Solus Products, LLC

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August 26, 2003

VIA OVERNIGHT MAIL

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:

By this letter Solus Products confirms its endorsement of the comments submitted to this docket by the International Formula Council ("IFC").

We believe these regulations are of great importance. An extraordinary amount of effort was expended by all members of the infant formula industry in the process of reviewing the proposed regulations and reaching the industry-wide consensus that is reflected in the IFC comments. These comments are the result of a detailed review of the proposed regulations by members of industry with long experience and a high level of expertise in the design, testing, and manufacture of infant formulas. The commitment of this amount of time and of this level of expertise is evidence of the importance that the industry places upon these regulations.

Like FDA, industry wants to ensure the continuing integrity and adequacy of all U.S. infant formulas. The regulatory review process conducted by the industry was constructive, and underscored to all of us the value of communication to accurately determining the effectiveness and impact of a proposed regulation. We hope that this effort can be continued in dialogue with FDA in a joint effort to craft final regulations that are clear, constructive, and effective.

Yours truly,

Dennis L Heuring

Dennis L. Heuring, Ph.D.
Managing Partner
Solus Products, LLC

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