Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2015-082

03 NOV 2015

SUBJECT: **Product Recall of Batch Specific Dobutamine (as Hydrochloride) 12.5 mg/mL (250 mg/20 mL) Solution for Injection (Dobucard)**

The public is hereby warned by the Food and Drug Administration (FDA) that the following batch of Dobutamine (Dobucard) (as Hydrochloride) 12.5 mg/mL (250 mg/20 mL) Solution for Injection is being recalled from the market. The details of the product are as follows:

REGISTRATION NUMBER	**DRP-4094**
BATCH NUMBER / EXPIRY DATE	**4OEB01011 / APRIL 2017**
MANUFACTURER NAME AND ADDRESS	**OBOI LABORATORIES – N-118, MIDC, TARAPUR, INDIA**
IMPORTER/DISTRIBUTOR	**PHIL. PHARMAWEALTH, INC. SUITE 3001, EAST TOWER, PSE CENTER, EXCHANGE RD., ORTIGAS CENTER, PASIG CITY**

Based on the result of laboratory analyses conducted by the Food and Drug Administration it was noted that all samples tested from this batch manifested discolored rubber stopper and aluminum seals. Thus, it was determined that the stated batch of the drug product presents safety risks and no guarantee of good quality.

Dobutamine (Dobucard) (as Hydrochloride) 12.5 mg/mL (250 mg/20 mL) Solution for Injection is used to increase the contractility of the heart failure, as occurs in cardiogenic shock and myocardial infarction and it is also used for septic shock. The product is packed in a 20 mL USP Type Amber glass vial.

The affected batch presents safety risks and potential adverse health consequences. Therefore, distributors, retailers, hospitals, pharmacies or clinics that have the affected batch of Dobutamine (Dobucard) (as Hydrochloride) 12.5 mg/mL (250 mg/20 mL) Solution for Injection are instructed to discontinue further distribution, sale and use. All consumers are likewise advised not to purchase or use the affected product batch. Please contact Phil. Pharmawealth, Inc. at telephone numbers 683 0053 to 57 or e-mail us at info@fda.gov.ph for any questions or additional information regarding the recall.

All field Food Drug Regulation Officers are ordered to monitor the availability of the product batch in the market, to seal the discovered stocks of the affected batch of the product, and to instruct the concerned establishment to give back the sealed stocks to the Marketing Authorization Holder (MAH) for proper destruction to be witnessed by an appropriate FDA Representative.

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

JANETTE P. LORETO-GARIN, MD, MBA-H
Secretary of Health
Acting Director General[1]

DTN: 20150914113430

[1]Pursuant to DPO 2015-1845