



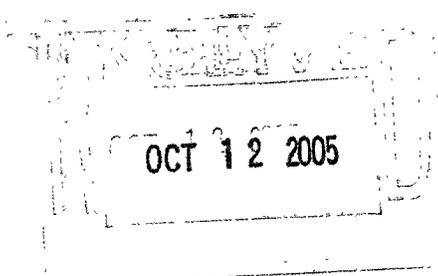
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Vice President  
Worldwide Regulatory & Government Affairs

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September 29, 2005

Dr. Robert J. Moore  
Branch Chief, Compliance & Enforcement Branch  
Office of Nutrition Products, Labeling & Dietary Supplements  
**FOOD & DRUG ADMINISTRATION (HFS-800)**  
5100 Paint Brush Parkway  
College Park, Maryland 20740



Ref: **Niteworks® Dietary Supplement (N579-05)**

Dear Dr. Moore:

Pursuant to 21CFR§101.93, please be advised Herbalife International of America, Inc. has revised Niteworks® dietary supplement labeling to modify structure/function claims:

Niteworks® Herbalife teamed with Nobel Laureate in Medicine, Dr. Lou Ignarro, to develop this refreshing lemon powder mix that helps you create more life supporting nitric oxide during the night, when nitric oxide levels are naturally lowest.\*

Research indicates that L-Arginine and L-Citrulline help produce nitric oxide, which can protect your cardiovascular health and helps circulatory vessel elasticity.\*

Niteworks® also contains Folic Acid to protect the vascular system and Lemon Balm to soothe and relax you.\*

So drink to your heart's health each night, and wake up feeling rejuvenated.\*

Dietary Supplement Niteworks® Produces Nitric Oxide to Support Energy, Vascular and Circulatory Health\*

Niteworks® dietary supplement is labeled and promoted with statements provided for in Section 403 (r) (6) of the Federal Food, Drug and Cosmetic Act.

The product label prominently bears the required ruled DSHEA disclaimer statement: "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."

Please be advised that we have substantiation on file that these claims are truthful and not misleading.

If you have any questions, please do not hesitate to ask.

Sincerely,

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# Niteworks

Enormised by Dr. Lou Ignarro,  
1998 Nobel Laureate in Medicine

Taking Nutrition to Heart™

Produces Nitric Oxide to Support Energy,  
Vascular and Circulatory Health\*

Dietary Supplement

NET WT 10.6 oz. (300 g)

\* 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.

**Niteworks®** Herbalife teamed with Nobel Laureate in Medicine, Dr. Lou Ignarro, to develop this refreshing lemon powder mix that helps you create more life supporting nitric oxide during the night, when nitric oxide levels are naturally lowest.\* Research indicates that L-Arginine and L-Citrulline help produce nitric oxide, which can protect your cardiovascular health and helps blood vessel elasticity.\* Rich in antioxidants natural vitamin E and vitamin C. According to the FDA, "Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancer."\*\* Niteworks® also contains Folic Acid to protect the vascular system and Lemon Balm to soothe and relax you.\* So drink to your heart's health each night, and wake up feeling rejuvenated.\*

\*\*Some scientific evidence suggests that consumption of antioxidant vitamins may reduce the risk of certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive

**DIRECTIONS:** Two scoops (two teaspoons or about 10 grams) in 8 oz. of cold water. May also be mixed with sparkling water or juice. Drink at night or before bedtime.

**INSTRUCCIONES:** Dos cucharas medidoras (dos cucharaditas o aproximadamente 10 gramos) en 8 onzas de agua fría. También puede ser mezclada con agua carbonatada o jugo. Tomar en la noche o antes de dormir.

We offer a **30-day money-back** guarantee to assure your complete satisfaction. This exclusively formulated product is only available through Herbalife Independent Distributors

**NOTICE:** This product contains 200 IU Vitamin E. **Not recommended for use by children, pregnant or lactating women.** Do not exceed recommended serving size if you have a bleeding disorder, use blood thinning medications or are contemplating surgery.

**AVISO:** Este producto contiene 200 UI de Vitamina E. **No se recomienda su uso con niños, mujeres embarazadas o en período de lactancia.** No exceder el tamaño de la porción recomendada si usted tiene alguna enfermedad sanguínea, está utilizando un medicamento anticoagulante o está planeando alguna cirugía. **CONTIENE INGREDIENTES DE SOYA.**

## Supplement Facts

Serving Size: 2 Scoops (2 tsp. or about 10g)  
Servings Per Container: 30

	Amount Per Serving	% DV***
Calories	40	
Total Carbohydrate	4 g	1%
Vitamin C (as ascorbic acid)	500 mg	833%
Natural Vitamin E (as d-alpha tocopheryl acetate from soybean oil)	200 IU	666%
Folic Acid (as folate & calcium folinate)	400 mcg	100%
Proprietary Blend		
L-Arginine, L-Citrulline	5.3 g	†
L-Taurine	300 mg	†
Lemon Balm Extract (leaves)	50 mg	†
Alpha Lipoic Acid	10 mg	†

\*\*\* Percent Daily Values (DV) are based on a 2,000 calorie diet  
† Daily Value (DV) not established.

**OTHER INGREDIENTS:** Citric Acid, Natural Flavor, Modified Food Starch, Sucralose, Maltodextrin, Silica Dioxide and Hydrogenated Vegetable Oil.  
**CONTAINS SOYBEAN INGREDIENTS.**



HERBALIFE INTERNATIONAL OF AMERICA, INC., Los Angeles, CA 90080-0210, U.S.A.

MADE IN U.S.A.

©2005 HERBALIFE™

2.75" x 10"



N579-05

8 oz



Niteworks

Endorsed by Dr. Lou Ignarro  
1998 Nobel Laureate in Medicine

Taking Nutrition to Heart™

Produces Nitric Oxide to Support Energy,  
Vascular and Circulatory Health\*

Dietary Supplement

NET WT 5.3 oz. (150 g)

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.

**Niteworks®** Herbalife teamed with Nobel Laureate in Medicine, Dr. Lou Ignarro, to develop this refreshing lemon powder mix that helps you create more life supporting nitric oxide during the night, when nitric oxide levels are naturally lowest.\* Research indicates that L-Arginine and L-Citrulline help produce nitric oxide, which can protect your cardiovascular health and helps blood vessel elasticity.\* Rich in antioxidants natural vitamin E and vitamin C. According to the FDA, "Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancer.\*\*" Niteworks® also contains Folic Acid to protect the vascular system and Lemon Balm to soothe and relax you.\* So drink to your heart's health each night, and wake up feeling rejuvenated.\*

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**CONTIENE INGREDIENTES DE SOJA.**

HERBALIFE INTERNATIONAL OF AMERICA, INC., Los Angeles, CA 90080-0210, U.S.A.

**Supplement Facts**

Serving Size: 2 Scoops (2 tsp. or about 10g)  
Servings Per Container: 15

	Amount Per Serving	% DV***
Calories	40	
Total Carbohydrate	4 g	1%
Vitamin C (as ascorbic acid)	500 mg	833%
Natural Vitamin E (as d-alpha tocopheryl acetate from soybean oil)	200 IU	666%
Folic Acid (as folate & calcium folinate)	400 mcg	100%
Proprietary Blend		
L-Arginine, L-Citrulline	5.3 g	†
L-Taurine	300 mg	†
Lemon Balm Extract (Leaves)	50 mg	†
Alpha Lipoic Acid	10 mg	†

\*\*\* Percent Daily Values (DV) are based on a 2,000 calorie diet.  
† Daily Value (DV) not established.

**OTHER INGREDIENTS:** Citric Acid, Natural Flavor, Modified Food Starch, Sucralose, Maltodextrin, Silicon Dioxide and Hydrogenated Vegetable Oil.

**CONTAINS SOYBEAN INGREDIENTS.**

MADE IN U.S.A.

©2005 HERBALIFE

2.5" x 7.875"

