



THE WESTON A. PRICE FOUNDATION®

for **Wise Traditions** IN FOOD, FARMING AND THE HEALING ARTS

Education • Research • Activism

BOARD OF DIRECTORS

Sally Fallon, MA, President and Treasurer
Mary Enig, PhD, FACN, CNS, Vice President
Geoffrey Morell, ND, JI, Secretary
Tom Cowan, MD
Cherie Calvert
Kaayla T. Daniel, PhD, CCN
Valerie Curry Joyner

GENERAL COUNSEL

James Turner, Esq.

HONORARY BOARD

H. Leon Abrams, Jr, MA, EDS
Jen Allbritton, BS, CN
Christian B. Allen, PhD
Naomi Baumslag, MD, MPH
Marie A. Bishop, CDC
Jerry Brunetti
Natasha Campbell-McBride, MD
Lee Clifford, MS, CCN
Christopher Cogswell, MA
Monica Conrado
Janice Curtin
Eric Davis, BDS, DAc, DCN
William Campbell Douglass, MD
Sara Bachman Ducey, MS, CNS
James A. Duke, PhD
Carol Esche, DNP, MA, RN, CNA
Mike Fitzpatrick, PhD
Donna Gates, BS, MEd
Zac Goldsmith, Editor, The Ecologist
Nicholas Gonzalez, MD
Trauger Groh
Joann S. Grohman
Barry Anthony Groves
Beatrice Trum Hunter, MA
Richard James, MBA, LLD
Valerie James, BA
Larry Klein
Kilmer McCully, AB, MD, MA (hon)
Frank Melograna, MD
Carlos Montiero
Joseph Mercola, DO
Kenneth Fielding Morehead, DOM
David Morris, BS, DC
Bruce Rind, MD
Julia Ross, MA
Jordan S. Rubin, NMD, CNC
Ethan Russo, MD
Adrienne Samuels, PhD
Jack Samuels, MSHA
Ron Schmid, ND
Andreas Schuld
Frederick I. Scott, Jr, BE, MS
C. Edgar Sheaffer, VMD
Ted Spence, DDS, ND
Rebecca L. Stearns, LAc, DAc
Alana Sugar, CN
Krispin Sullivan, CN
Joe Tarantolo, MD
John Umlauf
Charles Walters, MA
Susun S. Weed
David Wetzel, BS
Bruce West, DC
George Yu, MD

February 18, 2008

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852.

RE: Docket No. 2007N-0464

The Weston A. Price Foundation, a non-profit nutrition education foundation with offices in Washington DC, is pleased to submit these comments and petition pursuant to the Federal Food, Drug and Cosmetic Act (FFDCA). The Foundation urges the US Food and Drug Administration to amend the Final Rule Re Food Labeling: Health Claims; Soy Protein and Heart Disease, which became effective October 19, 1999. Foods containing soy protein should not carry a heart disease health claim.

Under section 403 (4) (3) (B) (i) of the Federal Food, Drug and Cosmetic Act, FDA can authorize a health claim only if the standard of significant scientific agreement is met. The data submitted with this petition establishes a lack of consensus among experts, qualified by scientific training and experience, about claims that soy protein prevents heart disease or even lowers cholesterol.

In this petition, we will establish the fact that this standard has not been met and that the benefits of soy are putative and unproven for the following reasons:

- ♦ The totality of the scientific evidence on soy protein and heart disease is contradictory and inconsistent.
- ♦ Studies published since 1999 undermine the conclusions drawn from key studies evaluated by the FDA when it approved the health claim in 1999.
- ♦ Recent studies show that soy can actually contribute to or cause heart disease, including endothelial damage (especially in women), heart arrhythmias and cardiomyopathy, an increasingly prevalent condition that afflicts 1 in 500 Americans.

We have included as part of this petition extended commentary, summaries of important journal articles, quotations from qualified researchers and complete references to publicly available studies, all of which raise questions about and/ or disprove the validity of the currently allowed soy protein/heart disease health claim.

Our petition includes three sections in which we rebut and refute the evidence used to establish the 1999 soy/heart disease health claim:

I. PRELIMINARY REQUIREMENTS: We establish the fact that the soy protein health claim failed to conform to the requirements of 21 CFR 101.14 (b). Furthermore, soy protein products are widely available in the food supply today but were not in common use in food prior to 1958 and soy protein isolated has not received GRAS (Generally Recognized As Safe) status.

II. SCIENTIFIC EVIDENCE: Our review of the scientific literature on soy and heart disease indicates that soy protein does not reliably lower cholesterol, does not lower homocysteine, does not prevent heart disease and may cause, contribute to or accelerate the development of heart disease.

III. CONCLUSION: We document longstanding concerns in the scientific community – including experts at the FDA’s own Laboratory for Toxicological Research, the National Center for Environmental Health Sciences, the Israeli Health Ministry, the French Food Agency and the German Institute for Risk Assessment – about soy’s possible role in carcinogenesis, thyroid disease, reproductive health problems (including infertility) and other health problems.

In the light of the January 2006 Science Advisory published by the American Heart Association, we ask that the FDA give careful consideration to this petition. Although the AHA originally supported the FDA health claim, the AHA expert committee’s subsequent examination of the evidence led the AHA to conclude that soy protein does not reliably lower cholesterol and does not prevent heart disease. The U.S. Agency for Healthcare Reform and Quality has also examined the evidence, and the Agency concluded in 2005 in a 245-page report that soy products may exert a small benefit on LDL and triglyceride levels, but the effects may be of small clinical effect in individuals.

We maintain that the FDA in its mandated role as America’s foremost consumer protection agency has a duty to the American public to amend the Final Rule and thereby disallow use of a health claim regarding soy protein and heart disease health and to require all food manufacturers to cease and desist using this claim in their advertising and packaging.

Finally, we request a public hearing on these issues.

Sincerely,



Sally Fallon, MA, President
The Weston A. Price Foundation
202-333-4801
westonaprice@msn.com

Kaayla T. Daniel, PhD, CCN
wholenutritionist@earthlink.net

Kilmer S. McCully MD
Chief, Pathology and Laboratory Medicine Service
VA Boston Healthcare System
Medical Director, Network Consolidated Laboratories
VA New England Healthcare System
Kilmer.mccully@med.va.gov

Mary G. Enig, PhD, FACN, CNS
Fellow of the American College of Nutrition
President, Maryland Nutritionists Association
mgenig@aol.com

Galen D. Knight, PhD
galenvtp@highfiber.com