



JAN 29 1999 5 30 8 '99 FEB 23 P1:49

William J. Dunn, Esq.
Corporate Counsel
General Nutrition Corporation
300 Sixth Avenue
Pittsburgh, Pennsylvania 15222

Dear Mr. Dunn:

This is in response to your letter of January 20, 1999 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that General Nutrition Corporation is marketing a product named "GNC Women's PMS Formula."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product, namely the product name "GNC Women's PMS Formula" suggests that this product is intended to treat, prevent, cure, or mitigate a disease, namely premenstrual syndrome (i.e., PMS). This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, Philadelphia District Office, Office of Compliance, HFR-MA140

975-0163

LET 255

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (r/f, File)

HFS-450 (r/f, File)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-600 (Reynolds)

HFS-605 (Bowers)

GCF-1 (Dorsey)

f/t:HFS-456:rjm:1/29/99:docname:63428.adv:disc34

GNC

January 20, 1998

1/28/98

RECEIVED
1/28/98

Ms. Linda S. Kahl, Ph.D.
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W. (HFS-450)
Washington, DC 20204

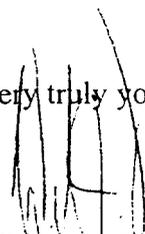
Dear Dr. Kahl:

Pursuant to section 403(r)(6) of the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), General Nutrition Corporation, located at 300 Sixth Avenue, Pittsburgh, Pennsylvania 15222 ("GNC"), hereby notifies the Food and Drug Administration that it is marketing dietary supplements that bear a nutritional support statement on their labels. Enclosed please find a listing of the products and their statements of nutritional support.

As required, the product labels contain the disclaimer that this statement has not been evaluated by the Food and Drug Administration and that the product is not intended to diagnose, treat, cure, or prevent any disease. Two (2) copies of this notification are enclosed for your convenience.

On behalf of GNC, I hereby certify that the information contained in this notice is complete and accurate and that GNC has substantiation that the statements are truthful and not misleading.

Very truly yours,



William J. Dunn, Esquire
Corporate Counsel

Enclosures

Also see docket 97S-0163

3428

COPPER		
GNC Women's PMS Formula	1/20/99	Copper is involved in red blood cell function.
GNC Men's Maximum Control Saw Palmetto 320	1/20/99	Copper is involved in red blood cell formation.

CO-Q10		
Nature's L-Carnitine	1/20/99	A combination of Co-Q 10 & L-Carnitine supports healthy heart & blood vessel function.
GNC Preventive Nutrition Coenzyme Q-10 Cocktail	1/20/99	A combination of Co Q-10 and Carnitine supports healthy heart function.

DCA		
GNC Pro Performance DCA Dichloroacetate	1/20/99	DCA helps slow the rate of accumulation of lactic acid in the body and lowers the rate of lactic acid produced in the muscles.

DHA		
GNC Women's 50 Plus Vita Pak	1/20/99	DHA, which is vital for a healthy nervous system development and a healthy heart.

ECHINACEA		
NNW Vitamin C	1/20/99	Echinacea supports natural resistance.
NNW Echinacea & Goldenseal	1/20/99	Echinacea and Goldenseal may provide dietary support for natural resistance.

EPA/DHA		
GNC EPA/DHA	1/20/99	Fish body oil containing DHA and EPA helps support the cardiovascular system. EPA is important for the circulatory system. DHA is vital for healthy nervous system development and support.

FEVERFEW		
NNW Feverfew	1/20/99	Feverfew provides dietary support to help maintain well being and for normal, healthy cerebral blood vessel tone.

FIBER		
Optibolic Chitosan	1/20/99	Fiber helps speed the transport of food through the body.
		Fiber is an important ingredient to your diet, encouraging colon health by helping to speed food through the digestive system by serving as a bulking agent.

FOLIC ACID		
GNC Preventive Nutrition Coenzyme Q-10 Cocktail	1/20/99	Vitamins E, B-6, B-12, and Folic Acid provide support for the cardiovascular system.

SILICON		
GNC Women's Ultra Nourishhair®	1/20/99	Silicon provides dietary support for healthy nails, hair and bones.

SOY ISOFLAVONES		
GNC Women's DHEA Vita Pak	1/20/99	Soy Isoflavones can help maintain bone density.

VALERIAN ROOT		
GNC Women's PMS Formula	1/20/99	Valerian Root promotes restful sleep.

VANADYL SULFATE		
GNC Pro Performance Pyrudyl	1/20/99	Vanadyl Sulfate may have a positive effect on glucose metabolism.
GNC Pro Performance Vanadyl Plus	1/20/99	Vanadyl may have a positive effect on Glucose metabolism.

VITAMIN B		
GNC Preventive Nutrition Coenzyme Q-10 Cocktail	1/20/99	Vitamins E, B-6, B-12 and Folic Acid provide support for the cardiovascular system.

VITAMIN C		
NNW Vitamin C	1/20/99	Vitamin C is essential for healthy bones, teeth, blood vessels and collagen.
NNW Vitamin C	1/20/99	Vitamin C may help support natural resistance.

ZINC		
GNC Women's PMS Formula	1/20/99	Zinc is required for normal reproductive function.
GNC Men's Maximum Control Saw Palmetto 320	1/20/99	Zinc is required for normal reproductive function.