Republic of the Philippines
Department of Health
**FOOD AND DRUG ADMINISTRATION**

FDA
Food and Drug Administration
PHILIPPINES

03 March 2014

**FDA Advisory**

No. 2014-014

**SUBJECT: VOLUNTARY PRODUCT RECALL OF SPECIFIC BATCHES OF B. BRAUN'S 8.4% SODIUM BICARBONATE SOLUTION FOR IV INFUSION**

This is to inform the public that B. Braun Medical Supplies, Inc. is initiating a voluntary recall of 8.4% Sodium Bicarbonate Solution for IV Infusion (glass bottles of 100mL) with the batch numbers 131558021, 124638022, and 121148021 up to the pharmacy level.

The reason for the recall was 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.

All pharmacies carrying the said batches of 8.4% Sodium Bicarbonate Solution for IV Infusion are instructed to discontinue from further distributing and selling these to the public and to hold the products in quarantine. Likewise, pharmacists and healthcare professionals are advised not to use these particular batches.

8.4% Sodium Bicarbonate Solution for IV Infusion is a registered prescription drug with registration number DR-XY15571 manufactured by B. Braun Melsungen AG, Germany. It is used in the treatment of metabolic acidosis that arises from a variety of disorders including diabetic coma, diarrhea, kidney disturbances and shock. It may also be used to treat severe respiratory acidosis.

For more information and inquiries, please e-mail us at info@fda.gov.ph. Any adverse reactions caused by the aforementioned product should be reported immediately to FDA at report@fda.gov.ph.

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Acting Director General