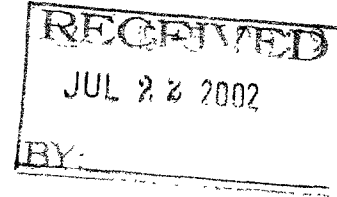


# NUTRA THERAPEUTICS™

4721



July 18, 2002

Division of Compliance and Enforcement  
Office of Nutritional Products, Labeling and Dietary Supplements  
US Food & Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

Via Courier

Dear Sirs:

Please find enclosed copies of labels for a line of dietary supplements we have recently begun to distribute.

These labels each contain statements allowed for under section 403 (r) (6) of the Federal Food, Drug, & Cosmetic Act.

As President of this company, I hereby certify that the statements made are complete and accurate and our company has substantiation that the statements are truthful and not misleading.

Should you require any further information with regards to this matter, please contact me at (888) 251-1010 or by email, [jim@nutratherapeutics.com](mailto:jim@nutratherapeutics.com).

Sincerely yours,

A handwritten signature in black ink, appearing to read "Jim Meschino", with a long horizontal flourish extending to the right.

Dr. James Meschino DC, MS.  
President, Nutra Therapeutics International

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10668

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**Suggested Supplementations:** Premenopausal: Adults take 1 capsule per day as a dietary supplement. Postmenopausal: Adults take 1 capsule in the morning and 1 capsule in the evening as a dietary supplement.

**Women's Hormonal Support** contains three herbal agents that have been shown to reduce menopausal symptoms, help balance female hormones, reduce the symptoms of premenstrual syndrome, support female reproductive health and enhance the feeling of well being.

This unique blend of proven ingredients has been formulated to support a woman's hormonal health and well being throughout her adult life.<sup>SM</sup>

Do not use if outer seal is broken or missing.  
Store in a cool, dry location. Keep out of reach of children.

\*\*The FDA has not evaluated this statement. This product is not intended to diagnose, treat, cure, or prevent disease.



**NUTRA THERAPEUTICS**

*The Natural Choice of  
Healthcare Professionals*

**WOMEN'S  
HORMONAL  
SUPPORT**

• All Natural Support for  
Women's Hormonal Health and Well Being\*\*

• With Black Cohosh,  
Soy Extract & Gamma-oryzanol

DIETARY SUPPLEMENT / 60 CAPSULES

**Supplement Facts**

Serving Size 2 Capsules	Servings per Container 30	
	Amount Per Serving	%Daily Value
Black Cohosh (std. 2.5% Iridopenes)	160 mg	*
Soy Extract (std. 10% Soy Isoflavones)	500 mg	*
Gamma-oryzanol (as Ferulic acid)	300 mg	*
*Daily Value Not Established**Daily Value Not Established		

Other Ingredients: Microcrystalline Cellulose, Stearic Acid (vegetable source), Potatoes, Gelatin.

Does not contain artificial preservatives, colors, flavors, or added sugar, corn, starch, milk products, egg, wheat, yeast, and is salt free.

Guaranteed quality, purity and potency.

Distributed by: Nutra Therapeutics International  
40 East Main Street, #168, Newark, DE 19711

For research articles and education visit [www.nutra-education.com](http://www.nutra-education.com)

**ARTWORK APPROVAL**

FAX APPROVAL TO #: 905-470-5450


ARTIST: AMANDA / # OF PAGES:


DATE: OCT. 23/01

CONTACT: BRUNO

CUSTOMER: MESCHINO

FAX #: ( 905) 470-9074

 269 577  
PURPLE GREEN

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DIE# AF41 DOCKET#:00000  
LABEL SIZE: 2.25" X 6.25"

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SECOND PROOF REQUIRED

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APPROVED AS IS: \_\_\_\_\_



APPROVAL DATE: \_\_\_\_\_

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Supplement Facts		
Serving Size	Amount Per Serving	% Daily Value
120 Caplets	2,500 IU	50
Vitamin A (as palmitate)	10,000 IU	200
Biotin	400 IU	100
Vitamin D (as cholecalciferol)	400 IU	1,333
Vitamin E (as d-alpha-tocopherol succinate)	1,000 mg	1,664
Vitamin C (as ascorbic acid)	50 mg	3,333
Vitamin B1 (as thiamine mononitrate)	50 mg	2,500
Vitamin B2 (as riboflavin)	50 mg	2,500
Vitamin B3 (as pyridoxine hydrochloride)	50 mg	250
Niacin (as niacinamide)	50 mg	453
Vitamin B12 (as cyanocobalamin)	50 mcg	500
D-Folate (as calcium L-folate)	100 mcg	100
Edible	300 mg	100
Biotin	300 mg	100
Calcium (as calcium carbonate and citrate)	200 mg	50
Magnesium (as magnesium oxide)	200 mg	50
Copper (as copper gluconate)	2 mg	33
Manganese (as manganese gluconate)	2 mg	100
Chromium (as chromium picolinate)	50 mcg	72
Molybdenum (as molybdenum L-glutamate)	50 mcg	72
Selenium (as selenium L-methionine)	100 mcg	182
Zinc (as zinc citrate)	50 mg	100
Hydroxyapatite (as silica complex)	50 mg	50
Proprietary Blend	6 mg	6

\*Daily Value Not Established  
 Other Ingredients: Microcrystalline Cellulose, Croscarmellose Sodium, Stearic Acid (vegetable source), Magnesium Stearate (vegetable source), Calcium Silicate.

**NUTRA THERAPEUTICS**  
*The Natural Choice of Healthcare Professionals*

**ALL-IN-ONE MULTI-VITAMIN & MINERAL**

- Enriched with Antioxidants B-SO Complex & 500 mg of Elemental Calcium
- With 25 Vitamins and Minerals

DIETARY SUPPLEMENT / 120 CAPLETS

Suggested Supplementations: Adults take two caplets twice daily with meals as a dietary supplement.

The All-in-One Multi-Vitamin and Mineral provides a number of essential nutrients, including 300 mg of elemental calcium, 500 mg of vitamin E, as well as beta-carotene, lycopene, lutein, luteinamide and other important health-promoting nutrients.

Do not use if caplet is broken or missing. Store in a cool, dry location. Keep out of reach of children.

\*The FDA has not evaluated this statement. This product is not intended to diagnose, treat, cure, or prevent disease.

Guaranteed quality, purity and potency. Does not contain artificial preservatives, colors, flavors, or added sugar, corn, starch, milk products, egg, wheat, yeast, and is salt free.

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**ARTWORK APPROVAL**  
 FAX APPROVAL TO #: 905-470-5450  
 ARTIST: AMANDA / # OF PAGES:  
 DATE: Sept 26/01  
 CONTACT: BRUNO  
 CUSTOMER: MESCHINO  
 FAX #: (905) 470-9074

269 5777  
 PURPLE GREEN  
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FINAL

**Suggested Supplementation:** Adults take one capsule twice daily with meals as a dietary supplement.

Prostate 40 Plus contains a special blend of all-natural, high-grade nutrients that are known to reverse prostate enlargement and defend the prostate against age-related changes. These ingredients have been shown to block the age-related build up of dihydrotestosterone, which causes prostate enlargement and an undesirable rapid prostate cell division rate. This product also contains the antioxidants, lycopene and soy isoflavones, which are known to protect the prostate against free radical damage.\*\*

Prostate 40 Plus is an essential supplement for all men 40 and older.\*\*

Do not use if outer seal is broken or missing. Store in a cool, dry location. Keep out of reach of children.

\*\*The FDA has not evaluated this statement. This product is not intended to diagnose, treat, cure, or prevent disease.



**NUTRA THERAPEUTICS**

*The Natural Choice of  
Healthcare Professionals*

**PROSTATE 40  
PLUS**

- Anti-aging Prostate Protection\*\*
- With Saw Palmetto & Beta-Sitosterol

DIETARY SUPPLEMENT / 60 CAPSULES

Supplement Facts	
Serving Size: 2 Capsules	
Amount Per Serving	
	% Daily Value
Saw Palmetto Extract (std. 45% fatty acids and saponins)	640 mg
Pygeum Africanum (std. 12% pterocarpans)	200 mg
Soy Extract (std. 10% Soy Isoflavones)	200 mg
beta-Sitosterol	130 mg
5mg mg. Nettle Extract (std. 5:1 extract)	60 mg
Pumpkin Seed Extract (std. 4:1 extract)	50 mg
Lycopene Powder	25 mg

\*Daily Values Not Established

Other Ingredients: Organic Brown Rice Flour, Stearic Acid (vegetable source) and Cellulose.

Does not contain artificial preservatives, colors, flavors, or added sugar, corn, wheat, milk products, eggs, yeast, yeast, and is salt free.

Guaranteed quality, purity and potency.

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FAX APPROVAL TO #: 905-470-8450

ARTIST: ANANDA / # OF PAGES:

DATE: Dec. 10/01

CONTACT: BRUNO

CUSTOMER: MESCHINO

FAX #: (905) 470-9074



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OK

**Suggested Supplementation:** For general health maintenance, take one capsule per day with a meal. For therapeutic applications, take 2 to 4 capsules per day with meals.

Immuno-Detox Prime contains bioactive phytonutrients that are known to enhance immune system function and aid in the detoxification of environmental toxins, contaminants, pollutants and other chemicals. As a daily supplement it supports the health and function of the immune system and liver.\*\*

Do not use if outer seal is broken or missing. Store in a cool, dry location. Keep out of reach of children.

\*\*The FDA has not evaluated this statement. This product is not intended to diagnose, treat, cure, or prevent disease.



**NUTRA THERAPEUTICS**

*The Natural Choice of  
Healthcare Professionals*

**IMMUNO-DETOX  
Prime**

- WITH REISHI MUSHROOM EXTRACT •
- Natural Agents for Enhanced Immune Function\*\*
- Phytonutrients that Boost Detoxification\*\*

DIETARY SUPPLEMENT / 60 CAPSULES

Supplement Facts		
Serving Size: 1 Capsule	Servings per Container: 60	
	Amount Per Serving	%Daily Value
Milk Thistle (80% silymarin content)	150 mg	*
Indole-3-Carbinol (97% grade)	25 mg	*
Astragalus (2:1 grade)	100 mg	*
Reishi Mushroom Extract (std. to 10% polysaccharides, 4% triterpenes)	30 mg	*
*Daily Value Not Established		

Other Ingredients: Stearic Acid (vegetable source), Organic Brown Rice Flour and gelatin.

Does not contain artificial preservatives, colors, flavors, or added sugar, corn, starch, milk products, egg, wheat, yeast, and is salt free.

Guaranteed quality, purity and potency.

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**Suggested Supplementation:** For general health maintenance, take one capsule per day with a meal. For therapeutic applications, take 2 to 4 capsules per day with meals.

Immuno-Detox Prime contains bioactive phytonutrients that are known to enhance immune system function and aid in the detoxification of environmental toxins, contaminants, pollutants and other chemicals. As a daily supplement it supports the health and function of the immune system and liver.\*\*

Do not use if outer seal is broken or missing. Store in a cool, dry location. Keep out of reach of children.

\*\*The FDA has not evaluated this statement. This product is not intended to diagnose, treat, cure, or prevent disease.

Supplement Facts		
Serving Size: 1 Capsule	Servings per Container: 60	
	Amount Per Serving	%Daily Value
Milk Thistle (80% silymarin content)	150 mg	*
Indole-3-Carbinol (97% grade)	25 mg	*
Astragalus (2:1 grade)	100 mg	*
Reishi Mushroom Extract (std. to 10% polysaccharides, 4% triterpenes)	30 mg	*
*Daily Value Not Established		

Other Ingredients: Stearic Acid (vegetable source), Organic Brown Rice Flour and gelatin.

Does not contain artificial preservatives, colors, flavors, or added sugar, corn, starch, milk products, egg, wheat, yeast, and is salt free.

Guaranteed quality, purity and potency.

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ARTIST: AMANDA / # OF PAGES:  
DATE: JAN. 07/02  
CONTACT: BRUNO  
CUSTOMER: MESCHIND  
FAX #: (905) 470-9074

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PURPLE GREEN  
DIE# AF41 DOCKET#:00000  
LABEL SIZE: 2.75" X 7.25"

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THIS COLOUR OUTPUT IS NOT A PRESS PROOF • CONSULT A PANTONE COLOUR CHART OR A PRESS PROOF FOR A MORE ACCURATE COLOUR REPRESENTATION

**Suggested Supplementations:** Adults take one capsule three times daily with meals as a dietary supplement.

Body Burn contains three naturally occurring nutrients that are proven to facilitate body fat reduction and support lean mass and metabolism. It's the perfect supplement to a healthy diet and exercise routine for weight loss subjects and athletes interested in lean mass support and performance enhancement.\*\*

The three active agents contained in Body Burn work together to produce results. Studies have shown that chromium enhances insulin action, thereby reducing insulin requirements. This effect helps block the conversion of carbohydrates into fat. Similarly, hydroxycitric acid also has this blocking effect. In addition, chromium enhances lean mass gains, which in turn increases metabolism. Ginseng has been shown to enhance fat burning and endurance during physical activity.\*\*

Do not use if outer seal is broken or missing.  
Store in a cool, dry location. Keep out of reach of children.

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**NUTRA THERAPEUTICS**

*The Natural Choice of  
Healthcare Professionals*

**BODY BURN**

- With 3 Proven Fat Metabolizers\*\*
- Effective Fat Burning Formula\*\*
- Ephedra-free

DIETARY SUPPLEMENT / 90 CAPSULES

### Supplement Facts

Serving Size: 3 Capsules		Servings per Container: 30	
	Amount Per Serving	% Daily Value	
Chromium (as Chromium HVP Chelate)	200 mcg	571	*
Garcinia Cambogia (50% Hydroxycitric acid)	2,000 mg		*
Panax Ginseng (std. 5% ginsenosides)	200 mg		*

\*Daily Value Not Established

Other Ingredients: Microcrystalline Cellulose, Stearic Acid (vegetable source), Malto-dextrin, Gelatin.

Does not contain artificial preservatives, colors, flavors, or added sugar, corn, starch, milk products, egg, wheat, yeast, and is salt free.

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ARTIST: AMANDA / # OF PAGES:

DATE: Oct. 18/01

CONTACT: BRUNO

CUSTOMER: MESCHINO

FAX #: (905) 470-9074

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APPROVAL DATE: \_\_\_\_\_

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Supplement Facts		Serving Size: 30 Caplets	
	Amount Per Serving	% Daily Value	
Vitamin A (as palmitate)	2,500 IU	50%	
Vitamin C (as ascorbic acid)	10,000 IU	200%	
Vitamin D (as cholecalciferol)	400 IU	100%	
Vitamin E (as d-alpha-tocopheryl succinate)	400 IU	333%	
Vitamin K (as menaquinone-2)	1,000 mcg	1,666%	
Vitamin B1 (as thiamine mononitrate)	50 mg	3,333%	
Vitamin B2 (as riboflavin)	50 mg	3,333%	
Vitamin B6 (as pyridoxine hydrochloride)	50 mg	2,500%	
Niacin (as niacinamide)	50 mg	250%	
Vitamin B12 (as cyanocobalamin)	50 mcg	833%	
D-Panthenol Acid (as calcium D-Panthenolate)	50 mg	500%	
Biotin	400 mcg	100%	
Calcium (as calcium carbonate and citrate)	500 mg	50%	
Magnesium (as magnesium oxide)	200 mg	50%	
Iron (as ferrous fumarate)	6 mg	33%	
Copper (as copper gluconate)	2 mg	100%	
Manganese (as manganese gluconate)	5 mg	250%	
Chromium (as chromium hypochlorite)	50 mcg	42%	
Molybdenum (as molybdenum hypochlorite)	50 mcg	66%	
Selenium (as selenium hypochlorite)	100 mcg	125%	
Zinc (as zinc citrate)	15 mg	100%	
Biotinamide (as chitosan complex)	50 mg	-	
Isocyanate - 5%	6 mg	-	
Lactin - 5%	6 mg	-	

\*Daily Value Not Established

Other Ingredients: Microcrystalline Cellulose, Croscarmellose Sodium, Stearic Acid (vegetable source), Magnesium Stearate (vegetable source), Calcium Silicate.

# NUTRA THERAPEUTICS

The Natural Choice of Healthcare Professionals

## SKIN ESSENTIALS

• ADVANCED ANTI-AGING FORMULA •  
• Nutritional Therapy for Skin Hair & Nails

DIETARY SUPPLEMENT / 120 CAPLETS

**Suggested Supplementations:** Adults take four caplets daily with any meal as a dietary supplement. Skin Essentials provides vital nutrients that give the skin great and rejuvenation of skin while maintaining an optimal level of moisture and appearance. This combination of natural formula helps guard against damage caused by free radicals, including damage caused by sun.

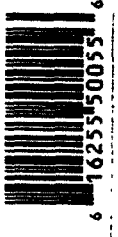
Skin Essentials also contains important nutrients that support and enhance the appearance of hair and nails. It also provides nutritional support for healthy bones and general well-being.

**Do not use if either seal is broken or missing. Store in a cool, dry location. Keep out of reach of children.**

\*The FDA has not evaluated this statement. This product is not intended to diagnose, treat, cure, or prevent disease.

Guaranteed quality, purity and potency. Does not contain artificial preservatives, colors, flavors, or added sugar, corn, starch, milk products, egg, wheat, yeast, and is cell free.

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**ARTWORK APPROVAL**  
 FAX APPROVAL TO #: 905-470-5450  
 ARTIST: AMANDA / # OF PAGES:  
 DATE: OCT. 29/01  
 CONTACT: BRUNO  
 CUSTOMER: MESCHINO  
 FAX #: (905) 470-9074

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269 5777  
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**Suggested Supplementation:** Adults take one or two capsules twice daily with meals as a dietary supplement.

Cardio Essentials contains vital natural agents to support heart function and provide antioxidant protection to the cardiovascular system. Both co-enzyme Q10 and the standardized grade of hawthorn are known to enhance energy production at the cellular level. Studies have shown that these agents support normal blood pressure regulation and guard against the age-related decline in heart function that often begins by age 50.\*\*

Do not use if outer seal is broken or missing. Store in a cool, dry location. Keep out of reach of children.

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**NUTRA THERAPEUTICS**

*The Natural Choice of  
Healthcare Professionals*

**CARDIO  
ESSENTIALS**

- Vital Nutrients that Strengthen Heart Function Naturally\*\*
- With Co Q-10 & Hawthorn Extract

DIETARY SUPPLEMENT / 60 CAPSULES

**Supplement Facts**

Serving Size: 2 Capsules	Servings per Container: 30	
	Amount Per Serving	%Daily Value
Co-enzyme Q-10	60 mg	*
Hawthorn Plant Extract (Std. 5% Plant Extract)	75 mg	*
Guarashi	100 mg	*

\*Daily Value Not Established

Other Ingredients: Stearic Acid (vegetable source), Organic Brown Rice Flour and Gelatin.

Does not contain artificial preservatives, colors, flavors, or added sugar, corn, starch, milk products, egg, wheat, yeast, and is salt free.

● Guaranteed quality, purity and potency.

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ARTIST: AMANDA / # OF PAGES:

DATE: Oct. 16/01

CONTACT: BRUNO

CUSTOMER: MESCHINO

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