

Pure Research Products Naturally, LLC

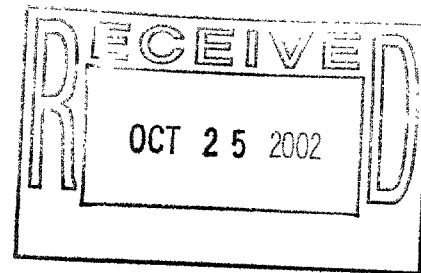
6107 Chelsea Manor Court
Boulder, Colorado 80301 USA

303 530-7761

Fax: 303 530-0222

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Robert Moore, PhD
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



22 October 2002

Dear Dr. Moore:

As required in Title 21, Part 101, Sec 101.93 label information for Del-Immune Capsules is attached. Ms Rhonda Kane reviewed the Pre-market Notification II (The second effort) and confirmed receipt of the submission. She also alerted me to this requirement.

This information is being submitted, with three copies, within the 30 day requirement after initiating marketing. Your previous assistance in providing label information is genuinely appreciated.

Please contact me with any questions or comments.

Respectfully,

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

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LET 11130

**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

22 October 2002

303 530-7761
Fax 303 5630-0222

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Del-Immune

TITLE 21—FOOD AND DRUGS

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

PART 101—FOOD LABELING

Sec. 101.9 Nutrition labeling of food

And

Sec. 101.36 Nutrition labeling of dietary supplements

Del-Immune has completed the FDA Pre-Market Notification safety phase and marketing started 16 October 2002. This submission fulfills the requirement to notify "Labeling and Dietary Supplements (HFS-810) within 30 days after initial marketing.

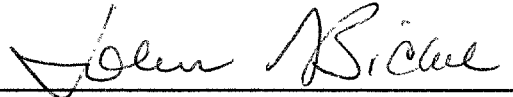
This document is prepared in an original and two copies and signed by the distributor for review by the:

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 nutritional ingredient:
Lactobacillus delbrueckii ssp bulgaricus lysate powder
- (iv) The name of the nutritional supplement including the brand name: see 2(iii)
Lactobacillus delbrueckii ssp bulgaricus 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 1/16th 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:

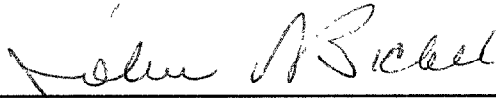
Lactobacillus delbrueckii ssp bulgaricus 125 milligrams

Other ingredients: Brown rice powder filler
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

Enclosure: Labels : 10, 30, 100 capsules

Supplement Facts
 Serving Size: 1 capsule
 Servings Per Container: 10

| Amount Per Capsule | %Daily Value* |
|---|---------------|
| Lactobacillus delbrueckii ssp bulgaricus lysed powder | 125 mg * |

* Daily Value not established

Other Ingredients: ...
 powder and vegetable capsules

Imported and distributed by:
 Pure Research Products
 Naturally LLC
 Boulder, Colorado
 del-immune.com
 On the web: www.del-immune.com

Pure Research Products
 Naturally LLC

Del-Immune
 Lactobacillus delbrueckii
 ssp. bulgaricus lysed powder
 dietary supplement
 from St. Petersburg, Russia
**immediate immune
 system support***

Net Contents: 10 capsules

*This statement has not been evaluated
 by the Food and Drug Administration.
 The product is not intended to diagnose,
 treat, cure or prevent disease

Daily Usage:
 Take 1 capsule daily.

Keep in a cool, dry place. For freshness,
 reseal after each use and store in a
 cool, dry place out of the reach of
 children.

Lactobacillus delbrueckii ssp.
 bulgaricus is typically used in
 yogurt and other probiotic
 products. It is a strain of Lacto-
 bacillus that has been shown to
 support the immune system. A produc-
 tion of "young" cells of the cell to
 support the immune system. The product
 has been professionally tested for
 over 10 years in
 clinical studies.

Imported and distributed by:
 Pure Research Products
 Naturally LLC
 Boulder, Colorado
 del-immune.com
 On the web: www.del-immune.com

8 55602 00001 5

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

| Amount Per Capsule | %Daily Value* |
|---|---------------|
| Lactobacillus delbrueckii ssp bulgaricus lysed powder | 125 mg * |

* Daily Value not established

Other Ingredients: ...
 powder and vegetable capsules

Imported and distributed by:
 Pure Research Products
 Naturally LLC
 Boulder, Colorado
 del-immune.com
 On the web: www.del-immune.com

Pure Research Products
 Naturally LLC

Del-Immune
 Lactobacillus delbrueckii
 ssp. bulgaricus lysed powder
 dietary supplement
 from St. Petersburg, Russia
**immediate immune
 system support***

Net Contents: 30 capsules

*This statement has not been evaluated
 by the Food and Drug Administration.
 The product is not intended to diagnose,
 treat, cure or prevent disease

Daily Usage:
 Take 1 capsule daily.

Keep in a cool, dry place. For freshness,
 reseal after each use and store in a
 cool, dry place out of the reach of
 children.

Lactobacillus delbrueckii ssp.
 bulgaricus is typically used in
 yogurt and other probiotic
 products. It is a strain of Lacto-
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 support the immune system. A produc-
 tion of "young" cells of the cell to
 support the immune system. The product
 has been professionally tested for
 over 10 years in
 clinical studies.

Imported and distributed by:
 Pure Research Products
 Naturally LLC
 Boulder, Colorado
 del-immune.com
 On the web: www.del-immune.com

8 55602 00002 2

Supplement Facts
 Serving Size: 1 capsule
 Servings Per Container: 100

| Amount Per Capsule | %Daily Value* |
|---|---------------|
| Lactobacillus delbrueckii ssp bulgaricus lysed powder | 125 mg * |

* Daily Value not established

Other Ingredients: ...
 powder and vegetable capsules

Imported and distributed by:
 Pure Research Products
 Naturally LLC
 Boulder, Colorado
 del-immune.com
 On the web: www.del-immune.com

Pure Research Products
 Naturally LLC

Del-Immune
 Lactobacillus delbrueckii
 ssp. bulgaricus lysed powder
 dietary supplement
 from St. Petersburg, Russia
**immediate immune
 system support***

Net Contents: 100 capsules

*This statement has not been evaluated
 by the Food and Drug Administration.
 The product is not intended to diagnose,
 treat, cure or prevent disease

Daily Usage:
 Take 1 capsule daily.

Keep in a cool, dry place. For freshness,
 reseal after each use and store in a
 cool, dry place out of the reach of
 children.

Lactobacillus delbrueckii ssp.
 bulgaricus is typically used in
 yogurt and other probiotic
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 On the web: www.del-immune.com

8 55602 00003 9