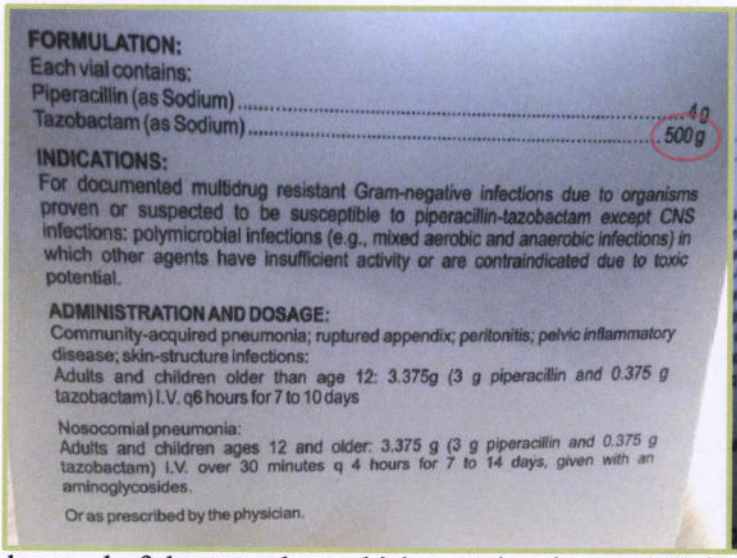
Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

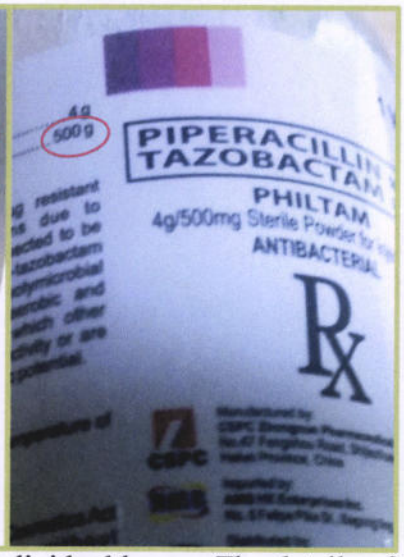
22 SEP 2015

FDA Advisory No. 2015-071

SUBJECT: VOLUNTARY PRODUCT RECALL OF BATCH SPECIFIC PIPERACILLIN (AS SODIUM) + TAZOBACTAM (AS SODIUM) 4 g/500 mg POWDER FOR INJECTION (PHILTAM)

This is to inform the public that PhilRx Pharma Inc. is voluntarily recalling the impacted batch of Piperacillin (as sodium) + Tazobactam (as sodium) 4 g/500 mg Powder for Injection with brand name Philtam due to mislabeling reasons. The error which shows the dosage strength of Tazobactam (as sodium) as 500 g instead of 500 mg can be seen under Formulations on the vial, on the side panels of the individual





box and of the outer box which contains the ten (10) individual boxes. The details of the affected batch are as follows:

BRAND NAME	**PHILTAM**
REGISTRATION NUMBER	**DRP-3555-01**
BATCH NUMBER/ EXPIRY DATE	**773150402 / APRIL 2017**
MANUFACTURER	**CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUNG) CO. LTD. – 188 GONGNONG ROAD, SHIJIAZHUANG, HEBEI PROVINCE, CHINA**

IMPORTER	**AMB HK ENTERPRISES INC. – NO. 6 FELIPE PIKE ST., BAGONG ILOG, PASIG CITY**
DISTRIBUTOR	**PHILRX PHARMA INC. – AMB BLDG. NO. 6 FELIPE PIKE ST., BAGONG ILOG, PASIG CITY**

Piperacillin (as sodium) + Tazobactam (as sodium) 4 g/500 mg Powder for Injection (Philtam) is used for documented multidrug resistant Gram-negative infections due to organisms proven or suspected to be susceptible to piperaciilin-tazobactam except CNS infections: polymicrobial infections (e.g. mixed aerobic and anaerobic infections) in which other agents have insufficient activity or are contraindicated due to toxic potential. The drug product is packed in type I glass vial in a plastic tray enclosed in an individual box. An outer box contains ten (10) individual boxes of the drug product.

The affected product batch presents safety risks due to mislabeling. Therefore, distributors, hospitals, retailers or pharmacies that have the affected 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 affected product batch.

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

Consumers may contact PhilRx Pharma Inc. at telephone number +632 655-5492 or e-mail us at info@fda.gov.ph for any question or additional information regarding the recall.

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

JANETTE P. LORETO-GARIN, MD, MBA-H
Secretary of Health
Acting Director General[1]

DTN: 20150815111428
[1]Pursuant to DPO 2015-1845