

### INTEGRATIVE THERAPEUTICS INC.

NF Formulas PhytoPharmica
Tyler Encapsulations Vitaline Formulas

# ENZYMATIC THERAPY' & PHYTOPHARMICA'

9755 SW Commerce Circle, Suite B2
Wilsonville, OR 97070
P: 503.582.8386 F: 503.582.0467

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 F: 888.570.6460 (Enzymatic) P: 920.469.9099 F. 920.469.4418 (Phyto)

2006

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ENZYMATIC THERAPY

January 16, 2006

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

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 Enzymatic Therapy, 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. Enzymatic Therapy, Inc. 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.

PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM: REFERS
Super Milk Thistle® X	Milk thistle enhances bile	Milk Thistle (Silybum marianum) Fruit
_	production, which supports	Phytosome, Artichoke (Cynara scolymus) Leaf
	healthy digestion and	Extract, Dandelion (Taraxacum officinale) Root
	detoxification.*	Extract, Licorice (Glycyrrhiza glabra) Root and
		Rhizome Extract

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

By: KLPCILL

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 1-16-06

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

Sincerely,

Chief Operations Officer

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Super Milk Thistle® X	Dandelion enhances immune	Dandelion (Taraxacum officinale) Root
_	function and has specific effects	Extract
	on TNF alpha activity.*	

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

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-	Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 1-16-06

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Sincerely.

Michael P. Devereux Chief Operations Officer



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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Super Milk Thistle® X	Supper Milk Thistle X supports	Milk Thistle (Silybum marianum) Fruit
	immune system function by	Phytosome, Artichoke (Cynara scolymus) Leaf
	promoting an increase in	Extract, Dandelion (Taraxacum officinale) Root
	interferon gamma, interleukin	Extract, Licorice (Glycyrrhiza glabra) Root and
	(IL)-4 and IL-10 cytokines.*	Rhizome Extract

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Robert C. Doster

Title: Senior Vice President of Scientific Affairs

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Super Milk Thistle® X	Artichoke promotes bile flow, which supports healthy gastrointestinal function.*	Artichoke (Cynara scolymus) Leaf Extract

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