Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

15 June 2015

FDA Advisory
No. 2015-039

SUBJECT: PRODUCT RECALL OF BATCH SPECIFIC CEFUROXIME AXETIL 125 mg/5 mL SUSPENSION (CEFUROX)

The public is hereby warned by the Food and Drug Administration (FDA) that a specific batch of Cefuroxime Axetil 125 mg/5 mL Suspension with brand name Cefurox is being recalled from the market due to the result of FDA laboratory analysis that the potency of the drug product is below the required specifications. The details of the product are as follows:

BRAND NAME	**CEFUROX**
REGISTRATION NUMBER	**DRP-2563 (PRINCIPAL PRODUCT)**
BATCH NUMBER	**304D03**
EXPIRATION DATE	**MARCH 2016**
MANUFACTURER	**MEDICAIDS PAKISTAN (PVT.) LTD. – PLOT NO. 10, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI, PAKISTAN**
IMPORTER/DISTRIBUTOR	**SAHAR INTERNATIONAL TRADING, INC. – 354 AGUIRRE AVENUE, PHASE III, BF HOMES, PARAÑAQUE CITY**

Cefuroxime Axetil (Cefurox) 125 mg/5 mL Suspension is used for infections due to susceptible organisms such as in otitis media, orbital cellulitis, urinary tract, skin and soft tissue, bone and joint infections and post-splenectomy sepsis of unclear etiology. The drug product is packed in 50 mL & 70 mL Amber Glass Bottle (Box of 1's).

Moreover, the public is also informed that an Identical Drug Product with the same indication is also registered with FDA and is subject for recall with the following details:

BRAND NAME	**SITIROXIME**
REGISTRATION NUMBER	**DRP-2563-01 (IDENTICAL DRUG PRODUCT)**
BATCH NUMBER	**304D03**

EXPIRATION DATE	**MARCH 2016**
MANUFACTURER	**MEDICAIDS PAKISTAN (PVT.) LTD. – PLOT NO. 10, SECTOR 27, KORANGI INDUSTRIAL AREA, KARACHI, PAKISTAN**
IMPORTER	**SAHAR INTERNATIONAL TRADING, INC. – 354 AGUIRRE AVENUE, PHASE III, BF HOMES, PARAÑAQUE CITY**
DISTRIBUTOR	**GEOFMAN PHARMACEUTICALS SUBIC, INC. – SUBIC BAY INDUSTRIAL PARK, SUBIC BAY FREEPORT ZONE, OLONGAPO CITY**

The affected product batch presents safety risks and potential adverse health consequences. Therefore, distributors, hospitals, retailers or pharmacies that have the affected batch of Cefuroxime Axetil 125 mg/5 mL Suspension with brand names Cefurox and Sitiroxime are instructed to discontinue further distribution, sale and use. All consumers are likewise advised not to purchase or use the affected product batch.

All Field Regulatory Operations Officers (FROOs) 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 give back the sealed stocks to the Marketing Authorization Holder (MAH) for proper destruction to be witnessed by an appropriate FDA Representative.

Consumers may contact Sahar International Trading, Inc. at telephone numbers +632 794-3088 or +632 788-0022 or e-mail us at info@fda.gov.ph for any question or additional information regarding the recall.

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

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Secretary of Health
Acting Director General[1]

DTN: 20150525145148

[1]Pursuant to DPO 2015-1845