DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

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JAN 14 2003

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 December 18, 2002 to the Food and Drug Administration (FDA). Your letter is in response to our letter dated December 10, 2002 concerning your submission made pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)) for your product **PNer Plus™** In your letter, you asserted that the claims that we identified as disease claims for **PNer Plus™**, that is, the claims "...reduce neuropathic pain" and the acronym "PNer" are appropriate structure or function claims.

In your letter, you assert that a claim that a product may reduce a symptom of a disease, such as pain, "does not at all suggest that it treats, etc., a disease." While you concede that the acronym "PNer" can refer to people with peripheral neuropathy, you assert that the use of that designation does not imply that the product treats a disease, but rather it merely targets a class of people who might derive symptomatic benefit from its use. Finally, you assert that peripheral neuropathy is "really a nerve disorder rather than a disease. We disagree with your conclusion that the claim "reduce neuropathic pain" and the acronym "PNer" are not implied disease claims.

In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1012-1015[1]), FDA discussed the agency's conclusion that implied disease claims are in fact disease claims under section 201(g)(1)(B) of the Act that subject a product to regulation as a drug. Moreover, in that same document, FDA explained that pain claims are implied disease claims because they represent that the product will have an affect on a characteristic sign or symptom of a disease (see 21 CFR 101.93(g)(2)(ii)). In the preamble to the final rule (see 65 FR 1000 at 1030)

[1]A copy of the January 6, 2000 final rule can be obtained from FDA's website at http://www.cfsan.fda.gov/~dms/ds-ind.html.

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FDA discussed the circumstances under which claims about pain would imply disease treatment. We stated that since pain is not a normal state, nor are there "normal pain levels," a claim about pain treatment or prevention is ordinarily a disease claim. Although we added, however, that a acceptable structure/function claim could be made for pain associated with non-disease states, such as muscle pain following exercise, the claim contained in your notification does not refer to pain associated with a non-disease state.

You asserted in your letter that peripheral neuropathies are disorders rather than diseases. We disagree. Peripheral neuropathies are diseases squarely within the scope of the term "disease" defined in the agency's regulations (21 CFR 101.93(g)(1)). A peripheral neuropathy is a condition that exists because of "damage to an organ, part, structure, or system of the body such that it does not function properly."

For these reasons, we are not persuaded that the conclusion expressed in our December 10, 2002 letter is incorrect and we stand by our original determination that the claims for your product are disease claims that subject your product to regulation under the drug provisions of the Act.

You also conclude that a claim that simply identifies a patient population that would benefit from using a product is not an implied disease claim. We disagree that such a claim is not a disease claim in the instant matter. As you state in your letter, the statements you are making are intended to identify "a class of people who might derive symptomatic benefit from its use." The claims clearly, therefore, evidence that the product is intended to treat or mitigate a disease and is, therefore, a drug under the Act.

Finally, in your letter you appear to advance the position that the statements you make for your product are appropriate because you include the disclaimer statement required by 21 U.S.C. 343(r)(6). In the preamble to the final rule on structure/function claims, we explained why the use of the required disclaimer does not demonstrate an intention of the Act to permit implied disease claims (see 65 FR 1000 at 1014). Therefore, the use of the disclaimer does not create a safe harbor for the use of disease claims in the labeling of a dietary supplement. A disease claim (other than an authorized health claim) subjects a product to regulation under the drug provisions of the Act, regardless of the fact that the product may be labeled as a dietary supplement and/or may contain a perfunctory disclaimer that the product is not a "drug" or intended for use as a drug. Moreover, the fact that other firms may be marketing products in violation of the Act does not provide a basis for you to also market a violative product. You are responsible for ensuring that your products comply with the Act and its implementing regulations and products that violate the Act may be subject to enforcement action by FDA.

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

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Log to Bob Moore

Neuro Help

Products For PNers

December 18, 2002

John B. Foret
Director, Division of Compliance
Office of Nutritional Products
Center for Food Safety and Applied Nutrition
Food and Drug Administration
College Park, MD 20740

Dear Mr. Foret:

I have your letter dated December 10, 2002, where you question the claim made for our product, PNer Plus™, that it can "reduce neuropathic pain," as presented in our filing dated November 26, 2002. You refer to 21 U.S.C. 343(r) (6), which provides that one may not claim that a product labeled thereunder "diagnoses, mitigates, treats, cures, or prevents a specific disease or class of diseases."

I submit that the claim a product may reduce a symptom such as pain does not at all suggest that it treats, etc., a disease. There are many claims being made today, for example, for various nutrient supplement products concerning the relief or reduction of pain- e.g., arthritic pain, fibromyalgia pain, even cancer pain. Our labeling, in fact, explicitly states that our "formulation is not intended to diagnose, treat, cure, or prevent any disease."

On your other point, it is true that the acronym "PNer" can refer to people with peripheral neuropathy. Again the use of that designation does not imply that the product treats, etc., the "disease" (peripheral neuropathy is really a nerve disorder rather than a disease.) It merely targets a class of people who might derive symptomatic benefit from its use.[1] Again I would point out our disclaimer specifically negates any suggestion that it is meant to achieve anything more.

If there is anything further you require, kindly let me know.

Sincerely,

John Senneff

[1] There perhaps would be more of a question if our product bore the name of PN Plus rather than PNer Plus, as it would then point more directly to peripheral neuropathy rather than a class of people (PNers) who have it. Even then I note that there are supplement products on the market such as FM Relief (FM being an even more well-understood acronym for a disease condition) which seem to point directly to a disease.

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