December 27, 2002

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C St. SW., Washington, D.C. 20204 0348 °03 JAN 23 P2:07

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RE: 21 U.S.C. 343(r)(6), Notification of Statements on Dietary Supplements

Dear Sir or Ma'am:

I hereby notify the Food and Drug Administration (FDA) of the use of statements of nutritional support in the labeling of Oil of Oregano Capsules a dietary supplement. Planetary Formulas[®] is the manufacturer of Oil of Oregano Capsules.

Statements being made in the labeling of Oil of Oregano Capsules:

- (1) Planetary Oil of Oregano is from wildcrafted true oregano (*Origanum vulgare*), an aromatic herb that is native to the Mediterranean region.
- (2) Traditionally, oregano was used to support digestive, respiratory and joint health.
- (3) Recent *in vitro* research indicates that carvacrol, an active constituent of oil of oregano, may provide support to the immune system.

To the best of my knowledge and belief, and based upon information available at the time of the execution of this notice, I certify that the above information is accurate and complete. Planetary Formulas® possesses substantiation that the statements are truthful and not misleading.

Ira Goldberg

President, Planetary Formulas

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