Nestlé USA

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August 26, 2003

**VIA E-MAIL & 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:

Nestlé USA is happy to confirm, by this letter, its endorsement of the comments submitted to this docket by the International Formula Council ("IFC").

Nestlé believes these regulations are of the utmost importance to ensuring the ongoing integrity and adequacy of U.S. infant formulas. In large part, over the last seven years, we and the rest of the industry have treated the proposed requirements as already in effect. The resulting experience has enhanced our expertise, which, in turn, has informed our insights and commentary and shaped the contours of our response.

The industry's recognition of the importance of these regulations is reflected in the extraordinary amount of time, human resources and expertise already contributed to the process of reaching industry-wide consensus on the substance of the IFC comments. This effort represents a level of commitment and dialogue within the industry that has not been seen for many years, motivated by the strong desire to ensure that regulations for the manufacture of infant formula are both clear and constructive. We hope this effort will form the basis for a continuing dialogue with the agency in a joint attempt to work toward a shared end – that end being, not regulation in and of itself – but rather the broader assurance of the quality of formula available to American infants.

Yours truly,

Melanie Fairchild-Dzanis, Director
Regulatory Issues – Special Nutritionals
Nutrition Division