Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA
Food and Drug Administration
PHILIPPINES

20 June 2014

FDA Advisory
No. ~~2014~~-048

SUBJECT: QUALITY HOLD ON HEPARIN SODIUM 1000 IU/mL SOLUTION FOR INJECTION WITH BRAND NAMES DIASEA 5 AND MEPARIN 5 IMPORTED BY PHARMA-SURREY INTERNATIONAL, INC.

In the interest of public health and safety, the Food and Drug Administration (FDA) and Pharma-Surrey International, Inc. will jointly undertake a quality hold of all batches of Heparin Sodium (Diasea 5) 1000 IU/mL Solution for Injection, as well as, batches of Heparin Sodium (Meparin 5) 1000 IU/mL Solution for Injection other than batch no. N-3176 (Batch number N-3176 is subject for recall).

Heparin Sodium 1000 IU/mL Solution for Injection with brand names Diasea 5 and Meparin 5 are manufactured by Medchem International, Ltd., at A6 Banjara Gardens, Road No. 12, Banjara Hill, Hyderabad 500034, India and registered in the Philippines with FDA Registration No. DRP-3912-01 and DRP-3912, respectively.

All consumers and health professionals are advised not to use any batch of Heparin Sodium (Diasea 5 &Meparin 5) 1000 IU/mL Solution for Injection until such time that the FDA and Pharma-Surrey International, Inc. shall have issued an advisory that the quality hold has been lifted. Likewise, distributors and drug outlets are ordered to remove the stocks from their shelves and hold the said stocks until the FDA and Pharma-Surrey International, Inc. shall have conducted the quality check. For inquiries, email us at info@fda.gov.ph.

For strict compliance of all concerned.

KENNETH HARTIGAN-GO, MD
Acting Director General

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