



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

d15596 → HFI-35

4/10/98

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (714) 798-7600

February 10, 1998
W/L 18-8

WARNING LETTER

Mr. Simon Chalpin, President
Hi-Health Supermart Corp.
15021 West 74th Street
Scottsdale, AZ 85260

Dear Mr. Chalpin:

This letter is written in reference to your firm's marketing and distribution of "Supreme Herbal Alternative to Fen-Phen" which consists of two separately packaged ingredients, "Herbal Alternative, Thermogenics, (Step 1)" and "Herbal Alternative St. John's Wort (Step 2)." Your product is labeled as an alternative 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 product as an alternative to Fen-Phen (fenfluramine and phentermine), represents it as intended for the same uses as phentermine and fenfluramine. Thus, you are representing Supreme Herbal Alternative to Fen-Phen as a treatment for obesity. In this regard, Supreme Herbal Alternative to Fen-Phen is a drug as defined in Section 201(g)(1)(B) of the Federal Food, Drug and Cosmetic Act (the Act). Labeling is not limited to the immediate product containers but includes all promotional literature which you distribute in connection with your products. Supreme Herbal Alternative to Fen-Phen is also a "new drug" under Section 201(p) of the Act based on: 1) the trade name, Supreme Herbal Alternative to Fen-Phen 2) the lack of any evidence that this product is generally recognized as safe and effective for the treatment of obesity. Since this drug is a "new drug," it may not be legally marketed in the United States without an approved new drug application (Section 505(a) of the Act).

Also, Supreme Herbal Alternative to Fen-Phen is misbranded because its labeling fails to bear adequate directions for use (Section 502(f)(1) of the Act) and further the labeling is false and misleading since it suggests that the product is recognized as safe and effective for the intended use (Section 502(a) of the Act) and this is not the case. Intended use of your product is also demonstrated by an advertisement in the October 16, 1997, issue of the Arizona Republic which states "If you have been using Fen-Phen... now there is an option. The benefits without the side effects!"

In addition, we are aware of promotional material (labeling) included in Hi-Health's Internet website which promotes your Firm's St. John's Wort product as an alternative to Prozac and your Glucosamine product as a treatment for Arthritis. These statements represent disease treatment claims and may cause these products to be "new drugs" and to be misbranded.

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 addressed to:

John A. Nicholson, Consumer Safety Officer
U.S. Food and Drug Administration
Phoenix Resident Post
4615 East Elwood Street, #200
Phoenix, AZ 85040

Sincerely,



Elaine C. Messa, District Director
Los Angeles District Office