



09 JUL 2019

FDA ADVISORY
No. 2019-189

TO : THE GENERAL PUBLIC

SUBJECT : Public Health Warning Against the Purchase and Use of the Unregistered Drug Product: HYSSOP Mineral Drops 15 mL

The Food and Drug Administration (FDA) warns the public from purchasing and using the following unregistered drug product:



Figure 1. **Unregistered Product:**
HYSSOP
Mineral Drops 15 mL



The FDA has verified through post-marketing surveillance that the abovementioned drug product is not registered and the Certificate of Product Registration (CPR) has not been issued. Pursuant to the Republic Act No. 9711, otherwise known as "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 health product without the proper authorization is prohibited.

Since this unregistered drug product has not gone through evaluation process of the FDA, the agency cannot assure its efficacy, quality and safety. The use of this violative product may pose health risk to consumers.

In light of the foregoing, the public is advised not to purchase this violative product. Moreover, the public is advised to always check if a drug product is registered with the FDA. The FDA website (www.fda.gov.ph) has a *Search* feature which may be used by typing in the name of the product before purchasing.

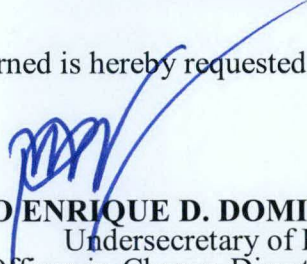
All concerned establishments are warned not to distribute the violative drug product until it has been issued the appropriate authorization, a License to Operate (LTO) for the establishment, and a CPR for the drug product.

All FDA Field Officers and Regulatory Enforcement Unit (REU) in coordination with the law enforcement agencies and Local Government Units (LGUs) are requested to ensure that violative products are not sold or made available in the market or areas of jurisdiction.

The Bureau of Customs is urged to restrict entry of this unregistered product.

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)809-5596**. For any suspected adverse drug reaction (ADR), report immediately to FDA through this link: www.fda.gov.ph/adr-report-new and fill out all the required fields.

Dissemination of this advisory to all concerned is hereby requested.


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