

Horizon Nutraceuticals
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December 8, 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

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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 **Aller-Defense**, a dietary supplement. Horizon[®] is the manufacturer of **Aller-Defense**.

Statements being made in the labeling of **Aller-Defense**:

- (1) Human cell culture studies with quercetin demonstrated the capability to inhibit the release of histamines
- (2) Vitamins A and C, along with the mineral zinc, help support the immune system.
- (3) Ginkgolide B, in human cell culture studies, was found to be a potent inhibitor of platelet activating factor, a substance that stimulates the release of histamine from immune cells.

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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