

Lichtwer Pharma U.S., Inc.

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June 26, 1997

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

Attn: Statement of Nutritional Support Coordinator

To whom it may concern:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994, Lichtwer Pharma U.S., Inc. wishes to notify the Food and Drug Administration that it has commenced marketing an herbal dietary supplement that bears a statement of nutritional support.

The dietary supplement for which the statement is made is called "Kira" (St. John's Wort tablets). The statement of nutritional support provides that "Kira" is "clinically proven to maintain a healthy emotional balance and well-being." This statement is accompanied by the required disclaimer, which is prominently displayed in bold-faced type. This statement of nutritional support is based on data that renders this statement substantiated, truthful and non-misleading.

Sincerely,

Michael Moore (PQR)

Michael Moore  
President

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