Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

29 FEB 2016

FDA ADVISORY
No. 2016-024

TO: **GENERAL PUBLIC**

SUBJECT: **Product Recall of All Lots of Ethyl Alcohol 70% Solution of Roz Laboratories, Inc.**

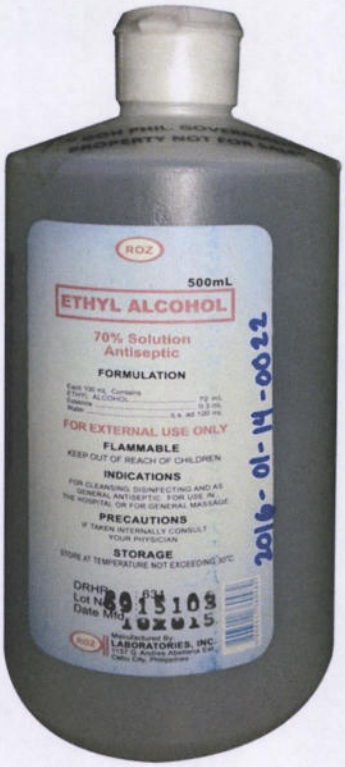
The public is hereby warned by the Food and Drug Administration (FDA) that all lots of Ethyl Alcohol 70% Solution of Roz Laboratories, Inc. are being recalled from the market. The trigger for this was the results of laboratory analysis done by the Common Services Laboratory (CSL)-Cebu Testing & Quality Assurance Laboratory on Lot Number 6915103 of the product wherein samples tested do not conform to the specifications of the test for ethyl alcohol (or ethanol). The result of the analysis was that the product contained 68.6% v/v methyl alcohol or methanol instead of the active ingredient claimed on the label. According to the Centers for Disease Control and Prevention (CDC), adverse health effects from methanol poisoning may manifest, upon ingestion, skin contact, or eye contact, the following: (1) decreased level of consciousness including coma, (2) seizure, (3) ataxia, and (3) blindness. Therefore, it was deemed that all lots of the product are to be recalled and the details are the following:

REGISTRATION NUMBER	**DRHR-631**
LOT NUMBER/ MANUFACTURING DATE	**ALL LOTS / OCTOBER 2015**
MANUFACTURER NAME AND ADDRESS (MAH)	**ROZ LABORATORIES, INC. – 1137 G. ANDRES ABELLANA EXTENSION, CEBU CITY**

Ethyl Alcohol 70% Solution is used as a skin disinfectant. The product is packed in 50 mL, 150 mL, 250 mL, 460 mL, 500 mL, 1 L or 1 gallon of PE White Bottles.

Therefore, distributors, retailers, hospitals, pharmacies or clinics that have any lot of Ethyl Alcohol 70% Solution manufactured by Roz Laboratories, Inc. are instructed to discontinue further distribution, sale and use. All consumers are likewise advised not to purchase or use the product and may contact Roz Laboratories, Inc. at telephone number (032) 253-7483 or e-mail Ms. Evelyn dela Torre at

evelyn_rozlab@yahoo.com or e-mail us at info@fda.gov.ph for any question or additional information regarding the recall.



All Officers of the Field Regulatory Operations Office (FROO) are ordered to monitor the availability of all product lots in the market, appropriately seal discovered stocks of the product, and instruct the concerned establishment to give back the sealed stocks to the Marketing Authorization Holder (MAH) for proper destruction to be witnessed by an appropriate FDA Representative.

Any suspected adverse reaction experienced from the use of any lot of the product should be reported immediately to FDA by visiting www.fda.gov.ph/adr-report-new and fill-out all of the required fields.

Dissemination of the above information to all concerned is requested.

By Authority of the Secretary of Health

MARIA LOURDES C. SANTIAGO, MSc, MM
Officer-in-Charge, Director General

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