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Worldwide Regulatory & Government Affairs

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RECEIVED
SEP 09 2004

September 8, 2004

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: **Total Control® (N536-03-05)**

Dear Dr. Moore:

Pursuant to 21CFR§101.93, please be advised Herbalife International of America, Inc. has begun commercializing Total Control®.

1) LABEL

Left Side:

Promotes Weight Loss*, Boosts Metabolism*, Builds Energy*

Center:

Total Control® can be used to promote weight loss as part of a calorie-controlled diet that includes moderate exercise.* Our specialty-selected green tea extract contains catechins that boost metabolism and promote weight loss.* This unique herbal blend combines the thermogenesis and metabolism boosting properties of Green Tea Extract, Yerba Mate, and Cocoa Extract with Ginger, which is widely recognized for its calmative effects.* Formulated to help calm your stomach.*

Please note: adjacent to the claim on the label, required by DSHEA is a disclaimer box.

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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6.125" x 2.1875"

ShapeWorks™
Total Control™
 Promotes Weight Loss*
 Boosts Metabolism*
 Builds Energy*
 Dietary Supplement
 90 TABLETS
 PATENT PENDING

New & Improved

*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.

Total Control™ can be used to promote weight loss as part of a calorie-controlled diet that includes moderate exercise. Our specially-selected green tea extract contains catechins that boost metabolism and promote weight loss. This unique herbal blend combines the thermogenesis and metabolism boosting properties of Green Tea Extract, Yerba Mate, and Cocoa Extract with Ginger, which is widely recognized for its catechins effects. Formulated to help calm your stomach. **DIRECTIONS:** Take one tablet three times per day. Take one tablet with breakfast, one tablet with lunch, and one tablet with a mid-afternoon snack. **INSTRUCCIONES:** Tome una tableta tres veces al día. Tome una tableta con el desayuno, una con el almuerzo y una con un bocadillo a media tarde. **For Best Results:** Use as a part of a complete ShapeWorks™ weight-loss program. 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:** Children pregnant or lactating women and people with high blood pressure or cardiovascular disorders should consult a physician before using this product. Our unique caffeine blend is similar to a cup of drip coffee. **ANSO:** Los niños, mujeres embarazadas o en periodo de lactancia y personas con presión sanguínea alta o problemas cardiovasculares deben consultar un doctor antes de usar este producto. El contenido de cafeína en nuestra exclusiva mezcla herbal es similar al de una taza de café. **HERBALIFE INTERNATIONAL OF AMERICA, INC.**, Los Angeles, CA 90080-0710 U.S.A. **MADE IN U.S.A.** www.herbalife.com © 2004 **HERBALIFE**

Supplement Facts

Serving Size 1 Tablet	Amount Per Serving	% DV**
	Herbal Blend	
	Dried Green Tea Extract (Leaves), Dried Ginger Extract (Root)	475 mg
	Dried Tripholoma cacao Extract (Seeds), Dried Yerba Mate Extract (Leaves), Astragalus (Root), Cherry (Seeds) Fruit	
	(Seeds), Hawthorne Berry (Fruit), Licorice (Root), Marshmallow (Root), Parsley (Leaves), Sassa (Root), Dried Cinnamon Extract (Bark), Amla (Leaves)	
	Caffeine (80 mg from natural caffeine and 4 mg from herbal blend)	84 mg
	** Percent Daily Values (DV) are based on a 2,000 calorie diet.	
OTHER INGREDIENTS: Microcrystalline Cellulose, Maltodextrin, Corn Starch, Sodium Starch Glycolate, Silicon Dioxide, Sodium Carboxymethylcellulose, Magnesium Stearate		
Hypocrellin and Polyethylene Glycol		

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