



DEPARTMENT OF HEALTH AND HUMAN SERVICES

M 2059N
Food and Drug Administration
Nashville District Office

297 Plus Park Boulevard
Nashville, TN 37217

September 11, 1998

CERTIFIED - RETURN RECEIPT REQUESTED

Charles T. Stokes
President/Chief Executive Officer
Power Source Distributors, Inc.
dba USA Laboratories, Inc.
1438 Highway 96
Burns, TN 37029

WARNING LETTER - 98-NSV-20

Dear Mr. Stokes:

This letter is written in reference to your firm's marketing and distribution of Herbal Phen-Thin, Herbal Phen-Thin II, Herbal Valum, Herbal PRO-S.A.C., Herbal Asprin, and Shark Cartilage II. These products are labeled with names that imply drug claims or make other therapeutic claims in their labeling.

Herbal Phen-Thin and Herbal Phen-Thin II are offered for weight loss as an alternative to the drug, Phentermine, which is commonly known as "Phen" in the combination "Fen-Phen." Phentermine is a prescription drug intended to treat obesity. Labeling your products as alternatives to Phentermine represents claims that your products are intended for the same use as Phentermine. Thus, you are representing Herbal Phen-Thin and Herbal Phen-Thin II as treatments for obesity. Herbal Valum is offered as an alternative to the prescription anti-anxiety drug, Valium, and therefore, is offered as treatment for anxiety. Herbal PRO-S.A.C. is offered as an alternative to the prescription antidepressant drug Prozac, and therefore, is offered as treatment for depression. Herbal Asprin is represented as an alternative to aspirin and for reducing pain and fever. Shark Cartilage II is represented as an anti-inflammatory.

These products are drugs as defined in Section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) and "new drugs" [section 201(p)] based on:

The trade names Herbal Phen-Thin, Herbal Phen-Thin II, Herbal Valum, Herbal PRO-S.A.C., and Herbal Asprin.

Statements on the immediate product labels that Shark Cartilage II has "excellent recovery, anti-inflammatory and muscle tissue repair properties" and that Herbal Asprin is a "Pain Reliever/Fever Reducer."

Statements in the USA Laboratories catalog that Shark Cartilage II has "Inflammation Reducing Herbs," and the description of Herbal PRO-S.A.C. as an "Antidepressant Alternative to Pro-Zac."

Since they are new drugs they may not be legally marketed in this country without approved New Drug Applications [section 505(a) of the Act].

These drugs are also misbranded because their labeling fails to bear adequate directions for the conditions for which they are offered [section 502(f)(1) of the Act] and their labeling is false and misleading. The labeling suggests that these products are safe and effective for their intended uses, when in fact, this has not been established [section 502(a) of the Act].

Herbal Aspirin is also misbranded because its labeling suggests that this product is equivalent to the drug aspirin, when in fact, this has not been established [section 502(a) of the Act].

In addition, we are aware that the USA Sports Labs, Inc. Internet web site promotes shark cartilage as "treatment for arthritis, joint inflammation, and cancer prevention." It also promotes Cat's Claw for treatment of "Arthritis, and gastrointestinal disorders," and CO Q10 to "reduce risk of heart attacks."

Further, under USA Best™ your catalog lists, St. John's Wort as a "Safe and Effective Alternative to Many Prescription Antidepressants" and "Glucosamine Plus for Arthritis." Your catalog also states that Shark Cartilage is intended for "Recovery and Inflammation of Joints."

We have been advised that during FDA's inspection of July 1998, you indicated that your firm was willing to bring your products into compliance once you received official notification that the products were misbranded. We look forward to your corrective actions which may be included in your response to this letter.

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

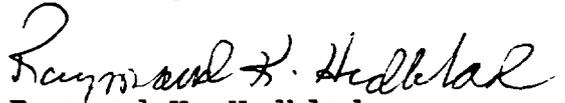
We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug and Cosmetic Act provides for the seizure of illegal products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

Charles T. Stokes - Page 3

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 fifteen (15) working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be directed to the attention of, Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, TN 37217.

Sincerely,


Raymond K. Hedblad
Director, Nashville District

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