Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2016-016

05 FEB 2016

SUBJECT: **Product Recall of Specific Batches of Paliperidone 6 mg Extended-Release Tablet (Invega)**

The public is hereby warned by the Food and Drug Administration (FDA) that specific batches of Paliperidone 6 mg Extended-Release Tablet (Invega) are being recalled from the market. This is due to the notification of the Marketing Authorization Holder (MAH), Johnson & Johnson (Philippines), Inc., regarding an Out-of-Specification (OOS) result of the release rate at the 12th-month in the long-term stability testing (30^{0}C/75%RH) of one (1) batch, DCZSK00, of the drug product. This batch was packed in PVC-Aclar/Aluminum Blister pack.

It was reported that the release rate was affected by higher levels of humidity when the PVC-Aclar/Aluminum Blister Pack was used. Batch DCZSK00 already expired last February 2015. The other affected batches distributed in the Philippine market which are ordered for recall bear the following details:

REGISTRATION NUMBER	**DR-XY33920**
BATCH NUMBER / EXPIRY DATE	**ECZU100 / FEBRUARY 2016** **EJZT600 / SEPTEMBER 2016** **FAZS600 / DECEMBER 2016**
MANUFACTURER NAME AND ADDRESS	**JANSSEN-CILAG MANUFACTURING L.L.C. – STATE ROAD 933 KM. 0.1, MAMEY WARD, GURABO, 00778-9629, PUERTO RICO**
IMPORTER (MAH)	**JOHNSON & JOHNSON (PHILIPPINES), INC. – EDISON ROAD, BO. IBAYO, PARAÑAQUE CITY**
DISTRIBUTOR	**ZUELLIG PHARMA CORPORATION – KM. 14 WEST SERVICE ROAD, SOUTH SUPER HIGHWAY COR. EDISON AVE., SUN VALLEY, PARAÑAQUE CITY**

Paliperidone 6 mg Extended-Release Tablet (Invega) is used for the recurrence prevention and maintenance therapy for Schizophrenia; for the treatment of acute manic episodes associated with bipolar I disorder; for the treatment of schizoaffective disorder as monotherapy and as an adjunct to mood stabilizers and/or anti-depressants. The product is packed in Alu/Alu blister pack x 7 tablets in boxes of 28 tablets.

Therefore, distributors, hospitals, retailers, pharmacies or clinics that have the affected batches of the drug product are instructed to discontinue further distribution, sale and use. All consumers are likewise advised not to purchase or use the affected product batches and may contact Johnson & Johnson (Philippines), Inc. at telephone number +632 368-8946 or mobile no. +63 917 8261588 or e-mail us at info@fda.gov.ph for any question or additional information regarding the recall.

All Officers of the Field Regulatory Operations Office (FROO) are ordered to monitor the availability of the product batches in the market, appropriately seal discovered stocks of the affected batches of the product, and instruct the concerned establishment to return the sealed stocks to the MAH for proper destruction to be witnessed by an appropriate FDA Representative.

Any suspected adverse reaction experienced from the use of the aforementioned product batches should be reported immediately to FDA through this link: www.fda.gov.ph/adr-report-new and fill-out all of the required fields.

MARIA LOURDES C. SANTIAGO, MSc, MM
Officer-in-Charge, Director General
Food and Drug Administration

DTN: 20151110161214