DEPARTMENT OF HEALTH & HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Public Health Service

Memorandum

Date JAN 19 2000

From Senior Regulatory Scientist, Regulatory Branch, Division of Programs & Enforcement Policy (DPEP), Office of Special Nutritionals, HFS-456

Subject 75-day Premarket Notification for New Dietary Ingredient

To Dockets Management Branch, HFA-305

New Dietary Ingredient:	L-Se-methylselenocysteine
Firm:	PharmaSe, Inc.
Date Received by FDA:	December 6, 1999
90-day Date:	February 18, 2000

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 February 18, 2000.

Robert J. Moore

Robert J. Moore, Ph.D.

95S-0316

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

JAN 19 2000

Julian Spallholz, Ph.D.
President and CEO
PharmaSe, Inc.
3416 Knoxville Avenue
Lubbock, Texas 79413

Dear Dr. Spallholz:

This is to notify you that your submission pursuant to section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act) dated November 30, 1999, concerning the marketing of a substance that you assert is a new dietary ingredient (i.e., L-Se-methylselenocysteine) was received by the Food and Drug Administration (FDA) on December 6, 1999. Your submission will be kept confidential for 90 days from the date of receipt, and after February 18, 2000, your submission will be placed on public display at Dockets Management Branch (Docket No. 95S-0316). Commercial and confidential information in the notification will not be made available to the public.

Please contact us if you have questions concerning this matter.

Sincerely,

Robert J. Moore, Ph.D.
Senior Regulatory Scientist
Division of Programs and Enforcement Policy
Office of Special Nutritionals

Office of Special Nutricuticals
HFS 450
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. SW.
Washington, DC 20204

November 30, 1999

Dear Dr. Larsen:

Thank you for your letter of November 12th in reply to our submission of documentation to distribute a new dietary supplement, L-Se-methylselenocysteine.

I spoke with Dr. Robert Moore to help clarify the additional needed information for complying with the requirements of 21 CRF 190.6.

Our target population for this supplement will be adults only. The label we propose to use is as follows:

Suggested Dose: As a dietary supplement for adults only (18 years or older), one(1) to two (2) capsules daily at mealtime or as directed by a healthcare practitioner.

Each capsule provides:
Selenium (L-Se-methylselenocysteine).....50 mcg

The human nutritional requirement for Selenium has been established and the Food and Nutrition Board, National Academy of Science have recommended a USRDA.

Packaging is planned for gelcaps with starch and calcium phosphate filler.

If this information is insufficient to complete our notification or if additional information is needed we will be pleased to respond.

Thank you,

Sincerely,

Julian Spallholz, PhD
President and CEO

PharmaSe, Inc
3416 Knoxville Ave
Lubbock, TX 79413 email: setech@door.net ph: 806-784-0104