Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2016-023

29 FEB 2016

TO: **GENERAL PUBLIC**

SUBJECT: **Voluntary Product Recall of Omeprazole 20 mg Tablet (Omepracid)**

This is to inform the public that Ritzen Philippines, Inc., the Marketing Authorization Holder (MAH), is voluntarily recalling specific batches of Omeprazole 20 mg Tablet (Omepracid) in line with the disapproval of the Renewal Application (RA) of the drug product due to the non-conformance to the approved finished product specifications. The product is round, moss green tablet instead of the approved specifications, round, white, bevel-edge tablet with score on one side and plain on the other. The details of the non-conforming batches are as follows:

REGISTRATION NUMBER		**DR-XY36525**	
BATCH NUMBER	MANUFACTURING DATE / EXPIRY DATE	**X4N33**	**JULY 2014 / JULY 2016**
		5J219	**MAY 2015 / MAY 2017**
MANUFACTURER		**ASHFORD PHARMACEUTICAL LABORATORIES, INC. – 145 P. OLIVEROS ST., ANTIPOLO CITY**	
TRADER (MAH)		**RITZEN PHILIPPINES, INC. – 7/F SOUTH CENTER TOWER, 2206 MARKET ST., MADRIGAL BUSINESS PARK II, ALABANG, MUNTINLUPA CITY**	

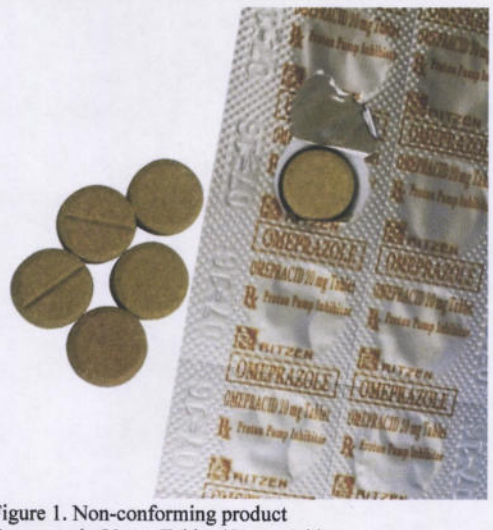

Figure 1. Non-conforming product
Omeprazole 20 mg Tablet (Omepracid)

Omeprazole 20 mg Tablet (Omepracid) is used for the treatment of conditions where inhibition of gastric acid secretion is beneficial, such as peptic ulcer, gastro-esophageal reflux disease, dyspepsia, and Zollinger-Ellison syndrome. This product is packaged in blister packs of ten (10) tablets in box of fifties (50's).

The renewal of marketing authorization of the drug product has been disapproved. Therefore,

all product batches in the Philippine market must be recalled. Distributors, retailers, hospitals, pharmacies or clinics that have any batch of the drug product are instructed to discontinue further distribution, sale and use. All consumers are likewise advised not to purchase or use the product and may contact Ritzen Philippines, Inc. at telephone number +632 850-6844 or mobile nos. +63 905 3580247 or +63 908 6072874 or e-mail us at info@fda.gov.ph for any question or additional information regarding the recall.

All Officers of the Field Regulatory Operations Office (FROO) are ordered to monitor the availability of the product in the market, to appropriately seal discovered stocks of the product, and to instruct the concerned establishment to return the sealed stocks to the MAH for proper destruction to be witnessed by an appropriate FDA Representative.

Any suspected adverse reaction experienced from the use of the aforementioned product batches should be reported immediately to FDA through this link: www.fda.gov.ph/adr-report-new and fill-out all of the required fields.

Dissemination of the above information to all concerned is requested.

By Authority of the Secretary of Health

MARIA LOURDES C. SANTIAGO, MSc, MM
Officer-in-Charge, Director General