

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



FDA ADVISORY No. 2017-289 3 0 OCT 2017

TO:

GENERAL CONSUMING PUBLIC

SUBJECT:

Public Health Warning Against the Use of Unnotified Cosmetic Products Found to Contain Toxic Mercury (Hg)

Levels (Batch 2)

The Food and Drug Administration (FDA) advises the public against the purchase and use of the following cosmetic products which tested and found to contain toxic mercury (Hg) levels beyond the 1 ppm (parts per million) limit set by the FDA, and as published in the ASEAN Cosmetic Directive (refer to the attached annex for the product particulars/details):

- 1. RENOW-D NEW FACIAL CREAM FORMULA-ONE
- 2. GOREE® DAY & NIGHT WHITENING CREAM OIL FREE
- 3. GOREE® BEAUTY CREAM WITH LYCOPENE WITH SPF 30 AVOCADO & ALOEVERA

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.

Mercury salts in cosmetic products inhibits the formation of skin melanin which will result to lighter skin tone. Adverse health effects brought about by highly toxic mercury in cosmetics products include kidney damage, skin rashes, skin discoloration and scarring. Chronic use reduces the skin's normal resistance against bacterial and fungal infections. Other effects include anxiety, depression or psychosis and peripheral neuropathy. The transfer of mercury to fetuses of pregnant women may manifest as neurodevelopment deficits later in life.

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 <a href="https://www.fda.gov.ph.">www.fda.gov.ph.</a>

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="mailto: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 20171003094217

## ANNEX Details on the Unnotified Cosmetic Products

|   | PRODUCT NAME                      | PRODUCT DETAILS   | PRODUCT IMAGE/S  |
|---|-----------------------------------|---|--|
| 1 | RENOW-D NEW                       | Manufactured by: RE-X Products                                      |  |
|   | FACIAL CREAM                      | Co. LTD.  | RENOW-D  |
|   | FORMULA-ONE                       | Manufacturer's Address:   | The state of the s |
|   |                                   | Nonthaburi, Thailand  |  |
|   |                                   | and the same of   |  |
|   |                                   | Local Company Responsible for<br>Placing the Product in the Market: | district .   |
|   |                                   | C.C. Dino General Merchandise                                       |  |
|   |                                   |   | DESCRIPTION AND ADDRESS OF THE PARTY.  |
|   |                                   | Address: 1108 A. Rivera St., 7th Fl.,                               | and determine the control of the con |
|   |                                   | Tondo, Metro Manila, Philippines                                    | Marine Service September 2 p.  |
|   |                                   | Country of Manufacture:   |  |
|   |                                   | Thailand  |  |
|   |                                   | Lot/Batch Number: RC-F150401  |  |
|   |                                   | Lov Batch Number: RC-1 150401                                       |  |
| 2 | GOREE® DAY & NIGHT                | Manufactured by: H Pharmacy®  |  |
|   | WHITENING CREAM                   | N. C All Delica.  |  |
|   | OIL FREE                          | Manufacturer's Address: Pakistan                                    |  |
|   |                                   | Local Company Responsible for                                       | A Garage   |
|   |                                   | Placing the Product in the Market:                                  | Govee  |
|   |                                   | Not Indicated   | DAY & NEXHT<br>myrphis cran  |
|   |                                   | Address: Not Indicated  | Title felome Span  |
|   |                                   |   | DNY KNORTH MINISTRAL COLOR   |
|   |                                   | Country of Manufacture:   |  |
|   |                                   | Pakistan  |  |
|   |                                   | Lot/Batch Number: Not Indicated                                     |  |
| 3 | GOREE® BEAUTY                     | Manufactured by: H Pharmacy®  |  |
|   | CREAM WITH                        | M. C. J. M. D. D. L.  |  |
|   | LYCOPENE WITH SPF<br>30 AVOCADO & | Manufacturer's Address: Pakistan                                    |  |
|   | ALOEVERA                          | Local Company Responsible for                                       |  |
|   |                                   | Placing the Product in the Market:                                  | 6  |
|   |                                   | Not Indicated   | CHOICE   |
|   |                                   | Address: Not Indicated  | SEAUTY CREAM Goree D   |
|   |                                   |   | BAITY CHAM   |
|   |                                   | Country of Manufacture:<br>Pakistan                                 |  |
|   |                                   | r akistati  |  |
|   |                                   |   |  |

Lot/Batch Number: Not Indicated