

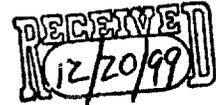
# Lichtwer Pharma U.S., Inc.

Meridian Center One  
2 Industrial Way West  
Eatontown, NJ 07724  
Phone: (732) 389-9100  
Fax: (732) 389-9102

**VIA FACSIMILE (202-205-5295) AND FIRST CLASS MAIL**

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

68437



Re. Statement of Nutritional Support Notifications

To Whom It May Concern:

We are hereby informing you that Lichtwer Pharma U.S. Inc. ("Lichtwer") expects to initiate marketing of two new dietary supplement products that require the submission of notifications to FDA under 21 C.F.R. § 101.93.

The first product, marketed under the trade name Cynara-SL™, contains artichoke extract. The following claims are made for the product:

- (1) clinically proven to help maintain a healthy liver and digestive system
- (2) clinically proven to provide fast and effective herbal support for the digestive system when you eat and drink too much
- (3) helps support the normal functioning of the liver
- (4) helps support the normal cleansing process of the liver

The second product, marketed under the trade name Sedonium™, contains valerian extract. The following claims are made for the product:

- (1) clinically proven to help promote restful sleep, awake refreshed and alert
- (2) helps support normal sleep patterns so you can awake refreshed
- (3) improves sleep quality
- (4) supports normal GABA production

Lichtwer's address is: Meridian Center One, 2 Industrial Way West, Eatontown, NJ 07724.

I hereby certify that the information contained in this notice is complete and accurate, and that Lichtwer has substantiation that the statements are truthful and not misleading.

Sincerely,

David P. Illingworth  
President and CEO  
Lichtwer Pharma U.S., Inc.

Doc. 492617

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