Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

12 FEB 2016

FDA ADVISORY
No. 2016 -019

SUBJECT: **Product Recall of Lot Specific Propofol 10 mg/mL Emulsion for Injection (I.V.) with brand name (Aeprofol)**

The public is hereby warned by the Food and Drug Administration (FDA) that a certain lot of Propofol (Aeprofol) 10 mg/mL Emulsion for Injection (I.V.) is being recalled from the market due to the failed assay result from the analysis of the FDA Common Services Laboratory (CSL). The details of the product lot are as follows:

REGISTRATION NUMBER	**DR-XY42190**
LOT NUMBER / EXPIRY DATE	**IN140611/ JUNE 2016**
MANUFACTURER NAME AND ADDRESS	**ORIENTAL CHEMICAL WORKS, INC. – NO. 12, LANE 195 CHUNG-SAN RD., LU-CHOU CITY, TAIPEI, HSIEN 247, TAIWAN R.O.C.**
IMPORTER/DISTRIBUTOR (MAH)	**EDRENE DRUG ENTERPRISES – 2202-A CONCHA ST., SAN ANDRES BUKID, STA. ANA, MANILA**
DISTRIBUTOR	**DYNASTY PHARMACEUTICALS – 2432 LEGARDA ST., SAMPALOC, MANILA**

Propofol (Aeprofol) 10 mg/mL Emulsion for Injection (I.V.) is used in the induction and maintenance of anaesthesia. It is also used for sedation in patients undergoing diagnostic procedure, in those undergoing surgery in conjunction with local or regional anaesthesia, and in ventilated adult patients under intensive care for a period of up to three (3) days. The drug product is packed in a 20 mL Clear Glass Ampoule in boxes of 5's.

Therefore, distributors, hospitals, retailers, pharmacies or clinics that have the affected lot 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 lot and may contact Edrene Drug Enterprises at telephone number +632 353-8399 or mobile no. +63 917 5553739 or e-mail us at info@fda.gov.ph for any questions or additional information regarding the recall.

All Officers of the Field Regulatory Operations Office (FROO) are ordered to monitor the availability of the product lot in the market, appropriately seal discovered stocks of the affected lot of the product, and instruct the concerned establishment to return 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 lot should be reported immediately to the 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

DTN: 20151125135703