Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA Food and Drug Administration PHILIPPINES

03 JUL 2019

FDA ADVISORY
No. 2019-177

TO : **THE GENERAL PUBLIC AND ALL HEALTHCARE PROFESSIONALS**

SUBJECT : **Public Health Warning Against the Purchase and Use of the following Unregistered Medical Devices:**

1. **Smileplus Bandage Children's Cartoon**
2. **Smileplus Bandage Children's Colored for Kids**

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

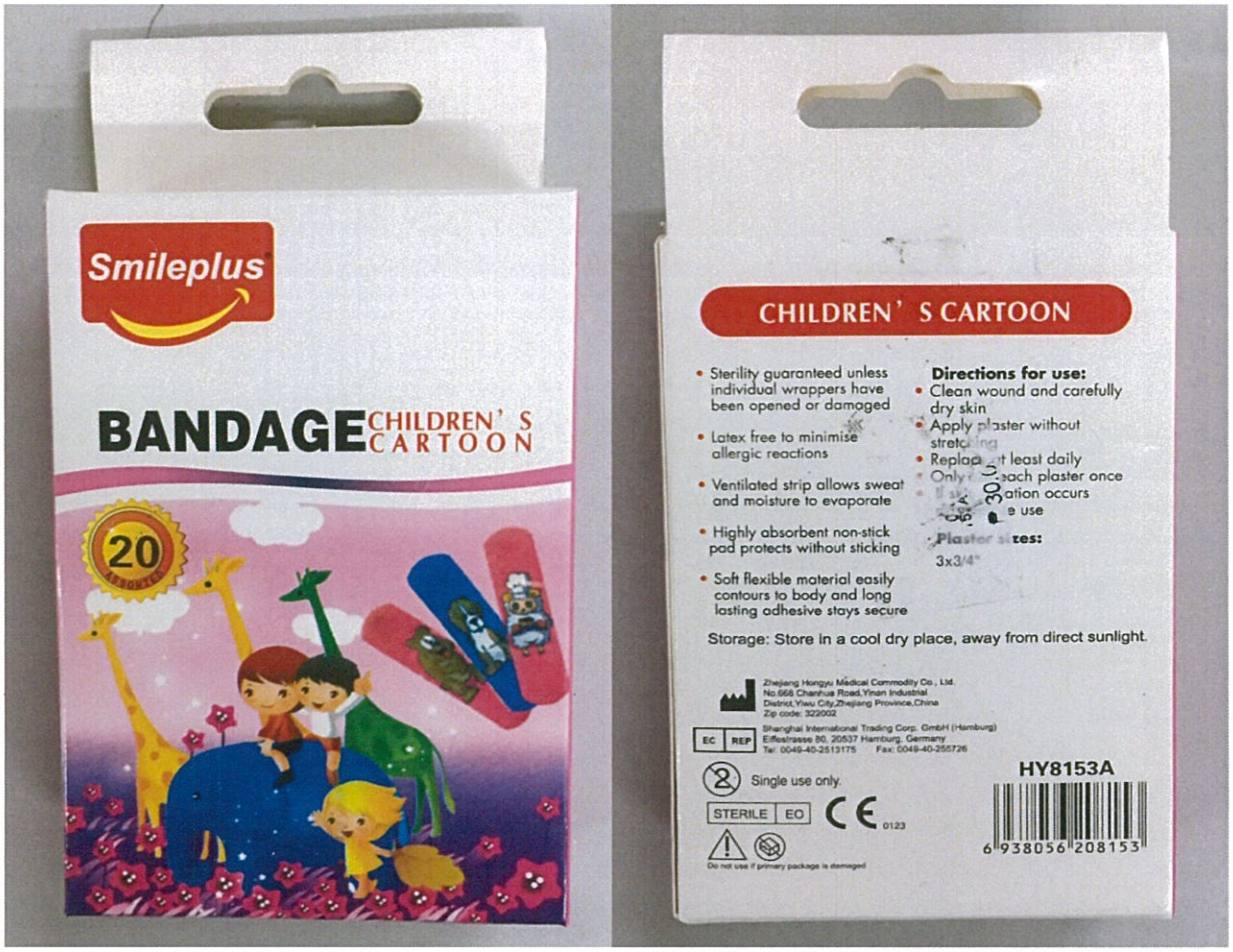

Figure 1. Unregistered Smileplus Bandage Children's Cartoon

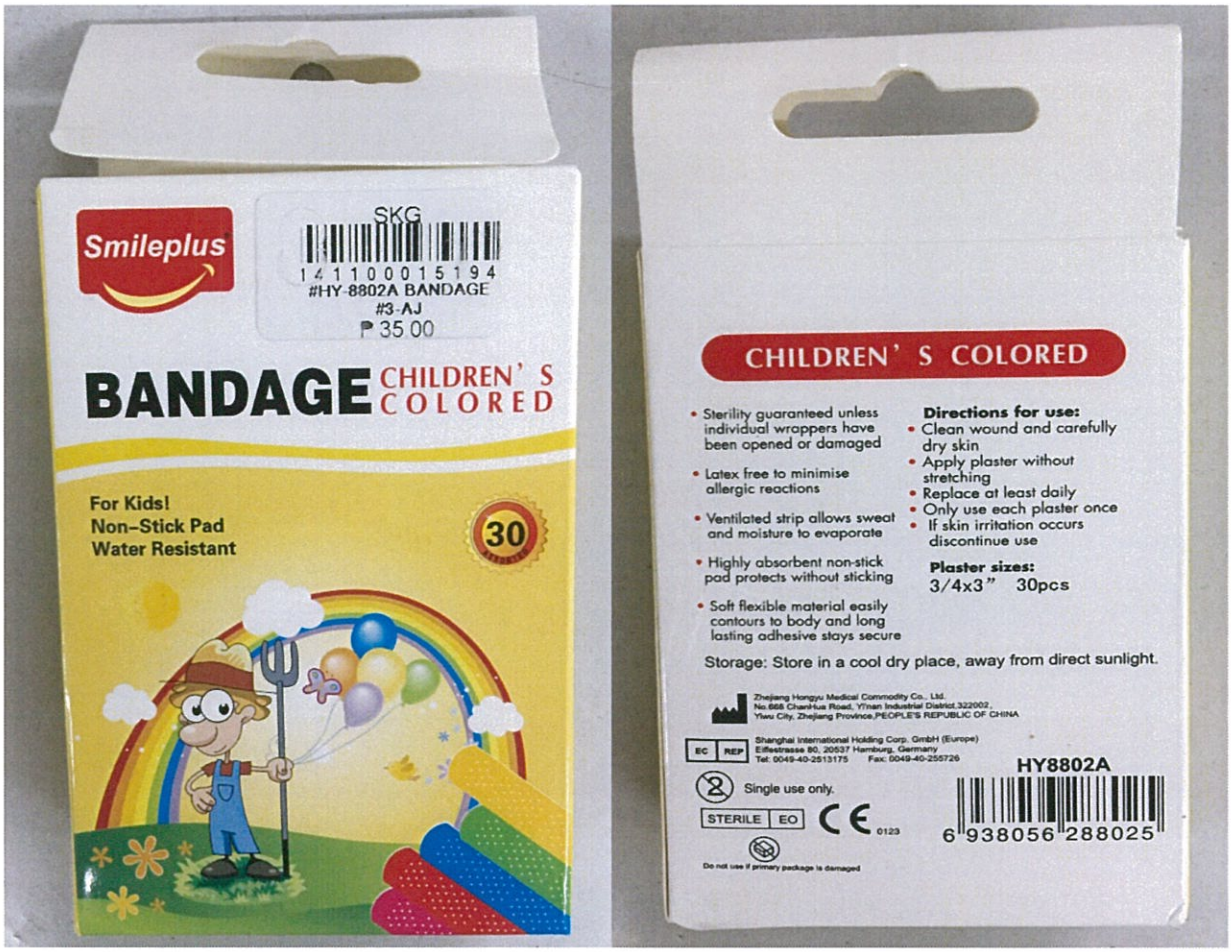

Figure 2. Unregistered Smileplus Bandage Children's Colored for Kids

The FDA verified through post-marketing surveillance that the abovementioned medical devices are not registered and the Certificate of Product Registration (CPR) have not yet been issued. Pursuant to 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 from FDA is prohibited.

Since these unregistered medical devices have not gone through evaluation process of the FDA, the agency cannot assure the quality and safety.

In light of the above, the public is advised not to purchase these products in the market. Moreover, the public is advised to always check if a medical device is registered with the FDA. The FDA website (www.fda.gov.ph) has a *Search* feature which may be used by typing in the name of the product before purchasing.

All concerned establishments and/or entities are warned not to distribute the above-identified violative medical device product until it has already been covered by the appropriate authorization, otherwise, regulatory actions and sanctions shall be strictly pursued.

All FDA Field Officers and Regulatory Enforcement Unit in coordination with the law enforcement agencies and Local Government Units are requested to ensure the violative products are not sold or made available in the market or areas of jurisdiction.

Kindly contact the FDA Center for Device Regulation, Radiation Health and Research through e-mail at **cdrrhr@fda.gov.ph,** or call **(02) 857-1900 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, DPBO
Undersecretary of Health
Officer-In-Charge, Director General

DTN: 20190502173532
DTN: 20190327150400