

FDA NEWS RELEASE

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FDA Issues Health Information Advisory on Infant Formula

In response to reports of contaminated milk-based infant formula manufactured in China, the U.S. Food and Drug Administration (FDA) today is issuing a Health Information Advisory. This is to assure the American public that there is no known threat of contamination in infant formula manufactured by companies that have met the requirements to sell infant formula in the United States. Although no Chinese manufacturers of infant formula have fulfilled the requirements to sell infant formula in the United States, FDA officials are investigating whether or not infant formula manufactured in China is being sold in specialty markets which serve the Asian community.

The FDA is advising caregivers not to feed infant formula manufactured in China to infants. This should be replaced with an appropriate infant formula manufactured in the United States as mentioned below. Individuals should contact their health care professional if they have questions regarding their infant's health or if they note changes in their infant's health status.

The FDA began investigating the reports of contamination immediately and received information from the companies who manufacture infant formula for the American market that they are not importing infant formula or source materials from China. The following manufacturers have met the necessary FDA requirements for marketing milk-based infant formulas in the United States: Abbott Nutritionals, Mead Johnson Nutritionals, Nestle USA, PBM Nutritionals, and Solus Products LLC. Also, one manufacturer, SHS/Nutricia, Liverpool, England, markets an amino acid based exempt infant formula that does not contain any milk-derived ingredients.

We are asking state officials to work with the Agency to assist with the removal of any Chinese infant formula found on store shelves, and to warn members of the Asian community to avoid using Chinese manufactured infant formula.

It has been reported that a number of infants in China who have consumed Chinese manufactured infant formula are suffering from kidney stones, a condition which is rare in infants. The Chinese manufactured infant formula may be contaminated with melamine. Melamine artificially increases the protein profile of milk and can cause kidney diseases such as those seen in these Chinese infants.

FDA requires that all infant formula manufacturers register with the Agency and adhere to specific labeling and nutritional requirements. All properly registered infant formula manufacturers marketing infant formula in the United States undergo an annual inspection of their production facilities.

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