



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:

I am writing on behalf of the American Soybean Association (ASA), a membership-driven, grassroots policy organization representing nearly 30,000 U.S. soybean producers, 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).

We understand that recent data, generated primarily in animal models using purified genistein derived from soy, has led some groups to question the safety and efficacy of soy-based infant formula. Numerous studies support normal growth and development in term infants consuming soy-based infant formula. In addition, more than 20 million infants have been fed modern soy-based infant formula in the United States alone, and there has been no documentation of adverse health conditions greater than breast-fed or cow's milk formula-fed infants. In fact, no health advantages have been documented for feeding cow's milk infant formulas over soy-based infant formulas.

The majority 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 American Soybean Association continues to support that position.

Thank you for your consideration of our views.

Sincerely,

A handwritten signature in black ink that reads "Ron Heck". The signature is written in a cursive, slightly slanted style.

Ron Heck
President