Republic of the Philippines
Department of Health
**FOOD AND DRUG ADMINISTRATION**

**FDA ADVISORY**
No. 2020-746

23 APR 2020

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

**SUBJECT:** **Product Recall of Specific Batches of Ranitidine (as Hydrochloride) 150 mg Film-Coated Tablet (Peptica)**

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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 batches of the subject product from the market. The details of the product are as follows:

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|---|---|---|
| DRUG PRODUCT | **RANITIDINE (AS HYDROCHLORIDE) 150 mg FILM-COATED TABLET (PEPTICA)** | |
| REGISTRATION NO. | **DR-XY32636** | |
| BATCH NO./EXP. DATE | **1701784** | **May 2020** |
| | **1900704** | **March 2022** |
| | **1900705** | **March 2022** |
| MANUFACTURER | **BERLIN PHARMACEUTICAL INDUSTRY CO. LTD. – 222 ROMKLAO ROAD, KLONGSAMPRAVET, LATKRABANG, BANGKOK 10520, THAILAND** | |
| IMPORTER/ DISTRIBUTOR [Marketing Authorization Holder (MAH)] | **LITTMAN DRUG CORPORATION – 3RD FLOOR NO. 3 JAIME CARDINAL SIN ST., PLEASANT HILLS, MANDALUYONG CITY** | |

The MAH pursued the voluntary recall of the drug product due to the presence of the impurity, N-nitrosodimethylamine (NDMA), a probable human carcinogen (a substance that could cause cancer) in the active pharmaceutical ingredient supplied or manufactured by SMS Lifesciences India Ltd., in India. Therefore, the stated batches present quality and safety concerns.

Ranitidine is indicated for the treatment of duodenal and gastric ulcer, including that associated with H pylori, NSAID-associated peptic ulcer, post-operative ulcer, acute reflux esophagitis, Zollinger-Ellison syndrome, chronic episodic dyspepsia, symptomatic relief in gastro-esophageal reflux disease, and prophylaxis of Mendelson's syndrome. Ranitidine (as Hydrochloride) 150 mg Film-Coated Tablet (Peptica) is packed in a foil strip x 10 tablets (box of 100's).

Therefore, distributors, hospitals, retailers, pharmacies, or clinics that have the affected batches 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 batches and may contact Littman Drug Corporation at telephone no. (02) 8696-3294 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 batches 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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