Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

01 FEB 2016

FDA ADVISORY
No. 2016-006

SUBJECT: **Product Recall of Lot Specific Carbocisteine 250 mg/5 mL Syrup (Oflem)**

The public is hereby warned by the Food and Drug Administration (FDA) that a certain lot of Carbocisteine (Oflem) 250 mg/5 mL Syrup is being recalled from the market due to the failed assay result from the analysis of the FDA Common Services Laboratory (CSL). The details of the product lot are as follows:

REGISTRATION NUMBER	**HRP-122**
LOT NUMBER / EXPIRY DATE	**24139 / OCTOBER 2016**
MANUFACTURER NAME AND ADDRESS (MAH)	**DIAMOND LABORATORIES, INC. – #8 FERIA ROAD, COMMONWEALTH AVENUE, DILIMAN, QUEZON CITY**
DISTRIBUTOR	**RILEM PHARMA CORP. – #572 E. DELOS SANTOS AVE., MALIBAY, PASAY CITY**

Carbocisteine (Oflem) 250 mg/5 mL Syrup is used for reduction of sputum viscosity. The product is packed in 60 mL Amber Bottle.

The affected product lot presents safety risks and potential adverse health consequences. Therefore, distributors, retailers, hospitals, pharmacies or clinics that have the affected lot of Carbocisteine (Oflem) 250 mg/5 mL Syrup are instructed to discontinue further distribution, sale and use. All consumers are likewise advised not to purchase or use the affected product lot and may contact Diamond Laboratories, Inc. at telephone number +632 932-7555 loc. 129 or mobile no. +63 917 528 7368 or e-mail us at info@fda.gov.ph for any question or additional information regarding the recall.

All Officers of the Field Regulatory Operations Office (FROO) are ordered to monitor the availability of the product lot in the market, appropriately seal discovered stocks of the affected lot 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.

Any suspected adverse reaction experienced from the use of the aforementioned product lot should be reported immediately to FDA by visiting 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

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