



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

JAN 15 2004  
0056 '04 FEB -4 21:57

Rifat Parvez, Ph.D.  
President  
Lyons Health Products  
PO Box 933  
Dayton, New Jersey 08810

Dear Dr. Parvez:

This is in response to your letter of November 17, 2003 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 Lyons Health Products is making the following claim for the product **CalPhos-D**:

“...osteoporotic...”

This statement is not a claim subject to 21 U.S.C. 343(r)(6), but a claim subject to 21 U.S.C. 343(r)(1)(B). FDA has authorized a health claim on the relationship between calcium and osteoporosis (see 21 CFR 101.72). A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between calcium and osteoporosis. A health claim on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in 21 CFR 101.72 would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, failure to make a claim in accordance with the requirements in 21 CFR 101.72 subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease, osteoporosis.

You also state that the product **ProstaVites** is using the claim “Some scientific evidence suggests that consumption of antioxidant vitamins may reduce the risk of certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive.” This statement is not a claim subject to 21 U.S.C. 343(r)(6), but a claim subject to 21 U.S.C. 343(r)(1)(B) because it implies that the product will prevent a disease (i.e., cancer). In a April 1, 2003 letter, we stated that we had concluded that three alternative disclaimers best meet the criteria specified by the court in its order to FDA to re-evaluate a proposed qualified health claim “Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancer” (Whitaker, et al. V. Thompson, et al., Civil No. 01-1539). See <http://www.cfsan.fda.gov/~dms/ds-ltr34.html>.

975-0163

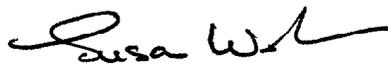
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FDA announced in its April 1, 2003 letter that it intended to exercise enforcement discretion to permit dietary supplements labels and labeling to bear a qualified health claim about the relationship between antioxidant vitamins and cancer; this announcement clarified further the model claim and disclaimer that the agency believed to be appropriate. FDA stated that it would exercise its enforcement discretion for a qualified claim about the relationship between antioxidant vitamins and cancer for claims and products that complied with the conditions set forth in its letters on the matter dated February 11, 2003 and May 4, 2001.

Please contact us if we may be of further assistance.

Sincerely yours,



Susan J. Walker, M.D.  
Director  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
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, New Jersey District Office, Office of Compliance, HFR-CE340

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cc:

all w/copy of incoming

HFA-224

HFA-305 (docket 97S-0163) ✓

HFS-800 (file)

HFS-810 (file)

HFS-811 (Moore w/original incoming)

HFD-40 (Behrman)

HFS-607

HFV-228 (Benz)

GCF-1 (Nickerson)

f/t:HFS-810:ljw:1/9/04:docname:lyons\_health.wpd:H:\Documents:cts:86809

# Lyons Health Products

PO Box 933, Dayton, NJ 08810 • Tel. 732-438-0745, Fax 732-438-1414  
E-mail: LyonsHealth@AOL.com

November 17, 2003

Office of Special Nutritionals (HFS 450)  
Center for Food Safety & Applied Nutrition  
FOOD & DRUG ADMINISTRATION  
200 C Street NW  
Washington, DC 20204



Dear Sir/Madam,

This is to notify you that we are introducing into commerce our product PROSTAVITES, Dietary Supplement tablets containing multivitamins, minerals and lycopene.

Due to the inclusion of Lycopene and anti-oxidant vitamins in the formula, we are making the following statement on our label:

"Some scientific evidence suggests that consumption of antioxidant vitamins may reduce the risk of certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive."

A product label is attached herewith.

Sincerely,

*Rifat Parvez*  
Rifat Parvez, Ph.D.  
President

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encl



Supplement Facts		
Serving Size 1 Tablet		
	Amount Per Tablet	% Daily Value
Vitamin A (60% as beta carotene)	10000 IU	200%
Vitamin C (as ascorbic acid)	120 mg	200%
Vitamin D (as cholecalciferol)	400 IU	100%
Vitamin E (as d-alpha tocopherol)	90 IU	200%
Vitamin K (as phytonadione)	80 mcg	100%
Vitamin B1 (as thiamine mononitrate)	1.50 mg	100%
Vitamin B2 (riboflavin)	1.70 mg	100%
Niacin (as niacinamide)	20 mg	100%
Vitamin B6 (as pyridoxine hydrochloride)	10 mg	500%
Folic Acid	400 mcg	100%
Vitamin B12 (as cyanocobalamin)	6 mcg	100%
Biotin	300 mcg	100%
Pantothenic Acid (as calcium pantothenate)	10 mg	100%
Calcium (as calcium carbonate)	175 mg	17.5%
Zinc (as zinc oxide)	30 mg	200%
Selenium (as sodium selenate)	200 mcg	200%
Lycopene	5 mg	
* Daily Value not established		

**Other Ingredients:** Microcrystalline cellulose, croscarmellose sodium, maltodextrin, acacia gum, silica, talc, stearic acid, magnesium stearate, hydroxypropyl methylcellulose, propylene glycol, red # 40, blue # 1, yellow # 5, titanium dioxide.

**Directions:** Take one tablet daily with a meal.

KEEP OUT OF REACH OF CHILDREN. Store in a cool, dry place.

Do not use if safety seal under cap is broken or missing.

Some scientific evidence suggests that consumption of antioxidant vitamins may reduce the risk of certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive.

Lot No. 08152 Exp. 7/05

Distributed by:  
**Lyons Health Products**  
Dayton, NJ 08810  
Tel: 732-438-0745

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