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Food and Drug Administration  
Minneapolis District  
240 Hennepin Avenue  
Minneapolis MN 55401-1999  
Telephone: 612-334-4100

May 5, 2000

xc: HFI-35  
DWA

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Refer to MIN 00 - 32

Terrence J. Lemerond  
President  
Enzymatic Therapy, Inc.  
825 Challenger Drive  
Green Bay, Wisconsin 54311

Dear Mr. Lemerond:

This letter is written in reference to your marketing of products containing the ingredient glucosamine sulfate and nasal decongestant products.

Immediate container labels and product labeling, namely your "Enzymatic Therapy Natural Medicines" product catalog, "PhytoPharmica Natural Medicines" product catalog, and "Enzymatic Therapy Vitamins & Supplements International Catalog," represent and suggest that the products GS-500, GS Complex, GS 1500 Packets, Glucosamine Sulfate, Glucosamine Sulfate Complex, and Glucosamine Sulfate Packets, may be useful in the treatment of osteoarthritis. In addition, intended use is also established by the claims on your Internet web sites.

AllerClear, AllerPlus, SinuClear, and SinuCheck are nasal decongestants containing pseudoephedrine as the active ingredient. These products are subject to final rules covering over-the-counter (OTC) nasal decongestant drug products (Title 21, Code of Federal Regulations, Part 341 [21 CFR 341]).

The referenced products containing glucosamine sulfate and products that are nasal decongestants are drugs within the meaning of Section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act.)

Each of the products containing glucosamine sulfate and the nasal decongestants are "new drugs" [Section 201(p) of the Act] which may not be legally marketed in the United States without an approved new drug application (Section 505 of the Act).

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The products containing glucosamine sulfate and the nasal decongestants are also misbranded under Section 502(a) of the Act because their labeling suggests that there is evidence that these drugs are safe and effective for their intended use when, in fact, such evidence does not exist. These drugs are further misbranded within the meaning of Section 502(f)(1) of the Act because their labeling fails to bear adequate directions for use.

Your nasal decongestant drug products are further misbranded under Section 502(f)(2) of the Act because their labels fail to bear adequate warnings. Each of the products fails to comply with the regulations as follows: (1) the "statement of identity" does not meet 21 CFR 341.80(a); (2) the labeling fails to bear all the warnings required by 21 CFR 341.80(c), the accidental ingestion warning required by 21 CFR 330.1(g), and the complete pregnancy warning required by 21 CFR 201.63; and (3) the directions for use do not conform to 21 CFR 341.80(d)(1)(ii).

Further, the nasal decongestant products are misbranded [Section 502(a) of the Act] because the tamper-evident packaging statement, "DO NOT USE IF TAMPER RESISTANT SEAL IS BROKEN," fails to identify the tamper-evident feature used. Further, if the tamper-evident feature used is one that requires an identifying characteristic, that characteristic must be referenced in the labeling statement [21 CFR 211.132(c)(1) and (c)(2)]. Also, the term "Tamper-Resistant" must be replaced with the term "Tamper-Evident" for products initially introduced into interstate commerce after November 6, 2000 (see November 4, 1998, Federal Register, 63 FR 59463).

We request that you notify this office in writing within 15 working days of receipt of this letter stating the action you will take to correct the violations and to prevent their recurrence. 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 completed.

Failure to make prompt corrections may result in enforcement action being initiated by the Food and Drug Administration (FDA). This could include seizure of illegal products and injunction against the manufacturer and/or distributor of illegal products.

Further, as you are aware, you and your firm are currently operating under a Consent Decree of Permanent Injunction entered into on November 5, 1992, in the United States District Court, Eastern District of Wisconsin. Paragraph 3B of this Consent Decree prohibits the marketing of drug products that are represented for treating disease unless and until an approved new drug application is in effect or such representations are in compliance with effective over-the-counter monographs. Therefore, failure to make prompt corrections could also result in the

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FDA seeking enforcement action based on a lack of compliance with this court order.

For your information, we have the following additional comments based on a review of your "Enzymatic Therapy Natural Medicines" product catalog, your "Enzymatic Therapy Vitamins & Supplements International Catalog," your "PhytoPharmica Natural Medicines" product catalog, and your Internet web sites:

Reference to FDA registration in labeling and promotional materials including Internet web sites, creates an impression of official approval and is misleading and constitutes misbranding (21 CFR 207.39).

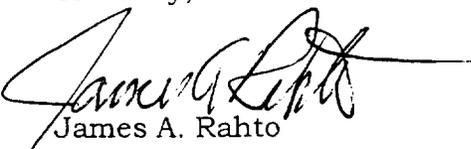
We note that you market products that are intended for the OTC treatment of acne, e.g., Akne-Zyme, known as Healthy Skin in Texas, Derma Care, and Derma-Klear Akne Treatment Cream. Topical OTC products offered for the treatment of acne are subject to final rules found in 21 CFR 333.310. It is your responsibility to ensure that the products are in compliance with these regulations with respect to formulation and labeling.

Products that are intended for OTC treatment of psoriasis, e.g., Simicort and Alticort, are subject to the final rules found in 21 CFR 358.701. You must ensure that these products are in compliance with those regulations.

This letter does not represent a comprehensive review of all of the products distributed by your firm, nor does it represent a complete review of all product labeling including immediate container labels, product brochures, product catalogs, and newsletters. Also, this letter does not represent a comprehensive review of all your promotional materials including Internet web sites. As president, it is your responsibility to ensure that all products distributed by your firm are in compliance with the Act and its implementing regulations.

Your reply should be directed to Compliance Officer Carrie A. Hoffman at the address indicated at the letterhead. Ms. Hoffman may be reached at (612) 334-4100 ext. 159.

Sincerely,

  
James A. Rahto  
Director  
Minneapolis District

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