

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. __2022-1525

D 1 SEP 2022

TO

ALL HEALTHCARE PROFESSIONALS AND THE GENERAL

PUBLIC

SUBJECT:

Public Health Warning Against the Purchase and Use of the

Following Unregistered Drug Products:

1. Polar Bear Brand Essential Embrocation 27 mL

2. Eagle Brand Medicated Oil 24ml

3. Ketoconazole + Clobetasol Propionate Cream SF PKW Cream 10 Grams

4. Triamcinolone Acetonide Acetate + Miconazole Nitrate + Neomycin Sulfate Cream SF PKS Cream 10 Grams

5. Conc. Piyenchin Naphzoline HCl Solution 1:1000 10 ml.

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



Figure 1. Unregistered drug product



Manufactured by: Nantong Zhongbao Pharmaceutical Co., Ltd.

Imported & Distributed by: Tekson Marketing 940-A Benavidez st. Brgy 295, Binondo Manila



Figure 2. Unregistered drug product

Sole Distributor: DKSH Hong Kong LTD

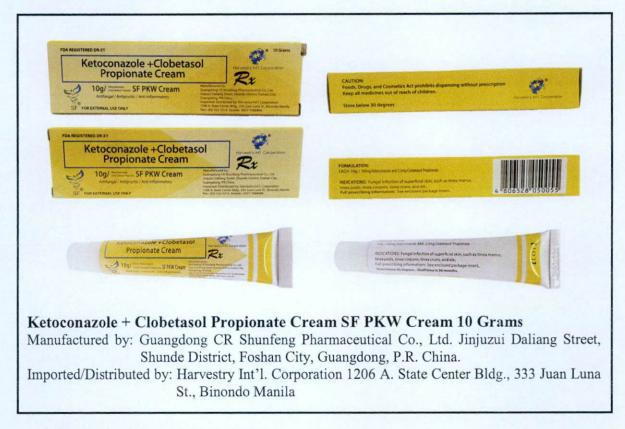


Figure 3. Unregistered drug product



Triamcinolone Acetonide Acetate + Miconazole Nitrate + Neomycin Sulfate Cream 10 Grams Manufactured by: Guangdong CR Shunfeng Pharmaceutical Co., Ltd. Jinjuzui Daliang Street, Shunde District, Foshan City, Guangdong, P.R. China.

Imported/Distributed by: Harvestry Int'l. Corporation 1206 A. State Center Bldg., 333 Juan Luna St., Binondo Manila

Figure 4. Unregistered drug product



Figure 5. Unregistered drug product

FDA Post-Marketing Surveillance (PMS) activities have verified that the abovementioned drug products 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. Thus, the Agency cannot guarantee their quality, safety and efficacy. Therefore, consumption of such violative products 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 products without proper authorization from FDA is prohibited.

All concerned establishments and/or entities are warned not to distribute the above-identified violative drug products until they have already been covered by the appropriate authorization, otherwise, regulatory actions and sanctions shall be strictly pursued. Always check if the products are 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 these products are 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 unregistered health products, kindly e-mail us via ereport@fda.gov.ph. 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: https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH and fill out all the required fields.

Dissemination of the information to all concerned is requested.

DTN:

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