



FDA ADVISORY  
No. **2019-257**

05 SEP 2019

**TO: THE GENERAL PUBLIC**

**SUBJECT: VOLUNTARY RECALL OF LACTUM INFANT FORMULA POWDER 0-6 MONTHS (350 grams) WITH BATCH NO. PL9GDL5B**

The public is hereby advised by the Food and Drug Administration (FDA) regarding the voluntary recall of Mead Johnson Nutrition of LACTUM Instant Formula Powder 0-6 Months, with batch no. PL9GDL5B, manufacturing date 12 July 2019 and expiration date 12 January 2021 due to difference in the actual product inside the box which instead contains LACTUM Infant Formula Powder 6-12 Months.



Figure 1. Incorrect Secondary Packaging of (Foil Bag) with Markings of LACTUM Instant Formula Powder 6-12 Months (left) and Primary Packaging (Carton Box) LACTUM Instant Formula Powder 0-6 Mos. (right)



Mead Johnson Nutrition received a report from their authorized retailer that there was a discrepancy between the product marked in their storage and the actual product. The affected batch contained LACTUM Infant Formula Powder 6-12 Months, intended for infants aged 6-12 months.


In line with this, the public is advised to stop feeding of the recalled batch to your infants aged 0-6 months as this may cause dehydration and electrolyte imbalance due to the formulation being intended for infants aged 6-12 months. Furthermore, there is a greater risk for *Cronobacter sakazakii* infection for infants under 2 months of age as the inappropriate formulation inside (Instant Infant Formula 6-12 Months), does not require verification testing and ingredient controls for *Cronobacter* spp.

Although Mead Johnson Nutrition 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. PL9GDL5B and no other Mead Johnson Nutrition products are affected by this recall.

Consumers who may have purchased the above product are advised to contact Mead Johnson Nutrition Center hotline at telephone no. (02) 841-8222 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](mailto: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 Mead Johnson Nutrition for proper disposal.

Dissemination of the above information to all concerned is requested.

  
**ROLANDO ENRIQUEZ DOMINGO, MD, DPBO**  
Undersecretary of Health  
Officer-in-Charge, Director General

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