Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2016-007

01 FEB 2016

SUBJECT: **Voluntary Product Recall of Batch Specific 5% Dextrose in Water Solution for IV Infusion of Fresenius Kabi Philippines, Inc.**

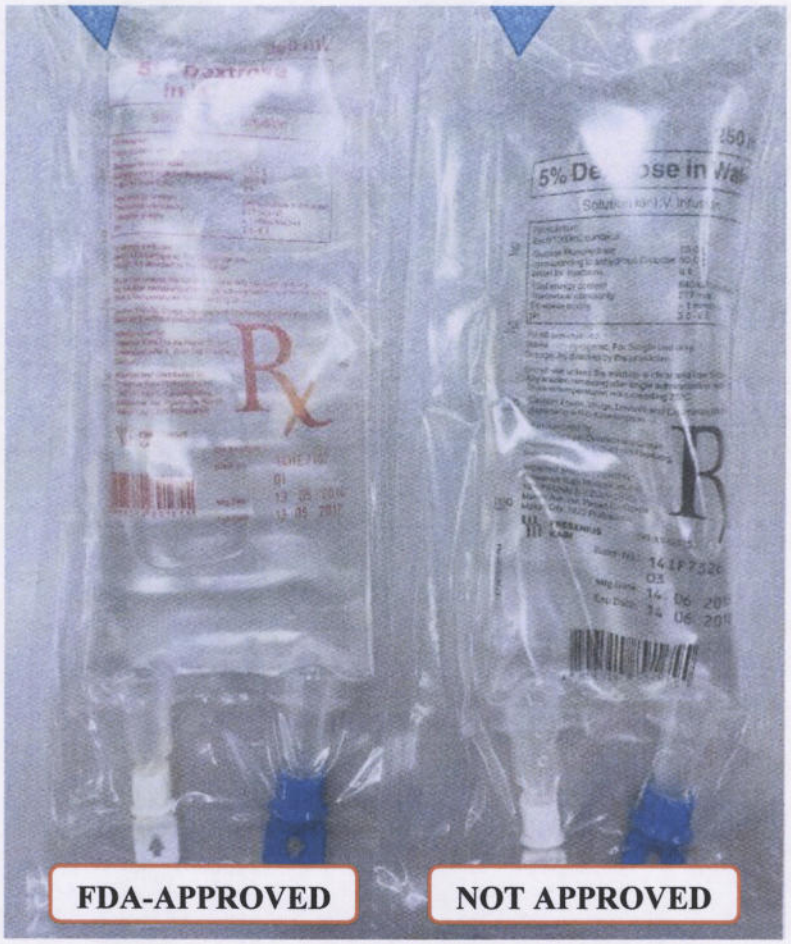
This is to inform the public that the Marketing Authorization Holder (MAH), Fresenius Kabi Philippines, Inc., is voluntarily recalling a certain batch of 5% Dextrose in Water Solution for IV Infusion due to the faulty packaging of the drug product as reported by the MAH. It was stated that the received shipment of the product batch bore labels printed in black instead of the Food and Drug Administration (FDA)-approved font color which is red. The details of the product batch are as follows:

REGISTRATION NUMBER	**DR-XY42375**
BATCH NUMBER / EXPIRY DATE	**14IF7326/ JUNE 2018**
MANUFACTURER NAME AND ADDRESS	**FRESENIUS KABI DEUTSCHLAND GMBH – FRESENIUSSTRAßE 1, 61169 FRIEDBERG, GERMANY**
IMPORTER/DISTRIBUTOR (MAH)	**FRESENIUS KABI PHILIPPINES, INC. – UNITS 5-7, 18TH FLOOR, ZUELLIG BUILDING, MAKATI AVENUE CORNER PASEO DE ROXAS, URDANETA VILLAGE, MAKATI CITY**

5% Dextrose in Water Solution for IV Infusion is used as a replacement therapy in conditions mainly due to water losses and it is also used to keep the vein open for IV drug administration. The drug product is packed in 250 mL freeflex bag. The affected product batch is deemed for recall due to the non-conformance to the FDA-approved label with font color red.

Therefore, distributors, retailers, hospitals, pharmacies or clinics that have the affected batch of the drug product are instructed to discontinue further distribution, sale and use. All consumers are likewise advised not to purchase or use the affected product

batch and may contact Fresenius Kabi Philippines, Inc. at telephone number +632 889-6492 loc. 111 or e-mail us at info@fda.gov.ph for any question or additional information regarding the recall.



All Officers of the Field Regulatory Operations Office (FROO) are ordered to monitor the availability of the product batch in the market, appropriately seal discovered stocks of the affected batch of the product, and instruct the concerned establishment to return the sealed stocks to the MAH for proper destruction to be witnessed by an appropriate FDA Representative.

Any suspected adverse reaction experienced from the use of the aforementioned product batch should be reported immediately to FDA through this link: www.fda.gov.ph/adr-report-new and fill-out all of the required fields.

MARIA LOURDES C. SANTIAGO, MSc, MM
Officer-in-Charge, Director General
Food and Drug Administration

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