Dr. Michael D. Shelby CERHR Director, NIEHS P.O. Box 12233 MD EC-32 Research Triangle Park, NC 27709

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Dear Dr. Shelby:

As a nutritionist with twenty years expertise in the health effects of soyfoods, I would like to submit the following comments in response to the *Federal Register* request (Vol 70, No. 241) regarding the NTP-CERHR; Announcement of the Genistein and Soy Formula Expert Panel Meeting and request for public comment on draft reports.

I am pleased to see that genistein and soy formula draft reports are being considered separately. However, the release of these reports has unfortunately created the possibility that the effects of soy formula will be equated with outcomes from studies designed to test the effects of exposure to high levels of isolated genistein given to animals either orally or by injection. The deliberate separation of such outcomes from soy formula consumption is critical to the appropriate assessment of the safety and potential health outcomes of soy formula use.

Furthermore, animal studies can provide only limited insight into the health effects of soy formula; therefore, future research emphasis should be placed on the cohort of 20 million adults who were fed soy formula as infants over the past 30 years and on infants currently using soy formula.

Finally, the current data are insufficient for drawing conclusions about the health effects of soy formula on infants beyond that it produces normal short term growth and development.

In conclusion, soy formula provides an important alternative dietary choice for women who choose not to breast feed or use cow's milk formula. Therefore, changes in recommendations regarding the use of soy formula must be done with utmost caution. Clearly, no change in recommendations – based upon the data presented in these reports – can be justified at this time.

Sincerely,

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