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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

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RECEIVED  
FEB 07 2002  
BY:

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 notify FDA that Jarrow Formulas' Fermented Soy Essence™ product bears the following statements:

1. Jarrow Formulas, Inc., 1824 S. Robertson Blvd., Los Angeles, CA 90035-4317  
[www.jarrow.com](http://www.jarrow.com)
2. Statements:

Fermented Soy Essence utilizes organic soy milk that is fermented (predigested) by the probiotic bacteria, *L. acidophilus*, *L. bulgaricus*, *L. casei*, *L. plantarum* and *S. thermophilus*. The cell wall contents and metabolites of beneficial bacteria used for fermentation promote optimal immune function and intestinal health.

The fermentation of soy improves the digestibility of soy protein. Isoflavone bioavailability is enhanced due to the conversion to more absorbable forms by the bacteria in the small intestine. Fermented Soy Essence is Organic and Non-GMO (non-genetically modified soy).

Calcium, added during fermentation, is converted to the soluble lactate form, thereby improving absorption. Predigestion makes Fermented Soy Essence superior to ordinary soy protein.

Bromelain and papain, enzymes from pineapple and papaya, further assist protein digestion.

Each serving provides 325 mg soluble Calcium, balanced with 160 mg magnesium, for additional benefit in preserving and maintaining bones.

Replacing animal protein with soy protein has been shown to reduce bone calcium loss.

(Inside box) Diets low in saturated fat and cholesterol that include 25 grams of soy protein a day may reduce the risk of heart disease. One serving of Fermented Soy Essence™ provides 11 grams of soy protein.

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**3. Disclaimer: 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



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

