



APR 17 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 April 3, 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 ZymaPro™.

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 876

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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

2006-3223

April 3, 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

APR 10 2006

**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 March of 2006. It will be sold under the name "ZymaPro™" (please refer to the label following this letter).

The new product has 250mg of *Nutra Flora scFOS*, 150mg of L-Glutamine and 149mg of a *proprietary enzyme blend*, which includes:

| <i>Proprietary Enzyme Blend</i> | Per Serving    |
|---------------------------------|----------------|
| Amylase                         | 3000 DU        |
| Amylase 6.6 <sup>†</sup>        | 160 BAU        |
| β-Glucanase                     | 5 BGU          |
| Bromelain                       | 250,000 FCC PU |
| Cellulase                       | 90 CU          |
| Glucoamylase                    | 4.5 AGU        |
| Hemicellulase                   | 320 HCU        |
| Invertase                       | 110 SU         |
| Lactase                         | 100 ALU        |
| Lipase                          | 80 FCC LU      |
| Lipase <sup>†</sup>             | 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 <sup>†</sup>       | 896 PC         |

<sup>†</sup> Enteric coated

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

#1666

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 (of enzymes)
3. Published articles on FOS (fructo-oligosaccharides)
4. Published articles on L-Glutamine

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 [michaelhjlee@seondalabs.com](mailto:michaelhjlee@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             |
|---|------------------|
| <b>Proprietary Enzyme Blend† 149 mg</b> |                  |
| Amylase                                 | 3000 DU *        |
| † Amylase 6.6                           | 160 BAU *        |
| β-Glucanase                             | 5 BGU *          |
| Bromelain                               | 250,000 FCC FU * |
| Cellulase                               | 90 GU *          |
| Glucoamylase                            | 4.5 AGU *        |
| Homoamylase                             | 320 HGU *        |
| 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                            | 3500 HUT *       |
| † Protease 7.0                          | 696 FC *         |
| NeutraFlora® scFOS†                     | 250 mg *         |
| L-Glutamine ‡                           | 150 mg *         |
| Other ingredients: Magnesium stearate   |                  |
| †Origin: S. Korea ‡Enteric Coated       |                  |
| *Daily value not established            |                  |

Manufactured in USA

**PROFESSIONAL USE ONLY**

A DIETARY SUPPLEMENT

**SEDONA LABS™**

SINCE 1987

**ZymaPro™  
ZY-18™****Triple Action Formula  
Digestive Enzymes with  
L-Glutamine****90 Vegetarian Capsules**

**ZymaPro™ ZY-18™** contains 18 digestive enzymes that work in the stomach and small intestine. Our Triple Formula introduces a revolutionary pH-dependent enteric coating technology that delivers pancreatic-type enzymes to the small intestine. **ZymaPro™ ZY-18™** replaces animal pancreatin and the L-Glutamine is added to support the integrity of the intestinal lining.\*\*

**Suggested Use:** One capsule before meals, or as directed by a health care professional.

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

**Sedona Labs**211 Jennifer Lane, Cottonwood AZ 86326  
888-816-8804 • [www.sedonalabapro.com](http://www.sedonalabapro.com)ITEM:  
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