



DEC 16 1998

Michael A. Helser, Ph.D.
Vice President of Merchandising
and Product Development
Square Roots, Inc.
1500 Jackson Street, N.E.
Minneapolis, Minnesota 55413

2070 '99 JAN -4 P2:59

Dear Dr. Helser:

This is in response to your letter of December 9, 1998 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 Square Roots, Inc. is marketing a product named "PMS Relief."

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 "PMS Relief" 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, Minneapolis District Office, Office of Compliance, HFR-MW340

975-0163

LET 248

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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:12/15/98:docname:62763.adv.disc34

Original.

Square Roots, Inc.

1500 Jackson Street N.E.
Minneapolis MN 55413
612.706.9679

December 9, 1998

RECEIVED
12/14/98

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. S.W.
Washington DC 20204

Dear Sir or Madam:

This document is a notification letter of statements of nutritional support, in compliance with 21 CFR section 101.93 "Notification procedures for certain types of statements on dietary supplements."

Name and address of the Company/Distributor making the following statements of support:

Square Roots, Inc., 1500 Jackson Street N.E., Minneapolis MN 55413.

Statement 1

"Antioxidant Defense"

- Square Roots Tough Cell
- Contains Beta-Carotene, Vitamin C, Vitamin E, Zinc and Selenium

Statement 2

"Joint Nutrition"

- Square Roots Bodywork
- Contains Glucosamine Sulfate and Chondroitin Sulfate

Statement 3

"Inflammation Formula"

- Square Roots Push Play
- Contains Vitamin C, Turmeric Root Extract (95% curcumin), Quercetin, Bromelain, Rutin

Statement 4

"PMS Relief"

- Square Roots Over Easy
- Contains Evening Primrose Oil

62763

Statement 5

"Healthy Urinary Tract"

- Square Roots Cran Can
- Contains Cranberry Extract

Statement 6

"Cardiovascular Health"

- Square Roots Full Circ
- Contains Vitamin E, Vitamin B6, Folic Acid, Vitamin B12, Selenium, Grapeseed Extract, Resveratrol, Pine Bark Extract, Co-Enzyme Q 10

Statement 7

"Healthy Cholesterol Levels"

- Square Roots Point Guard I
- Contains Tocotrienols from Rice Bran Oil

Statement 8

"Healthy Cholesterol Levels"

- Square Roots Point Guard II
- Contains Inositol Hexaniacinate, Gugulipids, Beta-Sitosterol, Chromium and Garlic Powder.

Statement 9

"Cardiovascular Health"

- Square Roots Top Seed
- Contains Flax Seed Oil

Statement 10

"Sleep"

- Square Roots Napsack
- Contains Melatonin

Statement 11

"Healthy Digestive Tract"

- Square Roots Belly Dance
- Contains Fructooligosaccharides, Lactobacillus acidophilus, Lactobacillus bulgaricus

December 9, 1998

Statement 12

"Relaxation"

- Square Roots Stress-O-S
- Contains Kava Kava

I certify that the information contained in this notice is complete and accurate and that Square Roots Incorporated has substantiation that these statements are truthful and are not misleading.



Michael A. Helser, Ph.D.

Vice President of Merchandising and Product Development

Square Roots, Incorporated