DEPARTMENT OF HEALTH & HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Public Health Service

Memorandum

Date MAR 25 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:	Leiner Health Products
Date Received by FDA:	March 24, 1999
90-day Date:	June 21, 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 June 21, 1999.

Robert J. Moore, Ph.D.

95S-0316

RPT 46

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

MAR 25 1999

Mr. Michael S. Bradley
Director of Regulatory Affairs
Leiner Health Products
901 E. 233rd Street
Carson, California 90745-6204

Dear Mr. Bradley:

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 March 23, 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 March 24, 1999. Your submission will be kept confidential for 90 days from the date of receipt, and after June 6, 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,

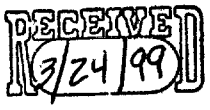
Robert J. Moore, Ph.D.
Senior Regulatory Scientist
Division of Programs and Enforcement Policy
Office of Special Nutritionals

LEINER
HEALTH PRODUCTS

901 E. 233rd Street
Carson, California
90745-6204
310/835-8400
Fax 310/835-6615

March 23, 1999

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



Re: Resubmission of 75 – Day Premarket Notification for New Dietary Ingredients to Increase Dosage.

Dear Sir or Madam:

In accordance with the requirements of section 8 of the Dietary Supplement Health and Education Act, Leiner Health Products is notifying the Food and Drug Administration that it will be marketing vinpocetine as a new dietary ingredient.

We take this action with the understanding that Leiner Health Products will not market this product for a period of at least 75 days after the FDA receipt of this notification.

Company Name and Address:

Leiner Health Products
901 E 233rd Street
Carson, CA 90745

Product Name and Chemical Name:

- Vinpocetine
- (3α, 16α) Eburnamenine –14-carboxylic acid ethyl ester

Description

The dietary supplement will be in tablet form with a suggested use of two tablets daily. This two tablet dose provides 10 mg of vinpocetine daily.

The labeling will include a warning against the use of this product by pregnant or lactating women.

64321

March 23, 1999
Office of Special Nutritionals (HFS-450)
Center for Food and Safety and Applied Nutrition
Food and Drug Administration
200 C Street SW
Washington DC 20204

Product Safety

Please find attached documentation, which establishes that the new dietary ingredient (vinpocetine) when taken under the suggested use is reasonably expected to be safe.

Respectfully Submitted,

Michael S. Bradley,
Director of Regulatory Affairs

Attached

LEINER
HEALTH PRODUCTS

901 E. 233rd Street
Carson, California
90745-6204
310/835-8400
Fax 310/835-6615

Leiner Health Products

Vinpocetine

75 – Day Premarket Notification for New Dietary Ingredients

(copy)

See report 34