



FDA ADVISORY
No. **2018-119**

02 APR 2018

TO: GENERAL CONSUMING PUBLIC

SUBJECT: Public Health Alert on Banned Korean Cosmetic Products Containing Antimony (Sb) in South Korea

In connection to the ban and recall order issued by the Ministry of Food and Drug Safety (MFDS), South Korea against the following cosmetic products for having been verified to contain dangerous levels of antimony:

	Product Name	Batch No. and Expiration Date
1	Aritaum Full Cover Stick Concealer (#1 Light Beige)	Batch No: AAH; Exp. Date: 2021.01.12 Batch No: BAH; Exp. Date: 2021.01.30 Batch No: CBH; Exp. Date: 2021.02.11
2	Aritaum Full Cover Stick Concealer (#2 Natural Beige)	Batch No: ELG; Exp. Date: 2020.12.17
3	Aritaum Full Cover Cream Concealer (#1 Light Beige & Natural Beige)	Batch No: GLG; Exp. Date: 2020. 12. 14 Batch No: AAH; Exp. Date: 2021. 01. 30
4	Aritaum Full Cover Cream Concealer (#2 Olive Green & Pink)	Batch No: AAH; Exp. Date: 2021. 01. 14
5	Etude House AC Clean Up Mild Concealer	Batch No: AAH; Exp. Date: 2021.01.08
6	Etude House Drawing Eyebrow Duo (#3 Gray Brown)	Batch No: GLG; Exp. Date: 2020.12.17
7	XTM Style Homme For Men Easy Stick Concealer	No information available
8	Black Monster Homme Black Erasing Pen	No information available
9	Skeda Homme Spot Concealer	No information available
10	Skinfood Cherry Full Lip Liner (Rose Cherry)	No information available
11	3CE Slim Eyebrow Pencil (Chestnut Brown)	No information available
12	Makeheal Naked Slim Brown Pencil Br0203	No information available
13	Makeheal Naked Slim Brown Pencil Y10801	No information available

the Food and Drug Administration (FDA) hereby informs the public that twelve (12) out of the thirteen (13) cosmetic products mentioned above are not notified with FDA and are not allowed to be distributed in the country.

Product # 5 – Etude House AC Clean Up Mild Concealer, on the other hand, has been notified with the agency and is currently available in the market. However, upon coordination with the Market Authorization Holder (MAH), Rosa Fiore House Corp., the FDA has verified that the batch imported into the country and subsequently sold in Etude House Boutiques are not affected by the ban and recall order. According to Rosa Fiore House Corp., the specific batches imported and distributed by the company are **BCG** and **CCG** with expiration dates 29 February 2020 and 20 March 2020 respectively.

Antimony (Sb) is a heavy metal found naturally in the environment which has been proven to cause adverse health effects in humans. Exposure to the metal can result to damages to the lung, heart muscle and liver. Symptoms of antimony toxicity includes skin irritation,



headache, nausea, vomiting, insomnia and abdominal pain among others. In case these symptoms occur, the public is advised to consult a doctor or go to the nearest health clinic.


Anyone who has bought the aforementioned cosmetic products, either from international travel (i.e. South Korea) or social media sites illegally offering them for sale, you are highly advised to immediately stop using them and throw them away.

To ensure the public's safety, the FDA urges all consumers to please refrain from buying unnotified and verified counterfeit cosmetic products. Unnotified and counterfeit cosmetic products, because they have not been subjected to stringent quality assurance procedures and have not gone through the verification process of FDA (1) may contain putrid, banned or restricted ingredients beyond the maximum authorized concentration, (2) may be substandard and (3) may be of low quality which could pose different health hazards to its users including but not limited to skin irritation, itchiness, anaphylactic shock and organ failure. If unsure of a product's notification status, consumers may access the FDA website and check the product's notification status using the *Search* feature embedded in the website.

Moreover, the public is also highly encouraged to assist FDA in monitoring the market, including social media sites and online shopping websites, for any sellers offering the aforementioned cosmetic products. Reports may be submitted to FDA through any of the following channels:

1. Send an e-mail via report@fda.gov.ph
2. Call the Center for Cosmetics Regulation and Research (CCRR) hotline **(02) 857-1984**
3. Utilize the agency's online reporting facility, **eReport**, at www.fda.gov.ph/ereport.

Dissemination of the information to all concerned is requested.


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