



NF Formulas



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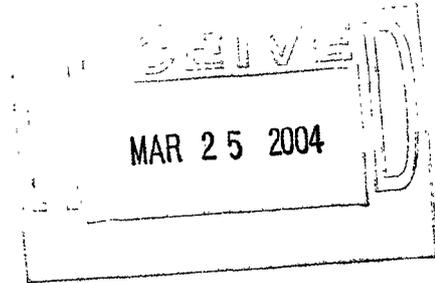


Tyler Encapsulations



Vitaline Formulas

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February 20, 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.

Product Name	Statement	Ingredient(s) to which claim refers
Eskimo-3®	Clinically studied to support cardiovascular health, Eskimo-3® has natural antioxidants to maintain stability, quality and freshness for optimal results.†	Vitamin E (Mixed Tocopherols) Omega-3 Fatty Acids EPA (Eicosapentaenoic Acid) DHA (Docosahexaenoic 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.

Mario Roxas, N.D. Director of Scientific and Technical Affairs Date 2/20/04

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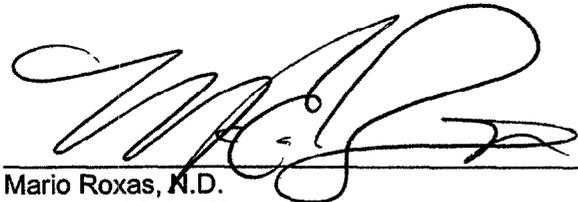
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Product Name	Statement	Ingredient(s) to which claim refers
Eskimo-3®	Published clinical studies have shown that Eskimo-3® helps maintain healthy cholesterol levels that are already within normal range.†	Vitamin E (Mixed Tocopherols) Omega-3 Fatty Acids EPA (Eicosapentaenoic Acid) DHA (Docosahexaenoic 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.


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


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Product Name	Statement	Ingredient(s) to which claim refers
Eskimo-3®	Eskimo-3® has been shown to significantly increase blood levels of EPA and DHA. Benefits associated with these increases in omega-3 fatty acids include: support for healthy homocysteine levels, retention of healthy cholesterol levels that are already within normal limits, retention of healthy blood pressure, supporting healthy circulation, maintaining healthy lipoprotein levels, and protecting LDL from unfavorable oxidation.†	Vitamin E (Mixed Tocopherols) Omega-3 Fatty Acids EPA (Eicosapentaenoic Acid) DHA (Docosahexaenoic Acid)

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2/20/04

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Product Name	Statement	Ingredient(s) to which claim refers
Eskimo-3®	Published clinical studies have shown that dietary supplementation with Eskimo-3® helps to maintain healthy levels of blood lipids.†	Vitamin E (Mixed Tocopherols) Omega-3 Fatty Acids EPA (Eicosapentaenoic Acid) DHA (Docosahexaenoic Acid)

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Product Name	Statement	Ingredient(s) to which claim refers
Eskimo-3®	Saturated straight fatty acids are closely packed together in the cell wall, which becomes stiff, while curved fatty acids such as EPA and DHA take up more space so subsequently the cell walls are more flexible. This flexibility helps support healthy joint function as well as skin and blood vessel elasticity.†	Vitamin E (Mixed Tocopherols) Omega-3 Fatty Acids EPA (Eicosapentaenoic Acid) DHA (Docosahexaenoic Acid)

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Product Name	Statement	Ingredient(s) to which claim refers
Eskimo-3®	Research also indicates that Eskimo-3® helps provide nutritional support for cardiovascular function.†	Vitamin E (Mixed Tocopherols) Omega-3 Fatty Acids EPA (Eicosapentaenoic Acid) DHA (Docosahexaenoic Acid)

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Product Name	Statement	Ingredient(s) to which claim refers
Eskimo-3®	Tyler Encapsulations has developed scientific solutions specifically designed to provide the nutritional support you need to ensure optimal cardiovascular health, maintain essential fats/lipid levels, support healthy circulation, and retain healthy blood pressure already within the normal range.†	Vitamin E (Mixed Tocopherols) Omega-3 Fatty Acids EPA (Eicosapentaenoic Acid) DHA (Docosahexaenoic Acid)

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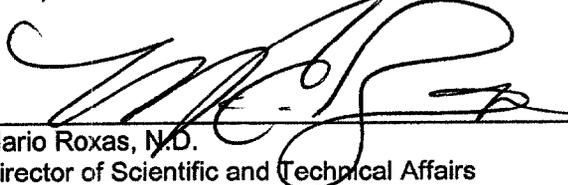
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Product Name	Statement	Ingredient(s) to which claim refers
Eskimo-3®	Research has demonstrated the efficacy of marine fish oils and their fatty acid constituents in support heart health.†	Vitamin E (Mixed Tocopherols) Omega-3 Fatty Acids EPA (Eicosapentaenoic Acid) DHA (Docosahexaenoic Acid)

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Product Name	Statement	Ingredient(s) to which claim refers
Eskimo-3®	These heart smart products from Tyler Encapsulations support your cardiovascular system.†	Vitamin E (Mixed Tocopherols) Omega-3 Fatty Acids EPA (Eicosapentaenoic Acid) DHA (Docosahexaenoic Acid)

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Product Name	Statement	Ingredient(s) to which claim refers
Eskimo-3®	Support for cardiovascular function, skin, and joint health.†	Vitamin E (Mixed Tocopherols) Omega-3 Fatty Acids EPA (Eicosapentaenoic Acid) DHA (Docosahexaenoic Acid)

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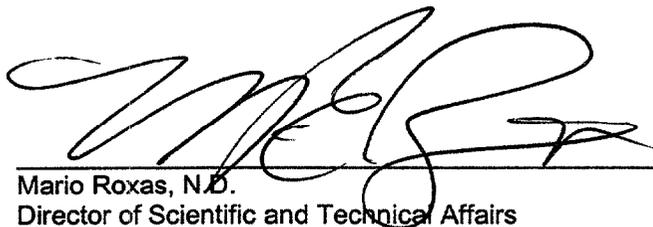
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Product Name	Statement	Ingredient(s) to which claim refers
Eskimo-3®	DHA is also important for the development and maintenance of neural structures such as the retina and brain.†	Vitamin E (Mixed Tocopherols) Omega-3 Fatty Acids EPA (Eicosapentaenoic Acid) DHA (Docosahexaenoic Acid)

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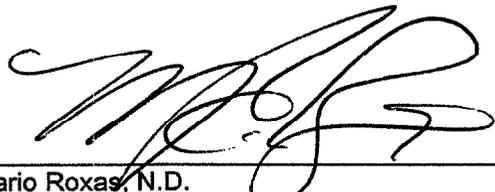
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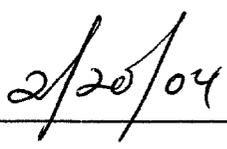
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Product Name	Statement	Ingredient(s) to which claim refers
Eskimo-3®	Dietary supplement with fish oils containing Omega-3 fatty acids has also been shown to provide nutritional support for joints and skin.†	Vitamin E (Mixed Tocopherols) Omega-3 Fatty Acids EPA (Eicosapentaenoic Acid) DHA (Docosahexaenoic Acid)

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