

Nestlé USA



NUTRITION DIVISION
800 NORTH BRAND BLVD.
GLENDALE, CA 91203

TEL (818) 549-6000

June 17, 2005

VIA OVERNIGHT MAIL

Food and Drug Administration
Office of Nutritional Products, Labeling and Dietary Supplements (HFS-800)
5100 Paint Branch Parkway
College Park, MD 20740

Re: PETITION FOR QUALIFIED HEALTH CLAIM:

**100% WHEY PROTEIN PARTIALLY HYDROLYZED
in Infant Formula and
REDUCING THE RISK OF ALLERGY**

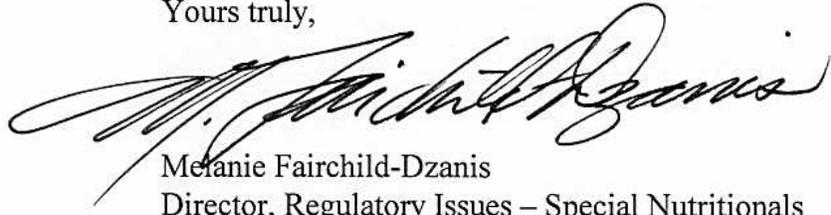
Dear Sir or Madam:

Enclosed with this letter is an original, one disk copy and one hard copy of a Nestlé Nutrition, Nestlé USA (Nestlé) petition requesting Center review and consideration of the evidence supporting the ability of 100% Whey Protein Partially Hydrolyzed, when used in infant formula, to reduce the risk in infants of common food allergy symptoms, as compared to the risk associated with standard intact (i.e., whole-protein) cow's milk formulas.

We hope you will find this submission clear and complete. For easy reference, a Table of Contents and Bibliography follows immediately after this letter, listing an inventory of the major components of this Petition and an alphabetized Bibliography of Clinical Trials relied upon to support the requested claim, grouped by design type. The Table of Contents, in turn, refers to the broader Reference List at Tab H, which provides an alphabetized bibliography of all the scientific literature referred to in Volume I of the Petition. Copies of the actual references listed follow in Volumes II and III. Volumes IV and V set forth the results of a Comprehensive Literature Search on this topic, along with copies of any articles responsive to the search that were not deemed relevant to the discussion in Volume I.

If you require any further information or clarification of the information provided, please contact me directly at (818) 549-5868.

Yours truly,

A handwritten signature in black ink, appearing to read "Melanie Fairchild-Dzani". The signature is fluid and cursive, with a large initial "M" and "F".

Melanie Fairchild-Dzani
Director, Regulatory Issues – Special Nutritionals

cc (w/encl.): Fred Degnan – King & Spalding