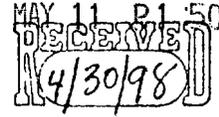


WOODLAND FARM LTD

798 Spring Road
Marathon, WI 54448-9986

54795

April 27, 1998
7884 '98



Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C. St. Sw
Washington, DC 20204

To Whom It May Concern:

Please find enclosed the document for notification related to a statement of nutritional support under section 403 (r) 6 §101.93 et al. Although the regulation provides for the elements of the notification, it does not provide for the format. Enclosed is my proposal. It is simple and concise,

We have recently redesigned all of our materials to take advantage of section 403 (r) § 101.93 et al. to better inform the consumer. We are currently in the process of redesigning all of our materials to conform with the new regulations regarding nutrition labeling, as set forth in §101.9 (21 CFR 101.9) that relates to herbal dietary supplements. If any elements of the proposed label are objectionable, please notify us within 30 days of the specific objection and the specific reason(s), so that we can make the appropriate adjustments.

The current notification is for a new product and therefore, it is being submitted. We presume that prior submissions do not need to be resubmitted for the addition of the Supplement Facts statement. If this is not the case, please notify us of this requirement.

Reasonable substantiation has been established related to benefits and especially safety, before any of my products are marketed. It is my policy to personally review the world-wide medical research literature as a part of product development. Having been involved in biochemical medical research in the past, I feel I am reasonably qualified to evaluate the quality and accuracy of the literature I review. It is my purpose to provide beneficial, safe products of the best possible quality to the consumer. I, or members of my immediate family, use my products on a regular basis, and have done so for a number of years.

Sincerely,

Sheldon A. Schooler, M.D.
Physician's Choice Herbal Products

P.S. This is the eighth of eight product notices to be sent.

(vi) Dietary supplement of an herb

Example used for format

| Supplement Facts | |
|-----------------------------------|----------|
| Serving Size 1 Capsule | |
| Amount Per Capsule | |
| Oriental Ginseng, powdered (root) | 250 mcg* |
| *Daily Value NOT established. | |

Other Ingredients: Gelatin, water, and glycerin.

(vii) Dietary supplement of amino acids:

| Supplement Facts | |
|--|---------|
| Serving Size 1 Tablet | |
| Amount Per Tablet | |
| Calories | 15 |
| Isoleucine (as L-isoleucine hydrochloride) | 450 mg* |
| Leucine (as L-leucine hydrochloride) | 620 mg* |
| Lysine (as L-lysine hydrochloride) | 500 mg* |
| Methionine (as L-methionine hydrochloride) | 350 mg* |
| Cystine (as L-cystine hydrochloride) | 200 mg* |
| Phenylalanine (as L-phenylalanine hydrochloride) | 220 mg* |
| Tyrosine (as L-tyrosine hydrochloride) | 900 mg* |
| Threonine (as L-threonine hydrochloride) | 300 mg* |
| Valine (as L-valine hydrochloride) | 650 mg* |
| *Daily Value not established | |

Other ingredients Cellulose, lactose, and magnesium stearate.

BILLING CODE 4190-01-C

(ii) If space is not adequate to list the required information as shown in the sample labels in paragraph (c)(10) of this section, the list may be split and

continued to the right as long as the headings are repeated. The list to the right shall be set off by a line that distinguishes it and sets it apart from

the dietary ingredients and percent of Daily Value information given to the left. The following sample label illustrates this display:

IN THE UNITED STATES

FOOD AND DRUG ADMINISTRATION

OFFICE OF SPECIAL NUTRITIONALS

Subject: Notification, Statement of Nutritional Support, as provided for in section 403 (r) (6) §101.93 et al.

Notification Mailing Date (Certified Mail): 4/27/98

Distributor: Woodland Farm, Ltd.
798 Spring Rd.
Marathon, Wisconsin 54448

Product Brand Name: Physician's Choice Prostate Plus

Dietary Ingredients: Saw Palmetto, Ginseng, and Zinc.

Statement(s) Attributable to Ingredient: Saw Palmetto-All.

Date of First Use In Commerce: 5/15/98

Actual Label Attached Below:

MY SUGGESTED DOSAGE: One capsule morning and evening with meals. Store in cool, dry place.

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

© 1998, Woodland Farm Ltd.
Physician's Choice Quality—the proof is in the amount.
® Physician's Choice is a registered trademark of Woodland Farm, Ltd.

Freshness Guar. to: LOT NO.

Physician's Choice Prostate Plus

Herbal Diet & Supplement with Saw Palmetto

Developed for you by SHELDON A. SCHOOLER, M.D.

525 mg 60 capsules

Can Help Maintain Prostate Function* Prostate Health*

Supplement Facts
Serving Size: 1 Capsule

| Amount per Capsule | |
|---|--|
| Saw Palmetto (S. repens) 320mg powdered (berries) | |
| Wisconsin ginseng (P. quinquefolium) 4 yr. old powdered (root) 197.5mg* | |
| Zinc (as zinc gluconate) 75mg** | |

*Daily value not established
**50% of U.S.RDA for Adults

Other Ingredients: Gelatin (capsule shell)

Prepared for:
Sheldon A. Schooler, M.D.
Woodland Farm, Ltd.
798 Spring Road
Marathon, WI 54448 U.S.A.

As per § 101.93 (c), the undersigned certifies that the information contained in this notice is complete and accurate, and that the notifying firm has reasonable substantiation that the statement is truthful and not misleading.

Sheldon A. Schooler, M.D., President

Notification receipt date, _____
Office of Special Nutritional _____