



**INTERNATIONAL FORMULA COUNCIL**  
*Formerly the Enteral Nutrition Council and Infant Formula Council*

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July 9, 2004

Division of Dockets Management [HFA-305]  
Food and Drug Administration  
5630 Fishers Lane, rm. 1061  
Rockville, MD 20852

Re: Docket No. 2004N-0205:  
Furan in Food, Thermal Treatment

Dear Sir or Madam:

This letter is prompted by the May 10, 2004 *Federal Register* notice requesting the submission of data and information on furan (69 *FR* 25911). These comments are submitted on behalf of all the major U.S. infant formula manufacturers by the International Formula Council ("IFC")<sup>1</sup>, an international association of manufacturers and marketers of formulated nutrition products (e.g., infant formula and adult nutritionals) whose members are predominately based in North America.

We would like to take this opportunity to advise you of our position regarding furan. IFC believes the history of use demonstrates that the levels of furan found in infant formulas by the Food and Drug Administration (FDA) scientists present no safety problem. Infant formulas are carefully quality controlled and manufactured to exacting FDA and industry standards. FDA can be assured that infant formula is safe and nutritious.

Further, we support the position of the Food Advisory Committee and Subcommittee on Contaminants and Natural Toxicants, namely that FDA's priority is to complete a risk assessment to determine if furan is a real concern.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read 'Mardi K. Mountford'.

Mardi K. Mountford  
Executive Director  
International Formula Council

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<sup>1</sup> International Formula Council members are: Mead Johnson Nutritionals; Nestlé USA, Inc., Nutrition Division; Ross Products Division, Abbott Laboratories; Solus Products; and Wyeth Nutrition.