



New Hampshire Health Alert Network

Health.Alert@nh.gov

Status: Actual
Message Type: Alert
Severity: Severe
Sensitive: Not Sensitive
Message Identifier: HAN #20110521 SimplyThick Alert
Delivery Time: 12 hours
Acknowledgement: No
Originating Agency: NH Department of Health and Human Services, Division of Public Health Services

DATE: May 21, 2011

TIME: 11:30 EDT

TO: Physicians, Nurses, Infection Control Practitioners, Hospital Emergency Departments, Manchester Health Department, Nashua Health Department, NHHA, Laboratory Response Network, DHHS Outbreak Team, DPHS Investigation Team, Public Health Network, and DPHS Management Team

FROM: Sharon Alroy-Preis, MD, MPH, State Epidemiologist

SUBJECT: FDA alert: SimplyThick may be related to Necrotizing Enterocolitis (NEC)

NH Department of Health and Human Services (NH DHHS) recommends:

- Not to feed SimplyThick, a thickening agent for the management of swallowing disorders, to infants born before 37 weeks as this product may cause necrotizing enterocolitis (NEC).
- Report cases of NEC in infants consuming SimplyThick to emergency.operations@fda.hhs.gov

As of May 20, 2011, the FDA 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. Illnesses have been reported from at least four different medical centers around the country. The illnesses of which FDA is aware involve premature infants. 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 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 US. Please read the MedWatch safety alert, including links to the Press Release and product photos, at: <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm256257.htm>

For any questions regarding the contents of this message, please contact NH DHHS Infectious Disease Investigation and Surveillance Sections at 603-271-4496 (after hours 1-800-852-3345 ext.5300).

DEFINITION OF TERMS AND ALERTING VOCABULARY

Message Type

- Alert: Indicates an original alert
Update: Indicates prior alert has been updated and superseded
Cancel: Indicates prior alert has been cancelled
Error: Indicates prior alert has been retracted

Status

- Actual: Communication or alert refers to a live event
Exercise: Designated recipients must respond to the communication or alert
Test: Communication or alert is related to a technical, system test and should be disregarded

Severity

- Extreme: Extraordinary threat to life or property
Severe: Significant threat to life or property
Moderate: Possible threat to life or property
Minor: Minimal threat to life or property
Unknown: Unknown threat to life or property

Sensitive

- Sensitive: Indicates the alert contains sensitive content
Not Sensitive: Indicates non-sensitive content

Message Identifier: A unique alert identifier that is generated upon alert activation.

Delivery Time: Indicates the timeframe for delivery of the alert.

Acknowledgement: Indicates whether an acknowledgement on the part of the recipient is required to confirm that the alert was received, and the timeframe in which a response is required.

Originating Agency: A guaranteed unique identifier for the agency originating the alert.

Alerting Program: The program sending the alert or engaging in alerts and communications using PHIN Communication and Alerting (PCA) as a vehicle for their delivery.

You have received this message based upon the information contained within our emergency notification database.

If you have a different or additional e-mail or fax address that you would prefer to be used please contact:

Denise M. Krol, MS
NH HAN Coordinator
Denise.Krol@dhhs.state.nh.us

Business Hours 8:00 AM – 4:00 PM
Tel: 603-271-4596
Fax: 603-271-0545