

## Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



3 1 MAY 2017

FDA ADVISORY 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 <a href="mailto:info@fda.gov.ph">info@fda.gov.ph</a>. To report continuous sale or distribution of the above unnotified cosmetic products, utilize our online reporting facility, eReport, at <a href="https://www.fda.gov.ph/ereport">www.fda.gov.ph/ereport</a>, or e-mail us via <a href="mailto:report@fda.gov.ph">report@fda.gov.ph</a>, 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

	PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
1	COLLAGEN SOAP BY ELLEN'S – WHITE / WHITE COLLAGEN SOAP	Local Company Responsible for Placing the Product in the Market: Bio Soap Industries, Inc.	Collagen Soan
		Address:	"Ellen's
		143 Old Tabang Road, Tabang,	The second second
		Guiguinto Bulacan, Philippines	
		Country of Manufacture:	WHITE COLLAGEN SOAP
		Philippines	and Demand
2	BLEACHING &	Local Company Responsible for	Bleaching %
	WHITENING SOAP BY ELLEN'S - GREEN	Placing the Product in the Market: Not Indicated	Whitening Soap
	ELLEN 5 - GREEN	Not indicated	history s
		Address:	"Ellen's
		Not Indicated	The same of the sa
		Country of Manufacture:	
		Not Indicated	
3	ACNE & WHITENING	Local Company Responsible for	
3	SOAP BY ELLEN'S -	Placing the Product in the Market:	Acne &
	YELLOW / YELLOW	Bio Soap Industries, Inc.	Whitening Soap
	WHITENING SOAP	W 384	"Ellen's
		Address:	Guerts
		143 Old Tabang Road, Tabang, Guiguinto Bulacan, Philippines	
		Sulgamo Bulletin, 1 milppinos	YELLOW METTENNIA SOAP
		Country of Manufacture:	National project lands many
		Philippines	and Opensors.
4	ELLEN'S OIL	Local Company Responsible for	
	CONTROL PRESSED	Placing the Product in the Market:	
	POWDER	Not Indicated	
		Address:	ion ,
		Not Indicated	Guens
		Country of Manufacture:	
		Not Indicated	
5	ELLEN'S DAY CREAM	Local Company Responsible for	
		Placing the Product in the Market: Not Indicated	
		Tot flidicated	
		Address:	AND DESCRIPTION OF THE PARTY OF
		Not Indicated	<b>Stlen's</b>
		Country of Manufacture:	Day Cream
		Not Indicated	A STATE OF THE PARTY OF THE PAR

	PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
6	ELLEN'S NIGHT CREAM	Local Company Responsible for Placing the Product in the Market:	
		Not Indicated	
		Address:	Ou .
		Not Indicated	Olle (L)
		Country of Manufacture:	NAME OF TAXABLE PARTY.
		Not Indicated	
7	ELLEN'S ADVANCE WHITE DAY CREAM	Local Company Responsible for Placing the Product in the Market:	
	WIIITE DAT CREAM	Not Indicated	A STATE OF
		Address:	
		Not Indicated	
		Country of Manufacture:	Wance Winds Day
		Not Indicated	A STATE OF S
8	FOREVER YOUNG	Local Company Responsible for	
	SERUM BY ELLEN'S	Placing the Product in the Market: Not Indicated	
		Tot Indicated	
		Address:	
		Not Indicated	
		Country of Manufacture:	
		Switzerland	
9	REVERSE AGE	Local Company Responsible for	
	EMULSION BY ELLEN'S	Placing the Product in the Market: Not Indicated	
		Address:	
		Not Indicated	
		Country of Manufacture:	
		France	
10	ELLEN'S MIRACLE	Local Company Responsible for	
	WHITENING LOTION	Placing the Product in the Market: Not Indicated	
		Not indicated	
		Address:	
		Not Indicated	
		Country of Manufacture:	
		Not Indicated	

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	PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
11	ELLEN'S WHITENING TONER	Local Company Responsible for Placing the Product in the Market: Not Indicated	
		Address:	Citizen
		Not Indicated	
		Country of Manufacture:	
		Not Indicated	
12	ELLEN'S PIMPLE	Local Company Responsible for	BROWN TOWNS
	SOLUTION	Placing the Product in the Market: Not Indicated	
		Address:	Shire s
		Not Indicated	
		Country of Manufacture:	
		Not Indicated	
13	7SCENTS BEAUTY	Local Company Responsible for	
	COMPANY LTD. ARBUTIN SKIN	Placing the Product in the Market: Not Indicated	ANCULAN
	BRIGHT SCRUB WITH	. Tot Indicated	SIGN BEIGHT SCRUR
	COLLAGEN	Address:	A HEALTHY SCOWNESSELE
		Not Indicated	(
		Country of Manufacture:	
		Not Indicated	
14	7SCENTS BEAUTY	Local Company Responsible for	1100
	COMPANY LTD. ARBUTIN LOTION	Placing the Product in the Market: Not Indicated	LOTTON
	POWERFUL SKIN	Tot Indicated	
	WHITENER	Address:	
		Not Indicated	
		Country of Manufacture:	1000000
		Not Indicated	
15	7SCENTS BEAUTY	Local Company Responsible for	
	COMPANY LTD. AHA ALPHA ARBUTIN	Placing the Product in the Market: Not Indicated	Consult of
	SOAP POWERFUL	A 44	y same 3
	SKIN WHITENER	Address: Not Indicated	ALTER AMERICAN
		Country of Manufacture:	6-3
		Not Indicated	and the second