



Whole Food Supplements

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November 1, 2005

The Office of Nutritional Products, Labeling and Dietary Support (HFS-810)

Center for Food Safety and Applied Nutrition

Food and Drug Administration

200 C. Street S.W.

Washington, DC 20204



Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

- (1) Supports optimal brain development for the fetus and nursing babies
- (2) Supports healthy eye development in children and newborns
- (3) Supports healthy emotional growth and response in children and adolescents
- (4) Helps maintain healthy brain and memory function
- (5) Supports healthy mood and helps address the challenges of stress
- (6) Supports healthy inflammatory responses and healthy immune system function
- (7) Supports joint health
- (8) Tuna Omega-3 Oil provides a naturally-occurring source of DHA and EPA for cardiovascular, nervous, and immune system health.
- (9) DHA is needed for proper brain development, as well as visual and neurological growth.
- (10) EPA helps moderate the body's natural inflammatory response and improves cardiovascular integrity.

These statements are made for a dietary supplement containing tuna oil, DHA, and EPA. Other ingredients include gelatin, glycerin, water, carob, and mixed tocopherols (soy). The name of the product is Tuna Omega-3 Oil.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden
Standard Process Inc.

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