Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

29 AUG 2018

FDA ADVISORY
No. 2018-269

TO: **THE GENERAL PUBLIC AND ALL HEALTHCARE CONCERNED PROFESSIONALS**

SUBJECT: **Public Health Warning Against the Purchase and Use of Unregistered Medical Devices "Durex KY Jelly".**

The Food and Drug Administration (FDA) advises all concerned healthcare professionals, establishment and general consuming public against the purchase and use of **Durex KY Jelly** whose pictures appear below.

FDA post-marketing surveillance (PMS) activities have verified that the abovementioned medical device product has not gone through the registration process of the agency and has not been issued with proper authorization in the form of Certificate of Product Registration. Pursuant to the provision of 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 any health product that is adulterated, unregistered or misbranded are prohibited.**

The abovementioned product did not undergo the evaluation process of the FDA. Thus, the agency cannot guarantee its quality and safety.

In this regard, the public is hereby advised not to purchase the above-mentioned violative product and to be vigilant against the medical device products that are not registered with FDA.

Distributors, retailers, hospitals and all healthcare professionals / users are advised to discontinue further distribution, sale and use of the said medical device product.

For more information and inquiries, please e-mail us at cdrrhr_prsdd@fda.gov.ph or call us at the Center for Device Regulation, Radiation Health and Research (CDRRHR) hotline (02) 857-1900 local 8301.

Dissemination of the information to all concerned is requested.

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Director General

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