



2429 6 APR 10 P1:59

APR - 3 2006

Mr. Michael H. Lee
Research Scientist
Sedona Laboratories, Inc.
211 Jennifer Drive
Cottonwood, Arizona 86326

Dear Mr. Lee:

This is in response to your letter to the Food and Drug Administration (FDA) dated March 20, 2006 pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)) for the product NextZyme™.

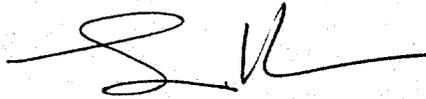
21 CFR 101.93(a)(3) requires that the notice submitted pursuant to 21 U.S.C. 343(r)(6) of this section be signed by a responsible individual who can certify the accuracy of the information presented and contained in the notice, and that the individual certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading. Your submission does not meet this requirement in that the notice does not contain the signature of the responsible individual designated on the notification; as such, it does not certify that the firm is in compliance with the requirements of the Act and the regulation. Therefore, your firm has not complied with the notification requirement in 21 U.S.C. 343(r)(6) and must submit a notification in accordance with the requirements in 21 CFR 101.93(a). The failure to submit a valid notice as required by the Act and the agency's regulation may subject the product that is the subject of the notification to regulation under the drug provisions of the Act.

97S 0163 LET 875

Page 2 - Mr. Michael H. Lee

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 flourish 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

March 20, 2006

Aims

2006-2471

MAR 23 2006

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: New Product – Food Labeling; Notification Procedures for Statements on
Dietary Supplements**

To Whom It May Concern,

A new product is to be launched in April of 2006. It will be sold under the name
“NextZyme™” (please refer to the label following this letter).

The new product has 400mg of *Nutra Flora scFOS* and 149mg of a *proprietary
enzyme blend*, which includes:

<i>Proprietary Enzyme Blend</i>	Per Serving
Amylase	3000 DU
Amylase 6.6 [†]	160 BAU
β-Glucanase	5 BGU
Glucoamylase	4.5 AGU
Hemicellulase	320 HCU
Invertase	110 SU
Lactase	100 ALU
Lipase	80 FCC LU
Lipase [†]	64 FCC LU
Malt Diastase	180 DP
Papain	225,000 FCC PU
Phytase	21 FTU
Protease 3.0	92.4 SAPU
Protease 4.5	18,000 HUT
Protease 6.0	9500 HUT
Protease 7.0 [†]	896 PC

[†] Enteric coated

The main ingredients of this product, the proprietary enzyme blend and *Nutra
Flora scFOS*, are widely used in dietary supplements sold in the U.S. Numerous articles
suggest that the above ingredients may yield digestive support.

#1640

I have attached the following items for your reference:

1. The new product label
2. Published articles on the effectiveness of each individual enzyme and/or a comprehensive study on a combination (or enzymes)
3. Published article on the effects of FOS (fructo-oligosaccharides)

I hereby certify that all of the information and data presented in this notice are both accurate and truthful. If I can be of any assistance, please contact me at michaelhlee@seondalabs.com or 928-634-0585. Thank you.

Very Respectfully,

Michael H. Lee, MS, MBA
Research Scientist
New Product Development
Sedona Laboratories, Inc.

Supplement Facts		
Serving Size: 1 capsule (550mg)		
Servings per container: 90		
Each Serving Contains:		% DV
Proprietary Enzyme Blend† 149 mg		
Amylase	3000 DU	*
‡Amylase 6.6	160 BAU	*
β-Glucanase	5 BGU	*
Glucoamylase	4.5 AGU	*
Hemicellulase	320 HCU	*
Invertase	110 SU	*
Lactase	100 ALU	*
Lipase	80 FCC LU	*
‡Lipase	64 FCC LU	*
Malt Diastase	180 DP	*
Papain	225,000 FCC PU	*
Phytase	21 FTU	*
Protease 3.0	92.4 SAPU	*
Protease 4.5	18,000 HUT	*
Protease 6.0	9500 HUT	*
‡Protease 7.0	896 PC	*
NutraFlora® seFOS†	400 mg	*
<small>*Daily values not established</small>		
Other Ingredients: Magnesium stearate		
†Origin: S. Korea ‡Enteric Coated		

SEDONA LABS

NO ANIMAL ENZYMES

THE NEXT GENERATION OF ENZYMES!
A Daily Supplement

NEXTZYME™
DUAL ACTION DIGESTIVE ENZYMES

WORKS IN STOMACH & SMALL INTESTINE
100% VEGETARIAN ENZYMES
REPLACES ANIMAL PANCREATIN

90 Vegetarian Capsules

NEXTZYME™. The Next Generation of Enzymes, replaces animal pancreatin with a safe, effective vegetarian formula for maximum digestive support. Dual action works in stomach and small intestine. NEXTZYME™ introduces a revolutionary pH-dependant enteric coating technology that delivers pancreatic-type enzymes to the small intestine.**

Suggested Use: 1 capsule before meals.

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

Sedona Labs, Inc.
211 Jennifer Lane, Cottonwood AZ 86326
888-816-8804 • www.sedonalabs.com

ITEM: 21602



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