



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY

No. 2018-121

02 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 PRODUCTS (SURE-GUARD DISPOSABLE VINYL GLOVES AND SURE-GUARD DISPOSABLE NITRILE GLOVES)

The Food and Drug Administration (FDA) advises the general public and all healthcare professionals against the purchase and use of the unregistered medical devices Sure-Guard Disposable Vinyl Gloves and Sure-Guard Disposable Nitrile Gloves:



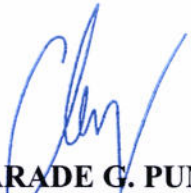
FDA post-marketing surveillance (PMS) activities have verified that the abovementioned medical devices have not gone through the registration process of the agency and have not been issued with proper authorization in the form of Certificate of Product Registration (CPR). Pursuant to Republic Act 9711, 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 these unregistered medical devices have not gone through evaluation and testing process of the FDA, the agency cannot guarantee its quality and safety. The consumption of such violative products may pose potential health hazards to the consuming public.

In light of the above, the public is advised not to purchase the aforementioned violative products 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 devices until such have 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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