Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 20220899

12 APR 2022

TO: **THE GENERAL PUBLIC**

SUBJECT: **Product Information Safety Alert on the Cosmetic Product Jergens® Ultra Healing Moisturizer Due to the Presence of *Pluralibacter gergoviae***

The Food and Drug Administration (FDA) hereby informs the general public on the safety alert on selected batch of **Jergens® Ultra Healing Moisturizer** due to the presence of Pluralibacter gergoviae, published by the U.S. Food and Drug Administration (USFDA) on 18 March 2022.

The company Kao USA Inc. conducted a voluntary recall on selected Jergens® Ultra Healing Moisturizer to warn the consumers to discontinue the use of the recalled lotion as a precautionary measure. According to the company, the amount of recalled product is limited to two (2) sizes, and only specific lots of the 3 oz. and 10 oz. are affected. Below are the details and identification of the affected products:

- Jergens® Ultra Healing Moisturizer, manufactured between October 1, 2021 and October 18, 2021, could be impacted.
- The affected lot codes for the 3 oz size (UPC 019100109971 for single bottles and 019100267114 for pack of 3) can be found on the back of the bottle printed in black ink and begin with the prefix "ZU":

  - ZU712851
  - ZU712911
  - ZU712861
  - ZU722851
  - ZU712871
  - ZU722881
  - ZU712881

- The affected lot codes for the 10 oz size (UPC 019100109988) can be found on the bottom of the bottle printed in black ink and begin with the prefix "ZU":

  - U722741
  - ZU732791
  - ZU722771
  - ZU732801
  - ZU722781
  - ZU732811
  - ZU732781
  - ZU732821

Accordingly, Kao USA Inc. removed the above affected products from warehouses, and working with retailers to ensure that the product is removed from store shelves, and proactively notifying consumers.

Pluralibacter gergoviae, a bacterium which typically poses little medical risk to healthy people. However, individuals with weakened immune systems, who suffer from a serious pre-existing condition, who have been treated surgically or belong to another sensitive group of persons are at particular risk of infection.

The Market Authorization Holder (MAH) placing the aforementioned cosmetic product in the Philippines have notified the FDA that the products with selected lots stated in the voluntary product recall published by the USFDA are not sold in the country.

To report any sale or distribution of the recalled health products to kindly email FDA via ereport@fda.gov.ph, or call us at the Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR) hotline **(02) 8857-1900 loc. 8113 or 8107**.

Dissemination of this information to all concerned is hereby requested.

DR. OSCAR G. GUTIERREZ, JR.
Officer-in-Charge Director General

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