Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

22 SEP 2015

FDA Advisory No. 2015 068

SUBJECT: PRODUCT RECALL OF LOT SPECIFIC SIMVASTATIN 20 mg TABLET (NOVOVAST)

The public is hereby warned by the Food and Drug Administration (FDA) that a specific lot of Simvastatin 20 mg Tablet with brand name Novovast is being recalled from the market due to the result of FDA laboratory analysis that the particular lot failed the dissolution test conducted. The details of the product are as follows:

BRAND NAME	**NOVOVAST**
REGISTRATION NUMBER	**DRP-3685 (PRINCIPAL PRODUCT)**
LOT NUMBER	**13P378B**
EXPIRATION DATE	**NOVEMBER 2015**
MANUFACTURER	**SQUARE PHARMACEUTICALS INC. – #3428 EAST SERVICE RD., UNITED PARAÑAQUE II, PARAÑAQUE CITY**

Simvastatin 20 mg Tablet (Novovast) is used to decrease total LDL-cholesterol, apolipoprotein B, and triglycerides, and to increase HDL-cholesterol in the treatment of hyperlipidaemias, including hypercholesterolaemias and combined hyperlipidaemia (type IIa or IIb hyperlipoproteinaemias). The drug product is packed in orange PVC/Alu blister pack x 10's in boxes containing 30 tablets or 100 tablets.

Moreover, the public is also informed that Identical Drug Products with the same indication and manufacturer are also registered with FDA and are subject for recall with the following details:

BRAND NAME	REG. NO.	LOT NO.	EXP. DATE	DISTRIBUTOR
SQUASTATIN	**DRP-3685-01**	**13P378B**	**NOVEMBER 2015**	**NOVOMED INC. – MANDALUYONG CITY**
QVAST	**DRP-3685-02**			**ALMAN PHARMACEUTICALS – PARAÑAQUE CITY**

No brand name	**DRP-3685-03**			**RESONATE TRADING – MUNTINLUPA CITY**

The affected product lot presents safety risks and may cause therapeutic failure. Therefore, distributors, hospitals, retailers or pharmacies that have the affected lot of Simvastatin 20 mg Tablet with brand names Novovast, Squastatin, Qvast and another generic product with a registration no. of DRP-3685-03 are instructed to discontinue further distribution, sale and use. All consumers are likewise advised not to purchase or use the affected product lot.

All Officers of the Field Regulatory Operations (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.

Consumers may contact Square Pharmaceuticals Inc. at telephone numbers +632 823-7266 or +632 824-5228 or e-mail us at info@fda.gov.ph for any question or additional information regarding the recall.

Any suspected adverse reaction experienced from the use of the aforementioned product lot should be reported immediately to FDA through this link: www.fda.gov.ph/adr-report-new and fill-out all of the required fields.

JANETTE P. LORETO-GARIN, MD, MBA-H
Secretary of Health
Acting Director General[1]

DTN: 20150810093758

[1]Pursuant to DPO 2015-1845