



January 11, 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

JAN 28 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: Estera Phase II – Transitions Formula

Statements:

- Supports healthy hormone balance
- Works with the liver to help promote a healthy ratio of estrogen metabolites
- Flaxseed powder and indole 3-carbinol work with the liver to balance a healthy ratio of estrogen metabolites
- Enzyme inducers consist of indole 3-carbinol and flaxseed lignans that provide protection by working with the liver to help maintain normal levels of estrogen metabolites
- Phytoestrogens should be incorporated into a woman's diet from any early age to help balance hormones, support bone strength and heart health.
- Helps relieve common symptoms associated with perimenopause such as night sweats, hot flashes, occasional sleeplessness, anxiousness, and mild mood swings
- Helps strengthen the body against the common symptoms of aging

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

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