Horizon Nutraceuticals P.O. Box 1806 Santa Cruz, CA 95066

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December 4, 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

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 **Calcium PM**, a dietary supplement. Horizon[®] is the manufacturer of **Calcium PM**.

Statements being made in the labeling of Calcium PM:

- (1) Research indicates that food eaten during the day usually maintains adequate calcium levels in the blood. Taking calcium supplements at night offers added protection until breakfast.
- (2) Calcium is perhaps best known for its role in the formation and structure of bones and teeth. It is integral to nerve transmission, muscle movement and several enzyme systems.

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

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