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A PARTNERSHIP INCLUDING PROFESSIONAL CORPORATIONS

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WRITER'S DIRECT NUMBER

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April 9, 1997

4/16/97 0114 '97 SEP 19 P1:39

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

Re: PROSTAGEN™: Statements of Nutritional Support

Ladies/Gentlemen:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994, 21 U.S.C. §343(r)(6), this letter notifies the Food and Drug Administration that our client BioTherapies, Inc. of Elmsford, New York has begun marketing a dietary supplement sold under the brand name of PROSTAGEN™, containing the soy isoflavones genistein, daidzein and glycitein and related conjugates, with the labeling statements of nutritional support indicated by asterisks on the enclosed label for this product.

Very truly yours,



Charles J. Raubicheck

CJR:dmp

cc (w/encl): BioTherapies, Inc..

975-0162

LET 624

PROSTAPLAN™

PROSTAPLAN™ consists of natural products associated with the promotion of prostatic health.* Prostagin™ can be taken in combination with Proscare™, Prostamega™ and Prostavite™ or separately. PROSTAPLAN™ natural products represent the optimal way to a healthy prostate.*

This product has a tamper-resistant seal. Use this product only if inner seal is intact.

* THESE STATEMENTS HAVE NOT BEEN APPROVED BY THE FDA. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT, PREVENT OR CURE ANY DISEASE.



Product number 3103

Several natural substances, including extracts of the Saw Palmetto Berry, Sunging Nettles (Urtica Dioica) and concentrates of Pygeum Africanum are frequently recommended as dietary supplements for prostatic health.*

SUGGESTED USE:
As a dietary supplement, take two capsules daily, prior to main meal.

Nutrition Facts
Serving size 2 Capsules
Amount per serving

Saw Palmetto standardized extract	20mg
Sunging Nettles standardized extract	30mg
Pygeum Africanum concentrate	50mg
Vitamin E (DL, alpha-tocopheryl acetate)	100IU

Distributed by:
BioTherapies USA, Inc.
200 Clearbrook Road
Elmsford, NY 10523
LA3104Rev1/97



NATURAL PROSTATE CARE*

The Michael B. Schachter, M.D.

Prostagen™

An Isolated Soy Protein and Isoflavone Dietary Supplement

Part of a Natural Physician Formulated Plan for Prostatic Health*

BIO THERAPIES, INC.
Remedies of Natural Origin

Net Wt. 24.8 oz. (705g)

PROSTAPLAN™ consists of natural products associated with the promotion of prostatic health.* Prostagin™ can be taken in combination with Proscare™, Prostamega™ and Prostavite™ or separately. PROSTAPLAN™ natural products represent the optimal way to a healthy prostate.*

SUGGESTED USE:
As a dietary supplement, take two capsules daily, prior to main meal.

Nutrition Facts
Serving size 2 Capsules
Amount per serving

Saw Palmetto standardized extract	20mg
Sunging Nettles standardized extract	30mg
Pygeum Africanum concentrate	50mg
Vitamin E (DL, alpha-tocopheryl acetate)	100IU

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LA3104Rev1/97

PROSTAPLAN™ consists of natural products associated with the promotion of prostatic health.* Prostagin™ can be taken in combination with Proscare™, Prostamega™ and Prostavite™ or separately. PROSTAPLAN™ natural products represent the optimal way to a healthy prostate.*

SUGGESTED USE:
As a dietary supplement, take two capsules daily, prior to main meal.

Nutrition Facts
Serving size 2 Capsules
Amount per serving

Saw Palmetto standardized extract	20mg
Sunging Nettles standardized extract	30mg
Pygeum Africanum concentrate	50mg
Vitamin E (DL, alpha-tocopheryl acetate)	100IU

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Several specific vitamins and minerals are required for prostatic health.* Prostavite™ is a unique collection of these vital nutrients.

Nutrition Facts
Serving size 3 capsules
Amount per serving

Vitamin B6 (Pyridoxine HCl)	200mg
Magnesium Oxide	300mg
Vitamin E (DL, alpha-tocopheryl acetate)	700 IU
Selenium (Yeast)	300mcg
Copper (Copper Selenate)	4mg

SUGGESTED USE:
As a dietary supplement, take one capsule three times a day or three capsules once a day, before main meal.

Distributed by:
BioTherapies USA, Inc.
200 Clearbrook Road
Elmsford, NY 10523
LA3103Rev1/97

Prostagen™ is a proprietary blend of high quality soy protein isolates selected to provide an optimal range of soy isoflavones. Each scoop contains approximately 28 mg of isoflavones (Genistein, Daidzein and Glycitein) and related conjugates. Soy protein is handled more efficiently by the kidney than animal protein, and soy-based diets are known to promote a healthy urinary tract.* Soy isoflavones promote prostatic health.*

Nutrition Facts

Serving size 2 heaping scoops (47 grams)
Servings per container 15

Amount per serving	Calories from Fat 13	% Daily Value*
Total Fat 1.5gm		2%
Saturated Fat 0.5gm		3%
Cholesterol 0mg		0%
Sodium 400mg		17%
Potassium 50mg		1%
Total Carbohydrate 17gm		6%
Dietary Fiber 1gm		4%
Protein 22gm		44%
Calcium		5%
Iron		25%
Folic Acid		14%
Phosphorus		22%
Zinc		7%
Copper		20%

*Not a significant source of Vitamin A or Vitamin C.

SUGGESTED USE:
As a dietary supplement, one serving per day stirred in an eight ounce glass of water or skim milk with ice. Mix in a blender for best results.

INGREDIENTS:
Isolated soy protein with Genistein, Daidzein and Glycitein, Fructose, Natural Orange Flavor, Citric Acid, Lecithin and Xanthan Gum.

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