



SEP 29 2004

Mr. Mo Kang  
Senior Scientist  
Sedona Laboratories, Inc.  
211 Jennifer Drive  
Cottonwood, Arizona 86326

Dear Mr. Kang:

This is in response to your letter of August 27, 2004 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 letter states that the product **EnzyTrim™** will use the claim “[M]aintain healthy blood cholesterol levels.”

In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because “many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease,” in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. Therefore, because the claim you are making for this product represents that the product is intended to affect blood cholesterol but does not also include a statement about it being intended to affect blood cholesterol that is already in the normal ranges, it is an implied disease claim.

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 statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is 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 20855.

975-0163

LET 781

Page 2 - Mr. Mo Kang

Please contact us if we may be of further assistance.

Sincerely yours,

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

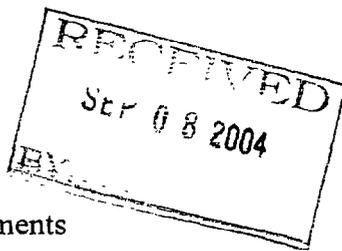
Susan J. Walker, M.D.  
Director  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

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, Los Angeles District Office, Office of Compliance, HFR-PA240



August 27, 2004

The Office of Nutritional Products, Labeling, and Dietary Supplements  
Division of Nutrition Programs and Labeling (HFS-800)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

**Title: EnzyTrim™ Food Labeling; Notification Procedures for Statements on Dietary Supplements**

Dear Whom It May Concern:

We launched a new product called EnzyTrim™ on August 2<sup>nd</sup>, 2004. We're going to sell it through our three companies (please refer to Appendix 1):

- Sedona Laboratories, Inc. (211 Jennifer Lane, Cottonwood, AZ 86326, 1-888-816-8804)
- Nutri-Health (218 Justin Drive, Cottonwood, AZ 86326, 1-800-914-6311)
- Metafoods (211 Jennifer Lane, Cottonwood, AZ 86326, 1-800-282-7809)

EnzyTrim™ has the following ingredients:

1. Chaga Mushroom Extract (CHP7), *Inonotus obliquus*
2. Bramble Berry Extract (BHP9), *Rubus coreanus*.
3. Mugwort Extract, *Artemisia capillaris*
4. Siberian Ginseng Bark Extract, *Acanthopanax cortex*
5. L-Carnitine
6. Polydextrose

EnzyTrim™ has been sold in Korea as a dietary supplement, coated rice, and beverage since 2003 with the brand name of Misol™ by RNL Life Science, Ltd. RNL is a research-oriented biotech company in Korea, and has studied the efficacy and safety of each ingredient since 2002. They have published an articles about the efficacy and safety of Misol™ (Reference 1). According to the published article, chaga mushroom extract (CHP7) and bramble berry extract (BHP9) showed inhibition effects on digestive enzyme such as  $\alpha$ -glucosidase and lipase (Figure 1 and 2 on Official Journal of Korean Society of Toxicology Vol. 20, No. 2). RNL also published an article about the effects of siberian ginseng bark extract and mugwort extract on Growth Hormone (GH) secretion (Reference 2). Several articles have proved that GH stimulates lipolysis (Reference 3~13), and some studies suggest that L-carnitine and polydextrose (dietary fiber) may be useful as part of a weight management program (Reference 14~24). In addition,

89512  
Sedona Labs, Inc.

211 Jennifer Drive • Cottonwood, AZ 86326  
tel: (888) 816-8804 • fax: (866) 887-8489  
www.sedonalabs.com



RNL did two clinical studies on human beings and one pre-clinical study using rats. The studies showed that EnzyTrim™ decreased body weight in humans and rats (Figure 3, Figure 4 and Table 1 on Official Journal of Korean Society of Toxicology Vol. 20, No. 2). In addition, EnzyTrim™ reduced blood cholesterol level in rats (Table 2 on Official Journal of Korean Society of Toxicology Vol. 20, No. 2).

I also have attached the following additional documents to substantiate that the EnzyTrim™ label is based on facts and studies published in science journals and magazines.

1. EnzyTrim™ Labels
2. Published Article
3. Certificate of Patent application
4. Food (Food Additives) Manufacturing Report; to substantiate that EnzyTrim™ is manufactured under Korean FDA rules and registered as food by Korean FDA.
5. Clinical and Pre-clinical Study Summary

I certify that all of the information and the attached data presented in this notice is accurate and truthful. If I can be of any assistance, please contact me at [mokang@sedonalabs.com](mailto:mokang@sedonalabs.com) or 1-800-914-6311.

Sincerely yours,

Mo Kang, MBA, MS  
Senior Scientist  
New Product Development Department  
Sedona Laboratories, Inc.

**Sedona Labs, Inc.**  
211 Jennifer Drive • Cottonwood, AZ 86326  
tel: (888) 816-8804 • fax: (866) 887-8489  
[www.sedonalabs.com](http://www.sedonalabs.com)

SUPPLEMENT FACTS	
Serving Size: 2 Capsule (1000mg)	%DV
Servings per container: 45	
Chaga Mushroom Extract (CHP7) *	*
Bramble Berry Extract (BHP9)	*
Mugwort Extract	*
Siberian Ginseng Bark Extract	*
L-Carnitine	*
Polydextrose	*
*Daily value not established	

\*These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.

For best results follow a healthy diet and exercise plan. Consult your physician before beginning any weight loss program.

Manufactured in USA

**SEDONA LABS**  
SINCE 1987

\*Safe  
\*Patented  
\*Ephedra Free  
\*Clinically Tested

**ÉnzyTrim™**  
WEIGHT MANAGEMENT  
A Dietary Supplement

90 - 500 mg Gelatin Capsules

**ÉnzyTrim™** helps inhibit carbohydrate and fat absorption by controlling enzyme activity. **ÉnzyTrim™** helps stimulate body lipolysis, and maintain healthy blood cholesterol levels.\*

**Benefits:** May help with weight management, especially individuals on low-carb diets, without the accompanying feelings of nervousness or drowsiness. An exclusive all natural herbal blend that supports healthy blood lipid levels.\*

**Suggested Use:** Take 2 capsules before breakfast, lunch and dinner.

Sedona Labs, Inc.  
211 Jennifer Lane, Cottonwood, AZ 86326 U.S.A.  
888-816-8804 • www.enzytrim.com

RNL  
Life Sciences



NUTRI-HEALTH																					
<table border="1"> <thead> <tr> <th colspan="2">SUPPLEMENT FACTS</th> </tr> </thead> <tbody> <tr> <td>Serving Size: 2 Capsule (1000mg)</td> <td>%DV</td> </tr> <tr> <td>Servings per container: 45</td> <td></td> </tr> <tr> <td>Chaga Mushroom Extract (CHP7) *</td> <td>*</td> </tr> <tr> <td>Bramble Berry Extract (BHP9)</td> <td>*</td> </tr> <tr> <td>Mugwort Extract</td> <td>*</td> </tr> <tr> <td>Siberian Ginseng Bark Extract</td> <td>*</td> </tr> <tr> <td>L-Carnitine</td> <td>*</td> </tr> <tr> <td>Polydextrose</td> <td>*</td> </tr> <tr> <td colspan="2">*Daily value not established</td> </tr> </tbody> </table> <p>*These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.</p> <p>For best results follow a healthy diet and exercise plan. Consult your physician before beginning any weight loss program.</p> <p>RNL Life Sciences</p> <p>6 48575 00080 5</p>	SUPPLEMENT FACTS		Serving Size: 2 Capsule (1000mg)	%DV	Servings per container: 45		Chaga Mushroom Extract (CHP7) *	*	Bramble Berry Extract (BHP9)	*	Mugwort Extract	*	Siberian Ginseng Bark Extract	*	L-Carnitine	*	Polydextrose	*	*Daily value not established		<p>A DIETARY SUPPLEMENT</p>  <p><b>ÉnzyTrim™</b> WEIGHT MANAGEMENT</p> <p>Safe * Patented Ephedra Free * Clinically Tested</p> <p>Manufactured by: NUTRI-HEALTH 218 Justin Drive, Cottonwood AZ 86326 800-914-6311 • www.bestflora.com</p>
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Manufactured in USA

90 - 500 mg Gelatin Capsules

**ÉnzyTrim™** helps inhibit carbohydrate and fat absorption by controlling enzyme activity. **ÉnzyTrim™** helps stimulate body lipolysis, and maintain healthy blood cholesterol levels.\*

**Benefits:** May help with weight management, especially individuals on low-carb diets, without the accompanying feelings of nervousness or drowsiness. An exclusive all natural herbal blend that supports healthy blood lipid levels.\*

**Suggested Use:** Take 2 capsules before breakfast, lunch and dinner.

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**EPHEDRA FREE • CLINICALLY TESTED**

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For best results, follow a healthy diet and exercise plan. Consult your physician before beginning any weight loss program.

RNL  
Life Sciences  
Manufactured by:  
Metafoods 1-800-282-7809  
www.metafoods.com



Metafoods

**ÉnzyTrim™**  
A DIETARY SUPPLEMENT  
WEIGHT MANAGEMENT

90 - 500 mg Gelatin Capsules

**ALL NATURAL**  
Safe • Patented

**ÉnzyTrim™** helps inhibit carbohydrate and fat absorption by controlling the enzyme activity. **ÉnzyTrim™** helps stimulate body lipolysis, and maintain healthy blood cholesterol levels.\*

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**Suggested Use:** Take 2 capsules before breakfast, lunch and dinner.

FDA Registered Facility • GMP Standard of Manufacturing

\*These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.

**BOTTLED IN USA**

EXP 032005