



FDA ADVISORY
No. 2019-355

09 OCT 2019

TO: THE GENERAL PUBLIC

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

1. THE RETRO HEALING BENTONITE CLAY SOAP
2. M CALAMANSI SOAP
3. ELITE SKIN INTERNATIONAL KOJIC SOAP
4. 3W CLINIC CHARCOAL SOAP
5. BUMBIME MASK NATURAL SOAP

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



Figure 1. Unnotified The Retro Healing Bentonite Clay Soap





Figure 2. Unnotified M Calamansi Soap



Figure 3. Unnotified Elite Skin International Kojic Soap



Figure 4. Unnotified 3W Clinic Charcoal Soap



Figure 5. Unnotified Bumbime Mask Natural Soap

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 1 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.

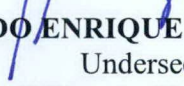
All concerned establishments are warned not to distribute violative cosmetic products until they have been issued the appropriate authorization, a License to Operate (LTO) for the establishment, and a Certificate of Product Notification (CPN) for the cosmetic product.

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 crr@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.


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