

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



1 8 DEC 2017

FDA ADVISORY

TO:

THE GENERAL PUBLIC AND ALL HEALTHCARE CONCERNED

PROFESSIONALS

SUBJECT:

VOLUNTARY RECALL OF THE NASOPORE STANDARD 8CM NASAL

DRESSING WITH PRODUCT REGISTRATION MDR NO. 02341

Easmed Medical Supplies, Inc., the importer/distributor of Nasopore Standard 8cm Nasal Dressing with the product registration number MDR-02341. has informed the Food and Drug Administration of the voluntary recall of the said product, specifically described as follows:

Product Information	Carton Label	Individual Product Label
Product Number	ND02-025/04B	ND01-025/08 B
Lot Number	NDA2017062014	NDA2017080412

Said items are being voluntarily recalled because of its incorrect product identification in the product label. They we distributed on 18 and 22 September 2017 by its main manufacturer from other countries. The barcode label affixed in the carton box contained incorrect Lot and Ref numbers that are critical in determining the identity of the product for traceability. In the report to the FDA, Easmed Medical Supplies Inc. disclosed that the affected lots were not distributed in the Philippine market as per their distribution list record.

At any rate, distributors, retailers and hospitals that have any lot of the stated medical device product are instructed to discontinue their further distribution, sale, and use. Furthermore, other distributors of said product shall coordinate with the FDA for the conduct of product recall. All consumers are likewise advised not to purchase or use the affected product lots.

Any suspected adverse reaction experienced or any incident of the same cases from the use of the device but not limited to the lots stated above, should be reported immediately to FDA at telephone no. (02) 857-1900 loc. 8301 or email us at cdrrhr prsdd@fda.gov.ph.

Dissemination of the information to all concerned is requested.

MARADE G. PUNO, R.Ph NELA C

Director General

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