



**FDA ADVISORY**  
No. **2019-346**

09 OCT 2019

**TO: THE GENERAL PUBLIC**

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

- SUNBRIGHT SERIES KERATIN & COLLAGEN HAIR COLOR 9.91 (SILVER ASH)**
- ELLIPS™ VITAMIN HAIR MASK NUTRI COLOR WITH TRIPLE CARE**
- SOFTSOAP® SOOTHING ALOEVERA MOISTURIZING HAND SOAP**
- ENZO PROFESSIONAL HAIR CARE HAIR SERUM KERATIN**
- ROUSHUN KERATIN & COLLAGEN CARE HAIR MASK STRONG REPAIR & NOURISH HAIR**

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



Figure 1. Unnotified Sunbright Series Keratin & Collagen Hair Color 9.91 (Silver Ash)







Figure 2. Unnotified Ellips™ Vitamin Hair Mask Nutri Color with Triple Care



Figure 3 Unnotified Softsoap® Soothing Aloe Vera Moisturizing Hand Soap



Figure 4. Unnotified Enzo Professional Hair Care Hair Serum Keratin



Figure 5. Unnotified Roushun Keratin & Collagen Care Hair Mask Strong Repair & Nourish Hair



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), like hair-smoothing products containing formaldehyde. Formaldehyde have been associated with reactions such as eye problems, nervous system problems (headaches, and dizziness), respiratory tract problems, nausea, chest pain, vomiting and rash. Skin sensitivity can develop after repeated contact with formaldehyde-related ingredients.

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](http://www.fda.gov.ph)) has a *Search* feature which may be used by typing in the name of the product before purchasing.

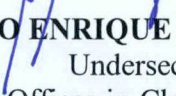
All concerned establishments are warned not to distribute violative cosmetic products until they have been issued the appropriate authorization, a License to Operate (LTO) for the establishment, and a Certificate of Product Notification (CPN) for the cosmetic product.

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](mailto: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](http://www.fda.gov.ph/ereport).

Dissemination of this advisory to all concerned is hereby requested.

  
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