



DEPARTMENT OF HEALTH & HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION


Public Health Service

Memorandum

Date . MAR 22 2000 1440 '00 MAR 23 AIO:16
From Acting Chief, Dietary Supplements Branch, Division of Compliance & Enforcement, Office of Nutritional Products, Labeling, and Dietary Supplements, HFS-811
Subject 75-day Premarket Notification for New Dietary Ingredient
To Dockets Management Branch, HFA-305

New Dietary Ingredients: S-adenosylmethionine
Firm: Leiner Health Products
Date Received by FDA: March 16, 2000
90-day Date: June 13, 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 June 13, 2000.


Robert J. Moore, Ph.D.

95S-0316

RPT 66



MAR 22 2000

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

Dear Mr. Farag:

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 8, 2000, concerning the marketing of a substance that you assert is a new dietary ingredient (i.e., S-adenosylmethionine) was received by the Food and Drug Administration (FDA) on March 16, 2000. Your submission will be kept confidential for 90 days from the date of receipt, and after June 13, 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.

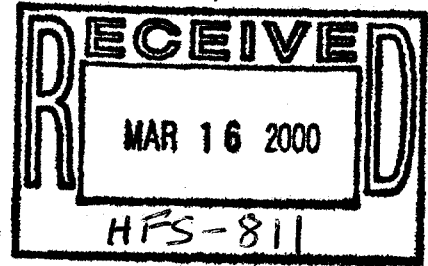
Acting Chief, Dietary Supplements Branch
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements



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

March 08, 2000

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: Submission of 75 – Day Premarket Notification For New Dietary
Ingredient.

Dear Sir or Madam:

In accordance with the requirements of section 8 of the Dietary Supplement Health and Education Act, Leiner Health Products Inc. is notifying the Food and Drug Administration that it will be marketing S-adenosylmethionine (SAM-e) as a new dietary ingredient.

We take this action with the understanding that Leiner Health Products Inc. 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 Inc.
901 E. 233rd Street
Carson, CA 90745

Ingredient Name:

- S-adenosylmethionine (SAM-e)

Description:

The dietary supplement will be in tablet form with a suggested use of 2 tablets (400 mg), 2 hours before or 3 hours after a meal.



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Product Safety:

The product will be packaged in a tamper evident seal to ensure safety.

Individuals who have bipolar (manic) depression or are taking prescription antidepressant medications will be instructed to consult their physician before taking the product.

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

Respectfully Submitted,


Hany Farag,
Director of Regulatory Affairs

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