



31 MAY 2017

FDA ADVISORY
No. **2017-144**

TO: GENERAL CONSUMING PUBLIC

SUBJECT: Public Health Warning Against the Use of Unnotified Cosmetic Products (Batch 38)

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. **COLLAGEN SOAP BY ELLEN'S – WHITE / WHITE COLLAGEN SOAP**
2. **BLEACHING & WHITENING SOAP BY ELLEN'S - GREEN**
3. **ACNE & WHITENING SOAP BY ELLEN'S – YELLOW / YELLOW WHITENING SOAP**
4. **ELLEN'S OIL CONTROL PRESSED POWDER**
5. **ELLEN'S DAY CREAM**
6. **ELLEN'S NIGHT CREAM**
7. **ELLEN'S ADVANCE WHITE DAY CREAM**
8. **FOREVER YOUNG SERUM BY ELLEN'S**
9. **REVERSE AGE EMULSION BY ELLEN'S**
10. **ELLEN'S MIRACLE WHITENING LOTION**
11. **ELLEN'S WHITENING TONER**
12. **ELLEN'S PIMPLE SOLUTION**
13. **7SCENTS BEAUTY COMPANY LTD. ARBUTIN SKIN BRIGHT SCRUB WITH COLLAGEN**
14. **7SCENTS BEAUTY COMPANY LTD. ARBUTIN LOTION POWERFUL SKIN WHITENER**
15. **7SCENTS BEAUTY COMPANY LTD. AHA ALPHA ARBUTIN SOAP POWERFUL SKIN WHITENER**

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 20170404151848



ANNEX
Details on the Unnotified Cosmetic Products

1	PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
	COLLAGEN SOAP BY ELLEN'S – WHITE / WHITE COLLAGEN SOAP	<p>Local Company Responsible for Placing the Product in the Market: Bio Soap Industries, Inc.</p> <p>Address: 143 Old Tabang Road, Tabang, Guiguinto Bulacan, Philippines</p> <p>Country of Manufacture: Philippines</p>	
	BLEACHING & WHITENING SOAP BY ELLEN'S - GREEN	<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>	
	ACNE & WHITENING SOAP BY ELLEN'S – YELLOW / YELLOW WHITENING SOAP	<p>Local Company Responsible for Placing the Product in the Market: Bio Soap Industries, Inc.</p> <p>Address: 143 Old Tabang Road, Tabang, Guiguinto Bulacan, Philippines</p> <p>Country of Manufacture: Philippines</p>	
	ELLEN'S OIL CONTROL PRESSED POWDER	<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>	
	ELLEN'S DAY CREAM	<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>	

6	PRODUCT NAME ELLEN'S NIGHT CREAM	PRODUCT DETAILS	PRODUCT IMAGE/S
		Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Not Indicated	
7	ELLEN'S ADVANCE WHITE DAY CREAM	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Not Indicated	
8	FOREVER YOUNG SERUM BY ELLEN'S	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Switzerland	
9	REVERSE AGE EMULSION BY ELLEN'S	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: France	
10	ELLEN'S MIRACLE WHITENING LOTION	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 ELLEN'S WHITENING TONER</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 ELLEN'S PIMPLE SOLUTION</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>13 7SCENTS BEAUTY COMPANY LTD. ARBUTIN SKIN BRIGHT SCRUB WITH COLLAGEN</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>14 7SCENTS BEAUTY COMPANY LTD. ARBUTIN LOTION POWERFUL SKIN WHITENER</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 7SCENTS BEAUTY COMPANY LTD. AHA ALPHA ARBUTIN SOAP POWERFUL SKIN WHITENER</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>	