




03 JUN 2020

FDA ADVISORY
No. **2020-1027**

TO: GENERAL CONSUMING PUBLIC

SUBJECT: Public Health Warning Against the Purchase and Use of Cosmetic Product THE ORIGINAL PORCELANA® ASTRINGENT IMPROVED FORMULA Containing Banned Ingredient/s

The Food and Drug Administration (FDA) warns the public from purchasing and using the adulterated cosmetic product **THE ORIGINAL PORCELANA® ASTRINGENT IMPROVED FORMULA** which tested positive for the presence of **HYDROQUINONE** and **TRETINOIN**. Such ingredients are not allowed to be part of a cosmetic product as per Annex II Part 1 of the ASEAN Cosmetic Directive. The table below indicates the particulars of the adulterated cosmetic product/s:

PRODUCT DETAILS	PRODUCT IMAGE/S
<p>Name and Address of Manufacturer/ Local Company Responsible for Placing the Product in the Market: Porcelana Beauty Products, Inc. - #8 Mactan St., San Antonio Village, Apas, Cebu City Philippines</p> <p>Country of Manufacture: Philippines</p> <p>Lot/Batch Number: P01OJ02 Mfg. Date: 10/19 Exp. Date: 10/21</p> <p>Lot/Batch Number: P01OJ03 Mfg. Date: 10/19 Exp. Date: 10/21</p> <p>Lot/Batch Number: P01OI02 Mfg. Date: 09/19 Exp. Date: 90/21</p> <p>Lot/Batch Number: P01OJ04 Mfg. Date: 10/19 Exp. Date: 10/21</p>	



Products containing Hydroquinone and/or Tretinoin (Retinoic Acid) shall be classified as home remedy, over-the-counter, or prescription drug depending on the amount present as per Administrative Order No. 13 s. 1999.

The aforementioned adulterated product is found to be non-compliant with the existing standards, and, thus pose potential hazards to the consuming public. The use of 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 foregoing, the public is advised not to purchase the aforementioned adulterated product. Moreover, the public is advised to always check if a cosmetic product is notified with the FDA. The FDA website (www.fda.gov.ph) has a *Search* feature which may be used by typing in the name of the product before purchasing.

All concerned establishments are warned not to distribute adulterated cosmetic products.

All FDA Regional Field Offices and Regulatory Enforcement Units, in coordination with law enforcement agencies and Local Government Units, are requested to ensure that violative products are not sold or made available in the market or areas of jurisdiction.

To report any sale, distribution, complaint and/or adverse event on the use of the violative cosmetic product, the online reporting facility, eReport can be accessed at ereport@fda.gov.ph, or call us at the Center for Cosmetics Regulation and Research (CCRR) hotline **(02) 8857-1900 loc. 8113 or 8107**.

Dissemination of this advisory to all concerned is hereby requested.


ROLANDO ENRIQUE D. DOMINGO, MD
Director General

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