IFC

INTERNATIONAL FORMULA COUNCIL

Formerly the Enteral Nutrition Council and Infant Formula Council

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Via Federal Express

May 6, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Request for Extension of Comment Period
Docket No. 95N-0309

The International Formula Council (IFC), the association of manufacturers and marketers of formulated nutrition products (e.g., infant formula and adult nutritionals), is requesting an extension of the reopened comment period for the agency's proposal entitled "Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports, for the Production of Infant Formula" [68 *FR* 22341, April 28, 2003].

FDA's initial proposed rule on infant formula GMPs was published in the *Federal Register* of July 9, 1996 (61 *FR* 36154) and IFC provided extensive comments. In the seven years that have elapsed since the 1996 proposal, the infant formula industry has attained significant additional experience and expertise in the manufacture of safe and wholesome liquid and powdered infant formulas. In the process, industry further continuously develops its own internal criteria, which include record development and maintenance, to ensure the safety of infant formula products.

The industry's experience and expertise provide the most meaningful basis available for evaluating the reasonableness of the agency's proposed requirements. Allowing sufficient time to engage in such a thorough evaluation is the best way to ensure the continued safety and quality of infant formulas without unnecessarily increasing consumer costs.

In light of the scope and importance of the proposal we believe an extension period of 60 days (i.e., to Tuesday, August 26, 2003) for comment on the original proposed requirements as well as the new issues that have arisen since 1996 is necessary to permit their careful evaluation and ensure thorough comment. The appropriateness of granting this extension is further underscored by the fact that only a few responders (i.e., manufacturers of infant formula and the International Formula Council) are affected directly and their comments are anticipated to be comprehensive and in-depth and to require significant preparation time. Additionally, IFC's consolidation of comments for submission to FDA will reduce the time needed by the agency to review submitted

comments. The lengthy period required to propose these regulations and the agency's statements to the effect that U.S. manufacturers already comply with most of the proposed regulations are further evidence that the requested comment period extension should be granted.

FDA has pioneered the use of the rulemaking process as an effective regulatory tool. The agency's success in this area is in large part related to the consistent desire to develop as strong and meaningful a record for agency action as possible. The International Formula Council's request for extension is grounded in and totally consistent with this agency practice and is designed to enhance the quality and accuracy of any forthcoming regulation. Thank you for your consideration of this request.

Respectfully submitted,

Robert C. Gelardi
President

Mardi K. Mountford
Executive Director

Note IFC members are: Mead Johnson Nutritionals, Bristol Myers Squibb; Nutrition Division, Nestlé USA, Inc; Ross Products Division, Abbott Laboratories; and Solus Products. This extension also is supported by Wyeth Nutrition. Thus, the request is being made on behalf of all U. S. manufacturers of infant formula.