Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

26 February 2015

FDA Advisory
No. 2015- 018

SUBJECT: TERMINATION OF PRODUCT RECALL ORDER ISSUED ON SPECIFIC BATCHES OF DOBUTAMINE (AS HYDROCHLORIDE) 12.5MG/ML (250MG/20ML) SOLUTION FOR INJECTION (DOBULON)

This is to inform the public that the recall order issued on batches DBI1301BC, DBI1302BC and DBI1303BC of Dobutamine (as hydrochloride) 12.5mg/mL (250mg/20mL) Solution for Injection with registration number DRP-3997 is hereby terminated by the Food and Drug Administration (FDA). This product is manufactured by Celon Laboratories Limited in India and imported by I.E. Medica, Inc.

As stated in the FDA Advisory No. 2014-055 dated 09 July 2014, I.E. Medica, Inc. voluntarily recalled the product batches due to the change in appearance of the product from clear pale yellowish solution to dark yellow solution.

After careful evaluation of the submitted documents, FDA has determined that reasonable efforts had been made by the Marketing Authorization Holder (MAH), I.E. Medica, Inc., to recall and properly destroy the impacted product batches 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