April 8, 2003

Mr. Robert Moore Office of Nutritional Products, Labeling & Dietary Supplements, HFS 811 Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Mr. Moore:

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. 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.

2452

03

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
PhytoPharmica (a Division of Integrative Therapeutics, Inc.).	Hyperimed™	St. John's Wort flower head extract	Clinically proven benefits for overall well- being.*

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.

975 0162 LET 11883

Bv

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

4/8/02 Date:

4252

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

Hyperimed 3p

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

** - **

*

April 9, 2003

6

Mr. Robert Moore Office of Nutritional Products, Labeling & Dietary Supplements, HFS 811 Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Mr. Moore:

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 provid for by section 403(r)(6) of the Food, Drug, and Cosmetic Act on the labels of the following product. 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.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	<u>STATEMENTS</u>
PhytoPharmica (a Division of Integrative Therapeutics, Inc.).	Hyperimed™	St. John's Wort flower head extract	PhytoPharmica's St. John's Wort Extract (300 mg) offers nutritional support for a healthy mental and nervous system, leading to a state of well-being.*

I certify that the information contained in this notice is complete and accurate and that PhytoPharmica 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: 4/9/0.3

825 CHALLENGER DRIVE GREEN BAY, WI 54311-832 920-469-9099 TOLL FREE 800-553-2370 FAX 920-469-4418 FAX TOLL FREE 888-311-5657 If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

. Jevenn Sincerely, Michael P

Michael P. Devereux Chief Financial Officer

đ

*_

4

April 10, 2003

Mr. Robert Moore Office of Nutritional Products, Labeling & Dietary Supplements, HFS 811 Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Mr. Moore:

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 provide for by section 403(r)(6) of the Food, Drug, and Cosmetic Act on the labels of the following product. 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.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
PhytoPharmica (a Division of Integrative Therapeutics, Inc.).	Hyperimed™	St. John's Wort flower head extract	More than 25 double-blind, controlled trials have confirmed this herb's support in stress and mood.*

I certify that the information contained in this notice is complete and accurate and that PhytoPharmica. 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: 4/10/03

825 CHALLENGER DRIVE GREEN BAY, WI 54311-8328 920-469-9099 TOLL FREE 800-553-2370 TAA 720-407-4410 FAX TOLL FREE 888-311-5657 If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

、 ·

Sincerely, Much even

Michael P. Devereux Chief Financial Officer

Silver Miles

, ne

.

.