

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



2 9 MAY 2019

FDA ADVISORY No. 2019-132

TO:

THE GENERAL PUBLIC

SUBJECT:

Public Health Warning Against the Purchase and Use of Unregistered Health Related Devices advertised for sale in Lazada.com.ph:

- 1. High Quality 3 in 1 Alkaline Water Purifier Complete Set
- 2. Central Nanyang 5-Stage Reverse Osmosis Water Filtration System Ultra Safe with Tank and Pump
- 3. Global 3 in 1 Water Purifier
- 4. Netwire Direct Alkaline Water Purifier with Ultraviolet Lamp
- 5. Semter Sink Alkaline Water Purifier
- 6. Premium 5 Stage Under Sink Water Filter System Drinking Home RO Membrane Purifier

The Food and Drug Administration (FDA) advises the general public against the purchase and use of the following unregistered health related device products.



Figure 1. High Quality 3 in 1 Alkaline Water Purifier Complete Set







Figure 2. Central Nanyang 5-Stage Reverse Osmosis Water Filtration System Ultra Safe with Tank and Pump



Figure 3. Global 3 in 1 Water Purifier



Figure 4. Netwire Direct Alkaline Water Purifier with Ultraviolet Lamp

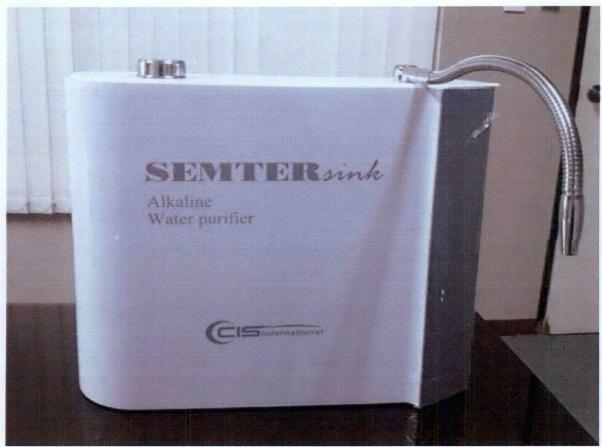


Figure 5. Semter Sink Alkaline Water Purifier



Figure 6. Premium 5 Stage Under Sink Water Filter Drinking Home RO Membrane Purifier

FDA post-marketing surveillance (PMS) activities have verified that the abovementioned health related device products have not gone through the registration process of the agency and have not been issued with the proper authorization in the form of Certificate of Health Related Device Registration (CHRDR). Pursuant to Republic Act No. 9711, otherwise known as the "Food and Drug Administration Act of 2009", the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising or sponsorship of health products without the proper authorization from FDA is prohibited.

Accordingly, since this unregistered health related device products have not gone through evaluation and testing process of the FDA, the agency cannot guarantee its quality and safety. The consumption of such violative product may pose potential health hazards to the consuming public. Health related device products especially water purification device/ system shall not bear any false, deceptive and misleading claims and promotional ploys on alkaline water, oxygenated water or ionized water (Please see FDA Advisory Nos. 2014-010-A, 2014-010 and 2011-013).

In light of the above, the public is advised not to purchase the aforementioned violative products. Moreover, the public is advised to be vigilant against health related device products that might not be duly registered with FDA. Always check if a health related device product has been registered with FDA before purchasing it by making use of the embedded *Search* feature of the FDA website accessible at www.fda.gov.ph.

All concerned establishments are warned not to distribute the above-identified violative health related device product until it has already been covered by the appropriate authorization, otherwise, regulatory actions and sanctions shall be strictly pursued.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that this product is not sold or made available in localities or areas or jurisdiction.

For more information and inquiries, please e-mail us at info@fda.gov.ph. To report continuous sale or distribution of the above unregistered health related device product, utilize our online reporting facility, eReport, at www.fda.gov.ph/ereport, or email us via report@fda.gov.ph, or call us at the Center for Device Regulation, Radiation Health, and Research (CDRRHR) hotline (02) 857-1900 local 8301.

Dissemination of the information to all concerned is requested.

ROLANDO ENRIQUE D. DOMINGO, MD, DPBO

Undersecretary of Health
Officer-In-Charge, Director General

DTN: 20190328134528