Abbott To Release Metabolic Nutrition Formulas

- Metabolic nutrition formulas previously on hold will be released free of charge to patients, in coordination with healthcare professionals based on need and on a case-by-case basis
- The lots being released were not included in the February recall and are now being released at the request of the U.S. FDA
- Patients, caregivers and healthcare professionals with questions should contact Abbott at +1-800-881-0876

ABBOTT PARK, Ill., April 29, 2022 /PRNewswire/ -- At the request of the U.S. Food and Drug Administration (FDA), Abbott (NYSE: ABT) is releasing limited quantities of metabolic nutrition formulas that were previously on hold following Abbott's recall of some powder infant formulas from its Sturgis, Mich., facility. The products have been tested and comply with all product release requirements before distribution. The lots being released were not included in the recall.

These products are used under the care of a healthcare professional and require a medical referral. Patients, caregivers and healthcare professionals in need of these products should contact Abbott at +1-800-881-0876 to provide necessary information. Abbott will work with metabolic centers and healthcare providers to fulfill requests based on need and on a case-by-case basis.

The metabolic products being released are:

- Calcilo XD®
- Cyclinex®-1 and 2
- Glutarex®-1 and 2
- Hominex®-1 and 2
- I-Valex®-1 and 2
- Ketonex®-1 and 2
- Phenex®-1 and 2
- Pro-Phree®
- Propimex®-1 and 2
- ProViMin®
- Tyrex®-1 and 2

The specialty product being released is:

- Similac® PM 60/40

Similac®, Alimentum® and EleCare® powder formulas that were voluntarily recalled in February are**not** included in this product release.

Abbott has limited inventory of these products. New product is not currently being manufactured. Abbott has implemented corrective actions and is working with the FDA to address the situation before resuming operations at the Sturgis facility. Once Abbott resumes production, it will take at least six to eight weeks for product to be available for distribution.

No Link Between Sturgis Facility and Reported Cases
On Feb. 17, 2022, Abbott issued a voluntary recall of some powder infant formula products manufactured at its Sturgis facility. The recall **did not include any of Abbott's metabolic nutrition formulas**, and included only a single batch of Similac PM 60/40. During the investigation, the metabolic nutrition formulas and all other batches of Similac PM 60/40 were placed on hold.

Abbott tests products prior to distribution, and no Abbott formula distributed to consumers tested positive for*Cronobacter sakazakii* or *Salmonella*. All finished product testing by Abbott and the FDA during the inspection of the facility likewise came back negative for *Cronobacter sakazakii* and/or *Salmonella*. No *Salmonella* was found at the Sturgis facility during the investigation. The *Cronobacter sakazakii* that was found in environmental testing during the investigation was in non-product contact areas of the facility and has not been linked to any known infant illness.

A thorough review of all available data indicates that the infant formula produced at our Sturgis facility is not likely the source of infection in the reported cases and that there was not an outbreak caused by products from the facility.

"We know this situation has worsened the industry-wide infant formula supply shortage and we regret the anxiety and stress this is causing," said Joe Manning, executive vice president, nutritional products, Abbott. "Abbott is committed to working with the FDA to address this situation so we can resume operations at this facility and continue serving the nutritional needs of people who rely on our infant and specialty formulas."

About Abbott
Abbott is a global healthcare leader that helps people live more fully at all stages of life. Our portfolio of life-changing technologies spans the spectrum of healthcare, with leading businesses and products in diagnostics, medical devices, nutritionals and branded generic medicines. Our 113,000 colleagues serve people in more than 160 countries.

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