



HERBALIFE INTERNATIONAL OF AMERICA, INC.
9800 La Cienega Blvd., Inglewood, CA 90301
Mailing Address: P.O. Box 80210, Los Angeles, CA 90080-0210
(310) 410-9600 • FAX: (310) 258-7124

JOHN P. VENARDOS
Vice President, Regulatory Affairs
International Product Management

August 4, 1998



Office of Special Nutritionals (HFS-450)
Center For Food Safety and Applied Nutrition
FOOD & DRUG ADMINISTRATION
200 C Street, S.W.
Washington, D.C. 20204

1 8 6 0 '98 AUG 21 P12:47

Ref.: **Ultimate Prostate Formula Dietary Supplement**

Dear Sir and/or Madam:

Pursuant to 21 CFR 101.93, please be advised that Herbalife International of America, Inc. has begun commercializing Ultimate Prostate Formula dietary supplement in the United States. This letter is intended to replace our June 15, 1998 notification letter to the FDA advising the agency of statements being made for the Ultimate Prostate Formula product. It contains a revision of certain statements made in our June 15 notification letter, and reflects the Company's response to the FDA's comments on the statements made in our June 15 letter, as set forth by the agency in its June 25, 1998 courtesy letter to us.

Ultimate Prostate Formula is labeled and promoted with statements provided for in section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act.

LABEL

Suggested Serving: One tablet in the morning and one tablet at bedtime.

Ultimate Prostate Formula contains a superior blend of zinc and herbs, including Saw Palmetto, which is associated with helping support good urinary function. This formula is rich in phytonutrient antioxidants which can support the prostate.

PRODUCT LITERATURE

Now there's a natural way that can help make men's mid-life transition a little easier and healthier. Introducing Ultimate Prostate Formula, Herbalife's dietary supplement to support the prostate.

- Contains a superior blend of vitamins, minerals and herbs.
- Includes Saw Palmetto, which is associated with helping to support good urinary function.
- Rich in phytonutrient antioxidants to help protect the prostate against the harmful effects of free radicals.

Product labeling prominently bears the required boxed statement, "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."

97S-0162

60634
LET 2027

Office of Special Nutritionals (HFS-450)
Center For Food Safety and Applied Nutrition
FOOD & DRUG ADMINISTRATION

August 4, 1998

Page 2

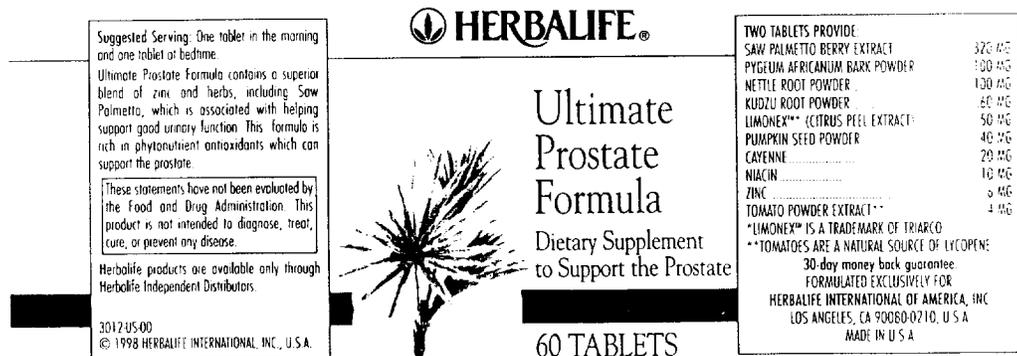
Herbalife International of America, Inc. certifies that the information contained in this notice is complete and accurate, and that the Company has substantiation that the foregoing statements are truthful and not misleading.

Please do not hesitate to advise should you have any questions.

Sincerely,



File: Ultimate Prostate Formula Dietary Supplement



HERBALIFE®

Ultimate Prostate Formula
Dietary Supplement to Support the Prostate
60 TABLETS

Suggested Serving: One tablet in the morning and one tablet at bedtime.

Ultimate Prostate Formula contains a superior blend of zinc and herbs, including Saw Palmetto, which is associated with helping support good urinary function. This formula is rich in phytonutrient antioxidants which can support the prostate.

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.

Herbalife products are available only through Herbalife Independent Distributors.

3012 US-00
© 1998 HERBALIFE INTERNATIONAL, INC., U.S.A.

TWO TABLETS PROVIDE:

SAW PALMETTO BERRY EXTRACT	320 MG
PYGAEUM AFRICANUM BARK POWDER	100 MG
NETTLE ROOT POWDER	100 MG
KUDZU ROOT POWDER	60 MG
LIMONEX** (CITRUS PEEL EXTRACT)	50 MG
PUMPKIN SEED POWDER	40 MG
CAYENNE	20 MG
NIACIN	10 MG
ZINC	5 MG
TOMATO POWDER EXTRACT**	4 MG

LIMONEX IS A TRADEMARK OF TRIARCO
**TOMATOES ARE A NATURAL SOURCE OF LYCOPENE
30 day money back guarantee
FORMULATED EXCLUSIVELY FOR
HERBALIFE INTERNATIONAL OF AMERICA, INC
LOS ANGELES, CA 90080-0710, U.S.A
MADE IN U.S.A

Supplements Designed For Men



Ultimate Prostate Formula

Dietary supplement to support the prostate. Now there's a natural way that can help make men's mid-life transition a little easier—and healthier. Introducing Ultimate Prostate Formula, Herbalife's dietary supplement to support the prostate.

- Contains a superior blend of vitamins, minerals and herbs.
- Includes Saw Palmetto, which is associated with helping to support good urinary function.
- Rich in phytonutrient antioxidants to help protect the prostate against the harmful effects of free radicals.

#3012 (case of 12)

#0165 (HAP or unit) \$17.95

Male Factor 1000®

Helps increase vitality, stamina and endurance in men.

Male Factor is a proprietary blend of premium Avena Sativa (Swissoats A111™), Nettle and Ginseng and is specially formulated for men.

- Designed to be beneficial for vitality, stamina, endurance and muscular integrity.
- Swissoats A111, derived from young oat shoots, is a potent source of Protein, B Vitamins, Vitamins A and E, and bone-strengthening Calcium.
- Ginseng has been used for centuries by Chinese and Korean herbalists and is one of the oldest and most respected herbs in the Chinese Pharmacopoeia.

#3300 (case of 6)

#0024 (HAP or unit) \$41.00

