

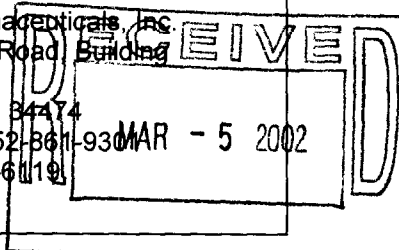
COPY

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: 352-861-9300
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:	Prostate health maintenance; Maintains prostate health; A natural complement for maintaining health; High potency standardized extract of <i>Serenoa repens</i> ; Promotes prostate health and optimizes urinary flow parameters; Dietary supplement.
Dietary Ingredient(s):	Saw palmetto extract (berry); Serving size: 1 soft gel/amount per soft gel: <i>Serenoa repens</i> (320mg); Standardized to contain (based on extract weight): Total fatty acids (85% - 95%); Total sterols (0.2% - 0.4%)
Other Ingredient(s):	Gelatin, Glycerine, Water
Brand/Trade Name:	Sitol™
Disclaimer:	Pursuant to 21 CFR 101.93(b),(c),(d),(e), the following disclaimer appears on all product labels and other printed material: "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
Sitol™
February, 2002*

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- 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:


D. Russell Locke, M.D.

Date:

2/27/02

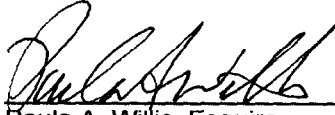
Attorney Representative:

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:


Paula A. Willis, Esquire

Date:

2/28/02