

HFI-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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P.S.
2/19/8

T1395M

CFN: 1125255
98-8CT-30

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4040

January 15, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Sharon Higginbotham, Owner
Practical Health
3818-A Rivanna River Reach
Portsmouth, Virginia 23703

Dear Ms. Higginbotham:

This letter is in reference to your firm's marketing and distribution of "Pycnogenol®." The promotional literature for the product makes serious disease claims, including:

- "... new, safe to use, non-drug, nutritional breakthrough methods of relief for as many as 60 degenerative health conditions ...";
- "...Pycnogenol® can help protect you from approximately *eighty* diseases, including: heart disease, cancer, arthritis, and most non-germ diseases ...";
- "...Pycnogenol® is unique because it also alleviates hay fever and other allergies ...";
- "... Health benefits of Pycnogenol® ... reduces risk of: heart disease, cancer ... arthritis ... more than 70 other radical-related diseases ... Reduces varicose veins ... Treats chronic venous insufficiency, Reduces the risk of phlebitis ... Effective against psoriasis, Protects against sun damage ... Fights inflammation ... Diabetes, Reduces diabetic retinopathy ... acts against stomach ulcers..."

We regard the promotional literature as labeling, since it makes therapeutic claims for this product. Because the product is labeled with the above statements which represent and suggest that it is intended to be used in the cure, mitigation, treatment, or prevention of diseases, it is a drug as defined in Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). Further, we are unaware of any substantial scientific evidence which demonstrates that this drug is generally recognized as safe and effective for the aforementioned conditions. This product is also considered a "new drug" within the meaning of Section 201(p) of the Act and, therefore,

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may not be marketed in the United States without an approved new drug application pursuant to Section 505(b) of the Act.

The drug is misbranded within the meaning of Section 502(a) of the Act, in that its labeling is false and misleading because it represents and suggests that there is substantial scientific evidence to establish that the drug is safe and effective for its intended uses when, in fact, such evidence does not exist.

It is further misbranded within the meaning of Section 502(f)(1) of the Act, because the labeling fails to bear adequate directions for the uses for which it is being offered. It is not exempt from this requirement under Title 21, Code of Federal Regulations, Part 201.115, since the article is a new drug and no approval of a new drug application filed pursuant to Section 505(b) is effective for this drug.

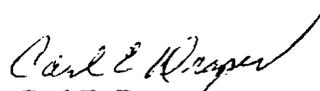
This letter is not intended to be an all-inclusive review of all labeling and products marketed by your firm. It is your responsibility to ensure that all such products are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to do so may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of such products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations. You should include an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to the Food and Drug Administration, Richmond Resident Post, 10710 Midlothian Turnpike, Suite 424, Richmond, Virginia 23235, to the attention of Scott J. MacIntire, Compliance Officer. Mr. MacIntire can be reached at (804) 379-1627, Ext. 14.

Sincerely,



Carl E. Draper

Acting Director, Baltimore District