



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

PHILADELPHIA DISTRICT

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

Telephone: 215-597-4390

WARNING LETTER

April 21, 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Christopher D. Cox, Co-Owner and Vice President of Sales
Performance Health, Inc.
1017 Boyd Road
Export, PA 15636

Dear Mr. Cox:

This letter follows the February 3, 1999 inspection of your firm conducted by Investigator Cynthia L. Rakestraw of the Food and Drug Administration's Philadelphia District Office and is in reference to the manufacture, promotion, marketing, and distribution of BIOFREEZE[®] with ILEX by your firm. During this inspection, Investigator Rakestraw collected copies of product labels and promotional material (labeling) distributed with your product.

BIOFREEZE[®] with ILEX is labeled to contain as active ingredients menthol 3.5% and camphor 0.2%. Although "herbal extract (ILEX Paraguariensis)" is listed as an inactive ingredient, it is featured prominently in the labeling and is intended to furnish pharmacological activity and to have a direct effect on the body of man. Consequently, "herbal extract (ILEX Paraguariensis)" is an active ingredient per *Title 21 Code of Federal Regulations* (21 CFR) § 210.3(b)(7). This product is labeled for post rotator cuff operations, to treated pulled hamstrings, tendonitis, and bursitis, and to decrease edema and myospasm, among others.

Based on the intended uses cited above, this product is a drug as described in Section 201(g) of the Federal Food, Drug, and Cosmetic (FD&C) Act. We do not have any information which shows that your product, or similarly labeled and formulated over-the counter (OTC) drug products, were marketed in the United States prior to December 4, 1975. We do not know of any substantial scientific evidence that demonstrates that your product is generally recognized as safe and effective for its intended uses.

Further, this product is a new drug as described in Section 201(p) of the FD&C Act which may not be legally marketed in this country without an approved new drug application (see Section 505(a) of the FD&C Act). This product is also misbranded under Section 502(f)(1) of the FD&C Act in that its labeling fails to bear adequate directions for use.

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Christopher D. Cox

The above list of violations is not intended to be an all-inclusive list of deficiencies at your firm. It is your responsibility to ensure that all your drug products are in compliance with federal law and regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations and to prevent future violations may result in regulatory action without further notice. Such actions may include seizure and/or injunction.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific actions you plan to take to correct these violations. Your response should also include an explanation of each step being taken to prevent recurrence of similar violations. If corrections cannot be completed within 15 working days, please state the reason for the delay and the time within which corrections will be completed.

Your reply should be addressed to Karyn M. Campbell, Compliance Officer, at the address noted on the letterhead.

Sincerely,



Thomas D. Gardine
District Director
Philadelphia District Office

cc: Robert E. Bastian, Director
Division of Primary Care and Home Health Services
PA Department of Health
132 Kline Plaza, Suite A
Harrisburg, PA 17104