Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

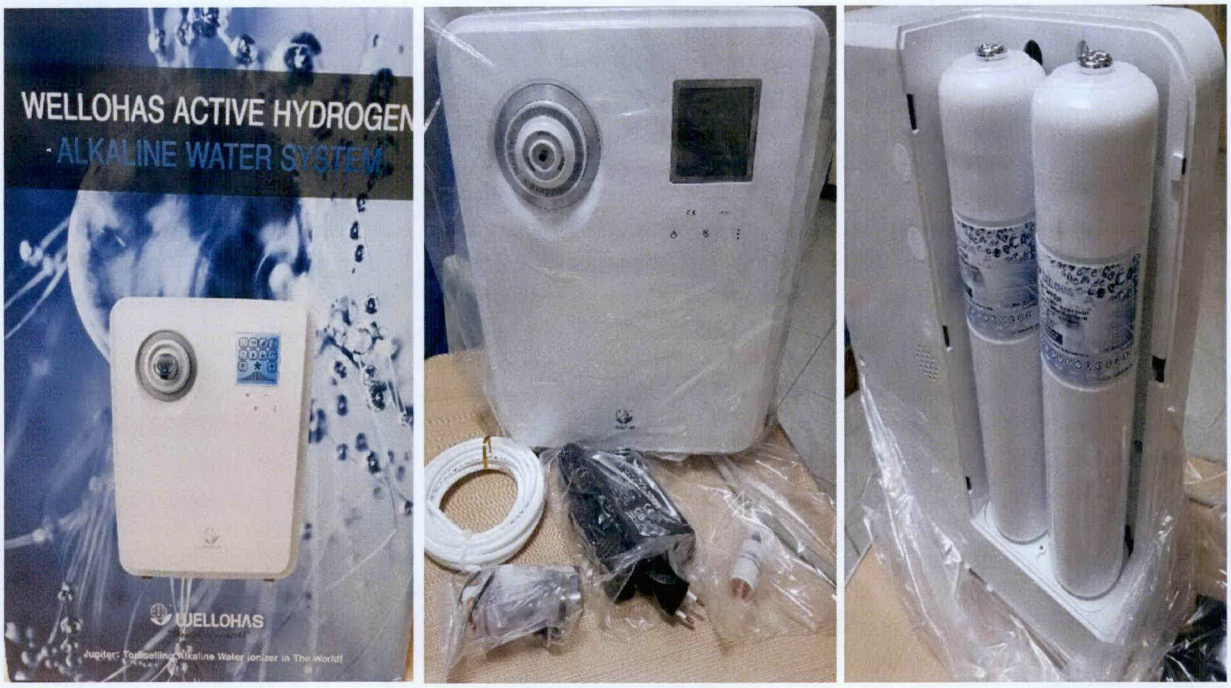
FDA ADVISORY
No. 2019-115

30 APR 2019

TO: **THE GENERAL PUBLIC**

SUBJECT: **Public Health Warning Against the Purchase and Use of Unregistered Health Related Device (Water Purification Device) "Wellohas Active Hydrogen Alkaline Water System"**

The Food and Drug Administration (FDA) advises the public against the purchase and use of the unregistered health related device Wellohas Active Hydrogen Alkaline Water System:



FDA post-marketing surveillance (PMS) activities have verified that the abovementioned health related device has not gone through the registration process of the agency and has not been issued the proper authorization in the form of Certificate of Health Related Device Registration (CHRDR). Pursuant to Republic Act 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 has 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. Water purification device/system should not bear any false, deceptive and misleading claims and promotional ploys on alkaline water, oxygenated water or ionized water.

Furthermore, the FDA has already issued two advisory (FDA Advisory Numbers 2011-013 and 2014-010) warning the general public against false, deceptive and misleading non-certified therapeutic claims and promotional ploys of water purification devices producing water labeled as alkaline, ionized, pi, oxygenated or energized water.

In light of the above, the public is advised not to purchase the aforementioned violative product and to be vigilant against health related device that might not be duly registered with FDA. Always check if a health related device 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 concerned establishments and/or entities are warned not to distribute the above-identified violative health related device 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 their localities or areas of 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, utilize our online reporting facility, **eReport**, at **www.fda.gov.ph/ereport**, or e-mail 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.**

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Director General

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