

NOTICE OF DIETARY SUPPLEMENT DESCRIPT

21 CFR 101.93

StarCor Pharmaceuticals, Inc. 2500 SW 17th Road, Building From:

100, Suite 101

Ocala, Florida 34474 Telephone: 352-861-9301

Fax: 352-237-6119

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

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 17th Road, Building 100, Suite 101, Ocala, FL 34474

Statement(s)

Text:

Male sexual health:

Male hormone precursor;

A natural complement for maintaining health;

Extended release formulation to support consistent physiologic

testosterone biosynthesis and blood levels;

Promotes normal male sexual function and sense of well being,

Helps maintain muscle mass and bone density;

Dietary supplement.

Dietary

Ingredient(s):

Androstenedione extended release; Serving size: 1 tablet/amount per

tablet: Androstenedione (50mg

Other

Ingredient(s):

Calcium phosphate; Cellulose; Vegetable stearates; Silicon dioxide:

Polyethylene glycol

Brand/Trade

Name:

Androl XL™

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 Androl XL™ February, 2002

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NOTICE OF DIETARY SUPPLEMENT DESCRIPTIVE CLAIM

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Responsible Individual:	D. Russell Locke, M.D.
Title:	President
Address:	2500 SW 17 th 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: 102
Attorney Representative:	Paula A. Willis Attorney for StarCor Pharmaceuticals, Inc. 2500 SW 17 th Road, Building 100, Suite 101 Telephone: 352-861-9301 Fax: 352-237-6119
Certificate of Service:	I herby certify that the original and two copies of this Notice of Dietary Supplement Descriptive Claim is furnished on the day of forward, 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