



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. **2018-140**

11 APR 2018

TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT : Public Health Warning Against the Purchase and Use of the Following Unregistered Drug Products:

- 1. Pharmacy's Prescription Solution of Hydrogen Peroxide 3% H₂O₂ U.S.P. Topical Anti-infective**
- 2. Coralite[®] Extra Strength Menthol Pain Relieve Sleeve Medicated Sleeve Pain Relieving Lotion on a Breathable Sleeve**

The Food and Drug Administration (FDA) advises the public against the purchase and use of the following unregistered drug products:



PHARMACY'S PRESCRIPTION SOLUTION OF Hydrogen Peroxide 3% H₂O₂ U.S.P. TOPICAL ANTI-INFECTIVE

Exclusively Distributed by: American Consumer Products, LLC – Los Angeles, CA, U.S.A

Figure 1. Unregistered drug product





Coralite® Extra Strength Menthol Pain Relieve Sleeve Medicated Sleeve Pain Relieving Lotion on a Breathable Sleeve

Distributed by: UNITED EXCHANGE CORP. – 17211 Valley View Ave. Cerritos, CA 90703 USA

Figure 2. Unregistered drug product

FDA Post-Marketing Surveillance (PMS) activities have verified that the abovementioned drug products have not gone through the registration process of the agency and have not been issued with proper authorization in the form of Certificates 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, promotion, advertising or sponsorship of health products without proper authorization from FDA is prohibited.

Accordingly, since these unregistered drug products 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 danger or injury if administered.

In light of the above, the public is advised not to purchase the aforementioned violative products and to be vigilant against drug products that might not be duly registered with the FDA. Always check if a drug product has been registered with the FDA before purchasing it by making use of the embedded *Search* feature of the FDA

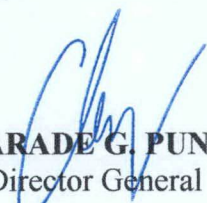
website accessible at www.fda.gov.ph. You may also look for the FDA Registration number on the product label.

All concerned establishments and/or entities are warned not to distribute the above-identified violative drug products until they have 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 these products are 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 unregistered health products, kindly e-mail us via report@fda.gov.ph, or through the online reporting facility, **eReport**, at www.fda.gov.ph/ereport. You may also call the Center for Drug Regulation and Research at telephone number (02)809-5596. For any suspected adverse drug reaction (ADR), report immediately to FDA through this link: www.fda.gov.ph/adr-report-new and fill out all the required fields.

Dissemination of the information to all concerned is requested.


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Director General



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