



August 10, 2005

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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

AUG 24 2005

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: DuoLean™

Statements:

- Contains a unique combination of natural ingredients formulated to be used in conjunction with the TRA Weight Management Program, which includes a healthy diet and regular exercise
- Preliminary evidence suggests that the ingredient NeOpuntia® in DuoLean™ can attract fat
- NeOpuntia® has been shown in laboratory studies to attract and bind fat
- NeOpuntia® attracts fat particles through hydrophobic interactions. Then the fibers form a protective gel that stabilizes those hydrophobic interactions, effectively binding some fat particles
- AlphaTrim- W™ has been shown in experimental studies to inhibit alpha-amylase, the enzyme responsible for the breakdown of carbohydrates into simple sugars
- Can reduce carbohydrate breakdown
- Preliminary evidence suggests that the ingredient AlphaTrim- W™ in DuoLean™ can inhibit and or delay the breakdown of carbohydrates

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,

Lori Blackner

Lori Blackner, D.Ph.
Senior Scientist Nutrition Research
Pharmanex, LLC

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