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

**FDA ADVISORY No. 2016-004**

01 FEB 2016

**SUBJECT: Product Recall of Specific Lots of Rifampicin 200 mg/5 mL Suspension (Famtricin Forte)**

The public is hereby warned by the Food and Drug Administration (FDA) that affected lots of Rifampicin (Famtricin Forte) 200 mg/5 mL Suspension are being recalled from the market. The details of the product lots are as follows:

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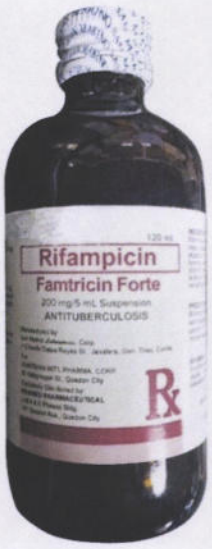
|---|---|
| REGISTRATION NUMBER | **DR-XY29703** |
| LOT NUMBER / EXPIRY DATE | **140918 A/SEPTEMBER 2017**<br>**150424 C/APRIL 2018** |
| MANUFACTURER NAME AND ADDRESS | **SAN MARINO LABORATORIES CORP. – 1 CRISANTO DELOS REYES ST., JAVALERA, GENERAL TRIAS, CAVITE** |
| TRADER (MAH) | **JOHNTANN INTERNATIONALE PHARMACEUTICAL CORP. – 25 KABIGNAYAN ST., QUEZON CITY** |
| DISTRIBUTOR | **REGIMED PHARMACEUTICAL DISTRIBUTOR – NO. 491 QUEZON AVE., STO. DOMINGO (MATALAHIB), QUEZON CITY** |




Based on the results of the laboratory analyses conducted by FDA, it was found that the affected product lots did not conform to the specifications of pH and physical appearance. A pharmaceutical suspension should settle slowly and should readily redisperse upon gentle shaking. However, caking was observed in the concerned lots which made the suspension not readily redispersable upon shaking and also prevented the suspension to be readily poured from the container. The suspension was homogenized only upon the exertion of extra effort in shaking the bottle through the help of a mechanical device. The stated lots of the drug product present safety risks if the suspension is not homogenized before administration to the patient. Some parts will have low potency and

other parts will have high doses of the active ingredient. Erratic potency of doses unknowingly taken by the patient may possibly cause either therapeutic failure or toxicity.

Rifampicin (Famtricin Forte) 200 mg/5 mL Suspension is used in the treatment of infections due to *mycobacteria* and other susceptible organisms. The product is packed in 60 mL and 120 mL Boston Round Amber Bottles in boxes of 1's.

Therefore, distributors, hospitals, retailers, pharmacies or clinics that have the affected lots of the drug product are instructed to discontinue further distribution, sale and use. All consumers are likewise advised not to purchase or use the affected product lots and may contact Johntann Internationale Pharmaceutical Corp. at telephone numbers +632 711-6116 or +632 731-0408 or at mobile no. +63 917 8824572 or e-mail us at info@fda.gov.ph for any questions or additional information regarding the recall.

All Officers of the Field Regulatory Operations Office (FROO) are ordered to monitor the availability of the product lots in the market, appropriately seal discovered stocks of the affected lots of the product, and instruct the concerned establishment to return 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 lots should be reported immediately to the FDA through this link: www.fda.gov.ph/adr-report-new and fill-out all of the required fields.

**MARIA LOURDES C. SANTIAGO, MSc, MM**
Officer-in-Charge, Director General
Food and Drug Administration

DTN: 20151110085600