DEPARTMENT OF HEALTH & HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Public Health Service

Memorandum

Date . MAY 13 1999

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:	vinpocetine
Firm:	Pharmavite Corporation
Date Received by FDA:	May 12, 1999
90-day Date:	August 9, 1999

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 9, 1999.

Robert J. Moore, Ph.D.

95S-0316

RPT 48

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

MAY 13 1999

Mr. David Kropp
Acting Director, Regulatory and Consumer Affairs
Pharmavite Corporation
15451 San Fernando Mission Boulevard
P.O. Box 9606
Mission Hills, California 91346-9606

Dear Mr. Kropp:

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 May 11, 1999, concerning the marketing of a substance that you assert is a new dietary ingredient (i.e., vinpocetine) was received by the Food and Drug Administration (FDA) on May 12, 1999. Your submission will be kept confidential for 90 days from the date of receipt, and after August 9, 1999, 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,

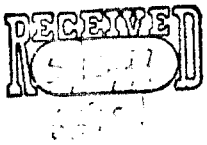
Robert J. Moore

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

PHARMAVITE

May 11, 1999

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



Dear Sir or Madam:

In accordance with 21 CFR 190.6, Pharmavite Corporation is hereby notifying the Food and Drug Administration that we intend to market a dietary supplement containing a new dietary ingredient.

1. The name and complete address of the manufacturer or distributor of the dietary supplement that contains a new dietary ingredient:
   Pharmavite Corporation
   15451 San Fernando Mission Blvd.
   Mission Hills, CA 91345

2. The name of the new dietary ingredient that is the subject of the premarket notification:
   vinpocetine

3. A description of the dietary supplement or dietary supplements that contain the new dietary ingredient including:
   (i) The level of the new dietary ingredient in the dietary supplement:
   Maximum daily intake of 30 mg vinpocetine
   (ii) The conditions of use recommended or suggested in the labeling of the dietary supplement:
   Maximum daily intake of 30 mg vinpocetine

4. The history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe:
   See attached articles:
   Palosi E, Szporny L. Arzneim-Forsch. 1976;26(10):1926-1929
   Cholnoky E, Domok L.I. Arzneim-Forsch. 1976;26(10):1938-1944
   Fenyes Gy, Tarjanyi J, Ladvanszky Cs. Arzneim-Forsch. 1976;26(10):1956-1962

Peruzza M, DeJacobis M. Advances in Therapy. 1986;3(4):201-209
Manconi E, Binaghi F, Pitzus F. Current Therapeutic Research. 1986;40(4):7702-7709
Balestreri R, Fontana L, Astengo F. JAGS 1987;35:425-430
Hayakawa M. Arzneim-Forsch. 1992;42(1)Nr.4:425-427

The above articles are identical to those submitted by Amrion, Inc. in their submission received by the FDA on July 8, 1997.

An original and two copies of this notice are being filed. Pursuant to 21 CFR 190.6(c), please confirm your receipt of this notice. We also request that this information be kept confidential for 90 days under the provisions of 21 CFR 190.6(e).

Sincerely,

David Kropp
Acting Director, Regulatory and Consumer Affairs

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