. Data from scientific research and laboratory analysis supporting and proving the claims of the manufacturer of the product.

5. Section V - B.1 POLICIES AND PROCEDURES FOR CERTIFICATE OF PRODUCT REGISTRATION - Specific Procedures

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

To: Applicant shall submit properly filled up application form and all other requirements to HRDRD Secretariat. All information must be submitted in English. When material is not originally in English, an

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authenticated translation shall be submitted. BHDT may request the original material at any time.

All other provisions of Administrative Order No. 2005-0003 as amended which are not inconsistent with the foregoing shall remain valid and in effect.

This order shall take effect immediately.

Adopted: 6 June 2005

(SGD.) FRANCISCO T. DUQUE III, MD, MSc.
Secretary of Health

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