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June 6, 2005

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20857

RE: Docket Nos. 91N-384H and 96P-0500
Food Labeling: Nutrient Content Claims, Definition of Sodium Levels for the Term “Healthy”

To Whom It May Concern:

Campbell Soup Company is very concerned about the timing of the determination by the Food and Drug Administration (FDA) as to whether to continue the stay of the second-tier sodium levels in §101.65(d)(2)(ii)(C) and (d)(4)(ii)(B).

We note that as of this date the FDA has not determined whether to implement its stayed regulation, even though the next effective date is January 1, 2006. FDA has stayed the implementation of this regulation for a number of years. Nevertheless, we believe it would be unfair to impose it at this time on notice of seven months or less. Companies require a longer period in which to implement any needed changes in formulating, labeling, and distributing products. In fact, the practical challenges imposed by such a short notice could force a temporary withdrawal of “healthy” products from the market, from which it may be difficult to recover commercially.

Thank you for acting promptly to resolve the commercial uncertainty under which the food industry is currently operating.

Sincerely,

Chor San Khoo, Ph.D.

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