



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY

29 FEB 2016

No. **2016-022**

TO: GENERAL PUBLIC

SUBJECT: Termination of Product Recall Order (PRO) on Batch Specific Tamoxifen (as citrate) 20 mg Tablet (Nolvadex®-D)

This is to inform the public that the Product Recall Order (PRO) issued on batch number 60002877 of Tamoxifen (as citrate) 20 mg Tablet (Nolvadex®-D) is hereby terminated by the Food and Drug Administration (FDA). The product batch was manufactured by AstraZeneca UK Ltd.

As stated in the FDA Advisory No. 2015-075 dated 22 September 2015, FDA informed the public on the recall of the affected batch due to a packaging issue wherein there were imperfect sealing of blister packs of the subject product.

After due and thorough evaluation of the submitted documents by AstraZeneca Pharmaceuticals (Phils.), Inc., the Marketing Authorization Holder (MAH), FDA has determined that reasonable efforts had been made to recall and properly destroy the affected product batch 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.

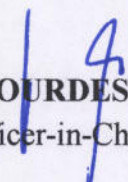
All Officers of the Field Regulatory Operations Office (FROO) are ordered to inventory and seal any discovered stocks of the affected batch of the subject product, and to instruct the concerned establishment to return the sealed stocks to the MAH for proper destruction to be witnessed by an appropriate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



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 product.

Dissemination of the information to all concerned is requested.

By Authority of the Secretary of Health


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