Communicable Disease Epidemiology and Immunization Section
401 5th Avenue, Suite 1250
Seattle, WA 98104
206-296-4774 Fax 206-296-4803
TTY Relay: 711
www.kingcounty.gov/health

Public Health
Seattle & King County

Health Advisory - FDA raises concerns about probiotic products sold for use in hospitalized preterm infants - November 14, 2023

Actions Requested[1,2]

- **Be aware of the recent U.S. Food and Drug Administration (FDA) important safety advisory on the risk of invasive disease in preterm infants given products containing live bacteria or yeast (commonly called probiotics) in hospital settings.**
    - The FDA is aware that certain probiotic products used in hospital settings to prevent necrotizing enterocolitis have contributed to invasive disease, including one infant death in 2023, and have been associated with more than two dozen other reported adverse events in the United States since 2018.
- **Be aware that the FDA has not approved any probiotic product for use as a drug or biological product in infants of any age.**
    - Unapproved, unlicensed probiotics that are used to treat or prevent a disease or condition in preterm infants have not undergone FDA's through premarket for safety and effectiveness, nor have they been evaluated for compliance with the FDA's rigorous manufacturing and testing standards for drugs and biological products, including testing for extraneous organisms.
    - The FDA has issued warning letters to two companies (Abbott Laboratories and Infinant Health, Inc formerly Evolve Biosystems Inc.) for illegally selling probiotic products to treat diseases in preterm infants.
- **Be aware of the requirement for healthcare providers to submit an Investigational New Drug Application (IND) to the FDA when administering probiotics containing live bacteria or yeast to treat, mitigate, cure, or prevent a disease or condition.**
- **Report adverse events following the use of probiotics to the manufacturer, the FDA's MedWatch program and CFSAN Adverse Event Reporting System (CAERS).**

Background[2,3]

Probiotic products contain live organisms such as bacteria or yeast and are commonly marketed as foods, including as dietary supplements. The FDA is concerned these products can be dangerous for preterm infants and are being illegally sold to treat or prevent diseases in preterm infants in hospital settings, such as to reduce the risk of necrotizing enterocolitis. Preterm infants who are administered a probiotic product are at risk of invasive, potentially fatal disease, or infection, caused by the bacteria or yeast contained in the probiotics.

In 2021, the American Academy of Pediatrics released a clinical report on the Use of Probiotics in Preterm Infants, which stated "Given the lack of FDA-regulated pharmaceutical grade products in the United States, conflicting data on safety and efficacy, and potential for harm in a highly vulnerable population, current evidence does not support the routine, universal administration of probiotics to preterm infants, particularly those with a birth weight of <1000 g."

References

1. Dear Provider Letter, Warning Regarding use of Probiotics in Preterm Infants, September 29, 2023, U.S. Food and Drug Administration (FDA)
2. FDA News Release: FDA Raises Concerns About Probiotic Products Sold for Use in Hospitalized Preterm Infants, October 26, 2023, U.S. Food and Drug Administration (FDA)
3. Use of Probiotics in Preterm Infants, *Pediatrics* 2021; American Academy of Pediatrics

To be added to the King County health advisory email distribution list, please visit:
https://kingcounty.gov/depts/health/communicable-diseases/health-care-providers/advisories.aspx