DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC

JUL 30 1996

Mr. Vic Rathi
President
Specialty Enzymes and Biochemicals Co.
13591 Yorba Avenue
Chino, California 91710

Dear Mr. Rathi:

This is in response to your letter dated May 9, 1996, concerning the marketing of Enzyme-Peptidase (Trade Name: Serratiopeptidase) as a dietary supplement. This letter addresses the requirements for marketing Enzyme-Peptidase as a new dietary ingredient and the requirements for marketing a dietary supplement with certain claims on its label.

Section 413 of the Federal Food, Drug, and Cosmetic Act (the act) requires a manufacturer or distributor of a dietary supplement which contains a new dietary ingredient to submit certain information to the agency. Specifically, the act requires that at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient provide the FDA with information which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe. Because you submitted to FDA information which is the basis on which you concluded that the dietary supplement will reasonably be expected to be safe, the agency will consider your submission to be the required 75-day premarket notification of your intent to sell Enzyme-Peptidase as a dietary supplement. As required by section 413(a)(2) of the act, we will keep your submission confidential for 90 days from the date of receipt, and thus on August 15, 1996, it will be placed on public display at Dockets Management Branch. Commercial and confidential information in the notification will not be made available to the public.

Your letter suggests that you intend to make claims for this product. Pursuant to section 403(r)(6) of the act, a statement of nutritional support for a dietary supplement may be made if the statement

> (1) claims a benefit related to a classical nutrient deficiency disease and disclosed the prevalence of such disease in the United States,
> (2) describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans,
> (3) characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or
> (4) describes general well-being from consumption of a nutrient or dietary ingredient.

Section 403(r)(6) permits these statements, however, only under certain conditions. For example, the statement may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or

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class of diseases. In addition, a manufacturer of such a product must have substantiation that the nutritional support statement is truthful and not misleading. Furthermore, the nutritional support statement must prominently contain the following disclaimer:

> 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.

Finally, pursuant to section 403(r)(6) of the act, a manufacturer must notify FDA no latter 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. If you intend to make a nutritional support statement on the label or in the labeling of your dietary supplement product, you must submit to FDA a notification following the requirements listed in section 403(r)(6) of the act. The notification must include the nutritional support statement that will appear on the label or in the labeling of the dietary supplement.

We would like to comment on the nature of the information you submitted with regard to the use of Serratiopeptidase in humans. Most of the studies of this substance are for uses that would suggest that this substance is intended for use as a drug. If it is your intention to label or market Serratiopeptidase for such uses (i.e., Following expectoration failure Bronchitis, Tuberculosis, Bronchial Asthma; Expectoration failure after Anesthesia; Inflammation after surgery and external wounded [sic]; Following inflammatory: Otorthinolaryngology Area (Sinusitis), Obstetrics and Gynecology area, Urology area (Cystitis, Epididymitis), Dentistry, Oral hygiene area (Paradontitis, Alyeoysis); and Chronic Lung Disease), you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland, 20855.

Be advised that there is no requirement that dietary supplements be approved by the FDA prior to marketing. It is the responsibility of the person who introduces a dietary supplement into interstate commerce to ensure that the dietary supplement is safe for its intended use and is properly labeled.

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