Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

30 JUL 2015

FDA Advisory No. 2015-057

SUBJECT: TERMINATION OF PRODUCT RECALL ORDER ISSUED ON SPECIFIC BATCHES OF NICORANDIL (APRIOR) 5 mg AND 10 mg TABLETS WITH REGISTRATION NOS. DR-XY35217 & DR-XY31195

This is to inform the public that the Product Recall Order (PRO) issued on particular batches of the subject products is hereby terminated by the Food and Drug Administration (FDA). Nicorandil (Aprior) 5 mg and 10 mg Tablets were manufactured by Hizon Laboratories, Inc. in Antipolo City and distributed by Zuellig Pharma Corporation. The impacted batches were as follows:

Registration No. DR-XY35217 5 mg Tablet	Registration No. DR-XY31195 10 mg Tablet	
OAT5-005	OAT1-032	OAT1-033
OAT5-006	OAT1-034	OAT1-035
OAT5-007	OAT1-036	OAT1-037
OAT5-008	OAT1-038	

As stated in the FDA Advisory No. 2014-065 dated 12 August 2014, FDA informed the public of the recall of the listed affected batches of Nicorandil (Aprior) 5 mg and 10 mg Tablets due to the non-compliance with Good Manufacturing Practice (GMP) issued by the Italian Medicines Agency (AIFA) to the manufacturer, Societa Italiana Medicinali Scandicci, srl (SIMS), of the Active Pharmaceutical Ingredient (API), Nicorandil.

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, OEP Philippines, Inc., to recall and properly destroy the impacted product batches 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 any 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 batches of the products, and 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 the recalled products.

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Secretary of Health
Acting Director General[1]

DTN: 20150713110021
[1]Pursuant to DPO 2015-1845