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

December 5, 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 Saw Palmetto Extract, a dietary supplement. Horizon® is the manufacturer of Saw Palmetto Extract.

## Statements being made in the labeling of **Saw Palmetto Extract**:

(1) Saw Palmetto Berry (Sereona ripens) is the most widely used plant extract for prostate health. Research indicates that Saw Palmetto extract provides significant support for healthy urine flow and prostate function. The primary active components, phytosterols and fatty acids, function by inhibiting testosterone uptake into the prostate and the conversion of testosterone to its active form dihydrotesterone (DHT) within the prostate. Two Horizen SAW PALMETTO EXTRACT softgels provide the exact amount (320mg) and concentration (85-95%) fo saw palmetto phytosterols and fatty acids administered in clinical trials.

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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