DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

April 6, 2015

Ms. Monet Vela
Office of Environmental Health Hazard Assessment
P.O. Box 4010, MS-58D
Sacramento, California 95812-4010

RE: OEHHA Proposition 65, potential listing of BPA

Dear Ms. Vela:

This letter is in response to the OEHHA public call for comments and information concerning your evaluation of the Bisphenol A (BPA) and potential female reproductive toxicity. In December of 2014, FDA released an extensive, rigorous, and systematic four-year assessment of more than 300 scientific studies on BPA. The assessment, conducted by FDA experts in toxicology, analytical chemistry, endocrinology, epidemiology, and other fields, assessed multiple fields of toxicology, including reproductive toxicology which is directly relevant to your proposed evaluation. The findings of our assessment reaffirm FDA's determination that BPA is safe provided it is used in accordance with our regulations. FDA's latest assessments and supporting information can be found at http://www.fda.gov/food/ingredientspackaginglabeling/foodadditivesingredients/ucm166145.htm and http://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/ucm064437.htm.

We also submit for your consideration the extensive range of research studies completed at FDA's National Center for Toxicological Research (NCTR) specifically designed to address the safety of BPA, including its potential for reproductive toxicity. Based on the results of these studies, we now know that internal exposure in people would be less than 1% of the level of BPA they may ingest due to very efficient metabolic capabilities in humans. People process BPA better than rodents; even in rodents, studies have shown that exposure to BPA cannot be measured in the unborn offspring of pregnant rodents exposed to 100 to1000 times more BPA than people are reasonably expected to ingest. NCTR recently completed a large scale rodent toxicity study designed to characterize potential effects of BPA in a wide range of endpoints, including reproductive toxicity. The study included an *in utero* phase, direct dosing to pups to mimic bottle feeding in neonates, and employed a wide dose range covering low doses where toxic effects have been previously reported in some animal studies. The results from the large extent of reproductive, sperm, and hormone parameters evaluated in the NCTR study do not support BPA as a reproductive toxicant. For a full evaluation of this study, please consult the documents in the links provided above.

Sincerely,

Luciana Borio, M.D.
Acting Chief Scientist
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring MD 20993