Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

15 June 2015

FDA Advisory No. 2015-040

SUBJECT: PRODUCT RECALL OF BATCH SPECIFIC CO-AMOXICLAV 500 mg/125 mg FILM-COATED TABLET (KLAVIC)

The public is hereby warned by the Food and Drug Administration (FDA) that a specific batch of Co-Amoxiclav 500 mg/125 mg Film-Coated Tablet with brand name Klavic is being recalled from the market due to the result of FDA laboratory analysis that the potency of the Clavulanic Acid content of the drug product is below the required specifications. The details of the product are as follows:

REGISTRATION NUMBER	**DR-XY35064**
BATCH NUMBER	**S-006**
EXPIRATION DATE	**JULY 2016**
MANUFACTURER	**SWISS PHARMA PVT. LTD. – 7, B MEDICARE, B/H M.J. LIBRARY, ELLISBRIDGE, AHMEDABAD, INDIA**
IMPORTER/ DISTRIBUTOR	**INTERNATIONAL APEX PHARMACEUTICALS, INC. – SUITE 17-A BELVEDERE TOWER, SAN MIGUEL AVE., PASIG CITY**

Co-Amoxiclav 500 mg/125 mg Film-Coated Tablet (Klavic) is used for the treatment of infections caused by susceptible organisms such as upper and lower respiratory tract infections, urinary tract infections, skin and soft tissue infections, dental infections and animal bites. The drug product is packed in Alu-Alu Blister Pack x 10's (Box of 30's).

The affected product batch presents safety risks and potential adverse health consequences. Therefore, distributors, hospitals, retailers or pharmacies that have the affected batch of Co-Amoxiclav 500 mg/125 mg Film-Coated Tablet (Klavic) 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

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back the sealed stocks to the Marketing Authorization Holder (MAH) for proper destruction to be witnessed by an appropriate FDA Representative.

Consumers may contact International Apex Pharmaceuticals, Inc. at telephone number +632 634-3450 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: 20150525145242

[1]Pursuant to DPO 2015-1845