



MAR 12 2002

6383 '02 MAR 26 P2:20

Mr. John Hamlin  
Regulatory Affairs Manager  
Beutlich Pharmaceuticals  
1541 Watkins Drive  
Waukegan, Illinois 60085

Dear Mr. Hamlin:

This is in response to your letter of February 14, 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 Beutlich Pharmaceuticals is making the following claim, among others, for the product Peridin-C:

“Assists in wound healing.”

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, cure or mitigate a 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, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of 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

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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, Chicago District Office, Office of Compliance, HFR-MW140

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February 14, 2002

Office of Special Nutrition &  
Center for Food Safety & Applied Nutrition  
Food and Drug Administration  
200 C Street SW  
Washington, DC 20204

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BY: \_\_\_\_\_

Dear Sir or Madam:

In accordance with the requirements of 21 I.S.C. 343 (r) (6) section 403 (r) (6) of the Federal Food, Drug and Cosmetic Act, Beutlich L.P. hereby notifies the FDA that it has begun using the following statements on our dietary supplement Peridin-C: (These statements contain the statutory disclaimer.)

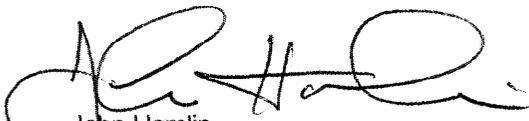
- 1) For Hot Flashes
- 2) Alleviates 'Hot Flashes' associated with menopause.
- 3) Improves capillary strength
- 4) Assists in wound healing

Peridin-C is a dietary supplement. Each tablet contains:

- Ascorbic Acid (Vitamin C).....200mg
- Hesperidin Complex (Bioflavonoids).....150mg
- Hesperidin Methyl Chalcone (Bioflavonoid).....50mg

We, as developer and distributor of the above mentioned product, affirm to the best of our knowledge that we have substantiation that the structure/function statements contained herein are truthful, not misleading, and that the product does not present a significant risk or unreasonable risk of illness or injury under the conditions of use recommended or suggested in the label or labeling.

Sincerely,

  
John Hamlin  
Regulatory Affairs Manager