

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. 2020-347

MAR 1 1 2020

TO

ALL HEALTHCARE PROFESSIONALS AND THE

GENERAL PUBLIC

SUBJECT

Public Health Warning Against the Purchase and Use of the

following Unregistered Drug Products:

1. Aural +

2. Optivisum 30ml

3. Aminofitin 50g

4. Cardio trust 250 mg

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





AURAL+

By: Aural+ LLC 225 Franklin Street Boston Massachussetts, 02110

Figure 1. Unregistered drug product



Figure 2. Unregistered drug product





Figure 4. Unregistered drug product

Marketing Surveillance (PMS) activities have verified that the abovementioned drug products have not gone through the registration and testing 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 and safety. 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.

In light of the above, the public is advised not to purchase the aforementioned violative products and to be vigilant against it. Always check if a drug product 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. You may also look for the FDA Registration number on the product label.

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.

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 report@fda.gov.ph, or through the online reporting facility, eReport, at www.fda.gov.ph/ereport. 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.

ROLANDO ENRIQUE D. DOMINGO, MD, DPBO Undersecretary of Health

Officer-in-Charge, Director General

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