

Ms Caroline Winters Director of Public Affairs,
Mr Danny Wilding Public Affairs Manager
Nutricia Ltd.,
Newmarket House, Newmarket Avenue,
White Horse Business Park,
Trowbridge,
Wiltshire BA14 0XQ

March 2018

Dear Ms Winters and Mr Wilding,

Re: The current nutriprem advert in health professional journals

As a group of experts involved in infant feeding in the UK, we would like to express our **serious concerns about this advert** for 'nutriprem' which has recently appeared in the health professional literature and ask you to **withdraw it immediately**.

The advert shows the nutriprem brand post-discharge formula most prominently, but it also shows nutriprem 1, hydrolysed nutriprem and breastmilk fortifiers.

The branding of Cow & Gate nutriprem at the top of the advert links this advert to all products in this range.

There is a strong implication in the advert that the use of a specialised infant formula for premature and low birthweight babies supports survival, and ensures a baby will thrive.



Reference: *Dietetics Today*,
Complete Nutrition Magazine
Dec. '17 & Jan. '18 & *Infant*
Nov. '17.

We the undersigned believe that this advert is inaccurate and misleading to health professionals and makes substantial claims that are not supported by evidence.

Analysis:

The following considers the claims in your advert, highlighting why they are misleading and inaccurate.

Claim 1: An implied link between the use of an infant formula and survival

Your advert's implied claim that formula milk is linked to survival is undermined by the following evidence:

- **Human milk and protection against NEC and mortality:** A review of human milk feeding in premature infants and risk of necrotizing enterocolitis (NEC) reported that an exclusive human milk diet provides protection against NEC, a neonatal condition which has undisputed high mortality rates (Cacho, Parker and Neu, 2017). Extremely premature infants who receive an exclusive human milk diet have been shown to have a significantly lower incidence of NEC and mortality as well as a reduction in late onset sepsis, bronchopulmonary dysplasia and retinopathy of prematurity (Hair et al, 2016). Preterm infants are particularly susceptible to NEC due to the immaturity of their gastrointestinal and immune systems. An exclusive human milk diet compensates for these immature systems in a number of ways: lowering gastric pH, enhancing intestinal motility, decreasing epithelial permeability and altering the composition of bacterial flora (Maffei and Schanler, 2017). The use of human donor milk is the first line of support should breastmilk from the baby's mother not be available for any reason.

- **Formula milk and risk of NEC:** A Cochrane review reported that the use of infant formula in premature babies significantly increases the risk of NEC (Quigley & McGuire, 2014).

The suggestion in your advert that an infant formula is linked to survival is therefore misleading, and goes against the current evidence that both supports the use of human milk in preventing illness and infection in vulnerable low birthweight infants, and highlights the risks associated with the use of any formula for premature and low birthweight babies requiring specialist care.

Claim 2: An implied claim that post-discharge formula is necessary for premature infants to thrive

- **The efficacy of post-discharge formula:** A Cochrane review in 2016 (Young et al, 2016) reviewed 16 eligible trials involving 1251 infants and concluded that there is no evidence to support the use of post-discharge formula for preterm infants after hospital discharge to improve growth and development. A separate Cochrane review investigating growth and development of infants given a nutrient- and energy-dense post-discharge infant milk found little evidence of efficacy at up to 18 months post-term compared with infants given a term infant milk (Henderson et al, 2007). In addition, a study by Rozé et al (2012) looked at a large (almost 3000 babies) cohort of preterm infants and found that those who were breastfed after discharge grew less well, but had better neurodevelopmental outcomes, which shows post discharge formula is not only not needed, but may have adverse long term developmental consequences.

Claim 3: “Nutritionally closer to breastmilk”

Your advert states that this specialised formula is ‘*nutritionally closer to breastmilk than ever before*’ for which you provide two references.

- The first reference (Ballard & Morrow, 2013) is to a paper that discusses human milk composition and this does not provide any evidence related to this formula.
- The second is to a paper from 1994 by Innis et al, which suggests that palmitic acid esterified in the *sn-2* position in human milk is related to absorption efficiency, but suggests no metabolic significance for this. This paper again provides no evidence relevant to nutriprem formula.
- The European Food Safety Authority, in their comprehensive review of the composition of infant formula and follow on formula (EFSA, 2014), reviewed evidence on the potential benefit of altered fatty acid conjugation and concluded there was no convincing evidence for a beneficial effect of the use of palmitic acid predominantly esterified in the *sn-2* position.

The fat content of breastmilk is highly variable depending on stage of lactation, time of day and the mother’s diet, and is extremely complex, providing the primary energy source and having a range of metabolic and physiological functions important for growth and development. It is not possible to artificially recreate the fat profile of human milk.

We cannot see any evidence presented here which would substantiate a claim that these milks are ‘nutritionally closer’ to breastmilk.

Claim 4: Milk fat aids calcium and fat absorption

Your advert claims that the addition of milk fat aids calcium and fat absorption, eases digestion and softens stools. Claims related to milk fat use in other Danone Nutricia infant milks suggest that the use of milk fat provides a fatty acid profile closer to breastmilk related to an increased amount of palmitic acid esterified in the *sn-2* position.

- The first reference given (Bar-Yoseph et al, 2013) is a review written by staff of 'Enzymotec' in Israel – a company that supplies lipid based bio-functional ingredients and which therefore has a conflict of interest in the reporting of positive evidence on the potential use of structured triglycerides in formula. As we have said, the EFSA (2014) in their expert independent review found no evidence of benefit for the addition of palmitic acid predominantly esterified in the *sn-2* position found to infant formula.
- Two other references given relate to studies looking at the use of palmitate esterified in the *sn-2* position in infant formula, and these were both reviewed by EFSA (2014). Interestingly, these studies by Carnielli et al (1996) and Kennedy et al (1999) have previously been used to support claims by your company that the use of *synthetic* triglycerides made from vegetable fats with a higher proportion of palmitate in the *sn-2* position improves fat and calcium absorption. They are now being used to support the same claims for the use of milk fat.
- The study quoted from Quinlan et al (1995) considers factors relating to stool hardness in breastfed and formula fed infants and does not provide any evidence for your product. The study quoted from Carnielli et al (1995) is a small cross over study of 12 formula fed premature infants. Whilst this study reported improvements in absorption of some fatty acids, the study was subject to several methodological limitations including: small sample size, lack of wash out period between the test and control formulas and lack of power calculations which means it may have been underpowered in relation to some of the outcome measures tested.

Claim 5: Adding prebiotic oligosaccharides to infant formula supports gut health

A claim for a benefit to gut health of adding prebiotic oligosaccharides to infant formula is made for all the formula in the range, but hydrolysed nutripem has no prebiotics present.

- The EFSA (2014) states that there is no evidence for health benefits from the addition of prebiotic oligosaccharides (GOS/FOS) to infant or follow-on formula. Evidence given for the claim in your advertisement comes from a number of small or compromised studies. The study by Mihatsch et al (2006) showed changes to stool viscosity and transit time, but provided no evidence of a benefit to the addition of prebiotic oligosaccharides at 1mg/100ml to a feed. Based on the fibre content stated on your formula datacards, which we believe represents the level of prebiotics present, nutripem 1 and 2 contain 0.6mg prebiotic oligosaccharides/100ml.
- Additional evidence is cited from studies by Boehm et al (2002) and Knol et al (2005) which were funded by Numico. These studies also used a test formula supplemented with 1g/100ml oligosaccharides and showed an increase in faecal bifidobacteria, but this does not prove a health benefit. A systematic review and meta-analysis of the safety and efficacy of oligosaccharide supplementation of preterm infant milk (which included the studies by Mihatsch et al 2006 and Boehm et al, 2002) found no decrease in NEC, late onset sepsis or quicker establishment of full enteral feeds (Srinivasjois et al, 2013).

Your advert claims that the beneficial effects of prebiotics for gut health are 'proven', but provide evidence from small, single study references which do not link to health outcomes and which are inadequate evidence to support this claim.

Conclusion

We believe **your advert is misleading to health professionals** by making **inaccurate** claims about links to survival when a premature formula is used, an infant's ability to thrive when post-discharge formula is used, and through statements about your products' closeness to breastmilk in composition.

We believe your advert undermines breastfeeding and the use of human milk for sick and preterm infants. There is a strong body of evidence that accepts that no artificial milk product can replicate breastmilk nutritionally, that premature baby survival is strongly related to human milk intake and that the promotion of breastfeeding post-discharge is seen as the optimal strategy for infants to thrive.

We will be putting this letter in the public domain and hope that you will **withdraw this advert immediately**, and not use it in any of the countries in which you market your products.

Yours sincerely,

Dr Helen Crawley, Director, First Steps Nutrition Trust*

Ms Sue Ashmore, Programme Director, Baby Friendly Initiative, Unicef UK

Dr Natalie Shenker, Cofounder and Director, Hearts Milk Bank

Dr Cheryl Adams, Executive Director, Institute of Health Visiting

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Prof Mary J Renfrew BSc RN RM PhD FRSE, Professor of Mother and Infant Health, School of Nursing and Health Sciences, University of Dundee

Ms Alison Thewliss, MP for Glasgow Central, Chair of APPG Infant Feeding and Inequalities

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The GP Infant Feeding Network Executive Team

World Breastfeeding Trends Initiative (WBTi) UK Working Group

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