



SEP 17 2002

Mr. Steve Snyder
President
21st Century Nutritional Products, Inc.
2119 South Wilson Street
Tempe, Arizona 85282-2034

Dear Mr. Snyder:

This is in response to your letter of August 29, 2002 to the Food and Drug Administration (FDA). Your letter is in response to our letter dated July 25, 2002 concerning your submission made pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)) for your products **Organic Flaxseed Oil** and **Omega 3**. In your letter, you asserted that the claim that we identified as a disease claim for **Organic Flaxseed Oil**, that is the claim "...omega-3 fatty acids may...help maintain normal cholesterol levels," is an appropriate structure or function claim. You also stated that you will modify the claim we identified for **Omega-3**, namely "...helps control cholesterol" will be changed to a claim like "Helps maintain normal cholesterol levels."

We disagree that the claims "...omega-3 fatty acids may...help maintain normal cholesterol levels" and "Helps maintain normal cholesterol levels" are structure or function claims. In the preamble to the January 6, 2000 final rule, FDA stated that health maintenance claims that do not imply disease treatment or prevention would be acceptable structure function claims. We added, however, that if the health maintenance claim used terms that are closely identified with a specific disease or that clearly referred to a particular at-risk population, such a claim would be an implied disease claim (see discussion at 65 FR 1018).

You stated in your letter that you believe that your claims are appropriate structure or function claims that do not imply disease treatment, prevention, or mitigation. We disagree. We believe that, because many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease, an unqualified claim that a product is intended to maintain normal (or healthy) blood cholesterol levels is an implied disease claim. As we discussed in the preamble to the final rule, the context in which a particular claim is made is important in determining whether a claim is a disease claim or a structure/function claim. Consequently, if the context of a claim about a product intended to affect blood cholesterol makes clear that the product is not intended to have an effect on abnormal blood cholesterol (for example, the claim "helps maintain

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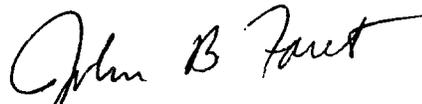
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cholesterol levels that are already within the normal range (emphasis added),” then such a claim may be an acceptable structure/function claim under 21 U.S.C. 343(r)(6). But, the claims that you submitted to us do not contain such context and therefore they differ materially from the claim in the preamble that we presented as an example of an appropriate structure or function claim. In contrast to the claim from the preamble (identified above), your claims imply that the products themselves will help bring about normal cholesterol levels, without reference to whether the affected cholesterol levels were initially within normal limits or not. Consequently, we are not persuaded that the position taken in our July 25, 2002 letter is incorrect, and we continue to believe that the cholesterol claims that you intend to make are disease claims that subjects your products to regulation as drugs.

Please contact us if we may be of further assistance.

Sincerely,



John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

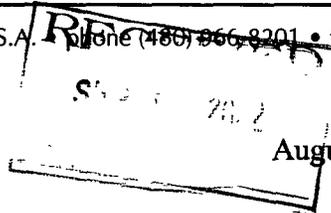
FDA, Los Angeles District Office, Compliance Branch, HFR-PA240

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Mr. John B. Foret
Director, Division of Compliance & Labeling
Office of Nutritional Products, Labeling, & Dietary Supplements
Center for Food Safety and Applied Nutrition

Dear Mr. Foret:

We have received your letter of July 25th in response to our submissions of statements of nutritional support for various of our products. In response to your particular objections we intend to take the following remedial actions:

Arthri-Flex The claim will be removed and labels will be reprinted before the next packaging.

Balanced Cholesterol The product has been discontinued.

Organic Flaxseed Oil You cite the claim "omega-3 fatty acids may...help maintain normal cholesterol levels." Further in the paragraph you state that "a cholesterol maintenance claim would have to clarify that the product is only for the maintenance of cholesterol levels that are already within the normal range." Since this is obviously the case with our claim, we do not understand your objection. We will therefore take no action without clarification from you.

Omega 3 We will modify the claim to something like "Helps maintain normal cholesterol levels."

Liquid Filled Calcium + D We will remove the claim and reprint labels before the next packaging.

Sincerely yours,

Steve Snyder
President