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January 11, 2005

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: Estera™ Phase I – Balance Formula

Statements:

- Supports healthy hormone balance
- Phytoestrogens, contained in genistein and pomegranate have a mild estrogenic receptor binding effect in the body
- Helps provide relief from common PMS symptoms like fatigue, mild mood swings, breast tenderness, and water retention
- Phytoestrogens provide benefits throughout life when included in a woman's diet at an early age
- Supports healthy estrogen metabolism
- Works with the liver to help promote a healthy ratio of estrogen metabolites
- Enzyme inducers help the body manage estrogen metabolism
- 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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