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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

RECEIVED
NOV 06 2002
BY:

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, 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:

Product: CORTITROL STRESS CONTROL FORMULA

Statements: Supports healthy cortisol levels.

Cortitrol Stress Control Formula combines natural ingredients that have been scientifically shown to have direct cortisol-balancing effects.

Theanine increases brain alpha waves associated with "relaxed alertness" so you may respond to stress more calmly and sleep more soundly.

Cortitrol Stress Control Formula is a unique, patent-pending dietary supplement that helps you cope with stress by maintaining healthy levels of the stress hormone, cortisol.

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

Sincerely,

Carsten Smidt, Ph.D., FACN
Sr. Director of New Product Research and
Development

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