Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

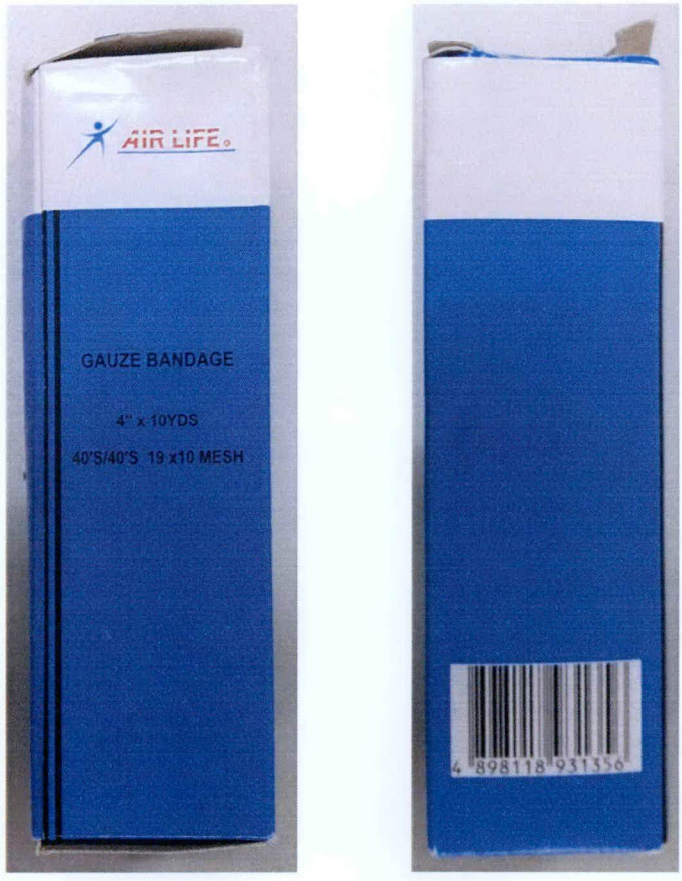
23 OCT 2018

FDA ADVISORY
No. 2018-309

TO: **THE GENERAL PUBLIC**

SUBJECT: **Public Health Warning Against the Purchase and Use of Medical Device with Expired Certificate of Product Registration (CPR)**

The Food and Drug Administration (FDA) advises the public against the purchase and use Air Life Gauze Bandage 4" x 10 yds, 40's/40's 19 x 10 mesh (see figure below) with expired CPR:



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Post-marketing surveillance activities conducted by the FDA have verified that the CPR of the above-mentioned medical device has already expired and that the FDA has not received any application for the renewal of such CPR from its importer/distributor.

Pursuant to the provisions of Republic Act 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 are prohibited.

Since the abovementioned product did not undergo the re-evaluation process of the FDA, the agency cannot guarantee its quality and safety.

In this regard, the public is hereby advised not to purchase the above-mentioned violative product. All concerned establishments are warned not to advertise, sell or distribute the said product until such has been issued with the corresponding new Cerificate of Product Registration, otherwise, regulatory actions and sanctions shall be strictly pursued.

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

For more information and inquiries, please email us at **info@fda.gov.ph.** To report continuous sale or distribution of the above medical device, utilize our online reporting facility, **eReport**, at **www.fda.gov.ph/ereport**, or email us via **report@fda.gov.ph**, or call us at the Center for Device Regulation, Radiation Health and Research hotline 857-1900 local 8301.

Dissemination of the information to all concerned is requested.

NELA CHARADE G. PUNO, RPh
FDA Director General

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