

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



FDA ADVISORY No. 2019-473

11 8 NOV 2019

TO:

THE GENERAL PUBLIC

SUBJECT:

Public Health Warning Against the Purchase and Use of the following Unnotified Cosmetic Products:

- 1. NIVEA® CRÈME SMOOTH BODY WASH SHEA BUTTER
- 2. <u>DR. TEAL'S® PINK HIMALAYAN FOAMING</u>
 BATH
- 3. WHITE BODY ALL SKIN DEEP SEA MUD NATURAL
- 4. <u>MUZ WHITENING PLUS FACIAL SHEET MASK</u> WHITENING + COLLAGEN
- 5. MEDIHEAL W.H.P. WHITE HYDRATING BLACK MASK EX

The Food and Drug Administration (FDA) warns the public from purchasing and using the following unnotified cosmetic products:



Figure 1. Unnotified Nivea® Crème Smooth Body Wash Shea Butter





Figure 2. Unnotified Dr. Teal's® Pink Himalayan Foaming Bath



Figure 3. Unnotified White Body All Skin Deep Sea Mud Natural



Figure 4. Unnotified Muz Whitening Plus Facial Sheet Mask Whitening + Collagen



Figure 5. Unnotified Mediheal W.H.P. White Hydrating Black Mask Ex.

The FDA verified through post-marketing surveillance (PMS) that the abovementioned cosmetic products are not authorized and the Certificates of Product Notification have not been issued. 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, non-consumer use, promotion, advertising or sponsorship of health products without the proper authorization from FDA is prohibited.

Since these unnotified cosmetic products have not gone through evaluation process of the FDA, the agency cannot assure their quality and safety. The use of such violative products may pose health risks to consumers.

Potential hazards may come from ingredients that are not allowed to be part of a cosmetic product as listed in the Annex II, Part I of the ASEAN Cosmetic Directive (ACD). The use of substandard and possibly adulterated cosmetic products may result to adverse reactions, including but not limited to, skin irritation, itchiness, anaphylactic shock, and organ failure.

In light of the foregoing, the public is advised not to purchase the aforementioned violative products. Moreover, the public is advised to always check if a cosmetic product is notified 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 violative cosmetic products until they have been issued the appropriate authorization, a License to Operate (LTO) for the establishment, and a Certificate of Product Notification (CPN) for the cosmetic product.

All FDA Regional Field Offices and Regulatory Enforcement Units, in coordination with Law Enforcement Agencies and Local Government Units, are requested to ensure that violative products are not sold or made available in the market or areas of jurisdiction.

Kindly contact the FDA Center for Cosmetics Regulation and Research through e-mail at ccrr@fda.gov.ph or call (02) 857-1900 local 8113 or 8107.

To report any sale or distribution of unnotified cosmetic products, the online reporting facility, **eReport** can be accessed at **www.fda.gov.ph/ereport**.

Dissemination of this advisory to all concerned is hereby requested.

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

Officer-in-Charge, Director General