Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2021-0683

29 MAR 2021

TO: **THE GENERAL PUBLIC**

SUBJECT: **Public Health Warning Against the Purchase and Use of the following Unregistered Health-Related Device Products**

- **MEGAFRESH ALKALINE WATER PURIFIER (NFS 3 ALKALINE)**
- **MEGAFRESH ALKALINE WATER FILTER (FA BIO ALK)**
- **MEGAFRESH ALKALINE WATER FILTER (D250 ALK GBS)**
- **MEGAFRESH ALKALINE WATER FILTER (D250 ABGB**

The Food and Drug Administration (FDA) warns the general public **NOT TO PURCHASE AND USE** the unregistered health-related device products:

Figure 1. Unregistered Megafresh Alkaline Water Purifier (NFS 3Alkaline)

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TÜVRheinland CERTIFIED
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Figure 2. Unregistered Megafresh Alkaline Water Filter (FA BIO ALK)

Figure 3 Unregistered Megafresh Alkaline Water Filter (D250 ALK GBS)

Figure 4 Unregistered Megafresh Alkaline Water Filter (D250 ABGB)

The FDA verified through post-marketing surveillance that the above mentioned health-related device products are unregistered and no corresponding product registration certificates have been issued. Pursuant to the 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 is prohibited.

Since these unregistered health-related device products have not gone through evaluation process of the FDA, the agency cannot assure 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).

All concerned establishments are warned not to distribute, advertise, or sell the said violative medical device product until the product registration certificate is issued, otherwise, regulatory actions and sanctions shall be strictly pursued. Always check if a product has been registered with the FDA before purchasing it by making use of the embedded Search feature of the FDA website accessible at www.fda.gov.ph.

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

The Bureau of Customs is urged to restrain the entry of this unregistered product.

For more information and inquiries about this advisory, kindly contact the FDA CDRRHR through e-mail at **cdrrhr@fda.gov.ph** indicating on the subject the concerned Advisory, or call **(02) 8857-1900 loc. 8301.**

To report any sale or distribution of unregistered health-related device, the online reporting facility, **eReport** can be accessed at **www.fda.gov.ph/ereport**.

Dissemination of this advisory to all concerned is hereby requested.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

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