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April 2, 2002

John B. Foret, Director 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

## Furnished via US Certified Mail/Return Receipt

Re: UroVite™ Dietary Supplement Descriptive Claim **Notice of Corrective Action** 

Dear Mr. Foret:

I am providing this notice on behalf of D. Russell Locke, President of StarCor Pharmaceuticals, Inc., in response to your letter of March 26, 2002, regarding our prior notice of descriptive claims for the above referenced dietary supplement.

It is not StarCor's intention to make a disease claim for the above referenced dietary supplement. Therefore, StarCor has taken corrective action to delete the claim, "Enhanced antioxidant capacity for free radical and carcinogen neutralization," from all marketing and other descriptive literature for UroVite™.

Thank you for your assistance in this matter.

Sincerely

Paula A. Willis Corporate Counsel StarCor Pharmaceuticals

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 975 0162 LET

> StarCor Pharmaceuticals, Inc. 2500 S.W. 17th Road, Building 100 • Suite 101 • Ocala, Florida 34474 (352) 861-9301 • 1 (877) 742-7262 • FAX: (352) 237-6119