



MAR 30 2001 10 39 '01 APR 13 P3:21

Mr. John Venardos
Vice President, Regulatory Affairs
Herbalife International of America, Inc.
1800 Century Park East
Century City, California 90067-1501

Dear Mr. Venardos:

This is in response to your letter of March 15, 2001 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Herbalife International of America, Inc. is making the following claim, among others, for the product Ultimate Prostate Formula:

"...inhibit excessive cell growth in the prostate gland that can lead to enlargement."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, cure, or mitigate disease, namely benign prostatic hypertrophy. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

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Please contact us if we may be of further assistance.

Sincerely,


John B. Foret

Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

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, Los Angeles District Office, Office of Compliance, HFR-PA240

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cc:

HFA-224

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-810 (Foret)

HFS-811 (Moore, w/original incoming)

HFD-40 (Behrman)

HFD-310

HFD-314 (Aronson)

HFS-607 (Bayne-Lisby)

HFV-228 (Benz)

GCF-1 (Nickerson)

r/d:HFS-811:RMoore:3/27/01

docname:75079.adv:disc55



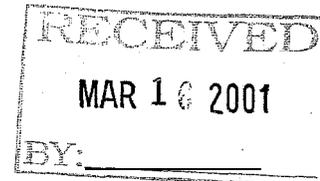
HERBALIFE INTERNATIONAL OF AMERICA, INC.
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 Century City, CA 90067-1501
 (310) 203-7746 . FAX (310) 557-3916
 Email: johnv@herbalife.com

JOHN VENARDOS
 Vice President, Regulatory Affairs
 International Product Management

March 15, 2001

15079

Office of Nutritional Products
 Labeling and Dietary Supplements
FOOD & DRUG ADMINISTRATION
 200 C Street, S.W.
 Washington, D.C. 20204



Ref: Ultimate Prostate Formula (Soft Gels)

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 in the United States.

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

1. LABEL

(Note: On the label, immediately adjacent to the following copy, appears a ruled DSHEA disclaimer box.)

Ultimate Prostate Formula contains a potent blend of prostate support factors, and Free Fatty Acids (FFA's) extracted from Saw Palmetto berries, which help support proper urinary function. A natural source of lycopene.

2. HERRALIFE FACT SHEET

(Note: The asterisks appearing in the copy shown, relate to the ruled DSHEA disclaimer box which is located on the same page of the product literature.)

Nature's Answer

Fortunately there is a natural and effective way to support healthy prostate function.* This advanced formula includes saw palmetto, lycopene and pumpkin seed oil, which collectively promote healthy prostate activity.*

Discussion Points

- **Only the best:** High-quality saw palmetto was used in over a dozen successful clinical trials on prostate health.*
- **Hormone regulation:** Saw palmetto extract may reduce the activity of the male hormone dihydrotestosterone, which may inhibit excessive cell growth in the prostate gland that can lead to enlargement.*
- **Tomato protection:** Lycopene is a natural antioxidant found in the pigment of tomatoes that may prevent cellular DNA damage.*
- **Pumpkin power:** Pumpkin seed oil has been used traditionally to promote and support healthy prostate activity.*

Fast Facts

- Saw palmetto helps support prostate health, improves urinary function and enhances potency.*

- Rich in phytonutrient lycopene, vitamin E and selenium, antioxidants that help protect the prostate from free-radical damage.*

3. PRODUCT FOCUS

(Note: The asterisks appearing in the copy shown, relate to the rules DSHEA disclaimer boxes which are located on the same page of the product literature.)

Support the Health of Your Prostate with NEW Improved Ultimate Prostate Formula
(Note: Just below the above text reads, "New Soft-Gel Capsule for Improved Absorption")

Clinical trials that suggest saw palmetto can help promote healthy prostate function and scientific advancements led us to substantially improve our prostate formula. As a result, we've increased the amount of saw palmetto in our formula to 180 mg.*

Why Ultimate Prostate Formula?

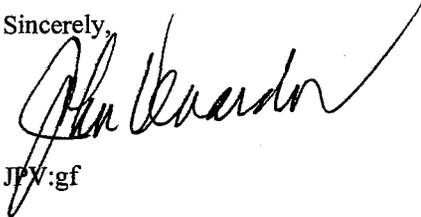
Regular use of our improved Ultimate Prostate Formula can help promote stronger urinary flow and encourage healthy prostate function with antioxidants that can help protect the prostate from free-radical damage.*

Product labeling and literature 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."

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

If you have any questions, please do not hesitate to ask.

Sincerely,



JWV:gf



New Improved Formula



Ultimate Prostate Formula

Dietary Supplement to Support the Prostate

30 SOFT GELS

Suggested Serving: Take one soft gelatin capsule daily.

Ultimate Prostate Formula contains a potent blend of prostate support factors, and Free Fatty Acids (FFAs) extracted from Saw

Palmetto berries, which help Herbalife products support proper urinary function. ^{where available} throughout Herbalife Independent Distributors.

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.

Supplement Facts

Serving Size: 1 Soft Gel Servings Per Container: 30

	Amount Per Serving	% DV*
Vitamin E (D-alpha-tocopheryl Acetate)	25 IU	83%
Selenium (Yeast)	25 mcg	36%
Saw Palmetto Lipid Extract	180 mg	†
Pumpkin Seed Oil	100 mg	†
Lycopene	1 mg	†
Dried Black Pepper Extract	1 mg	†

*Percent Daily Values are based on a 2000 calorie diet.
† Daily Value not established.

Other Ingredients: Gelatin, Glycerin, Purified Water, Soy Lactin, Beeswax, Carb Extract (color) and Titanium Dioxide (color).

Formulated exclusively for:

HERBALIFE INTERNATIONAL OF AMERICA, INC.
LOS ANGELES, CA 90009-0210, U.S.A. • MADE IN U.S.A.

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