

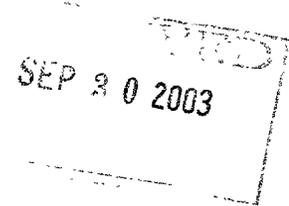


John Venardos Vice President  
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September 19, 2003

Dr. Christine L. Taylor  
Director, Office of Nutritional Products  
Labeling and Dietary Supplements  
**FOOD & DRUG ADMINISTRATION (HFS-800)**  
5100 Paint Brush Parkway  
College Park, Maryland 20740



Ref: **Snack Defense™ Dietary Supplement Tablets**

Dear Dr. Taylor:

Pursuant to 21 CFR 101.93, please be advised that Herbalife International of America, Inc. has begun commercializing Snack Defense™.

Product labeling and literature prominently bear the required ruled 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."

Snack Defense™ is labeled and promoted with statements provided for in Section 403 (r) (6) of the Federal Food, Drug and Cosmetic Act.

1) **LABEL**

All Day Craving Control\*

Snack Defense\* can be taken any time of the day or night for control of cravings.\* It contains garcinia cambogia, a natural source of hydroxycitric acid that aids in appetite control combined with gymnema sylvestre and chromium polynicotinate which have been shown to be helpful in controlling one's cravings for sweets.\*

2) **LABELLING**

a.) **SNACK DEFENSE™ President's Team Letter**

Herbalife is thrilled to announce the introduction of Snack Defense™, our new craving-control product.\* It updates our trusted Thermojetics® Yellow formula by drawing on the latest scientific advancements in craving control.\* New Snack Defense™ combines the best ingredients found in Thermojetics® Yellow with a cutting-edge botanical called Gymnema Sylvestre.\* Plus, thanks to Snack Defense's™ unique formula helps fight cravings all day long.\*

We think you'll be very pleased with the results: 87% reported that it was effective or very effective at controlling their appetite, and 77% reported that it was even more effective than Thermojetics® Yellow!\*

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Here are the key benefits of using Snack Defense™:

- Provides a beneficial herbal alternative for all-day craving control.\*
- Contains breakthrough craving-buster Gymnema Sylvestre.\*
- Has 50% more Chromium Polynicotinate, one of the active ingredients in Thermojetics® Yellow.\*
- Can be used in conjunction with all other Herbalife products, including Total Control® for added weight-management support.\*

Use one tablet twice a day, or as needed to control cravings whenever you need to, day or night!\*

Call your current weight-loss customers and tell them about Snack Defense™.\*

#### **b.) HERBALIFE TODAY NEWSLETTER**

##### **New Formula Fights Cravings\***

...Scientific advancements, however, have prompted Herbalife to reformulate the product, adding new ingredients and different forms of current ingredients that make the original formula even more beneficial than before.\* Snack Defense™ is an all-day craving-control supplement that provides extra protection against snacking.\* This product contains an Ayurvedic botanical called gymnema sylvestre, which helps tame a sweet tooth by reducing your desire for sweets.\* Snack Defense™ still contains Chromium Polynicotinate to help support metabolism, but 50% more than Yellow!\* A more powerful form of garcinia cambogia extract also is included for appetite suppression.\* Snack Defense\* is an extension of Herbalife's philosophy of addressing the underlying causes of being overweight and obese.\* Our basic program of Cellular Nutrition® provides the necessary nutrients to power cellular function, while products such as Snack Defense™ and Total Control™ provided appetite control to put you in control of your eating.\* Whether you're looking for more energy, better control over snacking, or a feeling of fullness and satiety, Herbalife has a targeted weight-loss supplement that can help you achieve your weight-loss goals.

##### **Use with Total Control™**

Together, Snack Defense™ and Total Control™ deliver complete craving control to your customers.\* Ingredients in Snack Defense™ balance the blood sugar fluctuations that cause cravings, while Total Control™ promotes the body's feeling of satiety or fullness.\*

Caffeine-free and stimulant-free, Snack Defense™ doesn't cause any unpleasant, jittery side effects, so there's no reason why you couldn't also use it in the evening to control after-dinner cravings.\*

- 87% reported that it was effective or very effective at controlling their cravings.\*
- 50% reported it was "very effective" at controlling cravings for "sweets"
- 77% reported that it was more effective than Thermojetics® Yellow at controlling their desire to snack.\*
- Almost 90% reported that they would purchase Snack Defense.\*

**c.) HERBALIFE SNACK DEFENSE™ FACT/FLYER SHEET**

Controls between-meal snacking.\*

Snack Defense™ is a scientifically advanced formula that provides all-day control against snacking\*. This powerful product contains ingredients that suppress appetite and aid metabolism.\* In addition, the combination of its key ingredients provide extra protection against the desire for sugar and fat-laden sweets.\*

One of the main ingredients in Snack Defense™, Chromium Polynicotinate, is an excellent mineral source of chromium and is known to help maintain blood sugar/glucose levels already within the normal range, and promotes the metabolism of carbohydrates.\* Garcinia Cambogia extract, derived from a fruit that grows in India, is a thermogenic ingredient that naturally suppresses appetite.\* An incredible herb from the plant world, Gymnema Sylvestre, inhibits the absorption of glucose, or sugar, in humans.\*

Snack Defense™ is recommended for use twice a day between meals, but it can be taken day or night, anytime you want to fight the urge to snack.\* By using Snack Defense™, you will notice a decrease in your desire to snack and add in appetite control throughout the day.\*

For maximum benefit, Snack Defense™ should be used regularly as part of Herbalife's Thermojetics® Weight-Management Program, and is an excellent complement to Total Control™ for overall weight-management support.\*

**DISCUSSION POINTS**

- **Improved metabolism:** Chromium Polynicotinate promotes the regulation and maintenance of the body's metabolism of fats and sugars. It's also known to help maintain blood sugar/glucose levels already within the normal range.\*
- **Appetite suppression:** Garcinia Cambogia extract comes from a tropical fruit grown on trees in India. It is an organic acid that suppresses appetite and increases the body's production of heat through thermogenesis.\*
- **Cravings reduction:** Drawing on the science of synergy, Snack Defense's™ unique blend of ingredients decreases cravings for between-meal snacks.\*
- **Combine with other products:** For optimum benefit, use in conjunction with Herbalife's complete line of weight-management products.

**FAST FACTS**

- Provides beneficial herbal support for all-day appetite control.\*
- Scientifically formulated blend of ingredients helps control your urge to snack.\*
- Take one-tablet two times per day, or as needed for all-day control.\*
- Can be used in conjunction with all other Herbalife products, including Total Control™ for added weight-management support.\*

**d.) HERBALIFE PRODUCT BROCHURE**

A scientific advancement in appetite control, Snack Defense™ works all day long to help you stop snacking between meals.\* Formulated with a blend of active ingredients, including gymnema sylvestre, a cutting-edge herb that helps to control one's appetite, Snack Defense™ takes weight loss to a whole new level.\*

- Includes gymnema sylvestre, a cutting-edge herb that helps to inhibit carbohydrate and fat absorption.

**e.) SNACK DEFENSE™ FAX FLYER**

New formula helps to control your appetite all day long.\*

Now you can – with Snack Defense™– Herbal's stunning new appetite product you can take day or night – anytime the desire to snack is present.\*

This incredibly helpful herbal formula reduces your desire for snacks.\* For all between-meal snackers, it's what you need to make your weight loss a success.\* You don't need to be strong when you've got Snack Defense™ to resist snacks for you!\*

- Offers helpful support for all-day appetite control.\*
- Cut down on between-meal snacking and late-night urges.\*
- Watch the pounds drop once snacking is under control.\*
- Eliminates temptation by taming your sweet tooth.\*

Each formula works through a separate mechanism to do its job, bringing you complete appetite control.

**f.) SNACK DEFENSE™ PRODUCT ANNOUNCEMENT**

This incredible new product is designed to be taken anytime, day or night, and contains ingredients known to be beneficial. Best of all, Snack Defense™ provides snacking control day or night.\*

When used daily, Snack Defense™ works to control one's urges to nibble throughout the day.\* This breakthrough product contains:

- **Gymnema Sylvestre**, a cutting-edge botanical that helps to inhibit carbohydrate and fat absorption.\*
- **Chromium Polynicotinate**, an excellent source of chromium known for helping to maintain blood sugar/glucose levels already within the normal range.\*
- **Garcinia Cambogia Extract**, a natural thermogenic ingredient that promotes appetite suppression.\*

Snack Defense™ makes it even easier for customers to lose unwanted pounds than ever before, and is certain to quickly become a top-selling part of your inventory. In the meantime, continue to use Thermojetics® Yellow while supplies last. And look for more details about the amazing new Snack Defense™ to be released soon.

**g.) SNACK DEFENSE™ POSTCARD**

These new postcards promote our new and improved all-day appetite-control product.\*

Help get the word out about Snack Defense™ with informative postcards that tell customers about this new snack-control product's incredible appetite-reducing effect!\*

These postcards are ready to be mailed and placed in orders, to let new customers know about Herbalife's newest product to help in the weight-loss battle.\*

Snack Defense™ contains Gymnema Sylvestre, a cutting-edge botanical to reduce a desire for sweets, and 50% more Chromium Polynicotinate to help regulate metabolism and naturally curb hunger.\*

**h.) FREQUENTLY ASKED QUESTIONS**

Q: Why is the product called Snack Defense™?

A: The name Snack Defense™ was chosen because it signifies the key benefit derived from the effects of the main ingredients — Chromium polynicotinate, Garcinia cambogia and Gymnema sylvestre — that improve appetite control.\*

Q: Will Snack Defense™ replace Total Control™?

A: No, in fact, Snack Defense™ is an excellent complement to Total Control™ as part of an overall weight management program for added appetite control, as necessary.\*

Q: How do I take the product?

A: The suggested serving for Snack Defense™ is one tablet, twice a day, as needed to assist with the management of snacking in between meals.\*

Q: How does Snack Defense™ compare to Thermojetics® Yellow?

A: The great majority of test participants liked Snack Defense™ better than Thermojetics® Yellow and found it to be more effective in controlling appetite and supporting weight loss and essentially everyone who tested the product said they would purchase the product if it were made available.\*

Q: What time of the day or night should I take Snack Defense™?

A: Snack Defense™ can be taken at anytime of day or night whenever you tend to have your "snacking urges."\*

Q: Have you tested Snack Defense™ with Distributors?

A: Our test results clearly indicate Distributors noticed and felt that Snack Defense™ was even more effective at controlling their urge to snacking than Thermojetics® Yellow.\*

Q: Can I use Snack Defense™ and CarboGuard together, as they both contain Gymnema Sylvestre?

A: CarboGuard helps to slow carbohydrate absorption and is most effective when taken before shakes or a meal.\* Snack Defense™ also supports slowing carbohydrate absorption, but is targeted more specifically at snacking control and is most effective when taken in between meals.\*

Q: Should I combine use of Snack Defense™ as an alternative to Total Control™?

A: You can combine use of Snack Defense™ with Total Control™

If you have caffeine-restrictions or prefer to follow a weight loss program without any stimulant effect, you can use Snack Defense™ as a substitute for Total Control™.\*

**i.) SNACK DEFENSE™ INTERNET (English and Spanish)**

Arm yourself against snacks.\* Armese en contra de los bocadillos.\*

Give your appetite control when you need it.\* Combate los antojos cuando usted lo necesita.\*

Get Snack Defense™ for all-day appetite control.\* Protect yourself from snacking naturally.\*  
Adquiera Snack Defense™ para controlar los antojos todo el día. Protéjase en forma natural de comer entre horas.\*

**j.) TESTIMONIALS – STOP A SNACK ATTACK IN ITS TRACKS**

Snack Defense, in combination with Total Control™, can be your biggest ally in getting through the holiday season without putting on extra weight. Here are just a few of the many people we've heard from who have tried Snack Defense™ and already made it an integral part of their weight-management program:

*Getting results: Kathy Schlegel*

"The very first day I tried Snack Defense, I had a shake for breakfast and wasn't hungry again until late afternoon. In 10 days on Snack Defense, I lost three pounds. \* In 20 days, I lost an entire pants size! \* With these kind of results, I immediately ordered 10 bottles for myself, my husband and my customers who I've told about this unbelievable new product. And I'm ordering more!

*Helps curbs snacking: Becky Smith*

I love Snack Defense™. I take it in the morning at 10:00 and later at 3:00 and sail through to dinner without the desire to snack.\* Not only does it put an end to my desire for snacking, but it really curbs appetite.\* In the afternoons, I often treat myself to a bowl of ice cream. Now, I have my Herbal Concentrate Tea and Snack Defense™ — and I don't even miss the ice cream! Snack Defense™ is a definite improvement on Yellow. Now I feel fuller longer, I'm not snacking and I'm not experiencing highs and lows throughout my day.\*

*First line of defense: Arlene Geraci*

Snack Defense™ works—and delivers results! Here is a typical example: One night I was so busy I hadn't had time for dinner. So about 10:00, I check the fridge and cabinets for something to eat. But this time, instead of snacking, I decided to go to my tablet box and take Snack Defense™. Once I left the kitchen, I didn't go back! Snack Defense™ works that quickly. I take it before going to a party and I don't overeat anymore. I've lost pounds and inches thanks to the better control I have with Snack Defense™. \* I call it my first line of defense against snacks attacks.

*Holding the line at parties*

Whether you want to keep yourself from gorging at holiday parties, or you just need extra help with between-meal snacking, put Snack Defense™ at the top of your holiday shopping list for yourself and your customers.\*

**k.) SNACK DEFENSE™ BROCHURE**

**Snack Defense™ Zaps One's Urge to Snack\***

Introducing Snack Defense™, for appetite control that lasts all day.\* This amazing herbal formula reduces your desire for snacks of all kinds.\*

Snack Defense™ is for anyone who needs a helpful to curb the appetite between meals.\* We believe there's no better product available to help you resist the temptation to indulge in these diet-busting snacks.\*

This new herbal formula contains ingredients that actually lessen your desire to snack, so you don't have to struggle with your appetite.\* Snack Defense™ does it for you.

With Snack Defense™, losing weight or maintaining your figure couldn't be easier. And since Snack Defense™ helps to maintain blood sugar/glucose levels that are already within the normal range, you'll feel healthier as you start making healthier choices.\*

*Snack Defense™ between meals*

Being healthy isn't just about what you do eat, it's about what you don't eat as well. In addition to using Cellular Nutrition\* to ensure a healthy diet, take Snack Defense™ to keep you away from junk foods and prevent yourself from overeating. \* Snack Defense™ also includes ingredients that aid metabolism, so your body can more effectively utilize nutrients from the foods you eat.\*

Whether you're looking to lose weight or maintain the figure you already have, Snack Defense™ is a great tool to help you achieve your goals.\*

*When You Need It*

This convenient herbal formula can be used, day or night and will not make you jittery or sleepless. It's just the solution you need when you crave a snack strike.\* Whether you're looking to cut down on eating between meals or trying to remove unhealthy junk foods from your diet, Snack Defense™ can help you control your appetite and keep your goals on track.\* Snack Defense™ also contains ingredients that help you battle temptation.\*

Next time you've got a desire to snack, don't reach for the refrigerator door, reach for Snack Defense™.\*

**Snack Defense™ and Total Control™**

Snack Defense™ can be used with Total Control™, our energy-boosting weight-loss formula.\*

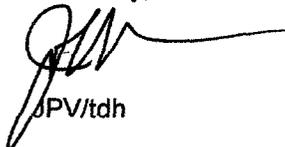
Snack Defense™ is extra tough in controlling one's appetite and the urge to snack, whenever it's needed.\*

**Key Ingredients**

Chromium Polynicotinate promotes the regulation and is known to help maintain blood sugar/glucose levels already within a normal range.\*

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

Sincerely,



JPV/tdh

|   <p><b>THERMOJETICS®</b><br/>         Dietary Supplement<br/> <b>All Day Craving Control®</b></p> <p><b>snack defense</b>      <b>60 TABLETS</b></p> | <p><b>Suggested Serving:</b> For adults, take one tablet two times a day. <b>THERMOJETICS®</b> Snack Defense™ can be taken any time of day or night for control of cravings.* It contains garcinia cambogia, a natural source of hydroxytyrosic acid that aids in appetite control, combined with gymnema sylvestre and chromium polynicotinate which have been shown to help reduce one's cravings for sweets.*</p> <p>*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.</p> <p><b>Notice:</b> This product is not recommended for pregnant or lactating women. Herbalife products are available only through Herbalife Independent Distributors. <b>Keep out of reach of children</b><br/> <b>30-day money-back guarantee. • Recycle this bottle.</b></p> <p>Formulated exclusively for: <b>HERBALIFE INTERNATIONAL OF AMERICA, INC.</b><br/>         LOS ANGELES, CA 90080-0210 • MADE IN U.S.A.<br/>         © 2003 HERBALIFE INTERNATIONAL, INC., U.S.A.</p> | <p><b>Supplement Facts</b></p> <p>Serving Size: 1 Tablet<br/>         Servings Per Container: 60</p> <table border="1"> <thead> <tr> <th></th> <th>Amount Per Serving</th> <th>% DV**</th> </tr> </thead> <tbody> <tr> <td>Calcium (as calcium carbonate)</td> <td>130 mg</td> <td>13%</td> </tr> <tr> <td>Chromium (as chromium polynicotinate)</td> <td>75 mcg</td> <td>65%</td> </tr> <tr> <td>Dried <i>Garcinia cambogia</i> Extract (Fruit)</td> <td>400 mg</td> <td>†</td> </tr> <tr> <td>Dried <i>Gymnema sylvestre</i> Extract (Leaves)</td> <td>100 mg</td> <td>†</td> </tr> </tbody> </table> <p>** Percent Daily Values (DV) are based on a 2,000 calorie diet.<br/>         † Daily Value (DV) not established.</p> <p>Other Ingredients: Microcrystalline Cellulose, Stearic Acid, Hypromellose, Acacia, Croscarmellose Sodium, Shellac, Silicon Dioxide, Magnesium Stearate, Titanium Dioxide, Triethyl Citrate and Polybutene.</p> |  | Amount Per Serving | % DV** | Calcium (as calcium carbonate) | 130 mg | 13% | Chromium (as chromium polynicotinate) | 75 mcg | 65% | Dried <i>Garcinia cambogia</i> Extract (Fruit) | 400 mg | † | Dried <i>Gymnema sylvestre</i> Extract (Leaves) | 100 mg | † |
|---|--|---|--|--------------------|--------|--------------------------------|--------|-----|---------------------------------------|--------|-----|--|--------|---|---|--------|---|
|   | Amount Per Serving   | % DV**  |  |                    |        |                                |        |     |                                       |        |     |  |        |   |   |        |   |
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| Dried <i>Garcinia cambogia</i> Extract (Fruit)  | 400 mg   | †   |  |                    |        |                                |        |     |                                       |        |     |  |        |   |   |        |   |
| Dried <i>Gymnema sylvestre</i> Extract (Leaves)   | 100 mg   | †   |  |                    |        |                                |        |     |                                       |        |     |  |        |   |   |        |   |