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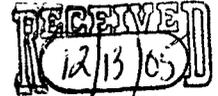
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December 12, 2005

VIA UPS NEXT DAY

Dr. Robert Moore
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: Fulfillment of Reporting Obligation
Under 21 U.S.C. § 343(r) and 21 C.F.R. § 101.93***

Dear Dr. Moore:

We hereby submit on behalf of Pure Encapsulations,¹ in accordance with 21 U.S.C. § 343(r) and 21 CFR § 101.93, an original and two copies of its notification. Pure Encapsulations retains scientific documentation supporting the statements. Please find enclosed a certification from Pure Encapsulations that the information contained in this notice is complete and accurate and that Pure Encapsulations has substantiation that the statements are truthful and not misleading.

1. Supplement Brand Name

DIM-PRO® 100

Supplement Ingredients

Diindolylmethane complex (starch, diindolylmethane, d-alpha tocopheryl succinate, phosphatidylcholine and silica) (standardized to contain 25% diindolylmethane), vitamin C (as ascorbyl palmitate), hypo-allergenic plant fiber added to complete capsule volume requirement

Text of Statements of Nutritional Support

- Concentrated support for breast, cervical and prostate health*

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¹ The address for Pure Encapsulations is 490 Boston Post Rd., Sudbury, MA 01776.

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- Animal and cell studies have found that diindolylmethane contributes to breast health in part by supporting cytochrome P450 activity as well as cell cycle function.*
- Results [of a double blind, randomized clinical trial] suggested that it promoted a healthy balance of 2-hydroxyestrone metabolites (2-OHE1) to 16 alpha-hydroxyestrone metabolites (16a-OHE1).*
- A healthy estrogen metabolite ratio has been associated with maintaining healthy breast cell function.*
- In addition, another randomized placebo-controlled crossover trial including 33 pre-menopausal women found that supplementing with BioResponse DIM® for 3 months promoted statistically significant breast comfort.*
- Furthermore, an additional double blind randomized clinical trial with 52 women found that BioResponse DIM® supported cervical cell health.*
- Animal and cell studies have also indicated that diindolylmethane enhances prostate cell health by supporting healthy gene expression and testosterone receptor function.*
- This form [specially developed for enhanced absorption] may be more supportive than I3C in cases of low gastric acidity.*
- DIM-PRO® 100 provides a highly absorbable form of diindolylmethane, a dietary indole from cruciferous vegetables that provides breast, cervical and prostate cell support, in part by supporting healthy hormone balance.*

2. Supplement Brand Name

Systemic Enzyme Complex

Supplement Ingredients

Pure pancreatin (porcine) (lactose-free) (50,000 USP units protease), protease 6.0 (60,000 HUT), bromelain (2,400 gdu/g), papain (800 TGU/mg), rutin, trypsin (porcine) (1:150) (11,250 USP units), chymotrypsin (porcine) (2,550 USP units), *Boswellia serrata* extract (gum resin) (standardized to contain 70% boswellic acids), vitamin C (as ascorbyl palmitate)

Text of Statements of Nutritional Support

- Systemic support for musculoskeletal and tissue health *

- This synergistic proteolytic enzyme formula provides systemic support for muscle, joint and overall tissue health.*
- Enzymes included in this formula have the potential to influence bradykinin formation, modulate the arachidonic cascade and prostaglandin E2 production, and provide fibrinolytic support.*
- All of these actions contribute to the potential of proteolytic enzymes to maintain healthy immune mediator activity at the cellular level and overall tissue health.*
- In addition, proteolytic enzymes have been found to support muscle comfort and recovery of contractile function, as indicated in one placebo controlled human study involving athletes.*
- Animal studies have indicated that some proteolytic enzymes may result in enhanced muscle recovery.*
- Furthermore, proteolytic enzymes support joint and cartilage comfort.*
- Rutin, a flavonol, was shown in several animal studies to promote joint health better than other flavonols and is included in this formula to complement both its musculoskeletal and tissue support potential.*
- Boswellia serrata is an Ayurvedic herb that has a long history of use for connective tissue and joint support.*
- Boswellic acids, the terpenoid constituents of boswellia, maintain healthy 5-lipoxygenase enzyme activity and healthy leukotriene metabolism.*
- In addition, boswellic acids may maintain healthy human leukocyte elastase enzyme activity, preserving the integrity of healthy connective tissue.*
- For systemic support, . . .*
- The proteolytic enzymes included in this formula support physiological homeostasis of musculoskeletal and other tissues for wide range systemic support, in part by maintaining healthy arachidonic, prostaglandin and eicosanoid production.*
- Protease 6.0 is active within a pH range of 2.75-7, providing optimal proteolytic activity.*

3. Supplement Brand Name

R-Lipoic Acid (stabilized)

Supplement Ingredients

R-lipoic acid (from 250 mg potassium-R-lipoate), vitamin C (as ascorbyl palmitate), hypo-allergenic plant fiber added to complete capsule volume requirement, cellulose, calcium, potassium carbonate

Text of Statements of Nutritional Support

- The natural R isomer of alpha-lipoic acid may provide enhanced antioxidant activity, energy production, and general metabolic function.*
- In a recent in vitro study ..., R-lipoic acid moderated oxidative stress in neurons.*
- A related study demonstrates the ability of R-lipoic acid to support memory tasks in animals by supporting mitochondrial function and protecting cells from free radicals.*
- An animal study suggested that R-lipoic acid supported healthy glucose metabolism and bile flow in the liver.*
- Additional studies suggest that R-lipoic acid offers support for glucose metabolism in skeletal muscle.*
- A ... study also indicates that R-lipoic acid may be protective against age-related oxidative stress in the liver.*
- Furthermore, a study ... established a potential role for R-lipoic acid in protecting the heart from age-related oxidative stress.*
- This potassium salt of R-lipoic acid provides a highly stable and bioavailable form of R-lipoic acid, with the potential for enhanced antioxidant protection and metabolic support.*

4. Supplement Brand Name

Boswellia AKBA

Supplement Ingredients

Boswellia serrata extract (gum resin) (standardized to contain 30% 3-acetyl-11-keto-beta-boswellic acid (AKBA)), vitamin C (as ascorbyl palmitate), hypo-allergenic plant fiber added to complete capsule volume requirement

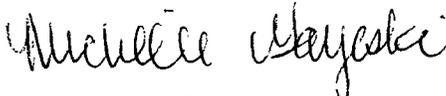
Text of Statements of Nutritional Support

- Powerful support for immune, joint, gastrointestinal and cell health.*
- Boswellic acids maintain healthy 5-lipoxygenase (5-LO) activity, moderating leukotriene biosynthesis.*
- AKBA helps preserve the structural integrity of joint cartilage, promotes gastrointestinal health and maintains a healthy immune mediator cascade at the cellular level.*
- In addition to maintaining healthy 5-LO activity, exciting new research has revealed that 5-LOXIN may influence healthy gene expression of immune compounds.*
- In studies, 5-LOXIN has demonstrated the potential to support joint motility and comfort, in part by promoting a healthy immune response.*
- It may also play a role in maintaining healthy matrix metalloproteinase (MMP) activity, supporting connective tissue structural composition.*
- Additionally, a randomized double blind study involving 102 individuals revealed that AKBA supports gastrointestinal health.*
- Further studies have indicated that AKBA may provide gastrointestinal support by maintaining healthy immune activity in the endothelial lining of the digestive tract.*
- Moreover, studies suggest AKBA supports healthy cell signaling and cell cycle function for high capacity cellular support.*
- Boswellia AKBA supports the structural integrity, motility and comfort of joint cartilage and promotes gastrointestinal health and cell health, primarily by maintaining healthy 5-lipoxygenase activity.*

In accordance with 21 USC § 343(r)(6) and 21 CFR § 101.93(c), each of the above statements will be followed by an asterisk that will be cross-referenced to another asterisk on the very same panel or page next to which the following statement will appear in a box in bold face type: **“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.”

Respectfully submitted,

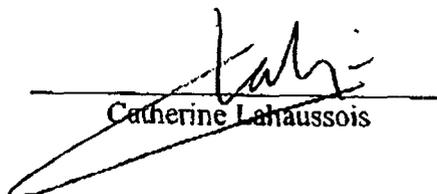
A handwritten signature in black ink that reads "Michelle Gayeski". The signature is written in a cursive style with a horizontal line above the name.

Jonathan W. Emord
Michelle C. Gayeski

Certification

I, Catherine Lahaussais, General Manager of Pure Encapsulations, Inc., hereby certify that the information contained in the foregoing notice is complete and accurate and that Pure Encapsulations has substantiation that the statements are truthful and not misleading.

Executed on: 12/12/05


Catherine Lahaussais