Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2020-1337

JUL 10 2020

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

SUBJECT: **Product Recall of Specific Lots of Iron Sucrose 20 mg/mL Solution for Injection (IV) (Maxifer)**

All healthcare professionals and the general public are hereby advised by the Food and Drug Administration (FDA) regarding the voluntary recall by the marketing authorization holder on the affected lots of the subject product from the market. The details of the product are as follows:

DRUG PRODUCT	**IRON SUCROSE 20 mg/mL SOLUTION FOR INJECTION (IV) (MAXIFER)**	
REGISTRATION NO.	**DRP-2437-01**	
LOT NO./EXP. DATE	**B5B0250**	**MAY 2021**
	B5C0283	**JULY 2022**
MANUFACTURER	**CLARIS LIFESCIENCES LIMITED – CHACHARWADI-VASANA, AHMEDABAD-382 213, INDIA**	
IMPORTER	**CLARIS LIFESCIENCES PHILIPPINES, INC. – 1108 11TH FLOOR, CITYLAND TOWER, 98 V.A. RUFINO ST. COR. VALERO ST., SALCEDO VILLAGE, MAKATI CITY**	
DISTRIBUTOR [Marketing Authorization Holder (MAH)]	**MULTICARE PHARMACEUTICALS PHILIPPINES, INC. – 26TH FLOOR RUFINO TOWER, 6784 AYALA AVENUE, MAKATI CITY**	

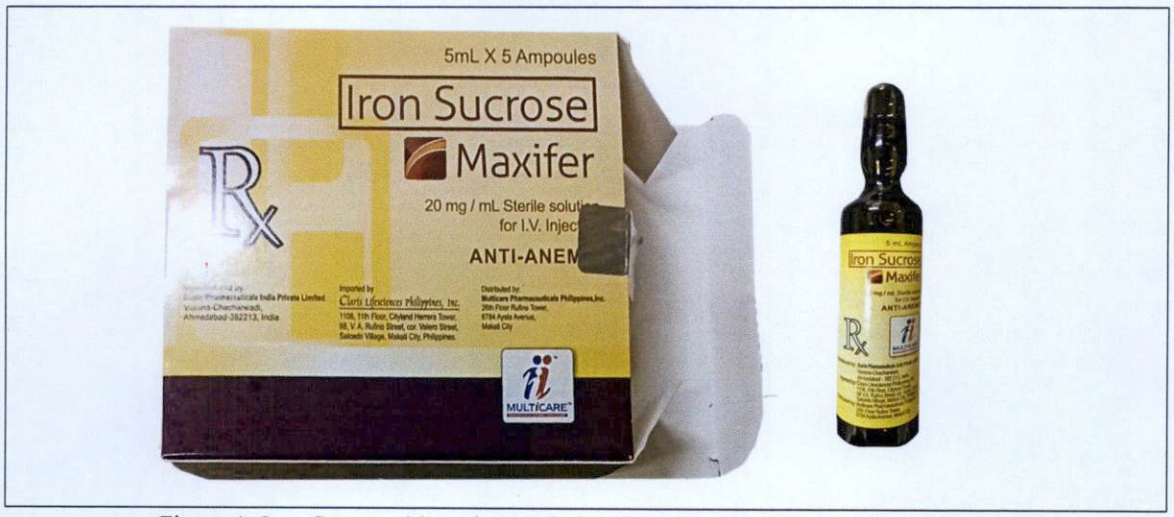

Figure 1. Iron Sucrose 20 mg/mL Solution for Injection (IV) (Maxifer) for recall

The MAH pursued the voluntary recall of the drug product due to the error in the calculation of the particulate matter which rendered the affected lots as out-of-specification. Therefore, the stated lots present quality, safety, and efficacy concerns.

Iron Sucrose is an iron replacement indicated for the treatment of iron deficiency anemia in patients with chronic kidney disease (CKD). Iron Sucrose 20 mg/mL Solution for Injection (IV) (Maxifer) is packed in a 5 mL glass ampoule in a blister pack (box of 5'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 Multicare Pharmaceuticals Philippines, Inc. at telephone number (02) 8811-0636 or mobile no. +639178854954 for any question or additional information regarding the recall.

All Local Government Units (LGU) and Law Enforcement Agencies (LEAs) are requested to ensure that the affected product lot are not sold or made available in their localities or areas of jurisdiction.

For more information and inquiries, please e-mail us at **cdrr_postmarketsurveillance@fda.gov.ph.** To report continuous sale or distribution of the abovementioned, kindly e-mail us via **ereport@fda.gov.ph**. You may also call the Center for Drug Regulation and Research at telephone number **(02) 8809-5596**. Any suspected adverse reaction experienced from the use of the product should be reported immediately to the FDA through this link: **https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH** and fill-out all of the required fields.

Dissemination of the information to all concerned is requested.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

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