Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

26 February 2015

FDA Advisory
No. 2015-016

SUBJECT: TERMINATION OF PRODUCT RECALL ORDER ISSUED ON SPECIFIC BATCHES OF PAROXETINE (SEROXAT) 20mg TABLET

This is to inform the public that the recall order issued on batches 601, 602M and 603 of Paroxetine (Seroxat) 20mg Tablet with registration number DR-XY16055 is hereby terminated by the Food and Drug Administration (FDA). This product is manufactured by S.C. Europharm S.A. in Romania and imported by GlaxoSmithKline Philippines, Inc.

As stated in the FDA Advisory No. 2014-038 dated 12 May 2014, GlaxoSmithKline Philippines, Inc. voluntarily recalled the product batches due to the critical deviation on the current Good Manufacturing Practice (cGMP) which caused the Paroxetine Active Pharmaceutical Ingredient (API) to be adulterated.

After careful evaluation of the submitted documents, FDA has determined that reasonable efforts had been made by the Marketing Authorization Holder (MAH), GlaxoSmithKline Philippines, Inc., to recall and properly destroy the impacted product batches 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 any findings of any violation of existing laws, rules and regulations.

All field Food and Drug Regulation Officers are ordered to monitor and seize the cited product batches if found available in the market.

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 this recalled product.

ATTY. NICOLAS B. LUTERO III, CESO III
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