



# Lower Protein in Infant Formula Supports Growth Rate Similar to Breast Milk, New Study Shows

Tuesday, November 09, 2010 - 06:00pm

"This study further supports the improved nutrient composition in our newly reformulated GOLD line of infant formula, which will allow us to continue to provide growing children with the right amount of the nutrients they need during their critical early years."

MADISON, N.J.--(BUSINESS WIRE)--Newly published findings indicate that infants fed a lower protein infant formula developed by Pfizer Nutrition gained weight at a similar rate to those who were breastfed,(1) according to a study published online today in the European Journal of Clinical Nutrition. Pfizer Nutrition has always recognized that breast milk is the best source of infant nutrition. The study established that infants fed a new, lower-protein infant formula attained the same growth rate and growth pattern as breastfed infants.(1)

The rate of growth of a child is an important indicator of overall health and reflects a child's nutritional well-being. The World Health Organization (WHO) recognizes that nutrition during the first years of life is crucial for life-long health and wellness.(2) Globally, twenty-three million children face nutritional challenges, with at least 20 million children under the age of five estimated to be overweight.(3)

"This study showed that when we fed infants with a formula that contained specially-adjusted levels of protein that more closely matched those found in breast milk, these babies grew at a rate similar to breastfed babies," said a leading study author Rosario Capeding, MD, Asian Hospital and Medical Center, Muntinlupa City, Philippines. "As we learn more about the importance of nutrition during early childhood, we recognize there is a critical need to ensure nutrients are received in the most appropriate proportions to

support appropriate growth and development." Dr. Capeding is a pediatrician who values the importance of breastfeeding because of the immunity that breast milk provides – a subject which was not determined in this study.

One of the ways in which breast milk and standard infant formulas differ is in their protein composition and concentration.(1) Mature human milk contains 10-12 g/L of protein and is rich in essential amino acids.(4,5,6,7) Standard infant formulas typically contain higher levels of protein in order to provide sufficient quantities of essential amino acids.(1) It has been hypothesized that these higher protein concentrations could be one cause of the increased growth velocity seen in some formula-fed infants when compared to growth of infants who are exclusively breastfed.(8) To allow for a reduction in total protein while preserving sufficient content of essential amino acids, the lower protein formula (New formula) used in this study was further enriched with alpha-lactalbumin, a protein that is found in human milk, and supplemented with small amounts of two amino acids, tyrosine and tryptophan.(1)

"At Pfizer Nutrition, we are committed to developing infant formulas that help formula fed babies to achieve growth and health outcomes similar to human milk-fed babies," said Patricia A. DeRusso, MD, chief medical officer, vice president, Pfizer Nutrition. "This study further supports the improved nutrient composition in our newly reformulated GOLD line of infant formula, which will allow us to continue to provide growing children with the right amount of the nutrients they need during their critical early years."

### About the Study

The study, "Effect of alpha-lactalbumin-enriched infant formula with lower protein on growth," was a randomized, controlled, double-blind study, supported by Wyeth Nutrition, of healthy term formula fed infants who were randomized to receive one of two infant formulas enriched with alpha-lactalbumin - one containing a standard level of protein (SF) or one with a lower protein level (New). A breastfed (BF) reference group was also included.(1) To be included in the study, criteria required that subjects were singleton infants born full term who were 5 to 14 days of age at enrollment, and who had a weight, length and head circumference greater than or equal to 5th and less than or equal to 95th percentile for age according to local growth reference standards.(1) The sample size, the gender stratification (50 percent males, 50 percent females) and the completion rate (97 percent) were all strengths of the study.(1)

The new formula met a critical safety guideline for all new formulas that are developed; growth of infants on the new formula was not significantly different from growth of infants

on the standard formula. The benefit to the infants consuming the new formula was that the weight gain was not significantly different from the BF group.(1)

The study demonstrated that the infants fed New formula had weight gain that was intermediate between those who were fed the SF and BF infants, and the weight gain in the New formula group was not significantly different from the BF group. Mean weight gain (g/d) did not significantly differ between SF vs. New ( $p=0.67$ ) nor between New vs. BF ( $p=0.11$ ); however weight gain (g/d) was significantly greater in the SF vs. BF group ( $p=0.04$ ).<sup>(1)</sup> At day 120, mean weight-for-age and weight-for-length did not significantly differ between the SF vs. New groups, nor between the New vs. BF groups; however the weight-for-age was significantly greater in the SP vs. BF groups ( $p=0.025$ ).<sup>(1)</sup>

Upon enrollment, infant subjects were randomized to the SF (14.1 g/L protein, 662 kcal/L) group ( $n=112$ ) or the New (12.8 g/L protein, 662 kcal/L) group ( $n=112$ ) for 120 days. A BF reference group ( $n=112$ ) was also included; 50 percent were females. <sup>(1)</sup> The main difference between the formulas was the total protein concentration. To provide the required amount of essential amino acids, the New formula was further enriched with alpha-lactalbumin and supplemented with small amounts of L-tyrosine and L-tryptophan.<sup>(1)</sup>

## Importance of Early Infant Nutrition

Pfizer Nutrition recognizes that successfully managing a child's nutritional intake to optimize growth and health outcomes is an extremely complex science. The latest clinical and scientific research drives our development of an optimal combination of nutrients – Biofactors – delivered in carefully balanced amounts. For infants age 6 months and older, the new GOLD range was designed, when consumed as directed, to deliver at least 100 percent of the five key "at risk" nutrients (vitamin A, vitamin D, iron, zinc, and iodine) identified by the WHO and by the United Nation's Food and Agriculture Organization (FAO) – nutrients that children are most at risk for consuming in less than the recommended amounts per day.<sup>(9)</sup>

## About Pfizer Nutrition

Pfizer Nutrition, a Pfizer Diversified Business, supports Pfizer's mission, bringing breadth and depth of consumer and scientific insight to new populations and new markets around the world, advancing health and wellness. For almost a century, Pfizer Nutrition, formerly Wyeth Nutrition, has been a global leader in infant and pediatric nutrition, building on a tradition of scientific innovation and providing superior quality and clinically-based products that offer parents confidence, help nourish children and support their healthy

futures. In keeping with Pfizer's commitments to finding solutions for the health challenges of our time, we remain committed to improving nutrition and wellness for infants, young children and mothers around the world.

Pfizer Inc. : Working Together for a Healthier World™

At Pfizer (NYSE: PFE), we apply science and our global resources to improve health and well-being at every stage of life. We strive to set the standard for quality, safety and value in the discovery, development and manufacturing of medicines for people and animals. Our diversified global health care portfolio includes human and animal biologic and small molecule medicines and vaccines, as well as nutritional products and many of the world's best-known consumer products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as the world's leading biopharmaceutical company, we also collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more about our commitments, please visit us at [www.pfizer.com](http://www.pfizer.com).

DISCLOSURE NOTICE: The information contained in this release is as of November 10, 2010. Pfizer assumes no obligation to update any forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about Nutrition products including their potential benefits, that involves substantial risks and uncertainties. A description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2009 and in its reports on Form 10-Q and Form 8-K.

## REFERENCES

(1) Trabulsi J, Capeding R, Lebumfacil J, et al. Effect of an alpha-lactalbumin-enriched infant formula with lower protein on growth. *Eur J Clin Nutr*. 2010.

(2) World Health Organization. WHO Child Growth Standards: What is the connection between the new WHO Child Growth Standards and infant and young child feeding practices? World Health Organization: Geneva, Switzerland. 2010; 2 pp.

(3) World Health Organization. WHO Child Growth Standards: What is the double burden of malnutrition? World Health Organization: Geneva, Switzerland. 2010; 2 pp.

- (4) Darragh AJ, Moughan PF. The amino acid composition of human milk corrected for amino acid digestibility. *Br J Nutr.* 1998; 80: 25 – 34.
- (5) Feng P, Gao M, Holley T, Zhou T, Burgher A, Trabulsi J, et al. Amino Acid Composition and Protein Content of Mature Human Milk from Nine Countries. *FASEB J.* 2009; 23: LB448.
- (6) Lonnerdal B, Forsum E, Gebre-Medhin M, Hambraeus L. Breast milk composition in Ethiopian and Swedish mothers. II. Lactose, nitrogen, and protein contents. *Am J Clin Nutr.* 1976; 29: 1134 – 1141.
- (7) Raiha N, Minoli I, Moro G. Milk Protein intake in the Term infant. I. Metabolic Responses and Effects of Growth. *Acta Paediatr.* 1986; 75: 881 – 886.
- (8) Koletzko B, von Kries R, Closa R, Escribano J, Scaglioni S, Giovannini M et al (2009). Lower protein in infant formula is associated with lower weight up to age 2 y: a randomized clinical trial. *Am J Clin Nutr.* 2009; 89: 1836 – 1845.
- (9) World Health Organization and Food and Agriculture Organization of the United Nations. Vitamin and mineral requirements in human nutrition: report of a joint WHO/FAO expert consultation. World Health Organization and Food and Agriculture Organization of the United Nations. Bangkok, Thailand. 1988; 20 pp.

Pfizer Inc., Rick Goulart, +1-212-733-7457, [Rick.Goulart@Pfizer.com](mailto:Rick.Goulart@Pfizer.com)