

1824 South Robertson Blvd.
Los Angeles, CA 90035-4317
310/204-6936 • 800/726-0886
www.Jarrow.com

FAX NUMBERS
Orders 800/890-8955
General 310/204-2520
Administrative 310/204-5132

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-810)
5100 Paint Branch Parkway
College Park, Maryland 20740
Reference phone #301-436-2373

July 2, 2004

AUG 12 2004

Dear CFSAN:

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act and Section 101.93 of FDA's regulations, we hereby notify you that we are using the following statement(s):

(1) Name and address of distributor:

Jarrow Formulas, 1824 South Robertson Blvd., Los Angeles, CA 90035

(2) Statements:

Black Cohosh has been shown to be effective in alleviating physiological discomforts during a woman's midlife transition in multiple clinical trials. Recent scientific studies exclude the estrogenic activity of Black Cohosh. The major identified phytochemicals in Black Cohosh are triterpene glycosides, which are suggested to contribute to its positive physiological effects. Warning: Not recommended during pregnancy, lactation or when trying to conceive. People with cancer should not use this product.

(3) Name of the dietary ingredient(s) if not provided in the text of the statement:

Black Cohosh 2.5% Extract (*Cimicifuga racemosa*)

(4) Name of the dietary supplement(s):

Black Cohosh

(5) The following disclaimer appears on the label in bold:

**These statements have not been evaluated by the Food and Drug Administration.
This product is not intended to diagnose, treat, cure or prevent any disease.**

These claims are limited to, and a result of, what we believe to be a substantial body of scientific evidence supporting the functional role of the nutrients.

Respectfully submitted,



Peilin Guo, MS, RD

Vice President of Functional Foods and Clinical Research

97S 0162

LET

14426

89280