



JUL 16 1999 2 7 8 1 '99 AUG -3 P3:27

Mr. Stephen L. Welling  
President  
Nature's Herbs  
600 East Quality Drive  
American Fork, Utah 84003

Dear Mr. Welling:

This is in response to your letter of June 30, 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 Nature's Herbs is making the following claim for the product **Nature's Herbs PMS.O.S.**:

“Nutritional support for PMS”

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, including the use of “PMS” in the product name, suggests that it is intended to treat, prevent, or mitigate disease, namely premenstrual syndrome. 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 you require 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

975-0163

LET 291

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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, Denver District Office, Office of Compliance, HFR-SW240

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (file)

HFS-450 (r/f, file)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-605 (Bowers)

HFV-228 (Benz)

GCF-1 (Dorsey, Barnett)

f/t:HFS-456:rjm:7/16/99:docname:66084.adv:disc39

**NATURE'S HERBS**  
AN INLAB Division

66084

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(801) 763-0700 • FAX: (801) 763-0789  
TOLL FREE: 800 HERBALS (437-2257)  
www.naturesherbs.com

RECEIVED  
7/15/99

June 30, 1999

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

Dear Sir or Madam

This letter will serve as a 30-day notification, pursuant to 403(r)(6) of the Federal Food, Drug & Cosmetic Act and regulations promulgated thereunder.

Product manufacturer: Nature's Herbs, 600 East Quality Drive, American Fork, UT 84003

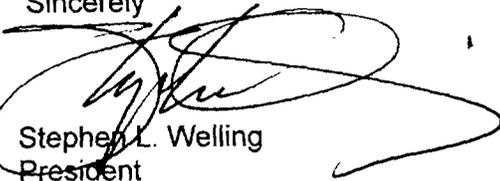
Nutritional support claim being made: Nutritional support for PMS

Dietary supplement ingredient(s): Vitamin B-6  
Chasteberry Fruit Extract

Product brand and name: Nature's Herbs PMS.O.S.

As required, enclosed are two photocopies of this notification.

Sincerely



Stephen L. Welling  
President

Enclosures

rec'd =  
AS