

June 12, 1995

Terry Lemerond
President
Enzymatic Therapy
825 Challenger Drive
Green Bay, Wisconsin 54311

Re: Nutritional Support Statement Notification

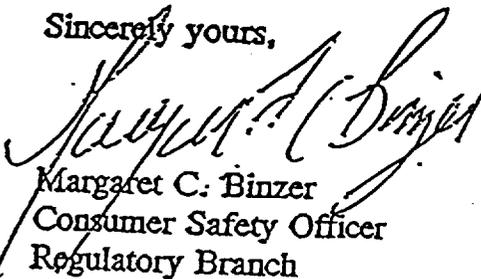
Dear Mr. Lemerond:

This acknowledges receipt on May 19, 1995 of your letter, dated May 5, 1995, notifying the Food and Drug Administration (FDA) on behalf of Schaper & Brummer that the dietary supplement product, Remifemin, is being marketed with a statement of nutritional support on its label or in its labeling.

Pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act), a manufacturer must notify FDA no later than 30 days after the first marketing of a dietary supplement product that bears a nutritional support statement on its label or in its labeling. Pursuant to the act, a manufacturer of such a product must have substantiation that the nutritional support statement is truthful and not misleading. In addition, the nutritional support statement must include, prominently displayed and in bold face type, the following: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

No action on the part of FDA is required before a manufacturer can market a dietary supplement product bearing a nutritional support statement on its label or in its labeling. While the act requires that certain information appear on the label of a dietary supplement in conjunction with such statements, FDA does not approve them. This letter serves only to acknowledge the receipt by FDA of your notification.

Sincerely yours,



Margaret C. Binzer
Consumer Safety Officer
Regulatory Branch
Division of Programs
and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

975-0162

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BINZER