

June 11, 2004



Dr. Michael D. Shelby  
Center for the Evaluation of Risks to Human Reproduction  
P.O. Box 12233  
Research Triangle Park, NC 27709



**Re: Evaluation of Genistein and Soy Formula**

Dear Dr. Shelby:

The United Soybean Board submits this letter in response to the National Toxicology Program (NTP) Center for the Evaluation of Risks to Human Reproduction (CERHR) request for comments on the future evaluation of Genistein and Soy Formula (Federal Register Docket No. 04-8269).

The United Soybean Board, created by the Farm Act of 1990 to manage and direct the National Soybean Checkoff, is dedicated to spreading knowledge and understanding of the soybean. The USB is comprised of 62 volunteer soybean farmers representing the interests of fellow growers nationwide. USB programs help the healthcare, foodservice and food manufacturing industries to better understand and utilize the complex soybean.

Soy-based infant formula has been widely used in the U.S. and around the world for nearly 40 years and its contribution to normal growth and development is well documented by the scientific literature. Soy protein currently plays a major role in the nutrition of approximately 25 percent of formula-fed infants in the United States and has a variety of applications for older children as well.

In response to the request for the nomination of scientists for the expert panel to evaluate genistein and soy formula, USB would like to nominate the following individuals (biographical sketches are attached).

1. Thomas M. Badger, Ph.D.  
Arkansas Children's Nutrition Center (ACNC)  
1212 Marshall Street, MS 512-20B  
Little Rock, AR 72202  
Phone: (501) 364-2785  
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2. John Erdman, PhD  
Professor of Food Science and Human Nutrition

Dept of Food Science and Human Nutrition  
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3. Mark Messina, PhD  
Consultant  
1543 Lincoln Street  
Port Townsend, WA 98368  
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The plethora of data clearly support the viewpoint of the American Academy of Pediatrics – that soy-based infant formula is a safe and effective alternative to provide appropriate nutrition for normal growth and development in term infants. The long history of safe use and the robust body of literature supporting the safety of soy-based formula consumption by human infants should not be overlooked in favor of data from a few ambiguous animal models studied under conditions that in no way mimic how soy formulas are ingested in the real world.

On behalf of the U.S. soybean producers, the United Soybean Board appreciates the opportunity to provide our recommendations to this important initiative.

Sincerely,

A handwritten signature in black ink, appearing to read "Criss Davis", with a long horizontal flourish extending to the right.

Criss Davis, Chairman  
United Soybean Board