Republic of the Philippines
Department of Health
**FOOD AND DRUG ADMINISTRATION**

**FDA ADVISORY**
No: 2018-073

05 MAR 2018

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

**SUBJECT:** **Public Health Warning Against the Purchase and Use of the Verified Counterfeit Drug Product Naproxen sodium (Flanax Forte) 550 mg Tablet**

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The Food and Drug Administration (FDA) advises the public against the purchase and use of the verified counterfeit drug product Naproxen sodium (Flanax Forte) 550 mg Tablet:

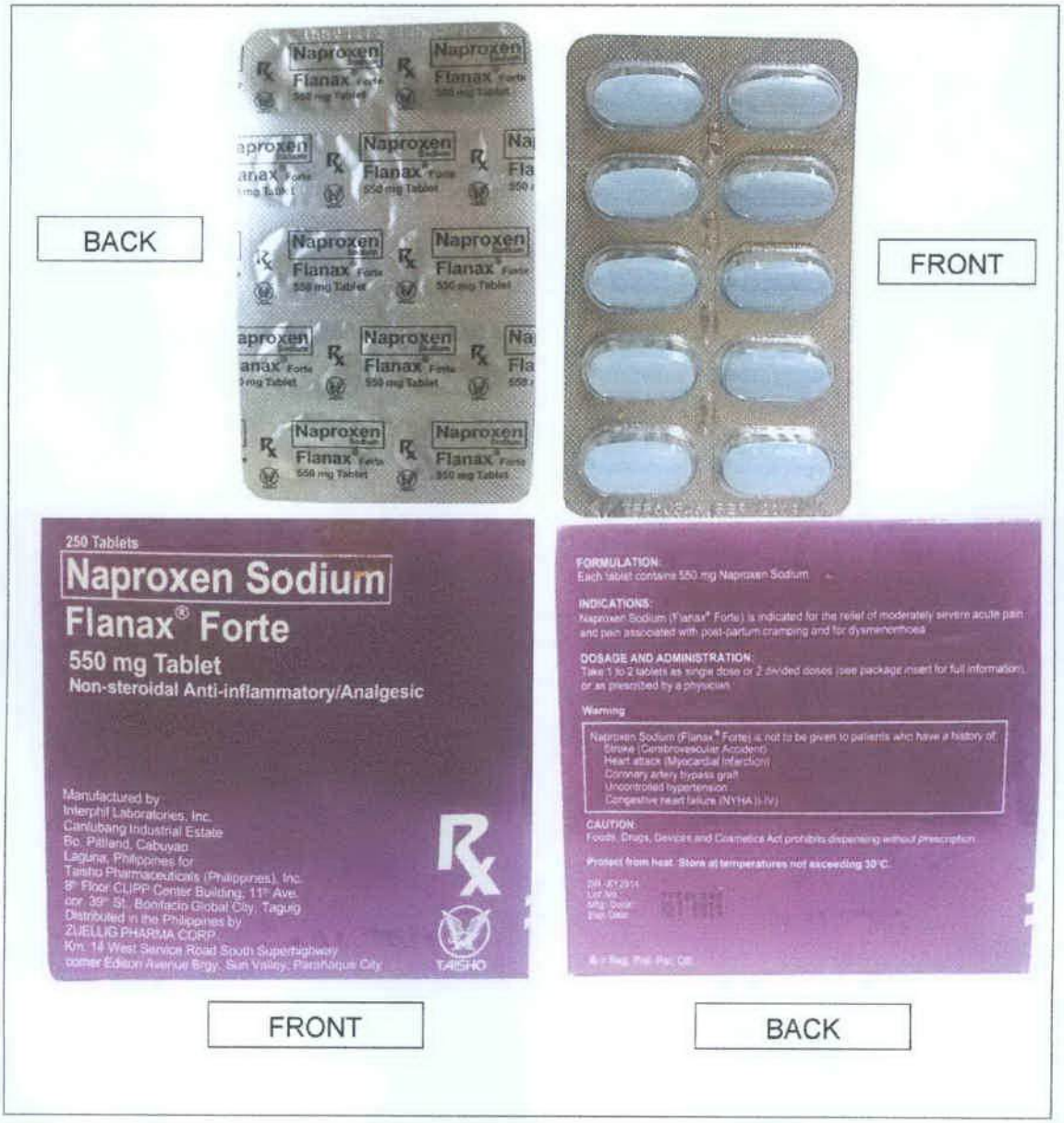
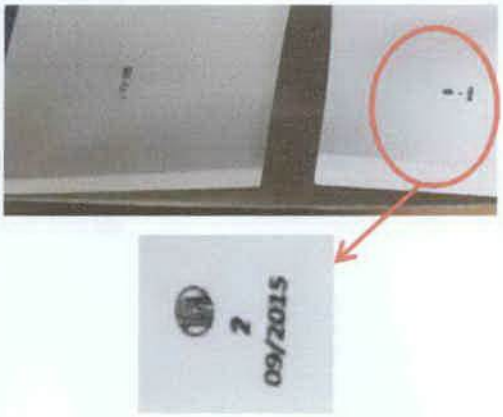



Figure 1. Verified counterfeit/fake Naproxen sodium (Flanax Forte) 550 mg Tablet


Civic Drive, Filinvest City, Alabang 1781 Muntinlupa, Philippines
Trunk Line +63 2 857 1900 Fax +63 2 807 0751
Website: www.fda.gov.ph Email: info@fda.gov.ph

The FDA together with the Marketing Authorization Holder (MAH), Taisho Pharmaceuticals (Philippines), Inc., have verified that the abovementioned sample drug product is counterfeit. The comparisons of the collected product and the registered and authentic one are as follows:

| AUTHENTIC | COUNTERFEIT |
|---|---|
| • Coding area has unvarnished area<br>  | • Coding area has no unvarnished area<br>  |
| • Supplier Printing Code/Date: Indicated<br>  | • Supplier Printing Code/Date: Not indicated<br>  |
| • Color: Blue; Uniform color<br>• Shape: Modified oval-shaped<br>  <br>  | • Color: Pale/Lighter Blue; Uneven color<br>• Shape: Oval-shaped (very different shape with authentic)<br>  <br>  |

All healthcare professionals and the general public are hereby warned as to the availability of this counterfeit drug product in the market which poses potential danger or injury to consumers. Consumers are also reminded to purchase drug products only from FDA-licensed establishments.

Likewise, all establishments and outlets are hereby warned against selling and/or dispensing of this verified counterfeit drug product with the abovementioned features. 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, and Republic Act No. 8203, or the Special Law on Counterfeit Drugs, therefore a penalty shall be imposed.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that this counterfeit product is not sold or made available in their localities or areas of jurisdiction.

For more information and inquiries, please e-mail us at **info@fda.gov.ph**. To report continuous sale or distribution of unregistered and/or counterfeit health products, kindly e-mail us via **report@fda.gov.ph**, or through the online reporting facility, **eReport**, at **www.fda.gov.ph/ereport**. You may also call the Center for Drug Regulation and Research at telephone number **(02) 809-5596**. 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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