Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

22 May 2015

FDA Advisory
No. 2015-028

SUBJECT: **PUBLIC WARNING AGAINST BATCH NO. EAS4300 OF EPOIETIN ALFA (RECOMBINANT HUMAN ERYTHROPOIETIN) 4000 IU/0.4 mL SOLUTION FOR INJECTION (I.V./ S.C.) WITH BRAND NAME EPREX OF JOHNSON & JOHNSON (PHILS.) INC.**

The public is hereby warned by the Food and Drug Administration (FDA) to be vigilant about the subject product due to the Rapid Alert Notification of a Quality Defect provided by Agence Nationale de Sécurité du Médicament et des Produits de santé (ANSM) in France coursed through the World Health Organization (WHO). The stated batch of the subject product along with other identified batch numbers were determined to be distributed to a total of fifty-nine (59) countries. The details of the subject product are as follows:

REGISTRATION NUMBER	**BR-701**
BATCH NUMBER	**EAS4300**
EXPIRY DATE	**JUNE 2015**
MANUFACTURER	**CILAG AG HOCHSTRASSE 201, 8200 SCHAFFHAUSEN, SWITZERLAND**
IMPORTER	**JOHNSON & JOHNSON (PHILS.) INC. EDISON ROAD, BO. IBAYO, PARAÑAQUE CITY**
DISTRIBUTOR	**ZUELLIG PHARMA CORPORATION KM. 14 WEST SERVICE ROAD, SOUTH SUPER HIGHWAY CORNER EDISON AVENUE, BRGY. SUN VALLEY, PARAÑAQUE CITY**

The drug product is for the treatment of anemia of chronic renal failure, anemia associated with HIV infections and anemia of malignancy. The subject product is also indicated in adult patients with mild to moderate anemia (hemoglobin >10 to <13 gm/dL) schedule for elective orthopedic surgery with an expected moderate blood loss (2-4 units or 900 to 1,800 mL) to reduce exposure to allogenic blood transfusion and to facilitate erythropoietic recovery.

Hospitals are instructed not to administer the said impacted batch of the drug product. Retail outlets (e.g. pharmacies) are directed not to offer for sale the said batch of the drug product and are hereby advised to remove the stated batch of Epoietin Alfa (Recombinant Human Erythropoietin) 4,000 IU/0.4 mL Solution for Injection (I.V./S.C.) with brand name, Eprex, from the selling areas due to identification of the manufacturer, Cilag AG, that the said batch does not fit the historical stability profile meant for oxidized methionine and may not meet the specification to end of shelf life.

Furthermore, consumers are instructed not to purchase or use the affected batch of the drug product and report to FDA at report@fda.gov.ph or call us at 802-8275 if the said batch is offered for sale.

Moreover, any adverse reaction experienced from use of the aforementioned product should be reported immediately to FDA by visiting www.fda.gov.ph. Look for the downloadable suspected adverse reaction form at the industry corner, fill-out all of the required fields and send via e-mail at adr@fda.gov.ph.

This is the initial course of action of FDA in order to inform the public accordingly. FDA is closely coordinating with the concerned company regarding the affected batch of the subject product for risk management actions and is pursuing other regulatory actions.

JANETTE P. LORETO-GARIN, MD, MBA-H
Secretary of Health
Acting Director General

DTN: 20150522161750
[1]Pursuant to DPO 2015-1845