



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

FEB 25 2000

17.32 '00 FEB 29 P2:11

Ms. Leslie Brenner Newman  
Marketing Manager  
Spectrum Essentials, Division of  
Spectrum Organic Products, Inc.  
1304 South Point Blvd., #280  
Petaluma, California 94954

Dear Ms. Newman:

This is in response to your letter of February 19, 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 Spectrum Essentials, Division of Spectrum Organic Products, Inc. is making the following claim, among others, for the product **Spectrum Essentials daily Essential Fiber™**:

“Use of dietary fiber on a daily basis can help maintain healthy cholesterol, normal blood sugar, reduce risk of colon cancer, relieve constipation and hemorrhoids.”

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 various diseases. 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, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

LET 337

Page 2 - Ms. Leslie Brenner Newman

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, San Francisco District Office, Office of Compliance, HFR-PA140

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (file)

HFS-450 (r/f, file)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-605

HFV-228 (Benz)

GCF-1 (Dorsey, Barnett, Nickerson)

f/t:HFS-456:rjm:2/24/00:docname:69373.adv:disc45

1304 SOUTHPOINT BLVD., STE. 280  
PETALUMA, CA 94954 USA

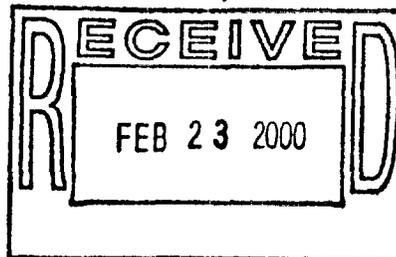
**Spectrum**  
ESSENTIALS®

TEL 707 778 8900  
FAX 707 765 8470



February 19, 20000

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food & Drug Administration  
200 C Street SW  
Washington DC 20204



### Notification for Certain Types of Statements on Dietary Supplements

This serves as notification that:

Spectrum Essentials, a division  
Of Spectrum Organic Products, Inc.  
1304 South Point Blvd.#280  
Petaluma, CA 94954

Markets dietary supplement products with the following statements:

**Statement:** Use of dietary fiber on a daily basis can help maintain healthy cholesterol, normal blood sugar, reduce risk of colon cancer, relieve constipation and hemorrhoids.

**Ingredient:** Fiber product made with partially defatted flaxseed meal and herbs

**Brand name:** Spectrum Essentials Daily Essential Fiber™

I certify that the information contained in this notice is complete and accurate, and that the above named company has substantiated that the statements are truthful and not misleading.

Sincerely,

A handwritten signature in cursive script that reads "Leslie Brenner Newman".

Leslie Brenner Newman  
Marketing Manager

The typical American diet does not supply enough fiber due to excessive consumption of processed and refined foods. Use of dietary fiber on a daily basis can help maintain healthy cholesterol, normal blood sugar, reduce risk of colon cancer, relieve constipation, hemorrhoids.\* Spectrum Essentials Daily Essential Fiber™ is a unique daily fiber formula with a combination of flaxseed meal, soothing and supportive herbs, essential amino acids and probiotics to encourage proper digestion and regular waste elimination. Daily Essential Fiber does not contain psyllium that can cause bloating, swelling and discomfort.

\*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent disease.

Suggested Use: Practitioners recommend taking 5 capsules on an empty stomach twice a day. For best results, drink plenty of water throughout the day.

Third party certified, inspected by Quality Assurance International, Inc. Spectrum Organic Flax Meal is organically grown and processed in accordance with the California Organic Foods Act of 1990.



MADE WITH

Spectrum ESSENTIALS

ORGANIC FLAX

DAILY

ESSENTIAL FIBER™

DIETARY SUPPLEMENT

300 VEGETARIAN CAPSULES  
750 MG EACH

Psyllium FREE

**Supplement Facts**

| Serving Size: 10 Capsules (2 grams)      |                | Amount Per Serving |  | % Daily Value* |
|--|----------------|--------------------|--|----------------|
| Servings per Container: 30               |                |                    |  |                |
| Amount Per Serving                       | % Daily Value* |                    |  |                |
| Calories from Fat 5                      | 1%             |                    |  |                |
| Saturated Fat 0g                         | 0%             |                    |  |                |
| Cholesterol 0mg                          | 0%             |                    |  |                |
| Sodium 0mg                               | 0%             |                    |  |                |
| Total Fat 1g                             | 2%             |                    |  |                |
| Total Carbohydrate 1g                    | 2%             |                    |  |                |
| Dietary Fiber 2g                         | 4%             |                    |  |                |
| Sugar 0g                                 | 0%             |                    |  |                |
| Ferrous Bisulfate 50mg                   | **             |                    |  |                |
| Bentonite Clay 100mg                     | **             |                    |  |                |
| Lactobacillus acidophilus Culture 100mg  | **             |                    |  |                |
| Acacia Root Powder 100mg                 | **             |                    |  |                |
| Marshmallow Root Powder 100mg            | **             |                    |  |                |
| L-Lysine 100mg                           | **             |                    |  |                |
| L-Theanine 100mg                         | **             |                    |  |                |
| Superglucosamine 100mg                   | **             |                    |  |                |
| Yellow Dock Powder 100mg                 | **             |                    |  |                |
| Vitamin E (as mixed tocopherols) 10mg 5% | **             |                    |  |                |

\*Daily values are based on a diet of 2,000 calories.  
\*\*Other Ingredients: Organic Flaxseed Meal, Capsule Material, Hydroxyethyl Cellulose, Water.  
Spectrum Organic Products, Inc.  
Spectrum Essentials  
Petaluma, CA 94954  
800.998.2705  
www.spectrumnutraceuticals.com  
PLEASE RECYCLE THE CONTAINER

- 7200 mg omega-3 per serving
- Marshmallow Root to ease digestion
- Fructooligosaccharides to nourish friendly intestinal flora
- Bentonite clay to absorb excess water and toxins while easing constipation and diarrhea
- Lactobacillus Acidophilus to provide important probiotic support for healthy gastrointestinal function
- Licorice Root to stimulate the production of digestive fluids
- Amino acids, L-lysine and L-methionine to support cellular integrity and tissue density
- Slippery Elm bark to reduce intestinal inflammation

**REFRIGERATION RECOMMENDED AFTER OPENING**

**Supplement Facts**

Serving Size: 1 Scoop (6g)  
Servings per Container: 30

| Amount Per Serving                       | % Daily Value* |
|--|----------------|
| Calories from Fat 5                      | 1%             |
| Saturated Fat 0g                         | 0%             |
| Cholesterol 0mg                          | 0%             |
| Sodium 0mg                               | 0%             |
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\*\*Other Ingredients: Organic Flaxseed Meal, Guar Gum.

- 14gm 4th organic flaxseed
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  - Marshmallow Root to ease digestion
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\*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent disease.

Suggested Use: Practitioners recommend 1 scoop mixed with 8 oz. of water or juice in the morning on an empty stomach. Taking this product without enough water could be a potential choking hazard. For best results, drink plenty of water throughout the day.

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