



FDA ADVISORY
No. **20231450**

19 JUN 2023

TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

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

- 1. H&E Isopropyl Alcohol 70% with Moisturizer 4.5 Liters**
- 2. H&E Isopropyl Alcohol 70% with Moisturizer 3.2 Liters**
- 3. H&E Ethyl Alcohol 70% with Moisturizer 3.78 Liters**
- 4. H&E Ethyl Alcohol 70% with Moisturizer 500 mL**

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

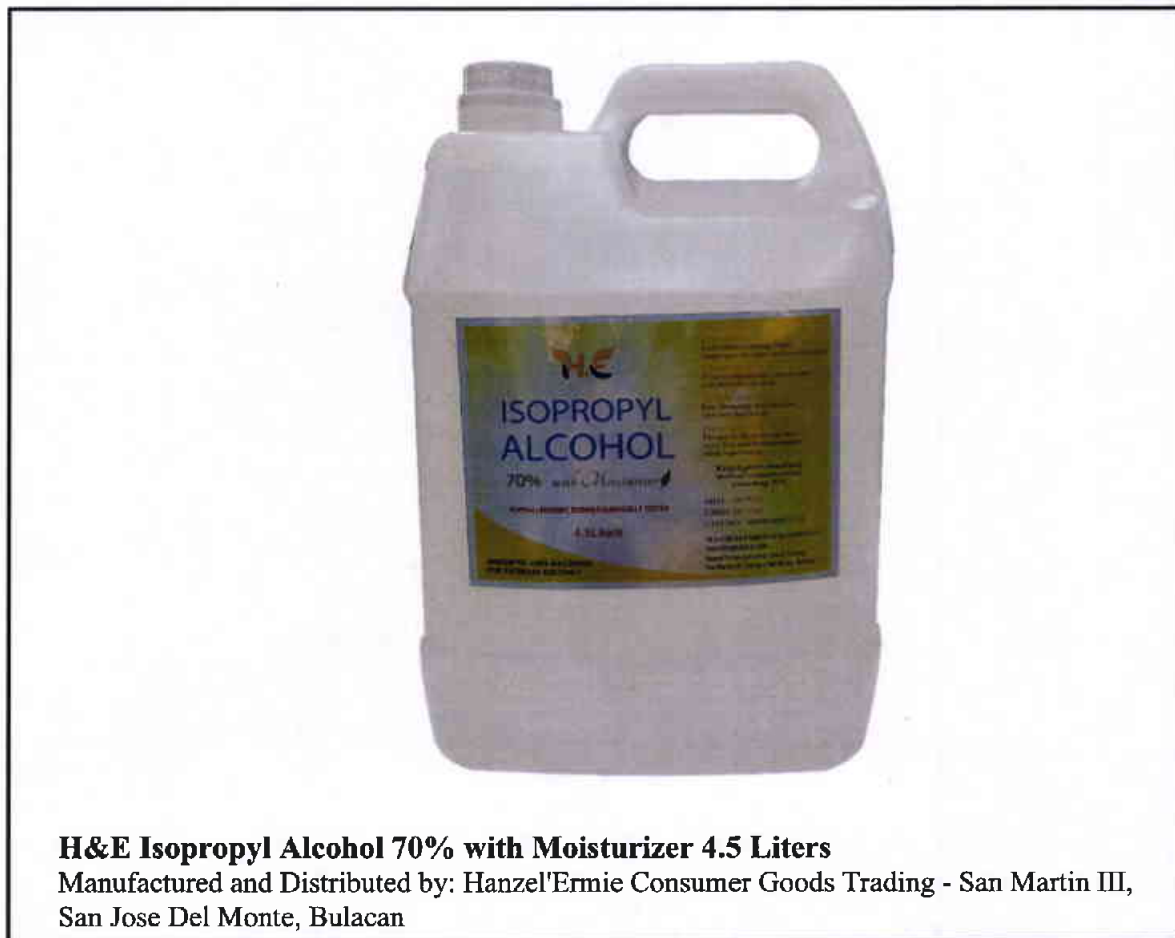


Figure 1. Unregistered and adulterated drug product





H&E Isopropyl Alcohol 70% with Moisturizer 3.2 Liters

Manufactured and Distributed by: Hanzel'Ernie Consumer Goods Trading - San Martin III, San Jose Del Monte, Bulacan

Figure 2. Unregistered and adulterated drug product



H&E Ethyl Alcohol 70% with Moisturizer 3.78 Liters

Manufactured and Distributed by: Hanzel'Ernie Consumer Goods Trading - San Martin III, San Jose Del Monte, Bulacan

Figure 3. Unregistered and adulterated drug product



H&E Ethyl Alcohol 70% with Moisturizer 500 mL

Manufactured and Distributed by: Hanzel'Ermie Consumer Goods Trading - San Martin III, San Jose Del Monte, Bulacan

Figure 4. Unregistered and adulterated 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 Certificate of Product Registration. Thus, the Agency cannot guarantee their quality, safety and efficacy.

In addition, the FDA laboratory analysis showed that the abovementioned drug products contain **Methanol**.

Methanol is a toxic alcohol that is used industrially as a solvent, pesticide, and alternative fuel source which can be absorbed into the body by inhalation, ingestion, skin contact, or eye contact. Effects of short-term exposure (less than 8-hours) may cause an accumulation of acid in the blood (metabolic acidosis), blindness, and death. Initial adverse health effects due to methanol poisoning include drowsiness, reduced level of consciousness (CNS depression), confusion, headache, dizziness, inability to coordinate muscle movement (ataxia), and heart and respiratory (cardiopulmonary) failure. Chronic poisoning from repeated exposure may produce inflammation of the eye (conjunctivitis), insomnia, stomach disturbances, visual failure, and irritation of the skin (dermatitis).

Therefore, consumption of such violative products may pose potential danger or injury to health.

Pursuant to Republic Act No. 9711, otherwise known as the “Food and Drug Administration Act of 2009”, Section 10 subsection (a) and (b), prohibits the following: (a) The manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising or sponsorship of any health product that is adulterated, unregistered or misbranded; (b) The adulteration or misbranding of any health product.

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. Always check if the products are registered with the FDA by using the **FDA Verification Portal feature** accessible at <https://verification.fda.gov.ph>.

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 ereport@fda.gov.ph. You may also call the Center for Drug Regulation and Research at telephone number (02) 8809-5596. For any suspected adverse drug reaction (ADR), report immediately to FDA through this link: <https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH> and fill out all the required fields.

Dissemination of the information to all concerned is requested.

DTN:



20230530162621


DR. SAMUEL A. ZACATE
Director General