Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. ~~2020-747~~

23 APR 2020

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

SUBJECT: **Product Recall of Specific Lots of Chloramphenicol 5 mg/mL (w/v) Otic Solution (Klorobiz)**

All healthcare professionals and the general public are hereby advised by the Food and Drug Administration (FDA) regarding the voluntary recall by the marketing authorization holder on the affected lots of the subject product from the market. The details of the product are as follows:

DRUG PRODUCT	**CHLORAMPHENICOL 5 mg/mL (w/v) OTIC SOLUTION (KLOROBIZ)**	
REGISTRATION NO.	**DRP-2867**	
LOT NO./EXP. DATE	**8C04A**	**AUGUST 2020**
	8C04B	**NOVEMBER 2020**
MANUFACTURER	**ASHFORD PHARMACEUTICAL LABORATORIES, INC. – 145 P. OLIVEROS ST., ANTIPOLO CITY, RIZAL**	
TRADER [Marketing Authorization Holder (MAH)]	**PHARMABIZ SOLUTIONS, INC. – SUITE 203 COLUMBIAN BLDG., 160 WEST AVE., QUEZON CITY**	

The MAH pursued the voluntary recall of the drug product due to the out-of-specification result on its assay observed in the 24th-month of its shelf-life. 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, safety, and efficacy concerns.

Chloramphenicol in otic solution is indicated for the topical treatment of bacterial infection of the external ear caused by pathogens which are sensitive to it. It is active against a wide range of Gram-negative and Gram-positive organisms. Chloramphenicol 5 mg/mL Otic Solution (Klorobiz) is packed in a 10 mL LDPE plastic bottle.

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 Pharmabiz Solutions, Inc. at mobile no. +639274121330 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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