

# Statement on Metabolic Formula Supply Issues As a Result of the Abbott Product Recall



3/15/2022: As you are likely aware, the FDA has placed a manufacturing and shipping hold on all products produced at Abbott's Sturgis, MI. plant due to reports of bacterial infection in several infants who consumed their Similac, Alimentum, or EleCare powdered infant formulas. Abbott has voluntarily recalled these products. All of Abbott's metabolic formula products are produced in this plant and are therefore affected by the manufacturing and shipping hold. There have been no reports of bacterial infection in individuals using these products and no metabolic products have been recalled. It is not known when this hold will be lifted.

The undersigned organizations have consulted with metabolic dietitians from across the U.S. and Canada, and representatives of Genetic Metabolic Dietitians International (GMDI), the Southeast Regional Genetics Network (SERN), Abbott, Nutricia, and Vitaflo, among others.

***While we hope that the situation at the Abbott plant will be resolved quickly, and that the FDA will release the hold and allow Abbott to resume manufacturing and shipping of metabolic products, we have concluded that the most prudent course of action is for all metabolic patients to work with their clinicians to transition to a new formula as soon as possible as the timeline cannot be predicted.***

Please be patient with your clinical teams as they reach out to you to facilitate this transition. This situation has placed an enormous burden on staff on top of their regular responsibilities. Please also understand that some metabolic disorders put people at higher risk of decompensation, and hospitalization, than others. Clinical teams must prioritize those patients, but rest assured they are working hard to make sure all patients have sufficient supply of a formula that is palatable and meets their nutritional needs. Your dietitians understand the challenges involved in changing formula and are doing their best to provide alternatives which will be acceptable to each patient.

**We have been in contact with the FDA to express our concerns. They are well aware that metabolic formulas are essential to the health of our community and have issued a [statement specifically regarding the metabolic products](#).**

**We will stay on top of this situation and keep you informed as new information becomes available.**

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## Products affected by the FDA hold:

Glutarex-1	Ketonex-1	ProViMin
Glutarex-2	Ketonex-2	Calcilo XD
Cyclinex-1	Phenex-1	Tyrex-1
Cyclinex-2	Phenex-2	Tyrex-2
Hominex-1	Phenex-2 Vanilla	Similac PM 60/40
Hominex-2	Pro-Phree	
I-Valex-1	Propimex-1	
I-Valex-2	Propimex-2	