FDA issues warning on dangers of probiotic products for preemie babies

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Federal regulators have sent warning letters to two companies for illegally selling probiotic products for use in preterm infants.

The U.S. Food and Drug Administration also sent a letter to health care providers warning of the risks.

Probiotic products contain live organisms such as bacteria or yeast. They are commonly found in dietary supplements.

These products may be dangerous for preterm infants and are being illegally sold to treat or prevent diseases in preemies in hospitals, such as necrotizing enterocolitis.

Those young babies who are given a probiotic product are at risk of invasive, potentially fatal disease, or infection, caused by the bacteria or yeast in the probiotics, the FDA said.

Certain products have contributed to invasive disease in hospitalized babies, including one death this year. They have been linked to more than two dozen other reported adverse events nationwide since 2018, according to the FDA.

"Adverse events in any infant following the use of a probiotic are a concern to the FDA. We especially want to make clear that products containing live microorganisms may present serious risks to preterm infants in hospital settings," Dr. Peter Marks, director of the FDA's Center for Biologics Evaluation and Research, said in an agency news release.

"With today's message, we want to warn parents, caregivers and health care providers that if these products are used for the prevention or treatment of disease, they have not undergone the agency's rigorous premarket process to evaluate their safety, effectiveness and quality for these medical uses," Marks added.

No probiotic product is approved by the FDA for infants of any age.

Products sold for this purpose have not gone through FDA safety evaluations or been checked for compliance with the agency's rigorous manufacturing and testing standards.

These products would need an approved Biologics License Application.

Without the approval, health care providers who administer products containing live bacteria or yeast to treat or prevent disease are required to submit an Investigational New Drug application to the FDA.

A warning letter was sent to Abbott Laboratories on Oct. 24 for its Similac Probiotic Tri-Blend, which contains *B. infantis* (Bb-02), *S. thermophilus* (TH-4) and *B. lactis* (BB-12).

Abbott has agreed to stop selling this product.

This situation is not related to other issues with powdered infant formula made by Abbott, the FDA noted.

The other warning letter was sent to Infinant Health, Inc. (formerly Evolve BioSystems Inc.) regarding its probiotic product, Evivo with MCT Oil.

It has been voluntarily recalled and is no longer available in the United States.

The two products violate the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, the FDA said.

"Protecting public health, especially of the most vulnerable populations such as preterm infants, is one of the highest priorities for the FDA," said James Jones, deputy commissioner for human foods.

"We are encouraging all involved in the care of preterm infants—including parents, caregivers and health care providers—to be aware of the possible risks associated with the administration of probiotic products to preterm infants in hospital settings," Jones added.

Jones said the FDA continues to investigate these incidents and is committed to identifying and addressing potentially unsafe products in the market.

The agency is investigating reports that these products may have contributed to additional adverse events, including death.

While there are conflicting data on safety and effectiveness of probiotics for preventing necrotizing enterocolitis, because of the potential for harm, the FDA urges the industrial, clinical and research funding communities to focus on high-quality clinical trials to provide definitive evidence.

Health care providers and caregivers can report adverse events following use of probiotics to the manufacturer, the FDA's MedWatch program and the Center for Food Safety and Nutrition's Adverse Event Reporting System.

More information: The Children's Hospital of Los Angeles has more on necrotizing enterocolitis.

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