

SEP 19 1996

Ms. Joy M. Erickson
Senior Product Manager
Optim Nutrition, Inc.
P.O. Box 58714
Salt Lake City, Utah 84158-0714

Dear Ms. Erickson:

This is in response to your letter of August 1, 1996 to the Food and Drug Administration (FDA) per the Dietary Supplement Health and Education Act of 1994. Your letter included a copy of the product brochure for Optim Nutrition's nutraceutical product, OPTIMUNE. Your letter does not state why you are making this submission to FDA. However, we have read the materials that you enclosed with your letter and have the following comments on the information included in the brochure.

Your brochure states:

OPTIMUNE is not a drug, but a naturally derived dietary supplement. As such, it is classified as a "nutraceutical" under the Dietary Supplement Health and Education Act of 1994 from the Food, Drug, and Cosmetic Act. Defined, a nutraceutical is a functional food designed to deliver a specific health benefit.

The Dietary Supplement Health and Education Act of 1994 (DSHEA) does not provide for the classification of any product as a "nutraceutical." The term "nutraceutical" is not defined in the Federal Food, Drug, and Cosmetic Act (the act). Therefore, the statement in your brochure is false.

Your brochure also states:

From that initial knowledge we began researching a product utilizing bovine whey protein concentrate to improve human health and nutrition. The result is OPTIMUNE, a nutraceutical product developed to help users maintain body weight and fight chronic weight loss.

Enlist bovine whey protein in your battle with chronic weight loss.

Chronic weight loss doesn't have to be fact of life. Rush the attached reply card to us and finally take the upper hand in "winning your fight" with chronic weight loss.

For people stressed by disease, chronic weight loss can be life threatening. The process begins in the human gut where malnutrition causes the lining of the intestine to lose its nutritional integrity. The composition of OPTIMUNE as a natural substance helps heal the intestine and promotes utilization of vital nutrients. In the absence of nutrition the

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body protects itself by shifting into a starvation mode, breaking down muscle and other valuable tissue necessary for nutrition, which can result in increased loss of appetite and weight loss

OPTIMUNE promoted digestion and utilization of vital nutrients, helping to end the cycle of chronic weight loss.

CHRONIC WEIGHT LOSS

- Gut Malnutrition
- Allows Organisms To Invade
- Negative Reaction In Gut
- Allows Fluid/Plasma To Pass Into Gut
- Causes Unrelenting Diarrhea
- Fluid Leaves The Body With Diarrhea
- Body Senses Starvation
- Breaks Down Fat And Muscle For Nutrients
- Causes Further Gut Immune Suppression
- And Process Repeats Itself

OPTIMUNE

The natural defense against chronic weight loss

Under the act a representation that a product is intended for medical or therapeutic use evidences that that product is a drug. Under the provisions of section 201(g) of the act, a drug is defined as an article intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or animals. The brochure you submitted makes numerous statements that suggest that this product is intended for these purposes in that it will help heal the intestine. A manufacturer of a drug must prove that its product is safe and effective for its intended use. We are not aware of any evidence that your product meets this test. 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, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,

James Tanner, Ph.D.
Acting Director,
Division of Programs and
Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition