



July 29, 2004

Office of Nutritional Products, Labeling and Dietary Supplements
HFS-810
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Pkwy.
College Park, MD 20740

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Re. Structure Function Claim Notification

To Whom It May Concern:

Pursuant to section 403(r)(6) for the Federal Food, Drug and Cosmetic Act, we hereby notify the FDA that Acatris Inc. 3300 Edinborough Way, Minneapolis, MN 55435 has included the following statements in labeling for a dietary ingredient that it manufactures and markets for use in dietary supplement products.

The brand name of the dietary ingredient that is subject of the following statements is LinumLife™ which is composed of flaxseed lignans.

- Flax lignans are phytoestrogens which studies have shown may help maintain normal hormone balance
- Lignans can support women's health by helping maintain healthy estrogen balance
- Lignans may offer support for women through the natural changes due to menopause
- Flax lignans are phytoestrogens that may support women going through menopause by easing menopausal symptoms
- Studies have shown that lignans may help support breast health, bone health and heart health
- Epidemiological, animal and human clinical research suggests that flaxseed lignans may support breast health
- Flax is a rich source of lignans, naturally occurring phytoestrogens that can help relieve symptoms of menopause

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- Flaxseed lignans can support female body, heart and bone health
- Lignans demonstrate antioxidant activity -- antioxidants can offer protection from harmful free radicals
- Lignans may help promote / support prostate health
- Research has shown that lignans can inhibit the production of the enzyme 5-alpha-reductase, which is responsible for converting testosterone to DHT
- Population-based studies suggest that men who eat a diet high in phytoestrogens, such as lignans, are more likely to maintain normal prostate health
- Animal and human clinical studies suggests that increased dietary intake of flaxseed lignans is associated with prostate health
- Epidemiological and animal studies suggest flaxseed lignans may promote heart health

I certify that, to the best of my knowledge, the information contained in this notice is complete and accurate and that Acatris has substantiation that the statements are truthful and not misleading.

Sincerely,

Laurent Leduc
President
Acatris Inc.