



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

June 26, 1986

REGULATORY LETTER

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-349-3900

Reply to MIN 24-6

• Mr. Terrence J. Lemerond
President
Enzymatic Therapy, Inc.
Box 1508
722 Bodart Street
Green Bay, WI 54305

HF-3140

Dear Mr. Lemerond:

An investigation conducted by the Food and Drug Administration indicates that your firm is currently marketing certain products with labeling statements which represent and suggest that the articles are intended to be used in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or any function of the body of man. The result of your labeling statements is that these products are drugs as defined in Section 201(g) of the Federal Food, Drug and Cosmetic Act (Act). Further, we are unaware of any substantial scientific evidence which demonstrates that any of the subject drugs are generally recognized as safe and effective for their intended use and may be considered "new drugs" etc.

Your product labels bear formula numbers identifying promotional labeling called "Research Bulletins" containing drug claims. For your information, reprints of articles, advertisements, and educational information accompanying your products are considered "labeling" as defined in section 201 (m) of the Act. Some examples of formulas we consider drug products under the Act are:

Hypo-Ade #235 Labeling represents the product and formula as useful in the prevention or treatment of diabetes or over fifty symptoms associated with high (hyperglycemia) or low (hypoglycemia) levels of blood sugar, such as chronic depression, anxiety, tension and exhaustion. The claim that this combination of nutritional factors will affect the metabolism of glucose and carbohydrates of any one or all of the patient population is a drug claim. Any claim that herbs, raw pancreas, or raw adrenal used in this formula have any effect on liver function also cause this article to be considered a drug.

Renatone #184 Labeling represents the product and formula as a useful diuretic which can prevent edema without enduring diuretic drugs and their harmful side effects. The Bulletin on "Kidney & Natural Diuretics" also claims that raw kidney tissue and herbal components enhance kidney function and are potassium sparing in their diuretic affects.

Hem-Tone #320 Labeling represents the formula as useful in treating minor itching of inflamed hemorrhoidal tissue without any drug or chemical ingredients. Research Bulletin #320 and other labeling (e.g. 20 ways to nutritionally rescue your body) claim the formula is useful for treating varicose veins, liver function, and damaged livers.

Nucleopro-M #215 Labeling represents the product as useful in the treatment of male and female problems, infertility, prostate disorders including prostatitis, nocturia, dribbling, male hormone problems, impotency, fatigue, lack of stamina, loss of sexual interest, low back pain, constipation, menstrual irregularity, breast soreness, female hormone problems, frigidity, inflammation or infection of the inner cervix wall, excessive menses, menstruation cramps, back pain, history of abortion, cervical inflammation or infection and menopause symptoms.

Liv-A-Tox #125 Labeling represents the product as useful in liver cleansing or detoxification, lowering cholesterol levels, lessening the chances of heart attack, treating arteriosclerosis, gall stone formation, fatty degeneration of the liver, venous congestion, hemorrhoids, constipation, malfunctions of the spleen, and it represents the product as having antianxiety effects.

Raw Pituitary Complex #442 Labeling represents the product as useful in the treatment of fatigue brought about by mental stress, digestive complaints, colitis, ulcers, diarrhea, gastritis, healing of wounds and in maintaining fluid balance and blood sugar levels.

Liver Fractions (20x) #500 Labeling represents the product as useful in the treatment of anemia including pernicious anemia, chronic degenerative disease, esophageal cancer, broken bones and high blood pressure. The labeling also indicates the product provides increased energy and endurance.

Vira Plex #135 Labeling indicates the product will improve the immune system, destroy viruses, bacteria, and their toxins and aid cortisone production. Labeling also indicates the product is useful in the treatment of mononucleosis, infectious hepatitis, kidney disease, lymph node congestion, infectious diseases, glandular disorders, skin and eye disorders and in the treatment of herpes simplex.

Accordingly, continued marketing of these drugs would be in violation of the Federal Food, Drug, and Cosmetic Act as follows:

<u>Section</u>	<u>Brief Description</u>
502(a)	The aforesaid articles of drugs are misbranded in that their labeling is false and misleading by representations and suggestions that there is substantial scientific evidence to establish that the articles are safe and effective for the above specified conditions.

502(f)(1)

The articles of drugs are misbranded in that their labeling fails to bear adequate directions for the use for which the articles are represented or suggested (as described above), and they are not exempt from this requirement under regulation 21 CFR 201.115 since the articles are new drugs within the meaning of Section 201(p) and no approvals of any application filed pursuant to Section 505(b) are effective for these drugs.

The articles of drugs are further misbranded in that this labeling does not contain adequate directions for use as this term is defined in 21 CFR 201.5 since the conditions for which they are offered are not amenable to self diagnosis and treatment by the laity; therefore, adequate directions for use cannot be written under which the layman can use these drugs safely and for the purposes for which they are intended.

505(a)

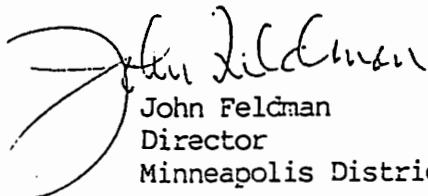
The articles are drugs within the meaning of Section 201(g) of the Federal Food, Drug, and Cosmetic Act which may not be introduced or delivered for introduction into interstate commerce under Section 505(a) of the Act, since they are new drugs within the meaning of Section 201(p) of the Act and no approval of any application filed pursuant to Section 505(b) is effective for such drugs.

The violations listed above are not meant to be all-inclusive. It is your responsibility as a drug distributor to market drug products which are in compliance with the Federal Food, Drug, and Cosmetic Act.

We request that you take prompt action to correct the above violations. If such action is not taken, the Food and Drug Administration is prepared to initiate legal actions to enforce the law. These include seizure and/or injunction.

Please notify this office within ten (10) days of receipt of this letter of the steps you have taken or intend to take to correct these violations and prevent their recurrence. You may address your response to Joseph R. Baca, Compliance Officer, at this address

Sincerely,


John Feldman
Director
Minneapolis District