



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

Memorandum

AUG 29 1997

Date

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: Vinpocetine 2052 '97 OCT -7 P1:18  
Firm: Amrion, Inc.  
Date Received by FDA: July 8, 1997  
90-Day Date: October 6, 1997

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 October 6, 1997.

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

Attachment

cc:

HFS-22, CCO

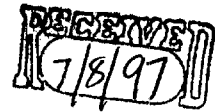
HFS-450 (r/f, OSN w/control slip:TRAC#53440 & cpy incoming)

HFS-456 (r/f, Latham, Moore)

r/d:HFS-456:JELatham;jel:08/19/97:DocName:#53440.mem:Disc4

95S-0316

RPT 12



June 27, 1997

CERTIFIED MAIL--RETURN RECEIPT REQUESTED

**TRADE SECRET--CONFIDENTIAL AND PROPRIETARY INFORMATION**

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

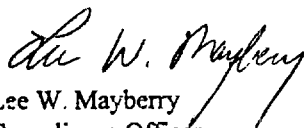
Dear Sir or Madam:

Notice is 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 Amrion, Inc. to introduce a new dietary ingredient, *vinpocetine* (the "Ingredient"), into interstate commerce on or after September 15, 1997. Based on the information available, we recommend a maximum daily intake of the Ingredient of 36 milligrams per day. The following documents evidencing the safety of the Ingredient are enclosed with this notice and incorporated herein by reference:

Cholonoky E, Domok LI. *Arzneim-Forsch.* 1976;26(10):1938-1944.  
Palosi E, Szporny L. *Arzneim-Forsch.* 1976;26(10):1926-1929.  
Balestreri R, Fontana L, Astengo F. *JAGS* 1987;35:425-430.  
Manconi E, Binaghi F, Pitzus F. *Current Therapeutic Research.* 1986;40(4):7702-709.  
Peruzza M, DeJacobis M. *Advances in Therapy.* 1986;3(4):201-209.  
Fenyés Gy, Tarjányi J, Ladvanszky Cs. *Arzneim-Forsch.* 1976;26,Nr.10:1956-1962.  
Hayakawa M. *Arzneim-Forsch.* 1992;42(1)Nr.4:425-427.

Pursuant to 21 CFR § 20.60-61 Amrion, Inc. specifically requests that this information be kept confidential and NOT be disclosed.

Sincerely,  
AMRION, INC.

  
Lee W. Mayberry  
Compliance Officer

enclosures

53440

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FOOD AND DRUG ADMINISTRATION  
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ROCKVILLE, MD 20852***