Rec'd 9-10-01

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September 4, 2001

Re: Change of Trade Name and Manufacturer for SeaGoldTM DHA-rich oil

Division of Standards and Labeling Regulations Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-820) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C Street, SW Washington, DC 20204

To the Food and Drug Administration (FDA):

This communication is to inform you of a change in the trade name and ownership of a dietary ingredient that was the subject of a December 19,1997 Notification of a New Dietary Ingredient, (SeaGoldTM DHA-rich oil) submitted by Wayne Stargel, Pharm.D, Nutrition and Consumers Products, Monsanto Company.

All facets of the notification, identified as Docket No. 95S-0316, remain unchanged with the exception of the following: change in tradename, change in the manufacturer, and a new contact person.

Your file will be accurate and complete with the following commercial/administrative changes:

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Trade name:

SeaGoldTM DHA-rich Oil

Manufacturer:

Monsanto Company 800 N. Lindbergh Blvd. St. Louis, MO 63167

Contact:

Robert C. Peterson Monsanto Company Worldwide Regulatory Affairs 5200 Old Orchard Road Skokie, IL 60077 New

DHA GoldTM Marine Microalgae Oil

OmegaTech, Inc. 4909 Nautilus Court N. Suite 208 Boulder, CO 80301-3242

Sam Zeller, Ph.D. OmegaTech, Inc. 4909 Nautilus Court N. Suite 208 Boulder, CO 80301-3242

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OmegaTech, Inc. 4909 Nautilus Court N., Suite 208, Boulder, Colorado 80301-3242 (303) 381-8100 • Fax (303) 381-8181 This information is submitted for your information to update your files on this previously notified dietary ingredient. DHA GoldTM is not a new dietary ingredient subject to notification under 21 C.F.R. § 190.6 "Requirement for premarket notification", and the information submitted herein is not a substantive amendment to previous notification. This information is submitted to inform the agency that a previously notified dietary ingredient is now sold under a new trade name by a new owner.

Respectfully submitted,

Lan Uller, Ph.D.

Sam Zeller, Ph.D. Associate Director, Regulatory Affairs OmegaTech, Inc.