

FDA is requesting public health partners report cases of necrotizing enterocolitis in infants consuming SimplyThick

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The FDA is advising parents, caregivers and healthcare providers not to feed SimplyThick, a thickening product, to premature infants. The product may cause necrotizing enterocolitis (NEC), a life-threatening condition.

FDA first learned of adverse events possibly linked to the product on May 13, 2011. To date, the agency 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 products.

Illnesses have been reported from at least four different medical centers around the country. The illnesses of which FDA is aware involve premature infants who became sick over the past six months. 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 current situation is unusual because NEC most often occurs in babies within the hospital early in their premature course. But among the ill babies FDA is aware of, some had been discharged from the hospital to home on a feeding regimen that included SimplyThick and then fell ill at home.