

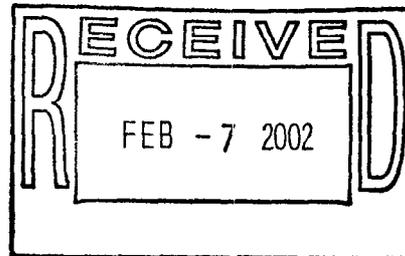
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General 310/204-2520
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3512 02 03 19 2019

Dec. 27, 2001

SECTION 403 (r) (6) NOTIFICATION

Office of Special Nutritionals (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. SW
Washington, DC 20204



Dear Sir or Madam:

In accordance with the requirement of Section 403 (r)(6) of the Federal Food, Drug and Cosmetic Act, and Rule CFR 101.93, we hereby notifying FDA that Jarrow Formulas' MenstraCalm product bears the following statements:

1. Jarrow Formulas, Inc., 1824 S. Robertson Blvd., Los Angeles, CA 90035-4317
www.jarrow.com
2. Statements:
 - a. Provides support before and during menstrual cycle
 - b. MenstraCalm combines natural phytonutrients, herbs, vitamins and minerals to provide support before and during your monthly menstrual cycle.
 - c. Chinese herbs Dong Quai, Xiang Fu, Shu Di Huang and Lindera, and the European herb Chaste-tree fruit (Vitex) have a long history of traditional use for menstrual support.
 - d. Muscle relaxation is promoted by magnesium and calcium.
 - e. Folic acid helps the replenishment of blood.
 - f. Disclaimer (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.

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

Sincerely

Handwritten signature of Peilin Guo in black ink.

Peilin Guo, MS, RD
Dir. Functional Foods Program and Clinical Research

Handwritten signature of Sid in black ink.

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