



INNOVATORS OF NATURAL PRODUCTS

November 25, 2003

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

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Dear Sirs:

Notice is hereby given pursuant to the requirements of section 403(r)(6) (21 U.S.C. 343(r)(6)) of the Federal Food, Drug and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93, that Naturade, Inc., located at 14370 Myford Road, Irvine, CA 92606, within the past 30 days commenced marketing a dietary supplement bearing the following statement(s) on the label and/or in the labeling:

**TEXT OF CLAIM**

- "Helps block absorption of starch calories"
- "Lose weight safely"
- "Block calorie absorption"
- "Take inches off your waist"
- "Neutralize starch calories—Diet Lean carb blocker can help you lose pounds safely by allowing starch calories to pass through your body without being digested. With fewer carbohydrates available, your body burns stored fat."
- "Works on all complex carbohydrates: Bread, pastries, pasta, corn, pancakes, rice, potatoes and more."
- "Have power over your food—Follow a reduced calorie meal plan and still feel full by including sensible starch-rich foods. Reward your good eating habits with an occasional treat and put an end to cravings."
- "Safe, steady weight loss—There's no stimulants, no ephedra and no caffeine. Clinical studies confirm safety and show better weight loss with more inches lost around the waist when given Phase 2™ compared to placebo."
- "Take ½ hour before each starch-rich meal (i.e. baked goods, pasta, potatoes, rice) to allow most starch to pass through your system without releasing calories."

**NAME OF INGREDIENT OR SUPPLEMENT THAT IS SUBJECT OF CLAIM**

Phase 2™ brand white kidney bean extract (phaseolus vulgaris)

**NAME OF SUPPLEMENT**

Diet Lean™

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The undersigned certifies that the information contained in this notice is complete and accurate and that Naturade, Inc. has substantiation that these statements are truthful and not misleading.

Sincerely,

A handwritten signature in black ink, appearing to read 'MZ', with a long horizontal flourish extending to the right.

Marwan Zreik  
Chief Operating Officer