



August 20, 1998

Food and Drug Administration
Cincinnati District Office
Central Region -
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2771

**WARNING LETTER
CIN-WL-98-295**

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

Elaine H. Parrish, President
EHP Products, Inc.
8 Kenton Furnace Drive
P.O. Box 1306
Ashland, KY 41105-1306

Dear Mrs. Parrish:

This letter is in reference to your firm's marketing and distribution of the products Myristin Capsules, Myrist-Aid Capsules and Myristin-TF Topical Lotion. Claims made in the labeling for these products cause them to be drugs [section 201(g) of the Federal Food, Drug and Cosmetics Act (the Act)].

Labeling claims in the brochure titled "Cetyl Myristoleate. Nature's Answer to Arthritis" by Dr. Charles L. Cochran; Cetyl Myristoleate include:

- "Mr. Diehl's many years of intensive research resulted in isolation of a nutrient that truly may be nature's answer to arthritis."
- "After using it his arthritis was totally gone!"
- "Now Cetyl Myristoleate has been in tens of thousands of patients with astounding results in the relief of arthritis."
- "In fact, there is one M.D. who wrote that it would be of benefit in treating anything from rheumatoid arthritis and diabetes to migraine headaches and schizophrenia. I also heard claims that arthritis sufferers had complete remission of symptoms after completing only one month of treatment".
- "But I can tell you this: Cetyl Myristoleate without any complementary nutrients has proven to be at least 70% effective in treating the various forms of arthritis."
- "By using the topical lotion of Cetyl Myristoleate and adding a few complementary nutrients like glucosamine sulfate and methylsulfonylmethane, I believe the effectiveness can be increased by another 15% or so."
- "As effective as cetyl myristoleate is in reversing arthritic conditions, I expect it to have equally far reaching effects in treating many chronic inflammatory conditions."
- "Mr. Diehl stated in his patent and article, that the real potential of this product lies in its ability to prevent arthritis. Now those individuals who are generally predisposed to developing arthritis or those who may develop arthritis after experiencing joint trauma, for example, may be able to turn around this whole inflammatory process."

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These products are "new drugs" (Section 201(p) of the Act) because they are not generally recognized as safe and effective for the claimed conditions and they have not been approved for these purposes (Section 505(a) of the Act).

These drugs are also misbranded [Section 502 (f)(1) of the Act] because the labeling fails to bear adequate directions for use. The labeling is false and misleading because it suggests that the products are safe and effective for their intended uses when this has not been established [Section 502(a) of the Act].

We are also aware of additional printed material, and your Internet pages that include unsubstantiated claims and testimonials for your products for the prevention and cure of arthritis and other disease conditions. These claims further demonstrate the intended drug use of your products.

This letter is not intended to be an all-inclusive review of all labeling and products that 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. (This includes all labeling and promotional materials).

We request that you take prompt action to correct these violations. Failure to promptly correct 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. You should also 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, please state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to Lawrence E. Boyd, Compliance Officer, Food and Drug Administration, 6751 Steger Drive, Cincinnati, OH 45237-3097.

Sincerely,



Carol A. Heppe
Acting District Director
Cincinnati District