Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

01 FEB 2016

FDA ADVISORY
No. 2016 014

SUBJECT: **Product Recall of Batch Specific Cefotaxime Sodium 1 g Powder for Injection (IM/IV) with brand name Haxim**

The public is hereby warned by the Food and Drug Administration (FDA) that a certain batch of Cefotaxime Sodium 1 g Powder for Injection (IM/IV) with brand name Haxim is being recalled from the market due to the discovery of a piece of broken glass in a vial of the reconstituted drug product. The details of the product batch are as follows:

REGISTRATION NUMBER	**DR-XY33532**
BATCH NUMBER / EXPIRY DATE	**A1410702-2 / OCTOBER 2016**
MANUFACTURER NAME AND ADDRESS	**HARBIN PHARMACEUTICAL GROUP CO. LTD. GENERAL PHARM. FACTORY – NO. 109 XUEFU ROAD, NANGANG DIST. HARBIN, PEOPLE'S REPUBLIC OF CHINA**
IMPORTER/DISTRIBUTOR (MAH)	**ENDURE MEDICAL, INC. – UNIT 17-A BELVEDERE TOWER, SAN MIGUEL AVENUE, ORTIGAS COMPLEX, PASIG CITY**

Cefotaxime Sodium (Haxim) 1 g Powder for Injection (IM/IV) is used for the treatment of infections due to sensitive Gram-positive and Gram-negative bacteria; gonorrhea; surgical prophylaxis; *Haemophilus* epiglottitis and meningitis. The product is packed in USP Type I clear glass vial with rubber stopper and blue flip-off seal in boxes of 10's.

The affected product batch is deemed for recall due to the potential threat that the piece of glass contained in the vial can pose to the safety of the end user. Therefore, distributors, hospitals, retailers, 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 Endure Medical, Inc. at telephone number +632 634-3450 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 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 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 batch 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: 20151125155134