Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY

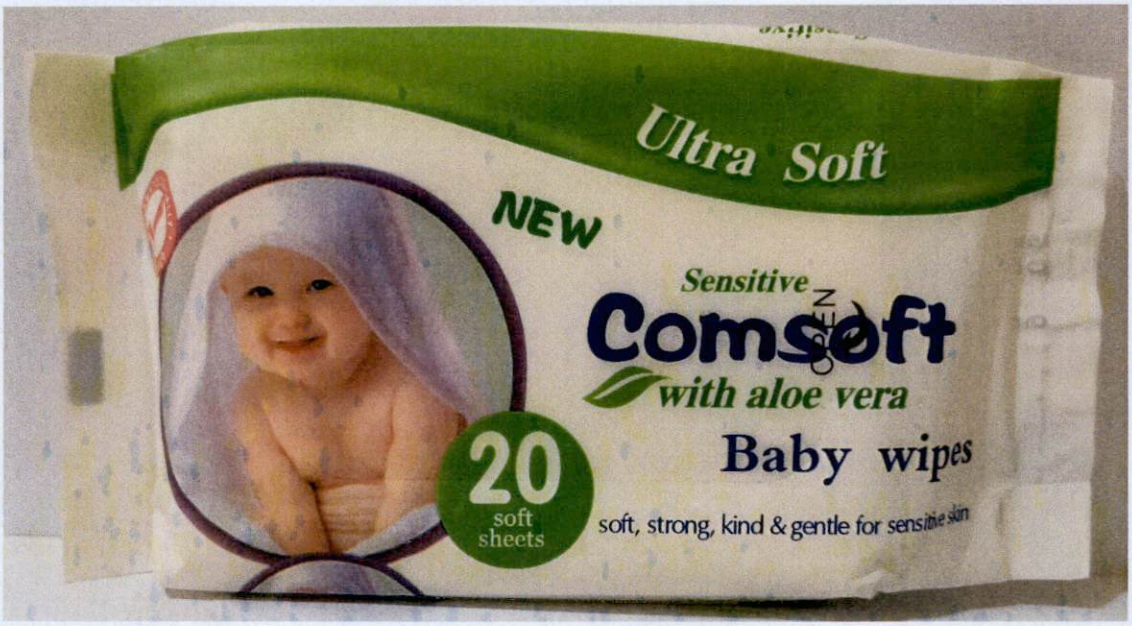
No. 2021-0544

12 MAR 2021

TO: **GENERAL CONSUMING PUBLIC**

SUBJECT: **Public Health Warning Against the Purchase and Use of Unauthorized Cosmetic ULTRA SOFT SENSITIVE COMSOFT WITH ALOE VERA BABY WIPES**

The Food and Drug Administration (FDA) warns the public from purchasing and using the unauthorized cosmetic product, **ULTRA SOFT SENSITIVE COMSOFT WITH ALOE VERA BABY WIPES** . (Refer to the image below)



The abovementioned product was verified by FDA through postmarketing surveillance and shows no valid Certificate of Product Notification (CPN) as of 09 March 2021. Pursuant to Book II, Article I, Section 1 (a) of the Rules and Regulations Implementing 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 any health product without the proper authorization from the FDA is prohibited.

Since the abovementioned unauthorized cosmetic product has not gone through the notification process of the FDA, the agency cannot assure their quality and safety. The use of such violative product may pose health risks to consumers.

(FROO) are hereby authorized to proceed, enter and conduct inspection on all establishments engaged in the manufacture, importation, exportation, distribution, retail, sale, offer for sale and transfer of the subject health product.

The FDROs or the REU personnel are further authorized to obtain copies of the documents related to their procurement and/or distribution including but not limited to purchase orders, inventory records, sale invoices and delivery receipts. The inventory and seizure of the aforestated violative health product that may be found in the subject establishments is likewise ordered pursuant to Section 3(b)(1), Article VII, Book III of the IRR of RA 9711 and the advisories previously issued.

If deemed warranted, and in view of the foregoing, the FDROs or the REU personnel shall comply with Section 4, Article IV, Book III of the IRR of RA 9711 and file a complaint in the form of a Report of Violation (ROV) in accordance with FDA's existing laws, rules and regulations.

In enforcing this Order, the concerned FDROs or the REU personnel may coordinate with other offices/units within FDA, other law enforcement agencies including but not limited to the Philippine National Police (PNP) and the Local Government Unit (LGU) concerned.

This Order shall take effect immediately and shall remain valid unless otherwise revoked.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

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