Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

03 NOV 2015

FDA ADVISORY
No. 2015-085

SUBJECT: **Product Recall of Specific Batches of Naproxen Sodium 550 mg Tablet**

The public is hereby warned by the Food and Drug Administration (FDA) that the following batches of Naproxen Sodium 550 mg tablet is being recalled from the market due to non conformance on physical appearance of the subject product where brown spots were noted during production, specifically during the compression prior to blistering of the tablets. The details of the product are as follows:

REGISTRATION NUMBER	**DRP-3974**
BATCH NUMBERS / EXPIRY DATE	**3Y799 / NOVEMBER 2015** **3Y800 / NOVEMBER 2015** **43036 / APRIL 2016** **43037 / APRIL 2016**
MANUFACTURER NAME AND ADDRESS	**SCHEELE LABORATORIES PHIL., INC - 007 LOPE DE GUZMAN ST., DALADANAN, VALENZUELA CITY**

Naproxen Sodium 550 mg tablet is used for ankylosing spondylitis, osteoarthritis and rheumatoid arthritis including juvenile arthritis and it is also used for dysmenorrheal headache, including migraine, post-operative pain, soft- tissue disorders, acute gout, and to reduce fever.

The affected product batches present safety risks and potential adverse health consequences. Therefore, distributors, retailers, hospitals, pharmacies or clinics that have the affected batches of Naproxen Sodium 550 mg tablet are instructed to discontinue further distribution, sale and use. All consumers are likewise advised not to purchase or use the affected product batch and may contact Scheele Laboratories Phil., Inc. at telephone numbers 632 293 7151 to 52 or e-mail us at info@fda.gov.ph for any questions or additional information regarding the recall.

All field Food Drug Regulation Officers are ordered to monitor the availability of the product batch in the market, to seal the discovered stocks of the affected batch of the product, and to 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.

Any suspected adverse reaction experienced from the use of the aforementioned product batch should be reported immediately to FDA by visiting 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: 20150914120336

[1]Pursuant to DPO 2015-1845