

May 2, 2011

Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2011-N-0098: Agency Information Collection Activities; Proposed Collection; Comment Request; Infant Formula Label Statements Experimental Study

Dear Division of Dockets Management,

The following comments on the U.S. Food and Drug Administration's (FDA) proposed collection of information regarding an Infant Formula Label Statements Experimental Study, published March 3, 2011, in the *Federal Register* [76 FR 11788], are submitted on behalf of a coalition of associations interested in the accurate and non-misleading communication of product benefits to consumers ("the Coalition").

The industries represented by this Coalition embrace and support FDA's role as a regulator of food and supplement labels and claims made thereon and in related labeling. We also commend FDA's interest in collecting information to support the agency's ability to regulate such claims fairly. We believe, however, that FDA initiatives should not reflect any bias in evaluating such claims; therefore, the instruments used to collect such information should be carefully structured to result in reliable conclusions regarding how a claim is actually perceived and understood by a consumer.

The study instrument that has been proposed in this notice has a number of design issues that have the potential to yield unreliable and perhaps biased results. We understand the traditional approach and desire to focus on the response by a consumer to a label claim. That approach is valuable in learning what factors affect consumer choice between/among like or similar products. With respect to any effort to study the possible effect of an infant formula label representation on a consumer's decision to choose infant formula for her baby, a focus on the label alone has the real potential to lead to skewed results. Infant formula is a food product category for which the decision as to *whether* to purchase the product at all is customarily made long before one sees a label on the store shelf. The decision is based on more considerations than simply label claims. Moreover, the decision as to *which* formula to purchase is often driven by recommendations by a healthcare professional or a trusted brand (information that will not be available to these study participants). The proposed study does not take either of these factors into consideration. Nor is the influence of WIC taken into account in the proposed study design, although WIC participation actually dictates the infant formula purchase decision for more than half of all US infants.

Additional concerns about methodology and assumptions that could bias the study results include, but are not limited to: the accuracy of the background information given to participants against which to evaluate the claims; the sequencing of exposures in a way that could bias the answers to later questions; and the choice of study participants -- including some subcategories who are *not* in the potential-purchaser population (women who are not pregnant and have no young children), and excluding others who *might* be (fathers).

In light of these concerns, we were encouraged to see FDA's more recent announcement proposing a study of label claims in the general category of foods. The April 13 *Federal Register* announced a proposed collection of information regarding an "Experimental Study on Consumer Responses to Labeling Statements on Food Packages," which appears to focus on all types of food label claims, including health claims, nutrient content claims, and structure-function claims. A study on the effect of label claims on consumer decisionmaking in the more general category of foods seems more likely to result in helpful information than a similar study focused on the specific context of infant formula – a

context that involves an array of multiple factors, including emotional, social and policy considerations. In light of this reality, the Coalition has substantive concerns with respect to the ability of the infant formula study to result in meaningful data capable of providing a clear, undistorted view of factors affecting consumer choice.

The specific claims that FDA proposes to study have been made on formulas for a number of years with the full knowledge of the agency. If the agency has concerns about the substantiation or propriety of such claims, it certainly has sufficient regulatory tools (in the Federal Food, Drug, and Cosmetic Act) to bring those concerns to the attention of the infant formula industry and to resolve them. Advancing a study with the degree of difficulty and potential for bias attached to testing claims in this specific subcategory of foods is of concern not only to the infant formula industry, but to the entire food and dietary supplement industries as well, because of its potential to set a precedent for an artificial threshold of how structure-function claims may be judged.

The Coalition recommends that the agency concentrate its efforts instead on testing in the general category of foods, as proposed in the April 13 FDA Federal Register announcement regarding a proposed collection of information regarding an “Experimental Study on Consumer Responses to Labeling Statements on Food Packages,”

Respectfully submitted,

Council for Responsible Nutrition
Grocery Manufacturers Association
International Formula Council