

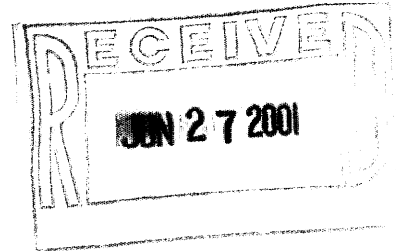
# Lichtwer Pharma U.S., Inc.

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

76554  
June 20, 2001

**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



Re. Statement of Nutritional Support Notification

To Whom It May Concern:

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

The product, marketed under the trade name Cynara-SL™, contains artichoke extract (leaves). 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 natural relief from the occasional discomfort associated with heartburn, acid indigestion and upset stomach
- (3) proven to reduce the uncomfortable feelings of bloating and gas
- (4) helps support the normal functioning of the liver
- (5) helps support the normal cleansing process of the liver
- (6) proven to provide fast, effective support for digestion after over eating and drinking
- (7) natural relief from occasional heartburn, acid indigestion, and upset stomach.

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,

A handwritten signature in black ink, appearing to read "David P. Illingworth".

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