Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

CENTER FOR DRUG REGULATION AND RESEARCH

12 May 2014

FDA Advisory
No. 2014-038

SUBJECT: GLAXOSMITHKLINE PHILIPPINES, INC. VOLUNTARY RECALLS BATCH NOS. 601, 602M, AND 603 OF PAROXETINE 20 mg TABLET (SEROXAT)

A Warning Letter was issued by the US FDA to GlaxoSmithKline (GSK), USA because the Active Pharmaceutical Ingredient (API) manufacturer, SmithKline Beecham (Cork) Ltd. at Currabinny, Carrigaline Cork, Ireland had critical deviations which caused the Paroxetine API to be adulterated.

Non-compliance to cGMP had resulted in the voluntary recall of specific batches of Paroxetine 20 mg Tablet (Seroxat).

REGISTRATION NUMBER	**DR-XY16055**
BATCH NUMBERS	**601 / 602M / 603**
MANUFACTURING NAME AND ADDRESS	**S.C. EUROPHARM S.A. 2 PANSELELOR STREET, BRASOV, 500419, ROMANIA**

Paroxetine is indicated for treatment of depression, obsessive-compulsive disorder and panic disorder with or without agoraphobia.

All consumers are advised to buy their medicines from legitimate pharmacies and drug outlets and ask for official receipts. If you happen to buy batches of Seroxat® that are subject of product recall, consumers may report to FDA via report@fda.gov.ph or to GlaxoSmithKline Philippines, Inc. at tel. nos.: +632 864 8516 and +632 892 0761 ext. 8643 or mobile nos.: +63 917 888 2315 and +63 917 859 4598.

For more information and inquiries, please e-mail us at info@fda.gov.ph. Any suspected adverse reaction experienced from the aforementioned product should be reported immediately to FDA by visiting www.fda.gov.ph. Look for the ADR Report tab, proceed and fill-out all of the required fields.

KENNETH HARTIGAN-GO, MD
Acting Director General