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INTEGRATIVE THERAPEUTICS INC."

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Tyler Encapsulations * Vitaline Formulas

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 * F: 503.582.0467 ENZYMATIC THERAPY
&
PHYTOPHARMICA*

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)

1729 6 JAN 23 P2:06

January 11, 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

JAN 17 2006

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
Cell Forte®	Purple Mushroom Defense™, Cell	Organic Purple Kculli Corn Agaricus (Agaricsu
Purple	Forte's first line of defense, helps you	blazei), Organic Purple Kculli Corn Matiake
Mushroom	take control naturally with 4 organic	(Grifola frondosus), Organic Purple Kculli Corn
Defense ^{TM*}	powerhouse mushrooms.*	Coryolis (Tremetes versicolor), Organic Purple
	,	Kculli Corn Reishi (Ganoderma lucidum), Organic
		Purple Kculli Corn 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: KURILL

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/11/06

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

Sincerely.

Michael P. Devereux Chief Operations Officer

975 0162

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INTEGRATIVE THERAPEUTICS INC."
NF Formulas * PhytoPharmica

Tyler Encapsulations & Vitaline Formulas

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

NZYMATIC THERAPY & PHYTOPHARMICA*

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)

January 11, 2006

What Better feels like."

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:

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Cell Forte®	Purple Mushroom Defense	Organic Purple Kculli Corn Agaricus (Agaricsu blazei),
Purple	contains antioxidant-rich,	Organic Purple Kculli Corn Matiake (Grifola frondosus),
Mushroom	organic purple kculli corn, for	Organic Purple Kculli Corn Coryolis (Tremetes versicolor),
Defense ^{TM*}	serious deep immune	Organic Purple Kculli Corn Reishi (Ganoderma lucidum),
	support.*	Organic Purple Kculli Corn 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: KLICHE

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/11/06

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

Sincerely.



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ENZYMATIC THERAPY

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)

January 11, 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:

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Cell Forte®	Providing the perfect	Organic Purple Kculli Corn Agaricus (Agaricsu blazei),
Purple	mushroom growth medium,	Organic Purple Kculli Corn Matiake (Grifola frondosus),
Mushroom	the purple kculli corn serves as	Organic Purple Kculli Corn Coryolis (Tremetes versicolor),
Defense TM *	the mushroom blend's power	Organic Purple Kculli Corn Reishi (Ganoderma lucidum),
	source for ultimate antioxidant	Organic Purple Kculli Corn Extract
	protection.*	

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.

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/1/06

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

Sincerely.

Michael P. Devereux



ENZYMATIC THERADY INDERPORATED

NF Formulas « PhytoPharmica Tyler Encapsulations * Vitaline Formulas 9755 SW Commerce Circle, Suite B2

INTEGRATIVE THERAPEUTICS INC.

Wilsonville, OR 97070 P: 503.582.8386 * F: 503.582.0467

PHYTOPHARMICA

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)

January 11, 2006

What Better feels like."

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

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Cell Forte®	Boosting the body's natural	Organic Purple Kculli Corn Agaricus (Agaricsu blazei),
Purple	defenses against harmful free-	Organic Purple Kculli Corn Matiake (Grifola frondosus),
Mushroom	radicals.*	Organic Purple Kculli Corn Coryolis (Tremetes versicolor),
Defense TM *		Organic Purple Kculli Corn Reishi (Ganoderma lucidum),
		Organic Purple Kculli Corn 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:

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date:

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

Sincerely,



NF Formulas * PhytoPharmica Tyler Encapsulations « Vitaline Formulas

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

INTEGRATIVE THERAPEUTICS INC.

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)

INCORPORATED

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January 11, 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

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PRODUCT	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE
NAME		<u>CLAIM REFERS</u>
Cell Forte®	Unlike other "kitchen sink" formulas, Purple	Organic Purple Kculli Corn Agaricus
Purple	Mushroom Defense is empowered with the 4	(Agaricsu blazei), Organic Purple Kculli
Mushroom	most clinically studied species of mushroom-all	Corn Matiake (Grifola frondosus),
Defense TM *	grown on antioxidant-rich Peruvian purple kculli	Organic Purple Kculli Corn Coryolis
	corn in a Certified Organic facility for targeted	(Tremetes versicolor), Organic Purple
	deep immune support.*	Kculli Corn Reishi (Ganoderma lucidum),
		Organic Purple Kculli Corn 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.

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

1/11/06

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

Sincerely

Michael P. Devereux



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INTEGRATIVE THERAPEUTICS INC."

NF Formulas & PhytoPharmica

Tyler Encapsulations & Vitaline Formulas

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ENZYMATIC THERAPY* & PHYTOPHARMICA*

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)

January 11, 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:

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Cell Forte®	The special blend features high levels of naturally	Organic Purple Kculli Corn Agaricus
Purple	occurring beta-glucans, arabinoxylans, and	(Agaricsu blazei), Organic Purple Kculli
Mushroom	arabinogalactans-types of polysaccharides that	Corn Matiake (Grifola frondosus),
Defense ^{TM*}	not only store energy, but also help strengthen the	Organic Purple Kculli Corn Coryolis
	immune system and balance your body's natural	(Tremetes versicolor), Organic Purple
	defenses.*	Kculli Corn Reishi (Ganoderma lucidum),
		Organic Purple Kculli Corn 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:	fillil
Title:	Robert C. Doster Senior Vice President of Scientific Affairs
Date:	1/11/06

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

Sincerely,

Michael P. Devereux

Chief Operations Officer



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ENZYMATIC THERAPY & Phytopharmica*

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)

January 12, 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

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Cell Forte®	Synergistically, all components activate	Organic Purple Kculli Corn Agaricus
Purple	antioxidant power to amplify your immune	(Agaricsu blazei), Organic Purple Kculli
Mushroom	functions and mobilize the natural killer cell	Corn Matiake (Grifola frondosus),
Defense ^{TM*}	"minutemen" into action.* As the troops	Organic Purple Kculli Corn Coryolis
1	scavenges free-radicals, it profoundly enhances	(Tremetes versicolor), Organic Purple
	your body's natural defenses.*	Kculli Corn Reishi (Ganoderma lucidum),
		Organic Purple Kculli Corn 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:	<u>.</u>
Robert C. Doster	

Title: Senior Vice President of Scientific Affairs

Date: 1/12/06

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

Sincerely,



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INTEGRATIVE THERAPEUTICS INC."

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

ENZYMATIC THERAPY' & PHYTOPHARMICA'

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)

January 12, 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

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Cell Forte® Purple	Protects against free radicals*	Organic Purple Kculli Corn Agaricus (Agaricsu
Mushroom Defense ^{TM*}	,	blazei)

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: Kuldlillet

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/12/06

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Sincerely.



INTEGRATIVE THERAPEUTICS INC." NF Formulas « PhytoPharmica

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PHYTOPHARMICA'

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)

What Better feels like.™ January 12, 2006

ENZYMATIC THERADY

INCORPORATED

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PRODUCT NAME	STATEMENTS.	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Cell Forte® Purple	Increases natural killer cell	Organic Pruple Kculli Corn Coryolis (Tremetes
Mushroom Defense™*	activity.*	versicolor)

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:

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/12/06

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Sincerely,

Michael P. Devereux



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INTEGRATIVE THERAPEUTICS INC."

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ENZYMATIC THERAPY & PHYTOPHARMICA

January 12, 2006

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Cell Forte® Purple	Stimulates deep immune activity.*	Organic Purple Kculli Corn Matiake (Grifola
Mushroom Defense TM *		frondosus)

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: Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/12/06

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

Sincerely,



ENZYMATIC THERADY NECRPORATED

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INTEGRATIVE THERAPEUTICS INC." NF Formulas * PhytoPharmica Tyler Encapsulations . Vitaline Formulas

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Cell Forte® Purple	Promotes longevity*	Organic Purple Kculli Corn Reishi (Ganoderma
Mushroom Defense TM *		lucidum)

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:

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Never f

Date: 1/12/010

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INTEGRATIVE THERAPEUTICS INC."

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ENZYMATIC THERAPY

TIC THERAPY

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White Beller Jees inc.

January 12, 2006

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PRODUCT NAME	The state of the s	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Cell Forte® Purple	Features ultimate antioxidant	Organic Purple Kculli Corn Extract
Mushroom DefenseTM*	strength.*	

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.

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/12/06

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