

3962 '01 MAY 10 P3:25

April 5, 2001

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

RE: Dietary Supplement Statement of Support Notification

To Whom It May Concern:

SOLSTICE MECICINE COMPANY, 1043 Cesar E. Chavez Avenue, Los Angeles, CA 90033, who is the distributor of the following dietary supplement product, intends to make the following statement of support:

"The human trachea has ciliarv cells all over all over its inner surface. These cilia constantly vibrate at a rate of about 1,500 times a minute, and the inner walls of the trachea secrete mucus. Dust and other foreign particles that come into the body through the trachea are caught by this mucus and are ejected out of the trachea by the vibration of the cilia. This is the natural process of keeping the respiratory system clean and healthy. Ryukakusan, because of its saponin content, stimulates the secretion of mucus from the inner surface of the trachea, invigorates the cilia to remove sputum and, therefore, promotes a health respiratory system. These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure. or m-event any disease."

This claim is being made for: RYUKAKUSAN Dietary Supplement

which is contained in: RYUKAKUSAN Dietary Supplement

This submission is being made in compliance with 21 CFR § 101.93.

The undersigned is an authorized representative of the SOLSTICE MECICINE COMPANY and certifies that the information contained in this notice is complete and accurate, and that SOLSTICE MECICINE COMPANY has substantiation that the above statement is truthful and not misleading.

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Wina Tran President

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