INTEGRATIVE THERAPEUTICS INC.

回念

**PhytoPharmica** 

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Tyler Encapsulations

YLER

Vitaline Formulas

April 24, 2002

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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

## Notification of structure-function claims

Dear Sir/Madam:

This letter is to notify you that the following products manufactured, packed, and/or distributed by Vitaline Formulas (9725 SW Commerce Circle, Suite A6, Wilsonville, OR 97070) have labels that contain statements provided for by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Vitaline wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and complies with section 403(r)(6) of the act.

Melatonin Forte

Product Name

Natural Sleep Aid for Occasional Sleeplessness\*

Statement

Ingredient(s) to which claim refers Melatonin

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

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Bruce Canvasser, N.D. **Executive Vice President** 

Page 1 of 1

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9725 SW Commerce Circle • Suite A6 • Wilsonville OR 97070 • Phone 503.582.8386 • Fax 503.582.0467



## Vitamins

Herbs



We Make Quality Affordable

Food

Cosmetics



April 23, 2002

MAY 0 a 2002

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

## Re: 21 U.S.C. Section 343(r)(6), Notification of Statements on Dietary Supplements

Dear Sir/Madam:

I hereby notify the Food and Drug Administration ("FDA") of the use of statements of nutritional support in the labeling of Curcumin, 800 mg Vcaps, an herbal supplement.

Statements being made in the labeling of Curcumin, 800 mg Vcaps

(1 Curcumin is the major component of Turmeric (*Curcuma longa* L.), which has a long history of use in India and Southeast Asia as a medicinal herb for a wide variety of health conditions. Extensive scientific research on Curcumin has demonstrated its potent anti-oxidant properties. Through its anti-oxidant mechanisms, Curcumin supports colon health, exerts neuroprotective activity, and helps maintain a healthy cardiovascular system.

To the best of my knowledge, and based upon information and belief present at the time of the executing of this notice, I certify that the above information is accurate and complete. NOW Foods possesses substantiation that the statements are truthful and not misleading.

> Jim Roza Director, Quality Assurance NOW Foods 395 S. Glen Ellyn Rd. Bloomingdale, IL 60108

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