Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

22 June 2015

FDA Advisory
No. 2015 045

SUBJECT: RECALL OF ALL BATCHES OF BUMETANIDE (BURINEX) 500 mcg/mL SOLUTION FOR INJECTION (I.M./I.V.) MANUFACTAURED BY CENEXI IN FRANCE

The public is hereby warned by the Food and Drug Administration (FDA) that all batches of Bumetanide (Burinex®) 500 mcg/ mL Solution for Injection (I.M./I.V.) manufactured by Cenexi in France are being recalled from the market. The affected product batches present safety risks and potential adverse health consequences due to increasing level of Formaldehyde which was detected during stability studies on the product after thirty-six (36) months of storage at 30°C/75% RH.

Bumetanide (Burinex®) 500 mcg/mL Solution for Injection (I.M./I.V.) is used in the treatment of oedema associated with heart failure and with renal and hepatic disorders. It is given in high doses in the treatment of oliguria due to renal failure or insufficiency. It has also been used in hypertension. This product is packed in a 5 mL type I amber glass ampoule containing 4 mL solution (box of 5's).

Therefore, distributors, hospitals, retailers or pharmacies that have the affected batches of Bumetanide (Burinex®) 500 mcg/mL Solution for Injection (I.M./I.V.) are instructed to discontinue its distribution, sale and use. All consumers are likewise advised not to purchase or use the affected product batches and may contact Zuellig Pharma Corporation (ZPC) at telephone number (02) 789-3444 or e-mail us at info@fda.gov.ph for any question or additional information regarding the recall.

All Field Regulatory Operations Office (FROO) Officers are ordered to monitor the availability of the product batches in the market, to seal discovered stocks of the affected batches 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 affected product batches should be reported immediately to FDA through this link: www.fda.gov.ph/adr-report-new and fill-out all of the required fields.

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Secretary of Health
Acting Director General[1]

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[1]Pursuant to DPO 2015-1845