Notification of a Structure/Function Statement, FFDCA § 403(r)(6); 21 U.S.C. § 343(r)(6).

Office of Special Nutritionals (HFS-450) To: Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C St., SW. WASHINGTON, DC 20204

Packer:

Bariatrix International, Inc. 40 Allen Road / P.O. Box 65069 SOUTH BURLINGTON, Vermont 05406

Tel: (802) 862-9242 Fax: (802) 862-9306

Text: The gamma-linolenic acid (GLA) present in borage seed oil (Borago officinalis), and the eicosapentaenoic and docosahexaenoic acids (EPA and DHA) present in many marine oils, are respectively members of the omega-6 and omega-3 families of essential fatty acids. Because they have already undergone some degree of metabolic transformation in the species from which they are obtained, they are more efficient precursors for eicosanoids (prostaglandins) than are the parent essential fatty acids from these families, linoleic acid (omega-6) and alpha-linolenic acid (omega-3). Eicosanoids are required for the optimal function of many physiological and metabolic systems in the human body. This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Body Shaper<sup>™</sup>. Name of Dietary Supplement:

(Healthy Performance, Wexford, PA 15090; private label)

I hereby certify that the information contained in this notification is complete and accurate, and that there is substantiation that the statement is truthful and not misleading.

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17 April, 2002.

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