

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



2 9 MAY 2020

FDA ADVISORY No. 2020-1013

TO:

ALL HEALTHCARE PROFESSIONALS AND THE GENERAL

PUBLIC

SUBJECT:

Public Health Warning Against the Purchase and Use of the

Unregistered Medical Device "Mama's Love Adhesive Plaster"

The Food and Drug Administration (FDA) warns all healthcare professionals and the general public against the purchase and use of the unregistered medical device:



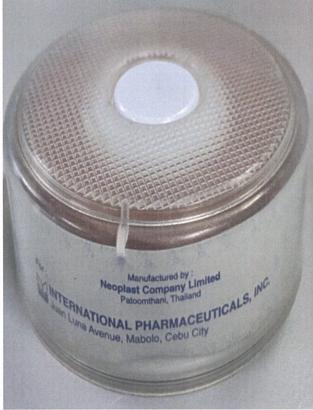


Figure 1. Unregistered Mama's Love Adhesive Plaster



The FDA verified through post-marketing surveillance that the abovementioned medical device is not registered and the Certificate of Product Registration (CPR) has not yet been issued as of 18 March 2020. Pursuant to the 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 health products without the proper authorization is prohibited.

Since this unregistered medical device has not gone through evaluation process of the FDA, the agency cannot assure its quality and safety.

In light of the foregoing, the public is advised not to purchase the violative product in the market.

All concerned establishments are warned not to distribute, advertise, or sell the said violative medical device until CPR is issued, otherwise, regulatory actions and sanctions shall be strictly pursued.

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

The Bureau of Customs is urged to restrain the entry of this unregistered product.

For more information and inquiries about this advisory, kindly contact the FDA CDRRHR through e-mail at cdrrhr-prsdd@fda.gov.ph, or call (02) 8857-1900 loc. 8301.

To report any sale or distribution of unregistered medical device, the online reporting facility, **eReport** can be accessed at **www.fda.gov.ph/ereport**.

Dissemination of this advisory to all concerned is hereby requested.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

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