

January 14, 2005

Office of Nutritional Products  
Labeling and Dietary Supplements (HFS-810)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Pkwy.  
College Park, MD 20740

FEB 16 2005

Gentlemen:

Complying with the requirements of 21CFR101.93, I am advising FDA of the initiation of marketing of **Immune Alert™ Daily Defense Orange Flavor** by Alert Nutrition, LLC. Initial marketing occurred during the week of January 9, 2005.

The distributor's address is Alert Nutrition, LLC; 1161 Wayzata Blvd. #51; Wayzata, MN 55391. Alert Nutrition's phone number is (763) 473-0096.

The label includes the Structure/Function claim "Immune Alert™ is a breakthrough nutritional product that contains 250 mg of Beta Glucan – which has been shown to help maintain an improved state of readiness of the innate (non-specific) immune function.\*" The label also includes the FDA disclaimer "\*\*This statement has not been reviewed by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any diseases."

The Structure/Function claim is based upon the research findings of laboratory and clinical investigations on beta glucan. Immune Alert Daily Defense Orange Flavor contains patented BetaRight® 3-6 of beta 1,3/1,6 glucan extracted from food-grade Baker's yeast (*Saccharomyces cerevisiae*), a FDA- approved food ingredient (21CFR170.30).

The label for Immune Alert Daily Defense Orange Flavor is below:

**Recommended Serving Size:** As a dietary supplement, chew 1 tablet per day. Best if taken on an empty stomach.

Immune Alert™ is a breakthrough nutritional product that contains 250mg of Beta 1,3/1,6 D-Glucan - which has been shown to help maintain an improved state of readiness of the innate (non-specific) immune function.\* The innate immune function is considered to be the body's first line of defense against all foreign challenges.

The immune system refers to all of the body's complex defense mechanisms that protect against foreign challenges. Health and survival depend on an effective and efficient immune response.

**Keep Out of Reach of Children.** If you are pregnant, nursing or have a yeast allergy, consult your physician.

\*This statement has not been reviewed by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any diseases

## Immune ALERT

with BetaRight 3-6

### Orange Flavor

Dietary Supplement

**SUPPLEMENT FACTS**  
Serving Size: 1 Tablet  
Servings Per Container: 30

Amount Per Serving	% Daily Value*
Calories 30	+
Total Carbohydrate 3g	1%
Sugars 3g	+
Dietary Fiber Less Than 1g	1%
BetaRight® 3-6 (Beta 1,3/1,6-Glucan) 250 mg	+
*Percent Daily Values are based on a diet of 2,000 tablets per day.	

Other Ingredients: Sucrose, Microcrystalline Cellulose, Natural Flavors, Magnesium Stearate, Citric Acid, Malic Acid, Artificial Color (FD&C Yellow #6), Maltodextrin and Sucralose.

BetaRight® 3-6 is covered by one or more of the following patents: 5,702,716; 4,992,840; 4,592,094; 6,032,401; 5,077,872; 5,304,079; 5,741,485; 6,030,336; 5,878,015.

Made in the USA

Immune Alert™ is a pending trademark of Alert Nutrition, LLC.  
BetaRight® is a registered trademark of BioActive Engineering, Inc.

Regards,

*Jerome Licari*  
Jerome Licari, Ph.D.  
President  
Alert Nutrition, LLC.

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CC: Judy E. Heisick, Compliance Officer; FDA; Minneapolis District