Republic of the Philippines
Department of Health
**FOOD AND DRUG ADMINISTRATION**

20 June 2014

**FDA Advisory**
No. **2014-047**

**SUBJECT: VOLUNTARY RECALL OF BATCH SPECIFIC HEPARIN SODIUM (MEPARIN 5) 1000 IU/ML SOLUTION FOR INJECTION (IV/SC) BATCH NUMBER N-3176 (DRP-3912)**

This is to inform the public that Pharma-Surrey International Inc. is initiating a product recall of Heparin Sodium 1000 IU/mL solution for injection (Meparin 5) with batch number N-3176 and registration number DRP-3912 due to reported serious Adverse Drug Reaction (ADR). The details of the affected batch are as follows:

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|---|---|
| REGISTRATION NUMBER | **DRP-3912** |
| BATCH NUMBER | **N-3176** |
| MANUFACTURING NAME AND ADDRESS | **MEDCHEM INTERNATIONAL LTD.-A6 BANJARA GARDENS, ROAD NO. 12, BANJARA HILLS, HYDERABAD 500034, INDIA.** |
| IMPORTER AND DISTRIBUTOR | **PHARMA-SURREY INTERNATIONAL INC – 46 BULUSAN STREET, STA. MESA HEIGHTS, QUEZON CITY** |

Heparin Sodium (Meparin 5) 1000 IU/mL Solution for Injection (IV/SC) is used as an anticoagulant principally in the treatment and prophylaxis of thromboembolic disorder. It is packed in a box containing ten (10) vials of Heparin Sodium 1000 IU/mL, and each vial contains 5 mL solution.

Distributors, retailers, hospitals, pharmacies, or clinics that have the affected batch of Heparin Sodium 1000 IU/mL solution for injection (Meparin 5) are instructed to discontinue further distribution, sale and use.

Consumers may contact Pharma-Surrey International Inc. at telephone number +632 412 8364 or e-mail us at info@fda.gov.ph for any questions or additional information regarding the recall.

Any adverse reaction experienced from the aforementioned product should be reported immediately to FDA by visiting www.fda.gov.ph. Look for the ADR Report tab and proceed to fill-out all of the required fields.

**KENNETH Y. HARTIGAN-GO, MD**
Acting Director General