International Formula Council

Via Email and Regulations.gov

March 26, 2014

Phillip C. Spiller
Acting Director
Office of Nutrition, Labeling, and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

Re: Docket No. FDA-1995-N-0036
(formerly 95N-0309)

Dear Mr. Spiller,

The International Formula Council[*] (IFC) is responding to your letter dated March 21, 2014 which declined IFC's request for an extension of the comment period for the interim final rule (IFR) titled, "Current Good Manufacturing Practices, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports, for Infant Formula."

As you know, the IFC welcomed FDA's publication of the GMPs for infant formula following many years of discussion. However, in light of the fact that several sections of the IFR which were either not included in the 1996 proposed rule or changed significantly from the 1996 proposed rule, we are requesting additional time to consider these new requirements and to prepare substantive comments. Our goal for these comments is to help provide clarity related to the feasibility of meeting the current effective date and to provide substantive science based information around certain provisions. We feel the agency and the industry would benefit from this additional time and the comments that will result

Specifically, we are providing explanation as to why we need an extension to the comment period for several topics:

- Quality Factors: FDA's expansion in the IFR of the definition of "Quality Factors" reflect several new requirements (e.g., "eligible" infant formulas, citizen petition option) and IFC members would appreciate having additional time to assess the impact and to prepare substantive, science-based comments.
- Manufacturers' ability to conform to additional stability requirements, based on our interpretation of the IFR, and related costs.
- Several sections of the IFR, namely Sections §106.6 and §106.30 would require development of specifications, construction, submission of thermal process filings and other actions which would make complying with the July 10 date difficult if not impossible for some members. IFC is requesting additional time to prepare detailed feedback and examples for consideration by the Agency

[*] The IFC is an association of manufacturers and marketers of formulated nutrition products, e.g., infant formulas and adult nutritionals, whose members are based predominantly in North America. IFC members are Abbott Nutrition, Mead Johnson Nutrition, Nestlé Infant Nutrition and Perrigo Nutritionals.

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- FDA's cost-benefit analysis: the IFC believes FDA's cost benefit analysis, the proposed benefit of which is derived largely from savings from avoided hospital costs as a result of fewer cases of *Cronobacter* infection, significantly overestimates the expected annual incidence of *Cronobacter* infection due to outdated data. We also believe FDA severely underestimated the cost of a clinical study and the time it takes to complete a clinical study.
- Last, but not least, members are also working on comments related to several other agency initiatives, including FSMA, the Nutrition Labeling proposed rule and the FDA guidance on INDs.

We are trying very hard to develop detailed IFC comments in response to the IFR despite the short comment period. However, we fear that the short comment period will result in final comments that do not allow our comments and proposed solutions to be adequately addressed. We therefore ask you to reconsider our request to extend the comment period for Docket No. FDA-1995-N-0036 for an additional 30-45 days. Thank you for your consideration.

Sincerely,

Mardi K. Mountford, MPH
Executive Vice President

cc: Benson Silverman, MD, Director, Infant Formula and Medical Foods Staff, Office of Nutrition, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition, Food and Drug Administration