

**O** sigma-tau  
PHARMACEUTICALS, INC. 2777

800 south frederick avenue  
Gaithersburg, MD 20877

JUL 25 P 2 :20

Telephone:

301-948-1041

Telefax:

Sales/Marketing/Finance

301-948-3194

General Administration

301-948-1862

Regulatory

301-948-8627

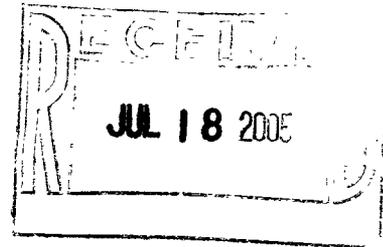
Corporate Affairs

301-948-2049

July 11, 2005

*Via Federal Express*

Office of Nutritional Products, Labeling  
and Dietary Supplements (HFS-800)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Pkwy  
College Park, MD 20740-3835



**Re: Section 6 Notification for PHOTOTROP®**

To Whom It May Concern:

On behalf of Sigma-Tau Pharmaceuticals, Inc., I am submitting this notification pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA). This notification letter contains the following information that is requested under 21 C.F.R. § 101.93(a).

**Name and Address of the Distributor:**

Sigma-Tau Pharmaceuticals, Inc.,  
800 S. Frederick Ave.,  
Gaithersburg, MD 20877

**Text of the Statements:**

- The metabolic approach to supporting visual function
- Supports the metabolism and maintenance of the photoreceptor cells in the eye
- Promotes metabolic activity in the retina
- Helps reduce oxidative damage to the retina

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July 11<sup>th</sup>, 2005  
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**Name of the Dietary Ingredients in the Product:**

- Omega-3 fatty acids (EPA and DHA)
- Coenzyme Q10
- Acetyl-L-Carnitine (ALC)

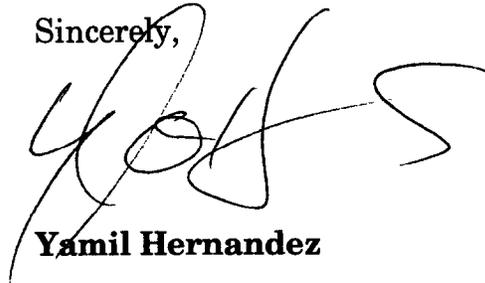
**Brand name of the Dietary Supplement:**

- PHOTOTROP®

We certify that the information in this notice is complete and accurate and that the company has information that the statement is truthful and not misleading.

If you have any questions regarding this notice, please feel free to contact me at 301-670-1515.

Sincerely,



**Yamil Hernandez**

**Product Manager**