

Recall Announcement (ODA/ODH) 2002-42

November 4, 2002

FDA ALERTS PUBLIC REGARDING RECALL OF POWDERED INFANT FORMULA

The Food and Drug Administration today is alerting the public to the voluntary recall of powdered infant formula announced by Wyeth Nutritionals Inc., Georgia, Vermont. Certain lots of powdered infant formula manufactured between July 12 and September 25, 2002, may be contaminated with *Enterobacter sakazakii*. *E. sakazakii* is a foodborne pathogen that can in rare cases cause sepsis (bacteria in the blood), meningitis (inflammation of the lining of the brain), or necrotizing enterocolitis (severe intestinal infection) in newborn infants, particularly premature infants or other infants with weakened immune systems. No illnesses have been reported to date in connection with this contamination.

The powdered infant formula was distributed nationwide in retail stores and amounts to approximately 1.5 million cans. The affected products can be identified by an expiration/use by date, embossed on the bottom of the can of: 07 28 05, 08 28 05 and 09 28 05. The products also can be identified by a six-digit character embossed on the bottom of the cans. The first four characters include: K12N through K19N; L07N through L30N; and N03N through N25N. The products include:

- Baby Basics by Albertson's Infant Formula with Iron 2 LB (908g)
- Baby Basics by Albertson's Infant Formula with Iron 1 LB (454g)
- Baby Basics by Albertson's Soy Infant Formula with Iron 2 LB (908g)
- Baby Basics by Albertson's Soy Infant Formula with Iron 1 LB (454g)
- Baby Basics by Albertson's Formula for older infants with iron 1 LB. 15.7 oz (900g)
- Kozy Kids Infant Formula with Iron 16 oz (454g)
- Kozy Kids Soy Infant Formula with Iron 16 oz (454g)
- CVS Soy Infant Formula with Iron 16 oz (454g)
- Hill Country Fare Infant Formula with Iron 32 oz (2 LB) 908g
- Hill Country Fare Infant Formula with Iron 16 oz (1 LB) 454g
- Hill Country Fare Soy Infant Formula with Iron 32 oz (2 LB) 908g
- Hill Country Fare Soy Infant Formula with Iron 16 oz (1 LB) 454g
- HEB Baby Infant Formula with Iron 32 oz (2 LB) 908g
- American Fare Little Ones Infant Formula with Iron 2 LB (908g)
- American Fare Little Ones Soy Infant Formula with Iron 2 LB (908g)

- American Fare Little Ones Formula for Older Infants with Iron & Calcium 1 LB 15.7 (900g)
- HomeBest Soy Infant Formula with Iron 2 LB. (908 g)
- Safeway Select Infant Formula with Iron 2 LB (908g)
- Safeway Select Infant Formula 2 1 LB 15.7 oz (900g)
- Healthy Baby Infant Formula with Iron 2 LB (908g)
- Healthy Baby Infant Formula with Iron 1 LB (454g)
- Healthy Baby Soy Infant Formula with Iron 2 LB (908g)
- Healthy Baby Formula for Older Infants with Iron 1 LB 15.7 oz. (900g)
- Walgreens Infant Formula with Iron 16 oz (454g)
- Parent's Choice Infant Formula with Iron 2 LB (908g)
- Parent's Choice Infant Formula with Iron 16 oz (454g)
- Parent's Choice Soy Infant Formula with Iron 2 LB (908g)
- Parent's Choice Soy Infant Formula with Iron 35oz (1 kg)
- Parent's Choice 2 Infant Formula with Iron 1 LB 15.7 oz (900g)

The contamination was first detected during a special *E. sakazakii* sampling FDA conducted at the Vermont facility. This special sampling and analysis is being conducted at all major, domestic manufacturers of powdered infant formula.

Consumers who have purchased the powdered infant formula are urged to return the product to the place of purchase for a full refund. Consumers with questions may contact Wyeth at 1-888-526-5376.