Horiion Mutraceuticals P.O. Box1806 Santa Cruz, CA 95061

December 28, 2000

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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

JAN - 8 2001

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 Black Cohosh, a dietary supplement. Horizon@ is the manufacturer of Black Cohosh.

## Statements being made in the labeling of **Black Cohosh**:

(1) Native Americans have traditionally used Black Cohosh to relieve the physiological changes associated with menopause. Horizon's Black Cohosh standardized extract, which has the same potency used in clinical research studies, may help reduce the occurrence of undesirable hot flashes.

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

Ira L. Goldberg

President, Horizon Nutraceuticals

