



03 AUG 2018

FDA ADVISORY
No. **2018-239**

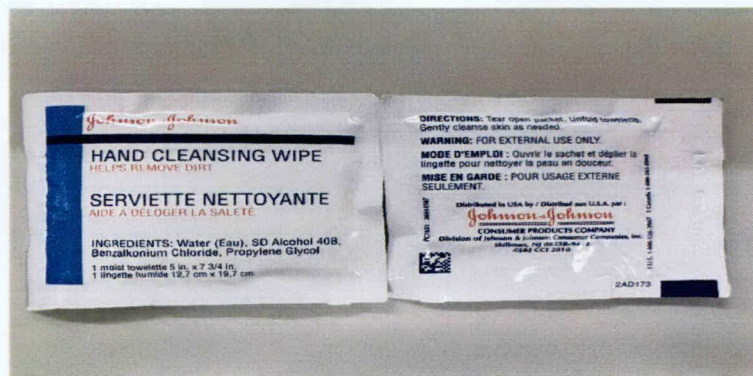
TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT: Public Health Warning Against the Purchase and Use of Unregistered Medical Devices included in Johnson & Johnson First Aid To Go

The Food and Drug Administration (FDA) advises the general public and all healthcare professionals against the purchase and use of the unregistered medical devices included in **Johnson & Johnson First Aid To Go** which are shown below:



Unregistered Medical Device Products included in the Johnson & Johnson First Aid To Go

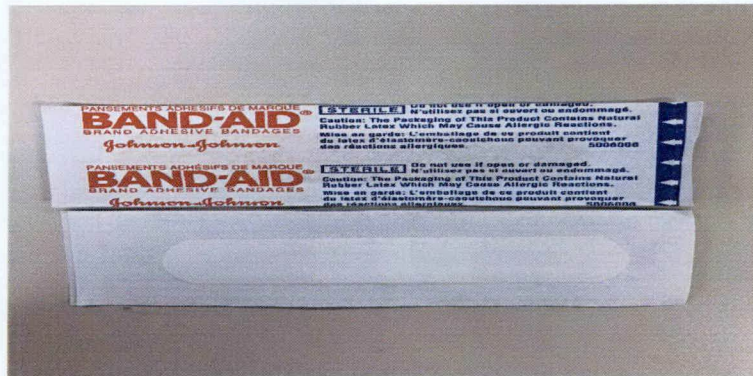


1) Johnson & Johnson Hand Cleansing Wipes 5 in x 7 ³/₄ in (12.7 cm x 19.7 cm)

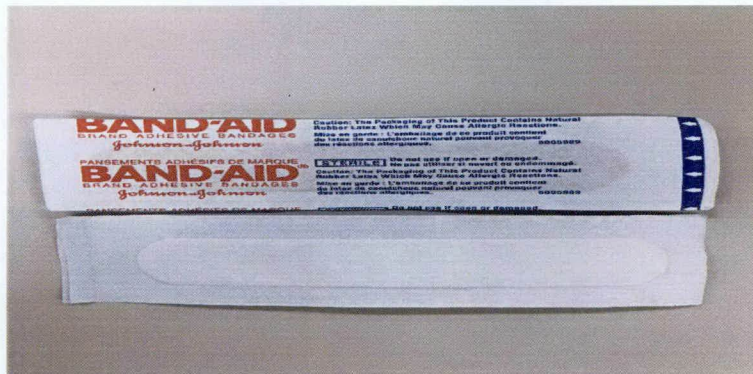




2) Johnson & Johnson Gauze Pads 2 in x 2 in (5 cm x 5 cm)



3) BAND-AID® Brand Flexible Fabric Adhesive Bandages ¾ in x 3 in (1.9 cm x 7.6 cm)



4) BAND-AID® Brand Flexible Fabric Adhesive Bandages 5/8 in x 2 ¼ in (1.5 cm x 5.7 cm)

FDA post-marketing surveillance (PMS) activities have verified that the abovementioned medical devices 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 (CPR). Pursuant to Republic Act 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 their quality and safety. The consumption of such violative products may pose potential health hazards to the consuming public.

Furthermore, the FDA, in coordination with the Market Authorization Holder (MAH), Johnson & Johnson Philippines, Inc., has verified that the above-stated medical device products are counterfeit.

In light of the above, the public is advised not to purchase the aforementioned violative product 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 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 of jurisdiction.

For more information and inquiries, please e-mail 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 local 8301**.

Dissemination of the information to all concerned is requested.


NELA CHARADE G. PUNO, RPh
Director General



20180618165810