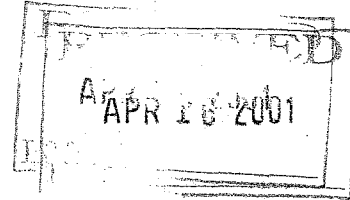




3978 '01 MAY 10 P3:26

April 11, 2001



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

SUBJECT: Submission of Label Claims

75908

Dear Sirs:


In compliance with 21 CFR 101.93, the following information is submitted:

1. Oleomed America, 3075 N.W. 107th Avenue, Miami, FL 33172, a company of Pharmed Group Corp, same address, is the exclusive distributor of Oleomed products in the United States.
2. The name of each product appears on the front label of each product container.
3. The claims made for each product appear on the front label of each product container.
4. The name and quantity of each active ingredient in a product appears on the back label of each product container.
5. The required disclaimer appears on the back label of the product container and bears the reference asterisk.

Enclosed herewith are product containers with original printed labels and copies of same.

The undersigned hereby certifies that the information contained herein is complete and accurate and that the statements made are truthful and not misleading.


Charles J. Sanchez
Director of Regulatory Affairs


MARISELA CASANOVA
COMMISSION # CC794085
EXPIRES DECEMBER 1, 2002



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LET 7594

Please visit our web site at: <http://www.pharmed.com>

3075 N.W. 107th Avenue (PHARMED WAY) • Miami, Florida 33172-2134 • Telephone: (305) 592-2324 • Fax: (305) 591-5938

03 805 076
0.2



OleoMed Mediterranean Formulas

are unique combinations of Pharmaceutical-Grade Olive Oil with vitamins, minerals, herbs and/or other nutrients, scientifically designed to provide natural nutrition solutions to help you support specific health needs. *

Pharmaceutical-Grade Olive Oil

goes beyond its health benefits as a highly effective natural active-ingredient. It is also a highly effective delivery-system for vitamins, minerals, herbal and dietary supplements to be efficiently used by the human body. *

OleoMed

bridges the health benefits of Pharmaceutical-Grade Olive Oil and the health benefits of dietary supplements to help you **Naturally Stay Healthy and Feel Better.** *

03/03

DIETARY SUPPLEMENT
60 Softgels



OleoMedTM

The Healthy Link to the Mediterranean

Mediterranean Formulas



FOR A HEALTHY CIRCULATORY AND
CARDIOVASCULAR SYSTEM.*
NATURALLY PROMOTES THE HEALTH
AND ELASTICITY OF BLOOD VESSELS.*

Lot No: N 2 Expiration Date: 11-2003



05-805-1685
0.2



OleoMed Mediterranean Formulas

are unique combinations of Pharmaceutical-Grade Olive Oil with vitamins, minerals, herbs and/or other nutrients, scientifically designed to provide natural nutrition solutions to help you support specific health needs. *

Pharmaceutical-Grade Olive Oil

goes beyond its health benefits as a highly effective natural active-ingredient. It is also a highly effective delivery-system for vitamins, minerals, herbal and dietary supplements to be efficiently used by the human body. *

OleoMed

bridges the health benefits of Pharmaceutical-Grade Olive Oil and the health benefits of dietary supplements to help you **Naturally Stay Healthy and Feel Better.** *

03/18

DIETARY SUPPLEMENT
60 Softgels



OleoMed™

The Healthy Link to the Mediterranean

Mediterranean Formulas



PROMOTES A HEALTHY CARDIOVASCULAR
SYSTEM AND SUPPORTS BRAIN AND
CENTRAL NERVOUS SYSTEM.*

Lot No: N 1 Expiration Date: 12-2003



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0.2

DIETARY SUPPLEMENT
60 Softgels

**OleoMed
Pharmaceutical-Grade
Olive Oil**
has a high content of
monounsaturated fatty acids
(friendly fat) and
antioxidants, natural
nutrients that play an
important role in general
wellness.

**OleoMed
Pharmaceutical-Grade
Olive Oil**
is scientifically tested and
meets the standards set by
the European and Royal
Spanish Pharmacopeias,
assuring you the highest-
grade olive oil available in
the world.

OleoMed
bridges the health benefits
of Pharmaceutical-Grade
Olive Oil and the health
benefits of dietary
supplements to help you
**Naturally Stay Healthy and
Feel Better. ***


OleoMedTM

The Healthy Link to the Mediterranean

**Pharmaceutical - Grade
Olive Oil**

**FOR A HEALTHY CARDIOVASCULAR
AND GASTROINTESTINAL SYSTEM.*
PROTECTS CELLS FROM FREE
RADICAL DAMAGE.*
PROMOTES GENERAL WELL-BEING.***

E/O/B

Lot No: N 6 Expiration Date: 10-2003



05 805 1883
02



DIETARY SUPPLEMENT
60 Softgels

OleoMed Mediterranean Formulas
are unique combinations of Pharmaceutical-Grade Olive Oil with vitamins, minerals, herbals and/or other nutrients, scientifically designed to provide natural nutrition solutions to help you support specific health needs. *

Pharmaceutical-Grade Olive Oil
goes beyond its health benefits as a highly effective natural active-ingredient. It is also a highly effective delivery-system for vitamins, minerals, herbal and dietary supplements to be efficiently used by the human body. *

OleoMed
bridges the health benefits of Pharmaceutical-Grade Olive Oil and the health benefits of dietary supplements to help you **Naturally Stay Healthy and Feel Better.** *

O/E/B



The Healthy Link to the Mediterranean

Mediterranean Formulas



**PROMOTES IMMUNE SYSTEM HEALTH
AND SUPPORTS A HEALTHY
CARDIOVASCULAR SYSTEM***

Lot No: N 1 Expiration Date: 12-2003





OleoMed Mediterranean Formulas are unique combinations of Pharmaceutical-Grade Olive Oil with vitamins, minerals, herbs and/or other nutrients, scientifically designed to provide natural nutrition solutions to help you support specific health needs. *

Pharmaceutical-Grade Olive Oil goes beyond its health benefits as a highly effective natural active-ingredient. It is also a highly effective delivery-system for vitamins, minerals, herbal and dietary supplements to be efficiently used by the human body. *

OleoMed bridges the health benefits of Pharmaceutical-Grade Olive Oil and the health benefits of dietary supplements to help you **Naturally Stay Healthy and Feel Better.** *

PO/B

DIETARY SUPPLEMENT
60 Softgels



The Healthy Link to the Mediterranean

Mediterranean Formulas



PROMOTES HEALTHY HORMONAL
BALANCE, JOINTS AND SKIN.
SUPPORTS A HEALTHY
CARDIOVASCULAR SYSTEM.*

Lot No: N 1 Expiration Date: 11-2003



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0.2



DIETARY SUPPLEMENT
60 Softgels



OleoMed™

The Healthy Link to the Mediterranean

Mediterranean Formulas



PROMOTES MENTAL ALERTNESS, OVERALL
BRAIN FUNCTION AND SUPPORTS A
HEALTHY CARDIOVASCULAR SYSTEM*

OleoMed Mediterranean Formulas

are unique combinations of Pharmaceutical-Grade Olive Oil with vitamins, minerals, herbs and/or other nutrients, scientifically designed to provide natural nutrition solutions to help you support specific health needs. *

Pharmaceutical-Grade Olive Oil

goes beyond its health benefits as a highly effective natural active-ingredient. It is also a highly effective delivery-system for vitamins, minerals, herbal and dietary supplements to be efficiently used by the human body. *

OleoMed

bridges the health benefits of Pharmaceutical-Grade Olive Oil and the health benefits of dietary supplements to help you **Naturally Stay Healthy and Feel Better.** *

9/8/8

Lot No: N ! Expiration Date: 11-2003



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DIETARY SUPPLEMENT
60 Softgels

OleoMed Mediterranean Formulas
are unique combinations of Pharmaceutical-Grade Olive Oil with vitamins, minerals, herbals and/or other nutrients, scientifically designed to provide natural nutrition solutions to help you support specific health needs. *

Pharmaceutical-Grade Olive Oil
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OleoMed
bridges the health benefits of Pharmaceutical-Grade Olive Oil and the health benefits of dietary supplements to help you **Naturally Stay Healthy and Feel Better.** *



The Healthy Link to the Mediterranean

Mediterranean Formulas



**PROMOTES A HEALTHY BONE SYSTEM
AND SUPPORTS A HEALTHY
CARDIOVASCULAR SYSTEM***

Lot No: **N 1** Expiration Date: **11-2003**



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OleoMed Mediterranean Formulas

are unique combinations of Pharmaceutical-Grade Olive Oil with vitamins, minerals, herbs and/or other nutrients, scientifically designed to provide natural nutrition solutions to help you support specific health needs. *

Pharmaceutical-Grade Olive Oil

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OleoMed

bridges the health benefits of Pharmaceutical-Grade Olive Oil and the health benefits of dietary supplements to help you **Naturally Stay Healthy and Feel Better.** *

SZ/B

DIETARY SUPPLEMENT
60 Softgels


OleoMedTM

The Healthy Link to the Mediterranean

Mediterranean Formulas



HELPS PROTECT CELL FROM FREE RADICAL
DAMAGE AND SUPPORTS A HEALTHY
CARDIOVASCULAR SYSTEM*

Lot No: N 1 Expiration Date: 11-2003





05 8905 1980
02



OleoMed Mediterranean Formulas

are unique combinations of Pharmaceutical-Grade Olive Oil with vitamins, minerals, herbals and/or other nutrients, scientifically designed to provide natural nutrition solutions to help you support specific health needs. *

Pharmaceutical-Grade Olive Oil

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OleoMed

bridges the health benefits of Pharmaceutical-Grade Olive Oil and the health benefits of dietary supplements to help you **Naturally Stay Healthy and Feel Better.** *

S/P/B

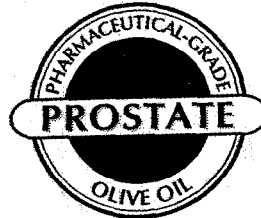
DIETARY SUPPLEMENT
60 Softgels



OleoMed™

The Healthy Link to the Mediterranean

Mediterranean Formulas



PROMOTES A HEALTHY PROSTATE
FUNCTION AND SUPPORTS A HEALTHY
CARDIOVASCULAR SYSTEM*

Lot No: N 1 Expiration Date: 11-2003



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0.2



OleoMed Mediterranean Formulas

are unique combinations of Pharmaceutical-Grade Olive Oil with vitamins, minerals, herbs and/or other nutrients, scientifically designed to provide natural nutrition solutions to help you support specific health needs. *

Pharmaceutical-Grade Olive Oil

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OleoMed

bridges the health benefits of Pharmaceutical-Grade Olive Oil and the health benefits of dietary supplements to help you **Naturally Stay Healthy and Feel Better.** *

SM/B

DIETARY SUPPLEMENT
60 Softgels



OleoMed™

The Healthy Link to the Mediterranean

Mediterranean Formulas



*PROMOTES GENERAL WELL BEING
AND POSITIVE MOOD BALANCE.
SUPPORTS A HEALTHY
CARDIOVASCULAR SYSTEM.**

Lot No: **N 1** Expiration Date: 12-2003



05-0005-1684
02



OleoMed Mediterranean Formulas

are unique combinations of Pharmaceutical-Grade Olive Oil with vitamins, minerals, herbs and/or other nutrients, scientifically designed to provide natural nutrition solutions to help you support specific health needs. *

Pharmaceutical-Grade Olive Oil

goes beyond its health benefits as a highly effective natural active-ingredient. It is also a highly effective delivery-system for vitamins, minerals, herbal and dietary supplements to be efficiently used by the human body. *

OleoMed

bridges the health benefits of Pharmaceutical-Grade Olive Oil and the health benefits of dietary supplements to help you **Naturally Stay Healthy and Feel Better.** *

KG/B

DIETARY SUPPLEMENT
60 Softgels



The Healthy Link to the Mediterranean

Mediterranean Formulas



PROMOTES ENERGY LEVELS
AND SUPPORTS A HEALTHY
CARDIOVASCULAR SYSTEM*

Lot No: N 1 Expiration Date: 11-2003



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