

INTEGRATIVE THERAPEUTICS INC.



NF Formulas



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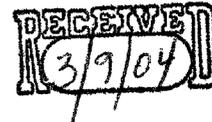
Tyler Encapsulations



Vitaline Formulas

03/23 10:13:17 AM '04

February 25, 2004



Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

**Notification of structure-function claims**

Dear Sir:

This letter is to notify you that the following product manufactured, packed, and/or distributed by Tyler Encapsulations (9755 SW Commerce Circle, Suite B2, Wilsonville, OR 97070) has a label that contains a statement provided for by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Tyler Encapsulations wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and complies with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

Product Name	Statement	Ingredient(s) to which claim refers
Black Cohosh Extract	Dietary Supplement for the relief of menopausal symptoms.†	Black Cohosh Root Extract (Triterpene Glycosides)

I certify that the information contained in this notice is complete and accurate, and that Tyler Encapsulations has substantiation that the statement is truthful and not misleading.

  
 \_\_\_\_\_  
 Mario Roxas, N.D. Date 2/25/04  
 Director of Scientific and Technical Affairs

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Product Name	Statement	Ingredient(s) to which claim refers
Black Cohosh Extract	Black Cohosh delivers relief from menopausal symptoms including hot flashes, night sweats, and mood swings.†	Black Cohosh Root Extract (Triterpine Glycosides)

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Mario Roxas, N.D.  
Director of Scientific and Technical Affairs

Date 2/25/04



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Product Name	Statement	Ingredient(s) to which claim refers
Black Cohosh Extract	Recent animal research shows that black cohosh bind to the estrogen receptor; however, it does not affect the luteinizing hormone level and does not exhibit estrogen-like effects.†	Black Cohosh Root Extract (Triterpine Glycosides)

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Product Name	Statement	Ingredient(s) to which claim refers
Black Cohosh Extract	Black Cohosh has been clinically studied for more than 40 years for its ability to reduce menopausal discomfort.†	Black Cohosh Root Extract (Triterpine Glycosides)

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Product Name	Statement	Ingredient(s) to which claim refers
Black Cohosh Extract	Dietary Supplement to relieve menopausal symptoms.†	Black Cohosh Root Extract (Triterpine Glycosides)

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Product Name	Statement	Ingredient(s) to which claim refers
Black Cohosh Extract	In a randomized, placebo-controlled, double-blind study, a researcher compared women who took standardized black cohosh extract with women taking a placebo. At the end of the study, the women taking the standardized black cohosh extract showed improvement relative to the placebo as measured by the Kupperman Menopausal Index, the Hamilton Anxiety Scale, and the Maturation index of vaginal epithelium. No clear improvement of menopausal complaints was observed in the control (placebo) group. This study demonstrated clinical and statistical improvement of menopausal symptoms by the women taking the standardized black cohosh extract.†	Black Cohosh Root Extract (Triterpine Glycosides)

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Product Name	Statement	Ingredient(s) to which claim refers
Black Cohosh Extract	The benefits of Black Cohosh may be first experienced in two to three weeks; however, the full benefits may not be realized until after four to eight weeks of administration.†	Black Cohosh Root Extract (Triterpine Glycosides)

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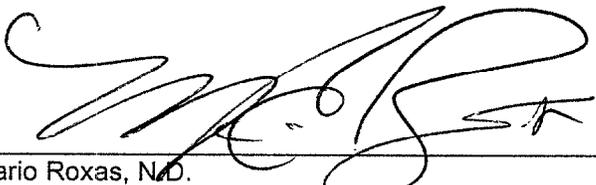
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Product Name	Statement	Ingredient(s) to which claim refers
Black Cohosh Extract	Its approved monograph in the Complete German Commission E Monographs discusses the well-documented use of Cimicifuga racemosa for the relief of menopausal complaints.†	Black Cohosh Root Extract (Triterpine Glycosides)

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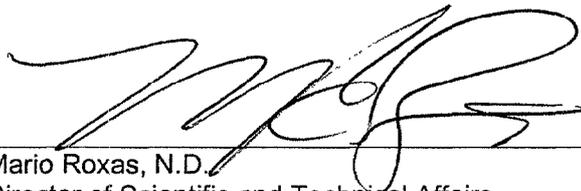
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Product Name	Statement	Ingredient(s) to which claim refers
Black Cohosh Extract	In a more recent 6-month randomized, open-label trial involving 53 women, significant decreases in unwanted menopause-related symptoms were reported following the administration of Cimicifuga racemosa.†	Black Cohosh Root Extract (Triterpine Glycosides)

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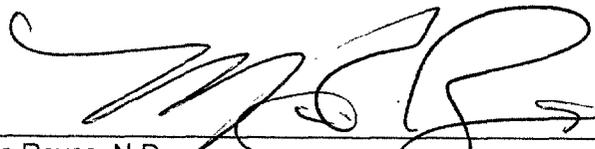
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Product Name	Statement	Ingredient(s) to which claim refers
Black Cohosh Extract	To date, there is no definitive published data available to clearly describe the process: however, forty years of clinical studies on a standardized black cohosh extract have shown efficacy in their relief of hot flashes, profuse sweating, occasional sleeplessness, and support of mood associated with menopause with few adverse effects.†	Black Cohosh Root Extract (Triterpine Glycosides)

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