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Crane, Nancy T

From:	William Winston [WEWinston@earthlink.net]
Sent:	Thursday, August 15, 2002 3:08 AM
To:	Crane, Nancy T
Cc:	jham@iahf.com; Bob Graham; Bill Nelson; John L Mica
Subject:	Comment on FDA Draft Proposal to Codex

02-022N
02-022N-508
Marie Winston

To: Beth Yetley, FDA c/o Nancy Crane : ncrane@cfsan.fda.gov, FDA

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

Dear Dr.Yetley:

Re FDA 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"

Dr.Yetley: When is the FDA going to STOP attempting to medicalize safe dietary supplements which are regulated in the USA as FOODS? We do not trust your current attack on melatonin, chromium picolinate, glucosamine, shark cartilage, or chaparral via the pharmaceutically dominated National Academy of Sciences so called "Safety Framework" and inform you now that if you think you are going to start banning any of these products based on these phony safety studies, you better think twice! We are calling on consumers to make comments to the NAS and to Congress about your ongoing attempts to hide behind the fact that NAS is not subject to the Freedom of Information Act so we can't get their raw data on these biased attacks: See NAS's "Framework for Evaluating the Safety of Dietary Supplements": http://www.nap.edu/catalog/10456.html?se_side

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 MD) 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 therefor INSIST that you STRIKE the above proposed revision in item 5.9 and replace it 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 is best left up to national authorities to decide."

Dr.Yetley: I remind you, and Congress, that you 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 INSIST that you replace that language with "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 is best left up to national authorities to decide."

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 a version of the EU dictatorship given the way the EU is attempting to ban consumer access to dietary supplements. See Pearson v Thomson http://www.emord.com Practice Areas- Also see Recent Complaints, because you are going to keep losing in court, and we will not tolerate your ongoing efforts to make an end run around US law by trying to set us up for harmonization to a grossly restrictive international standard.

Sincerely,

Marie Winston
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cc jham@iahf.com, Sen. Bob Graham, Sen. Bill Nelson, Rep. John Mica