



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



**FDA ADVISORY**

No. **2016-112**

05 OCT 2016

**TO: GENERAL CONSUMING PUBLIC**

**SUBJECT: Public Health Warning Against the Use of Unnotified Cosmetic Products (Batch 16)**

The Food and Drug Administration (FDA) advises the public against the purchase and use of the following unnotified cosmetic products:

1. **DERMAL THERAPY<sup>TM/MC</sup> MOISTURE**
2. **LIVE CLEAN<sup>TM/MC</sup> (BABY) SOOTHING OATMEAL RELIEF TEARLESS BABY WASH**
3. **CURÉL® ULTRA HEALING® INTENSIVE LOTION FOR EXTRA-DRY, TIGHT SKIN**
4. **ARM & HAMMER<sup>TM</sup> SENSITIVE TOOTHPASTE**

FDA post-marketing surveillance (PMS) activities has verified that a number of cosmetic products collected from Landers Superstore 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 lead and mercury. 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](http://www.fda.gov.ph).


For more information and inquiries, please e-mail us at [info@fda.gov.ph](mailto:info@fda.gov.ph). To report continuous sale or distribution of unnotified cosmetic products, kindly e-mail us via [report@fda.gov.ph](mailto:report@fda.gov.ph), call us at the Center for Cosmetics Regulation and Research (CCRR)





hotline (02) 857-1984, or utilize our online reporting facility, **eReport**, at [www.fda.gov.ph/ereport](http://www.fda.gov.ph/ereport).

Dissemination of the information to all concerned is requested.




  
**NELA CHARADE G. PUNO, RPh**  
Director General

DTN 20160919155505 ✓





**ANNEX**  
Details on the Unnotified Cosmetic Products

PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
<b>1 DERMAL THERAPY™/MC</b>	<p>Manufacturer's Name: Not Indicated</p> <p>Country of Manufacture: Canada</p> <p>Local Company Responsible for Placing the Product in the Market: Not Indicated</p> <p>Address: Not Indicated</p>	
<b>2 LIVE CLEAN™/MC (BABY) SOOTHING OATMEAL RELIEF TEARLESS BABY WASH</b>	<p>Manufacturer's Name: Hain-Celestial Canada, ULC.</p> <p>Country of Manufacture: Canada</p> <p>Local Company Responsible for Placing the Product in the Market: Not Indicated</p> <p>Address: Not Indicated</p>	
<b>3 CURÉL® ULTRA HEALING® INTENSIVE LOTION FOR EXTRA- DRY, TIGHT SKIN</b>	<p>Manufacturer's Name: Not Indicated</p> <p>Country of Manufacture: United States of America (U.S.A.)</p> <p>Local Company Responsible for Placing the Product in the Market: Not Indicated</p> <p>Address: Not Indicated</p>	
<b>4 ARM &amp; HAMMER™ SENSITIVE TOOTHPASTE</b>	<p>Manufacturer's Name: Church &amp; Dwight Co., Inc.</p> <p>Country of Manufacture: United States of America (U.S.A.)</p> <p>Local Company Responsible for Placing the Product in the Market: Not Indicated</p> <p>Address: Not Indicated</p>	