



NF Formulas



PhytoPharmica

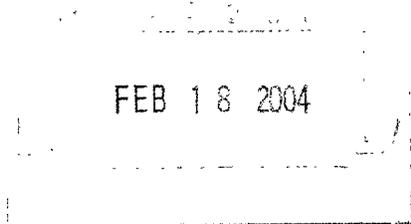


Tyler Encapsulations



Vitaline Formulas

1721 51 10 04 11 10



January 15, 2004

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

Notification of structure-function claims

Dear Sir:

This letter is to notify you that the following product manufactured, packed, and/or distributed by Tyler Encapsulations (9755 SW Commerce Circle, Suite B2, Wilsonville, OR 97070) has a label that contains a statement provided for by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Tyler Encapsulations 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.

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.

Table with 3 columns: Product Name, Statement, and Ingredient(s) to which claim refers. Row 1: Cardi-E, 'Research, however, has shown that a natural mixture of tocopherols may be more useful than pure alpha-tocopherol. †', Vitamin E (As alpha Tocopherol) Mixed Natural Tocopherols: Gamma Tocopherol, Delta Tocopherol, Alpha Tocopherol, Canola Oil Containing: (Oleic Acid, Linoleic Acid, Alpha-Linoleic Acid)

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

Handwritten signature of Mario Roxas

Mario Roxas, N.D. Director of Scientific and Technical Affairs

Date 1/15/04

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Product Name	Statement	Ingredient(s) to which claim refers
Cardi-E	" Free radicals are highly reactive molecules created as byproducts of metabolism. †"	Vitamin E (As alpha Tocopherol) Mixed Natural Tocopherols: Gamma Tocopherol Delta Tocopherol Alpha Tocopherol Canola Oil Containing: (Oleic Acid, Linoleic Acid, Alpha-Linoleic Acid)

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 Mario Roxas, N.D.
 Director of Scientific and Technical Affairs

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Product Name	Statement	Ingredient(s) to which claim refers
Cardi-E	" Extensively researched by cardiovascular medicine expert, Tom Saldeen, MD, Ph.D. †"	Vitamin E (As alpha Tocopherol) Mixed Natural Tocopherols: Gamma Tocopherol Delta Tocopherol Alpha Tocopherol Canola Oil Containing: (Oleic Acid, Linoleic Acid, Alpha-Linoleic Acid)

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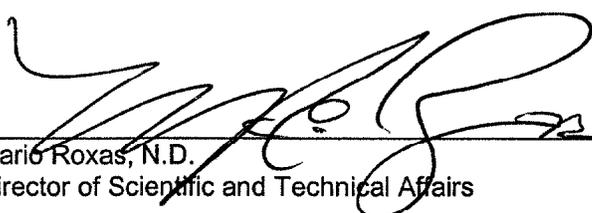
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Product Name	Statement	Ingredient(s) to which claim refers
Cardi-E	" Gamma tocopherol may be even more supportive of cardiac health than alpha. †"	Vitamin E (As alpha Tocopherol) Mixed Natural Tocopherols: Gamma Tocopherol Delta Tocopherol Alpha Tocopherol Canola Oil Containing: (Oleic Acid, Linoleic Acid, Alpha-Linoleic Acid)

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Product Name	Statement	Ingredient(s) to which claim refers
Cardi-E	" Vitamin E protects us against damage caused by excess free radicals. †"	Vitamin E (As alpha Tocopherol) Mixed Natural Tocopherols: Gamma Tocopherol Delta Tocopherol Alpha Tocopherol Canola Oil Containing: (Oleic Acid, Linoleic Acid, Alpha-Linoleic Acid)

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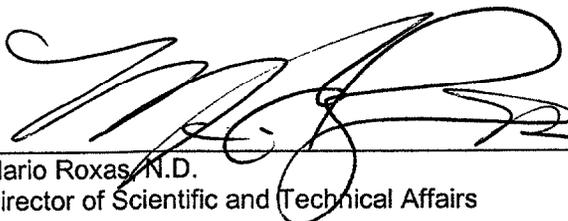
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Product Name	Statement	Ingredient(s) to which claim refers
Cardi-E	" Clinically recognized to be cardio-supportive when used in conjunction with Eskimo-3. †"	Vitamin E (As alpha Tocopherol) Mixed Natural Tocopherols: Gamma Tocopherol; Delta Tocopherol Alpha Tocopherol Canola Oil Containing: (Oleic Acid, Linoleic Acid, Alpha-Linoleic Acid)

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Cardi-E	"Cardio fitness. †"	Vitamin E (As alpha Tocopherol) Mixed Natural Tocopherols: Gamma Tocopherol Delta Tocopherol Alpha Tocopherol Canola Oil Containing: (Oleic Acid, Linoleic Acid, Alpha-Linoleic Acid)

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Cardi-E	"(Gamma tocopherol may be even more supportive of cardiac health than alpha). These components work together and must be present to be optimally utilized by the body. †"	Vitamin E (As alpha Tocopherol) Mixed Natural Tocopherols: Gamma Tocopherol Delta Tocopherol Alpha Tocopherol Canola Oil Containing: (Oleic Acid, Linoleic Acid, Alpha-Linoleic Acid)

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Product Name	Statement	Ingredient(s) to which claim refers
Cardi-E	"Cardi-E uses the clinically evaluated ratio of vitamin E and mixed tocopherol used in studies to support cardiovascular health. †"	Vitamin E (As alpha Tocopherol) Mixed Natural Tocopherols: Gamma Tocopherol Delta Tocopherol Alpha Tocopherol Canola Oil Containing: (Oleic Acid, Linoleic Acid, Alpha-Linoleic Acid)

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