



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

OCT 29 2002

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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 October 18, 2002 to the Food and Drug Administration (FDA) responding to our September 17, 2002 letter concerning the claims being made for the products **Organic Flaxseed Oil** and **Omega 3**.

In your letter, you proposed to change the claims being made for each of your products to:
"Has been shown to maintain cholesterol levels which are within normal range."

The replacement of the claims cited in our previous letter with the claim listed above appears to resolve the issues we raised in that letter and we have no further comment on the claims you intend to make for these two products.

Please contact us if we may be of further assistance.

Sincerely yours,

for 

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, Office of Compliance, HFR-PA240

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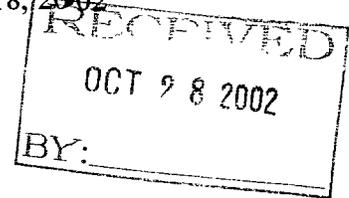
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21ST Century Nutritional Products, Inc.

2119 South Wilson Street, Tempe, Arizona 85282-2034, U.S.A. • phone (480) 966-8201 • fax (480) 927-9300



October 18, 2002



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 rebuttal letter of September 17th in response to our submissions of statements of nutritional support for our **Organic Flaxseed Oil** and **Omega-3** products. In response to your particular objections we intend to take the following remedial actions:

Organic Flaxseed Oil We will modify the claim to read to something like "Has been shown to maintain cholesterol levels which are within normal range".

Omega 3 We will modify the claim to read to something like "Has been shown to maintain cholesterol levels which are within normal range".

Please confirm that these actions will be acceptable in order to bring our claims into compliance.

Sincerely yours,


Steve Snyder
President

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