140

Crane, Nancy T

From: American Holistic Health Association [mail@ahha.org]
Sent: Thursday, August 22,2002 10:32 AM
To: Crane, Nancy T
Subject: CCNFSDU

02-022N
02-022N-140
Suzan Walter, President

August 22, 2002

Elizabeth Yetley, Ph.D.

Chief U.S. Delegate to CCNFSDU

c/o Nancy Crane

Submitted electronically to nancy.crane@cfsan.fda.gov

RE: AHHA Position Paper #3

The American Holistic Health Association (AHHA) submits these comments to be considered when drafting the United States position related to 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.

The Board of Directors of the American Holistic Health Association was pleased to note in your U.S. DRAFT POSITION AS OF JULY, 2002 PROPOSED DRAFT GUIDELINES FOR VITAMIN AND MINERAL SUPPLEMENTS that you were addressing the two areas of concern that we covered in our Position Papers #1 and #2, as submitted on July 25, 2002. However, as there are still serious opportunities for misinterpretation, we strongly believe that these two matters need more specific clarifications.

Purpose of the Guidelines

As Codex Alimentarius is about establishing standards for international trade, Codex directives are viewed as regulatory. It is not surprising that, without specific definition otherwise, the Guidelines are interpreted by many as mandatory regulations.

AHHA recommends that specific statement of purpose and scope must be added to the Guidelines so that there is absolute clarity among all participating governments. This statement needs to include whether optional or mandatory and the purpose for use of the Guidelines. For example, the statement might be "These optional Guidelines are offered as a resource for governments seeking scientific data, and are not to be used as an enforceable international trade standard."

In your July 2002 Draft Position, you include a recommendation to add to the Preamble as clarification of purpose. "These guidelines," you write, "are intended to ensure a high level of protection and to facilitate informed choice for consumers of vitamin and mineral supplements." But you also reference the need for these Guidelines to facilitate "resolution of international trade disputes." We view these as two very different purposes. Which one do you view as the key purpose of the Guidelines?

Other sources have stated that the Guidelines are being developed for use by nations without funds to establish nutritional supplement standards. Review of statements by a number of CCNFSDU participants leads us to believe that there is no consensus as to the purpose of the Guidelines. Until this lack of consensus is overcome, the members of CCNFSDU will continue to be working at cross-purposes.

Please remember that **AHHA** supports the Guidelines as ***optional suggestions based on scientific research*** for use by those governments seeking such data. Under no circumstances should these Guidelines be mandatory standards used to control the vitamin and mineral supplement industry. As Chief U.S. Delegate, you have a responsibility to protect the rights of U.S. consumers to purchase and use the nutritional supplements of their choice.

Role of Nutritional Supplements

We applaud your statement that "...from a public health perspective, some people need a vitamin-mineral supplement to meet specific nutrient needs." You go on to mention several specific situations where nutritional supplements are beneficial in a preventive role. **AHHA** believes, however, that this expanded role needs to be incorporated into the text of the document. We stated this belief in our Position Paper #2 of July 25, 2002. Rewriting the Preamble appears to us to be the most appropriate place to do this.

Reason for Minimum Level

Currently, the Guidelines state, "3.2.1 The minimum level of each vitamin and/or mineral contained in a vitamin and mineral supplement per daily portion of consumption as suggested by the manufacturer should be [15%] of the recommended daily intake as determined by FAO/WHO."

Your Rationale states, "The 15% level is consistent with the amount that a food product must contain (per serving or per 100g) to claim on its label that it is a 'source' of a vitamin or mineral based on recently adopted Codex provisions for conditions for vitamin and mineral claims."

Is the 3.2.1 statement to apply to any nutritional supplement product OR just to those claiming to be a "source" for a specific vitamin or mineral? If this statement is not clarified, we see situations where inclusion of a trace mineral for synergetic benefit might be prohibited.

Looking at the whole situation, we question why the establishment of a Minimum Level is included in these Guidelines if "claims" enforcement has been established elsewhere. We support removal of this section as inappropriate and unnecessary.

Personal Choice

You recommend that the Guidelines Preamble include the words "...to facilitate informed choice for consumers of vitamin and mineral supplements." Under 5.9, you support "All labels should bear a statement that the supplement should be taken on an advice of a nutritionist, a dietician or a medical doctor."

AHHA strongly supports empowerment of the individual to make effective healthcare decisions. While it is valuable to seek the advice of a nutritionist, a dietitian or a medical doctor, having that statement on a product could lead to this suggestion becoming a requirement. We believe that this statement is not needed on a label. We recommend that it NOT be included as a labeling suggestion.

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

Submitted by:

Suzan Walter, President