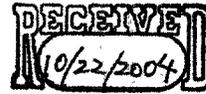


*The Solae<sup>®</sup>  
Company*

Solae, LLC  
P.O. Box 88940  
St. Louis, MO 63188 USA  
800.325.7108

FEDERAL EXPRESS



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Shellee Anderson  
Team Leader  
Nutrition Policy and Labeling Staff  
Office of Nutritional Products, Labeling and Dietary Supplements  
Center for Food Safety  
Department of Health and Human Services  
Public Health Service  
Food and Drug Administration  
College Park, MD 20740

RE: 2004Q-0151 Qualified Health Claim (QHC): Soy Protein and Cancer

Dear Ms. Anderson:

Enclosed please find four research articles on soy consumption and prostate cancer in men that we would submit as a supplement to our qualified health claim petition – Soy Protein and the Reduced Risk of Certain Cancers. These papers were published after we had submitted our petition to your office. Two of them are intervention studies, and two are epidemiological studies. Findings from these studies support a relationship between consumption of soy protein and a reduction in prostate cancer risk. Below are summaries of research findings from these publications.

Dalais et al (2004) conducted a one-month intervention study with 29 men who were diagnosed with prostate cancer and scheduled to undergo a radical prostatectomy. Soy grits were compared with wheat grits (control). Statistically significant differences were detected between soy group and the control group for the percentage change in total PSA (-12.7% vs. 40%,  $P = 0.02$ ) and the percentage change in free/total PSA ratio (27.4% vs. -15.6%,  $P = 0.01$ ). The authors concluded, "This work provides some evidence to support epidemiologic studies claiming that male populations who consume high phytoestrogen diets have a reduced risk of prostate cancer development and progress."

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Kumar et al (2004) completed a 12-week intervention study with 59 prostate cancer patients who were in the “watchful-waiting” phase (Gleason score, 6 or below). Soy protein beverage (evaluated as a total daily intake of 60 mg soy isoflavones) were compared with casein placebo. While findings were not statistically significant, serum free testosterone was reduced or showed no change in 61% of the subjects in soy protein group compared with 33% in the placebo group. Serum total PSA decreased or was unchanged in 69% of the subjects in the soy protein group compared with 55% in the placebo control. The investigators concluded, “This study establishes the need to explore further the effects of prolonged and consistent soy consumption, which could potentially delay onset of histologic disease in this patient population.”

Sonoda et al (2004) conducted a hospital-based case-control study on diet in relation to prostate cancer in Japan (140 cases, 140 controls). Soybean products were one of the food items assessed. The odds ratio for soybean products is 0.53 (95% confidence interval = 0.24 – 1.14) when the fourth quartile of intake is compared with the lowest one. The authors concluded, “Our results provide support to the hypothesis that the traditional Japanese diet, which is rich in soybean products and fish, might be protective against prostate cancer.”

Ozasa et al (2004) investigated serum isoflavones in relation to prostate cancer risk in Japanese men in a case-control study (52 cases, 151 controls) nested in Japanese Collaborative Cohort Study. The odds ratio is 0.38 (95% confidence interval = 0.13 – 1.13) for genistein, 0.41 (95% confidence interval = 0.15 – 1.11) for daidzein, and 0.34 (95% confidence interval = 0.11 – 1.10) for equol when the highest level is compared with the lowest level. The investigators concluded, “In conclusion, serum genistein, daidzein, and equol seemed to dose-dependently reduce prostate cancer risk.”

In summary, findings from these studies support a relationship between consumption of soy protein and a reduction in prostate cancer risk. Thank you for your consideration.

Sincerely,



Lin Yan, Ph.D.  
Director, Cancer Research  
Health and Nutrition



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

C: Gregory L. Paul, Ph.D.  
Cary Levitt, Esq.