

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



13 FEB 2018

FDA ADVISORY No. 2018-037

TO:

GENERAL CONSUMING PUBLIC

SUBJECT:

Public Health Warning Against the Use of Counterfeit Cosmetic

Products (Batch 1)

The Food and Drug Administration (FDA) hereby advises the public against the purchase and use of CALVIN KLEIN CK ONE EAU DE TOILETTE 15ML whose particulars/details are provided below:

## PRODUCT DETAILS

Local Company Responsible for Placing the Product in the Market:

Not Indicated

Address:

Not Indicated

Country of Manufacture:

U.S.A.

Lot/Batch Number:

Not Indicated

Date Manufacture:

Not Indicated

Expiry Date: Not Indicated

Other Label/Packaging Information:

- a. Authentic, commercially available single-bottle pack sizes are only 50mL, 100-mL and 200-mL
- b. Authentic product is contained in a frosted flask-shaped glass bottle with aluminum cap and packed in a white carton embossed with bottle silhouette with texts "ck one, eau de toilette, Calvin Klein"

## PRODUCT IMAGE/S





FDA, in coordination with the Market Authorization Holder (MAH), COTY Prestige SEA Philippines, Inc., has verified that CALVIN KLEIN CK ONE EAU DE TOILETTE 15mL products with the above pictures is **COUNTERFEIT**.

Counterfeit products, not having gone through the required safety assessment and the verification process of the FDA, pose potential health hazards to the consuming public since their safety and purity cannot be guaranteed. The dangers/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 to be vigilant against buying and using the aforementioned counterfeit cosmetic product. 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.

All concerned establishments are warned not to distribute the above-identified violative cosmetic product, otherwise, regulatory actions and sanctions shall be strictly pursued.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that the product is not sold or made available in their localities or areas of jurisdiction.

To report any suspicious and/or illegal activity involving the said products, the public may contact FDA through its online reporting facility, eReport, at <a href="www.fda.gov.ph/ereport">www.fda.gov.ph/ereport</a>, or email us at <a href="report@fda.gov.ph">report@fda.gov.ph</a>, or call the Center for Cosmetics Regulation and Research (CCRR) hotline (02) 857-1900 local 8107/8113.

Dissemination of the information to all concerned is requested

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