



SEP 24 1997

0573 '98 MAR 24 P2:44

Ms. Samia N. Rodriguez  
Hyman, Phelps & McNamara  
700 Thirteenth Street, NW  
Suite 1200  
Washington, D.C. 20005

Dear Ms. Rodriguez:

This is in response to your letter of June 4, 1997 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that Primary Services International, a raw materials supplier, is making claims for Masquelier's™ OPC, an oligomeric proanthocyanidin botanical extract. It is our understanding that Primary Services International is only making the claims contained in the letters dated June 2, 1997 that are marked as "Revised."

Masquelier's™ OPC

Masquelier's™ OPC inhibits cholesterol deposits from forming on the elastin tissue of vascular walls by stabilizing low density (LDL) cholesterol and preventing LDL oxidation.

Masquelier's™ OPC (ORTHICA label)

Masquelier's™ OPC protects the vascular wall against the potentially harmful effects of cholesterol by inhibiting cholesterol deposits from forming in the elastin tissue of vascular walls.

Masquelier's™ OPC strengthens the collagen against destructive enzymes and neutralizes free radicals, thus inhibiting LDL oxidation and plaque formation.

Section 403(r)(6) of the act 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 suggest that it is intended to prevent a disease, namely atherosclerosis, in that they prevent plaque formation and lipid deposition in blood vessels. These claims do not meet the requirements of section 403(r)(6) of the act. These claims suggest that these products are intended for use as drugs within the meaning of section 201(g)(1)(B) of the act, 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, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

LET 113

Page 2 - Ms. Samia N. Rodriguez

Please contact us if we may be of further assistance.

Sincerely yours,

James Tanner, Ph.D.  
Acting Director,  
Division of Programs and  
Enforcement Policy  
Office of Special Nutritionals  
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

cc:

HFA-224 (w/incoming)  
HFS-22 (CCO, KCarson)  
HFS-456 (r/f, Miles, Moore)  
HFS-450 (r/f)  
HFD-304 (Aronson)  
HFS-600 (Reynolds)  
r/d: C:\miles:7/1/97:C:\Miles\suppl\53206  
f/t:RMoore:8/27/97:53206.adv:disc22

LAW OFFICES

HYMAN, PHELPS & McNAMARA, P. C.

JAMES R. PHELPS  
PAUL M. HYMAN  
ROBERT A. DORMER  
STEPHEN H. McNAMARA  
ROGER C. THIES  
THOMAS SCARLETT  
JEFFREY N. GIBBS  
BRIAN J. DONATO  
FRANK J. SASINOWSKI  
DIANE B. McCOLL  
A. WES SIEGNER, JR.  
SAMIA N. RODRIGUEZ  
MARY BETH NERAAS  
GAIL P. MIDDLEKAUFF  
JUDITH E. BEACH  
JENNIFER B. DAVIS  
JOHN A. GILBERT, JR.  
F. GAIL BORMEL  
FRANCES K. WU\*  
DAVID B. CLISSOLD\*  
KATE DUFFY MAZAN\*

\*NOT ADMITTED IN DC

700 THIRTEENTH STREET, N. W.  
SUITE 1200  
WASHINGTON, D. C. 20005

TELEPHONE  
(202) 737-5600  
FACSIMILE  
(202) 737-9329  
DIRECT DIAL  
(202) 737-4290

HYMAN, PHELPS & McNAMARA  
2603 MAIN STREET  
SUITE 1066  
IRVINE, CALIFORNIA 92614  
TELEPHONE (714) 553-7400  
FACSIMILE (714) 553-7433  
ALAN M. KIRSCHENBAUM  
OF COUNSEL  
DOUGLAS B. FARQUHAR  
OF COUNSEL  
ROBERT T. ANGAROLA  
(1945-1996)

June 4, 1997



BY TELECOPIER\CONFIRMATION COPY  
WITH REVISED NOTIFICATIONS BY MAIL

Dr. Elizabeth A. Yetley  
Acting Director  
Office of Special Nutritionals  
Center for Food Safety and  
Applied Nutrition  
Food and Drug Administration  
200 C Street, HFS-450  
Washington, D.C. 20204

Re: Revisions to Notifications of Statements of Nutritional Support

Dear Dr. Yetley:

On June 2, 1997, we mailed to your office two notifications of statements of nutritional support on behalf of Primary Services International. We ask that you both disregard and discard those notifications, as revisions were necessary.

You will receive by mail the revised notifications, which will be dated as follows: "June 2, 1997 (Revised)."

Thank you for your attention to this matter. If you have any questions, please do not hesitate to contact us.

Very truly yours,

  
Samia N. Rodriguez

SNR/HMB/jhr

cc: Mr. Richard LeFebvre

53206  


LAW OFFICES  
HYMAN, PHELPS & MCNAMARA, P. C.

700 THIRTEENTH STREET, N. W.  
SUITE 1200  
WASHINGTON, D. C. 20005

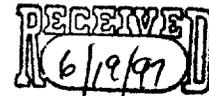
TELEPHONE  
(202) 737-5600  
FACSIMILE  
(202) 737-9329  
DIRECT DIAL  
(202) 737-4290

HYMAN, PHELPS & MCNAMARA  
2603 MAIN STREET  
SUITE 1066  
IRVINE, CALIFORNIA 92614  
TELEPHONE (714) 553-7400  
FACSIMILE (714) 553-7433  
ALAN M. KIRSCHENBAUM  
OF COUNSEL  
DOUGLAS B. FAROUHAR  
OF COUNSEL  
ROBERT T. ANGAROLA  
(1945-1996)

JAMES R. PHELPS  
PAUL M. HYMAN  
ROBERT A. DORMER  
STEPHEN H. MCNAMARA  
ROGER C. THIES  
THOMAS SCARLETT  
JEFFREY N. GIBBS  
BRIAN J. DONATO  
FRANK J. SASINOWSKI  
DIANE B. MCCOLL  
A. WES SIEGNER, JR.  
SAMIA N. RODRIGUEZ  
MARY BETH NERAAS  
GAIL P. MIDDLEKAUFF  
JUDITH E. BEACH  
JENNIFER B. DAVIS  
JOHN A. GILBERT, JR.  
F. GAIL BORMEL  
FRANCES K. WU\*  
DAVID B. CLISSOLD\*  
KATE DUFFY MAZAN\*

\*NOT ADMITTED IN DC

June 2, 1997  
(Revised)



Dr. Elizabeth A. Yetley  
Acting Director  
Office of Special Nutritionals  
Center for Food Safety and  
Applied Nutrition  
Food and Drug Administration  
200 C Street, HFS-450  
Washington, D.C. 20204

Re: 21 U.S.C. § 343(r)(6), Notification of Statements of  
Nutritional Support

Dear Dr. Yetley:

On behalf of Primary Services International (PSI), we hereby notify the Food and Drug Administration (FDA) of the use of statements of nutritional support in the labeling of Masquelier's™ OPC, an oligomeric proanthocyanidin botanical extract. PSI is a raw materials supplier of Masquelier's™ OPC to manufacturers of dietary supplements.

Statements of Nutritional Support  
in the Labeling of Masquelier's™ OPC

Masquelier's™ OPC strengthens collagen protein by affixing itself to the collagen microfibrils, or filaments, and forming hydrogen bridges which strengthen and protect tissues and organs.

The biochemical mechanism of Masquelier's™ OPC in forming hydrogen bridges promotes elasticity and resiliency of collagen, an important factor in maintaining the health of the body's connective tissues.

Masquelier's™ OPC offers protection to the body's cells from reactive molecules, known as free radicals, which can induce enzymatic cellular changes. Masquelier's™ OPC functions biochemically to stabilize cell membranes, an important factor in maintaining cellular and organ health.

Masquelier's™ OPC functions biochemically to neutralize the potentially harmful effects of reactive molecules such as hyaluronidase, collagenase, elastase and histidine decarboxylase, thereby supporting the body's natural antioxidant defense system. This is an essential process in preserving the skin's elasticity and maintaining the health of connective tissue.

Functioning as a powerful antioxidant, Masquelier's™ OPC is a potent free radical scavenger that can neutralize the naturally occurring pro-oxidative effects of cellular metabolism. Free radical scavenging of pro-oxidant molecules is an essential process in safeguarding the health and viability of the body's cells, tissues and organ systems.

The free radical scavenging activity of Masquelier's™ OPC supports the body's natural antioxidant defense system by providing important protection to cell membranes from the potentially harmful effects of alterations in cellular structure caused by free radicals, a process associated with the effects of aging.

Masquelier's™ OPC functions as an antioxidant to chelate transition metals such as iron, zinc, manganese and copper. When these metals are in ionic form, they can become dangerous pro-oxidants in the body.

Masquelier's™ OPC prevents the release of histamine by forming a barrier around cell membranes to block the entry of destructive enzymes onto the cells' lysosome, where histamine is contained. The release of histamine is known to increase capillary permeability that results in the leakage of serous fluid from cellular tissues.

As a powerful antioxidant, Masquelier's™ OPC provides nutritional support for the body's natural antioxidant defense system to insulate cells, protecting the integrity of cellular membranes and tissues from free radical induced changes that can trigger the development of inflammatory processes.

Because of its ability to strengthen vascular systems and neutralize the potentially harmful effects of free radicals, Masquelier's™ OPC provides nutritional support for the maintenance of good cardiovascular health.

Dr. Elizabeth Yetley  
June 2, 1997 (Revised)  
Page 3

HYMAN, PHELPS & MCNAMARA, P.C.

As a highly reactive antioxidant supporting the body's natural antioxidant defense system, Masquelier's™ OPC can penetrate both aqueous and lipid cellular membranes, functioning to protect LDL cholesterol from free radical attack. LDL cholesterol is essential to the maintenance of a strong and healthy heart.

Masquelier's™ OPC provides protection to vascular walls by activating the metabolism of collagen and elastin, which strengthens vascular membranes and helps the body to safeguard against cellular destruction.

Masquelier's™ OPC inhibits cholesterol deposits from forming on the elastin tissue of vascular walls by stabilizing low density (LDL) cholesterol and preventing LDL oxidation.

Masquelier's™ OPC inhibits premature aging by preventing over cross-linking of collagen proteins and polypeptides. Cross-linking increases as we grow older and may result in the hardening of tissues, producing both visible and non-visible signs of aging.

Vitamin C is essential for maintaining collagen's elasticity. As a scientifically proven co-factor of vitamin C, Masquelier's™ OPC stimulates the process of collagen biosynthesis, which enhances the recovery and production of collagen.

Masquelier's™ OPC acts to preserve vitamin C through a biochemical blocking mechanism which prevents the formation of ascorbate oxidase, an enzyme that destroys vitamin C.

\* \* \* \* \*

Please do not hesitate to contact us if you have any questions.

Very truly yours,

  
Samia N. Rodriguez

SNR/HMB/jhr

cc: Mr. Richard LeFebvre