

April 21, 2003

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Mr. Robert Moore
Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

RE:

Label Claims/Disclaimers

Dear Mr. Moore:

This letter is to notify you that Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 is a manufacturer and has included statements provided for by section 403(r)(6) of the Food, Drug, and Cosmetic Act on the labels of the following product. 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.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Ostivone®	Ipriflavone	Ostivone® supports the manufacture of bone-matrix proteins and bone mineral deposition.* As a result, it is most beneficial when used in conjunction with a calcium-rich, multi-nutrient, bone support product like Clinical Nutrients for Bone Health.*

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: KLICILL

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date:  $\frac{4/21/03}{}$ 

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www.enzv.com

Ostivone 6e

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If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs, at (920) 406-3608.

Sincerely,

Michael P. Devereux Chief Financial Officer