



FDA ADVISORY
No. **2019-238**

14 AUG 2019

TO: THE GENERAL PUBLIC

**SUBJECT: VOLUNTARY RECALL OF SIMILAC TUMMICARE®
ONE INFANT FORMULA (820 grams) WITH BATCH NO.
03518QU**

The public is hereby advised by the Food and Drug Administration (FDA) regarding the voluntary recall of Abbott Laboratories on **Similac Tummicare® One Infant Formula (820 grams)**, with batch no. **03518QU**, manufacturing date **March 2019** and expiration date **March 2022** due to difference in the label instructions and preparation scoop size of the product.



Bottom of the can:

Batch No. 03518QU
EXP 03 2022



Abbott Laboratories, Inc. received an inquiry from a customer regarding the inconsistency between the scoop size and preparation instructions at the label of the product. The affected batch contained a smaller red preparation scoop compared to the white preparation scoop that is shown on the label instructions. The product is safe to consume however, if the red scoop is used to prepare the formula according to the label instructions and provided to an infant as sole source of nutrition, it would not provide sufficient nutrition to support normal growth.

Although Abbott Laboratories has not received any adverse event reports for this incident, the company has decided to proceed with caution and voluntarily recalled the product from the market. This recall applies only to the product with **batch no. 03518QU** and no other Abbott Laboratories products are affected by this recall.

Consumers who may have purchased the above product are advised to contact Abbott Laboratories hotline at telephone no. **(02) 995-1555** (Manila) or **1800-10-995-1555** (Province) or email familyties.ph@abbott.com for information on how to obtain either a replacement product or full refund. The public may also email the FDA at info@fda.gov.ph for any question or additional information regarding the recall.

All Officers of the Field Regulatory Operations Office (FROO) are hereby ordered to monitor the availability of the product with the specified batch number in the market and instruct the concerned establishment to return the sealed stocks to Abbott Laboratories for proper disposal.

Dissemination of the above information to all concerned is requested.


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