



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



12 JUL 2016

FDA ADVISORY
No. **2016-076**

TO : GENERAL CONSUMING PUBLIC, FIELD REGULATORY OPERATIONS OFFICE OF THE FOOD AND DRUG ADMINISTRATION, LAW ENFORCEMENT AGENCIES, LOCAL GOVERNMENT UNITS AND COSMETIC RETAILERS

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

Article II, Section 15 of the 1987 Constitution of the Republic of the Philippines provided that "The State shall protect and promote the right to health of the people and instill health consciousness among them." In line with this, Republic Act (RA) No. 3720 otherwise known as "Foods, Drugs and Devices, and Cosmetics Act," as amended by RA No. 9711, otherwise known as "Food and Drug Administration Act of 2009" has mandated the Food and Drug Administration (FDA) to ensure the safety, quality and efficacy of health products under its jurisdiction.

FDA, being the national regulatory authority covering cosmetic products, requires companies intending to manufacture, import, export, distribute, sell, offer for sale, transfer, promote and advertise cosmetic products to apply with the aforementioned agency, prior to carrying out said activities, for the following market authorizations, specifically (1) License to Operate (LTO) as Cosmetic Establishments and (2) Cosmetic Product Notification.

ASEAN Cosmetic Directive (ACD), adopted and implemented through the issuance of Administrative Orders (A.O.) 2005-0015 and 2005-0025, states in Article 1.3

"The company or person responsible for placing the cosmetic products in the market, shall notify the regulatory authority responsible for cosmetics (hereafter referred to as regulatory authority) of each Member State where the product will be marketed of the place of the manufacture or of initial importation before the product is placed in the market"

Thus, FDA hereby advises the general public not to purchase/use the following cosmetic products which have not passed through the verification process of FDA thus have no valid cosmetic product notifications:

Civic Drive, Filinvest City, Alabang 1781 Muntinlupa, Philippines

Trunk Line +63 2 857 1900

Website: www.fda.gov.ph

Fax +63 2 807 0751


Email: info@fda.gov.ph

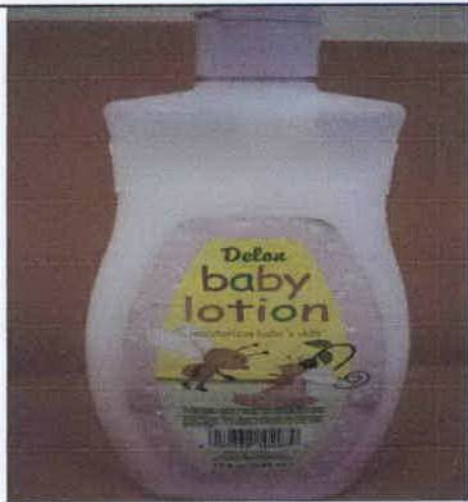


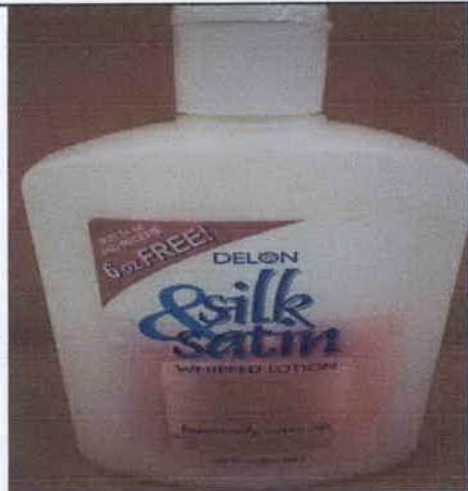
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1. DELON ALOE VERA SKIN CARE LOTION	
Manufacturer's Name: Delon Laboratories Ltd.	
Country of Manufacture: Canada	
Local Company Responsible for Placing the Product in the Market: Not Indicated	
Address: Not Indicated	
	
	Figure 1. Delon Aloe Vera Skin Care Lotion (Principal Display Panel)

2. DELON BABY LOTION	
Manufacturer's Name: Delon Laboratories Ltd.	
Country of Manufacture: Canada	
Local Company Responsible for Placing the Product in the Market: Not Indicated	
Address: Not Indicated	
	
	Figure 2. Delon Baby Lotion (Principal Display Panel)

3. DELON SILK & SATIN WHIPPED LOTION	
Manufacturer's Name: Delon Laboratories Ltd.	
Country of Manufacture: Canada	
Local Company Responsible for Placing the Product in the Market: Not Indicated	
Address: Not Indicated	
	
	Figure 3. Delon Silk & Satin Whipped Lotion (Principal Display Panel)


4. KERI BATH BOTANICALS SENSITIVE SKIN	
Manufacturer's Name: Bristol-Myers Squibb Company	
Country of Manufacture: Canada	
Local Company Responsible for Placing the Product in the Market: Not Indicated	
Address: Not Indicated	

Figure 4. Keri Bath Botanicals Sensitive Skin (Principal Display Panel)


5. SHINZU'I SKIN LIGHTENING BODY LOTION UV PROTECTION ISEIYA	
Manufacturer's Name: PT Bina Karya Prima	
Country of Manufacture: Indonesia	
Local Company Responsible for Placing the Product in the Market: Not Indicated	
Address: Not Indicated	

Figure 5. Shinzu'i Skin Lightening Body Lotion UV Protection Iseiya (Principal Display Panel)

Apart from not having passed through the verification process, and that as such, FDA cannot guarantee the quality and safety thereof, these cosmetic products have also been found to contain ISOBUTYLPARABEN and/or ISOPROPYLPARABEN, both of which are banned ingredients not allowed to be part of a cosmetic product, therefore, pose potential health hazards to the consuming public. The use of substandard and adulterated cosmetic products may result to adverse reactions including but not limited to skin irritation, skin sensitization, and anaphylactic shock. The public is advised to always verify if a cosmetic product has been notified with FDA before purchasing it. Consumers can do this by going to the FDA website (www.fda.gov.ph) and making use of the Search tab found in the upper right corner of the home page, as shown below:



Figure 6. FDA Website Homepage

The manufacture, importation, exportation, distribution, sale, offer for sale, transportation, promotion and/or advertisement of these cosmetic products are in direct violation of RA No. 9711.

In the interest of protecting public health and safety, the FDA Field Regulatory Operations Office (FROO) is ordered to monitor the market for the manufacture, importation, exportation, distribution, sale, offer for sale, transportation, promotion and/or advertisement of the abovementioned cosmetic products. FROO is further ordered to conduct inventory and seal all of the aforesaid unnotified cosmetic products found in the Philippine market, and to effect/conduct seizure of the same in accordance with existing laws, rules and regulations.

All local government units and law enforcement agencies are requested to ensure that these products are not sold or made available in their localities or areas of jurisdiction.

All cosmetic retailers are warned against selling these violative cosmetic products.

The public is enjoined to assist FDA in monitoring the market and to report any suspicious promotional or marketing activities for cosmetic products and their availability in the market through any of the following channels:

1. FDA's e-report (www.fda.gov.ph)

Reports can be sent to FDA via the e-Report section found in the upper right corner of the FDA website (refer to Figure 7). By clicking e-report, another page will appear where you will find the form that must be accomplished.

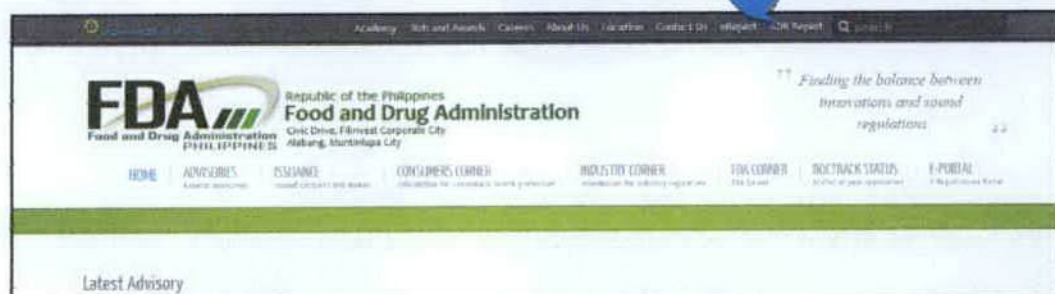


Figure 7. e-Report Section of the FDA Website

2. Send an email to report@fda.gov.ph
3. Contact the FDA Center for Cosmetics Regulation and Research (CCRR) Customer Service Hotline at (02) 857-1984.

Dissemination of the information to all is requested.


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OIC, Director General