



APR 23 2002

Alan G. Minsk, Esq.
Arnall Golden Gregory LLP
2800 One Atlantic Center
1201 West Peachtree Street
Atlanta, Georgia 30309-3450

Dear Mr. Minsk:

This is in response to your letter to the Food and Drug Administration (FDA) dated March 18, 2002 concerning the use of certain symbols on the labels of dietary supplements that you believe are outside the scope of claims that may be used in the labeling of dietary supplements pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). In your letter, you submitted copies of two labels that use a heart symbol that you believe cause the products to violate various provisions of the Act.

Thank you for bringing to our attention your concerns about the two labels you submitted along with your letter. Specifically, you assert in your letter that the use of a heart symbol on these labels causes the products to be subject to regulation under the drug provisions of the Act because the use of the heart symbol is an implied disease claim. However, after carefully considering the labels and other information in your letter, we disagree that the manner in which the heart symbol is used in these two labels constitutes a disease claim and believe that its use appears to be a claim that may be made in the labeling of a dietary supplement pursuant to 21 U.S.C. 343(r)(6). We explain the basis for this tentative conclusion below.

In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1021 and 1022), FDA discussed the use of the heart symbol in labeling of a dietary supplement. We stated that its use "would be ordinarily considered an implied heart disease prevention claim" because it is so widely associated with prevention of heart disease. However, we also stated that "there may be unusual cases in which, in context, the use of a heart symbol does not imply heart disease prevention." This position is consistent with our discussion in the preamble of the related circumstances surrounding the use of the word "heart" in a products name. In that same preamble, we stated that a dietary supplement could be called "Heart Tabs" if its claim was to maintain healthy circulation or some other role related to the structure or function of the heart that did not imply treatment or prevention of disease. Thus, the principle articulated in the

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final rule on structure/function claims was that if a label contained adequate context to make clear that a product is not intended to treat, cure, prevent, mitigate, or diagnose a disease, a claim (such as a symbol or a brand name) that would ordinarily be an implied disease claim could be considered a structure/function claim within the scope of 21 U.S.C. 343(r)(6).

In the case of the two labels you submitted, both clearly bear a prominent heart symbol on the label. However, both labels contain contextual statements that, in our opinion, establish that the products are not intended to treat, prevent, mitigate, diagnose, or cure heart disease. Therefore, in the manner that the heart symbols are used on both labels, they appear to be claims that may be made in the labeling of a dietary supplement under 21 U.S.C. 343(r)(6).

We hope that this adequately addresses the issues you raised in your letter. If you have further questions, please contact us.

Please contact us if we may be of further assistance.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert J. Moore". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

Robert J. Moore, Ph.D.
Chief, Dietary Supplements Branch
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

**Arnall
Golden
Gregory LLP**

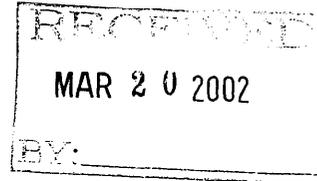
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March 18, 2002

VIA FEDERAL EXPRESS

Mr. Robert Eshelman
Office of Compliance
Center for Drug Evaluation and Research (HFD-312)
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857



Dr. Robert Moore
Office of Nutritional Product, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition (HFS-811)
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

Dear Mr. Eshelman and Dr. Moore:

We want to bring to the Food and Drug Administration's attention the enclosed product labels for CoQ-10 Ultimate™ softgels, distributed by Sundown Vitamins and manufactured by Rexall Sundown (a wholly-owned subsidiary of Royal Numico, N.V.), 6111 Broken Sound Pkwy, N.W.), Boca Raton, Florida 33487 (ph. 1-800-VITA-HELP), and Twinsorb™ CoQ10 softgels, manufactured for Twin Laboratories, Inc., 150 Motor Parkway, Suite 210, New York 11788 (ph. 631-467-3140). The labels for these dietary supplement products prominently display a heart symbol, which, FDA has said constitutes an implicit disease claim, requiring preapproval. Because we are unaware of any such approval, we believe that these products are unapproved new drugs, as well as misbranded, in violation of the Federal Food, Drug, and Cosmetic Act and FDA's regulations.

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According to 21 C.F.R. § 101.93(g)(2)(iv)(E), a statement:

claims to diagnose, mitigate, treat, cure, or prevent disease [and, therefore, requires FDA prior approval] if it claims, explicitly or implicitly, that a product:

... (iv) Has an effect on a disease or diseases through one or more of the following factors:

... (E) Use of pictures, vignettes, symbols, or other means...

In its Preamble to the Final Rule that defined the types of statements that can be made concerning the effect of a dietary supplement on the structure or function of the body, FDA discussed the use of pictures, vignettes, and symbols on dietary supplement product labels. 65 Fed. Reg. 999, 1026 (Jan. 6, 2000). Specifically, the agency said that, in general, a picture of a healthy organ should not be considered a disease claim if, in the context of the labeling as a whole, it does not imply disease treatment or prevention. Id. at 1026. However, FDA noted that there are certain symbols for organs, like the heart symbol, where, because they are so widely recognized as symbols for disease treatment or prevention, the agency will consider their use in labeling to constitute an implied disease claim. Id.

The enclosed product labels depict the heart symbol and, as such, make disease claims. The characterization of the products as dietary supplements does not negate this fact. Because we are unaware of any FDA approval of these disease claims for products, we respectfully request that FDA take immediate and appropriate enforcement action to stop this apparent unlawful promotion. If FDA has approved these claims, we would like to know.

Thank you for your prompt attention to this matter. Please feel free to contact us if you have any questions or require additional information.

Sincerely,



Alan G. Minsk

AGM:rd
Enclosures

Sundown

ULTIMATE™

Coenzyme Q-10 60 mg
150 IU of Natural E

Sundown

ULTIMATE™

[†]The CoQ-10 used in Sundown CoQ-10 Ultimate is clinically shown to be better absorbed than ordinary softgel CoQ-10 products. The patented Bio Solv® Process (also known as Q-Gel®) reduces the particle size of the CoQ-10 - allowing it to be better absorbed.

Better CoQ-10 absorption is important because CoQ-10 is essential for your body to convert food into energy. Heart tissues have one of the highest concentrations of CoQ-10 in the body, and the heart needs to maintain adequate levels of CoQ-10 for optimum health.* The lowering levels of CoQ-10 as you age and the limited availability from food make it important to take CoQ-10 daily.

*These statements have not been evaluated by the Food & Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

NEW!

Sundown

ULTIMATE™

Coenzyme Q-10 60 mg
and 150 IU of Natural E

Clinically
Shown To
Be Better
Absorbed[†]



30 Softgels

Dietary Supplement

01 18.02
WAL-MART
\$ 9.87

DIRECTIONS: TAKE ONE (1) TO TWO (2) SOFTGELS PER DAY WITH FOOD.

Supplement Facts

Serving Size 2 Softgels
Servings Per Container 15

Amount Per Serving	% Daily Value
Vitamin E 300 IU (as d-alpha-tocopherol)	1000%
Coenzyme Q-10 120 mg	††

††Daily Value not established.

Other Ingredients: Polysorbate 80, gelatin, medium chain triglycerides, glyceryl tributyrate, glycerin, sorbitol, soy lecithin, water, annatto extract (color), titanium dioxide.

FREE OF: yeast, wheat, corn and milk. No preservatives or synthetic colors.

Bio Solv® and Q-Gel® are registered trademarks of Tishcon Corporation.

Manufactured by the Bio Solv® Process (U.S. Patent No. 6,056,971) under an exclusive worldwide agreement with Biosytes, USA, Inc. Other U.S. and worldwide patents pending.

Date shown is rotation date ©2000 Rexall Sundown, Inc.
Manufactured for Distribution by
SUNDOWN VITAMINS®
Boca Raton, FL 33487 USA
www.rexallsundown.com
or call toll free 1-888-VITA-HELP

Sundown

ULTIMATE™

Sundown CoQ-10 Ultimate combines the patented Bio Solv® Process with natural vitamin E to work together in promoting heart health and proper blood circulation. CoQ-10 and Vitamin E provide powerful antioxidant protection to help protect cells from free-radical damage. Free radicals can cause cellular destruction and lead to premature aging.*

Give your body the CoQ-10 that has been clinically shown to be better absorbed[†] using the patented Bio Solv Process to help maintain your health and promote a healthy heart.*

*These statements have not been evaluated by the Food & Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

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PDIS7576

Supplement Facts	
Serving Size 1 Softgel	
Amount Per Serving	
Coenzyme Q10	50mg†
† Daily Value not established.	

OTHER INGREDIENTS: Proprietary Twinsorb Lecithin Enriched Phospholipid Transport System, Gelatin, Annatto Seed Extract, Titanium Dioxide.

DIRECTIONS: As a dietary supplement, take 1-2 softgels daily, preferably at mealtime or as directed by your health care professional.

KEEP OUT OF REACH OF CHILDREN.

Store in a cool, dry place.

Visit our website at www.twinlab.com

Manufactured by Twin Laboratories Inc. Ronkonkoma, New York 11779 USA

TWINLAB® TWINSORB™ CoQ10

CLINICALLY TESTED

SUPPORTS CARDIOVASCULAR FUNCTION*

Twinlab™ CoQ10 softgels are a highly bioavailable form of CoQ10 that have up to nine times the absorption rate of powder CoQ10 capsules. In a published human clinical study in Australia, using a randomized crossover format, healthy adults took two 50 mg of powder CoQ10 capsules or Twinlab CoQ10 softgels in the morning. Blood was drawn before taking the supplement and at intervals up to 36 hours. Blood serum CoQ10 levels were compared to the baseline levels. Peak absorption for Twinlab CoQ10 was 0.5 times higher than for powder CoQ10, and total absorption over the 36 hours studied was 0.27 times higher than the capsule of powder. The softgel form is also easy to swallow and dissolves quickly in the digestive system.

TWINLAB is the exclusive U.S. supplier of the Twinlab™ enhanced bioavailability system for CoQ10 and other nutritional products. Look for the Twinlab name on quality TWINLAB products.

*Anti Oxidant Journal of Clinical Nutrition (1999) Vol. 7, Number 1:27-46

9 TIMES BETTER ABSORPTION
 1  = 9
 50mg powdered capsules

30 SOFTGELS 50 mg

TWINLAB® TWINSORB™ CoQ10

9 TIMES BETTER ABSORPTION*

SUPPORTS CARDIOVASCULAR FUNCTION*



9 TIMES BETTER ABSORPTION

1  = 9
 50mg powdered capsules
DIETARY SUPPLEMENT

30 SOFTGELS 50 mg

TWINLAB® TWINSORB™ CoQ10

CLINICALLY TESTED

SUPPORTS CARDIOVASCULAR FUNCTION*

CoQ10 is an antioxidant that supports cellular energy production and healthy cardiovascular function. Also known as CoEnzyme Q10 or Ubiquinone, CoQ10 is an enzyme that activates cellular energy production in the mitochondria of the cell. Found throughout all cells in the body, but particularly in the heart and other muscle tissues, CoQ10 allows cells to generate the energy they need to function.*

CoQ10 is an antioxidant, carried in the bloodstream that has protective effects against oxidation by free radicals.* CoQ10 levels typically fall with age, and supplemental CoQ10 can restore serum and tissue stores of this important enzyme.

*These statements have not been evaluated by the Food & Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

9 TIMES BETTER ABSORPTION
 1  = 9
 50mg powdered capsules

30 SOFTGELS 50 mg



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