

Republic of the Philippines Department of Health

FOOD AND DRUG ADMINISTRATION



1 0 MAR 2023

FDA ADVISORY No. 20230408

> ALL HEALTHCARE PROFESSIONALS AND THE GENERAL TO

> > **PUBLIC**

SUBJECT: Public Health Warning Against the Purchase and Use of the

Following Unregistered Drug Products:

1. MSD Quadriderm* Cream 5 g [Label in foreign language]

2. Pharmaton® Capsules with Selenium 100 Capsules

3. Natureplex Triple Antibiotic Original Ointment 0.33 Oz (9.4 g)

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





Pharmaton® Capsules with Selenium 100 Capsules

Manufacturer: SwissCaps AG, Hausentrasse 35 CH-9533 Kirchberg, Switzerland

Distributor (in Singapore): sanofi-aventis Singapore Pte. Ltd. - 38 Beach Road #18-11, South Beach Tower, Singapore 189767

Trader (in Singapore): Sanofi-aventis Singapore Pte. Ltd. - 38 Beach Road #18-11, South Beach Tower, Singapore 189767

Packed by: Soho Flordis International Switzerland SA, Via Mulini 6934 Bioggio, Switzerland

Product Registration Holder in Malaysia: sanofi-aventis (Malaysia) Sdn Bhd (334110-P), Unit TB-18-1, Level 18, Tower B, Plaza 33, No. 1 Jalan Kemajuan, Seksyen 13, 46200 Petaling Jaya Selangir Darul Ehsan, Malaysia

Figure 2. Unregistered drug product



Figure 3. 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 <u>info@fda.gov.ph</u>. To report continuous sale or distribution of unregistered health products, kindly e-mail us via

<u>ereport@fda.gov.ph</u>. 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.

DR. SAMUEL A. ZACATE
Director General

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