

Memorandum

Date: = AUG 30 2005

From: Consumer Safety Officer, Division of Dietary Supplement Programs , Office of
Nutritional Products, Labeling and Dietary Supplements, HFS-810

Subject: 75-Day Premarket Notification of New Dietary Ingredients

To: Dockets Management Branch, HFA-305

Subject of the Notification: Brain Longevity

Firm: Aminocare Products, LP

Date Received by FDA: June 1, 2005

90-Day Date: August 30, 2005

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In accordance with the requirements of section 413(a) of the Federal Food, Drug, and
Cosmetic Act, the attached 75-day premarket notification and related correspondence for the
aforementioned substance should be placed on public display in docket number 95S-0316 as
soon possible since it is past the 90-day date. Thank you for your assistance.

 Victoria Lutwak

19955-0316

RPT290



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740

Azad Rastegar
Director
Aminocare Products, LP
9432 Old Katy Rd., Suite 248
Houston, Texas 77055

AUG 15 2005

Dear Mr. Rastegar:

This is to inform you that the notification, dated May 27, 2005, you submitted pursuant to 21 U.S.C. 350b(a)(2)(section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) was filed by the Food and Drug Administration (FDA) on June 1, 2005. Your two page notification includes the name of the distributor, a list of "names of new dietary ingredients subject to the notification" (curcumin, l-alanine, l-arginine, glycine, l-ornithine, l-serine, l-threonine, l-valine, Piperine) and details concerning a dietary supplement "Brain Longevity."

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement containing a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under section 350b(a)(2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is considered to be adulterated under 21 U.S.C. 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

Your submission of a notification for a new dietary ingredient makes clear that you have determined that your dietary supplement product contains one or more new dietary ingredients that are subject to the notification process under section 413(a)(2) of the Act. Specifically, you have determined that the dietary supplement does not only contain dietary ingredients which have been present in the food supply as an article used for food in a form which has not been chemically altered. Federal regulations found at 21 CFR 190.6 specify the requirements for a pre-market notification for a new dietary ingredient. Your notification does not comply with the requirements of 21 CFR 190.6 and is incomplete. Your notification does not contain a description of your new dietary ingredient(s), including the level in the dietary supplement product and the

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conditions of use (i.e., the number of capsules per day and the number of days recommended or suggested in the labeling, etc.).

A notification should contain history of use or other information which establishes that the dietary ingredient, when used under the conditions recommended or suggested in the dietary supplement, would reasonably be expected to be safe. A notification should include the Latin binomial (including the author) for any herb or botanical. Any reference to published information offered in support of the notification should be included in the notice. Any references to published information offered in support of the notification shall be accompanied by reprints or photostatic copies of such references.

Based on the information submitted in your notification, FDA is unable to determine whether your new dietary ingredient(s) will reasonably be expected to be safe because the information contained in your notice is incomplete. If you market your product without submitting a notification that meets the requirements of 21 CFR 190.6 (<http://www.cfsan.fda.gov/~lrd/cfr190-6.html>), or market your product less than 75 days after submitting such a notification, your product is considered adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

Your notification will be kept confidential for 90 days after the filing date of June 1, 2005. After the 90-day date, the notification will be placed on public display at FDA's Division of Dockets Management in docket number 95S-0316. Prior to that date, you may wish to identify in writing specifically what information you believe is proprietary, trade secret or otherwise confidential for FDA's consideration.

If you have any questions concerning this matter, please contact Linda S. Pellicore, Ph.D., at (301) 436-2375.

Sincerely yours,



Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Aminocare[®] PRODUCTS, L.P.

A Lifetime of Health & Beauty

May 27, 2005

Office of Nutritional Products,
Labeling and Dietary Supplements (HFS-820),
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

RECEIVED
JUN 1 2005
BY: FDA [Signature]

AIMS 2005-3216

Dear Madam/Sir:

In accordance with 21 CFR 190.6, Requirement for Premarket Notification, please find below the information required in the above regulation:

1. Distributed by: Aminocare Products, LP
9432 Old Katy Rd. Suite 248
Houston, Texas 77055
2. Names of the new dietary ingredients subject to this notification

Ingredient Name	Latin Binomial Name
Curcumin	Curcuma longa
L-alanine	
L-arginine	
Glycine	
L-ornithine	
L-serine	
L-threonine	
L-valine	
Piperine	Piper nigrum

3. We offer the following details on the new dietary supplement. The new supplement will be sold under the name **Brain Longevity**.

- i. Amounts of ingredients in the Brain Longevity per capsule

Ingredient Name	Amount per capsule
Curcumin	480 mg
L-alanine	22.5 mg
L-arginine	24.5 mg
Glycine	22.5 mg
L-ornithine	22.5 mg
L-serine	22.5 mg
L-threonine	22.5 mg
L-valine	22.5 mg
Piperine	10.5 mg

ii. The Brain Longevity dietary supplement will be recommended for use as a food for a forgetful and aging brain.

4. The safety of the ingredients included in the Brain Longevity Supplement have been demonstrated in multiple products since 1994.
- Amino acid combination products are ubiquitous, with a Google™ search revealing over 128,000 products containing combinations of amino acids. In addition, all of the amino acids contained in the Brain Longevity are utilized as prescription drugs in amino acid injections used for total parenteral nutrition.
 - The curcumin ingredient is also found in multiple dietary supplement products on the market since 1994. A Google™ search of curcumin revealed over 26,000 products available for sale containing this product, with many of these containing significantly more than the 480 mg contained in the Brain Longevity product. Curcumin is the yellow pigment of the spice turmeric, which is one of the main spices in Indian Curry and is used universally throughout the world.
 - The piperine component is also widely available in multiple dietary supplement products, with a Google™ search revealing over 2700 products available for sale. It is also used as an ingredient in the Indian Curry Spice. It is the main ingredient of the commonly used table spice black pepper.
 - Given the omnipresent availability and use of these ingredients throughout the world, Aminocare believes this product, when used as recommended in the labeling, to reasonably be expected to be safe.

Please contact me at 713-335-5675 if additional information is required

Sincerely yours,

A handwritten signature in black ink, reading "Azad Rastegar". The signature is written in a cursive style with a large, stylized initial 'A'.

Azad Rastegar, B.A.
Aminocare Company Director