Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

22 June 2015

FDA Advisory
No. 2015-049

SUBJECT: **VOLUNTARY RECALL OF SPECIFIC LOTS OF BENZATHINE BENZYLPENICILLIN (ZALPEN) 1,200,000 UNITS PER VIAL STERILE POWDER FOR INJECTION (I.M.)**

This is to inform the public that YSS Laboratories Co., Inc. is voluntarily recalling specific lots of Benzathine Benzylpenicillin 1,200,000 Units per vial Sterile Powder for Injection (IM) with brand name Zalpen, due to the complaints of clogging on the needle during patient administration. The details of the affected product lots are as follows:

REGISTRATION NUMBER	**DR-XY20237-B**
LOT NUMBERS	**1057 & 1058**
MANUFACTURING DATES	**NOVEMBER 2014 & DECEMBER 2014**
EXPIRATION DATES	**NOVEMBER 2018 & DECEMBER 2018**
MANUFACTURER NAME/ADDRESS	**YSS LABORATORIES CO., INC. – 1133 UNITED NATIONS AVENUE, PACO, MANILA**
DISTRIBUTOR NAME/ADDRESS	**THE CATHAY DRUG CO., INC. – 2/F VERNIDA, 120 AMORSOLO ST., LEGASPI VILLAGE, MAKATI CITY**

Benzathine Benzylpenicillin (Zalpen) 1,200,000 Units per vial Sterile Powder for Injection (IM) is used for the treatment of diphtheria, pharyngitis, rheumatic fever, spleen disorders and syphilis. This product is packed in a clear & colorless glass vial with rubber stopper and aluminum flip off seal (Box of 10's).

The affected product lots present safety risks and potential adverse health consequences. Therefore, distributors, hospitals, retailers or pharmacies that have the affected lots of Benzathine Benzylpenicillin (Zalpen) 1,200,000 Units per vial Sterile Powder for Injection (IM) are instructed to discontinue its distribution, sale and use. All consumers are likewise advised not to purchase or use the affected product lots and may contact YSS Laboratories Co., Inc. at telephone number (02) 524-0061 to 63 or e-mail us at info@fda.gov.ph for any question or additional information regarding the recall.

All Field Regulatory Operations Office (FROO) Officers are ordered to monitor the availability of the product lots in the market, to seal the discovered stocks of the affected lots of the product, and to 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.

Any suspected adverse reaction experienced from the use of the aforementioned product lots 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: 20150619143946

[1]Pursuant to DPO 2015-1845