



MAR 26 2002

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D. Russell Locke, M.D.
President
StarCor Pharmaceuticals, Inc.
2500 SW 17th Road
Building 100, Suite 101
Ocala, Florida 34474

Dear Dr. Locke:

This is in response to your letter of February 27, 2002 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 StarCor Pharmaceuticals, Inc. is making the following claim, among others, for the product **UroVite™**:

“Enhanced antioxidant capacity for...carcinogen neutralization.”

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 suggests that it is intended to prevent a class of diseases, namely cancers. 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.

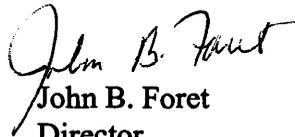
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Page 2 - Dr. D. Russell Locke

Please contact us if you require further assistance.

Sincerely,

Handwritten signature of John B. Foret in black ink.

John B. Foret

Director

Division of Compliance and Enforcement

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

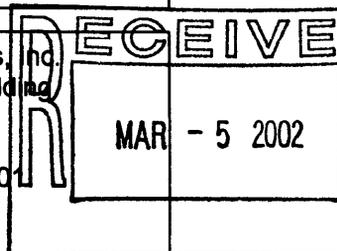
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Florida District Compliance, HFR-SE240

NOTICE OF DIETARY SUPPLEMENT DESCRIPTIVE CLAIM
21 CFR 101.93

To: Office of Nutritional Products, Labeling
 And Dietary Supplements (HFS-810)
 Center for Food Safety and Applied
 Nutrition
 Food and Drug Administration
 5100 Paint Branch Parkway
 College Park, MD 20740

From: StarCor Pharmaceuticals, Inc.
 2500 SW 17th Road, Building
 100, Suite 101
 Ocala, Florida 34474
 Telephone: 352-861-9301
 Fax: 352-237-6119



Authority:	21 CFR 101.93 (Notification of statement listed in Section 403 (r)(6) of the Federal Food, Drug, and Cosmetic Act.)
Name Bearing Statement:	Manufacturer/Labeler/Distributor StarCor Pharmaceuticals, Inc.
Address:	2500 SW 17 th Road, Building 100, Suite 101, Ocala, FL 34474
Statement(s) Text:	High antioxidant multivitamin and mineral supplement; A natural complement for maintaining health; Provides 100% daily value of the essential vitamins and higher levels of key antioxidants and minerals; Enhanced antioxidant capacity for optimal free radical and carcinogen neutralization; Promotes general and urologic (kidney, bladder, and prostate) health; Dietary supplement.
Dietary Ingredient(s):	High antioxidant multivitamin and minerals: Serving Size 1 Tablet/Amount per Tablet: Vitamin A (10,000 IU); Lycopene (3mg); Vitamin C (Ascorbic Acid) (300mg); Vitamin D (400 IU); Vitamin E (d-alpha-tocopherol) (100 IU); Vitamin B ₁ (Thiamin) (1.5mg); Vitamin B ₂ (Riboflavin) (1.7mg); Vitamin B ₃ (Niacin) (20mg); Vitamin B ₆ (Pyridoxine) (25mg); Folate (Folic Acid) (400mcg); Vitamin B ₁₂ (Cyanocobalamin) (6mcg); Vitamin B ₅ (Pantothenic Acid) (10mg); Vitamin K (80mcg); Biotin (300mcg); Zinc (30mg); Selenium (200mcg); Calcium (36mg); Phosphorus (28mg)
Other Ingredient(s):	Cellulose; Croscarmellose Sodium; Silica; Stearic Acid; Magnesium Stearate; Natural Glaze
Brand/Trade Name:	UroVite™
Disclaimer:	Pursuant to 21 CFR 101.93(b),(c),(d),(e) the following disclaimer appears on all product labels and other printed materials: "These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

*Dietary Supplement Claim Notice/StarCor Pharmaceuticals
 UroVite™
 February, 2002*

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NOTICE OF DIETARY SUPPLEMENT DESCRIPTIVE CLAIM

- Page Two -

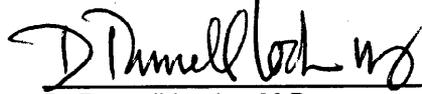
Responsible Individual: D. Russell Locke, M.D.

Title: President

Address: 2500 SW 17th Road, Building 100, Suite 101, Ocala, FL 34474

Certification: I, D. Russell Locke, M.D., hereby certify that the information contained in this notice is complete and accurate and that StarCor Pharmaceuticals has substantiated that the product statements herein are truthful and not misleading. Said certification is hereby made pursuant to 21 CFR 101.93.

Signature:



Date:

2/27/02

D. Russell Locke, M.D.

Attorney Representative:

Paula A. Willis
Attorney for StarCor Pharmaceuticals, Inc.
2500 SW 17th Road, Building 100, Suite 101
Telephone: 352-861-9301
Fax: 352-237-6119

Certificate of Service:

I hereby certify that the original and two copies of this Notice of Dietary Supplement Descriptive Claim is furnished on the 28 day of February, 2002, by U.S. Certified Mail/Return Receipt to the Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Parkway, College Park MD 20740.

Attorney Signature:



Date:

2/28/02

Paula A. Willis, Esquire