Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

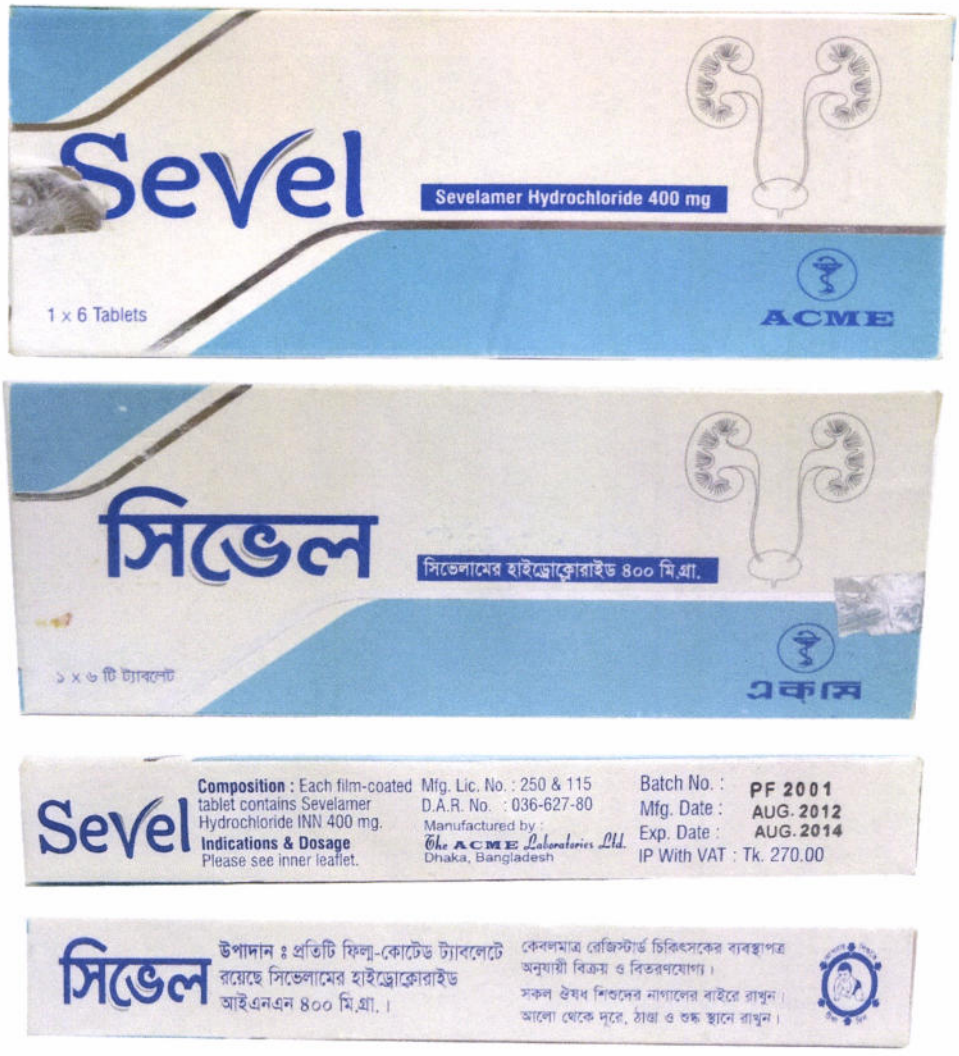
FDA ADVISORY
No. 2016-144

15 NOV 2016

TO: **ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

SUBJECT: **Public Health Warning Against the Use of the Unregistered Drug Product "Sevelamer Hydrochloride (Sevel) 400 mg Tablet" manufactured by The ACME Laboratories Ltd. – Dhaka, Bangladesh**

The Food and Drug Administration (FDA) advises the public against the use of the unregistered drug product Sevelamer Hydrochloride (Sevel) 400 mg Tablet:



Sevelamer Hydrochloride (Sevel) 400 mg Tablet
Manufactured by: The ACME Laboratories Ltd. – Dhaka, Bangladesh

Figure 1. Secondary packaging of the unregistered Sevelamer Hydrochloride (Sevel) 400 mg Tablet

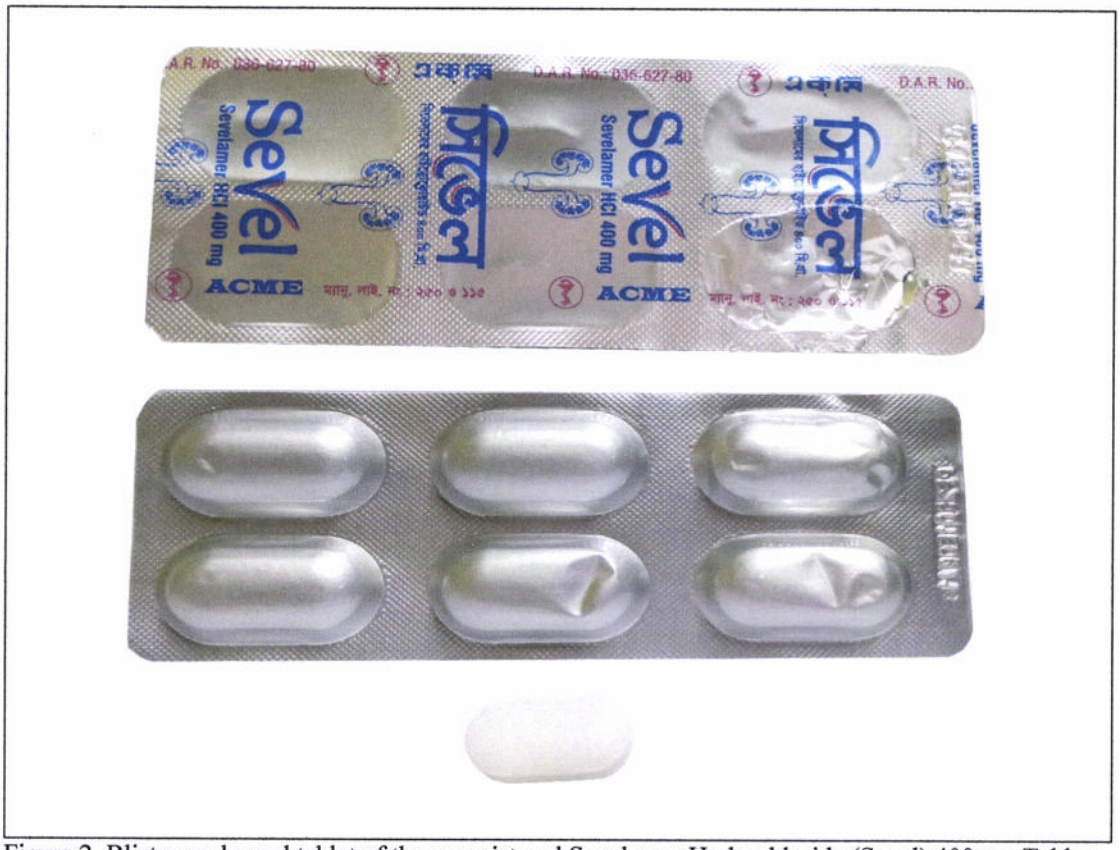


Figure 2. Blister packs and tablet of the unregistered Sevelamer Hydrochloride (Sevel) 400 mg Tablet

All healthcare professionals and the general public are hereby warned to be vigilant of the abovementioned unregistered drug product. This product poses potential danger or injury to the consuming public and the importation, selling or offering for sale of such is in direct violation of Republic Act No. 9711 or the Food and Drug Administration Act of 2009.

In the interest of protecting public health and safety, the Officers of the Field Regulatory Operations Office (FROO) are hereby mandated to exercise their regulatory function pursuant to Section 14 of Republic Act. No. 9711.

All establishments and outlets are hereby warned against selling and/or dispensing the unregistered product identified above. Anyone found selling the said product will be penalized.

Likewise, all local government units and law enforcement agencies are requested to ensure that this unregistered product is not sold or offered for sale in their localities or area of jurisdiction.

Consumers are advised to purchase their medications only from FDA-licensed establishments. In addition to inspection of establishments, product evaluation, registration, and testing are measures that the government undertakes to ensure the quality, safety, and efficacy of health products. Please look for the FDA Registration number on the product label. Be reminded that drug products registered with FDA Philippines bear in their labels information in English and/or in Filipino for all consumers to understand.

For more information and inquiries, please e-mail us at info@fda.gov.ph. To report continuous sale or distribution of unregistered health products, kindly e-mail us via report@fda.gov.ph or you may call telephone number (02)807-8275. For any suspected adverse drug reaction (ADR), report immediately to FDA through this link: www.fda.gov.ph/adr-report-new and fill out all the required fields.

Dissemination of the information to all concerned is requested.

NELA CHARADE G. PUNO, RPh
Director General

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