



DEC - 8 2006

Jerome Licari, Ph.D.
Owner
Alert Nutrition, LLC
1161 Wayzata Boulevard, #51
Wayzata, Minnesota 55391

Dear Dr. Licari:

This is in response to your letters of November 11, 2006 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)). Your submission stated that Alert Nutrition, LLC is making the following claims for the following products:

Immune Alert Children's Formula - Cherry Flavor Chewable Tablets

"Germs, virus, bacteria...kids pass them back and forth and bring them home to you. Taken daily, Immune Alert...puts your children's natural defenses on high alert to fight off these invaders."

Immune Alert Adults Formula- Capsules

Immune Alert Adult's Formula - Orange Flavor Chewable Tablets

"Each day your body fights off billions of disease-causing micro-organisms. Taken daily, Immune Alert...puts your natural defenses on high alert to fight off these invaders...."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these product suggest that they are intended to treat, prevent, or mitigate diseases, namely diseases caused by pathogenic microorganisms. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

97S 0163 LET 915

Page 2 - Dr. Jerome Licari

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Vasilios Frankos". The signature is written in a cursive style with a large, sweeping flourish at the end.

Vasilios H. Frankos, Ph.D.
Acting Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

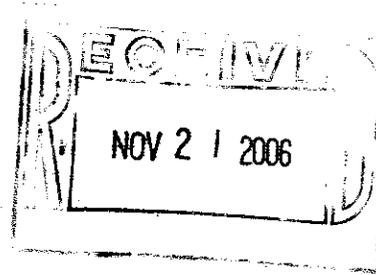
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Minneapolis District Office, Office of Compliance, HFR-CE840

November 11, 2006

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



Re: LABEL REVISION FOR "**Immune Alert^R Children's Formula - Cherry Flavor Chewable Tablets**"

Gentlemen:

Complying with the requirements of 21CFR101.93, I am advising FDA of the initiation of marketing **Immune AlertTM Children's Formula - Cherry Flavor Chewable Tablets** by Alert Nutrition, LLC bearing a revised label. Initial marketing of product with the new label occurred during the week of October 23, 2006.

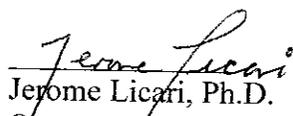
The distributor's address is Alert Nutrition, LLC; 1161 Wayzata Blvd. #51; Wayzata, MN 55391. Alert Nutrition's phone number is (763) 473-0096.

The label includes the Structure/Function statement "Germs, virus, bacteria...kids pass them back and forth and bring them home to you. Taken daily, Immune Alert with Beta 1,3/1,6 Glucan. (an all natural complex carbohydrate extracted from baker's yeast) puts your children's natural defenses on high alert to fight off these invaders.*" 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 Children's Formula Cherry Flavor Chewable Tablets contains patented BetaRight^R 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 and cap sticker (Spanish translation of label text copy) for Immune Alert Children's Formula - Cherry Flavor Chewable Tablets are attached.

Regards,


Jerome Licari, Ph.D.
Owner
Alert Nutrition, LLC.

2006-8829

CC: Judy E. Heisick, FDA; Minneapolis District

Immune Alert[®] Children's Formula

Cherry Flavor Chewable Tablets

Distributor: Alert Nutrition, LLC; 1161 Wayzata Blvd. #51; Wayzata, MN 55391
(763) 473-0096.

Germs, viruses, bacteria...kids pass them back and forth and bring them home to you.

Taken daily, Immune Alert with Beta 1,3/1,6 Glucan (an all-natural complex carbohydrate extracted from baker's yeast) puts your children's natural defenses on high alert to fight off these invaders.*

Recommended Serving Size: For children 3 to 8, chew 1 tablet daily. For children older than 8, chew 2 tablets daily. For children under 3 years of age, consult your physician before using. Best if taken on an empty stomach.

Keep out of reach of children. If there is a known or suspected yeast allergy, consult your physician before using.

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



Dietary Immune Supplement
Children's Formula

Immune Alert[®]

CLINICALLY TESTED ... THE ONE THAT WORKS!

Cherry Flavor

30 Chewable Tablets

Supplement Facts	
Serving Size: 1 Tablet	
Servings Per Container: 30	
Amount Per Serving	% Daily Value
Calories 10	
Total Carbohydrates 3 g	1%*
Dietary Fiber 0 g	†
Sugars 3 g	0%*
Beta 1,3/1,6 D-glucans 50 mg	†

† Daily value not established.
* Percent Daily Values are based on a 2,000 calorie diet.

Other Ingredients: Sucrose, Microcrystalline Cellulose, Natural Flavors, Magnesium Stearate, Citric Acid, Malic Acid and Stevia.

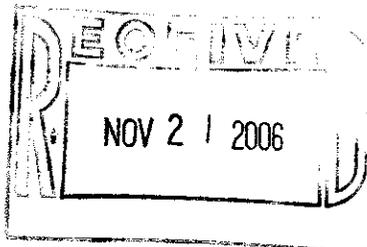
Covered by one or more of the following patents: 5,702,719; 4,992,540; 4,992,394; 5,082,401; 5,037,972; 5,504,079; 5,741,495; 6,020,324; 5,576,015.

© 2006 Distributed by Alert Nutrition, LLC, Minneapolis, MN 55391
Immune Alert[®] is a registered trademark of Alert Nutrition, LLC
Made in the USA



November 11, 2006

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



Re: LABEL REVISION FOR “Immune Alert^R Adult’s Formula - Orange Flavor Chewable Tablets”

Gentlemen:

Complying with the requirements of 21CFR101.93, I am advising FDA of the initiation of marketing **Immune AlertTM Adult’s Formula - Orange Flavor Chewable Tablets** by Alert Nutrition, LLC bearing a revised label. Initial marketing of product with the new label occurred during the week of October 23, 2006.

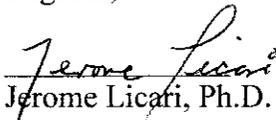
The distributor’s address is Alert Nutrition, LLC; 1161 Wayzata Blvd. #51; Wayzata, MN 55391. Alert Nutrition’s phone number is (763) 473-0096.

The label includes the Structure/Function statement “Each day your body fights off billions of disease-causing micro-organisms. Taken daily, Immune Alert with Beta 1,3/1,6 Glucan. (an all natural complex carbohydrate extracted from baker’s yeast) puts your children’s natural defenses on high alert to fight off these invaders – **stopping them before they stop you.***” 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 Adult Formula - Orange Flavor Chewable Tablets contains patented BetaRight^R 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 and cap sticker (Spanish translation of label text copy) for Immune Alert Adult Formula - Orange Flavor Chewable Tablets are attached.

Regards,


Jerome Licafi, Ph.D.
Owner
Alert Nutrition, LLC.

CC: Judy E. Heisick, FDA; Minneapolis District

06-8829

Immune Alert[®] Adult's Formula Orange Flavor Chewable Tablets

Distributor: Alert Nutrition, LLC; 1161 Wayzata Blvd. #51; Wayzata, MN 55391
(763) 473-0096.

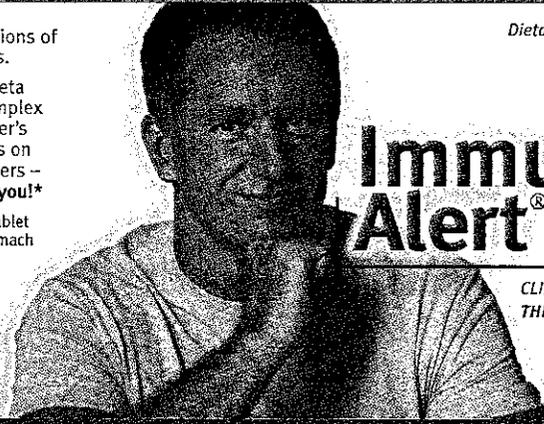
Each day your body fights off billions of disease-causing micro-organisms.

Taken daily, Immune Alert with Beta 1,3/1,6 Glucan (an all-natural complex carbohydrate extracted from baker's yeast) puts your natural defenses on high alert to fight off these invaders -- **stopping them before they stop you!***

Recommended Serving Size: Chew 1 tablet per day. Best if taken on an empty stomach

Keep out of reach of children. If you are pregnant, nursing or have a yeast allergy, consult your physician before taking.

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



Dietary Immune Supplement
Adult Formula

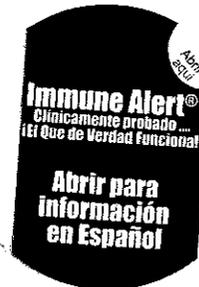
Immune Alert[®]

CLINICALLY TESTED ...
THE ONE THAT WORKS!

Orange Flavor
30 Chewable Tablets

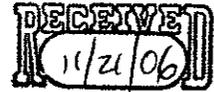
Supplement Facts	
Serving Size: 1 Tablet	
Servings Per Container: 30	
Amount Per Serving	% Daily Value
Calories 10	
Total Carbohydrates 3 g	1%*
Dietary Fiber 0 g	†
Sugars 3 g	0%*
Beta 1,3/1,6 D-glucans 250 mg	†

† Daily Value not established.
* Percent Daily Values are based on a 2,000 calorie diet.
Other Ingredients: Sucrose, Microcrystalline Cellulose, Natural Flavors, Magnesium Stearate, Citric Acid, Stevia and Malic Acid.
Covered by one or more of the following patents: 5,702,713; 4,992,540; 4,982,284; 5,102,491; 5,137,072; 5,204,078; 5,741,496; 6,102,924; 6,076,015.
© 2006 Distributed by Alert Nutrition, LLC Minneapolis, MN 55391
Immune Alert[®] is a registered trademark of Alert Nutrition, LLC
Made in the USA



November 11, 2006

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



Re: NEW PRODUCT "**Immune Alert^R Adult's Formula - Capsules**"

Gentlemen:

Complying with the requirements of 21CFR101.93, I am advising FDA of the initiation of marketing **Immune AlertTM Adult's Formula - Capsules** by Alert Nutrition, LLC. Initial marketing of product occurred during the week of October 23, 2006

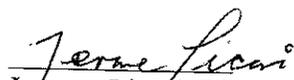
The distributor's address is Alert Nutrition, LLC; 1161 Wayzata Blvd. #51; Wayzata, MN 55391. Alert Nutrition's phone number is (763) 473-0096.

The label includes the Structure/Function statement "Each day your body fights off billions of disease-causing micro-organisms. Taken daily, Immune Alert with Beta 1,3/1,6 Glucan. (an all natural complex carbohydrate extracted from baker's yeast) puts your children's natural defenses on high alert to fight off these invaders - **stopping them before they stop you.***" 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 Adult Formula - Capsules contains patented BetaRight^R 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 and cap sticker (Spanish translation of label text copy) for Immune Alert Adult Formula - Capsules are attached.

Regards,


Jerome Licari, Ph.D.
Owner
Alert Nutrition, LLC.

CC: Judy E. Heisick, FDA; Minneapolis District

06-8829

Immune Alert[®] Adult's Formula Capsules

Distributor: Alert Nutrition, LLC; 1161 Wayzata Blvd. #51; Wayzata, MN 55391
(763) 473-0096.

Each day your body fights off billions of disease-causing micro-organisms.

Taken daily, Immune Alert with Beta 1,3/1,6 Glucan (an all-natural complex carbohydrate extracted from baker's yeast) puts your natural defenses on high alert to fight off these invaders – **stopping them before they stop you!***

Recommended Serving Size: Take 1 capsule per day. Best if taken on an empty stomach.

Keep out of reach of children. If you are pregnant, nursing or have a yeast allergy, consult your physician before taking.

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

*Dietary Immune Supplement
Adult Formula*



Immune Alert[®]

**CLINICALLY TESTED ...
THE ONE THAT WORKS!**

30 Capsules

Supplement Facts
Serving Size: 1 Capsule
Servings Per Container: 30

Amount Per Serving	% Daily Value
Beta 1,3/1,6 D-glucans 250 mg	†

† Daily Value not established.

Other Ingredients: Cellulose, Microcrystalline Cellulose, Magnesium Stearate and Silica.

Covered by one or more of the following patents:
5,702,719; 4,932,540; 4,982,094; 5,032,401; 5,037,972; 5,504,079;
5,741,485; 6,020,324; 5,576,015.

© 2006 Distributed by Alert Nutrition, LLC Minneapolis, MN 55391
Immune Alert[®] is a registered trademark of Alert Nutrition, LLC
Made in the USA



