Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

09 July 2014

FDA Advisory
No. **2014-055**

SUBJECT: VOLUNTARY RECALL OF THE SPECIFIC BATCHES OF DOBUTAMINE (as HYDROCHLORIDE) 12.5 MG/ML (250 MG/20ML) SOLUTION FOR INJECTION (DOBULON) WITH BATCH NUMBERS DBI1301BC, DBI1302BC and DBI1303BC (DRP-3997)

This is to inform the public that I.E. Medica, Inc. is initiating a product recall of the specific batches of Dobutamine (as Hydrochloride) 12.5 mg/mL (250 mg/20mL) Solution for Injection (Dobulon) with Batch Numbers DBI1301BC, DBI1302BC and DBI1303BC (DRP-3997) due to the change in appearance of the product from clear pale yellowish solution to dark yellow solution. The details of the affected batches are as follows:

Registration Number	DRP-3997
Batch Numbers	DBI1301BC, DBI1302BC and DBI1303BC
Importer/Distributor's Name and Address	I.E. Medica, Inc. – 5/F RFM Corporate Center, Pioneer St., Mandaluyong City
Manufacturer's Name and Address	Celon Laboratories Limited – No. 2, ALEAP Industrial Estate, Gajularamaram, Ranga, Reddy District, Andhra Pradesh, India

Dobutamine (as Hydrochloride) 12.5 mg/mL (250 mg/20mL) Solution for Injection (Dobulon) is used to increase the contractility of the heart in acute heart failure, as occurs in cardiogenic shock and myocardial infarction, and it is also used in septic shock. It is packed in a box containing one (1) vial of Dobutamine (as Hydrochloride) 12.5 mg/mL, and each vial contains 20mL solution.

All field Food and Drug Regulation Officers are ordered to monitor the availability of the product batches in the market.

Distributors, retailers, hospitals, pharmacies, or clinics that have the said batches of Dobutamine (as Hydrochloride) 12.5 mg/mL (250 mg/20mL) Solution for Injection (Dobulon) are instructed to discontinue further distribution, sale and use.

Consumers may contact I.E. Medica, Inc. at telephone number +632 634-4434, or e-mail at info@iemedica.com.ph. Consumers may also e-mail the FDA at info@fda.gov.ph for any questions or additional information regarding the recall.

Any 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 and proceed to fill-out all of the required fields.

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Acting Director General