

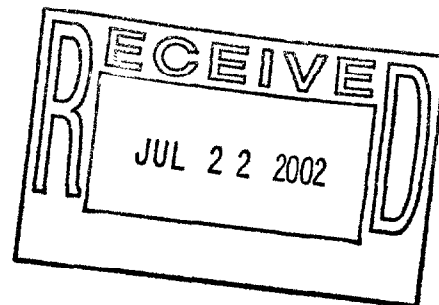
Pure Research Products *Naturally* LLC  
6107 Chelsea Manor Court  
Boulder, Colorado 80301

303 530-7761

[jsichel@ecentral.com](mailto:jsichel@ecentral.com) 722 02 815 -5 P2:09

Fax 303 530-0222

Robert Moore, Director  
Office of Nutritional Products  
Labeling and Dietary Supplements (HFS-810)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, Maryland 20740



18 July 2002

Dear Mr. Moore:

As required in Title 21, Part 101, Sec 101.93 the label information for Del-Immune Capsules is attached for review by your department. Ms Rhonda Kane is reviewing the Pre-market Notification II (The second effort) and alerted me to this requirement.

The information is being submitted during the required 75 day period for a PMN submission to save time and money. Your assistance in permitting the label review at this time is greatly appreciated.

Please contact me with any questions or comments.

Respectfully,

A handwritten signature in cursive that reads "John A. Sichel, RPh".

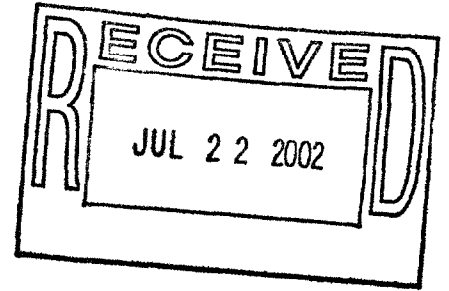
John A. Sichel, RPh  
President  
Pure Research Products Naturally LLC  
6107 Chelsea Manor Court  
Boulder, Colorado 80301

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**U.S. Food and Drug Administration  
TITLE 21—FOOD AND DRUGS  
FOOD LABELING  
Sec.101.93**

**Del-Immune**

***Lactobacillus delbrueckii* ssp bulgaricus lysate**

**A Dietary Supplement  
For  
Immediate Immune System Support**

Prepared by:  
John A. Sichel, RPh  
President  
Pure Research Products Naturally LLC  
6107 Chelsea Manor Court  
Boulder, Colorado 80301

18 July 2002

303 530-7761  
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Del-Immune

TITLE 21—FOOD AND DRUGS

CHAPTER 1—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 101—FOOD LABELING

Sec. **101.93** Certain types of statements for dietary supplements

(a) (1) This document is being submitted to comply with the requirement for a label review no later than 30 days after marketing a dietary supplement. I understand this is possible as my Pre-market Notification II (second submission) is being reviewed .

This document is prepared in an original and two copies signed by the distributor, for review by the:

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

- (2)(i) Name of distributor: Pure Research Products Naturally LLC  
John A. Sichel, RPh, President  
6107 Chelsea Manor Court  
Boulder, Colorado 80301 USA  
Telephone 303 530-7761
- (ii) The text of the statement being made: immediate immune system support
- (iii) The name of the dietary ingredient: Lactobacillus delbrueckii ssp bulgaricus  
lysate powder
- (iv) The name of the dietary supplement including the brand name: see 2(iii)  
Brand name: Del-Immune

3. This notice is to be signed by a responsible individual...

The information contained in this document is true and accurate. Pure Research Products Naturally LLC has substantiation that the statement is truthful and not misleading.



John A. Sichel RPh  
President  
Pure Research Products Naturally LLC  
6107 Chelsea Manor Court  
Boulder, Colorado 80301  
303 530-7761 Fax 303 530-0222

  
Date

- (b) (c) Disclaimer. The disclaimer is placed on the label where recommended and reads " This product has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent and disease." See Exhibit #1."
- (d) Placement: The disclaimer is appropriately placed adjacent to the statement. "See Exhibit #1".
- (e) Typesize: The disclaimer is presented in bold face and no copy is smaller than 1/16<sup>th</sup> of an inch. "See Exhibit #1"  
"See Exhibit #1"
- (f) Permitted structure/function statements: Lactobacillus delbrueckii supports the function of the immune system. Thus the classical statement "immediate immune system support".  
"See Exhibit #1"
- (g) Disease claims: The label does not contain disease claims.
- (2) Claims re: diagnosis etc... The statement does not make claims re: diagnosis, mitigate, treat, cure, or prevent disease.
- Items (i) through (iv) The statement does not make claims for any of these conditions.

(A) The name of the product: Del-Immune Capsules

(B) A statement about the formulation of the product: The formulation follows:

Each Del-Immune capsule contains:

Lactobacillus delbrueckii 125 milligrams  
Brown rice powder filler-sufficient quantity added to the  
lactobacillus delbrueckii powder to fill a size #1 vegetable capsule.

(C) Citation of a publication or reference: There is no citation intended .

(D), (E), (v), (vi), (vii), (viii) ,(ix) ,(x): Not applicable to this product, the product labeling, or the product packaging.

The information contained in this document is true and accurate. Pure Research Products Naturally LLC has substantiation that the statement is truthful and not misleading.

  
\_\_\_\_\_  
John A. Sichel, RPh  
President  
Pure Research Products LLC

  
\_\_\_\_\_  
Date

# PROOF

Exhibit # 1  
 Del-Immune Capsules  
 Pure Research Products  
 Naturally LLC  
 Boulder, Colorado 80301

<p><b>suggested use:</b>          1 to 2 capsules as needed.</p> <p>warnings: keep out of the reach of children.          store in a cool place.</p> <p><b>*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, cure, treat or prevent any disease.</b></p> <p>Manufactured by ELAN Ltd., St. Petersburg, Russia.          Distributed by Pure Research Products Naturally LLC,          Boulder, Colorado 80301.          pure@ecentral.com</p>	<p>Pure Research Products Naturally LLC</p> <p><b>Del-Immune</b></p> <p>a lysate powder of  <b><i>Lactobacillus delbrueckii ssp. bulgaricus</i></b></p> <p>immediate immune system support*</p> <p>Net Contents: 30 capsules</p> <p>a dietary supplement from St. Petersburg, Russia</p>	<p><b>supplement facts:</b></p> <table border="1"> <tr><td>servings per container</td><td>30</td></tr> <tr><td>amount per serving</td><td>125 mg</td></tr> <tr><td>calories per serving</td><td>2</td></tr> </table> <p><b>Active Ingredient:</b>          a lysate powder of  <b><i>Lactobacillus delbrueckii ssp. bulgaricus</i></b></p> <p>other ingredients: brown rice powder          in vegetable capsules</p> <p>natural product • chemical free</p> <p>©Pure Research Products Naturally LLC          Boulder, Colorado 80301          pure@ecentral.com</p>	servings per container	30	amount per serving	125 mg	calories per serving	2
servings per container	30							
amount per serving	125 mg							
calories per serving	2							

<p><b>suggested use:</b>          1 to 2 capsules as needed.</p> <p>warnings: keep out of the reach of children.          store in a cool place.</p> <p><b>*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, cure, treat or prevent any disease.</b></p> <p>Manufactured by          ELAN Ltd., St. Petersburg, Russia.          Distributed by          Pure Research Products Naturally, LLC.          Boulder, Colorado 80301          pure@ecentral.com</p>	<p>Pure Research Products Naturally LLC</p> <p><b>Del-Immune</b></p> <p>a lysate powder of  <b><i>Lactobacillus delbrueckii ssp. bulgaricus</i></b></p> <p>immediate immune system support*</p> <p>Net Contents: 100 capsules</p> <p>a dietary supplement from St. Petersburg, Russia</p>	<p><b>supplement facts:</b></p> <table border="1"> <tr><td>servings per container</td><td>100</td></tr> <tr><td>amount per serving</td><td>125 mg</td></tr> <tr><td>calories per serving</td><td>2</td></tr> </table> <p><b>Active Ingredient:</b>          a lysate powder of  <b><i>Lactobacillus delbrueckii ssp. bulgaricus</i></b></p> <p>other ingredients: brown rice powder          in vegetable capsules</p> <p>natural product • chemical free</p> <p>©Pure Research Products Naturally LLC          Boulder, Colorado 80301          pure@ecentral.com</p>	servings per container	100	amount per serving	125 mg	calories per serving	2
servings per container	100							
amount per serving	125 mg							
calories per serving	2							

Size: a. 1.5" x 4.625" DC    b. 2.25" x 5.875" DC

? Across

Unwind: 3-4

Colours: Black, PMS 2726, PMS 571, PMS 1225

Note: Colours are approximate and based on inkjet printer capabilities.

Proof should be used for colour breaks, layout and spelling.

Approved as is: \_\_\_\_\_

Make following changes and re-proof: \_\_\_\_\_

\_\_\_\_\_  
 \_\_\_\_\_

The Columbine Label Company  
 4131 S. Natches Ct., Unit K  
 Englewood, CO 80110  
 (303) 788-1504 FAX (303) 788-1539

**IMPORTANT:**

Please proofread carefully. Columbine Label Company cannot be held responsible for incorrect printing based on your approved proof.