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January 15, 2004

Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

JAN 28 2004

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by PhytoPharmica, (a Division of Integrative Therapeutics, Inc.) at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. PhytoPharmica wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Mental Acuity Formula™*	Dietary supplementation with ALA for 2 weeks completely reversed age-associated oxidative stress in elderly small mammals.*	Alpha-Lipoic Acid

I certify that the information contained in this notice is complete and accurate and that PhytoPharmica has substantiation that the statements are truthful and not misleading.

By: 

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/15/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608

Sincerely,



Michael P. Devereux
Chief Financial Officer

Mental Acuity Formula 23p

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13643

825 CHALLENGER DRIVE
GREEN BAY, WI 54311-8328
920-469-9099
TOLL FREE 800-553-2370
FAX 920-469-4418
FAX TOLL FREE 888-311-5657
WWW.PHYTOPHARMICA.COM



January 16, 2004

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RE: Label Claims/Disclaimers

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Mental Acuity Formula™*	An open observational clinical study examined the effect of supplemental ALA on older adults. The subjects received 600 mg of ALA daily. The subjects showed significant improvement in memory and other brain health support.*	Alpha-Lipoic Acid

I certify that the information contained in this notice is complete and accurate and that PhytoPharmica has substantiation that the statements are truthful and not misleading.

By: Robert C. Doster

Robert C. Doster

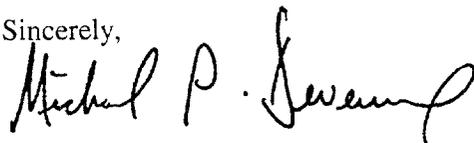
Title: Senior Vice President of Scientific Affairs

Date: 1/16/04

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Sincerely,

A handwritten signature in black ink that reads "Michael P. Devereux". The signature is written in a cursive style with a large initial "M" and a distinct "P".

Michael P. Devereux
Chief Financial Officer



January 17, 2004

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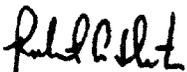
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Mental Acuity Formula™*	In a recent randomized, double blind, placebo controlled crossover study, healthy volunteers were given either ginkgo or placebo for two days. Following baseline measurements, testing was completed at the study's completion. The results demonstrated that ginkgo provided support for healthy memory.*	Ginkgo (Ginkgo biloba) Leaf Extract

I certify that the information contained in this notice is complete and accurate and that PhytoPharmica has substantiation that the statements are truthful and not misleading.

By: 

Robert C. Doster

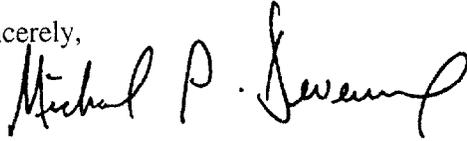
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Date: 1/17/04

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Michael P. Devereux
Chief Financial Officer



PhytoPharmica[®]

NATURAL MEDICINES[™]

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Mental Acuity Formula ^{™*}	A placebo controlled, multi-dose, double blind, balanced, crossover study examined the effect of ginkgo on four cognitive measurements in healthy volunteers. Speed of attention, accuracy of attention, speed of memory, and quality of memory were assessed prior to dosing and at established times thereafter. Compared with placebo, ginkgo provided support of several cognitive measures.* The most striking of these was support of the "speed of attention" score.*	Ginkgo (Ginkgo biloba) Leaf Extract

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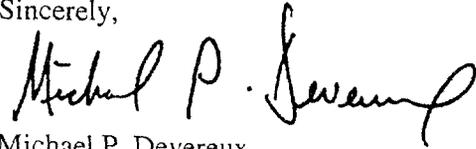
By: Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/17/04

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Michael P. Devereux
Chief Financial Officer



January 18, 2004

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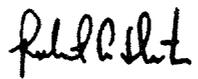
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Mental Acuity Formula™*	Scientists have recognized that individuals with low folic acid serum levels can exhibit health problems.*	Folic Acid

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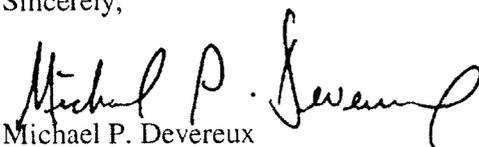
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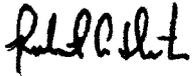
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Mental Acuity Formula™*	An ongoing, large, multi-center study is examining the role of folic acid in age-related memory loss. This study is examining over 600 older adult, volunteer participants. The researchers directing the study are collecting periodic blood samples, data on language and emotional status, and, at death, voluntary donation of the subjects' brain for postmortem study. The results, to date, have demonstrated that subjects with high folic acid levels showed healthy brain supportive effects.*	Folic Acid

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