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BY:

VIA FEDERAL EXPRESS

July 21, 2003

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

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: TRA™ –The Right Approach; package consisting the following three products:
Tēgreen® 97, CraveEase™, Cortitrol™
- Statements:
- TRA Fires up your metabolism
Helps control cravings for carbohydrates
Helps control stress that may cause weight gain
 - Tēgreen® 97 Keep that metabolism fired up and burn more calories
 - CraveEase™ Rein in those carbohydrate cravings and start enjoying healthier foods
 - Cortitrol™ Control stress and maintain healthy levels while supporting normal fat metabolism

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 R. Smidt, Ph.D.
Sr. Director of Research and Development

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