



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. **2016-020**

29 FEB 2016

TO: GENERAL PUBLIC

SUBJECT: Termination of Product Recall Order (PRO) on Specific Lots of Benzathine Benzylpenicillin 1,200,000 Units per Vial Sterile Powder for Injection (I.M.) (Zalpen)

This is to inform the public that the Product Recall Order (PRO) issued on lot numbers 1057 and 1058 of Benzathine Benzylpenicillin 1,200,000 Units per Vial Sterile Powder for Injection (I.M.) (Zalpen) is hereby terminated by the Food and Drug Administration (FDA). The product lots were manufactured by YSS Laboratories Co., Inc.

As stated in the FDA Advisory No. 2015-049 dated 22 June 2015, FDA informed the public on the voluntary recall of the said lots due to complaints of clogging on the needle during patient administration.

After due and thorough evaluation of the documents submitted by The Cathay Drug Company, Inc., the Marketing Authorization Holder (MAH), FDA has determined that reasonable efforts had been made to recall and properly destroy the affected product lots in accordance with Bureau Circular No. 8 s. 2001, known as the Guidelines to be Observed on the Implementation of Product Recall System.

The issuance of this advisory shall not in any manner preclude this Office from issuing subsequent orders it may deem necessary and appropriate, should there be findings of any violation of existing laws, rules and regulations.

All Officers of the Field Regulatory Operations Office (FROO) are ordered to inventory and seal any discovered stocks of the affected lots of the subject product, and to instruct the concerned establishment to give back the sealed stocks to the MAH for proper destruction to be witnessed by an appropriate FDA representative.

Consumers may contact FDA at telephone number +632 857-1900 or via e-mail at info@fda.gov.ph for any questions or additional information regarding the recalled products.

Dissemination of the information to all concerned is requested.

By Authority of the Secretary of Health

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

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