Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

29 September 2014

FDA Advisory
No.: 2014-077

SUBJECT: PRODUCT RECALL OF LOT SPECIFIC CEFACLOR (AS MONOHYDRATE) 50 MG/ML POWDER FOR SUSPENSION (ORAL DROPS) WITH BRAND NAME CECLOBID

This is to inform the public that The Cathay YSS Distributors Co., Inc. is voluntarily recalling the impacted batches of Cefaclor (as monohydrate) 50 mg/mL Powder for Suspension (Oral Drops) with brand name Ceclobid due to changes in physical appearance and decrease in potency of the product. The details of the affected lots are as follows:

REGISTRATION NUMBER	**DRP-2101**
LOT NUMBERS	**140350, 140351, 140629, 140630, 141041, and 141042**
MANUFACTURER NAME AND ADDRESS	**EL LABORATORIES, INC. – 109 NORTH MAIN AVE., LAGUNA TECHNOPARK, BIñAN LAGUNA**
TRADER NAME AND ADDRESS	**THE CATHAY YSS DISTRIBUTORS COMPANY, INCORPORATED – 2/F VERNIDA 1 CONDOMINIUM, 120 AMORSOLO STREET LEGASPI VILLAGE, MAKATI CITY**

Cefaclor (as monohydrate) 50 mg/mL Powder for Suspension (Oral Drops) with brand name Ceclobid is used for the treatment of susceptible infections including upper and lower respiratory tract infections. This product is packed in a 30mL amber bottle with dropper.

The affected product presents safety risk and potential adverse health consequences. Therefore, distributors, retailers, hospitals, pharmacies, or clinics that have the affected lots of Cefaclor (as monohydrate) 50 mg/mL Powder for Suspension (Oral Drops) with brand name Ceclobid are instructed to discontinue further distribution, sale and use. All consumers are likewise advised not to purchase or use the affected products.

All field Food and Drug Regulation Officers are ordered to monitor the availability of the product batches in the market.

Consumers may contact The Cathay YSS Distributors Co., Inc. at telephone number +632 892-5936 to 43 or e-mail us at info@fda.gov.ph for any questions or additional information regarding the recall.

Any adverse reaction experienced from the use of the aforementioned product batches should be reported immediately to FDA by visiting www.fda.gov.ph. Look for the downloadable suspected adverse reaction form at the industry corner, fill-out all of the required fields and send via e-mail at adr@fda.gov.ph.

KENNETH Y. HARTIGAN-GO, MD
Acting Director General