Recalls of Infant Feeding Products

Recall Class	Date	Product	Problem
Firm initiated recall	2005	Similac Advance with iron, 12.9 oz powdered infant formula; entire Lot Number 20307RB; (Ross Products)	Black plastic particles found in a number of cans; distributed between 9-15-04 and 10-18-04 in the Eastern half of the US and in IA, KS, and MO. Particles are a result of an isolated manufacturing event
III	2005	Enfamil LactoFree with Lipil, 13 oz concentrated liquid cans; 6408 cases (76,896 cans) (Mead Johnson)	May have an off odor, clumping, and product separation
I	2003	EnfaCare Lipil, 12.9oz powdered formula for preterm infants; 505 cases (3,030 cans) (Mead Johnson)	Contaminated with *Enterobacter sakazakii* which can cause sepsis, meningitis, and necrotizing enterocolitis particularly in preterm or immunocompromized infants. 505 cases were shipped to hospitals, retail stores, and WIC clinics nationwide in December 2002
II	2002	Powdered infant formula under the following labels: Baby Basics for older infants, American Fare for older infants, Healthy Baby formula for older infants, Parents Choice 2; (Wyeth Nutritionals)	Products may be contaminated with *Enterobacter sakazakii*
I	2002	Store brand powdered formula under the labels Baby Basics, Kozy Kids, CVS, Hill Country Fare, American Fare, Little Ones, HomeBest, Safeway Select, Healthy Baby, Walgreen's, Parent's Choice, Perfect Choice Sold in Wyeth Company Store in PA only; 1 and 2 lb standard and soy cans shipped nationwide, manufactured between July 12 and September 25, 2002; 1.5 million Cans (Wyeth Nutritionals)	Contaminated with *Enterobacter sakazakii* which can cause sepsis, meningitis, and necrotizing enterocolitis. Contamination was detected during a special sampling for *E. sakazakii* conducted by the FDA. Powdered formula is not sterile. All high-risk, non-breastfed infants should fed with commercially sterile liquid formula
I	2002	Portagen formula, 16oz powder; 17,358 cans shipped nationwide in February 2001 (Mead Johnson)	Portagen is a special formula used for infants with difficulty digesting fats. The recall was prompted by the death of a premature infant in April 2001from meningitis caused by Portagen contaminated with *Enterbacter sakazakii*
Firm initiated recall	2001	Carnation Follow-Up formula, 32 ounce liquid ready-to-feed; 120 cans (Nestle)	Excessive magnesium content in one batch; long term use could cause adverse health effects such as low blood pressure and irregular heart beat. The product was distributed only to Wal*Mart stores in 19 cities in Texas.
Firm initiated allergy alert	2001	LactoFree and Enfamil AR sample packs. The LactoFree pack has two 3oz ready-to-use Nursette bottles and two Easy One single serving powder packets. The Enfamil AR sample contains three	Ingredients are not listed on the back of the boxes. These sample packs were distributed to physicians nationwide to give to their patients. Infants allergic to milk protein run the risk of a serious or life threatening allergic reaction if they consume these products

		3oz ready-to-use Nursette bottles and a single hole nipple (Mead Johnson)	
Firm Initiated Recall	2001	LactoFree sample packs containing two 3 ounce ready-to-use nursette bottles and two Easy One single serving powder packets (Mead Johnson)	Packages failed to list the ingredients on the back of the box. Infants allergic to milk protein are at risk of life threatening allergic reaction if they consume the product. The sample packs were shipped to 30 stores in nine states, Colorado, Iowa, Kansas, Louisiana, Minnesota, Missouri, Oklahoma, Texas, & Tennessee.
Firm Initiated Recall	2001	Nutramigen powder (3.7 million 16 oz cans) and Nutramigen ready to feed (930,000 32oz cans) (Mead Johnson)	The cans have incorrect preparation instructions in Spanish that could lead to seizures, an irregular heartbeat, or death if the altered formula is consumed for several days. Infants already ill or who live in hot climates are at greater risk for potentially fatal complications. The formula was distributed nationwide as well as in Guam, the Dominican Republic, and Puerto Rico. The offending product was permitted to remain on the shelves in stores, with correct prepara tion instructions in Spanish posted as tear off sheets that the consumer was responsible for noticing
III Firm-initiated recall	2000	Repackaged infant formula: Isomil powder and concentrate; Similac with iron, low iron powder and concentrate; Neosure powder; Enfamil low iron and with iron powder, Enfamil Lacto-free powder; Prosobee soy powder; Nutramigen powder 2000-3000 cases	The infant formulas were repackaged in cardboard trays/boxes which are misbranded. All lots of cardboard cases and trays that were repackaged, labeled, and distributed by Unity Wholesale Grocery since April 25, 2000
III	2000	Carnation Good Start, Alsoy, and Follow-up in 13oz concentrate cans (2.5 million cans) (Nestle)	Processing may not have reached high enough temperatures to ensure sterility
II	1999	Isomil ready to feed soy formula in 32 oz metal cans; 17,821 cases (106,926 cans) (Ross Laboratories)	Product was held in cans with a low level of can lid defects allowing for post-processing contamination
Manufacturer's Voluntary Recall	1999	ProSobee soy formula; 8oz, ready to use cans sold in 4-pack cartons; 7000 cases	Cans in the batch mislabeled ProSobee when they actually contained vanilla Sustacal, an adult nutrition supplement. Consuming Sustacal has the potential to (Mead Johnson) cause severe medical problems in infants, especially if they are ill, highly sensitive to milk proteins or have galactosemia. Because it has a higher caloric density and renal solute load as compared to ProSobee, Sustacal also has the potential to cause dehydration in healthy infants.
I	1999	Heinz 3 Broccoli, Carrots and Cheese Junior Baby Food; 6oz glass jars; 5,269 cases (24 jars/ case) (Heinz USA)	Product contaminated with pieces of hard plastic
III	1999	Carnation Follow-Up formula; 32 oz cans; 12,651 cases (6 cans/ case) (Nestle USA)	Product has a lumpy, curdled appearance

II	1998	Beginner strained carrots 25,760 cases of 2.5oz jars (Heinz)	Product contains elevated levels of lead
Manufacturer's Voluntary recall	1998	Beginner strained carrots, Vegetable chicken dinner: 300,000 jars (Heinz)	20-22ug/oz of lead/4oz jar (usual intake is 4.1ug of lead/day from food)
II	1997	Gerber carrots for babies: 1st, 2nd,3rd foods; 2,141,880 jars (Gerber)	Products contain high levels of arsenic
III	1997	Isomil Soy Formula, 104 cases, 6 cans per case (Ross)	Did not contain the labeled amount of inositol. Product was originally formulated for distribution in the UK which did not require the addition of inositol
II	1997	Carnation Follow Up formula; 32 oz cans;11,317 cases (6cans/ case)	Adulterated-produced under insanitary conditions; linked with (Nestle) mild gastrointestinal illness; product is separated
II	1996	Heinz Apple-Prune juice for infants; 4oz bottles	Contain lead in excess of 80ppb
Market Withdrawal	1996	Carnation Alsoy Concentrate liquid, 13oz cans Carnation Nutritionals (Nestle)	Can top says "Do not add water" mislabeling could lead to infants consuming undiluted, concentrated formula (side label states to add water)
III	1996	Balsam Springs Baby Water with fluoride in gallon containers (Veryfine Products)	Unfit for food due to seal micro-leakage and contaminated with extraneous material
III	1996	Gerber Graduates apple juice for toddlers, 46oz clear, plastic bottles (Gerber)	Unfit for food due to vinegary and sour taste
III	1995	Oral water nursette, 3oz glass bottles (Bristol-Myers Squibb)	product contaminated with chlorine
II	1994	Carnation Good Start, concentrated liquid, 13oz cans; 16,878 cases Carnation Nutritionals (Nestle)	Some cans contained non-pathogenic spoilage organisms indicating product could be contaminated with other microorganisms
III	1993	Infant's Choice Water, calcium and fluoride added, sodium-free, in one gallon plastic jugs, 24,000 gallons, Magnetic Springs Water Co., Columbus, Ohio	Product is mislabeled
I	1993	Soylac Powder infant formula, 14 oz cans, distributed in US and Canada, (Nutricia, Inc)	Contaminated with Salmonella
I	1993	Promil, supplemental food for	Manufactured under conditions where it

		infants and children, distributed in Thailand, spray dried at Maple Island, Inc's facility, (Wyeth-Ayerst)	may have become contaminated with Salmonella
I	1993	Formance, fortified nutritional powder for use by pregnant and lactating women, 850g cans, spray dried at Maple Island, Inc's facility, distributed in Hong Kong (Ross Labs)	Manufactured under conditions whereby it may have become contaminated with Salmonella
II	1993	Nutramigen, 20 cal/oz, 3oz glass nursettes, 102,048 bottles (Mead Johnson Nutritionals)	Contaminated with glass particles
II	1993	Gerber 2nd Foods brand oatmeal with applesauce and bananas, 4oz jars, 25,590 cases (Gerber Products)	Product contained glass particles
III	1993	Isomil Soy Formula with iron, concentrated liquid, 13 oz cans, (Ross Labs)	Product is in cans with peeling can liners
II	1993	Nursoy Soy Protein, iron fortified concentrate, 13 oz cans, 10,250 cases (Wyeth-Ayerst)	Some contaminated with Klebsiella pneumoniae and Pseudomonas aeruginosa: hazard to infant health in form of gastrointestinal stress to infants and newborns
I	1990	I-Soyalac Concentrated Infant Formula, 13oz cans (Loma Linda Foods)	Contaminated with heat sensitive and heat resistant bacteria
III	1989	Similac PM 60/40 powder, 16oz metal cans, low iron infant formula (Ross Labs)	Deficient in vitamin D, below label claims for vitamin K
III	1989	Carnation Good Nature Infant Formula, 32oz containers, for babies over six months of age	Unfit for food because of physical appearance and will not pass through an ordinary bottle nipple
III	1989	Nutramigen Iron Fortified Protein Hydrolysate Formula, 4 & 8oz bottles (Mead Johnson)	Deficient in vitamin D
III	1986	Soyalac Powder, 1.2 oz foil pouches as physician samples (Loma Linda Foods)	Progressive vitamin A degredation
II	1986	SMA Ready to Feed 32 oz cans (Wyeth Labs)	Curdling, discoloration, off odor
II	1985	Gerber Meat Base Formula with iron, 15 oz cans of concentrated formula	Superpotent levels of vitamin A and subpotent levels of vitamin D
I	1985	Kama-Mil Powder, 14 & 16 oz cans, (Kama Nutritional Products)	Marked in violation of Infant Formula Act, deficient in folacin, vitamin D and zinc

I	1985	Nutra-Milk Powder infant formula, 8, 10, & 16 oz bottles	-as above-
I	1985	Kama-Mil Powder infant formula in 14 oz fiberboard cans, 14 & 16oz	-as above-
I	1985	Pamphlet labeled in part "Edensoy" promotional material for EdensoySoy Drinks (Eden Foods, Inc.)	Pamphlet erroneously suggests that Edensoy may be used as a substitute for mother's milk or for infant formula
II	1985	Cow & Gate Improved Modified Infant Formula, 450 gm & 1 kg cans, US Virgin Islands	Deficient in copper & linoleic acid, not in compliance with section 412 of Food, Drug and Cosmetic Act
III	1985	Lactogen Brand Infant Milk Formula in powder form with iron, 450gm, 227 gm, & 1135 gm cans (Cow & Gate)	-as above-
II	1985	5% glucose water in 4 oz bottles (Ross Labs)	Glass particles in product due to bottle necks chipping
III	1984	Similac with iron concentrate, 13 oz cans (Ross Labs)	Overprocessed resulting in its becoming lumpy, brown, and unfit for food consumption
II	1983	Soyalac Powder Milk-Free fortified soy formula, 16 oz cans (Loma Linda Foods)	Deficient in vitamin A
II	1983	Naturlac Infant Formula Powder, 22 3/4 oz cans and trial size 32 gm packets (Fillmore Foods)	Copper levels below minimum required by Infant Formula Act, thiamine and vitamin B-6 below label declaration
I	1982	Nursoy Concentrated Liquid 13 oz cans, Nursoy Ready to Feed 32 oz cans (Wyeth Labs)	Deficient in vitamin B-6
I	1982	SMA Iron Fortified Concentrated Liquid 13 oz cans, SMA Iron Fortified Ready to Feed 32 oz cans, SMA Powder 16 oz cans, SMA E-Z Nurser Ready to Feed Nursettes (Wyeth Labs)	Deficient in vitamin B-6, less than stated on the label

Source: FDA Enforcement Report, HFI-20, 5600 Fishers Lane, Rockville, MD 20857
Class I Recall: A product whose use will cause serious health consequences or death
Class II Recall: A product whose use may cause medically reversible health consequences
Class III Recall: A product whose use is not likely to cause adverse health consequences