Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

22 SEP 2015

FDA Advisory
No. 2015-075

SUBJECT: PRODUCT RECALL OF BATCH SPECIFIC TAMOXIFEN (AS CITRATE) 20 mg TABLET (NOLVADEX®-D)

The public is hereby warned by the Food and Drug Administration (FDA) that a specific batch of Tamoxifen (as citrate) 20 mg Tablet with brand name Nolvadex®-D is being recalled from the market due to a packaging issue reported by the Marketing Authorization Holder (MAH), AstraZeneca Pharmaceuticals (Phils.), Inc. The details of the affected product batch are as follows:

REGISTRATION NUMBER	**DR-XY14048**
BATCH NUMBER/ EXPIRY DATE	**60002877 / MAY 2016**
MANUFACTURER	**ASTRAZENECA UK LTD. MACCLESFIELD, CHESHIRE, UK**
PACKER	**ASTRAZENECA PHARMACEUTICAL CO., LTD. NO. 2 HUANGSHAN ROAD WUXI, JIANGSU, CHINA**
IMPORTER	**ASTRAZENECA PHARMACEUTICALS (PHILS.), INC. 16/F NET 3 CENTER CORNER 3RD AVE. AND 30TH STREET, BONIFACIO GLOBAL CITY, TAGUIG CITY**

Tamoxifen (as citrate) 20 mg Tablet (Nolvadex®-D) is used for metastatic breast cancer in women and men, and as treatment of both node-positive breast cancer in postmenopausal women and of axillary node-negative breast cancer in women following total mastectomy or segmental mastectomy, axillary dissection and breast irradiation. The drug product is packed in a blister pack containing 10 tablets (Box of 30 tablets).

The affected product batch presents safety risks and may cause therapeutic failure due to the packaging issue (some blister packs with imperfect sealing). 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 AstraZeneca Pharmaceuticals (Phils.), Inc. at telephone number +632 777-8700 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: 20150815160940
[1]Pursuant to DPO 2015-1845