

1037 01 APR 13 P3:21

MAR 26 2001

Mr. Ira Goldberg
President
Horizon Nutraceuticals
P. O. Box 1806
Santa Cruz, California 9003543 17

Dear Mr. Goldberg:

This is in response to your letter of December 1, 2000 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Horizon Nutraceuticals, is making the following claim, among others, for the product **Flax Seed-Primrose Oil:**

“...helping to maintain blood pressure levels within a normal range...”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD3 10, 7520 Standish Place, Rockville, Maryland 20855.

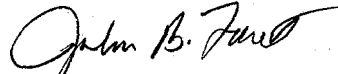
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Please contact us if you require further assistance.

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, Office of Compliance, HFR-PA240

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0 163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-8 11 (file)

HFD-40 (Behrman)

HFD-310

HFD-3 14 (Aronson)

HFS-605

HFV-228 (Benz)

GCF- 1 (Nickerson)

f/t:HFS-81 1:afp:03/20/01:docname:74368:disc1

Horizon Nutraceuticals
P.O. Box 1506
Santa Cruz, CA 95061

December 1, 2000

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 c St. SW.,
Washington, D.C. 20204

JAN - 8 2001

RE: Notification of Nutritional Support Statements

Dear Sir or Madam:

I hereby notify the Food and Drug Administration (FDA) of the use of statements of nutritional support in the labeling of **Flax Seed-Primrose Oil**, a dietary supplement. Horizon@ Nutraceuticals is the manufacturer of **Flax Seed-Primrose Oil**.

Statements being made in the labeling of Flax Seed-Primrose Oil:

- (1) Flax Seed-Primrose Oil EFA's act as precursors to prostaglandins, thromboxanes and leukotrienes, which help regulate cellular function.
- (2) They have been shown to play a role in helping to maintain blood pressure levels within a normal range, sustaining healthy skin and providing nutritional support during women's cycles.

To the best of my knowledge, and based upon information and belief present at the time of the execution of this notice, I certify that the above information is accurate and complete. Source Naturals possesses substantiation that the statements are truthful and not misleading.


Ira L. Goldberg
President, Horizon Nutraceuticals

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