Mead Johnson Nutritionals

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August 25, 2003

Dockets Management Branch, HFA-305
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket 95N-0309, Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Notification Requirements and Records and Reports, for the Production of Infant Formula

Dear Sir or Madam:

Mead Johnson & Company (Mead Johnson) submits these comments in response to the aforementioned proposed rule that would establish good manufacturing practice, quality control procedures, quality factors, notification requirements, and records and reports for the production of infant formulas. The Food and Drug Administration (FDA) issued this proposed rule on January 9, 1996 (61 Fed. Reg. 36154) and then re-opened the comment period for this proposed rule on April 28, 2003 (68 Fed. Reg. 22341). When re-opening the comment period, FDA asked for comments on issues covered by the original proposed rule as well as comments on seven additional issues.

Mead Johnson has worked closely with the International Formula Council (IFC) in the development of comprehensive comments submitted in response to the re-opening of the comment period. Mead Johnson fully endorses the IFC comments.

Mead Johnson submitted comments to the original 1996 proposed rule [*See* Letter from Thomas A. Swinford, Ph.D. to Dockets Management Branch (Dec. 3, 1996)]. Since submitting those original comments, Mead Johnson has gained extensive knowledge relevant to many of the provisions that has caused the company to re-evaluate some of the positions articulated in our 1996 comments. To the extent that our December 1996 comment advances positions that differ from the August 2003 IFC comments, the agency should defer to the positions advanced in the August 2003 IFC comments.

We thank you for this opportunity to comment on this important proposed rule.

If you have any questions on this or other matters, please feel free to contact us.

Sincerely,

Thomas L. Ferguson
Director, Regulatory Affairs
Mead Johnson & Company

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