



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



30 JUL 2015

FDA Advisory
No. **2015-058**

SUBJECT: TERMINATION OF PRODUCT RECALL ORDER ISSUED ON SPECIFIC LOTS OF CEFACLOR (AS MONOHYDRATE) 50 mg/mL POWDER FOR SUSPENSION (ORAL DROPS) WITH BRAND NAME CECLOBID

This is to inform the public that the Product Recall Order (PRO) issued on affected lots of Cefaclor (as monohydrate) 50 mg/mL Powder for Suspension (Oral Drops) with brand name Ceclobid is hereby terminated by the Food and Drug Administration (FDA). This product was manufactured by EL Laboratories, Inc. in Biñan, Laguna.

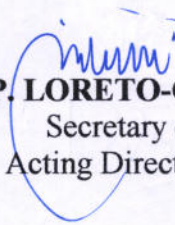
As stated in the FDA Advisory No. 2014-077 dated 29 September 2014, FDA informed the public of the recall of the impacted lots (140350, 140351, 140629, 140630, 141041 & 141042) of the subject product due to changes in the physical appearance and with potency below the required specifications.

After due and thorough evaluation of the submitted documents by the Marketing Authorization Holder (MAH), FDA has determined that reasonable efforts had been made by the MAH, The Cathay YSS Distributors Company, Incorporated, to recall and properly destroy the impacted product lots in accordance with Bureau Circular No. 8, s. 2001, known as the Guidelines to be Observed on the Implementation of Product Recall System.

The issuance of this advisory shall not in any manner preclude this Office from issuing subsequent orders it may deem necessary and appropriate, should there be findings of any violation of existing laws, rules and regulations.

All Field Regulatory Operations Office (FROO) Officers are ordered to appropriately seal discovered stocks of the affected lots of the product, and to instruct the concerned establishment to give back the sealed stocks to the MAH for proper destruction to be witnessed by an appropriate FDA representative.

Consumers may contact FDA at telephone number +632 857-1900 or via e-mail at info@fda.gov.ph for any questions or additional information regarding this recalled product.


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¹Pursuant to DPO 2015-1845

