



NF Formulas



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Tyler Encapsulations

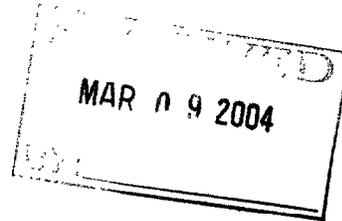


Vitaline Formulas

975 0162 TEL 503.582.8386 FAX 503.582.0467

February 20, 2004

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



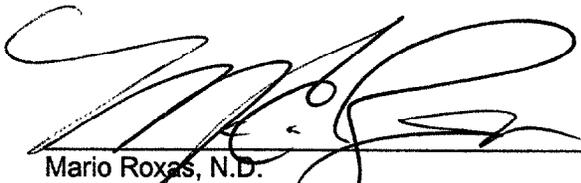
Notification of structure-function claims

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®	Research also indicates that Eskimo-3® provides nutritional support for healthy cardiovascular function.†	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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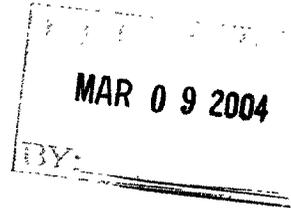
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Product Name	Statement	Ingredient(s) to which claim refers
Eskimo-3®	Dietary supplementation with Eskimo-3® helps to maintain normal levels of blood lipids.†	Vitamin E (Mixed Tocopherols) Omega-3 Fatty Acids EPA (Eicosapentaenoic Acid) DHA (Docosahexaenoic Acid)

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

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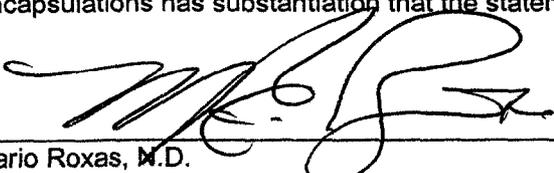
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Product Name	Statement	Ingredient(s) to which claim refers
Eskimo-3®	We may be young at heart, but our hearts aren't getting any younger. That's why we use the Whole Heart System from Tyler Encapsulations, a simple 4-step program that delivers the nutrition our heart desires.†	Vitamin E (Mixed Tocopherols) Omega-3 Fatty Acids EPA (Eicosapentaenoic Acid) DHA (Docosahexaenoic Acid)

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



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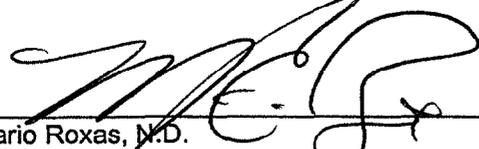
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Product Name	Statement	Ingredient(s) to which claim refers
Eskimo-3®	Haglund, et al showed the effects of Eskimo-3® versus placebo in a clinical trial, which demonstrated superior support for maintaining healthy blood pressure that is already within normal limits.†	Vitamin E (Mixed Tocopherols) Omega-3 Fatty Acids EPA (Eicosapentaenoic Acid) DHA (Docosahexaenoic Acid)

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

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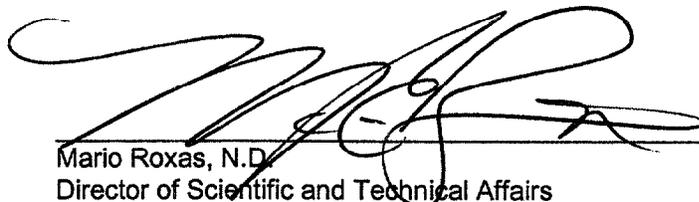
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Product Name	Statement	Ingredient(s) to which claim refers
Eskimo-3®	Natural Stable Fish Oil supplement. Clinically Studied to support cardiovascular health.†	Vitamin E (Mixed Tocopherols) Omega-3 Fatty Acids EPA (Eicosapentaenoic Acid) DHA (Docosahexaenoic Acid)

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

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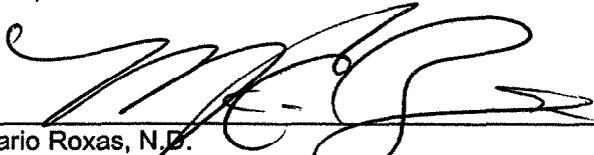
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Product Name	Statement	Ingredient(s) to which claim refers
Eskimo-3®	Clinical studies show that Eskimo-3® better supports healthy lipoprotein (a) [Lp(a)] levels than highly purified fish oil (HPFO).†	Vitamin E (Mixed Tocopherols) Omega-3 Fatty Acids 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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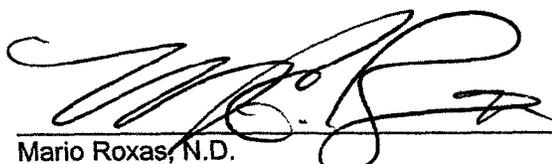
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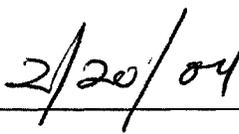
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Product Name	Statement	Ingredient(s) to which claim refers
Eskimo-3®	Eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) are examples of omega-3 fatty acids. EPA is a precursor for the formation of prostaglandins that have beneficial effects on the liver, immune and cardiovascular systems.†	Vitamin E (Mixed Tocopherols) Omega-3 Fatty Acids EPA (Eicosapentaenoic Acid) DHA (Docosahexaenoic Acid)

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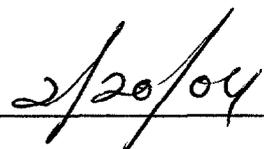
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Product Name	Statement	Ingredient(s) to which claim refers
Eskimo-3®	Eskimo-3® provides support for musculoskeletal and joint health.†	Vitamin E (Mixed Tocopherols) Omega-3 Fatty Acids EPA (Eicosapentaenoic Acid) DHA (Docosahexaenoic Acid)

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Product Name	Statement	Ingredient(s) to which claim refers
Eskimo-3®	Research indicates that Eskimo-3® helps to 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®	Dietary supplementation with fish oil containing omega-3® fatty acids has 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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Product Name	Statement	Ingredient(s) to which claim refers
Eskimo-3®	Tyler Encapsulation's targeted heart products help support your cardiovascular system and keeps it strong!†	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®	Five separate studies on Eskimo-3® showed support for healthy circulation.†	Vitamin E (Mixed Tocopherols) Omega-3 Fatty Acids EPA (Eicosapentaenoic Acid) DHA (Docosahexaenoic Acid)

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