



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")¹, 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,

Mardi K. Mountford
Executive Director
International Formula Council

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

2004N-0205

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F A C S I M I L E

To: Division of Dockets Management

Company: Food and Drug Administration

From: Rachel Spector, Ph.D.

Date: July 9, 2004

Number of pages including cover: 2

Comments: We are unable to submit comments using the electronic submission program on Docket No. 2004N-0205. According to the May 10, 2004 Federal Register notice we have until today, July 9, to submit comments; thus, I am faxing our comments and will also email and Fed Ex them to the Division of Dockets Management. Please confirm that our comments have been accepted (rspector@kellencompany.com).