



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

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AUG 4 2005

Melanie Fairchild-Dzanic  
Director, Regulatory Issues – Special Nutritionals  
Nestlé USA  
Nutrition Division  
800 North Brand Boulevard  
Glendale, CA 91203

RE: Qualified Health Claim Petition – 100% Whey Protein Partially Hydrolyzed  
in Infant Formula and Reducing the Risk of Allergy in Infants (Docket No.  
2005Q-0298)

Dear Ms. Fairchild-Dzanic:

On June 20, 2005, the Food and Drug Administration (FDA) acknowledged receipt of the petition you submitted, on behalf of Nestlé USA (Nestlé), pursuant to Section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 343(r)(4)) and in accordance with the July 10, 2003 Task Force Final Report on the Consumer Health Information for Better Nutrition Initiative. The petition requests a qualified health claim for the relationship between the consumption of 100% whey protein partially hydrolyzed in infant formula and a reduction in the risk of allergy in infants.

In accordance with the FDA's guidance, "Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements," (<http://www.cfsan.fda.gov/~dms/nuttftoc.html>), FDA is to determine, within 45 days of receipt of a qualified health claim petition, whether the petition is complete and can be filed for further review. The 45-day period for the filing review of your petition is August 4, 2005. Consequently, today we are filing the qualified health claim for 100% whey protein partially hydrolyzed in infant formula and its relationship to allergy in infants. The petition is posted on Dockets web page (<http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm?AGENCY=FDA>) and we are requesting comment on it for 60 days. Interested persons may submit comments until October 3, 2005. Within 225 days of the filing date, we will notify you of our final decision regarding the requested qualified health claim. We have calculated that date to be March 17, 2006.

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Please feel free to contact Vincent de Jesus at 301-436-1450, if you have any questions concerning this petition.

Sincerely yours,

A handwritten signature in black ink, reading "Barbara O. Schneeman". The signature is written in a cursive style with a long horizontal flourish at the end.

Barbara O. Schneeman, Ph.D.  
Director  
Office of Nutritional Products,  
Labeling, and Dietary Supplements  
Center for Food Safety and Applied  
Nutrition