Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2020-514

03 APR 2020

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

SUBJECT: **Product Recall of Specific Lots of Salbutamol (as sulfate) 2 mg/5 mL Syrup (Strawberry Flavor)**

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

DRUG PRODUCT	**SALBUTAMOL (AS SULFATE) 2 mg/5 mL SYRUP (STRAWBERRY FLAVOR)**	
REGISTRATION NO.	**DR-XY30527**	
LOT NO./EXP. DATE	**NL001K**	**APRIL 2020**
	NL003K	**OCTOBER 2020**
MANUFACTURER [Marketing Authorization Holder (MAH)]	**INTERCHEMEX LABORATORIES, INC. – 900 PALACE ST., BF INTERNATIONAL, LAS PIÑAS CITY**	

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.

Salbutamol is a selective β2-agonist bronchodilator which provides short acting bronchodilation in reversible airways obstruction. It is indicated to rapidly treat asthma, bronchospasm, and reversible airways obstruction by widening the airways of the lungs in adults, adolescents, and children aged 2 to 12 years. Salbutamol (as sulfate) 2 mg/5 mL Syrup (Strawberry Flavor) is packed in a 60 mL amber glass bottle (box of 1's).

Therefore, distributors, hospitals, retailers, pharmacies, or clinics that have the affected lots of the drug product are instructed to discontinue further distribution, sale, and use. All consumers are likewise advised not to purchase or use the affected product lots and may contact Interchemex Laboratories, Inc. at telephone number (02) 8829-7605 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 product 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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