Ms. Cynthia Oshita  
Office of Environmental Health Hazard Assessment  
Sacramento, California 95812-4010

Dear Ms. Oshita:

On behalf of Mead Johnson Nutrition, I write to urge you not to list bisphenol A (BPA) as a  
"chemical known to the state to cause reproductive toxicity" under Proposition 65 by the  
authoritative bodies mechanism.

Bisphenol A does not meet the criteria to be added to the list under Proposition 65 through this  
mechanism because the authoritative body cited in the petition has not determined that BPA is  
hazardous to health. According to section 25249.8(b) of the Act, and 27 Cal. Code Reg. §  
25306, this requirement must be met before a chemical is listed.

Perhaps of greatest importance is the fact that the NTP’s peer-reviewed analysis of BPA found  
no serious concern about its effects on human reproduction or development in adults or  
children. Rather, it was the NTP's opinion that there are insufficient data from studies in humans  
to reach a conclusion on reproductive or developmental hazards presented by current  
exposures to bisphenol A and more research is needed to better understand its implications for  
human health.

Using its five-level scale of concern, the NTP used the term ‘some concern’ to characterize  
possible effects of BPA on fetuses. The definition of ‘some concern’ means that further studies  
are recommended to better understand any implications to human health. It does not mean that  
the NTP deemed BPA harmful or its use should be restricted.

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NTP conclusions regarding the possibilities that human development or reproduction might  
be adversely affected by exposure to bisphenol A. The NTP uses a five-level scale of concern:

- **SERIOUS Concern** for adverse effects
- **CONCERN** for adverse effects
- **SOME Concern** for adverse effects
- **MINIMAL Concern** for adverse effects
- **NEGLIGIBLE Concern** for adverse effects

- Developmental toxicity for fetuses, infants, and children (effects on the brain, behavior, and prostate gland)
- Developmental toxicity for fetuses, infants, and children (effects on the mammary gland and early puberty in females), and reproductive toxicity in workers
- Reproductive toxicity in adult men and women and malformations in newborns
As recently as January 15, 2010, the FDA reaffirmed the safety of BPA. Joshua Sharfstein, FDA’s principal deputy commissioner said in a news conference, “if we thought [BPA] was unsafe, we would be taking strong regulatory action.” Our confidence in the safety of BPA is further reinforced by expert opinions of numerous recognized scientific and regulatory bodies confirming the safety of its use. These include:

- U.S. Food and Drug Administration
- Health Canada
- European Food Safety Authority
- Japanese National Institute for Advance Industrial Science and Technology
- Food Safety Australia New Zealand
- German Federal Institute for Risk Assessment
- Japanese Ministry of Environment

The FDA is currently conducting its most extensive review of BPA to date and is expected to be complete a safety assessment within the next 15 to 21 months. In addition, the National Institutes of Health has devoted $30 million to study the safety of BPA. If the FDA or other competent regulatory authorities conclude that BPA is a health risk to our consumers we will move quickly to address these risks. The health and safety of infants and children are our top priorities.

We respect the commitment of the State of California to protect the health and well-being of its youngest citizens and ask that you continue to abide by the requirements of the California Code of Regulations and not list BPA under Proposition 65 by the authoritative bodies mechanism taking into consideration the above arguments.

Sincerely,

Hugh N. Tucker, Ph.D.
Distinguished Research Fellow
Global Research and Development