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10/25/16

Susan T. Mayne
Director, Center for Food Safety and Applied Nutrition
c/o Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket Number FDA-2016-D-2241 for "Substantiation for Structure/Function Claims Made in Infant Formula Labels and Labeling."

Dear Dr. Mayne,

We at the Nutrition Policy Institute in the University of California's Division of Agriculture and Natural Resources would like to voice strong support for the Food and Drug Administration's proposed *Substantiation for Structure/Function Claims Made in Infant Formula Labels and Labeling: Guidance for Industry*. We commend FDA for taking up this important issue and urge continued and stronger oversight of the infant formula manufacturers' labeling claims. We endorse and support the more detailed technical comments submitted by ChangeLab Solutions (Comment Tracking #1k0-8sgj-78i7) in the public interest.

As an academic institute that conducts research to inform, build and evaluate nutrition related policy, we work with and behalf of families who are trying to make healthy food choices for themselves and their children. The claims made by infant formula companies on product labels and in marketing materials are confusing and misleading to mothers, which undermines their decision to breastfeed and their efforts to exclusively breastfeed their infants for as long as possible. The apparent lack of adequate scientific support for structure/function claims on infant formula products warrant stronger oversight by FDA. This proposed Guidance is an important first step in that reassessment process, which is badly needed and long overdue.

In brief, we strongly support key elements of the Proposed Guidance, and urge that they be included in the final version of this guidance:

- The statement that "[h]uman milk is the recommended source of nutrition for infants" and infant formula is a food product that simulates or substitutes for human milk.

- Clear substantiation standards for defining, testing and designing meaningful and rigorous studies of actual efficacy, as outlined in detail in the proposed guidance, are needed to prevent untruthful and misleading claims in the labeling of infant formula that are prohibited by law.

- Infant formula makers should retain all scientific documentation substantiating each claim they make in their files, and comply with the Federal Trade Commission (FTC) concurrent requirements for pre-claim substantiation and documentation.

Moreover, we strongly urge that the following additions and corrections be included, in order to more fully protect the public from untruthful and misleading structure/function claims on infant formula labels:

- ***Remove the Blanket Exclusion of Breast Milk Comparison Claims.*** Infant formula labels now routinely imply that an added ingredient confers benefits found in breast milk itself ("now closer to breast milk than ever"). These claims can be confusing and misleading, particularly to mothers with low literacy and education levels. The Proposed Guidance *must* be revised to ensure breast milk comparisons that are used to make claimed structure/function benefits in infants *are included*.

- ***Clarify that Claims Related to Human Milk Supplementation and Replacement Are Structure/Function Claims.*** The guidance should make clear that supplementation claims on infant formula will be analyzed as structure/function claims and require substantiation with competent and reliable scientific evidence.

- ***Require full disclosure and other ethical and scientific safeguards*** for nutrition research, such as the International Life Sciences Institute (ILSI) *Conflict of Interest Guidelines*.

While we support the proposed guidance – with some strengthening -- as a useful step forward, we believe that the **FDA must also pursue formal rulemaking on the issue of structure/ function claims on infant formula**. Infant formula is a unique and highly specialized product that is the sole source of nutrition for many infants and is used as a substitute for human breast milk, a living, changing tissue which confers substantial, irreplaceable health benefits and protections to both mother and baby.

This product should not be treated in the same manner as vitamins and supplements. Because of the impact of health claims on the initiation and duration of exclusive breastfeeding – a feeding decision with proven protective benefits -- structure/function claims made about this product need and deserve stricter criteria and more careful FDA oversight.

Thank you for the opportunity to comment.

Sincerely yours,

Lorrene D. Ritchie

Lorrene D. Ritchie, PhD, RD
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