

Dolisos

A Leader In Worldwide Homeopathy

September 1, 1998

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Linda S. Kahl, Ph.D.
Office of Special Nutritionals
Center For Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" Street, S.W. (HFS-450)
Washington, D.C. 20204

OCT - 6 1998

Dear Dr. Kahl:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994, Dolisos America, Inc. wishes to notify the Food and Drug Administration that it has within the past 30 days, commenced marketing a dietary supplement which bears a statement of nutrition support.

The herbal supplement for which the statement is made is **Elusanes® Natural Sleep**.

The statement of nutritional support reads as follows:

ELUSANES® NATURAL SLEEP is a standardized extract of Passiflora incarnata (Passion Flower) aerial parts traditionally used to support normal sleep patterns

This statement is accompanied by the required disclaimer which is prominently displayed in bold-face type.

This statement of nutritional support is based on data which renders these statements substantiated, truthful, and non-misleading.

Sincerely,



William Nicoletti, R. Ph.
President

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