

September 30, 2005

Dear Sirs:

Mead Johnson & Company respectfully submits these comments in response to the request for public comment on the petition for a Qualified Health Claim (QHC). The petition was received by the Agency on 20 June 2005 from **Nestlé USA, Inc.**; 800 North Brand Boulevard; Glendale, CA 91203 (“petitioner”) for the evaluation of the following QHC:

“Breast feeding is the best way to nourish infants. For infants who are not exclusively breastfed, emerging clinical research in healthy infants with family history of allergy shows that feeding a 100% Whey-Protein Partially Hydrolyzed formula may reduce the risk of common food allergy symptoms, particularly allergic skin rash, when used instead of whole-protein cow’s-milk formula from the initiation of formula feeding.

Partially hydrolyzed formulas are not intended to treat existing food allergy symptoms. If you suspect your baby is already allergic to milk, or if your baby is on a special formula for the treatment of allergy, your baby’s care should be under a doctor’s supervision.”

Based on our understanding of the FDA standards of credible scientific evidence, it is our belief that the petition should be denied, given the body of scientific evidence provided in the petition in support of the QHC and the risks posed by the presence of the claim on the label for infants in the U.S..

In light of our understanding of FDA standards, we believe the proposed QHC exaggerates the existing evidence to include common food allergy symptoms. Specifically, in the German Infant Nutrition Intervention study (GINI), partially hydrolyzed formulas (PHF) were shown to be protective only for atopic dermatitis, not for other allergic manifestations as shown for extensively hydrolyzed formulas (EHF). In fact, the authors also concluded that the use of PHF for allergy prevention needs to be clinically evaluated (Von Berg et al, 2003). Importantly, these study findings are consistent with the evidence that only EHF have been clearly shown to reduce the overall incidence of the allergic manifestations in infants at high risk of allergies (Oldaeus et al, 1997; Halcken et al. 2000; Von Berg et al, 2003). Lastly, the final recommendations of the Cochrane review cited by the petitioner are not conclusive, as the authors recommend that “further trials are required... to determine if there is any additional benefit from use of an extensive compared to a partially hydrolyzed formula” (Osborn & Sinn, Cochrane review, 2003).

We consider it inappropriate and misleading to include the study by Marini et al. (1996), to substantiate the claim intended by the petitioner, as the results of this study were accomplished through a comprehensive preventive program that included environmental measures and dietary measures other than the use of a PHF, in the intervention group of infants.

We also consider it inappropriate and misleading to include the study by Exl et al. (2000). The outcomes evaluated in this study refers to overall general health problems and not specifically allergic conditions, including diseases that have no allergic cause, like nappy rash, cradle cap and seborrheic dermatitis, among others.

It is important to note that allergenicity tests in children sensitized to cow’s milk protein have demonstrated that PHF have low levels of allergens, with lower residual allergenicity

(Niggemann et al, 1999). Therefore, by having a claim of risk reduction on the label, the inadvertent use of such formula by a cow's milk allergic infant has the potential for causing a severe allergic reaction. In fact, even the petitioner's document stating the appropriate dietary strategy for managing infants at high risk of developing a food allergy recognizes the evidence provided from the above studies.

“At the present time, the best means to prevent [sic] food allergy is food allergen avoidance. In infancy, this is generally achieved through the exclusive feeding of breast milk or extensively hydrolyzed infant formulas.”

http://www.fda.gov/ohrms/dockets/dockets/05q0298/05q-0298-qhc0001-007_Tab-C-Sci-Data-vol1.pdf Tab C - Scientific Data, page 3, first paragraph)

Lastly, the allergy risk reduction claim on the product label may mislead the U.S. consumer to believe that the product may be suitable for the management of existing allergic conditions, posing a serious risk of an allergic or anaphylactic response. Specifically, in light of previous Agency decisions on the use of disclaimers in the U.S. [Qualified Health Claims: Letters of Denial – Calcium and a Reduced Risk of Menstrual Disorders (Docket No 2004Q-0099)], it is our interpretation that the Agency should not consider the long disclaimer language *“Partially hydrolyzed formulas are not intended to treat existing food allergy symptoms. If you suspect your baby is already allergic to milk, or if your baby is on a special formula for the treatment of allergy, your baby's care should be under a doctor's supervision.”* sufficient to prevent deception of U.S. consumers and consequently inappropriate use of the labeled product.

In conclusion, in light of our understanding of the FDA standards of credible scientific evidence, it is our belief that the petition should be denied, given the body of scientific evidence provided in the petition in support of the QHC and the risks posed by the presence of the claim on the label for infants in the U.S..

Sincerely,

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Mead Johnson & Company

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