



FDA ADVISORY
No. **2019-392**

23 OCT 2019

TO: THE GENERAL PUBLIC

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

- 1. TIFANNY CLAIRE'S CONCEAL INSTANT GRAY HAIR TOUCH-UP SOLUTION (DARK MOCHA BROWN)**
- 2. SALLY HANSEN EXTRA STRENGTH EXTRA FAST NAIL POLISH REMOVER WITH VITAMIN E**
- 3. ANDREA SECRET CAT WINK (3)**
- 4. KAXIER BB EFFECTIVE GENTLE BB CREAM (04)**
- 5. MEIYA HAND AND BODY LOTION PAPAYA WITH SPF 30+ (ME-5081)**

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



Figure 1. Unnotified Tiffany Claire's Conceal Instant Gray Hair Touch-Up Solution (Dark Mocha Brown)





Figure 2. Unnotified Sally Hansen Extra Strength Extra Fast Nail Polish Remover with Vitamin E



Figure 3. Unnotified Andrea Secret Cat Wink (3)



Figure 4. Unnotified Kaxier BB Effective Gentle BB Cream (04)



Figure 5. Unnotified Meiya Hand and Body Lotion Papaya with SPF 30+ (ME-5081)

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), and from the contamination of heavy metals such as Mercury (Hg), Lead (Pb) and Antimony (Sb) especially in eye and face cosmetic products. Antimony (Sb) exposure can result to damages to the lung, heart muscle and liver. Symptoms of antimony toxicity includes skin irritation, headache, nausea, vomiting, insomnia and abdominal pain among others. Lead (Pb) exposure may cause anaemia, hypertension, renal impairment, immunotoxicity and toxicity to the reproductive organs. Mercury salts in cosmetic products inhibits the formation of skin melanin which will result to lighter skin tone. Adverse health effects brought about by highly toxic mercury in cosmetics products include kidney damage, skin rashes, skin discoloration and scarring. Chronic use reduces the skin's normal resistance against bacterial and fungal infections. Other effects include anxiety, depression or psychosis and peripheral neuropathy. The transfer of mercury to fetuses of pregnant women may manifest as neurodevelopment deficits later in life.

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.

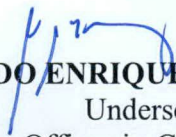
All concerned establishments are warned not to distribute violative cosmetic products until they have been issued the appropriate authorization, a License to Operate (LTO) for the establishment, and a Certificate of Product Notification (CPN) for the cosmetic product.

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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