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February 11, 2004

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852

**Re: Food Labeling: Health Claims; Dietary Guidance 21 CFR Part 101**

Dear Sir or Madame:

This letter, submitted by Solae, LLC (a joint-venture between DuPont Protein Technologies and Bunge/Central Soya; herein as "Solae"), is in response to the Food and Drug Administration's (FDA) request for comments on the proposed regulations regarding authorization of health claims, including qualified health claims (Docket No. 2003n-0496). Although the Advance Notice of Proposed Rulemaking (Food Labeling: Health Claims; Dietary Guidance 21 CFR Part 101) covers other areas of food labeling, Solae's comments are restricted to certain aspects of health claims.

In general, Solae supports a robust regulatory framework that allows for clear, science-based communications to consumers and requires manufacturers to develop the detailed data needed to obtain Significant Scientific Agreement (SSA) for an unqualified health claim. We also urge FDA to continue to closely administer the process of approved health claims from an internal, governmentally based review process.

Solae is a leading manufacturer of high quality soy ingredients, including proteins, lipids, lecithin, and fibers. These products are used in a wide variety of food applications such as meat products, meat alternatives, beverages, baked goods, fresh and frozen desserts, pasta, cereals, bars, and nondairy products. Solae has a precedence of commitment to nutrition research that has focused on the impact of soy products on human health. The parent companies of Solae have a history of involvement in FDA Nutrition Labeling. Protein Technologies International authored and submitted the Soy Protein Heart and Coronary Heart Disease Health Claim (64 FR 57700) that was authorized in 1999. Central Soya authored and submitted the Choline Nutrient Content Claim Notification based on an authoritative statement. Implications on Health Claim Regulation and impact on consumers is of paramount importance to our company. Our specific comments to the issues of concern to Solae are as follows:

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*FDA is requesting comments on how to provide incentives for manufacturers to develop the data needed to obtain Significant Scientific Agreement (SSA) for an unqualified health claim.*

Solae strongly supports a time period during which proprietary use of health claims that meet SSA can be used exclusively by the company submitting the petition. Due to the heavy cost burden associated, not only with development of the scientific data, but with documentation, positioning, and marketing of the potential health claim, there is debatable strategic value associated with a nonproprietary health claim. Further, based on the time and additional heavy cost burden on the manufacturer associated with product development, market testing, and all the processes undertaken to ultimately get the product to the grocery store shelf, we recommend that a period of a minimum of six (6) years following the date of approval of the health claim be granted for the proprietary period. During this time, the company submitting the petition may use the newly authorized health claim on its products or products and/or the company submitting the petition may transfer such rights to a third party.

*FDA is considering removing the requirement for the word “may” from unqualified health claims to eliminate the uncertainty about the science underlying claim that meet SSA.*

Solae supports such a change for health claims that meet SSA and are approved by the FDA (so-called unqualified health claims). However, Solae suggests that qualified health claims continue to use the term “may” in order to create differentiation.

Paramount to discussion, however, is the terminology of the titles differentiating unqualified and qualified health claims. The term “unqualified”, while defined within FDA guidelines, places a negative connotation on an authorized health claim that meets the highest criteria of scientific agreement—SSA. Because of this concern, we suggest health claims that meet the rigors of criteria set for SSA be designated as such. Therefore, two classifications of health claims would exist:

- a. Health Claims—those that meet SSA (grade A<sup>1,2</sup>)
- b. Qualified Health Claims—those that have grade levels B-D<sup>1,2</sup>

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<sup>1</sup> Guidance for the Industry and FDA: Interim Evidence-Based Ranking System for Scientific Data.

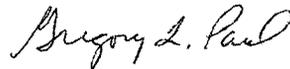
<sup>2</sup> Guidance for the Industry and FDA: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Dietary Supplements.

Solae wishes to again thank FDA for the opportunity to provide comments on this Advance Notice of Proposed Rulemaking. We support FDA's efforts to provide regulatory oversight in a manner that is clear, science-based, and in the best interest of the American Public. Our comments are offered in an effort to achieve these same objectives. We look forward to the Agency's consideration of the measures proposed in our comments.

Sincerely,



Susan M. Potter, Ph.D.  
Global Director, Health and Nutrition



Gregory L. Paul, Ph.D.  
Director, Health and Nutrition  
and Nutraceuticals

cc.

Cary A. Levitt, Vice President and General Counsel  
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