

Food & Drug

E-ALERT

November 14, 2008

FDA Issues Broad Import Alert for Milk and Milk-derived Products from China

On November 12, 2008, FDA issued Import Alert No. 99-30, "Detention Without Physical Examination of All Milk Products, Milk Derived Ingredients and Finished Food Products Containing Milk from China Due to the Presence of Melamine and/or Melamine Analogs." The Alert specifically covers the following categories of finished human food, pet food, and animal feed products, but says that, "Districts may detain without physical examination all milk products, all milk derived ingredients, and finished food products containing milk from China." The full list of food categories is in Attachment A.

- Breakfast foods/bakery items
- Snack Foods
- Dairy products
- Soft drinks
- Candy
- Chocolate/cocoa products
- Puddings
- Baby food products
- Casein for medicated animal feed
- Animal feed
- Pet and laboratory animal food

The Alert is available at: http://www.fda.gov/ora/fiars/ora_import_ia9930.html.

For release of products in a particular shipment that are covered by the Import Alert, importers will need to perform independent laboratory tests verifying that the products do not contain melamine or cyanuric acid. Alternatively, importers can provide documentation in English showing that there are no milk or milk-derived ingredients in the products. Documentation should include product formulation, such as process or batch records from the manufacturer, and labeling. If importers elect to perform laboratory tests, the testing laboratories may use any method found acceptable to FDA that meets the performance of the LC-MS/MS methods available at: <http://www.cfsan.fda.gov/~comm/labmeth.html#melamine>

Firms seeking removal from the Import Alert must provide to FDA:

1. Documentation showing that a minimum of five (5) consecutive non-violative shipments have been released by FDA based upon results of third party laboratory analyses that verify the products do not contain melamine or cyanuric acid;

2. Documentation from a third-party in whom FDA has confidence demonstrating that controls are in place such that products will not be contaminated with melamine and melamine analogs; and
3. Documentation that the firm is in compliance with all Chinese government requirements for exporting the products to the United States.

In our experience, FDA is currently taking a minimum of three months to act on requests for removal from an import alert.

FDA issued the Import Alert No. 99-30 because of the melamine contamination of the milk used to make infant formula in China, which resulted in over 53,000 cases of acute formation of kidney stones and crystals in Chinese infants and at least four deaths. The alert indicates that at a bulk fluid milk collection point in China, water was added to the bulk fluid milk to increase the apparent volume of the milk and melamine was then added to the water/milk mixture to increase the nitrogen content in order to artificially inflate the apparent protein content of the milk. The Chinese government has indicated that the melamine contamination is not limited to infant formula and that milk components, especially dried milk powder, used in the manufacture of a variety of finished foods are also contaminated. These contaminated milk components appear to have been dispersed throughout the Chinese food supply chain.

As the events surrounding 2007's pet food recalls revealed, melamine, when bonded to its analogue, cyanuric acid, forms large crystals that can block kidney tubules. In some cases, these blockages have been fatal. As a result of the pet food recalls and other recent instances of melamine contamination of human food, FDA issued three earlier Import Alerts, No. 99-29 for all vegetable protein products from China for animal or human food use due to the presence of melamine and/or melamine analogs, No. 72-05 for the pet and laboratory animal food products of specific Chinese manufacturers whose products had tested positive for melamine in 2007, and No. 99-31 for human food products made by certain Chinese manufacturers.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our food & drug practice group:

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This information is not intended as legal advice, which may often turn on specific facts. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

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