



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY

No. 2018-130

06 APR 2018

TO: THE GENERAL PUBLIC AND ALL HEALTHCARE CONCERNED PROFESSIONALS

SUBJECT: PUBLIC HEALTH WARNING AGAINST THE PURCHASE AND USE OF THE UNREGISTERED MEDICAL DEVICE PRODUCT "SURE-GUARD PREGNANCY TEST KIT"

The Food and Drug Administration (FDA) advises the general public and all healthcare professionals against the purchase and use of the unregistered medical Sure-Guard Pregnancy Test Kit:



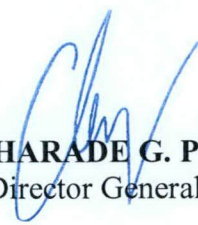
Food and Drug Administration (FDA) post-marketing surveillance (PMS) activities have verified that the abovementioned medical device product has expired Certificate of Product Registration (CPR) and there is no pending application for renewal. Pursuant to Republic Act 9711, otherwise known as the "Food 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.



In light of the above, the public is advised not to purchase the aforementioned violative product and to be vigilant against medical device that might not be duly registered with FDA. Always check if a medical 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 medical device until it has already been covered by the appropriate authorization, otherwise, regulatory actions and sanctions shall be strictly pursued.

For more information and inquiries, please e-mail us at info@fda.gov.ph. To report continuous sale or distribution of the above unregistered medical 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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