

Nestlé USA



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Tomoko Shimakawa  
Division of Nutrition Programs and Labeling  
Office of Nutritional Products, Labeling and Dietary Supplements  
Center for Food Safety and Applied Nutrition  
U. S. Food and Drug Administration  
5100 Paint Branch Parkway, HFS-830  
College Park, MD 20740-3835

Re: Docket 2005Q-0298 – Petition for Qualified Health Claim for  
100% Whey Protein, Partially Hydrolyzed, in Infant Formula and  
Reducing the Risk of Allergy in Infants

Dear Ms. Shimakawa:

Thank you so much for your time and that of the team of experts you brought together for the meeting held last week at our request (agenda attached). We appreciated the opportunity to explain how useful such a claim could be in the context of the growing public health concern regarding allergy. We understand the communication challenges presented by such a claim and are committed to meeting them. We hope you will consider the results of our additional consumer research in that light.

As promised, I have enclosed an additional hard copy (and a CD) of the information presented to you at that meeting. I have also enclosed a letter from Dr. Saavedra concerning the work of Dr. Ranjit Chandra at Memorial University. In his letter, Dr. Saavedra provides some history with respect to the current controversy surrounding Dr. Chandra's work. Dr. Saavedra then points out that since Dr. Chandra's data first appeared, a convincing body of clinical data has been published that is uniformly and convincingly consistent with Dr. Chandra's work. In this context, Dr. Saavedra explains our conclusion that there is no scientific need to support our petition with the data from the one study on which Dr. Chandra's three publications are based.

As we pointed out during the meeting, the information we presented does not represent any new clinical research in support of the petition. In fact, our updated search (using the same search terms as our original search) discloses that no new relevant clinical research has emerged that is relevant to the conclusion we have urged you to reach with respect to our petition.

Yours truly,

Melanie Fairchild-Dzanis  
Regulatory Director, Nestlé Nutrition

cc: Fred Degnan – King & Spalding

## **Meeting with Nestlé USA**

**March 29, 2006, 2:00 – 3:00 pm**  
**Room 3B047**

### **Agenda**

1. Update on scientific literature published or pending since petition date
2. Impact of CBC broadcast on the body of science supporting the petition
3. Assessing the potential public health impact of claim approval
4. Results of Nestlé consumer research: Distinguishing the "emerging science" claim from an unqualified claim. How "not intended to treat" language could be improved.
5. Nestlé responses to additional comments to the Docket, as time permits (this includes comments dated 2/7/06)

### **The Attendees/Presenters from Nestlé**

- Jose M. Saavedra, MD - Medical and Scientific Director, Nestlé Nutrition
- Alan Lake, MD - Associate Professor Pediatrics, Johns Hopkins School of Medicine; Community Pediatrician, Greenspring Associates, and member of Nutrition Advisory Panel, Nestlé Nutrition
- William Klish, MD - Professor of Pediatrics, Baylor College of Medicine and member of Nutrition Advisory Panel, Nestlé Nutrition
- Frederick Degnan, Esq. - King & Spalding
- Melanie Fairchild-Dzanic - Regulatory Director, Nestlé Nutrition