Crane, Nancy T

From: Candace Campbell [candace.campbell@verizon.net]
Sent: Monday, August 19,2002 5:32 PM
To: Crane, Nancy T; Crane, Nancy T
Subject: Comments on Codex position paper

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Untitled Attachment


Comments on July 2002 draft FD...

02-022N
02-022N-141
Candace Campbell

Crane, Nancy T

Ms. Crane:
I have attached our comments on the FDA Codex position paper. I am also pasting it into the body of this message, in case you are prohibited from opening attachments.

AMERICAN ASSOCIATION FOR HEALTH FREEDOM
FORMERLY THE AMERICAN PREVENTIVE MEDICAL ASSOCIATION

Submitted by electronic transmission

August 19, 2002

U.S. Delegation to the CODEX Convention
Elizabeth Yetley, Ph.D.
C/o Nancy Crane

RE: Comments on the U.S. Draft Position (July 2002) to the Codex Committee on Nutrition and Foods for Special Dietary Uses

It is the position of the American Association for Health Freedom that the United States, through representation by the Food and Drug Administration, should not be participating in the work of the Codex Committee on Nutrition and Foods for Special Dietary Use (CCFSNDU) to harmonize regulations for dietary supplements.

While many organizations and individuals have expressed concerns about specific language in the proposed international guidelines and have urged the FDA to press for amendments, we have chosen to take a less compromising position: the FDA should not be at the table at all. Other countries may justifiably feel the need to establish guidelines, especially if they are without such guidelines now, and we respectfully acknowledge their desire to participate in the Codex process. The United States, however, already has the benefit of the Dietary Supplement Health and Education Act (DSHEA) and a very active Food and Drug Administration to regulate supplements and protect consumers. DSHEA clearly expresses both the will of the American public and the intent of Congress and, as such, we believe the United States does not need additional restrictions, especially those drafted by an international body that is insensitive to the specific wishes of the American public, and driven in large part by the interests of large, multinational pharmaceutical companies in countries that

classify supplements as drugs.

Language in the FDA Modernization Act of 1997 was written to expressly forbid the Food and Drug Administration from participating in the harmonization process for foods and dietary supplements. Conference report language and conversations with the authors of the language make this abundantly clear. The agency has chosen, however, to interpret this language to mean that it is not obligated to participate but it may, at its own discretion, decide to do so.[1] Notwithstanding the Kafka-esque machinations of agency employees, we believe the author of the language when he reiterates that it was the intent of Congress to create a specific statutory prohibition against the FDA participating in the Codex harmonization process for foods and dietary supplements.

Congress took this action because of concerns that the United States could be forced to harmonize its regulations with those of other countries. In the case of dietary supplements, Americans have access to a wide range of products, including high-potency vitamins and minerals, which could be threatened by efforts under Codex to mandate upper and lower limits, regulate many natural products as drugs, and eliminate the use of supplements for the treatment and prevention of disease.

We are aware of the FDA's stated position that "Nothing in the trade agreements or process will restrict either the sale of dietary supplements in the United States or the type of information that manufacturers may provide to consumers about their products." We are also aware that the agency believes that "The United States, by participating in the process, does not surrender to an international organization any of its sovereign authority to protect the health and safety of Americans." This is a disingenuous position for the agency to hold. First, it ignores the FDA Policy on Standards, which states: "The development of an international standard that achieves the agency's public objectives is generally, but not always, given a higher priority than the development of a domestic standard... Where a relevant international standard exists, or completion is imminent, it will generally be used in preference to a domestic standard..." In addition, the agency's "fear not" position ignores the fact that the United States has already, on several occasions, changed its laws to comply with World Trade Organization dictates. Some 40 complaints against the United States between January 1995 and May 2000 included challenges to our Clean Air Act regulations on gasoline; imports of underwear; safeguards on imported wool products, import prohibitions on shrimp; antidumping duties on semiconductors; tax treatment for foreign sales corporations, and countervailing duties on steel, among other things. In 9 out of 10 instances, the U.S. received adverse panel reports – this in spite of the exemption clause 19 USC 3512 (a)(1) in the General Agreements on Tariffs and Trade (GATT) Trade Agreement which appears to protect U.S. laws from harmonization. The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) and the Agreement on Technical Barriers to Trade (TBT) recognize the Codex

Alimentarius standards as appropriate recommendations against which countries' trade restrictions can be measured. The North American Free Trade Agreement (NAFTA) also exposes the United States to forced harmonization or risk trade sanctions. NAFTA has been used by multinational corporations on numerous occasions to force changes in federal and state laws.

Further complicating matters is the fact that we cannot trust the FDA to honestly and impartially defend the official U.S. position on dietary supplement regulation. In spited of repeated requests from Members of Congress, the agency representative to Codex has still failed to withdraw a position paper titled "A Risk Assessment Model for Establishing Upper Intake Levels for Vitamins" from its' submission to CCFSNDU. This paper does not represent an official U.S. position on the subject and its submission also violates the Administrative Procedures Act.

. The draft position prepared by the agency is highly flawed and also deviates from the Congressionally-established U.S. position on such issues as minimum and maximum amounts of vitamins and minerals in products; warnings about toxicity; specific nutrient needs of individuals; access to a balanced diet; and labeling requirements regarding the advice of nutritionists, dietitians or medical doctors. Many of the key points in this position paper are unsupportable and unscientific. For instance, it is widely accepted that most people do not have a balanced diet in the United States. Most Americans are significantly deficient in nutrients such as Vitamin D, C and B12. The draft position paper says, however, that "Some people need a vitamin-mineral supplement to meet specific nutrient needs." To propose this language denies reality and misses an opportunity to aid not only Americans, but also people in less developed countries who should know that they should take supplements. In any case, the flaws in the position paper are moot because the FDA should not even be participating in the Codex process.

By continuing to participate in the CCFSNDU work on Codex, the FDA is supporting international standards that could be used by other nations to claim that the FDA's current regulatory requirements are illegal trade barriers. By failing to withdraw from the proceedings, the FDA is facilitating a challenge by a foreign country before a dispute resolution panel of the WTO. By continuing to promote positions that run counter to official U.S. positions, the agency is helping to craft international standards that violate the intent of Congress. And, by continuing to participate in the proceedings, after specifically being prohibited by Congress from doing so, the agency is breaking the law.

In light of the above, AAHF submits that the FDA should withdraw the "Risk Assessment" paper from consideration and cease all CCFSNDU work on Codex.

[1] "Section 803(c) was added to the Federal Food Drug and Cosmetic Act by section 410(b) of the Food and Drug Administration Modernization Act of 1997, Public Law No. 105-115, 11 Stat 2296 (1007). Paragraphs (1) through (4) of section 803(c) impose an affirmative requirement on the agency to, among other things, regularly participate in meetings with foreign governments to discuss and reach agreement on approaches to harmonize regulatory requirements. Paragraph 5(c) of Section 803 negates that requirement with regard to dietary supplements saying, Paragraph (I) through (4) shall not apply with respect to [dietary supplements.]. Thus paragraph (c)(5) operates solely to release FDA from the affirmative obligation established by paragraph (c)(3) of participating in international harmonization efforts with regard to dietary supplements. It does not prohibit FDA from participating in those efforts," according to L. Robert Lake, Director, Office of Regulations and Policy, Center for Food Safety and Applied Nutrition, FDA, June 16, 2000.

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