



MAR 26 2002 13:07

Mr. John Morley

President

Natural Factors Nutritional Products, Inc.

1111 80th Street, S.W.

Suite 100

Everett, Washington 98203

Dear Mr. Morley:

This is in response to your letters of November 20, 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 Natural Factors Nutritional Products, Inc. is making the following claims for the following products:

The product **Glucose Balance Herbal Formula** uses the claims "...help support blood sugar levels," "maintains healthy blood [sic] sugar levels," and "...maintain healthy cholesterol." The product **Garlic Factors™ Enteric Coated Garlic** uses the claim "maintain healthy cholesterol levels." In the preamble to the January 6, 2000 final rule on structure/function claims for dietary supplements (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The cholesterol claims for your products contain no such clarification, however. Therefore, FDA considers them to be implied claims to prevent coronary heart disease by preventing the development of elevated cholesterol levels or reducing elevated cholesterol. The same principle applies to your claims about support and maintenance of blood sugar levels; that is, a claim that does not make clear that the product is only for people with blood sugar that is already within normal limits implies that the product is intended to treat diabetes, which is a disease.

The products **Kava Kava Extract (150 mg and 300 mg potencies)** use the claim "...promotes relaxation during times of anxiety and insomnia." Under 21 CFR 101.93(g)(2)(ii), a claim that a product has an effect on the characteristic signs or symptoms of a disease or class of diseases is an implied disease claim. Anxiety and insomnia are characteristic symptoms of anxiety disorders. In addition, insomnia is itself a disease. Thus, your claim implies that the product is intended to treat, prevent, or mitigate diseases, namely, anxiety disorders and insomnia.

975-0163

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The product **Cranberry Juice Extract** uses the claim "...contains factors that inhibit bacteria from attaching themselves to the urinary tract and bladder." In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1030), FDA stated that the claim "deters bacteria from adhering to the wall of the bladder and urinary tract" is a disease claim because it implies prevention of bacterial infections of the bladder and urinary tract. Your claim is essentially identical to the claim quoted in the final rule and, like that claim, implies prevention of a class of diseases.

The product **ProstCare Saw Palmetto with Pygeum** uses the claims ".....beneficial for supporting normal urine flow rate and moderating nighttime urinary frequency." It uses these claims in the context that the product will "support healthy prostate function" and "make a positive difference for men over 40." 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 the claim "helps to maintain normal urine flow in men over 50 years old," which is similar to your claims. 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.

The product **Echinamide™ Active Defense Echinacea Syrup** uses the claim "...a natural remedy to combat the flu and associated distress.." This claim establishes that the product is intended to treat or mitigate influenza, a disease.

The product **Echinamide™ Anti-V Formula** uses the claims "support the body's resistance to pathogens" and "supports resistance to pathogens." Under 21 CFR 101.93(g)(2)(viii), a claim that a product has a role in the body's response to a disease or a vector of a disease is a disease claim. The claims for your product represent that this product is intended to treat or prevent specific diseases, that is, diseases caused by pathogenic microorganisms.

The product **Bone factors with Ipriflavone** uses the claims "...designed for women to strengthen and protect their bones as they gracefully age, "increases bone density," and "promotes bone health before and after menopause." In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that a claim to "maintain normal bone density in post-menopausal women" is a disease claim because post-menopausal women characteristically develop osteoporosis, a disease whose principal sign is decreased bone mass. The claim for your product is a disease claim because it, in major part, represents the product as being intended to increase and

preserve bone density in post menopausal women and, therefore, to prevent or treat the disease osteoporosis.

The product **Aller-Ease Formula** uses the claims "...support the respiratory tract, especially during the spring season," "soothe the throat and lungs," "ease seasonal respiratory distress," and "seasonal support for the respiratory tract." These claims, including the name of the product itself (i.e., Aller Ease Formula), are disease claims because they suggest that the product is intended to treat, prevent, or mitigate a disease, namely allergies.

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 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 stated that you were making claims that imply that the product **Riboflavin B2 100 mg** is useful to treat or prevent riboflavin deficiency. 21 U.S.C. 343(r)(6)(A) provides, among other things, that the labeling of a dietary supplement may bear a statement that "claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States."

The statements that you are making for **Riboflavin B2 100 mg** misbrand this product under 21 U.S.C. 343(r)(6)(A) because they describe a benefit related to a classical nutrient deficiency disease but do not disclose the prevalence of the subject deficiency disease in the United States.

21 U.S.C. 321(g)(1) (last sentence) provides that a food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 403(r)(6) is not a drug under clause (C) (i.e., 21 U.S.C. 321(g)(1)(C)) solely because the label or the labeling contains such a statement. The statements being made for the product **Riboflavin B2 100 mg** are not made in accordance with 21 U.S.C. 343(r)(6), however, and these statements suggest that the products are intended to treat, prevent, mitigate, or cure diseases or are articles (other than food) intended to affect the structure or any function of the body of man. Therefore, these claims suggest that the product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B) and (C), and that it is subject to regulation under the drug provisions of the Act. Your submission also states that Natural Factors Nutritional Products, Inc. is marketing the product **Echinamide™ Throat Spray Formula** as a dietary supplement. This

product does not appear to meet the statutory definition of a dietary supplement contained in 21 U.S.C. 321(ff), and therefore, cannot be marketed as a dietary supplement. We explain the basis for our opinion below.

The term "dietary supplement" is defined in 21 U.S.C. 321(ff). 21 U.S.C. 321(ff) provides that the term means a product (other than tobacco) intended to supplement the diet that bears or contains a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any of the above ingredients. 21 U.S.C. 321(ff) further states that dietary supplements are intended for ingestion in a form described in 21 U.S.C. 350(c)(1)(B)(i) or in compliance with 21 U.S.C. 350(c)(1)(B)(ii), are not represented as conventional food or as a sole item of a meal or the diet, and are labeled as a dietary supplement.

This product is not "intended for ingestion." As stated above, the definition of dietary supplement in 21 U.S.C. 321(ff) states that a dietary supplement is a product "intended for ingestion." The term "ingestion" has been addressed by the court in United States v. Ten Cartons, Ener-B Nasal Gel, 888 F. Supp. 381, 393-94 (E.D.N.Y.), aff'd, 72 F.3d 285 (2d Cir. 1995), which states:

The ordinary and plain meaning of the term "ingestion" means to take into the stomach and gastrointestinal tract by means of enteral administration. See Stedman's Medical Dictionary (4th Lawyer's Ed. 1976) (defining ingestion as the "introduction of food and drink into the stomach."); Webster's Third New International Dictionary (1976) (defining ingestion as "the taking of material (as food) into the digestive system.")....

The interpretation of the term "ingestion" to mean enteral administration into the stomach and gastrointestinal tract is also supported by the language of the statutory sections immediately preceding and following section 350(c)(1)(B)(ii). Section 350(c)(1)(B)(i) states that the vitamin must be intended for ingestion in tablet, capsule or liquid form. Each of these forms denotes a method of ingestion that involves swallowing into the stomach. Section 350(c)(2) states that a food is intended for ingestion in liquid form under section 350(c)(1)(B)(i) "only if it is formulated in a fluid carrier and is intended for ingestion in daily quantities measured in drops or similar small units of measure." This elaboration of "liquid form" also denotes ingestion by swallowing the fluid.

Therefore, because the term "ingestion" means introduced into the gastrointestinal tract, a product that is used to "soothe a scratchy, raw throat and freshen the breath as well as lubricate a dry mouth and throat" is not subject to regulation as a dietary supplement because it is not "intended for ingestion."

Page 5 - Mr. John Morley

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

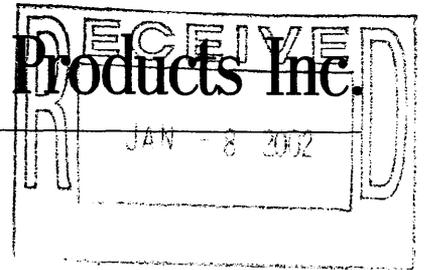
Copies:

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, Seattle District Office, Office of Compliance, HFR-PA340

Natural Factors Nutritional Products Inc.



December 3, 2001

Food and Drug Administration
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
200 C St. SW
Washington, DC 20204

Dear Sir or Madam:

This is to provide the required information to comply with our obligation under DSHEA labeling regulations.

Supplement: Echinacea Throat Spray

Manufacturer, packer: Natural Factors Nutritional Products, Ltd.
1550 United Blvd.
Coquitlam, B.C.
Canada V3K 6Y7

Distributor: Natural Factors Nutritional Products, Inc.
1111 80th St. SW, Suite 100
Everett, WA 98203

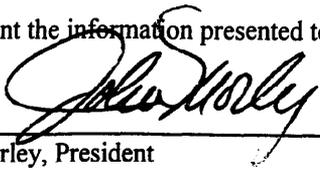
Text of side Panel: A throat spray to soothe a scratchy, raw throat and freshen the breath as well as lubricate a dry mouth and throat.*

Text of PDP: EASES THROAT DISCOMFORTS*

Name of dietary ingredient that is the subject of statement: Echinacea

Name of dietary supplement: ECHINAMIDE™ Throat Spray Formula

I represent the information presented to be accurate and in compliance with supplement label regulations.



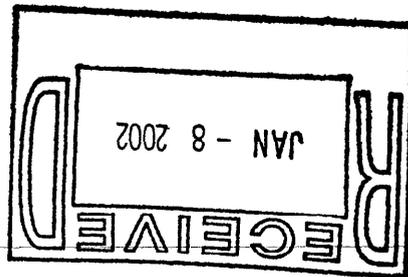
John Morley, President

12/10/01
Date

1111 80th Street S.W., Suite 100
Everett, WA, USA 98203
Phone: (425) 513-8800
Fax: (425) 348-9050

78861

Natural Factors Nutritional Products Inc.



December 3, 2001

Food and Drug Administration
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
200 C St. SW
Washington, DC 20204

Dear Sir or Madam:

This is to provide the required information to comply with our obligation under DSHEA labeling regulations.

Supplement: Riboflavin (Vitamin B2)

Manufacturer, packer: Natural Factors Nutritional Products, Ltd.
1550 United Blvd.
Coquitlam, B.C.
Canada V3K 6Y7

Distributor: Natural Factors Nutritional Products, Inc.
1111 80th St. SW, Suite 100
Everett, WA 98203

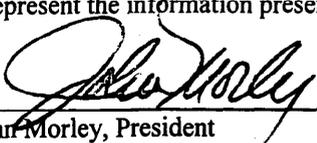
Text of side Panel: Riboflavin (vitamin B2) functions in important enzymes involved in the production of energy.* Riboflavin deficiency is characterized by cracking of the lips and corner of the mouth; an inflamed tongue; visual disturbances such as sensitivity to light and loss of visual acuity; cataract formation; burning and itching of the eyes, lips, mouth and tongue and other signs of disorders of mucous membranes.

Text of PDP: SUPPORT FOR ENERGY AND NORMAL METABOLISM*

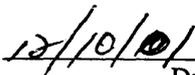
Name of dietary ingredient that is the subject of statement: Riboflavin

Name of dietary supplement: Riboflavin B2 100mg

I represent the information presented to be accurate and in compliance with supplement label regulations.



John Morley, President



Date

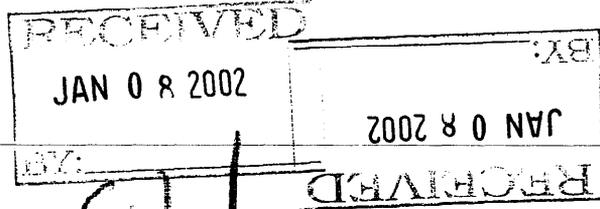
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Center for Food Safety and Applied Nutrition
200 C St. SW
Washington, DC 20204



Dear Sir or Madam:

This is to provide the required information to comply with our obligation under DSHEA labeling regulations.

Supplement: Aller-Ease

Manufacturer, packer: Natural Factors Nutritional Products, Ltd.
1550 United Blvd.
Coquitlam, B.C.
Canada V3K 6Y7

Distributor: Natural Factors Nutritional Products, Inc.
1111 80th St. SW, Suite 100
Everett, WA 98203

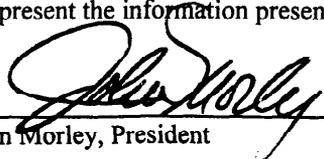
Text of side Panel: Aller-Ease combines powerful antioxidants and standardized herbal extracts to support the respiratory tract, especially during the spring season. Ephedra, Licorice and Wild Cherry Bark soothe the throat and lungs. Proanthoxidants™, a 6-herb complex of plant extracts, is added with Quercitin for respiratory support, particularly in polluted environments.* An ideal comforting formula to ease seasonal respiratory distress.

Text of PDP: SEASONAL SUPPORT FOR THE RESPIRATORY TRACT*

Name of dietary ingredient that is the subject of statement: Ephedra, Licorice, Wild Cherry Bark

Name of dietary supplement: Aller-Ease Formula

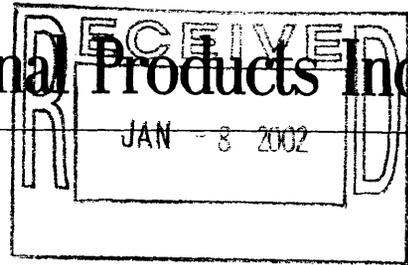
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Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
200 C St. SW
Washington, DC 20204

Dear Sir or Madam:

This is to provide the required information to comply with our obligation under DSHEA labeling regulations.

Supplement: Bone Factors with Ipriflavone

Manufacturer, packer: Natural Factors Nutritional Products, Ltd.
1550 United Blvd.
Coquitlam, B.C.
Canada V3K 6Y7

Distributor: Natural Factors Nutritional Products, Inc.
1111 80th St. SW, Suite 100
Everett, WA 98203

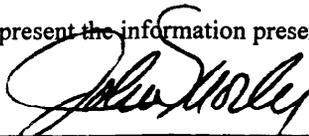
Text of side Panel: Bone Factors is a synergistic blend designed for women to strengthen and protect their bones as they gracefully age. Scientific studies have shown that Ipriflavone, a bone-building nutrient, increases bone density.*

Text of PDP: PROMOTES BONE HEALTH BEFORE AND AFTER MENOPAUSE*

Name of dietary ingredient that is the subject of statement: Ipriflavone

Name of dietary supplement: bone factors with Ipriflavone

I represent the information presented to be accurate and in compliance with supplement label regulations.



John Morley, President

12/10/01
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Natural Factors Nutritional Products Inc.



December 3, 2001

Food and Drug Administration
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
200 C St. SW
Washington, DC 20204

Dear Sir or Madam:

This is to provide the required information to comply with our obligation under DSHEA labeling regulations.

Supplement: ECHINAMIDE™ Anti-V Formula

Manufacturer, packer: Natural Factors Nutritional Products, Ltd.
1550 United Blvd.
Coquitlam, B.C.
Canada V3K 6Y7

Distributor: Natural Factors Nutritional Products, Inc.
1111 80th St. SW, Suite 100
Everett, WA 98203

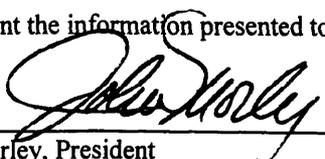
Text of side Panel: Anti-V Formula is the optimal formula to support the body's resistance to pathogens.*

Text of PDP: SUPPORTS RESISTANCE TO PATHOGENS*

Name of dietary ingredient that is the subject of statement: Echinacea, Lomatium, Astragalus, Reishi, Licorice

Name of dietary supplement: ECHINAMIDE™ Anti-V Formula

I represent the information presented to be accurate and in compliance with supplement label regulations.



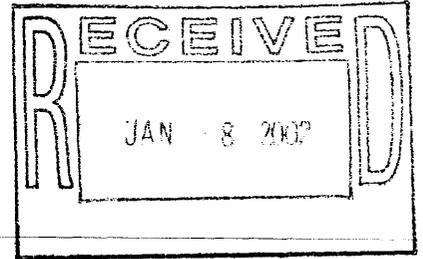
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200 C St. SW
Washington, DC 20204

Dear Sir or Madam:

This is to provide the required information to comply with our obligation under DSHEA labeling regulations.

Supplement: ECHINAMIDE™ Active Defense Syrup

Manufacturer, packer: Natural Factors Nutritional Products, Ltd.
1550 United Blvd.
Coquitlam, B.C.
Canada V3K 6Y7

Distributor: Natural Factors Nutritional Products, Inc.
1111 80th St. SW, Suite 100
Everett, WA 98203

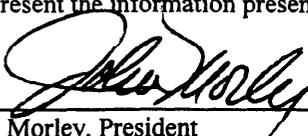
Text of side Panel: Natural Factors Active Defense syrup combines the potent effects of Echinamide™ with supporting herbs to create a natural remedy to combat the flu and associated distress. Soothing and effective, Natural Factors Echinamide™ means guaranteed levels of the key actives, alkylamides, polysaccharides and cichoric acid.

Text of PDP: IMMUNE SUPPORT*

Name of dietary ingredient that is the subject of statement: Echinacea

Name of dietary supplement: ECHINAMIDE™ Active Defense Echinacea Syrup

I represent the information presented to be accurate and in compliance with supplement label regulations.



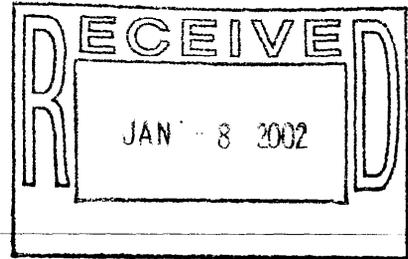
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Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
200 C St. SW
Washington, DC 20204

Dear Sir or Madam:

This is to provide the required information to comply with our obligation under DSHEA labeling regulations.

Supplement: ProstCare Saw Palmetto with Pygeum

Manufacturer, packer: Natural Factors Nutritional Products, Ltd.
1550 United Blvd.
Coquitlam, B.C.
Canada V3K 6Y7

Distributor: Natural Factors Nutritional Products, Inc.
1111 80th St. SW, Suite 100
Everett, WA 98203

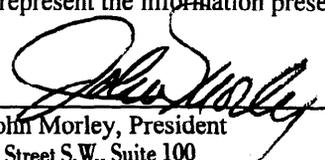
Text of side Panel: Natural Factors ProstCare Formula is a synergistic blend of standardized herbs known to support healthy prostate function in an easy-to-swallow softgel capsule. Substantial scientific research shows both Saw Palmetto berry extract and *Pygeum africanum* are key herbs for prostate health. They have been proven to be safe, well-tolerated and beneficial for supporting normal urine flow rate and moderating nighttime urinary frequency.* This blend is designed to be used with Natural Factors Prost Cleanse for extra genitourinary tract support. When combined with a balanced program of diet, rest and exercise, this special dietary supplement makes a positive difference for men over 40.

Text of PDP: SUPPORT FOR HEALTHY PROSTATE FUNCTION*

Name of dietary ingredient that is the subject of statement: Saw Palmetto & Pygeum africanum

Name of dietary supplement: ProstCare Saw Palmetto with Pygeum

I represent the information presented to be accurate and in compliance with supplement label regulations.

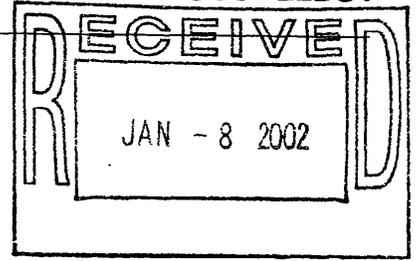

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200 C St. SW
Washington, DC 20204

Dear Sir or Madam:

This is to provide the required information to comply with our obligation under DSHEA labeling regulations.

Supplement: Cranberry Juice Extract

Manufacturer, packer: Natural Factors Nutritional Products, Ltd.
1550 United Blvd.
Coquitlam, B.C.
Canada V3K 6Y7

Distributor: Natural Factors Nutritional Products, Inc.
1111 80th St. SW, Suite 100
Everett, WA 98203

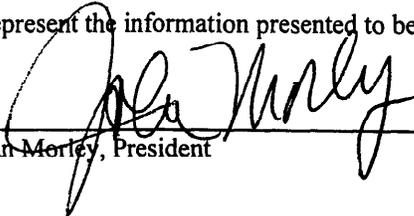
Text of side Panel: Natural Factors Cranberry Juice is a concentrated, standardized extract derived from the juice of unsweetened cranberries. Cranberry Juice contains factors that inhibit bacteria from attaching themselves to the urinary tract and bladder, important for urinary health. Cranberry Juice supports a healthy urinary tract in men as well as women.* Natural Factors Cranberry Juice extract is a superior way to benefit from the health-enhancing effects of cranberry without sugar.

Text of PDP: PROMOTES A HEALTHY URINARY TRACT*

Name of dietary ingredient that is the subject of statement: Cranberry Juice Extract

Name of dietary supplement: Cranberry Juice Extract 500mg

I represent the information presented to be accurate and in compliance with supplement label regulations.

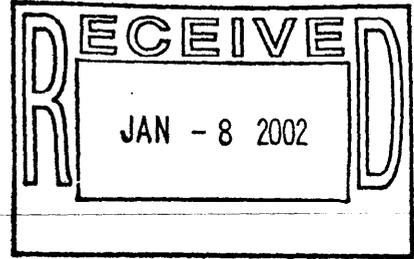

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Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
200 C St. SW
Washington, DC 20204

Dear Sir or Madam:

This is to provide the required information to comply with our obligation under DSHEA labeling regulations.

Supplement: Kava Kava

Manufacturer, packer: Natural Factors Nutritional Products, Ltd.
1550 United Blvd.
Coquitlam, B.C.
Canada V3K 6Y7

Distributor: Natural Factors Nutritional Products, Inc.
1111 80th St. SW, Suite 100
Everett, WA 98203

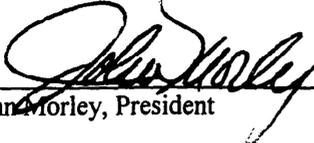
Text of side Panel: Scientific research shows that Kava promotes relaxation during times of anxiety and insomnia, without slowing memory or reaction time.* A sensible program of diet and exercise can enhance the benefits of this standardized herbal product.

Text of PDP: PROMOTES RELAXATION NATURALLY*

Name of dietary ingredient that is the subject of statement: Kava Kava Extract

Name of dietary supplement: Kava Kava Extract 150mg (30% Kavalactones)

I represent the information presented to be accurate and in compliance with supplement label regulations.

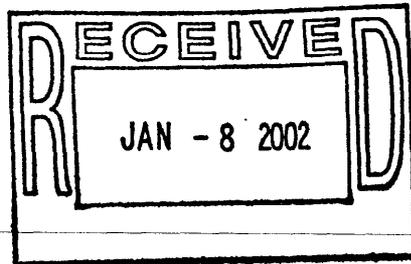

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Supplement: Kava Kava

Manufacturer, packer: Natural Factors Nutritional Products, Ltd.
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Coquitlam, B.C.
Canada V3K 6Y7

Distributor: Natural Factors Nutritional Products, Inc.
1111 80th St. SW, Suite 100
Everett, WA 98203

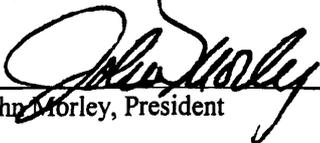
Text of side Panel: Scientific research shows that Kava promotes relaxation during times of anxiety and insomnia, without slowing memory or reaction time.*
Remember that a sensible program of diet and exercise can enhance the benefits of this standardized herbal product.

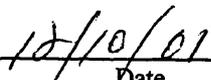
Text of PDP: PROMOTES RELAXATION NATURALLY*

Name of dietary ingredient that is the subject of statement: Kava Kava Extract

Name of dietary supplement: Kava Kava Extract 300mg (30% Kavalactones)

I represent the information presented to be accurate and in compliance with supplement label regulations.

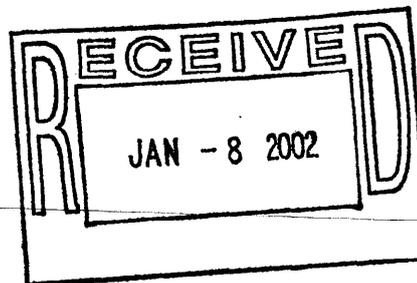

John Morley, President


Date

1111 80th Street S.W., Suite 100
Everett, WA, USA 98203
Phone: (425) 513-8800
Fax: (425) 348-9050

78861

Natural Factors Nutritional Products Inc.



November 29, 2001

Food and Drug Administration
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
200 C St. SW
Washington, DC 20204

Dear Sir or Madam:

This is to provide the required information to comply with our obligation under DSHEA labeling regulations.

Supplement: Enteric Coated Garlic

Manufacturer, packer: Natural Factors Nutritional Products, Ltd.
1550 United Blvd.
Coquitlam, B.C.
Canada V3K 6Y7

Distributor: Natural Factors Nutritional Products, Inc.
1111 80th St. SW, Suite 100
Everett, WA 98203

Text of side Panel: Garlic Factors™ odor controlled enteric coated tablets help maintain healthy cholesterol levels & support a healthy heart. Formulated for maximum bioavailability, Garlic Factors™ delays the breakdown of Alliin until the tablet reaches the small intestine.

Text of PDP: SUPPORTS HEART & CARDIOVASCULAR HEALTH*

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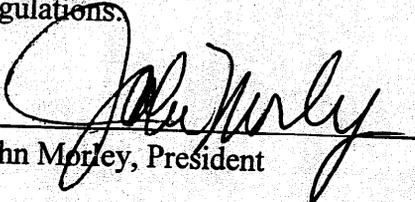
78861

Natural Factors Nutritional Products Inc.

Name of dietary ingredient that is the subject of statement: Garlic

Name of dietary supplement: **GarlicFactors™**

I represent the information presented to be accurate and in compliance with supplement label regulations.


John Morley, President

Dec 12, 2001
Date

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