Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

22 June 2015

FDA Advisory
No. 2015 047

SUBJECT: **RECALL OF SPECIFIC BATCH OF FUROSEMIDE (AS SODIUM) 10 MG/ML (20 MG/2 ML) SOLUTION FOR INJECTION (IV/IM) WITH BRAND NAME LASIX**

The public is hereby warned by the Food and Drug Administration (FDA) that specific batch of Furosemide (as sodium) 10 mg/mL (20 mg/2 mL) Solution for Injection (IV/IM) with brand name Lasix is being recalled from the market due to the potential risk of cracked/broken ampoules. Patients may suffer from possible thromboembolic events due to unseen glass particles in the ampoule if the subject product was not thoroughly examined prior to administration. The details of the product are as follows:

REGISTRATION NUMBER	**DR-1111**
BATCH NUMBER	**4F202A**
MANUFACTURING DATES	**MARCH 2014**
EXPIRATION DATES	**FEBRUARY 2019**
MANUFACTURER NAME/ADDRESS	**AVENTIS PHARMA DEUTSCHLAND GmbH – FRANKFURT AM, MAIN GERMANY**
DISTRIBUTOR NAME/ADDRESS	**SANOFI-AVENTIS PHILIPPINES, INC. – MAKATI CITY**

Furosemide (as sodium) 10 mg/mL (20 mg/2 mL) Solution for Injection (IV/IM) with brand name Lasix is being used in conditions where adequate diuresis is not obtained with oral administration, for the treatment of oedema due to cardiac and hepatic disease and renal disease, pulmonary oedema, reduced urinary output due to gestoses. This product is packed in an amber ampoule containing two (2) mL solution (Box of 5's).

The affected product batch presents safety risks and potential adverse health consequences. Therefore, distributors, hospitals, retailers or pharmacies that have the affected batch of Furosemide (as sodium) 10 mg/mL (20 mg/2 mL) Solution for Injection (IV/IM) with brand name Lasix are instructed to discontinue its distribution, sale and use. All consumers are likewise advised not to purchase or use the affected product batch and may contact Sanofi-Aventis Philippines, Inc. at telephone number

+632 859-5555 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 batch in the market, to seal the discovered stocks of the affected batch 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 aforementioned product lots should be reported immediately to FDA through this link: www.fda.gov.ph/adr-report-new and fill-out all of the required fields.

JANETTE P. LORETO-GARIN, MD, MBA-H
Secretary of Health
Acting Director General[1]

DTN: 20150527105907

[1]Pursuant to DPO 2015-1845