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Robert Smiley

Dr.Yetley, the FDA should stop attempting to medicalize safe dietary supplements which are regulated in the USA as foods.

You have no legal mandate to attempt to go beyond the firm dictates of US law when you are at Codex meetings in Germany. FDA has lost on first amendment grounds in the Pearson decision, and when FDA refused to obey the court's decision, FDA was sued again and lost. FDA has no choice but to allow health claims to be put on labels pertaining to folic acid and the prevention of neural tube defects, and other similar matters.

This is as it should be, not only in the USA, but throughout the world. Consumers have a right to learn about the beneficial health properties of dietary supplements on the label, at the point of sale. By putting the above language on the label (that supplements should be taken on the advice of a nutritionist, dietician, or an M.D.), you are attempting to violate the spirit of DSHEA in an international forum, and you have no legal right to do that. You are attempting to waste valuable space on the label that can be put to better use directly informing consumers regarding the beneficial properties of these safe food substances, you are attempting to medicalize dietary supplements, and you are attempting to go through CODEX to make an end run around US domestic laws by attempting to set us up for harmonization to restrictive international standards.

I therefore must request that the above proposed revision in item 5.9 be replaced with the following language instead: "item 5.9 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 while reading the label on the product. The USA again reiterates its desire that all attempts to continue creating an international standard for vitamins and minerals cease at Codex and that this matter be left up to national authorities to decide."

Must I remind you that FDA lost the Pearson court decision, and when you attempted to ignore the judge, you were sued and lost again on this issue? Do not attempt to get around US law when you are in Germany representing the USA at Codex meetings. You have no legal right to make the statement in item 5.9, "All labels should bear a statement that a supplement should be taken on an advice of a nutritionist, a dietician, or a medical doctor."

I am copying this letter to you to my Senators and Congressmen and am asking them to oppose all efforts to erode US sovereignty via FTAA. The last thing we need in this hemisphere is the higher prices and reduced availability of supplements seen in some European countries. (See Pearson v Thomson http://www.emord.com.)

Sincerely,
Robert Smiley
[redacted]

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received
8/20/02

Dr. Elizabeth Yetley, FDA c/o Nancy Crane, FDA
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mment on FDA Draft Proposal to Codex CCNFSDU on Dietary Supplements

ear Dr.Yetley:

The FDA has proposed language (item 5.9) which states, "We recommend the following revision: 'All labels should bear a statement that a supplement *should be taken on an advice of a nutritionist, a dietician, or a medical* doctor.'"

Printed for robert smiley <rsmiley4@mindspring.com> **8/8/02**