

## Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. 2022-1091

MAY 2 4 2022

TO

ALL HEALTHCARE PROFESSIONALS AND THE

**GENERAL PUBLIC** 

SUBJECT:

Public Health Warning Against the Purchase and Use of the

Unregistered Drug Product KarLee Tetracycline 15 g

**Ointment** 

The Food and Drug Administration (FDA) advises the public against the purchase and use of the unregistered drug product:



Figure 1. Unregistered drug product

FDA Post-Marketing Surveillance (PMS) activities have verified that the abovementioned drug 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. Thus, the Agency cannot guarantee their quality, safety and efficacy. Therefore, consumption of such violative product may pose potential danger or injury to health.



Pursuant to 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, promotion, advertising, or sponsorship of health product without proper authorization from FDA is prohibited.

All concerned establishments and/or entities are warned not to distribute the above-identified violative drug product until they have already been covered by the appropriate authorization, otherwise, regulatory actions and sanctions shall be strictly pursued. Always check if the product is registered with the FDA by using the FDA Verification Portal feature accessible at https://verification.fda.gov.ph.

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 <a href="mailto:info@fda.gov.ph">info@fda.gov.ph</a>. To report continuous sale or distribution of unregistered health product, kindly e-mail us via <a href="mailto:ereport@fda.gov.ph">ereport@fda.gov.ph</a>. You may also call the Center for Drug Regulation and Research at telephone number (02) 8809-5596. For any suspected adverse drug reaction (ADR), report immediately to FDA through this link: <a href="mailto:https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH">https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH</a> and fill out all the required fields.

Dissemination of the information to all concerned is requested.

DR. OSCAR G/GUTIERREZ, JR. Officer-in-Charge Director/General

DTN:

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