IFC
INTERNATIONAL FORMULA COUNCIL
Formerly the Enteral Nutrition Council and Infant Formula Council

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CERHR

June 11, 2004

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P.O. Box 12233
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Research Triangle Park, NC
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RE: April 13, 2004 NTP CERHR *Federal Register* notice re future evaluations of Genistein and Soy Formula

Dear Sir or Madam:

This letter is prompted by the April 13, 2004 *Federal Register* announcement for future evaluations of Methylphenidate and Adderall ®, Magnesium Sulfate, and Genistein and Soy Formula and plans to convene 3 expert panels to evaluate potential reproductive and developmental toxicities of these substances (69 *FR* 19444). These comments are submitted on behalf of all the major U.S. infant formula manufacturers by the International Formula Council ("IFC")[1], an international association of manufacturers and marketers of formulated nutrition products (e.g., infant formula and adult nutritionals) whose members are predominately based in North America.

We would like to remind you that in May of 1997 the National Institutes of Health (NIH) and the United States Food and Drug Administration (FDA), convened a meeting to discuss the potential health hazards and/or benefits of phytoestrogens in soy formula; the infant formula industry was asked to participate as well as to identify other experts to present and participate in this one day meeting on the *Significance of Phytoestrogens in Infant Soy Formula*. Drs. Samuel Foman, Ekhard Ziegler, Karen Klein, Kenneth Setchell and Daniel Sheehan were among the speakers. Although NIH never provided a written summary of the meeting, Chair Frederick Naftolin, MD, concluded at the meeting: "We've heard the concerns, but there is no evidence that there is a problem." He then suggested possible future studies, including a retrospective evaluation.

Subsequently, clinical investigators at the University of Pennsylvania and the University of Iowa completed the largest retrospective study to date that examined use of soy formula in infancy and subsequent adult health. The study was sponsored by the National Institutes of Health and the Infant Formula Council (now the International Formula Council) and was published in the August 15, 2001 issue of the *Journal of American Medical Association* (Volume 286, Number 7). The results indicate those adults fed soy formulas, as infants, were no different from those fed cow-milk formula when any of a large number of health and reproductive outcomes were evaluated. According to lead author Brian Strom, MD, MPH, Director of the Center for Clinical Epidemiology and Biostatistics, University of Pennsylvania School of Medicine, "This

[1] International Formula Council members are: Mead Johnson Nutritionals; Nestlé USA, Inc., Nutrition Division; Ross Products Division, Abbott Laboratories; Solus Products; and Wyeth Nutrition.

large study reaffirms the safety of soy infant formula. We saw no significant differences between the formula groups, in either female or males, with over 30 outcomes, including height, usual weight, body mass index, indices of pubertal maturation, and a large number of reproductive and other outcomes, including cancer and fertility."

In light of the 1997 NIH/FDA meeting and the 2001 University of Pennsylvania/University of Iowa study, we do not believe there is sufficient justification for an evaluation of genistein and soy formula.

If however, after considering our comments you do chose to proceed, we respectfully submit the following qualified scientists to serve on the expert panel to consider the potential toxicities of genistein and soy formula:

- Dennis Bier, M.D. (Expertise: pediatric endocrinology and nutrition), Professor of Pediatrics, Chief, Nutrition Section, Baylor College of Medicine; Director, USDA/ARS, Children's Nutrition Research Center, Baylor College of Medicine; Program Director, NIH General Clinical Research Center, Baylor College of Medicine
- Ekhard Ziegler, M.D. (Expertise: pediatric nutrition; Co-author of 2001 University of Pennsylvania/University of Iowa study), Professor of Pediatrics, College of Medicine, University of Iowa.

The International Formula Council appreciates the opportunity to comment. Thank you for your consideration.

Respectfully submitted,

[Redacted]

Mardi K. Mountford
Executive Director
International Formula Council

Enclosures: Dennis Bier's Curriculum Vitae
Ekhard Ziegler's Curriculum Vitae