



10 JUL 2017

FDA ADVISORY
No. **2017-205**

TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT: Public Health Warning Against the Purchase and Use of the Unregistered Medical Device Product "Stay Fresh Anion Premium Pantyliner"

The Food and Drug Administration (FDA) advises the public against the purchase and use of the unregistered medical device product *Stay Fresh Anion Premium Pantyliner*:

The screenshot shows a Facebook post from the page 'stay fresh'. The main image is a box of 'Stay Fresh Anion Premium Pantyliner'. The box is yellow and orange with a pink and blue design at the bottom. Text on the box includes 'Stay Fresh', 'Anion Premium Pantyliner', and '25'. To the right of the image, the post text reads: 'stay fresh', 'Sold by STAY FRESH - pantyliner', 'P225.00', and a 'Message' button. Below the image, there are 'Share' and 'Save' icons. To the right of the image, there is a 'Product Details' section with the following text: 'Stay Fresh pantyliner with anion chips and far infrared', 'Benefits: *prevent/treat U.T.I, *eliminates odor, *treats dysmenorrhea, *less fatigue/stress', and a 'Report Product' button. At the bottom right, there are 'Like' and 'Comment' buttons, a '1' like count, and a 'Chronological' sorting option.

FDA post-marketing surveillance (PMS) activities have verified that the abovementioned medical device product has not gone through the registration process of the agency and has 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 this unregistered medical device product has 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 product and to be vigilant against medical device that might not be duly registered with FDA. Always check if the medical device product 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 *Stay Fresh Anion Premium Pantyliner* 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 pantyliner, 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.


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