A.H.H.A.
AMERICAN
HOLISTIC
HEALTH
ASSOCIATION

Post Office Box 17400
Anaheim. CA 92817

714 / 779-6152
ahha.org
me10ahha.org



July 25, 2002

Food Safety Inspection Service (FSIS) Docket Room
U.S. Department of Agriculture
Food Safety and Inspection Service, Room 102, Cotton Annex
300 12th Street SW
Washington, DC 20250-3700

02-022N
02-022N-2
Suzan Walter, President

RE: Docket 02-022N
AHHA Position Paper #1

The American Holistic Health Association (AHHA) submits this document to be considered when drafting the United States' position related to **Sections 1.0 and 3.0 of the "Proposed Draft Guidelines for Vitamin and Mineral Supplements"** that will be discussed at the 24th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) to be held in Berlin, Germany, November **4-8,** 2002.

One of the most controversial issues is whether the document "Proposed Draft Guidelines for Vitamin and Mineral Supplements" **is** to be a set of optional guidelines for use by governments needing technical guidance OR if it is to be an international standard that will be fully enforced by the World Trade Organization (WTO) for all member governments.

The American Holistic Health Association urges the U.S. delegation to take an active role to:

- Clarify that this document is to be OPTIONAL guidelines (as was the original intent).
- Add clear legal terminology to the document to establish this without any room for misinterpretation.

As our lead representative at Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU), the Food and Drug Administration (FDA) has a responsibility to present and aggressively promote positions that will protect the rights of the people of the United States under the Dietary Supplement Health and Education Act (DSHEA). This is a priority issue that needs to be addressed.

Currently those attending CCNFSDU sessions verbally state that the intent of the document is to be optional guidelines. However, only what the document actually states has legal impact. When we review what is currently in the document and place it in the context of the Codex Alimentarius Rules of Procedure and the General Principles of the Codex Alimentarius, the document is definitely one to be fully enforced as a standard by the WTO. We specifically call your attention to the following:

- The "Proposed Draft Guidelines for Vitamin and Mineral Supplements" in section 1.2 states "It is left to national authorities to decide whether vitamin and mineral supplements are drugs or foods. These Guidelines do apply in those jurisdictions where products defined in **2.1** are regulated as foods." Nowhere in the document does it state that these are optional guidelines, and it clearly states the Guidelines "do apply."
- The "Proposed Draft Guidelines for Vitamin and Mineral Supplements" is being drafted according to the eight-step procedure designed to create a document to be submitted to member governments for acceptance and enforcement. On page 18 of the "Procedures for the Elaboration of Codex Standards and Related Texts" it states, "Throughout this text the word 'Standard' is meant to include any of the recommendations of the Commission intended to be submitted to Governments for acceptance." The "any of the recommendations" includes the "Guidelines for Vitamin and Mineral Supplements" being drafted for submittal to member governments. When the "Guidelines for Vitamin and Mineral Supplements" are submitted to member governments for acceptance, they will be enforceable as standards for all member governments. Therefore, they will not be optional.
- The wording throughout the "Proposed Draft Guidelines for Vitamin and Mineral Supplements" **is** in directive, not suggestive voice. There is no indication that these will not become an enforced standard.

Individuals who have been active in CCNFSDU sessions from the beginning note that development of this document has not progressed in the direction initially intended - Optional Guidelines. The CCNFSDU delegates have a responsibility to be sure that everyone understands what is being created.

The American Holistic Health Association presents our position that establishing the "Guidelines" as a set of OPTIONAL guidelines in section 1.0, plus the acknowledgement of the expanded role of nutrients in the Preamble (presented in a separate position paper), will require revision of Section **3.0** of the document. The new focus could then be supporting the original purpose of this Committee - to create optional guidelines for use by governments needing technical guidance from the World Health Organization (WHO).

If these things do not happen, and the "Guidelines" are ultimately implemented as an international standard enforced by WTO, the U.S. will be required to select one of the three Acceptance Options. In-depth analysis of these options reveals that each will remove some degree of our sovereign rights. Particularly with Section 3.0 essentially as it is now, the Acceptance Options 1 and 2 would allow the WTO to force the U.S. to reverse our rights granted under DSHEA.

We respectfully encourage the U.S. delegation to enact our recommendations.

Submitted by:
Suzan Walter, President
American Holistic Health Association
PO Box 17400
Anaheim, CA 92817-7400
(714) 779-6152
mail@ahha.org
www.ahha.org