

May 22, 2003

## 2901 03 JUN-6 P2:24

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

Dear Sir/Madam:

We previously had correspondence with Mr. John B. Foret, Director, Division of Compliance, with respect to a dietary supplement we had begun, or were planning, to market under the name, PNer Plus<sup>™</sup>. We were adopting the claim that this product could "reduce neuropathic pain." Mr. Foret suggested both the name and claim would be determined to be disease claims subject to regulation. We agreed, and are changing the name of the product to NeuroHelp Premium. We also have deleted the reference to reduction of neuropathic pain.

The claim that we now will be making under section 403 (r) (6) of the Federal Food,  $\neg$  Drug, and Cosmetic Act, and in accordance with the requirements of 21CFR101.93, is that:

"The nutrient supplements in the NeuroHelp Premium<sup>TM</sup> formulation, when taken over an appropriate period, can often help support nerve function and reduce neural discomfort."

The following disclaimer is made in connection with the claim:

"Information and statements regarding the NeuroHelp Premium<sup>™</sup> 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 based, for example, on medications you are taking such as blood thinning drugs, 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., contains the following ingredients:

- 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. 975 0162 LET 12054

P.O Box 690145 • San Antonio, TX 78269 • Ph: 210-699-9007 • Fax: 210-641+6334

84576

www.neurohelp.com



- 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.
- 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

Also, a formulation containing the above ingredients except for the last three items will be marketed under the name NeuroHelp Basic [or NeuroHelp Essential] with the same claim indicated above.

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

Sincerely, 2 a. Senneff

John/A. Senneff Scientific Director