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VIA FEDERAL EXPRESS

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OFFICE OF SPECIAL NUTRITIONAL PRODUCTS LABELING AND DIETARY SUPPLEMENTS Center for Food Safety and Applied Nutrition U.S. Food and Drug Administration (HFS 800) 5100 Paint Branch Parkway College Park, MD 20740-3835 RECFIVED
JUL 2 9 2002
BY:

Dear Sir orMadam:

RE:

As required by Section 403(r)(6)(c) of the Food, Drug and Cosmetic Act, Pharmanex, LLC, 75 West Center Street, Provo, Utah 84601, intends to market a dietary supplement product with the following label and marketing statements on nutritional support:

Notification for Certain Types of Statements on Dietary Supplements

Product: Statements: REISHI MAX GLP Immune Defense

Optimal immune system support

Formulated to provide long-term nutritional support for a healthy immune system, ReishiMax GLp has been demonstrated to help maintain the immune response and the normal function of immune cells.

ReishiMax GLp supports healthy immune system function through cellular protection with a proprietary standardized Reishi formula. According to the results of laboratory studies, Reishi mushroom has been demonstrated to help maintain the immune system by supporting immune cells and normal antibody production.

ReishiMax GLp is intended for adults who wish to maintain a healthy immune system, or who smoke or are frequently exposed to environmental pollutants, do not get enough sleep, or feel run down.

As a dietary supplement, ReishiMax GLp provides long-term nutritional support for a healthy immune system.

ReishiMax GLp has been demonstrated to support healthy immune system function and promotes natural killer cell function.

I certify that the information contained in this notice is complete and accurate and that Pharmanex, LLC, has substantiation that this statement is truthful and not misleading.

Sincerely

Carsten Smidt

Sr. Director of New Product Research and

Development

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