

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



The coalition of organizations named above would like to provide the following update on the situation created by the FDA hold on Abbott's Sturgis, MI facility. Our original statement is provided [here](#). We are communicating with NORD, the FDA, the American Academy of Pediatrics (AAP), Genetic and Metabolic Dietitians International (GMDI) and metabolic formula suppliers to provide as much information as possible and work toward a resolution of the situation. To make progress, we need your help. [Submit your story to help the FDA understand the impact on our community.](#)

The FDA has not yet provided a date for releasing the hold on Abbott's Sturgis, MI. plant so that metabolic formula from that facility can be released for distribution. Their response to our request for an update was as follows:

The FDA fully understands the risk to metabolic patients of inadequate access to medical foods and have given a resolution of this issue their highest priority. They cannot provide additional information about process and timeline as this is an ongoing investigation. (As of 4/5/2022).

[This article from the Food Poisoning Bulletin](#) contains additional details on the FDA's inspection of the plant. As does this from [EFoodAlert.com](#).

The situation remains urgent for thousands of families who use Abbott metabolic products. Transition to a new product is difficult, time-consuming, and incredibly stressful. In addition, other formula companies have been reporting supply issues, with some products on backorder, as patients switch from an Abbott product to another metabolic formula. Statements from Nutricia and Vitaflo are [below](#), and we await statements from Cambrooke and Mead-Johnson.

As a coalition of patient organizations supporting the IEM community, the health and safety of those in our community is paramount. We also understand that the FDA has a set of procedures they must follow to clear the plant. That said, the impacts on the metabolic community are severe, and our request to the FDA is to prioritize above all else the testing and clearing of the metabolic products that have been manufactured already so that they be distributed to the patient community. To support this request, the FDA needs to hear from affected individuals and their families. [Please click here](#) to share how the

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formula shortage— of products from Abbott or other companies — has affected you. As a coalition we will share your stories with the FDA and with the media where appropriate.

**Statement from Nutricia North America (full statement [here](#)).**

4/20/2022: Some of our metabolic products are temporarily in short supply due to higher demand and delays in obtaining some of our essential supplies. Please know that we are working around the clock to increase manufacturing capacity to support your metabolic product needs. This is especially true for our Complex MSD, GlutarAde and PhenylAde products where we expect to have ample supply in May. We will let you know more as soon as we have confirmed back-in-stock dates.

**Statement from Vitaflo (full statement [here](#)).**

- We have increased stock of certain products and are working closely with our supply chain to adjust based on demand
- We continue to sample products\* to help you and your dietitian find the best option to suit your lifestyle needs and preferences
- Territory managers will be offering sampling on clinic days or during upcoming events (camps, walks etc.) as permitted by your local metabolic clinic
- Our team at [formula4success](#) is here to support with product access

\*The only products we are unable to sample are PKU trio (unflavored and vanilla) and UCD trio (unflavored) due to surge in demand. While we do have stock available, we want to ensure that existing patients have the supply they need. We are actively working on building up our inventory and will resume sampling these products as soon as we can.

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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	