



August 30, 2004

SEP 20 2004

Barbara O. Schneeman
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling and
Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

Dear Dr. Schneeman:

By this letter, please be advised that ProEthic Pharmaceuticals, Inc.,
Montgomery, AL, is marketing dietary supplement products that bear structure/function
statements on currently distributed labeling. Pursuant to 21 CFR § 101.93, please be
advised of the following:

Name of the Products: UDAMIN®; UDAMIN® SP

09598

Dietary Ingredients:

UDAMIN®

Vitamin E (as d-alpha tocopheryl succinate). 150 IU
Vitamin E (as d-gamma tocopherol).....25 mg
Vitamin E (as d-delta, d-beta tocopherol).....9 mg
Selenium (as Selenium Chelate).....200 mcg
Lycopene Complex.....5 mg
Zinc (as Zinc Gluconate).....15 mg
Folic Acid.....2 mg
Cyanocobalamin (B12)..... 500 mcg
Pyridoxine HCL (B6).....25 mg

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UDAMIN® SP

Saw Palmetto.....	320 mg
Vitamin E (as d-alpha tocopheryl acid succinate).....	75 IU
Vitamin E (as d-gamma tocopherol).....	12.5 mg
Vitamin E (as d-delta, d-beta tocopherol).....	4.5 mg
Selenium (as Selenium Chelate).....	100 mcg
Lycopene Complex.....	2.5mg
Zinc (as Zinc Gluconate).....	7.5 mg
Folic Acid	1 mg
Cyanocobalamin (B12).....	250 mcg
Pyridoxine HCL (B6)	12.5 mg

Statements:

- “The once-a-day prescription formula to support overall prostate health in patients 35 and older”;
- “Natural E vitamins included y-tocopherol plus selenium, lycopene, and zinc gluconate to support prostate health”;
- Plus the cardiovascular benefits of folic acid, vitamin B12 and vitamin B6”; and
- “... specially formulated to support prostate health.”

Please be advised that the disclaimer required by and noted in September 101.93(c) appears on the product labeling bearing these statements.

I certify that the information contained in this notice is accurate and complete and that we have substantiation that the above statements are truthful and not misleading.

Sincerely,

Carl L Whatley Jr
Chief Executive Officer
ProEthic Pharmaceuticals, Inc.