Ardil Comercial Issues Voluntary Nationwide Recall of Limar Hand Sanitizer packaged in 4 oz Bottles Because They Resemble Drink Containers

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FOR IMMEDIATE RELEASE – June 30, 2021 – Santo Domingo, Dominican Republic – Ardil Comercial is voluntarily recalling one lot of Limar Hand Sanitizer, packaged in 4 oz bottles to the consumer level. The hand sanitizer is being recalled because it is packaged in containers that resemble water bottles**.** The product poses a risk of ingestion.

Ingesting hand sanitizer, which is intended for topical use, could potentially result in alcohol toxicity. Symptoms of alcohol toxicity may range from lack of coordination, slowed or slurred speech, drowsiness to coma, which can be fatal. Furthermore, ingesting alcohol can affect the brain and cause impaired driving or operating heavy machinery. Alcohol can also interact with numerous drugs which may result in serious adverse effects. Ingesting alcohol by people with alcohol addiction may interfere with maintaining abstinence. Additionally, people with alcohol addiction may seek large amounts of ethanol-based hand sanitizers as a substitute. To date, Ardil Comercial has not received any reports of adverse events related to this recall.

The product is intended to be applied topically to help reduce bacteria on the skin that could cause diseases when soap and water are not available and is packaged in 4 oz bottles. under the brand Limar. The product can be identified by the bottle's labels pictured below. The affected product lots include the following lot number: 079932-4611-05-J with the following expiration date: May 2022. Hand Sanitizer 4 oz Limar was distributed nationwide to a distributor who may have further distributed nationwide in the USA.

Ardil Comercial is notifying its distributors and customers by **telephone, press release** and is arranging for **a replacement** of all recalled products. Consumers and distributors that have the product which is being recalled should return to place of purchase.

Consumers with questions regarding this recall can contact Ardil Comercial by the phone number 809-231-2583 Ext.: 9 or administracion@ardilcomercial.com on Monday-Friday from 8am – 5pm, AST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm[1]
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm[2] or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.