



MAR 26 2002

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President  
Neways, Inc.  
150 East 400 North  
Salem, Utah 84653

Dear Sir:

This is in response to your letters of February 13, 2002 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 Neways, Inc. is making the following claims for the following products.

The product **Prostality** uses the claims "supports prostate health," "supports healthy prostate size and function," "supports maintenance of healthy urine flow," "supports the body's natural defense mechanisms to aid prostate health," "...ease minor pain and inflammation of the urethra and soothe urinal urgency," and "supports the protection of health prostate growth." It uses these claims in the context that the product will support prostate health and which will promote urine flow and easing minor pain and inflammation of the urethra and mitigate urinal urgency. The claims for your product describe a characteristic set of symptoms associated with abnormal prostate function in aging men, that is, the disease benign prostatic hypertrophy (BPH). Thus, they are disease claims under 21 CFR 101.93(g)(2)(ii). They are also disease claims under 21 CFR 101.93(g)(2)(iii), which provides that a claim about an effect on an abnormal condition associated with a natural state or process is a disease claim if the abnormal condition is uncommon or can cause significant or permanent harm. In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR at 1020-21), FDA discussed BPH and claims about the effect of a product on the prostate. The agency explained that BPH is not a normal consequence of the natural process of aging but rather is an abnormal condition associated with that process. Although BPH is common, claims to treat or prevent it are disease claims because failure to obtain effective treatment can cause significant or permanent harm.

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 statements that you are making for these products suggest that they are intended to treat, prevent, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they

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Page 2 - President, Neways, Inc.

are 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.

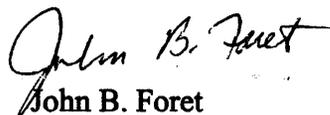
Your submission also states that you are making the following claim, among others, for the product **calQlat**:

“Regular exercise and a health diet with enough calcium helps teen and young adult white and Asian women maintain good bone health and may reduce their high risk of osteoporosis later in life....”

This statement is not a claim subject to 21 U.S.C. 343(r)(6), but a claim subject to 21 U.S.C. 343(r)(1)(B). FDA has authorized a health claim on the relationship between calcium and osteoporosis (see 21 CFR 101.72). A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between calcium and osteoporosis. A health claim on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in 21 CFR 101.72 would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, failure to make a claim in accordance with the requirements in 21 CFR 101.72 subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease, osteoporosis.

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

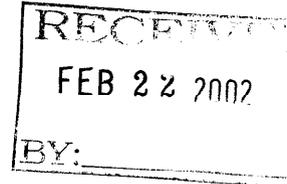
FDA, Denver District Office, Office of Compliance, HFR-SW240

79337

## NOTICE OF STATEMENT

Pursuant to 21 CFR 101.93

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



a. Name and address of manufacturer or distributor:

Neways, Inc.  
150 East 400 North  
Salem, UT 84653

b. The text of the statement:

- Supports prostate health.
- Supports healthy prostate size and function.
- Enhances the support for function of the genitourinary system.
- Supports maintenance of healthy urine flow.
- Enhances prostate health.
- Supports the body's natural defense mechanisms to aid prostate health.
- May also support the maintenance of a full, healthy head of youthful-looking hair.
- Supports the body's fight to ease minor pain and inflammation of the urethra and soothe urinal urgency.
- Promotes nutritional support for the health of the male genitourinary system.
- Supports the protection of healthy prostate growth.

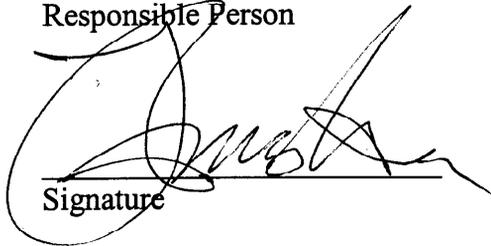
c. The name of the dietary ingredient or supplement:

Saw Palmetto Berry Extract, Pygeum Africanum Bark Extract, Nettle Root Extract, Tomato Fruit Extract.

c. The name of the dietary supplement including brand name:

Prostality

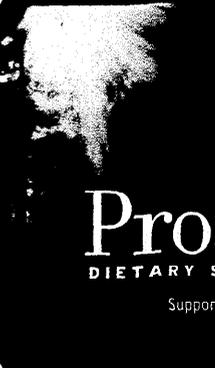
Responsible Person



Signature

President  
Title

2/13/02  
Date



NUTRITIONALS  
HEALTH FOR MEN



# Prostality™

DIETARY SUPPLEMENT

Supports Prostate Health\*

60 Soft Caps (340 mg Each)

## Supplement Facts

Serving Size 1 Capsule

Servings Per Container 60

Amount Per Serving	% Daily Value
Proprietary Blend	334 mg*
Saw Palmetto Berry Extract, Pygeum Africanum Bark Extract, Nettle Root Extract, Tomato Fruit Extract (6.8% lycopene).	

\* Daily Value not established

Other ingredients: Soybean oil (GMO free), gelatin, glycerin, water, yellow beeswax, carob extract, lecithin.

**DIRECTIONS:** Take one capsule twice daily or two capsules at bedtime with a meal or a snack.

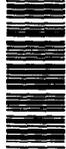
**CAUTION:** Possible mild stomach upset. Do not use if inner seal is broken or missing. Consult your health care provider prior to use if you are pregnant or nursing, have a medical condition or when taking any medication.

**STORAGE:** Keep tightly closed and store in a cool, dry place.

**STORE OUT OF REACH OF CHILDREN**

Neways uses natural source materials that may cause color variation in the product.

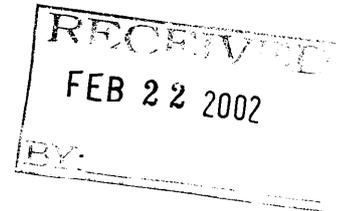
\* This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.



LBL-1375 • ITEM #1036 • Distributed by NEWAYS, INC., Salem, Utah 84653  
<http://www.neways.com> • Made in the U.S.A.

# NOTICE OF STATEMENT

Pursuant to 21 CFR 101.93



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

a. Name and address of manufacturer or distributor:

Neways, Inc.  
150 East 400 North  
Salem, UT 84653

b. The text of the statement:

- Regular exercise and a healthy diet with enough calcium helps teen and young adult white and Asian women maintain good bone health and may reduce their high risk of osteoporosis later in life. Adequate calcium intake is important, but daily intakes above about 2,000 mg are not likely to provide any additional benefit.
- Taking calcium supplements during childhood and young adulthood supports bone health and boosts the potential for optimal bone health later in life.
- Supports effective weight management, and colon, cardiovascular, and hormonal health.
- Supports, strengthens and protects your bones and teeth.
- Supports normal bone growth and development.
- CalQlat may also have a positive effect on cardiovascular and colon health, and enhance effective weight management programs.
- CalQlat fortifies and maintains bone mineral density.
- Supports optimal calcium absorption.
- Supports nutrition for heart, cardiovascular system, and blood as well as acting as powerful antioxidants.

c. The name of the dietary ingredient or supplement:

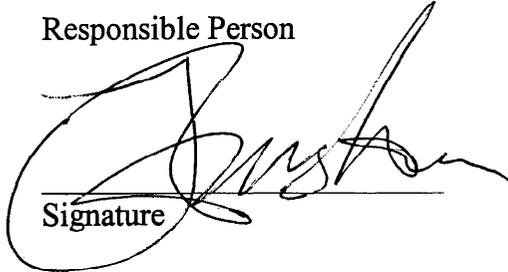
TruCal FX (with galactooligosaccharides), Fulvic Acid

79337

c. The name of the dietary supplement including brand name:

calQlat

Responsible Person



Signature

President  
Title

2/13/02  
Date

# calQlat™

Mineral Supplement

Calcium, Magnesium & Phosphorus

Prohydroxyapatite™

chewable

NO SUGAR ADDED

60 CHOCOLATE CHEWS

6.9g, 24 mg Ca

Building Strong Bones\*

## Supplement Facts

Serving Size 1 Chocolate Chew

Amount Per Serving		% Daily Value
Calories	27	
Calories from Fat	13.5	
Total Fat	1.5 g	2%*
Saturated Fat	1.2 g	6%*
Sodium	15 mg	1%
Total Carbohydrate	3 g	1%*
Sugar	0.6 g	
Protein	340 mg	1%*
Vitamin D (as cholecalciferol)	260 IU	65%*
Calcium	480 mg	48%*
Phosphorus	260 mg	26%*
Magnesium	28 mg	7%*
Potassium	16 mg	< 1%*

Proprietary Blend  
TruCal FX® (with galactooligosaccharides)\*\*, Fulvic Acid 1799 mg†

\*Percent Daily Values are based on a 2,000 calorie diet.

†Daily Value not established

**OTHER INGREDIENTS:** Maltitol syrup, unsalted butter, chocolate, calcium caseinate, partially hydrogenated soybean oil, mono and diglycerides, soya lecithin, natural chocolate flavor.

\*\*TruCal FX® is a registered trademark of Glanbia Ingredients USA and is the source of Newways Prohydroxyapatite™.

**DIRECTIONS:** Take one piece two times daily.

**CAUTION:** Consult your health care provider prior to use if you are pregnant or nursing, have a medical condition, or when taking any medication.

**STORAGE:** Keep tightly closed and store in a cool, dry place.

**STORE OUT OF REACH OF CHILDREN**

## BONE UP ON CALQLAT—

- Prohydroxyapatite™ is Newways' unique form of soluble minerals—minerals that are essential for peak health. Prohydroxyapatite™ found in calQlat provides calcium, phosphorus, and other minerals in the proper ratio required by the body.
- calQlat provides a simple way to supplement a calcium and major mineral deficient diet and contains ingredients that aid the body in absorbing calcium.
- Regular exercise and a healthy diet with enough calcium helps teen and young adult white and Asian women maintain good bone health and may reduce their high risk of osteoporosis later in life. Adequate calcium intake is important, but daily intakes above about 2,000 mg are not likely to provide any additional benefit.
- Taking calcium supplements during childhood and young adulthood supports bone health and boosts the potential for optimal bone health later in life.\*
- In addition to boosting bone health, the calcium found in calQlat supports effective weight management, and colon, cardiovascular, and hormonal health.\*

\* 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.