



DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

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WARNING LETTER

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

HAND DELIVERED

98-PHI-03

November 5, 1997

Mr. Brian Haveson
President
HPF L.L.C.
1210 Northbrook Drive, Suite 420
Trevose, PA 19053

Dear Mr. Haveson:

This letter is written in reference to your firm's marketing and distribution of Herbal Phen-Fen and Herbal Phen-Fen Stage 2. Your products are labeled as alternatives to the combination of the prescription drugs, fenfluramine and phentermine, which is commonly known as "Fen-Phen". These prescription drugs are intended to treat obesity. Labeling your products as alternatives to Fen-Phen (fenfluramine and phentermine), represents them as intended for the same uses as phentermine and fenfluramine. Thus, you are representing Herbal Phen-Fen and Herbal Phen-Fen Stage 2 as treatments for obesity. In this regard, Herbal Phen-Fen and Herbal Phen-Fen Stage 2 are drugs as defined in Section 201(g)(1)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

Herbal Phen-Fen and Herbal Phen-Fen Stage 2 are "new drugs" under Section 201(p) of the Act based on: 1) the trade names, Herbal Phen-Fen and Herbal Phen-Fen Stage 2, and 2) the lack of any evidence that these products are generally recognized as safe and effective for the treatment of obesity.

Since these drugs are "new drugs," they may not be legally marketed in the United States without approved new drug applications (Section 505(a) of the Act).

Herbal Phen-Fen and Herbal Phen-Fen Stage 2 are also misbranded because their labeling fails to bear adequate directions for use (Section 502(f)(1) of the Act) and the labeling is false and misleading since it suggests that the products are recognized as safe and effective for the intended use (Section 502(a) of the Act) and this is not the case. Labeling is not limited to the immediate product containers but includes all promotional literature which you distribute in connection with your products.

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F# _____	DATE 11-6-97
Reviewed by: <u>Ann D. DeMarco, C.O.</u>	

Page 2
November 5, 1997
Brian Haveson

In addition, brochures for both Herbal Phen-Fen and Herbal Phen-Fen Stage 2 include the statement "DOES NOT CONTAIN PHENTERMINE OR FENFLURAMINE". This statement does not negate the drug claim made for these products and instead provides further evidence that these products are intended for the same use as the prescription drugs.

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

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal 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, including 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, Philadelphia District Office, Attention: Ann deMarco, Compliance Officer.

Sincerely,


Diana J. Kolaitis
District Director
Philadelphia District