Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

26 February 2015

FDA Advisory
No. 2015-012

SUBJECT: TERMINATION OF PRODUCT RECALL ORDER ISSUED ON SPECIFIC BATCHES OF RABBIT ANTI-HUMAN THYMOCYTE IMMUNOGLOBULIN (THYMOGLOBULINE)

This is to inform the public that the recall order issued on batches C1272H08, C1282H20 and C1282H31 of Rabbit Anti-human Thymocyte Immunoglobulin (Thymoglobuline) with registration number BR-289 is hereby terminated by the Food and Drug Administration (FDA). This product is manufactured by Genzyme Polyclonals S.A.S. in France and imported by Sanofi-Aventis Philippines, Inc.

As stated in the FDA Advisory No. 2014-035 dated 28 April 2014, Sanofi-Aventis Philippines, Inc. voluntarily recalled the product batches due to Out of Specification (OOS) findings on the product stability prior to expiration date.

After careful evaluation of the submitted documents, FDA has determined that reasonable efforts had been made by the Marketing Authorization Holder (MAH), Sanofi-Aventis Philippines, Inc., to recall and properly destroy the impacted 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 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
OIC-Director IV, Food and Drug Administration