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September 24, 2014

Infant Formula and Medical Foods Staff  
Office of Nutrition, Labeling, and Dietary Supplements  
Center for Food Safety and Applied Nutrition (HFS-850)  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: IFC Citizen Petition on Final Rule for Infant Formula Good Manufacturing Practices

This document is to supplement the Citizen Petition submitted by the International Formula Council (IFC)\* regarding the final rule, "Current Good Manufacturing Practices, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports, for Infant Formula."

As noted in the Petition, we do not believe that the requirement (under the most prescriptive interpretation) of 21 CFR §106.91(b)(2) in the Interim Final Rule to test all production aggregates (e.g., batches) at the end of shelf-life will provide any additional public health benefit. In support of this position, please see the information below on the defect rate for the industry regarding production aggregates tested at the end of shelf-life in 2012 and 2013.

[Redacted]

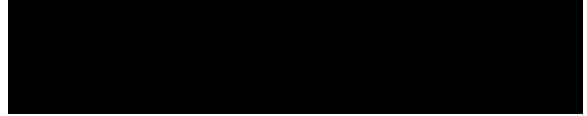
Total Number of Production Aggregates that Reached End of Shelf-Life in 2012 and 2013	Number of Production Aggregates Tested at the End of Shelf-Life in 2012 and 2013	Number of Defects <sup>1</sup> among Production Aggregates Tested at the End of Shelf-Life in 2012 and 2013
[Redacted]	[Redacted]	0

\* The International Formula Council 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.

<sup>1</sup> A “defect” is defined as a confirmed finding that the level of a nutrient in the production aggregate of an infant formula being tested is below the minimum level required or, if applicable, above the maximum level specified by 21 CFR §107.100.

We appreciate the ability to submit this information confidentially. If there are any questions regarding this information, please do not hesitate to contact me.

Sincerely,



Mardi K. Mountford, MPH  
Executive Vice President  
International Formula Council