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DEC 10 2002

Mr. John A. Senneff
Scientific Director
Neuro Help
P.O. Box 690145
San Antonio, Texas 78269

Dear Mr. Senneff:

This is in response to your letter of November 26, 2002 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 Neuro Help is making the following claim, among others, for the product PNER Plus™:

“...reduce neuropathic pain.”

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 disease (i.e., peripheral neuropathy). Moreover, the name of the product (i.e., PNER Plus™) itself is an implied disease claim. The acronym “PN” is widely used as an acronym for “peripheral neuropathy” and “PNER” is also widely used as an acronym for a person with this disease. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest 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.

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Please contact us if we may be of further assistance.

Sincerely yours,



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, Dallas District Office, Office of Compliance, HFR-SW140

Neuro Help

Products For PNeers

November 26, 2002

Office of Nutritional Products
Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. SW
Washington, DC 20204

DEC 03 2002

Dear Sir/Madam:

Notice is hereby given pursuant to section 403 (r) (6) of the Federal Food, Drug, and Cosmetic Act, and in accordance with the requirements of 21CFR101.93, that NeuroHelp has within the last 30 days commenced marketing a dietary supplement with the following label claim:

"The nutrient supplements in the PNeer Plus™ formulation, when taken over an appropriate period, can often help support nerve function and reduce neuropathic pain."

The following disclaimer is made in connection with the claim and product:

"Information and statements regarding the PNeer Plus™ formulation have not been evaluated by the Food and Drug Administration and the formulation is not intended to diagnose, treat, cure, or prevent any disease. If you have any doubt as to the appropriateness of this formulation for you, it is suggested you consult with a qualified medical adviser."

The formulation, which is manufactured for NeuroHelp by Essentially Pure Ingredients, a division of Natrol, Inc., 21411 Prairie Street, Chatsworth, CA 91311, contains the following ingredients in the indicated daily serving strengths:

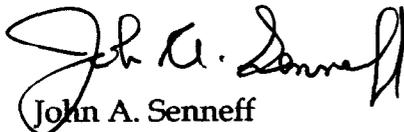
1. Vitamin B 50 complex providing a combination of all the B vitamins in 50 mg strengths (except B12, which is set forth below, and folic acid 400 mcg)
2. 200 mg additional B1
3. 1000 mcg (1 mg) B12 in the form of sublingual methylcobalamin.
4. 1000 mg (1 g) of vitamin C as calcium ascorbate with flavenoids added.
5. 400 IU of vitamin E in the natural d-alpha tocopherol form.
6. 200 mg of magnesium chelate.

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7. 50 mg of zinc picolinate with supplemental copper.
8. 600 mg of alpha-lipoic acid or ALA.
9. 4000 mg (4 g) of evening primrose oil.
10. 4000 mg (4 g) of fish oil.
11. 1000 mg of acetyl L-carnitine or ALC

I hereby certify that that the information presented above is complete and accurate and that NeuroHelp has substantiation that the above statements are truthful and not misleading.

Sincerely,


John A. Senneff
Scientific Director