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**PhytoPharmica** 

Tyler Encapsulations

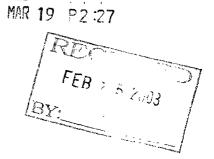
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Vitaline Formulas

03

February 17, 2003

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 Tyler Encapsulations (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. Tyler 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.

Product Name		Statement	Ingredient(s) to which claim refers
•	Tyler: Vision Complex	For support of vision and eye health.*	Vitamin A Vitamin C Vitamin E Riboflavin Folic Acid Vitamin B12 Zinc Selenium Copper Manganese Taurine Bilberry Fruit Extract Lutein Zeaxanthin

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

Mario Roxas, N.D.

Director of Technical Services

Date

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Product Name		Statement	Ingredient(s) to which claim refers
•	Tyler: Vision Complex	For the support of eye health and visual acuity.*	Vitamin A Vitamin C Vitamin E Riboflavin Folic Acid Vitamin B12 Zinc Selenium Copper Manganese Taurine Bilberry Fruit Extract Lutein Zeaxanthin

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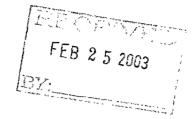
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Product Name		Statement	Ingredient(s) to which claim refers
•	Tyler: Vision Complex	For the support of eye health and visual acuity.*	Vitamin A Vitamin C Vitamin E Riboflavin Folic Acid Vitamin B12 Zinc Selenium Copper Manganese Taurine Bilberry Fruit Extract Lutein Zeaxanthin

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Product Name		Statement	Ingredient(s) to which claim refers
•	Tyler: Vision Complex	A rich supply of nutrients to support eye health.*	Vitamin A Vitamin C Vitamin E Riboflavin Folic Acid Vitamin B12 Zinc Selenium Copper Manganese Taurine Bilberry Fruit Extract Lutein Zeaxanthin

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Product Name		Statement	Ingredient(s) to which claim refers
•	Tyler: Vision Complex	Carotenoids (plant pigments) with proven anti-oxidative properties.*	Vitamin A Vitamin C Vitamin E Riboflavin Folic Acid Vitamin B12 Zinc Selenium Copper Manganese Taurine Bilberry Fruit Extract Lutein Zeaxanthin

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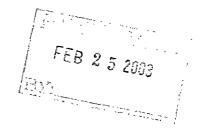
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Product Name		Statement	Ingredient(s) to which claim refers
•	Tyler: Vision Complex	Because the body does not synthesize lutein or zeaxanthin, these nutrients must come from diet and supplementation.*	Vitamin A Vitamin C Vitamin E Riboflavin Folic Acid Vitamin B12 Zinc Selenium Copper Manganese Taurine Bilberry Fruit Extract Lutein Zeaxanthin

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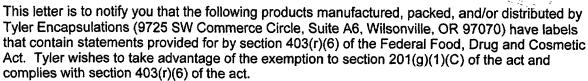
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•	, , ,		
Product Name	Statement	Ingredient(s) to which claim refers	
Tyler: Vision Complex	The amount of lutein and zeaxanthin in the retinal layer, known as macular pigment density, appears to be key to eye health and has been experimentally increased by lutein and zeaxanthin supplementation.*	Vitamin A Vitamin C Vitamin E Riboflavin Folic Acid Vitamin B12 Zinc Selenium Copper Manganese Taurine Bilberry Fruit Extract Lutein Zeaxanthin	

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Product Name		Statement	Ingredient(s) to which claim refers
•	Tyler: Vision Complex	Precursors of Vitamin A that the body converts into active vitamin A.*	Vitamin A Vitamin C Vitamin E Riboflavin Folic Acid Vitamin B12 Zinc Selenium Copper Manganese Taurine Bilberry Fruit Extract Lutein Zeaxanthin

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Product Name		Statement	Ingredient(s) to which claim refers
•	Tyler: Vision Complex	Vitamin A appears to promote clear vision.*	Vitamin A Vitamin C Vitamin E Riboflavin Folic Acid Vitamin B12 Zinc Selenium Copper Manganese Taurine Bilberry Fruit Extract Lutein Zeaxanthin

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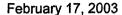


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Product Name	Statement	Ingredient(s) to which claim refers
Tyler: Vision Complex	Vitamin C is an essential nutrient and important antioxidant found in high concentrations in the lens of the human eye.*	Vitamin A Vitamin C Vitamin E Riboflavin Folic Acid Vitamin B12 Zinc Selenium Copper Manganese Taurine Bilberry Fruit Extract
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Product Name		Statement	ingredient(s) to which claim refers
•	Tyler: Vision Complex	Long term supplementation with Vitamin C has been associated with maintaining healthy vision.*	Vitamin A Vitamin C Vitamin E Riboflavin Folic Acid Vitamin B12 Zinc Selenium Copper Manganese Taurine Bilberry Fruit Extract Lutein Zeaxanthin

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Product Name		Statement	Ingredient(s) to which claim refers
•	Tyler: Vision Complex	Vitamin E is an essential antioxidant.*	Vitamin A Vitamin C Vitamin E Riboflavin Folic Acid Vitamin B12 Zinc Selenium Copper Manganese Taurine Bilberry Fruit Extract Lutein Zeaxanthin

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Product Name		Statement	Ingredient(s) to which claim refers
•	Tyler: Vision Complex	Higher Vitamin E concentrations have been associated with healthy, clear vision in the elderly.*	Vitamin A Vitamin C Vitamin E Riboflavin Folic Acid Vitamin B12 Zinc Selenium Copper Manganese Taurine Bilberry Fruit Extract Lutein Zeaxanthin

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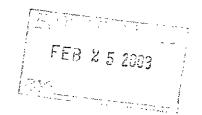
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Pro	duct Name	Statement	Ingredient(s) to which claim refers
•	Tyler: Vision Complex	Higher intake of Vitamin E may increase the amount of Vitamin E in the retina.*	Vitamin A Vitamin C Vitamin E Riboflavin Folic Acid Vitamin B12 Zinc Selenium Copper Manganese Taurine Bilberry Fruit Extract Lutein Zeaxanthin

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Pro	oduct Name	Statement	Ingredient(s) to which claim refers
•	Tyler: Vision Complex	Bilberry has strong associations with eye health.*	Vitamin A Vitamin C Vitamin E Riboflavin Folic Acid Vitamin B12 Zinc Selenium Copper Manganese Taurine Bilberry Fruit Extract Lutein Zeaxanthin

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Product Name		Statement	Ingredient(s) to which claim refers
•	Tyler: Vision Complex	Anthocyanins, bilberry's key active ingredient, appear to enhance microcirculation in the eye.*	Vitamin A Vitamin C Vitamin E Riboflavin Folic Acid Vitamin B12 Zinc Selenium Copper Manganese Taurine Bilberry Fruit Extract Lutein Zeaxanthin

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Pro	duct Name	Statement	Ingredient(s) to which claim refers
•	Tyler: Vision Complex	Eye health appears to respond well to synergistic combinations of nutrients with anti-oxidative properties or those nutrients that support these properties.*	Vitamin A Vitamin C Vitamin E Riboflavin Folic Acid Vitamin B12 Zinc Selenium Copper Manganese Taurine Bilberry Fruit Extract Lutein Zeaxanthin

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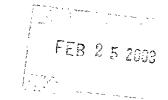
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Product Name		Statement	Ingredient(s) to which claim refers
•	Tyler: Vision Complex	Combinations of Vitamins C and E, Vitamin B2, (riboflavin), folic acid, beta-carotene, zinc, and copper have been associated with healthy vision function as have combination of pro-vitamin A Carotenoids, Vitamin E, and zinc.*	Vitamin A Vitamin C Vitamin E Riboflavin Folic Acid Vitamin B12 Zinc Selenium Copper Manganese Taurine Bilberry Fruit Extract Lutein Zeaxanthin

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Product Name		duct Name	Statement	Ingredient(s) to which claim refers
	•	Tyler: Vision Complex	Glutathione levels have been implicated in antioxidant capabilities within the lens of the eye.*	Vitamin A Vitamin C Vitamin E Riboflavin Folic Acid Vitamin B12 Zinc Selenium Copper Manganese Taurine Bilberry Fruit Extract Lutein Zeaxanthin

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Product Name		Statement	Ingredient(s) to which claim refers
•	Tyler: Vision Complex	Recommended balance of zeaxanthin and lutein in amounts that supply a nutritional supplement targeting eyes.*	Vitamin A Vitamin C Vitamin E Riboflavin Folic Acid Vitamin B12 Zinc Selenium Copper Manganese Taurine Bilberry Fruit Extract Lutein Zeaxanthin

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Product Name		Statement	Ingredient(s) to which claim refers
•	Tyler: Vision Complex	Vitamins E and C and selenium all enhance glutathione levels.*	Vitamin A Vitamin C Vitamin E Riboflavin Folic Acid Vitamin B12 Zinc Selenium Copper Manganese Taurine Bilberry Fruit Extract Lutein Zeaxanthin

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Product Name	Statement	Ingredient(s) to which claim refers
Tyler: Vision Complex	Supports healthy vision.*	Vitamin A Vitamin C Vitamin E Riboflavin Folic Acid Vitamin B12 Zinc Selenium Copper Manganese Taurine Bilberry Fruit Extract Lutein Zeaxanthin

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

Mario Rexas, N.D.

Director of Technical Services









**NF** Formulas

PhytoPharmica

Tyler Encapsulations

Vitaline Formulas

February 17, 2003

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 Tyler Encapsulations (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. Tyler 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.

Product Name		Statement	Ingredient(s) to which claim refers
•	Tyler: Vision Complex	Promotes eye health.*	Vitamin A Vitamin C Vitamin E Riboflavin Folic Acid Vitamin B12 Zinc Selenium Copper Manganese Taurine Bilberry Fruit Extract Lutein

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

Mario Roxas, N.D.

Director of Technical Services

Date

Zeaxanthin

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