

May 4, 1998

Office of Food Labeling  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration (HFS-150)  
200 C Street SW  
Washington, D.C. 20204

**Re: Proposed Health Claim for Soy Protein Containing Products  
and a Reduced Risk of Coronary Heart Disease**

The undersigned, Protein Technologies International, Inc. (PTI), St. Louis, Missouri, submits this petition pursuant to section 403(r)(4) of the Federal Food, Drug and Cosmetic Act (FFDCA) with respect to the relationship between soy protein and a reduced risk of coronary disease. The data submitted as part of this petition, including clinical studies, establish that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, regarding the relationship between isoflavone containing soy protein products and a reduced risk of coronary heart disease.

Attached hereto, and constituting part of this petition are the following:

- A. Preliminary Requirements: Data establishing that isoflavone containing soy protein products such as isolated soy protein, soy protein concentrate and soy flour conform to the requirements of 21 C.F.R. 101.14(b) in that they are commonly consumed foods that are generally recognized as safe (GRAS) based on common use in food prior to 1958.
- B. Summary of Scientific Data: Data establishing that, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), there is significant scientific agreement among experts qualified by scientific training and experience that a relationship exists between the consumption of certain isoflavone containing soy protein products and a reduced risk of coronary heart disease.

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- C. Analytical Data: Data establishing the amount of soy protein present in foods and the levels of isoflavones found in such soy proteins.
- D. Model Health Claim: This petition contains the recommended text for the model health claim.
- E. Environmental Impact: PTI claims a categorical exclusion from the environmental assessment (EA) and environmental impact statements (EIS).
- F. Appendices: The petition also includes numerous attachments, including copies of the articles cited in the petition, information relied upon in support of the petition, all information concerning adverse consequences to any segment of the population (e.g., those that may be sensitive to soy proteins), and all information pertaining to the U.S. population.

\* \* \* \* \*

To the best of the knowledge of the undersigned, this petition is a representative and balanced submission that includes unfavorable information as evaluation of the proposed health claim.

Any question regarding this petition should be directed to Susan M. Potter, Protein Technologies International, Inc. at 314/982-5031.

Yours very truly,

Protein Technologies International, Inc.

By

  
\_\_\_\_\_  
Marshall M. Marcus

Director of Regulatory and Trade Affairs

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