## **GENERAL VITAMIN CORP**

PO Box 15005 Chapel Hill NC 27516 919-929-5785 fax 919-929-2458

February 22, 2001

## CERTIFIED MAIL Return Receipt Requested

FEB 2 7 2001

Office of Special Nutritionals H FS-450 Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C Street, SW Washington, D.C. 20204

To Whom it May Concern,

This letter is submitted pursuant to Section 406 (r)(6) of the Federal Food, Drug, and Cosmetic Act for the purpose of notifying the agency of statements being made in connection with the marketing of dietary supplements being distributed by this company.

The product name and the dietary ingredients for which the statement is being made is as follows:

## Menopause Nutritional System

Vitamin Mineral Formula	
Vitamin A (as retinyl acetate and	5000 IU
50% as beta carotene)	
Vitamin C (as ascorbic acid)	500mg
Vitamin D (as cholecalciferol)	200 IU
Vitamin E (as d-alpha tocopheryl	400 IU
Succinate)	
Vitamin B1 (as thiamin hydro-	25mg
Chloride)	
Vitamin B2 (as riboflavin)	25mg
Vitmain B3 (as niacinamide)	25mg
Vitamin B6 (as pyridoxine hydro-	15mg
Chloride)	
Folate (as folic acid)	200mcg
Vitamin B12 (as cyanocobalamin)	25mcg
Biotin	100mcg
Pantothenic acid (as d-calcium	25mg
Pantothenate)	
Calcium (as calcium citrate)	500mg
Iron (as ferrous fumarate)	7mg

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lodine (from kelp)	75mcg	
Magnseium (as magnesium oxide) Zinc (as zinc gluconate)	250mg 7mg	
Selenium (as L-Selenomethionine)	12mcg	
Copper (as copper gluconate)	1mg	
Manganese (as manganese Gluconate)	5mg	
Chromium (as chromium poly- Nicotinate)	50mcg	
Potassium (as potassium gluconate)	50mg	
Bioflavonoids (from citrus)	400mg	
Rutin	100mg	
Bromelain (from pineapple stem)	50mg	
Papain (Carica papaya)	32.4mg	
Choline (as choline bitartrate)	25mg	
Inositol	25mg	
PABA (para-Aminobenzoic acid)	25mg	
Boron (as amino acid chelate)	1.5mg	
Other ingredients: Cellulose, stearic acid, guar gum,		
croscarmellose sodium, silicon dioxic coating (pharmaceutical glaze)	de, magnesium stearate, and	

## Herbal Formula

Fennel (Foeniculum vuigare) (seed) 1 00mg Black Cohosh (Cimicifuga racemosa)100mg (root)

Anise (Pimpineila anisum) (seed) 100mg Blessed Thistle (Cnicus benedictus) 1 00mg (leaves)

Other ingredients: Capsule (gelatin, lauryl sulfate and silicon dioxide), stearic acid, magnesium stearate and silicon dioxide.

The text of the statements that are being made in regards to the above stated product are listed below:

-Has menopause got you down?

-...addresses the special nutritional needs of women like you

-Get support for your health

Sincerely,

GENERAL VITAMIN CORP.

Megan Joslin

Product Development Coordinator