

# Nationwide Voluntary Product Recall of Neocate<sup>®</sup> Infant Specialized Formula Lot P91877



Rockville, Maryland – September 28 2009 – Nutricia North America, Inc. (“Nutricia”) has contacted customers to undertake the voluntary recall and replacement of one (1) lot of the specialized infant formula product, Neocate<sup>®</sup>. This recall involves a limited quantity of individual cans (approximately 3700) from Lot # P91877, and does not affect any other Neocate<sup>®</sup> products or lot numbers.

Neocate<sup>®</sup> is a hypoallergenic dry powder formula packaged in 14 oz. cans distributed to pharmacies, health care professionals and consumers nationwide. Neocate<sup>®</sup> is not intended for general use and is usually given to infants in the care of health care professionals. The affected cans were distributed in commerce between September 1, 2009 and September 11, 2009.

Nutricia has been informed by the manufacturer of Neocate<sup>®</sup> that, due to a one-time blending error, a limited quantity of the individual cans of Neocate<sup>®</sup> Infant (original formula) contain protein levels lower than that declared on the label.

This limited formulation concern does not present *any* immediate risks of injury or other adverse health consequences. No adverse events have been reported as a result of this issue. The affected product from Lot # P91877 has a reduced protein level equivalent to 1.75g protein/100kcal - a shortfall of approximately 0.05g protein/100kcal based on the U.S. infant formula minimum requirement of 1.8g protein/100kcal. However, the affected product from Lot # P91877 continues to meet the minimum guidelines for protein established by the World Health Organization.

Although short-term consumption of product from the affected batch is very unlikely to cause immediate nutritional issues, longer term consumption might influence the healthy growth curve in certain infants. Because the quality and safety of Nutricia’s products and the well-being of its customers are the company’s primary concerns, the voluntary recall has been initiated. The Food and Drug Administration has been apprised of this recall. The company apologizes for any inconvenience to our customers and consumers.

## **Recommended Action to be Taken by the User**

The affected products have the Lot # P91877; this number can be found at the bottom of each can and on the right hand side of the case label.

Parents, caregivers, and health care professionals who have questions or concerns related to the consumption of the affected product are advised to contact the Nutricia North America Customer Helpline at 1-800-365-7354, option 8-6061. We can be reached during normal business hours Monday through Friday from 8:30am EDT to 5:00pm EDT and for special extended hours 8:30 am EDT to 8:00 pm EDT on Monday and Tuesday, September 28 and 29th.

Working with Nutricia, the manufacturer of Neocate<sup>®</sup> has implemented appropriate corrective and preventative actions, to ensure that this blending error in the manufacture of the product is not repeated. Nutricia will continue to carefully monitor the situation and follow-up with its customers to ensure prompt replacement of the affected product.

For more information please visit [www.nutricia-na.com](http://www.nutricia-na.com) or [www.neocate.com](http://www.neocate.com).

For further information regarding this release, please contact Meredith Klein, Edelman PR at (312) 233-1236.