



04 APR 2017

FDA ADVISORY
No. **2017-130**

TO: GENERAL CONSUMING PUBLIC

SUBJECT: Public Health Warning Against the Use of Unnotified Cosmetic Products (Batch 35)

The Food and Drug Administration (FDA) advises the public against the purchase and use of the following unnotified cosmetic products whose particulars/details are provided in the attached annex:

1. **BN WHITENING SHOPPE EXTREME WHITENING FACE AND BODY SOAP**
2. **BN WHITENING SHOPPE ULTRA WHITE TONER**
3. **BN WHITENING SHOPPE FACIAL SCRUB**
4. **BN WHITENING SHOPPE EXTREME WHITENING LOTION SPF 40**
5. **TAILAIME LIP GLOSS #07**
6. **TAILAIME LIP GLOSS #22**
7. **MELS COSMETICS LIP GLOSS 01**
8. **MELS COSMETICS LIP GLOSS 02**
9. **MELS COSMETICS LIP GLOSS 04**
10. **MELS COSMETICS LIP GLOSS 10**
11. **MELS COSMETICS LIP GLOSS 12**
12. **ELLEFAR PRINCESS NUDY LIP – PEACH 57**
13. **OCEAN POTION® PROTECT & NOURISH ENRICHED WITH SEA PLANT BOTANICALS™ SPF 50 SUN PROTECTION LOTION – SCENT OF SUMMER**
14. **CASINO EAU COIFFANTE ANTI-EPIS SPRAY**
15. **BEAUTY SECRET 4 RADISH SOAP**

FDA post-marketing surveillance (PMS) activities have verified that the abovementioned cosmetic products have not gone through the verification process of the agency and have not been issued the proper authorization in the form of acknowledged cosmetic notifications. 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.

Accordingly, because unnotified cosmetic products have not gone through the verification process of the FDA, the agency cannot guarantee their quality and safety. The use of such violative products may pose potential health hazards to the consuming public. Potential hazards may come from ingredients that are not allowed to be part of a cosmetic product or from the contamination of heavy metals such as mercury especially in whitening cosmetic products. 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 above, the public is advised not to purchase the aforementioned violative products. Moreover, the public is also advised to be vigilant against cosmetic products that might not be duly notified with FDA. Always check if a cosmetic product has been notified with FDA before purchasing it by making use of the embedded *Search* feature of the FDA website accessible at www.fda.gov.ph.

All concerned establishments are warned not to distribute the above-identified violative cosmetic products until they have already been covered by the appropriate authorization (cosmetic notification), otherwise, regulatory actions and sanctions shall be strictly pursued.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that these products are not sold or made available in their localities or areas of jurisdiction.

For more information and inquiries, please e-mail us at info@fda.gov.ph. To report continuous sale or distribution of the above unnotified cosmetic products, utilize our online reporting facility, **eReport**, at www.fda.gov.ph/ereport, or e-mail us via report@fda.gov.ph, or call us at the Center for Cosmetics Regulation and Research (CCRR) hotline (02) 857-1979 or (02) 857-1984.

Dissemination of the information to all concerned is requested.


NELA CHARADE G. PUNO, RPh
Director General

DTN 20170320152722



ANNEX
 Details on the Unnotified Cosmetic Products

PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
1 BN WHITENING SHOPPE EXTREME WHITENING FACE AND BODY SOAP	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Not Indicated	
2 BN WHITENING SHOPPE ULTRA WHITE TONER	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Not Indicated	
3 BN WHITENING SHOPPE FACIAL SCRUB	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Not Indicated	
4 BN WHITENING SHOPPE EXTREME WHITENING LOTION SPF 40	Local Company Responsible for Placing the Product in the Market: Patricia Bianca Beauty Solutions Address: Not Indicated Country of Manufacture: Not Indicated	
5 TAILAIME LIP GLOSS #07	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Not Indicated	

PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
6 TAILAIME LIP GLOSS #22	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Not Indicated	
7 MELS COSMETICS LIP GLOSS 01	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Not Indicated	
8 MELS COSMETICS LIP GLOSS 02	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Not Indicated	
9 MELS COSMETICS LIP GLOSS 04	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Not Indicated	
10 MELS COSMETICS LIP GLOSS 10	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Not Indicated	

PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
<p>11 MELS COSMETICS LIP GLOSS 12</p>	<p>Local Company Responsible for Placing the Product in the Market: Not Indicated</p> <p>Address: Not Indicated</p> <p>Country of Manufacture: Not Indicated</p>	
<p>12 ELLEFAR PRINCESS NUDY LIP – PEACH 57</p>	<p>Local Company Responsible for Placing the Product in the Market: Not Indicated</p> <p>Address: Not Indicated</p> <p>Country of Manufacture: China</p>	
<p>13 OCEAN POTION® PROTECT & NOURISH ENRICHED WITH SEA PLANT BOTANICALS™ SPF 50 SUN PROTECTION LOTION – SCENT OF SUMMER</p>	<p>Local Company Responsible for Placing the Product in the Market: RPG Distribution Services, Inc.</p> <p>Address: #898 M. Eusebio Avenue Brgy. San Miguel Pasig City 1600</p> <p>Country of Manufacture: United States of America (U.S.A.)</p>	
<p>14 CASINO EAU COIFFANTE ANTI- EPIS SPRAY</p>	<p>Local Company Responsible for Placing the Product in the Market: Not Indicated</p> <p>Address: Not Indicated</p> <p>Country of Manufacture: Not Indicated</p>	
<p>15 BEAUTY SECRET 4 RADISH SOAP</p>	<p>Local Company Responsible for Placing the Product in the Market: Not Indicated</p> <p>Address: Not Indicated</p> <p>Country of Manufacture: Thailand</p>	