

March 8, 2002

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition U. S. Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740-3835

RE: Label Claims/Disclaimers

Dear Sir/Madam:

This letter is to notify you that PhytoPharmica (A Division of Integrative Therapeutics, Inc.) at 825 Challenger Drive, Green Bay, Wisconsin 54311 is a manufacturer and has included statements provided for by section 403(r)(6) of the Food, Drug, and Cosmetic Act on the labels of the following product.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	<u>STATEMENTS</u>
PhytoPharmica (A Division of Integrative Therapeutics, Inc.)	Mental Sharpness Formula	Folic Acid, Vitamin B12 (as cyanocobalamin), Vitamin B6 (as pyridoxine HCl), Bacopa monnieri Extract, Alpha Lipoic Acid, Ginkgo Biloba Extract	Dietary Supplement for mild memory problems associated with aging.*

I certify that the information contained in this notice is complete and accurate and that PhytoPharmica (A Division of Integrative Therapeutics, Inc.) has substantiation that the statements are truthful and not misleading.

By:

Robert C. Doster Title: Senior Vice President of Scientific Affairs

Date: 3802

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 469-3608.

Michael P. Devereux Chief Financial Officer Mental Sharpness Formula 1p

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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

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March 9, 2002

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition U. S. Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740-3835

## RE: Label Claims/Disclaimers

Dear Sir/Madam:

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COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
PhytoPharmica (A Division of Integrative Therapeutics, Inc.)	Mental Sharpness Formula	Folic Acid, Vitamin B12 (as cyanocobalamin), Vitamin B6 (as pyridoxine HCl), Bacopa monnieri Extract, Alpha Lipoic Acid, Ginkgo Biloba Extract	Mental Sharpness Formula supplies a unique blend of vitamins and herbs that deliver nutritional support for mild memory problems associated with aging, as well as enhanced focus and concentration*

I certify that the information contained in this notice is complete and accurate and that PhytoPharmica (A Division of Integrative Therapeutics, Inc.) has substantiation that the statements are truthful and not misleading.

Bv:

Robert C. Doster Title: Senior Vice President of Scientific Affairs

Date: 3/9/02

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 469-3608.

Michael P. Devereux Chief Financial Officer Mental Sharpness Formula 2p

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March 10, 2002

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition U. S. Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740-3835

RE: Label Claims/Disclaimers

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COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
PhytoPharmica (A Division of Integrative Therapeutics, Inc.)	Mental Sharpness Formula	Folic Acid, Vitamin B12 (as cyanocobalamin), Vitamin B6 (as pyridoxine HCI), Bacopa monnieri Extract, Alpha Lipoic Acid, Ginkgo Biloba Extract	The key ingredients-Bacopa monnieri extract and alpha lipoic acid-have each been clinically studied to support brain function*

I certify that the information contained in this notice is complete and accurate and that PhytoPharmica (A Division of Integrative Therapeutics, Inc.) has substantiation that the statements are truthful and not misleading.

Bv:

Robert C. Doster Title: Senior Vice President of Scientific Affairs

Date: 310/02

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 469-3608.

Michael P. Devereux

Chief Financial Officer

Mental Sharpness Formula 3p

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March 11, 2002

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition U. S. Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740-3835

RE: Label Claims/Disclaimers

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COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	<u>STATEMENTS</u>
PhytoPharmica (A Division of Integrative Therapeutics, Inc.)	Mental Sharpness Formula	Folic Acid, Vitamin B12 (as cyanocobalamin), Vitamin B6 (as pyridoxine HCl), Bacopa monnieri Extract, Alpha Lipoic Acid, Ginkgo Biloba Extract	These ingredients reduce homocysteine levels*

I certify that the information contained in this notice is complete and accurate and that PhytoPharmica (A Division of Integrative Therapeutics, Inc.) has substantiation that the statements are truthful and not misleading.

By:

Robert C. Doster Title: Senior Vice President of Scientific Affairs

Date: 3/11/02

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 469-3608.

Michael P. Devereux Chief Financial Officer

Mental Sharpness Formula 4p

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



March 12, 2002

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition U. S. Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740-3835

RE: Label Claims/Disclaimers

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COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	<u>STATEMENTS</u>
PhytoPharmica (A Division of Integrative Therapeutics, Inc.)	Mental Sharpness Formula	Folic Acid, Vitamin B12 (as cyanocobalamin), Vitamin B6 (as pyridoxine HCI), Bacopa monnieri Extract, Alpha Lipoic Acid, Ginkgo Biloba Extract	B vitamins and folic acid have been shown to reduce homocysteine levels*

I certify that the information contained in this notice is complete and accurate and that PhytoPharmica (A Division of Integrative Therapeutics, Inc.) has substantiation that the statements are truthful and not misleading.

By:

Robert C. Doster Title: Senior Vice President of Scientific Affairs

3/102 Date: \_\_\_

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 469-3608.

Michael P. Devereux Chief Financial Officer

Mental Sharpness Formula 5p

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March 13, 2002

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COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
PhytoPharmica (A Division of Integrative Therapeutics, Inc.)	Mental Sharpness Formula	Folic Acid, Vitamin B12 (as cyanocobalamin), Vitamin B6 (as pyridoxine HCl), Bacopa monnieri Extract, Alpha Lipoic Acid, Ginkgo Biloba Extract	Low homocysteine levels have been associated with healthy brain function*

I certify that the information contained in this notice is complete and accurate and that PhytoPharmica (A Division of Integrative Therapeutics, Inc.) has substantiation that the statements are truthful and not misleading.

'LU'.UL By:

Robert C. Doster Title: Senior Vice President of Scientific Affairs

Date: 3/13/02

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 469-3608.

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Michael P. Devereux Chief Financial Officer

Mental Sharpness Formula 6p

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