



SEP - 8 2000

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Mr. Siddharth Shastri  
Vice President, Director of Product Development  
Jarrow Formulas, Inc.  
1824 South Robertson Boulevard  
Los Angeles, CA 90035-4317

Dear Mr. Shastri:

This is in response to your letters of July 24, 2000 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Jarrow Formulas, Inc. is making the following claims, among others, for the products below:

**Ginkgo biloba**

“...increased cerebral circulation...”

**CogniFlex**

“Age associated cognitive decline (AACD) and compromised brain function...”

**Vinpocetine**

“By reducing platelet aggregation Vinpocetine increases blood flow to the brain...”

**Lutein**

“...protect the macula from degeneration...”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, cure, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

LET-389

Page 2 - Mr. Siddharth Shastri

Please contact us if we may be of further assistance.

Sincerely,

John B. Foret  
Director  
Division of Compliance and Enforcement  
Office of Nutritional Products, Labeling,  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200  
FDA, Los Angeles District Office, Office of Compliance, HFR-PA240

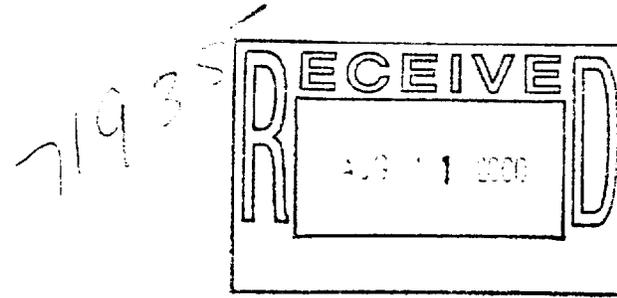
cc:

HFA-224 (w/incoming)  
HFA-305 (docket 97S-0163)  
HFS-22 (CCO)  
HFS-800 (r/f, file)  
HFS-810  
HFS-811 (file)  
HFD-40 (Behrman)  
HFD-310  
HFD-314 (Aronson)  
HFS-605  
HFV-228 (Benz)  
GCF-1 (Dorsey, Nickerson)  
f/t:HFS-811:rjm:9/5/00:docname:71935.adv:disc50



Monday, July 24, 2000

Division of Compliance and Enforcement/ONPLDS  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
HFS-810  
200 C Street, S.W.  
Washington, DC 20204  
202-205-5229



Dear CFSAN:

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act and Section of 101.93 of FDA's regulations, we hereby notify you that we are using the following statement(s):

**(1) Name of Address of distributor:**

Jarrow Formulas, 1824 South Robertson Blvd., Los Angeles, CA 90035

**(2) Text of the statement(s):**

**Promotes Circulation, Brain Function and Antioxidant Status:** Jarrow Formulas' Ginkgo Biloba 50:1 is standardized at 24% ginkgo flavonoglycosides (or heterosides) and a minimum of 6% terpene lactone. Ginkgolides A and B are the most active fractions. Ginkgo Biloba has a wide range of beneficial effects, including inhibition of platelet activating factor (PAF), increased cerebral circulation and antioxidant protection.

**(3) Name of the dietary ingredient if not provided in the text of the statement:**

Ginkgo biloba

**(4) Name of the dietary supplement**

Ginkgo Biloba 50:1 120 mg.-120 capsule count

Ginkgo Biloba 50:1 120 mg.-60 capsule count

Ginkgo Biloba 50:1 60 mg.-120 capsule count

Ginkgo Biloba 50:1 60 mg.-60 capsule count

Ginkgo Biloba 50:1 40 mg.-125 tablet count

Ginkgo Biloba 50:1 40 mg.-50 tablet count

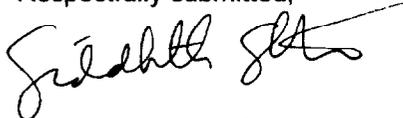
Ginkgo Biloba 50:1 60 ml. liquid

**(5) The following disclaimer appears on the label in bold:** These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

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These claims are limited to, and a result of, what we believe to be a substantial body of scientific evidence supporting the functional role of these nutrients. A compendium of relative published research substantiating the above statement(s) is on file at the corporate office.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Siddharth Shastri', written in a cursive style.

Siddharth Shastri, CCN

Vice President, Director of Product Development  
Licensed Dietitian/Clinical Nutritionist, #002378  
(by the University of the State of New York, State Board of Education)

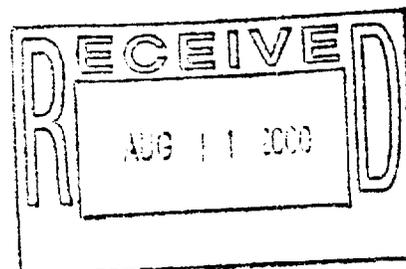
JARROW FORMULAS, INC.  
SUPERIOR NUTRITION  
AND FORMULATION

1824 South Robertson Boulevard  
Los Angeles, CA 90035-4317  
(310) 204-6936  
Toll Free (800) 726-0886  
FAX (310) 204-2520

**JARROW**  
**FORMULAS™**

July 25, 2000

Division of Compliance and Enforcement/ONPLDS  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
HFS-810  
200 C Street, S.W.  
Washington, DC 20204  
202-205-5229



Dear CFSAN:

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act and Section of 101.93 of FDA's regulations, we hereby notify you that we are using the following statement(s):

- (1) **Name of Address of distributor:**  
Jarrow Formulas, 1824 South Robertson Blvd., Los Angeles, CA 90035
- (2) **Text of the statement(s):** "For Brain Metabolism" – Vinpocetine supports brain metabolism by increasing cerebral synthesis of ATP, the universal currency of energy. By reducing platelet aggregation, Vinpocetine increases blood flow to the brain and improves utilization of oxygen. Vinpocetine also increases the synthesis of several neurotransmitters that affect critical brain functions such as memory recall, focus and mood.
- (3) **Name of the dietary ingredient if not provided in the text of the statement:**  
Vinpocetine
- (4) **Name of the dietary supplement**  
Vinpocetine 5 mg
- (5) **The following disclaimer appears on the label in bold:** These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

These claims are limited to, and a result of, what we believe to be a substantial body of scientific evidence supporting the functional role of these nutrients. A compendium of relative published research substantiating the above statement(s) is on file at the corporate office.

Respectfully submitted,

Siddharth Shastri, CCN

Vice President, Director of Product Development  
Licensed Dietitian/Clinical Nutritionist, #002378  
(by the University of the State of New York, State Board of Education)

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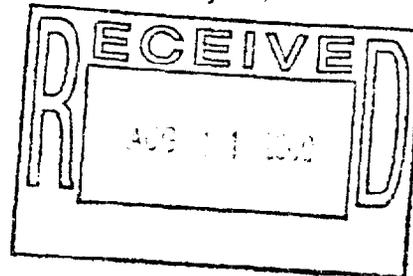
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July 25, 2000



Dear CFSAN:

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act and Section of 101.93 of FDA's regulations, we hereby notify you that we are using the following statement(s):

**(1) Name of Address of distributor:**

Jarrow Formulas, 1824 South Robertson Blvd., Los Angeles, CA 90035

**(2) Text of the statement(s):**

Age associated cognitive decline (AACD) and compromised brain function are commonly associated with decreased levels of phosphatidylserine (PS) which begins at the onset of middle age.

**(3) Name of the dietary ingredient if not provided in the text of the statement:**

Combination of Phosphatidylserine, Ginkgo biloba and gamma tocopherol

**(4) Name of the dietary supplement(s)**

CogniFlex (60 capsule and 120 capsule count)

**(5) The following disclaimer appears on the label in bold:** These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

These claims are limited to, and a result of, what we believe to be a substantial body of scientific evidence supporting the functional role of these nutrients. A compendium of relative published research substantiating the above statement(s) is on file at the corporate office.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Siddharth Shastri".

Siddharth Shastri, CCN

Vice President, Director of Product Development  
Licensed Dietitian/Clinical Nutritionist, #002378  
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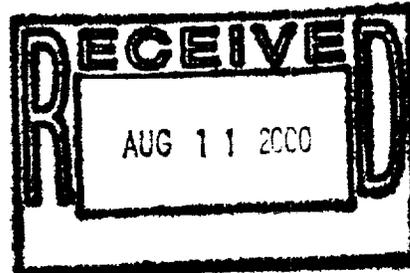
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Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act and Section of 101.93 of FDA's regulations, we hereby notify you that we are using the following statement(s):

**(1) Name of Address of distributor:**

Jarrow Formulas, 1824 South Robertson Blvd., Los Angeles, CA 90035

**(2) Text of the statement(s):**

"Supports Visual Function and Protects the Macula" –Dietary lutein and zeaxanthin concentrate in the eye's macula and lens, as well as the skin, breast and cervical tissue. Both lutein and zeaxanthin protect the macula from degeneration normally associated with aging and oxidative stress. The macula is located behind the lens of the eyes and is responsible for focus and color differentiation.

**(3) Name of the dietary ingredient if not provided in the text of the statement:**

Lutein

**(4) Name of the dietary supplement**

Lutein 20 mg.-30 softgel size

Lutein 20 mg-60 softgel size

**(5) The following disclaimer appears on the label in bold:** These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

These claims are limited to, and a result of, what we believe to be a substantial body of scientific evidence supporting the functional role of these nutrients. A compendium of relative published research substantiating the above statement(s) is on file at the corporate office.

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