Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

17 SEP 2018

FDA ADVISORY
No. 2018-278

TO : **ALL HEALTH CARE PROFESSIONALS AND THE GENERAL PUBLIC**

SUBJECT : **Public Health Warning Against the Purchase and Use of Unregistered Medical Device Products:**

1. **Mumuso Adhesive Bandage Waterproof Transparent (High Elastic)**
2. **Mumuso Adhesive Bandage Micro Hole Breathable (Skin Color)**
3. **Mumuso Adhesive Bandage Waterproof Transparent (High Elastic)**
4. **Mumuso Adhesive Bandage Waterproof**

The Food and Drug Administration (FDA) hereby advises the general public and healthcare professionals against the purchase and use of the following medical device products:

Figure 1. Mumuso Adhesive Bandage Waterproof Transparent (High Elastic)

Figure 2. Mumuso Adhesive Bandage Micro Hole Breathable (Skin Color)

Figure 3. Mumuso Adhesive Bandage Waterproof Transparent (High Elastic)

Figure 4. Mumuso Adhesive Bandage Waterproof

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FDA post-marketing surveillance (PMS) activities have verified that the abovementioned medical device products have not gone through the registration process of the agency and have not been issued with proper authorization in the form of Certificate of Product Registration. 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.

Accordingly, since these unregistered medical devices have not gone through evaluation and testing process of the FDA, the agency cannot guarantee its quality and safety. The consumption of such violative product may pose potential health hazards to the consuming public.

In light of the above, the public is advised not to purchase the aforementioned violative products and to be vigilant against medical device that might not be duly registered with FDA. Always check if a medical device has been registered with the FDA before purchasing it by making use of the embedded *Search* feature of the FDA website accessible at www.fda.gov.ph.

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

For more information and inquiries, please email us at info@fda.gov.ph. To report continuous sale or distribution of the above unregistered medical device, utilize our online reporting facility, eReport, at www.fda.gov.ph/ereport, or e-mail us via report@fda.gov.ph, or call us at the Center for Device Regulation, Radiation Health and Research (CDRRHR) hotline (02) 857-1900 loc. 8301.

Dissemination of the information to all concerned is requested.

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FDA Director General

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