Mead Johnson™
Nutritionals

2400 West Lloyd Expressway Evansville, IN 47721-0001 812-429-5000

4274 1645 '99 AUG -6 P4:30 6/8/99

HFS-456

June 7, 1999

Robert J. Moore, Ph.D.
Center for Food Safety and Applied Nutrition (HFS-456)
Food and Drug Administration
200 C Street, SW.
Washington, DC 20204

Re: Codex Alimentarius Commission – Vitamin and Mineral Supplement Background Paper Comments

Dear Dr. Moore:

This letter is in response to the FDA's request for comments on the *Codex Alimentarius Commission's Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) Background Paper to Identify Perspectives and Issues Pertaining to International Guidelines on Vitamin and Mineral Supplements* that appeared in the April 9 *Federal Register* notice. Mead Johnson Nutritionals and Worldwide Consumer Medicines divisions of Bristol-Myers Squibb Company submit responses below to each of the FDA's requested topics. Overall, however, given the national regulatory differences applied to vitamin and mineral supplements in terms of their classification (food, drug or other), acceptable levels and acceptable labeling, in addition to differences in medical and cultural practices involving such supplements, Bristol-Myers Squibb Company concurs with the FDA in finding it difficult to support the development of guidelines or a standard by the Codex Alimentarius Commission. Although the use of Codex guidelines and standards in worldwide trade is recognized, the extent of divergence among countries on the topic of vitamin and mineral supplements suggests lengthy negotiations with little possibility of agreement.

1. Terminology -

The terminology should be flexible and allow for the interchangeable use of options such as vitamin supplement, vitamin C supplement, and dietary supplement.

2. Purpose and Role –

The purpose and role of vitamin and mineral supplements should describe the full spectrum of rationales ranging from support for correcting nutritional deficiencies to enhancing quality of life (e.g., promotes relaxation) and body structure/function (e.g., helps promote healthy cholesterol levels).

3. Approved Nutrients –

If a list of approved nutrients is agreed upon, and since the science is rapidly evolving and healthcare professionals cannot always reliably identify responders or non-responders, approved vitamins and minerals should be comprehensive. Any international limitations on the type of vitamins and minerals used in dietary supplements should be based on scientific analysis and data. Approved nutrients should have evidence of effectiveness and safety based on standards/recommendations from established scientific organizations like the Food and Nutrition Board of the Institute of Medicine. That said, a list of

99N-0391 C 11

approved nutrients may limit the access of both practitioner and consumer to substances which are safe and acceptable according to the science and medical practice of a country, and in that light, such a list would not be desirable.

4. Setting Maximum Limits –

Any vitamin and mineral supplement upper limits should be based on scientific risk assessment models (*Dietary Reference Intakes: A Risk Assessment Model for Establishing Upper Intake Levels for Nutrients*, Institute of Medicine, 1998). Misinterpretation of the RDA or "safe and adequate" nutrient levels to mean a "safety limit" may impose excessive restrictions that could limit consumer benefit. Substantial and rapidly growing scientific evidence indicates that intakes greater than the RDA of certain vitamin and minerals, such as vitamins C and E, may safely provide some people health benefits (Carr, A.C. and Frei, B. Toward a new recommended level dietary allowance for vitamin C based on antioxidant and health effects in humans. *Am. J. Clin. Nutr.* 69:1086-1107, 1999; *Preventative Nutrition, The Comprehensive Guide for Health Professionals*, Eds. Bendich and Deckelbaum, Humana Press, 1997). Overly restricted limitations may preclude people from obtaining effective vitamin and mineral supplements. Moreover, health and medical practices as well as regulations vary from one country to another, and an acceptable level in one country is considered excessively high in another. Again, international consensus on this topic seems very difficult to obtain.

5. Setting Minimum Limits –

Vitamin and mineral supplements should contain at least 10% of the RDI as a reasonable lower limit to help avoid misleading dietary supplement consumers. This level is sufficient in the US to make nutrient content claims.

6. Purity and Good Manufacturing Practices (GMP) –

The international standards should be consistent with FDA's anticipated dietary supplements GMP regulations.

7. Labeling –

Vitamin and mineral supplement labels should be allowed to make scientifically substantiated structure/function claims and vitamin levels at 90% of label claim at expiration date should be allowed to help companies manage the wide range of temperature and humidity encountered in international markets.

8. Packaging and Marketing –

Packaging and Marketing are outside the scope of this background paper.

Since the topics described in the FDA notice adequately cover the vitamin and mineral supplement issues, additional topics are not recommended for the CCNFSDU background paper. We are available to provide further assistance in helping to finalize the CCNFSDU paper or in preparing for and participating in the year 2000 CCNFSDU meeting.

Sincerely,

Mark L. Dreher

Mark Dreher, Ph.D.
Director, Global Regulatory Affairs
Mead Johnson Nutritionals
Bristol-Myers Squibb Company

Connie McDuffee Dominguez

Connie McDuffee Dominguez
Director, Global Regulatory Affairs
Worldwide Consumer Medicines
Bristol-Myers Squibb Company