



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

0518 6 FEB 16 P2 33
FEB 10 2006

Don Ford, M.D., P.A.
President
Atlas Productions, Inc.
325 S.W. 15th Avenue
Pompano Beach, Florida 33069

Dear Dr. Ford:

This is in response to your letter of January 16, 2006 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 Atlas Productions, Inc. is making the following claims:

Nutra/MD™ High Blood Pressure Essential Nutrients Supplement

“[D]esigned for consumers and doctors who know that many blood pressure lowering medicines can hinder or deplete essential nutrients....”

Nutra/MD™ High Cholesterol Essential Nutrients Supplement

“[D]esigned for consumers and doctors who know that many cholesterol-lowering medicines can hinder or deplete essential nutrients....”

Nutra/MD™ Diabetes Essential Nutrients Supplement

“[D]esigned for consumers and doctors who know that many diabetes medications can hinder or deplete essential nutrients....”

Nutra/MD™ Arthritis Essential Nutrients Supplement

“[D]esigned for consumers and doctors who know that many medications given to treat arthritic pain can hinder or deplete essential nutrients....”

In the preamble to the January 6, 2000 final rule on structure/function claims (65 FR 1000 at 1028) FDA agreed that “a general statement that a dietary supplement provides nutritional support would be an acceptable structure/function claim, provided that the statement does not suggest that the supplement is intended to augment or have the same purpose as a specific drug, drug action, or therapy for a disease.” FDA further stated (65 FR at 1029) that “a claim that a product is useful because it counterbalances the effects of a drug in depleting a nutrient or interfering with the metabolism of a nutrient would be acceptable as a structure/function

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claim” if such a claim “would not suggest treatment of an adverse reaction that meets the definition of disease.” However, “if the claim expressly or impliedly suggests that the supplement is intended to augment a specific drug, drug action, or therapy for a disease, or serve the same purpose as a specific drug or therapy for a disease, then the statement may be considered a disease claim.”

While the products described above are nominally represented to replace nutrients lost as a consequence of the use of a drug therapy for various diseases, in fact, other claims unambiguously represent that the products are in fact intended to treat or prevent diseases. High Blood Pressure Essential Nutrients® contains “Heartshield-MD a proprietary blend of 9 different nutrients documented in scientific studies, to aid in the prevention of cardiovascular disease risk factors.” High Cholesterol Essential Nutrients® contains “LipidGuard-MD a proprietary blend of 6 different nutrients which are documented in scientific studies, to help the body fight free radical damage known to be caused by LDL (bad) cholesterol.” It is further represented “to work with your medication and protect your body from the damage induced by LDL (bad) cholesterol.” Diabetes Essential Nutrients® is “designed to work with your medication and aid in blood sugar control.” Arthritis Essential Nutrients® is represented to contain nutrients “necessary to help the body maintain collagen needed for healthy joints.” These claims go beyond representing the products as intended to replace nutrients lost as a consequence of the use of a specific therapy. Rather, they expressly are represented to treat the underlying diseases for which a consumer would be consuming a drug. These claims are disease claims under 21 CFR 101.93(g)(2)(vii) and (ix).

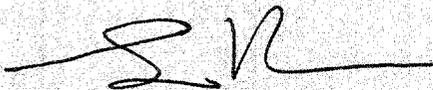
Your submission also states that Menopause Essential Nutrients® contains “HeartGuard-MD a proprietary blend of 4 essential nutrients that have been shown in scientific studies to lower heart disease risk by lowering homocysteine levels” and that “HeartGuard is a proprietary blend of highly bioactive nutrients designed to work with your medication and help reduce the risk of heart disease, stroke, and cancer.” Nutra/MD Contraceptive Hormone Therapy Essential Nutrients® uses the claim that it contains ingredients “to lower the occurrence of neural tube defects in newborn babies” and that it is “designed to work with your medication and help in the prevention of neural tube defects.” “[F]olic acid may reduce the risk of neural tube birth defects” for the product Vitamin B12/Folate.”

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, including the use of disease names in the product names, 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, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

Page 3 - Dr. Don Ford

Please contact us if you require further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'S. Walker', with a long horizontal line extending to the right.

Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
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-310
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Florida District Compliance, HFR-SE240

2006-596

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HFS 870

January 16, 2006

Via CMRRR# 7003 1680 0005 3616 6617

Division of Compliance and Enforcement (HFS-8 10)
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Pain Branch Parkway
College Park, MD 20740

RE: Section 403(r)(6) Notification

Dear Sir or Madam:

Pursuant to Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C § 343(r)(6) and implementing regulation, 21 C.F.R. § 101.93, Don Ford, M.D., P.A., submits this notification that the following statements are being made in the labeling for the dietary supplements, Nutra/MD™ High Blood Pressure Essential Nutrients Supplement, Nutra/MD™ High Cholesterol Essential Nutrients Supplement, Nutra/MD™ Menopause Essential Nutrients Supplement, Nutra/MD™ Contraceptive Hormone Therapy Essential Nutrients Supplement, Nutra/MD™ Diabetes Essential Nutrients Supplement, Nutra/MD™ Arthritis Essential Nutrients Supplement, and Nutra/MD™ Antacid Essential Nutrients Supplement.

Nutra/MD™ High Blood Pressure Essential Nutrients Supplement

NutraMD's High Blood Pressure Essential Nutrients® was designed for consumers and doctors who know that many blood pressure lowering medicines can hinder or deplete essential nutrients required by our bodies to function properly. Many nutritional products on the market today contain supplement nutrients in poorly bio-available forms, and doses that are marginal and ineffective. High Blood Pressure Essential Nutrients® provides meaningful doses of powerful supplement nutrients in their most bio-available forms for enhanced absorption and usage by the body.

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High Blood Pressure Essential Nutrients® contains over 20 different essential nutrients including:

- * *Heartshield-MD®* a proprietary blend of 9 different nutrients documented in scientific studies, to aid in the prevention of cardiovascular disease risk factors.
- * *Ultrasome®* - a patented delivery system of emulsified Coenzyme Q 10.
- * *Optizinc®* - a patented form of highly bio-available zinc
- * *Calcium and magnesium* in 3 different bio-available forms to provide optimal absorption and metabolism by the body.
- * *Chromium* in a polynicotinate form for superior absorption and utilization by the body.
- * *Selenium* as selenomethionine is the most superior form of this mineral available.
- * *Vitamin D* as cholecalciferol is the most bio-available form of this vitamin.
- * *Vitamin C* as buffered calcium and magnesium ascorbates provides enhanced cellular uptake and utilization.
- * *Potassium* chelated (bound) to citrate to increase the absorption and bioavailability.

High Blood Pressure Essential Nutrients® is a blend of highly bioavailable nutrients. Each ingredient is individually assayed for purity, quality, and potency. This supplement product is encapsulated with vegetarian gel caps. It is free of corn, egg, gluten, milk, rice, sodium, soy, wheat, yeast, sugar, synthetic dyes, artificial flavorings, and preservatives.

Heartshield-MD® is a proprietary blend of highly bio-active nutrients designed to protect the cardiovascular system.**

Other Ingredients:

Stearic Acid

Suggested Use:

As a dietary supplement, take 3-7 supplement capsules daily in divided doses with food or as directed by your health practitioner

NutraMD™ High Cholesterol Essential Nutrients Supplement

NutraMD's High Cholesterol Essential Nutrients® was designed for consumers and doctors who know that many cholesterol-lowering medicines can hinder or deplete essential nutrients required by our bodies to function normally. Many nutritional products on the market today contain supplement nutrients in poorly bio-available forms, and doses that are marginal and ineffective. High Cholesterol Essential Nutrients® provides meaningful doses of powerful supplement nutrients in their most bio-available forms for enhanced absorption and usage by the body.

High Cholesterol Essential Nutrients® contains over 20 different essential nutrients including:

* *LipidGuard-MD®* a proprietary blend of 6 different nutrients which are documented in scientific studies, to help the body fight free radical damage known to be caused by LDL (bad) cholesterol.

* *Vitamin B6* in two different forms including pyridoxal 5' phosphate, the most superior active form of vitamin B6.

Two different forms of vitamin B2 including riboflavin 5' phosphate, the most bio-active

form of this vitamin.

- * *Optizinc*® - a patented form of highly bio-available zinc
- * *Chromium* in a polynicotinate form for superior absorption and utilization by the body.
- * *Selenium* as selenomethionine - the most superior form of this mineral available.
- * *Vitamin D* as cholecalciferol - the most bio-available form of this vitamin.
- * *Vitamin C* as buffered calcium and magnesium ascorbates provides enhanced cellular uptake and utilization.

High Cholesterol Essential Nutrients® is a blend of highly bioavailable nutrients. Each ingredient is individually assayed for purity, quality, and potency. This supplement product is encapsulated with vegetarian gel caps. It is free of corn, egg, gluten, milk, rice, sodium, soy, wheat, yeast, sugar, synthetic dyes, artificial flavorings, and preservatives.

LipidGuard-MD® is a proprietary blend of highly bio-active nutrients designed to work with your medication and protect your body from the damage induced by LDL (bad) cholesterol.**

Other Ingredients:

Stearic Acid Ultrasome® is a registered trademark of Herbamed Ltd.

Suggested Use:

As a dietary supplement, take 3-7 supplement capsules daily in divided doses with food or as directed by your health practitioner

Nutra/MD™ Menopause Essential Nutrients Supplement

NutraMD's Menopause Essential Nutrients® was designed for consumers and doctors who know that replacing lost nutrients is a vital part of health maintenance. Many nutritional supplement products on the market today contain nutrients in poorly bio-available forms, and doses that are marginal and ineffective. Menopause Essential Nutrients® sets a new industry standard by providing meaningful doses of powerful supplement nutrients in their most bio-available forms for enhanced absorption and usage by the body.

Menopause Essential Nutrients® contains all of the essential nutrients known to be affected by hormone therapy including:

- * *HeartGuard-MD*® a proprietary blend of 4 essential nutrients that have been shown in scientific studies to lower heart disease risk by lowering homocysteine levels.
- * *Buffered Vitamin C* for enhanced cellular uptake.
- * *Magnesium* in three forms for optimal absorption and utilization by the body.
- * *Selenium* in a highly bio-available monomethionine form
- * *Optizinc*® - a patented form of zinc for better absorption.

Menopause Essential Nutrients® is a blend of highly bioavailable nutrients. Each ingredient is individually assayed for purity, quality, and potency. This supplement product is encapsulated with vegetarian gel caps. It is free of corn, egg, gluten, milk,

rice, sodium, soy, wheat, yeast, sugar, synthetic dyes, artificial flavorings, and preservatives.

HeartGuard-MD® is a proprietary blend of highly bioactive nutrients designed to work with your medication and help reduce the risk of heart disease, stroke, and cancer.**

Other Ingredients:

Magnesium Stearate.

Suggested Use:

As a dietary supplement, take 3 supplement capsules daily with food or as directed by your health practitioner

Nutra/MD™ Contraceptive Hormone Therapy Essential Nutrients Supplement

NutraMD's Contraceptive Hormone Therapy Essential Nutrients® was designed for consumers and doctors who know that replacing lost nutrients is a vital part of health maintenance. Many nutritional supplement products on the market today contain nutrients in poorly bio-available forms, and doses that are marginal and ineffective. Contraceptive Hormone Therapy Essential Nutrients® provides meaningful doses of powerful nutrients in their most bio-available forms for enhanced absorption and usage by the body.

Contraceptive Hormone Therapy Essential Nutrients® contains all of the essential supplement nutrients known to be affected by hormone contraceptive medications including:

* *NTD/Guard-MD®* a proprietary blend of 6 essential nutrients. The doses used have been shown in scientific studies to lower the occurrence of neural tube defects in newborn babies

* *Buffered Vitamin C* for enhanced cellular uptake.

* *Vitamin B12* in a methylated form for greater metabolic activity.

Hormone Therapy Essential Nutrients® is a blend of highly bioavailable nutrients. Each ingredient is individually assayed for purity, quality, and potency. This supplement product is encapsulated with vegetarian gel caps. It is free of corn, egg, gluten, milk, rice, sodium, soy, wheat, yeast, sugar, synthetic dyes, artificial flavorings, and preservatives.

NTD/Guard-MD® is a proprietary blend of highly bioactive nutrients designed to work with your medication and help in the prevention of neural tube defects.**

Other Ingredients:

Magnesium Stearate.

Suggested Use:

As a dietary supplement, take 3 supplement capsules daily with food or as directed by your health practitioner.

Nutra/MD™ Diabetes Essential Nutrients Supplement

NutraMD's Diabetes Essential Nutrients® was designed for consumers and doctors who

know that many diabetic medications can hinder or deplete essential nutrients required by our bodies to function normally. Many nutritional products on the market today contain supplement nutrients in poorly bio-available forms, and doses that are marginal and ineffective. Diabetes Essential Nutrients® provides meaningful doses of powerful supplement nutrients in their most bio-available forms for enhanced absorption and usage by the body.

Diabetes Essential Nutrients® contains over 20 different essential nutrients including:

- * *SugarGuard-MD®* a proprietary blend of 5 different nutrients that are necessary to help the body metabolize sugars properly.
- * *Vitamin B6* in two different forms including pyridoxal 5' phosphate, the most superior active form of vitamin B6.
- * *Vitamin E* in an all natural (non synthetic) form.
- * *Vitamin B12* in a methylated form for enhanced metabolic action.
- * *Emulsified Coenzyme Q10* as Ultrasome® - a patented delivery system for greater absorption and availability.
- * *Selenium* as selenomethionine - the most superior form of this mineral available.
- * *Vitamin D* as cholecalciferol - the most bio-available form of this vitamin.
- * *Vitamin C* as buffered calcium and magnesium ascorbates provides enhanced cellular uptake and utilization.

Diabetes Essential Nutrients® is a blend of highly bioavailable nutrients. Each ingredient is individually assayed for purity, quality, and potency. This supplement product is encapsulated with vegetarian gel caps. It is free of corn, egg, gluten, milk, rice, sodium, soy, wheat, yeast, sugar, synthetic dyes, artificial flavorings, and preservatives.

SugarGuard-MD® is a proprietary blend of highly bio-active nutrients designed to work with your medication and aid in blood sugar control. **

Other Ingredients:

Stearic Acid

Suggested Use:

As a dietary supplement, take 3-7 supplement capsules daily in divided doses with food or as directed by your health practitioner.

NutraMD™ Arthritis Essential Nutrients Supplement

NutraMD's Arthritis Essential Nutrients® was designed for consumers and doctors who know that many medications given to treat arthritic pain can hinder or deplete essential nutrients required by our bodies to function normally. Many nutritional products on the market today contain supplement nutrients in poorly bio-available forms, and doses that are marginal and ineffective. Arthritis Essential Nutrients® sets a new industry standard by providing meaningful doses of powerful supplement nutrients in their most bio-available forms for enhanced absorption and usage by the body.

Arthritis Essential Nutrients® contains over 10 different forms of essential nutrients including:

* *JointShield-MD®* a proprietary blend of 4 different nutrients that are necessary to help the body maintain collagen needed for healthy joints.

* *Magnesium* in three different forms for enhanced absorption and usage by the body.

* *Vitamin B12* in a methylated form for enhanced metabolic action.

* *Vitamin D* as cholecalciferol - the most bio-available form of this vitamin.

Arthritis Essential Nutrients® is a blend of highly bioavailable nutrients. Each ingredient is individually assayed for purity, quality, and potency. This supplement product is encapsulated with vegetarian gel caps. It is free of corn, egg, gluten, milk, rice, sodium, soy, wheat, yeast, sugar, synthetic dyes, artificial flavorings, and preservatives.

Other Ingredients:

Magnesium Stearate and Silicon Dioxide.

Suggested Use:

As a dietary supplement, take 2 supplement capsules twice daily with food or as directed by your health practitioner.

Nutra/MD™ Antacid Essential Nutrients Supplement

NutraMD's Antacid Essential Nutrients® was designed for consumers and doctors who know that replacing lost nutrients is a vital part of health maintenance. Many nutritional supplement products on the market today contain nutrients in poorly bio-available forms, and doses that are marginal and ineffective.

Antacid Essential Nutrients® sets a new industry standard by providing meaningful doses of powerful supplement nutrients in their most bio-available forms for enhanced absorption and usage by the body.

It contains over 10 different forms of essential nutrients including:

* *MineralGuard-MD?* a proprietary blend of 7 forms of minerals in highly bioavailable forms to enhance absorption and ensure adequate intake.

* *Buffered Vitamin C* for enhanced cellular uptake.

* *Selenium as selenomethionine* – a highly bio-available form to increase absorption.

* *Vitamin B12* in a methylated form for enhanced metabolic action.

* *Vitamin D* as cholecalciferol - the most bio-available form of this vitamin.

Antacid Essential Nutrients® is a blend of highly bioavailable nutrients. Each ingredient is individually assayed for purity, quality, and potency. This supplement product is encapsulated with vegetarian gel caps. It is free of corn, egg, gluten, milk, rice, sodium, soy, wheat, yeast, sugar, synthetic dyes, artificial flavorings, and preservatives.

Other Ingredients:

Magnesium Stearate and Silicon Dioxide.

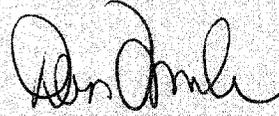
Suggested Use:

The manufacturer and packer of these dietary supplements is Atlas Productions, Inc. The address of Atlas Productions, Inc., 325 S. W. 15th Avenue, Pompano Beach, Florida 33069.

I certify that the information contained in this notification is complete and accurate and that Don Ford, M.D., P.A. has substantiation that the foregoing statements are truthful and not misleading.

Thank you for your time and attention to this matter. If you have any questions, please do not hesitate to contact me.

Sincerely,

A handwritten signature in black ink, appearing to read "Don Ford", written in a cursive style.

Don Ford, MD
President

DF/mdp