



DEPARTMENT OF HEALTH & HUMAN SERVICES

HFA-305  
Public Health Service

Food and Drug Administration  
College Park, MD 20740

6260 '03 SEP 23 P2:10

SEP 4 2003

Mr. James Baccus  
Marketing Director  
Immudyne  
11200 Wilcrest Green Drive  
Houston, Texas 77042

Dear Mr. Baccus:

This is in response to your letter of August 5, 2003 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 states that Immudyne Inc. is making the following claims, among others, for its product **MacroForce®**:

“...stimulating macrophage cells to fight against disease and foreign invaders.”

“...ideally suited to those with serious immune challenges.”

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 this product suggests that it is intended to prevent disease (i.e., infectious diseases). These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and it is 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.

975-0163

LET 721

Page 2 - Mr. James Baccus

Please contact us if we may be of further assistance.

Sincerely yours,

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

Susan J. Walker, M.D.  
Acting Director  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

**Copies:**

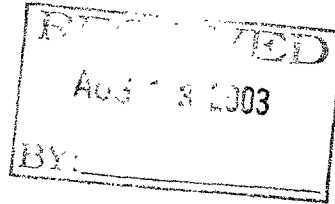
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

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

FDA, Dallas District Office, Office of Compliance, HFR-SW140

# IMMUDYNE

11200 WILCREST GREEN DRIVE  
HOUSTON, TEXAS 77042  
713.783.7034 TELEPHONE  
713.783.6819 FAX



August 5, 2003

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

Dear Sirs:

Notice is hereby given pursuant to 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 C.F.R. 101.93, that Immudyne, Inc., 11200 Wilcrest Green Drive, Houston, Tx. 77042, is marketing a dietary supplement bearing the following statement (s) on the label and/or in labeling:

**The text of the statement that is being made is as follows:**

See attached ad and labels

**The names of the products are as follows:**

MacroForce, MacroForce Plus C, MacroForce Plus IP-6, ArthroForce, CardioShield, ProstaForce

The undersigned certifies that the information contained in this notice is complete and accurate and that Immudyne, Inc. has substantiation that the statement is truthful and not misleading.

Sincerely,  
Immudyne, Inc.

James Baccus  
Marketing Director

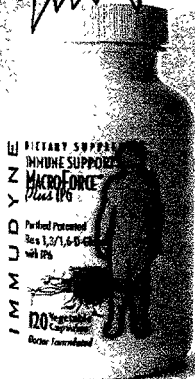
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# IMMUDYNE®

MAXIMIZE YOUR IMMUNE SYSTEM

## MACROFORCE® Beta-1,3/1,6-D-glucan

Proven  
Powerful



*MacroForce® is a powerful and patented formula that supports the body's natural defenses by stimulating macrophage cells to fight against disease and infection. MacroForce Plus IP6 is ideally suited to those with serious immune deficiencies. MacroForce Plus C is intended for those with mild immune challenges. MacroForce provides immune enhancement for adults, children, and animals. MacroForce Spray is ideal for those who cannot take capsules or for those on the go.*

*Other products by ImmuDyne include: AthroForce®, CardioShield® and ProstaForce®.*



Distributed by  
ImmuDyne Inc.  
11200 Wilcrest Green Drive  
Houston, Texas 77042  
Patent Pending



For more information:  
1-888-246-8839  
www.immudyne.com  
Made in the USA



Standardized and Guaranteed Potency

**DIETARY SUPPLEMENT**  
**ARTHROFORCE™**

**For People On The Move**

**60 Capsules**  
Doctor Formulated

**Directions:** As a dietary supplement take 1 capsule two times a day at least 30 minutes before a meal.

| SUPPLEMENT FACTS                                |         |
|---|---------|
| Serving Size 1 Capsule                          |         |
| Amount per serving                              |         |
| Collagen Type II (from young chicken's sternum) | 20 mcg* |
| Glucosamine Sulfate                             | 250 mg* |
| Chondroitin Sulfate                             | 300 mg* |
| *Daily Value not established                    |         |

Other ingredients: Magnesium stearate, Silicon dioxide, Titanium dioxide and Gelatin.  
Storage: In cool, dry place, tightly closed.  
Note: If pregnant or lactating, consult a physician before use. Keep out of reach of children.  
Important: Do not use if the tamper evident seal is broken or missing.

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Houston, Texas 77042

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ImmuDyne Inc.  
11200 Wilcrest Green Drive  
Houston, Texas 77042  
U.S. Patent No. 4,891,220 and 5,798,343



For more information:  
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Standardized and Guaranteed Potency

**DIETARY SUPPLEMENT**  
**CHOLESTEROL SUPPORT.**  
**CARDIOSHIELD™**  
with Purified Patented  
Beta-1,3/1,6-D-Glucan  
& Inositol hexanicotinate

**60 Vegetable Capsules**  
Doctor Formulated

**Directions:** As a dietary supplement, take 1 capsule two times a day after a meal.

| SUPPLEMENT FACTS   |             |
|--|-------------|
| Serving Size 1 Capsule   |             |
| Amount per serving   |             |
| Vitamin C (as ascorbic acid)   | 100 mg 167% |
| Guggulipids (from Commiphora mukul)  | 300 mg      |
| Inositol hexanicotinate  | 100 mg      |
| Beta-1,3/1,6-D-Glucan (from cell walls of yeast, Saccharomyces cerevisiae) | 10 mg       |
| *Daily Value not established   |             |

Other ingredients: Magnesium stearate, Silicon dioxide, and Modified Cellulose (Kosher Certified).  
Storage: In a cool, dry place, tightly closed.  
Note: If pregnant or lactating, consult a physician before use. Keep out of reach of children.  
Important: Do not use if the tamper evident seal under cap is broken or missing.

\*This statement has not been evaluated by the FDA. This product is not intended to diagnose, cure, treat, or prevent any disease.

**DIETARY SUPPLEMENT**  
**MACROFORCE™**

Purified  
Beta-1,3-D-Glucan

**30 Capsules**  
Doctor Formulated

**Directions:** As a dietary supplement, take 1 capsule two times a day on an empty stomach or between meals.

| SUPPLEMENT FACTS   |         |
|--|---------|
| Serving Size 1 Capsule   |         |
| Amount per serving   |         |
| Beta-1,3-D-glucan (from cell walls of yeast, Saccharomyces cerevisiae) | 2.5 mg* |
| *Daily Value not established   |         |

Other ingredients: Beta-lactone, Adipic acid, Mg, Magnesium stearate, Cellulose.  
Storage: In a cool, dry place, tightly closed.  
Note: If pregnant or lactating, consult a physician before use. Keep out of reach of children.  
Important: Do not use if the tamper evident seal under cap is broken or missing.

Distributed by  
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11200 Wilcrest Green Drive  
Houston, Texas 77042



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www.immudyne.com  
Made in the USA



Standardized and Guaranteed Potency

**DIETARY SUPPLEMENT**  
**PROSTATE SUPPORT.**  
**PROSTAFORCE™**  
with Purified  
Beta-1,3/1,6-D-Glucan  
& Lycopene

**For Men Over 40 Years of Age**

**60 Vegetable Capsules**  
Doctor Formulated

**Directions:** As a dietary supplement, take 1 capsule two times a day after a meal.

| SUPPLEMENT FACTS             |         |
|------------------------------|---------|
| Serving Size 1 Capsule       |         |
| Amount per serving           |         |
| Saw Palmetto berries extract | 150 mg* |
| Beta-1,3/1,6-D-Glucan        | 2.5 mg* |
| Nettle leaf extract          | 50 mg*  |
| Quercetin                    | 50 mg*  |
| Lycopene (from tomatoes)     | 5 mg*   |
| *Daily Value not established |         |

Other ingredients: Magnesium stearate, and Modified Cellulose (Kosher Certified).  
Storage: In a cool, dry place, tightly closed.  
Note: Keep out of reach of children.  
Important: Do not use if the tamper evident seal under cap is broken or missing.

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Distributed by  
ImmuDyne Inc.  
11200 Wilcrest Green Drive  
Houston, Texas 77042  
U.S. Patent No. 5,786,343



For more information:  
1-888-246-8839  
www.immudyne.com  
Made in the USA



Standardized and Guaranteed Potency

**DIETARY SUPPLEMENT**  
**IMMUNE SUPPORT**  
**MACROFORCE® Plus C**

Purified Patented  
Beta-1,3/1,6-D-Glucan  
7.5 mg

**90 Vegetable Capsules**  
Doctor Formulated

**Directions:** As a dietary supplement, take 1-2 capsules a day on an empty stomach or between meals.

| SUPPLEMENT FACTS   |             |
|--|-------------|
| Serving Size 1 Capsule   |             |
| Amount per Capsule   |             |
| Vitamin C (as calcium ascorbate)   | 164 mg 273% |
| Calcium (as calcium ascorbate)   | 44 mg 4%    |
| Beta-1,3/1,6-D-glucan (from cell walls of yeast, Saccharomyces cerevisiae) | 7.5 mg      |
| *Daily Value not established   |             |

Other ingredients: SiO<sub>2</sub>, Magnesium stearate, Modified Cellulose (Kosher Certified).  
Storage: In a cool, dry place, tightly closed.  
Note: If pregnant or lactating, consult a physician before use. Keep out of reach of children.  
Important: Do not use if the tamper evident seal under cap is broken or missing.

\*This statement has not been evaluated by the FDA. This product is not intended to diagnose, cure, treat, or prevent any disease.

Distributed by  
ImmuDyne Inc.  
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Houston, Texas 77042  
U.S. Patent No. 5,786,343



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www.immudyne.com  
Made in the USA



Standardized and Guaranteed Potency

**DIETARY SUPPLEMENT**  
**IMMUNE SUPPORT**  
**MACROFORCE® Plus IP6**

Purified Patented  
Beta-1,3/1,6-D-Glucan  
with IP6

**120 Vegetable Capsules**  
Doctor Formulated

**Directions:** As a dietary supplement, take 2 capsules three times a day on an empty stomach or between meals.

| SUPPLEMENT FACTS   |             |
|--|-------------|
| Serving Size 2 Capsules  |             |
| Amount per Serving   |             |
| Vitamin C (as calcium ascorbate)   | 328 mg 546% |
| Calcium (as calcium ascorbate)   | 88 mg 8%    |
| IP-6 (inositol hexaphosphate from rice)                                    | 1100 mg     |
| Beta-1,3/1,6-D-glucan (from cell walls of yeast, Saccharomyces cerevisiae) | 15 mg       |
| *Daily Value not established   |             |

Other ingredients: SiO<sub>2</sub>, Magnesium stearate, Modified Cellulose (Kosher Certified).  
Storage: In a cool, dry place, tightly closed.  
Note: If pregnant or lactating, consult a physician before use. Keep out of reach of children.

Important: Do not use if the tamper evident seal under cap is broken or missing.

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