Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

23 January 2015

FDA Advisory No. 2015-011

SUBJECT: VOLUNTARY RECALL OF LOT SPECIFIC FERROUS SULFATE (AS HEPTAHYDRATE) 2 MG/ML SOLUTION WITH BRAND NAME LA ROSA VINO DE QUINA

This is to inform the public that Dann's Aid Laboratories, Inc. is voluntarily recalling the impacted lot of their product, Ferrous Sulfate (as heptahydrate) 2 mg/mL solution with brand name La Rosa Vino de Quina. The product lot was found to contain Thiamine Hydrochloride as its Active Pharmaceutical Ingredient (API) whereas the approved API in its Certificate of Product Registration (CPR) is Ferrous Sulfate (as heptahydrate). The details of the affected lot are as follows:

REGISTRATION NUMBER	**DRHR-1329**
LOT NUMBER	**130205**
DATE MANUFACTURED	**02-2013**
EXPIRY DATE	**02-2015**
MANUFACTURER NAME AND ADDRESS	**DANN'S AID LABORATORIES, INC. – LOT 11 FIRST VALENZUELA INDUSTRIAL COMPOUND MEYCAUAYAN, BULACAN**

La Rosa Vino de Quina is used for nutritional anemia and loss of appetite. It is also used in cases of convalescence after illness and chronic debilitating condition by increasing the appetite. The product is packed in a clear glass bottle containing 320 mL solution.

The affected product lot presents safety risk and potential adverse health consequences. Therefore, distributors, retailers, hospitals, pharmacies, or clinics that have the affected lot of La Rosa Vino de Quina are instructed to discontinue further distribution, sale and use. All consumers are likewise advised not to purchase or use the affected product lot.

All field Food and Drug Regulation Officers are ordered to monitor the availability of the product lot in the market.

Consumers may contact Dann's Aid Laboratories, Inc. at telephone number +63 44 292-1485 or e-mail us at info@fda.gov.ph for any questions or additional information regarding the recall.

Any adverse reaction experienced from the use of the aforementioned product lot should be reported immediately to FDA by visiting www.fda.gov.ph. Look for the downloadable suspected adverse reaction form at the industry corner, fill-out all of the required fields and send via e-mail at adr@fda.gov.ph.

ATTY. NICOLAS B. LUTERO III, CESO III
Assistant Secretary of Health
OIC, Food and Drug Administration