



Food and Drug Administration Washington, DC 20204

NOV 24 2000

0200 '00 DEC -7 P3:07

Mr. Dewayne Dailey
VP Marketing
Sonrich Corporation
908 Court Street
Saginaw, Michigan 48602-4172

Dear Mr. Dailey:

This is in response to your letter of November 10, 2000 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)). You included labels for two products that were recently introduced into interstate commerce in the United States.

This letter is intended solely to inform you that the product "Murphy Slim" is misbranded under the Act because it does not conform to the labeling requirements in 21 U.S.C. 403 and 21 CFR Part 101.

- The product is misbranded under 21 U.S.C. 343(q)(5)(F) and 343(s)(2)(A) because the quantity of the proprietary blend is not declared in the supplement facts box. It is also misbranded under 21 U.S.C. 343(s)(2)(C) because it contains a botanical or herbal dietary ingredient (i.e., aloe vera) and the label does not identify the part of the plant from which the dietary ingredient is derived.
- The product is misbranded under 21 U.S.C. 343(I)(2) and 21 CFR 101.4(a) because it contains an ingredient (i.e., "fruit juice concentrates") that is not declared by its common or usual name (the common or usual name of this type of ingredient must identify the fruits from which each juice concentrate is obtained).

The product "Murphy Zymes is misbranded under 21 U.S.C. 343(q)(5)(F) and 21 CFR 101.36(b)(1) because the serving size in the "Supplement Facts" label (i.e., 2 capsules) is not the serving sized that is suggested for use in each eating occasion (i.e., 1 capsule).

The "Supplement Facts" labels of both products have one or more deviations from the format requirements in 21 CFR 101.36(e)(5) and (6) that you should correct.

You should take steps to correct these labeling violations. Misbranded dietary supplements may be subject to enforcement action.

978-016-3

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### Page 2 - Mr. Dewayne Dailey

Please contact us if we may be of further assistance.

Sincerely,

John B. Foret
Director
Division of Compliance and Enforcement
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-300 FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200 FDA, Chicago District Office, Office of Compliance, HFR-MW140

### cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-800 (r/f, file)
HFS-811 (file)
HFD-40 (Behrman)
HFD-310
HFD-314 (Aronson)

HFS-605

HFV-228 (Benz)

GCF-1 (Dorsey, Nickerson)

r/d:HFS-811:RMoore:11/16/00

revised per HFS-800:VWilkening:11/22/00

f/t:HFS-811:rjm:11/22/00:docname:73332.adv:disc52



November 10, 2000

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, DC 20204

Dear Sir or Madam:

This is notification that Sonrich Corporation, of Saginaw, MI has marketed two new products with structure/function label claims as permitted under the Dietary Supplements Health and Education Act of 1994. Each of these products was sold into interstate commerce starting. November 1, 2000.

I certify that I believe the information presented and contained within this notice and on the label on page 2 enclosed, to be accurate and, believe the company has substantiation that the statements found here in are truthful and not misleading.

Sincerely,

Dewayne Dailey
VP Marketing
SONRICH CORPORATION

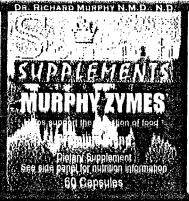
Suggested Use: As a dietary supplement, adults take (1) one capsule with each meal, or as directed by a health care professional. Store in a cool, dry place and away from direct light. Keep out of reach of children.

#### QUALITY AND POTENCY GUARANTEED.

These statements have not been evaluated by the Food and Over Administration. These statements are not intended to diagnose, treat cure or prayent any disease.

# Manufactured For SONRICH CORPORATION

Saginaw, MI 48602 USA (517) 792-3910 114



#### Supplement Facts Serving Size 2 Capsules Amount Per Servino % Daily Value antothetic Acid 133% roprietary Blend 980mg Plant Enzyme Blend Protease, Amylase, Lipase, Cellulase, Lactase, Sucrase, Maltase Peppermint (leaf) Lactobacillus Acidolphilus Papain Daily Value not established Other Ungredients: Gelatin Capsule.

Soggested Use: As a dietary supplement, addits take 102. (1 capful) with glass of viator 30 minutes before bedtime, and 102. (1 capful) in the morning upon arising from sleep, or as directed by a health care protessional.

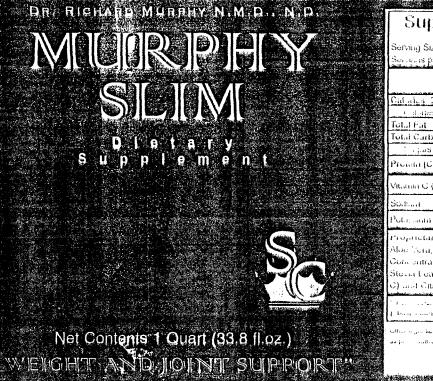
A diet supplement that is one of the most effective and advanced fat-burning joint supporting formulas known to science. This powerful liquid supplement burns fat in the body while you sleep. Aloe Vera, collagen, MSM, fruit juice concentrates with a strawberry shortcake flavor, and other components make this proprietary blend of Murphy. Slim the best of the best.\*\*

WARNING: This product contains fruit juice concontrolors (and thus high levels of natural tractorse) and is not resonanced for individuals can diabetes or hypoglycemia. If you are diabetic or hypoglycemic, please consult your physician before use.

"These statements have not been evaluated by the rood and Brug Administration. This product is no intended to diagnose, frest, cure or prevent any

# Manufactured For SONRICH CORPORATION

Sagmaw, MF 48602 USA (517) 792-3910



## Supplement Facts

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