Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY No. 2016-003

01 FEB 2016

SUBJECT: Product Recall of Specific Lots of Particular Drug Products Manufactured by La Croesus Pharma Inc.

The public is hereby warned by the Food and Drug Administration (FDA) that specific lots of particular drug products manufactured by La Croesus Pharma Inc. are being recalled from the market. This is due to the findings during inspection that the manufacturer used expired raw materials in the production of the following pharmaceutical products:

PRODUCT NAME (1)	**EACH CAPSULE CONTAINS: GUAIFENESIN 100 mg PARACETAMOL 325 mg PHENYLPROPANOLAMINE HYDROCHLORIDE 25 mg CHLORPHENIRAMINE MALEATE 1 mg DEXTROMETHORPHAN HYDROBROMIDE 10 mg (AC-NEX FORTE)**
REGISTRATION NUMBER	**DR- XY33162**
LOT NUMBER / EXPIRY DATE	**603649 / MAY 2017**
TRADER (MAH)	**MEDICAL & PHARMACEUTICAL SPECIALTIES, INC. – 176 BULUSAN ST., BRGY. MALAMIG, MANDALUYONG CITY**

PRODUCT NAME (2)	**COTRIMOXAZOLE 400 mg/80 mg per 5 mL SUSPENSION (BACXAL DS)**
REGISTRATION NUMBER	**DR- XY33783**
LOT NUMBER / EXPIRY DATE	**702507 / JULY 2015 702508 / FEBRUARY 2016 702509 / OCTOBER 2016**
TRADER (MAH)	**PHARMACARE PRODUCTS CORPORATION – 25 KABIGNAYAN ST., BANAWE, QUEZON CITY**

PRODUCT NAME (3)		**MULTIVITAMINS + LYSINE HYDROCHLORIDE TABLET (BEVON-C)**	
REGISTRATION NUMBER	LOT NUMBER / EXPIRY DATE	**DRP-4125**	**50063 / JANUARY 2015** **50064 / JANUARY 2015**
		DRP-5590	**831501 / FEBRUARY 2017**
			831502 / FEBRUARY 2017
			831503 JUNE 2017
TRADER (MAH)		**LA CROESUS PHARMA INC. – BRGY. STO. TOMAS, BIÑAN, LAGUNA**	

Guaifenesin 100 mg + Paracetamol 325 mg + Phenylpropanolamine Hydrochloride 25 mg + Chlorpheniramine Maleate 1 mg + Dextromethorphan Hydrobromide 10 mg Capsule (Ac-Nex Forte) is used for the relief of cough, nasal congestion and postnasal drip associated with common cold, allergic rhinitis, sinusitis, flu and upper respiratory infections. The product is packed in PVC/Alu blister pack by 10's in box of 100's.

Cotrimoxazole 400 mg/80 mg per 5 mL Suspension (Bacxal DS) is used in a wide variety of infections due to susceptible organisms, particularly those of the urinary, respiratory and gastrointestinal tracts. It is also used mainly for the treatment of *Pneumocystis carinii* pneumonia, toxoplasmosis and nocardiosis. The product is packed in 60 mL Amber Glass bottle.

Multivitamins + Lysine Hydrochloride Tablet (Bevon-C) is used for the prevention and treatment of multivitamins and lysine deficiencies. The drug product with Reg. No. DRP-5590 is packed in Alu/PE foil by 4's in boxes of 12's & 60's, and by 10's in box of 100's. As for Reg. No. DRP-4125, the product is packed in Foil Strip by 10's in box of 100's and Foil Strip by 4's in box of 12's.

Therefore, distributors, hospitals, retailers, pharmacies or clinics that have the affected lots of the stated drug products are instructed to discontinue further distribution, sale and use. All consumers are likewise advised not to purchase or use the affected product lots and may contact the corresponding Marketing Authorization Holders (MAHs) of each product lot concerned or e-mail us at info@fda.gov.ph for any questions or additional information regarding the recall. The contact information of the involved MAHs are the following:

MAH	CONTACT INFORMATION
Medical and Pharmaceutical Specialties, Inc.	(02) 534-2516 or +63 918 9213445
Pharmacare Products Co.	(02) 410-1980 or +63 922 8083374
La Croesus Pharma Inc.	(049) 512-8569 or (02) 911-8969

All Officers of the Field Regulatory Operations Office (FROO) are ordered to monitor the availability of the product lots in the market, appropriately seal discovered stocks of the affected lots of the products stated, and instruct the concerned establishment to return the sealed stocks to the MAH for proper destruction to be witnessed by an appropriate FDA Representative.

Any suspected adverse reaction experienced from the use of the aforementioned lots of the above-stated products 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: 20151127090213