Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

12 August 2014

FDA Advisory
No. 2014-065

SUBJECT: VOLUNTARY RECALL OF SPECIFIC BATCHES OF NICORANDIL (APRIOR) 5 MG AND 10 MG TABLETS WITH REGISTRATION NOS. DR-XY35217 AND DR-XY31195

This is to inform the public that OEP Philippines, Inc. is initiating a product recall of specific batches of Nicorandil (Aprior) 5 mg and 10 mg tablet with registration nos. DR-XY35217 and DR-XY31195 in response to the statement of non-compliance with Good Manufacturing Practice (GMP) issued by the Italian Medicines Agency (AIFA) to Societa Italiana Medicinali Scandicci, srl. (SIMS), the manufacturer of the active pharmaceutical ingredient, Nicorandil.

The active pharmaceutical ingredient Nicorandil was used in the manufacture of the products Aprior 5 mg and 10 mg tablets by Hizon Laboratories, Inc. located at Assumption Rd., Sumulong Highway, Antipolo City. The products were distributed by Zuellig Pharma Corporation located at Km. 14, West Service Rd., South Super Hi-way cor. Edison Ave., Brgy. Sun Valley, Parañaque City.

The details of the affected batches are as follows:

Nicorandil (Aprior) 5 mg Tablet Registration No. DR-XY35217		**Nicorandil (Aprior) 10 mg Tablet Registration No. DR-XY31195**	
Batch No.	**Expiry Date**	**Batch No.**	**Expiry Date**
OAT5-005	March 2015	OAT1-032	October 2014
OAT5-006	April 2015	OAT1-033	January 2015
OAT5-007	July 2015	OAT1-034	February 2015
OAT5-008	November 2015	OAT1-035	May 2015
		OAT1-036	May 2015
		OAT1-037	July 2015
		OAT1-038	November 2015

Nicorandil (Aprior) 5 mg and 10 mg tablet are used for the treatment of angina pectoris. Nicorandil (Aprior) 5 mg tablet is packed in an alu-alu foil strip x 10's (box of 30's), while Nicorandil (Aprior) 10 mg tablet is packed in an alu-alu foil strip x 4's (box of 48's).

Distributors, retailers, hospitals, pharmacies, or clinics that have the affected batches of Nicorandil (Aprior) 5 mg and 10 mg tablet are instructed to discontinue further distribution, sale and use.

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

Consumers may contact OEP Philippines, Inc. at telephone number +632 815-1209 to 12 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 ADR Report tab and proceed to fill-out all of the required fields.

KENNETH Y. HARTIGAN-GO, MD
Acting Director General