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Robert P. Carraher  
Vice President, General Manager

Boehringer Ingelheim  
Pharmaceuticals Inc.

Pharmaton Natural Health  
Products

June 21, 1999

VIA HAND DELIVERY



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

Dear Sir/Madam:

Telephone 203-798-4628  
Telefax 203-798-5771  
E-Mail rcarrahe@rdg.boehringer-  
ingelheim.com

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), Pharmaton Natural Health Products (Pharmaton), Division of Boehringer Ingelheim Pharmaceuticals, Inc., 900 Ridgebury Road, Ridgefield, Connecticut 06877, wishes to notify the Food and Drug Administration that within the past 30 days the Company has begun marketing a dietary supplement with a label which bears statements of nutritional support. Pharmaton is the distributor of the product.

900 Ridgebury Rd/P.O. Box 368  
Ridgefield, CT 06877-0368  
Telephone (203) 798-9988

The dietary supplement for which the statements are made is Ginkoba® M/E™ Suppli-Caps™, which consist principally of standardized GK501™ ginkgo biloba extract (leaf), 60 mg, and standardized G115® ginseng extract (root), 100mg. The statements of nutritional support for this ingredient read as follows:

Mental Performance Dietary Supplement

Promotes Fast and Accurate Thinking

Reduces Mental Fatigue

97S - 0162

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Office of Special Nutritionals  
June 21, 1999  
Page 2

. . . GINKOBA M/E, the daily supplement for Mental Energy™

GINKOBA® M/E™. . . the only clinically proven formula shown to promote fast, accurate thinking and reduce mental fatigue.

GINKOBA M/E . . . contains a standardized formula of GK50 1™ Ginkgo biloba extract and G115® ginseng extract, to safely enhance the circulation of oxygen to the brain.

When taken as directed, GINKOBA M/E's standardized herbal formula safely and effectively promotes efficient mental processing and enhanced mental endurance by safely promoting blood circulation and oxygen supply to the brain.

A copy of the package for each size of the product is attached.

These statements are accompanied by the required disclaimer indicating that the statements have not been evaluated by FDA and that the product is not intended to diagnose, treat, cure, or prevent any disease. (The information is printed in bold in a box on the principal display panel and back panel of the package).

The Company certifies that it possesses adequate substantiation for these statements of nutritional support which renders the statements truthful and non-misleading, and thus permissible under the DSHEA, and that the information contained in this notice is complete and accurate.

Sincerely,



Robert P. Carraher  
Vice President and General Manager

Enclosure

Original plus two copies enclosed

# Ginkoba M/E<sup>™</sup>

Mental Energy<sup>™</sup>

To get more out of life requires you to get more out of your brain. That's the spirit behind GINKOBA M/E<sup>™</sup>, the daily supplement for Mental Energy<sup>™</sup>. GINKOBA M/E is the only clinically proven formula shown to promote fast, accurate thinking and reduce mental fatigue.\* GINKOBA M/E is unique because each Suppli-Cap<sup>™</sup> capsule contains a standardized formula of GK501<sup>™</sup> Ginkgo biloba extract and G115<sup>®</sup> ginseng extract, to safely enhance the circulation of oxygen to the brain.\*

**Suggested Use:** When taken as directed, GINKOBA M/E's standardized herbal formula safely and effectively promotes efficient mental processing and enhanced mental endurance by safely promoting blood circulation and oxygen supply to the brain.\*

**Recommended Adult Intake:** Adults should take one GINKOBA M/E Suppli-Cap<sup>™</sup> capsule with water twice daily. Optimal results have been shown after 4 weeks of continuous daily use. Like most herbal supplements, it works gradually over time and should be taken as part of an on-going healthy regimen.

### SUPPLEMENT FACTS

Serving Size 1 Suppli-Cap<sup>™</sup> Capsule

Amount Per Suppli-Cap <sup>™</sup> Capsule:
Standardized G115 <sup>®</sup> Ginseng Extract 100mg* (Panax Ginseng, C.A. Meyer) (root)
Standardized GK501 <sup>™</sup> Ginkgo Biloba Extract (leaf)

\* Daily Value not established.

**Other Ingredients:**  
Mannitol, gelatin, silicon dioxide, magnesium stearate, hydroxypropyl methylcellulose, titanium dioxide, synthetic iron oxides.

**Contains no sugar, caffeine, or artificial stimulants.**

**Precautions:** As with other vitamins and supplements, please keep this product out of the reach of children. No serious side effects have been reported to date. As with any supplement, if you are taking a prescription medicine, such as an anticoagulant agent, are pregnant, or are lactating, please contact your doctor before taking this product. In case of accidental ingestion/overdosage, seek the advice of a professional immediately.

**Pharmaton Quality Guarantee:**  
This formula has been proven safe and effective in well controlled clinical studies and is manufactured according to the highest quality standards.

Questions about GINKOBA M/E?  
Call toll-free 1-800-451-6688

**Satisfaction or your money back.**  
Safety sealed for your protection. Do not use if seal is broken.

\*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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# Mental Energy<sup>™</sup>

# Ginkoba M/E<sup>™</sup>

1216

## Ginkoba M/E

Store at room temperature and avoid excessive heat above 104°F (40°C) to maintain optimal freshness.



Unique Standardized Formula  
GK501<sup>™</sup> Ginkgo Biloba/G115<sup>®</sup> Ginseng

**New!**

# Ginkoba M/E<sup>™</sup>

Mental Energy<sup>™</sup>

### ▲ MENTAL PERFORMANCE DIETARY SUPPLEMENT

- ▲ Promotes Fast and Accurate Thinking
- ▲ Reduces Mental Fatigue
- ▲ Natural Herbal Extracts

**\$1.50** Cash Rebate Inside

**20** Suppli-Caps<sup>™</sup>  
Only Twice Daily!

*Clinically-proven safe & effective*

\*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.



G115 and GK501 are trademarks of Pharmaton, Ltd., Switzerland. GINKOBA M/E, Mental Energy and Suppli-Caps are trademarks of Pharmaton Natural Health Products, Division of Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877

7 93190 06005 2 Product of Switzerland.

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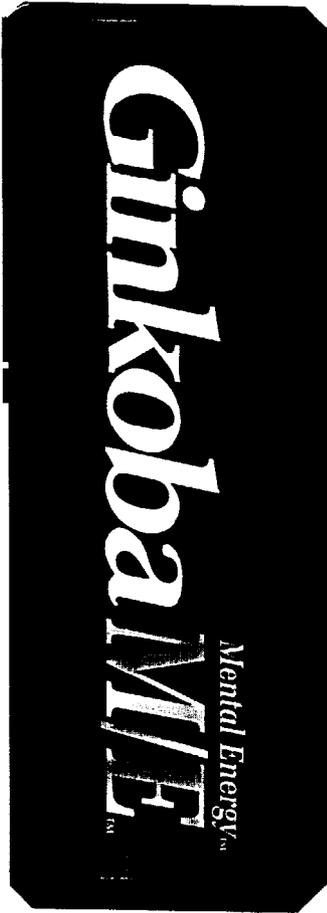
Mental Performance Dietary Supplement  
20 Capsule Size Package

Ginkoba M/E

1217

GINKOBA M/E

Mental Performance Dietary Supplement  
40 Capsule Size Package



To get more out of life requires you to get more out of your brain. That's the spirit behind GINKOBA M/E™, the daily supplement for Mental Energy™. GINKOBA M/E is the only clinically proven formula shown to promote fast, accurate thinking and reduce mental fatigue. GINKOBA M/E is unique because each Suppli-Cap™ capsule contains a standardized formula of GK501™ Ginkgo biloba extract and G115® ginseng extract, to safely enhance the circulation of oxygen to the brain.\*

**Suggested Use:** When taken as directed, GINKOBA M/E's standardized herbal formula safely and effectively promotes efficient mental processing and enhanced mental endurance by safely promoting blood circulation and oxygen supply to the brain.\*

**Recommended Adult Intake:** Adults should take one GINKOBA M/E Suppli-Cap™ capsule with water twice daily. Optimal results have been shown after 4 weeks of continuous daily use. Like most herbal supplements, it works gradually over time and should be taken as part of an on-going healthy regimen.

SUPPLEMENT FACTS	
Serving Size 1 Suppli-Cap™ Capsule	
Amount Per Suppli-Cap™ Capsule:	
Standardized G115® Ginseng Extract 100mg* (Panax Ginseng, C.A. Meyer) (root)	
Standardized GK501™ Ginkgo Biloba Extract (leaf)	60mg*
* Daily Value not established.	

**Other Ingredients:** Mannitol, gelatin, silicon dioxide, magnesium stearate, titanium dioxide, synthetic iron oxides.

**Contains no sugar, caffeine, or artificial stimulants.**

**Precautions:** As with other vitamins and supplements, please keep this product out of the reach of children. No serious side effects have been reported to date. As with any supplement, if you are taking a prescription medicine, such as an anticoagulant agent, are pregnant, or are lactating, please contact your doctor before taking this product. In case of accidental ingestion/overdosage, seek the advice of a professional immediately.

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*This formula has been proven safe and effective in well controlled clinical studies and is manufactured according to the highest quality standards.*

Questions about GINKOBA M/E?  
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**Ginkoba M/E**

Store at room temperature and avoid excessive heat above 104 F (40 C) to maintain optimal freshness.



Unique Standardized Formula  
GK501™ Ginkgo Biloba/G115® Ginseng

**New!**

**Ginkoba M/E** Mental Energy™

▲ MENTAL PERFORMANCE DIETARY SUPPLEMENT

- ▲ Promotes Fast and Accurate Thinking
- ▲ Reduces Mental Fatigue
- ▲ Natural Herbal Extracts

**\$150** Cash Rebate Inside

**40** Suppli-Caps™  
Only Twice Daily!

*Clinically-proven safe & effective*

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G115 and GK501 are trademarks of Pharmaton, Ltd., Switzerland. GINKOBA M/E, Mental Energy and Suppli-Caps are trademarks of Pharmaton Natural Health Products, Division of Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877. Product of Switzerland.

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