Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2022-1968

21 DEC 2022

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

SUBJECT: **Voluntary Product Recall of All Batches of Iron + Vitamin B-Complex Syrup [Sangobion Kids]**

All healthcare professionals and the general public are hereby advised by the Food and Drug Administration (FDA) that all batches of the subject product are being voluntarily recalled from the market. The details of the product are as follows:

DRUG PRODUCT	**IRON + VITAMIN B-COMPLEX SYRUP [SANGOBION KIDS]**
REGISTRATION NO.	**DR-XY32945**
MANUFACTURER	**PT Merck Tbk – Simatupang No. 8, Kelurahan Gedong, Kecamatan Pasar Rebo, Kota Jakarta Timur, Provinsi Dki Jakarta, Indonesia**
IMPORTER [MARKETING AUTHORIZATION HOLDER (MAH)]	**Procter & Gamble Philippines, Inc. – 10F Seven/NEO, 5th Avenue, Crescent Park West, Bonifacio Global City, Fort Bonifacio, Taguig City**

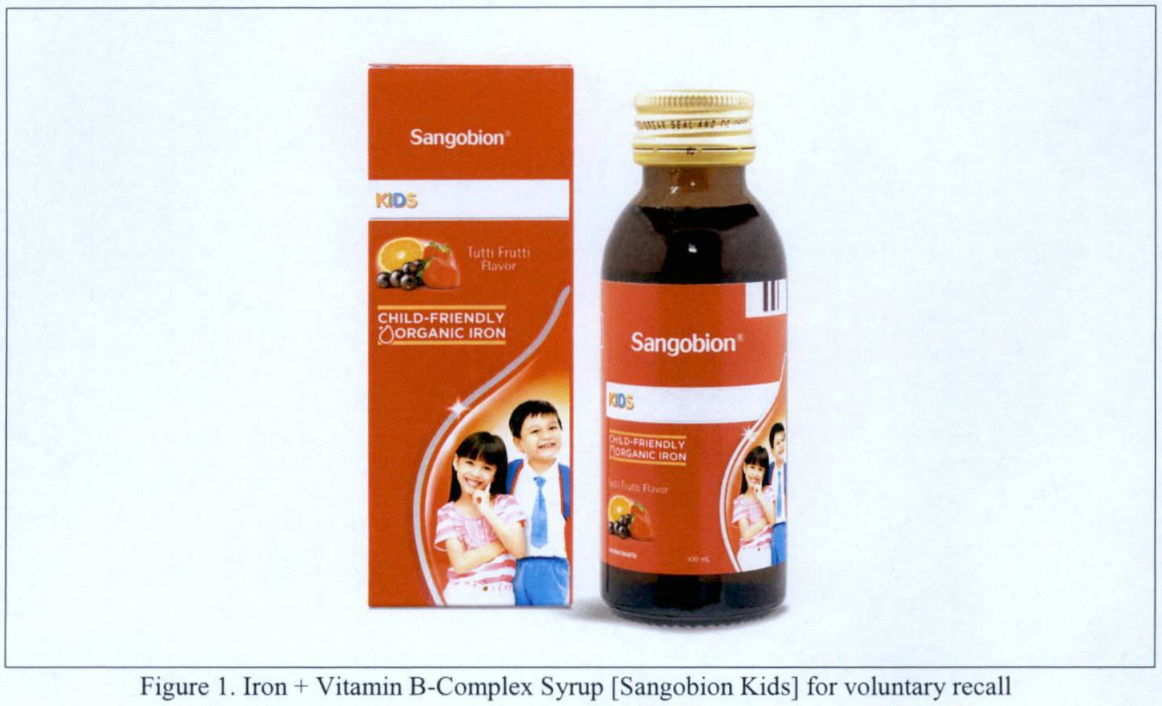

Figure 1. Iron + Vitamin B-Complex Syrup [Sangobion Kids] for voluntary recall

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The voluntary recall is pursued by the MAH due to the detection of ethylene glycol above the maximum allowable limit of 0.1% in 1 batch of the raw material propylene glycol which is used as an excipient to the subject product. As part of the MAH's precautionary measure to protect the right to health of the public, the affected batch including all other available batches will be voluntarily recalled.

The potential risk of high doses of ethylene glycol may result to abdominal pain, vomiting, diarrhea, inability to pass urine, headache, altered mental state and acute kidney injury which may lead to death in younger kids.

Iron + Vitamin B Complex is indicated for the treatment and prevention of iron deficiency anemia (IDA) in children, latent insufficiency of iron and vitamin B during the growth period; iron deficiency after loss of blood. It may also be used as supplement during conditions of chronic illnesses and during convalescence. Iron + Vitamin B Complex Syrup [Sangobion Kids] is packed in 100 mL amber glass bottle.

Therefore, distributors, hospitals, retailers, pharmacies, or clinics that have stocks of the product are instructed to discontinue further distribution, sale, and use. Likewise, all consumers are advised not to use or purchase Sangobion Kids Syrup. If you have purchased the subject product, you may contact Procter & Gamble Philippines, Inc. at 88943955 (Metro Manila) or 1800 1888 8008 (Outside Metro Manila) for guidance on return and refund, and for any question or additional information regarding the recall.

If your child has consumed Sangobion Kids Syrup and experienced adverse reactions including but not limited to the abovementioned reactions, please contact the National Poison Management and Control Center at (02) 8524 1078 (PLDT), or +63 966 718 9904 (Globe), or Fax: 02-526, seek urgent medical attention and please report to the P&G Consumer Care contacts above.

All Local Government Units (LGU) and Law Enforcement Agencies (LEAs) are requested to ensure that said product is not sold or made available by concerned distributors, after the issuance of this advisory, 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 the 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.

DR. SAMUEL A. ZACATE
Director General

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