



The Vitamin Marketing Experts

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March 10, 1998

Dr. Elizabeth Yetley  
Director of the Office of Special Nutritionals  
Division of Programs and Enforcement Policy  
Center for Food Safety and Applied Nutrition FDA  
200 C Street HFS-455  
Washington, D.C. 20204

Dear Dr. Yetley:

Notice is hereby given pursuant to the requirements of Section 403(r)(6)(21 U.S.C. 343(r)(6) of the Federal Food, Drug and Cosmetic Act of statements of nutritional support which have been made on the label and/or in the labeling in connection with the marketing of the dietary supplement FAMILY ESSENTIALS™ WITH REFERENCE TO ANY CLAIM CONCERNING BLACK COHOSH. FAMILY ESSENTIALS™ WITH REFERENCE TO ANY CLAIM CONCERNING BLACK COHOSH was first marketed with these statements of nutritional support on Friday, March 6, 1998. The statements of nutritional support are as follows:

"*Black Cohosh*, one of the most widely used herbs for women during menopause because of its ability to suppress LH (luteinizing hormone)- the hormone believed to be at the root of menopausal discomfort."

"*Black Cohosh* helps in lessening the discomfort associated with menopausal changes"

The *Black Cohosh* herb (latin name: cimicifuga racemosa) is a North American forest plant whose root was traditionally used by American Indians for a variety of medicinal purposes. Physicians in 19<sup>th</sup> century America recommended *Black Cohosh* for a variety of female uses.

In over 40 years of extensive research *Black Cohosh* has been shown to have estrogen-like effects through its ability to bind to estrogen receptors and lower luteinizing hormone levels. The decline in ovarian function during a woman's menopause leads to an increase in luteinizing hormone which may result in hot flashes. *Black Cohosh* has been known to help lessen such menopausal discomforts. In addition, several studies report that *Black Cohosh* stimulates the vaginal mucosa which may help lessen the occurrence of vaginal dryness. In numerous studies it was discovered that the main active ingredients responsible for *Black Cohosh's* estrogen-like activity were the triterpene glycosides. Family Essentials™ for the Mature Woman contains *Black Cohosh* that is standardized using the triterpene glycoside content most successfully used in scientific studies.

Very truly yours,  
MASON VITAMINS, INC.

Sonia C. Rodriguez  
VP Marketing & Regulatory Affairs

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**STUDIES FOR BLACK COHOSH CLAIMS**

Duker, E. et al: "Effects of Extracts from *Cimicifuga Racemosa* on gonadotrophin Release in Menopausal Women and Ovariectomized Rats" *Planta Medica* 57 (1991), 399-510, No. 5

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Daiber, W., et al; Abstract 2, *Arztl. Praxis* 35, 1946-1947 (1983), *ZFA* 60, 626-629 (1984).

Warnecke, G: Abstract 3, *Med. Welt* 36, 871-874 (1985)

Stoll W: Abstract 4, *Therapeutikon* 1, 23-31 (1987)

Duker, E.M. et al; Abstract 6, *Planta Med.* 57, 420-424 (1991)

Lehmann-Willenbrock E. et al; Abstract 5, *Zent. Bl. Gynkol* 110, 611-618 (1988)

Brucker, A: Essay on the Phytotherapy of Hormonal Disorders in Women. *Med. Welt* (1960), 44: 2331-2333

Jarry, H. et al; Studies on the Endocrine Efficacy of the Constituents of *Cimicifuga Racemosa*: 1. Influence on the Serum Concentration of Pituitary Hormones in Ovariectomized Rats. *Planta Medica* 1985, 1-80.

Lehmann-Willenbrock, E. et al; Clinical and Endocrinologic Examinations Concerning Therapy of Climacteric Symptoms Following Hysterectomy with Remaining Ovaries. *Zent. Bl Gynokol.* 110 (1988): 611-618