



Memorandum

Date JUL 30 1996

From Acting Director, Division of Programs and Enforcement Policy, Office of Special Nutritionals, HFS-455

Subject 75-Day Premarket Notification for New Dietary Ingredients

To Dockets Management Branch, HFS-305

New Dietary Ingredient:	Enzyme-Peptidase (Trade Name: Serratiopeptidase)
Firm:	Specialty Enzymes and Biochemicals Co.
Date Received by FDA:	May 17, 1996
90-Day Date:	August 15, 1996

In accordance with the requirements of section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification for the aforementioned new dietary ingredient should be placed on public display in docket number 95S-0316 after August 15, 1996.

Sincerely yours,

Nicholas Ruyfor

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

Attachment 0899 '95 AUG 12 09:50

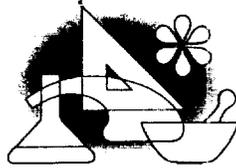
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95S-0316

VOLUME 1

RPT 4

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RECEIVED BY THE
OFFICE OF SPECIAL
NUTRITIONALS, HFS-450

**Specialty Enzymes and Biochemicals Co.*

MAY 17 P2:33

May 09, 1996

CERTIFIED MAIL-RETURN RECEIPT REQUESTED

TRADE SECRET-CONFIDENTIAL AND PROPRIETARY INFORMATION

Mr. John Gordon
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street
HFS-455
Washington, DC 20204

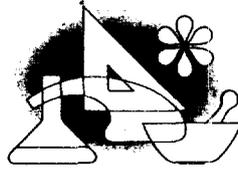
Dear Mr. Gordon,

Notice hereby given pursuant to the requirements of 413(a)(2)[(21 U.S.C.350b)] of the Federal Food, Drug, and Cosmetic Act of the intent of Specialty Enzymes and Biochemicals Co. to introduce a new dietary ingredient, ENZYME-PEPTIDASE (TRADE NAME: SERRATIOPEPTIDASE) (the "Ingredient"), into interstate commerce on or after August 13, 1996. Based on the information available, we recommend a maximum daily intake of the Ingredient of 30 miligrams per day. The following documents evidencing the safety of the Ingredient are enclosed with this notice and incorporated herein by reference.

- (1) Technical Bulletin of Serratiopeptidase
- (2) Repression of Fabrinolsis in scalded Rats by administration of Serratia Protease.
- (3) Bioequivalence study of Rifampicin with and without Serratiopeptidase.
- (4) Evaluation of Serratiopeptidase in the control of Hypertrophic Allergic Rhinitis, associated with extrinsic Bronchial Asthama.
- (5) Clinical drug trials of Serratiopeptidase.
- (6) Drug trial of Serratiopeptidase.
- (7) Drug trial of Serratiopeptidase (An anti-inflammatory oral enzyme).

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**Specialty Enzymes and Biochemicals Co.*

- (8) Serratiopeptidase clinical trials.
- (9) Detailed report of Serratiopeptidase clinical trial.
- (10) Trial of Serratiopeptidase on different groups of patients with Plastic Surgery problems.
- (11) Serratiopeptidase in chronic Lung Disease.

Pursuant to 21 CFR 20.60-61 Specialty Enzymes specifically requests that this information be kept confidential and NOT be disclosed.

Sincerely,
Specialty Enzymes and Biochemicals Co.

V. Rath

Vic Rath
President