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11/15/99

By Federal Express

November 9, 1999

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
200 C St. SW
Washington, DC 20204

RE: Notification for Certain Types of Statements on Dietary Supplements

Dear Sir or Madam:

As required by Section 403 (r)(6)(c) of the Food, Drug and Cosmetic Act, Pharmanex, Inc., 2000 Sierra Point Parkway, Brisbane, California 94005, intends to market a dietary supplement product with the following label statements of nutritional support:

Product identified as **Goldenseal** with the following label statements:

- *Helps maintain healthy immune function.*
- *Provides nutritional support to your body's immune system.*
- *Nutritionally complements Echinacea during the cold and wet season.*

I certify that the information contained in this notice is complete and accurate and that Pharmanex, Inc. has substantiation that these statements are truthful and not misleading.

Sincerely,

A handwritten signature in cursive script, appearing to read "C. Smidt".

Carsten Smidt
Director of Nutrition Research

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