

491

**Crane, Nancy T**

**From:** Virgili, Maureen [JJCUS] [MVIRGIL@CORUS.JNJ.com]  
**Sent:** Wednesday, August 14, 2002 2:27 PM  
**To:** Crane, Nancy T  
**Cc:** 'jham@iahf.com'  
**Subject:** Comment

02-022N  
02-022N-491  
Maureen E. Virgil

To: Beth Yetley, FDA c/o Nancy Crane, FDA

Re: Comment on FDA Draft Proposal to Codex CCFSDU on Dietary Supplements

Dear Dr. Yetley:

The FDA proposed language, item 5.9, is an obvious attempt to "medicalize" and restrict safe dietary supplements. By recommending that "All labels should bear a statement that a supplement should be taken on the advice of a nutritionist, a dietitian, or a medical doctor," the FDA is setting us up to "harmonize" with restrictive international standards and ignoring the fact that in America, supplements are classified as foods and consumers have the right to be educated on their benefits.

I, therefore, insist that you strike the above proposed revision in item 5.9 and replace it with the following language "we recommend the following revision 'All labels should bear scientific structure function health claims similar to those provided for under the American Dietary Supplement Health and Education Act of 1994 to directly assist consumers in making positive health decisions for themselves and their families at the point of sale.'" I demand the discontinuance of all attempts to create an international standard for vitamins and minerals at Codex, so that this matter may be left up to national authorities to decide.

Dr. Yetley, the FDA lost the Pearson court decision on First Amendment grounds and was forced to allow health claims on labels pertaining to folic acid and the prevention of neural tube defects. This is as it should be. Americans do not want to be restricted by international standards for vitamins and minerals, and we do not want you to continue trying to circumvent US law while you are in Germany representing the USA at Codex meetings. Please do not violate the spirit of DSHEA in an international forum.

We will not tolerate being subjected to anything similar to the EU's attempt to ban consumer access to dietary supplements (Pearson v Thomson, [www.emord.com](http://www.emord.com) <<http://www.emord.com>>).

Sincerely,

Maureen E. Virgili  
East Brunswick, NJ