This is an official

CDC Health Advisory

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FDA Warns Not to Feed SimplyThick® to Premature Infants

NOTE TO READERS: This advisory is an FDA notice that is being distributed via CDC's Health Alert Network.

The U.S. Food and Drug Administration (FDA) is recommending that parents, caregivers, and health care providers should not feed the thickening product called SimplyThick to infants born before 37 weeks gestation because it may cause necrotizing enterocolitis (NEC), a life-threatening condition characterized by inflammation and death of intestinal tissue.

SimplyThick is a brand of thickening agent—available to consumers and medical centers—to help manage swallowing difficulties. It is sold in packets of individual servings and in 64-ounce dispenser bottles. The product can be purchased from distributors and local pharmacies throughout the United States.

FDA first learned of adverse events possibly linked to SimplyThick on May 13, 2011. At least four different medical centers around the United States have reported NEC in infants who became sick over the past six months. To date, the agency is aware of 17 reports of NEC, including five deaths, involving premature infants born before 37 weeks who were fed SimplyThick mixed with mothers' breast milk or infant formula products. The mixture was fed to infants for varying amounts of time.

This situation is unusual because NEC most often occurs in infants while they are in the hospital early in their premature course. However, some of the ill infants of which FDA is aware became ill after they had been discharged from the hospital and sent home on a feeding regimen that included SimplyThick.

At this time, the mechanism by which SimplyThick might contribute to the development of NEC in premature infants is not known, nor is it known whether other thickening agents in addition to SimplyThick might also contribute to the development of NEC. FDA is actively investigating the possible link between SimplyThick and these illnesses and deaths and is attempting to determine whether other thickening agents in addition to SimplyThick could elevate the risk of development of late onset NEC in premature infants.

Recommendations for Parents and Caregivers

- Do not feed SimplyThick to premature infants (born before 37 weeks gestation), including those in the hospital and those sent home from the hospital within the past 30 days.
- Contact your health care professional if your baby has symptoms of bloating, greenish-tinged vomit, or bloody stools, or if you have other concerns related to using SimplyThick.
- You or your health care professional can report side effects related to using SimplyThick or other thickening agents to FDA's MedWatch Safety Information and Adverse Event Reporting Program by:
    - Completing and submitting the report online: www.fda.gov/MedWatch/report.htm;
    - Downloading the pre-addressed, postage-paid FDA Form 3500 (or calling 1-800-332-1088 to request the form), completing it, and faxing it to 1-800-FDA-0178; or
    - Mailing the completed form to MedWatch, 5600 Fishers Lane, Rockville, MD 20857.

What FDA Is Doing

FDA is actively investigating the possible link between SimplyThick and these illnesses and deaths and is attempting to determine whether thickening agents in addition to SimplyThick could elevate the risk of development of late-onset NEC in premature infants. FDA will provide updates as information is made available.

For More Information

- FDA: Do not feed SimplyThick to premature infants
- FDA Warns Not to Feed SimplyThick to Premature Infants
- SimplyThick product packaging and labels