Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2021-1689

21 JUN 2021

TO: **ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

SUBJECT: **Product Recall of Specific Lots of Ascorbic Acid 100 mg/5 mL Syrup (Citruvit)**

All healthcare professionals and the general public are hereby warned by the Food and Drug Administration (FDA) that the affected lots of the subject product are being recalled from the market. The details of the product are as follows:

DRUG PRODUCT	**ASCORBIC ACID 100 mg/5 mL SYRUP (CITRUVIT)**		
REGISTRATION NO.	**HRP-128-03**		
NET CONTENT/LOT NO./EXP. DATE	**120 mL**	**2005038**	**MAY2022**
	60 mL	**2005039**	**MAY2022**
MANUFACTURER	**Azarias Pharmaceutical Laboratories Inc.– 001 Service Road, Zone 1, Pandayan, Meycauayan, Bulacan**		
DISTRIBUTOR [MARKETING AUTHORIZATION HOLDER]	**999 Seth Pharmaceutical Inc. – J.P. Rizal Avenue corner Jaena Street, Kalayaan Village, Brgy. Quebiawan, San Fernando, Pampanga**		

Figure 1. Ascorbic Acid 100 mg/5 mL Syrup (Citruvit) for recall

Based on the results of the laboratory analyses conducted by the FDA, it was found that the affected lots did not conform to the set specifications of assay test. The assay of a drug product determines the (1) presence of a substance and the amount of that substance, or (2) the pharmaceutical potency of a drug. Therefore, the stated lots present quality and efficacy concerns.

Ascorbic Acid is used in the prevention and treatment of scurvy. The affected lots of Ascorbic Acid 100 mg/5 mL Syrup (Citruvit) are packed in an Amber Glass Bottle x 60 mL and 120 mL (Box of 1's).

Therefore, distributors, hospitals, retailers, pharmacies, or clinics that have the affected lots of the product are instructed to discontinue further distribution, sale, and use. Likewise, all consumers are advised not to use or purchase the affected product lots and may contact 999 Seth Pharmaceutical Inc. by sending an e-mail to **999sethpharmaceutical@gmail.com** for any question or additional information regarding the recall.

All Local Government Units (LGU) and Law Enforcement Agencies (LEAs) are requested to ensure that the affected product lots are not sold or made available in their localities or areas of jurisdiction.

For more information and inquiries, please e-mail us at **cdrr_postmarketsurveillance@fda.gov.ph**. To report continuous sale or distribution of the abovementioned, 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**. Any suspected adverse reaction experienced from the use of the products should be reported immediately to the FDA through this link: **https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH** and fill-out all of the required fields.

Dissemination of the information to all concerned is requested.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

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