



SCHOLARS
STRATEGY NETWORK

Re: Draft Guidance for Industry on Substantiation for Structure/Function Claims in Infant Formula Labels and Labeling

Marlene Schwartz, University of Connecticut
Sally Mancini, University of Connecticut

The Rudd Center supports the CFSAN's Proposed Guidance Industry on Substantiation for Structure/Function Claims in Infant Formula Labels and Labeling.

We commend the CFSAN for the Proposed Guidance for companies to provide competent and reliable scientific evidence to substantiate on-label marketing claims about the effects of ingredients or additives in infant formula on the structure of function of infants' bodies. We agree with all the critical elements and quality considerations for intervention studies stated in the guidance. Furthermore, we applaud the CFSAN for urging manufacturers and distributors to consider which scientific evidence is clinically meaningful, rather than focus on results that are statistically significant. Finally, we agree that structure/function claims should encompass the context of labeling as a whole, including all statements, phrases, and graphics.