DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

JAN 26 2006 05144 6 FEB 16 P2:33

Mr. Michael P. Devereux
Chief Operations Officer
Enzymatic Therapy, Inc.
825 Challenger Drive
Green Bay, Wisconsin 54311

Dear Mr. Devereux:

This is in response to your letter of January 7, 2006 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Enzymatic Therapy, Inc. is making the following claim, among others, for the product **Remifemin® Good Night**:

> "[A]nd a safe alternative for women in whom estrogen therapy is contraindicated."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate diseases for which estrogen therapy is indicated. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

97S 0163 LET 858

Please contact us if we may be of further assistance.

Sincerely yours,

Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, Minneapolis District Office, Office of Compliance, HFR-CE840

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January 7, 2006

Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Remifemin® Good Night	Uncontrolled reports, postmarketing surveillance, and human clinical trials of more than 2,800 patients demonstrate a low incidence of adverse events (5.4%). Of the reported adverse events, 97% were minor and did not result in discontinuation of therapy, and the only severe events were not attributed to Cimicifuga treatment. Confirms the safety of specific Cimicifuga extracts, particularly isopropanolic preparations (RemiSure™ black cohosh), for use in women experiencing menopausal symptoms and as a safe alternative for women in whom estrogen therapy is contraindicated.	Black Cohosh Extract, (Root and Rhizome), Herbal Sleep Blend: Balm Leaves Extract, Hop Strobile Extract, Valerian Root Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Robert C. Doster
Robert C. Doster
Title: Senior Vice President of Scientific Affairs

Date: 1-7-06

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3698.

Sincerely,

Michael P. Devereux
Chief Operations Officer

#1565

Remifemin Good Night 44e