Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

26 February 2015

FDA Advisory No. 2015-017

SUBJECT: TERMINATION OF PRODUCT RECALL ORDER ISSUED ON SPECIFIC BATCHES OF 8.4% SODIUM BICARBONATE SOLUTION FOR IV INFUSION

This is to inform the public that the recall order issued on batches 131558021, 124638022, and 121148021 of 8.4% Sodium Bicarbonate Solution for IV Infusion with registration number DR-XY15571 is hereby terminated by the Food and Drug Administration (FDA). This product is manufactured by B.Braun Melsungen AG, Germany and imported by B.Braun Medical Supplies, Inc.

As stated in the FDA Advisory No. 2014-014 dated 03 March 2014, FDA ordered a recall of the product batches due to aluminum salt precipitation in the solution caused by the fluctuation in the quality of bromobutyl stopper which resulted in the leaching of aluminum compounds.

After careful evaluation of the submitted documents, FDA has determined that reasonable efforts had been made by the Marketing Authorization Holder (MAH), B. Braun Medical Supplies, 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
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