Horizon Nutraceuticals P.O. Box 1806 Santa Cruz, CA 95061

3320 "01 MAR 16 A658

December 4, 2000

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



RE: Notification of Nutritional Support Statements

Dear Sir or Madam:

I hereby notify the Food and Drug Administration (FDA) of the use of statements of nutritional support in the labeling of **Hot Flash**™, dietary supplement. Horizon<sup>®</sup> Nutraceuticals is the manufacturer of **Hot Flash**.

## Statements being made in the labeling of Hot Flash:

- (1) Helps reduce hot flash frequency
- (2) Horizon's Hot Flash formula may help minimize the body's response to declining levels of estrogen. After menopause the pituitary gland releases increased levels of luteinizing hormone (LH). Researchers have found an association between pulses of LH secretion and the onset of hot flashes. Hot Flash formula includes optimal amounts of phytoestrogens, which may reduce the frequency of hot flashes and lessen the effects of luteinizing hormone.

To the best of my knowledge, and based upon information and belief present at the time of the executing of this notice, I certify that the above information is accurate and complete. Horizon Nutraceuticals possesses substantiation that the statements are truthful and not misleading.

Ira L. Goldberg

President, Horizon® Nutraceuticals

975 0162 LET 7/0/

VOIST814381