Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

CENTER FOR DRUG REGULATION AND RESEARCH

28 April 2014

FDA Advisory
No. 2014-035

SUBJECT: SANOFI-AVENTIS PHILIPPINES, INC. VOLUNTARY RECALLS BATCH NOS. C1272H08, C1282H20, AND C1282H31 OF RABBIT ANTI-HUMAN THYMOCYTE IMMUNOGLOBULIN (THYMOGLOBULIN)

Due to out of specification (OOS) findings on the product stability prior to the expiration date, specific batches of Rabbit Anti-Human Thymocyte Immunoglobulin (Thymoglobuline) 5 mg/mL Powder for Solution, for IV Infusion has been voluntarily recalled.

REGISTRATION NUMBER	**BR-289**
BATCH NUMBERS / EXPIRY DATE	**C1272H08 / MARCH 2014** **C1282H20 / MAY 2014** **C1282H31 / MAY 2014**
MANUFACTURING NAME AND ADDRESS	**GENZYME POLYCLONALS S.A.S.** **1541 AVENUE MARCEL MERIEUX BATIMENTS C4 ET C5, 69280 MARCY L'ETOILE, FRANCE**

Rabbit Anti-Human Thymocyte Immunoglobulin is a biological product indicated for immunosuppression in transplantation or prophylaxis and treatment of graft rejection. It is also used for the treatment of severe aplastic anemia.

The batches of Thymoglobuline® showed a trend of increasing molecular size, approaching the upper limit of 5.0% for polymers, with observed aggregation and fragmentation. The unusual trend was attributed to technical issues in preventive maintenance of the stoppers, which increased the residual moisture inside the product and caused aggregation of the lyophilized powder.

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 Thymoglobuline® that are subject of product recall, consumers may report to FDA via report@fda.gov.ph or to Sanofi-Aventis Philippines, Inc. at tel. no.: +632 859 5555.

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