



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



24 JUL 2017

FDA ADVISORY
No. **2017-212**

TO: THE GENERAL PUBLIC

SUBJECT: Public Health Warning Against the Purchase and Use of Unregistered Health Related Device (Water Purification Device) "Biocera Alkaline Antioxidant Stick"

The Food and Drug Administration (FDA) advises the public against the purchase and use of the unregistered health related device product Biocera Alkaline Antioxidant Stick:

Change your water, Change your life!

BIOCERA
Alkaline Antioxidant Stick
바이오세라 알칼리 환원스틱

NSF
Water Filtration
NSF International
Standard 42

Biocera Alkaline Stick has
removes bad taste and odor,
reduces lead and chlorine,
and is the first
line of defense against
the health and taste quality.

NSF
Water Filtration
NSF International
Standard 42

Change your water, Change your life!

BIOCERA
Alkaline Antioxidant Stick

CHANGE YOUR WATER
CHANGE YOUR LIFE
BIOCERA
ALKALINE ANTIOXIDANT STICK SET

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Website: www.fda.gov.ph

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FDA post-marketing surveillance (PMS) activities have verified that the abovementioned health related device have not gone through the registration process of the agency and have 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 unregistered health related device products have not gone through evaluation and testing process of the FDA, the agency cannot guarantee their quality and safety. The consumption of such violative products may pose potential health hazards to the consuming public. Health related device products especially water purification device/system should not bear any false, deceptive and misleading claims and promotional ploys on alkaline water, oxygenated water or ionized water.

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 have already been covered by the appropriate authorization (product registration), 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 product, 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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