

PHARMATON
NATURAL HEALTH PRODUCTS

Rec
1/19/98

Thomas W. Peterson
VICE PRESIDENT, GENERAL MANAGER

1685 '98 FEB 18 A8:52

January 7, 1998

VIA HAND DELIVERY

Linda S. Kahl, Ph.D.
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 Dr. Kahl:

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.

The dietary supplement for which the statements are made is Ginkoba® tablets, which consist principally of standardized ginkgo biloba extract. The statements of nutritional support for this ingredient read as follows:

Mental Performance Dietary Supplement

Improves Memory and Concentration

Enhances Mental Focus

GINKOBA® is a safe and natural way to enhance mental focus and improve memory and concentration.

When taken as directed, GINKOBA's unique herbal extract safely sharpens mental focus, enhances memory and concentration, and helps contribute to an overall sense of well-being by increasing the natural blood flow of oxygen to the brain.

975-0162

LET1123 56545

Linda S. Kahl, Ph.D.
January 7, 1998
Page 2

A copy of the package and container label of the product is attached. This notification amends the prior notification dated October 4, 1995, filed with your office on October 11, 1995.

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.)

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,

A handwritten signature in black ink, appearing to read "Thomas W. Peterson", with a stylized, cursive script.

Thomas W. Peterson

Enclosure

Original plus two copies enclosed

INSTANT COUPON

Save \$1⁰⁰ Now!

Ginkoba™ 36's
Mental Performance
Dietary Supplement

Lift

Lift

Ginkoba

MENTAL PERFORMANCE DIETARY SUPPLEMENT

8A1274

MENTAL ALERTNESS DIETARY SUPPLEMENT
Ginkoba™



Save
\$1⁰⁰
Now!
See top
of box

- ▲ Improves Memory & Concentration
- ▲ Enhances Mental Focus
- ▲ All Natural Herbal Extract



36

TABLETS
40 mg Each

U.S. Patent No. 5,399,348

8A2112

GinkobaTM
MENTAL ALERTNESS DIETARY SUPPLEMENT



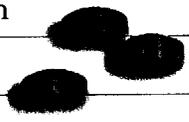
Ginkoba

Ginkoba

MENTAL PERFORMANCE DE

\$2.00
Cash
Rebate
Inside

- ▲ Improves Memory & Concentration
- ▲ Enhances Mental Focus
- ▲ All Natural Herbal Extract



ECONOMY SIZE 90
TABLETS 40 mg Each

U.S. Patent No. 5,399,348

8