



FDA ADVISORY
No. **2020-446**

20 MAR 2020

TO: ALL CONCERNED HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT: Product Recall of Lot. No. 130418 of Ormed Elastic Bandage 15cm x 4.5m

All concerned healthcare professionals and the general public are hereby warned by the Food and Drug Administration (FDA) that a specific lot of the subject product is being recalled from the market. The details of the product are as follows:

Medical Device Product	Ormed Elastic Bandage 15cm x 4.5m
Registration Number	MDR-00282
Lot Number/Expiry Date	130418 / 180418 (18 April 2018)
Manufacturer	Ningbo Greetmed Medical Instruments Co. Ltd. – China mfd by: Anji Jixiang Medical Co., Ltd. – China
Importer/Distributor (Marketing Authorization Holder)	Impexcos Co. – Room 303 Ormed Building, #212-A V. Luna Road Extension, Sikatuna Village, Diliman, Quezon City



Figures 1, 2 and 3: Photos of a Sample of Expired Ormed Elastic Bandage (Lot No. 130418)



Based on the post-marketing surveillance conducted by the FDA, it was found out that the product with the above-specified lot number is expired with expiration date 180418 (18 April 2018) printed on the primary packaging of the product.

Therefore, distributors, hospitals, retailers, pharmacies or clinics that have the affected lot of the medical device product are instructed to discontinue further distribution, sale and use. All consumers are likewise advised not to purchase or use the affected product lot and may call Impexcos Co. at telephone number (02) 3433 8844 or (02) 3433 8855 or email the FDA Center for Device Regulation, Radiation Health and Research at cdrrhr-prsdd@fda.gov.ph for any question or additional information regarding the recall.

All FDA Regional Field Offices and Regulatory Enforcement Units in coordination with law enforcement agencies and Local Government Units are requested to ensure that the affected product lot is not sold or made available in the market or their areas of jurisdiction.

Dissemination of the information to all concerned is requested.


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Director General

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