Indiana State Department of Health
An Equal Opportunity Employer

Mitchell E. Daniels, Jr.
Governor

Gregory N. Larkin, M.D., F.A.A.F.P.
State Health Commissioner

DATE: May 23, 2011

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: FDA News Release on SimplyThick

SUGGESTED ACTION: **Information provided in case of consumer inquiry.**

****

FDA PRESS RELEASE

For Immediate Release: May 20, 2011
Media Inquiries: Stephanie Yao, 301-796-0394, stephanie.yao@fda.hhs.gov
Consumer Inquiries: 888-INFO-FDA

FDA: Do not feed SimplyThick to premature infants

The thickening product may cause necrotizing enterocolitis (NEC), a life-threatening condition

Fast Facts

- FDA is warning parents, caregivers and health care providers not to feed SimplyThick, a thickening agent for management of swallowing disorders, to infants born before 37 weeks.
- The product may cause necrotizing enterocolitis (NEC), a life-threatening condition characterized by inflammation and death of intestinal tissue.
- Health care providers should stop administering the product to premature infants.
- Parents and caregivers who have questions or concerns related to the use of the product and/or who have medical concerns should contact their health care provider.

What is the Problem?

The FDA is advising parents, caregivers and health care providers not to feed SimplyThick, a thickening product, to premature infants. The product may cause necrotizing enterocolitis (NEC), a life-threatening condition.

FDA first learned of adverse events possibly linked to the product on May 13, 2011. To date, the agency is aware of 15 cases of NEC, including two deaths, involving premature infants who were fed SimplyThick for varying amounts of time. The product was mixed with mothers' breast milk or infant formula products.

Illnesses have been reported from at least four different medical centers around the country. The illnesses of which FDA is aware involve premature infants who became sick over the past six months. SimplyThick was added to the feeding regimen of those infants who later developed NEC to help with swallowing difficulties stemming from complications of premature birth.

The current situation is unusual because NEC most often occurs in babies within the hospital early in their premature course. But among the ill babies of which FDA is aware, some had been discharged from the hospital to home on a feeding regimen that included SimplyThick and then fell ill at home.

What are the Symptoms of Illness/Injury?
NEC is a life-threatening condition characterized by inflammation and death of intestinal tissue. The condition is most often diagnosed in babies who are born prematurely.

Signs and symptoms of NEC include appearance of a bloated abdominal area, appearance of illness, feeding intolerance, greenish-tinged (bile) vomiting and bloody stools.

Who is at Risk?
Premature infants currently receiving hospital care and premature infants discharged from the hospital within the past 30 days should not be fed SimplyThick.

What Do Parents, Care Givers and Health care Providers Need To Do?
Do not feed SimplyThick to premature infants.

Parents and caregivers who have questions or concerns related to the use of the product and/or who have medical concerns should contact their health care provider.

What Does the Product Look Like?
SimplyThick is one brand of thickening agent available to medical centers and consumers. The product 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.

Images of the SimplyThick label and packaging can be viewed here[1].

Where is it Distributed?
SimplyThick is distributed and can be purchased throughout the United States.

What is Being Done about the Problem?
FDA is actively investigating the link between SimplyThick and these illnesses and deaths. FDA will provide updates as information is made available.

Who Should be Contacted?
Parents and caregivers who have questions or concerns related to the use of the product and/or who have medical concerns should contact their health care provider.

Health care professionals and patients are encouraged to report adverse events or side effects related to the use of this product to the FDA's MedWatch Safety Information and Adverse Event Reporting Program by:

- Completing and submitting the adverse report online: www.fda.gov/MedWatch/report.htm[2]
- Downloading the pre-addressed, postage-paid FDA Form 3500[3] (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.

The information in this press release reflects the FDA's best efforts to communicate what it has learned from medical centers, the distributor and the state and local public health agencies involved in the investigation. The agency will update this page as more information becomes available.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

#