

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



20 November 2013

FDA ADVISORY No. 2013-053

SUBJECT: CONSUMER WARNING AGAINST TOXIC MERCURY-LADEN SKIN WHITHENING COSMETIC PRODUCTS WITHOUT NOTIFICATION THAT WERE TESTED BY THE FDA

The Food and Drug Administration (FDA) - Center for Cosmetic Regulation and Research received a number of skin whitening cosmetic products coming from a certain non-government organization (NGO). All cosmetic products submitted by the said NGO have no FDA notification and should not be sold, nor offered for sale to or use by the consumers.

After careful review of the products, fifteen (15) were assayed by the FDA - Central Laboratory for toxic mercury (Hg) levels. Laboratory results showed that 11 out of the 15 products or 73.33% were found to contain mercury levels more than 1 ppm (parts per million).

The finding is not surprising for cosmetic products without FDA market authorization. Unknown to consumers, there are unscrupulous manufacturers and traders that add mercury salts in cosmetic products to inhibit the formation of skin melanin which will result to lighter skin tones. Adverse health effects brought about by highly toxic mercury in cosmetic 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.

Cosmetics products without FDA notification that were found to contain mercury beyond the 1 ppm limit set by the FDA and as published in the ASEAN Cosmetic Directives are as follows:

- 1. Sanli Eliminating Freckie Cream Plus Complex Vitamin C & E
- 2. Erna Whitening Cream
- 3. Top Shirley® Nourishing Cream
- Jiao Li Huichunsu Specific Eliminating Freckle Cream
- Jiao Li Speckle-Dispelling & Whitening Cream
- 6. LMSER Cream
- 7. Gemli Beauty Series Freckles Cream Plus Placenta Extract
- Zhjren 7 Day Beauty Elegant Moisturizing & Whitening Day Cream & Night Cream
- 9. Zhjren Whitening Ruddy Combination Suit
- 10. White Magnolia Intensive Repair Essence & Powerful Spot Remover
- 11. Angela Placenta Whitening Cream (Tender Skin & Whitening)





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The following products have no FDA market authorization or notification, and should not be sold, or offered for sale to or use by the consumers:

- Excellent Royalsuffi Fade-Out Cream-Day Cream
- o Yu Yan ® Excellent Yest Intensive Night-Cream
- Baschi Day & Night Cream
- Baschi Whitening Cream
- o Feique Herbal Exract Whitening Freckle-Removing Series

All consumers are advised to buy cosmetics products that have FDA market authorization and to buy them only from legitimate outlets.

The FDA appeals to all mall owners' sense of corporate social responsibility to require their tenants to sell, offer for sale or use cosmetic products that are sourced from distributors and importers that have FDA License to Operate (LTO) and product Certificates of Notification.

All field Food and Drug Regulation Officers are hereby ordered to cause the inventory and seizure of all cosmetic products that have no FDA Certificate of Notification and those that contained violative levels of toxic mercury. Local government units are requested to ensure that cosmetic products that do not have market authorization are not sold or offered for sale or use by ambulant and sidewalk vendors. The Bureau of Customs is also requested to remain vigilant against unregistered health products from entering the country that may be toxic.

Consumers are enjoined to access the FDA website (http://www.fda.gov.ph) to check if a particular cosmetic product has FDA notification by simply typing the name of the product on the SEARCH button. To report any adverse reactions from using a specific cosmetic product, please email us at report@fda.gov.ph. For more information and clarification, kindly email us at report@fda.gov.ph.

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