



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

0017 7 OCT -2 P12:42

Food and Drug Administration
College Park, MD 20740

SEP 26 2007

Mr. Paul Bolar
Pharmavite LLC
PO Box 9606
Mission Hills, California 91346-9606

Dear Mr. Bolar:

This is in response to your letters of September 12, 2007 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 Pharmavite LLC is making the following claims, among others, for the following products:

Rx Essentials/Generic products containing Vitamin C, Vitamin D and Folic Acid

"Provides essential nutrients for people taking arthritis medication."

"[N]ature Made science experts have identified essential nutrients helpful when taking certain arthritis prescription medications."

"Studies show that people taking Anti-inflammatory medications to treat arthritis may benefit from taking vitamin C which is essential in maintaining health cartilage and joints."

"Some experts recommend that people taking anti-inflammatories such as NSAIDs and medications containing aspirin take additional folic acid.."

Rx Essentials/Generic products containing Vitamin D, B6, Folic Acid, Vitamin B12, and Calcium.

"Provides essential nutrients for people taking heartburn & acid reflux medication."

"[N]ature Made science experts have identified essential nutrients helpful when taking certain heartburn and acid reflux prescription medications."

Rx Essentials/Generic products containing Vitamin B6, Folic Acid, Vitamin B12, and Coenzyme Q-10.

"Provides essential nutrients for people taking cholesterol medication."

"[N]ature Made science experts have identified essential nutrients helpful when taking certain cholesterol prescription medications."

Rx Essentials/Generic products containing Vitamin B6, Folic Acid, and Vitamin B12.

"Provides essential nutrients for people taking diabetes medication."

"[N]ature Made science experts have identified essential nutrients helpful when taking certain diabetes prescription medications."

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Rx Essentials/Generic products containing Vitamin B6, Folic Acid, and Vitamin B12.

“Provides essential nutrients for people taking antidepressant medication.”

“[N]ature Made science experts have identified essential nutrients helpful when taking certain antidepressant prescription medications.”

“Studies show that people suffering from depression may have lower blood levels of B6, B12, Folic Acid and Vitamin D which are essential in maintaining emotional well being.”

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 these products suggest that they are intended to treat, prevent, or mitigate diseases. Taken together, the claims appear to go beyond merely representing the products to meet specific nutrient needs that may exist as a consequence of a disease or disease therapy. Rather, they appear to represent the products to treat an existing disease or to augment a therapy for a disease. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If your client intends to make claims of this nature, they 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.

Please contact us if we may be of further assistance.

Sincerely yours,



Vasilios H. Frankos, Ph.D.
Director
Division of Dietary Supplement Programs
Office of Nutrition, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Los Angeles District Office, Office of Compliance, HFR-PA240



September 12, 2007

Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

Pharmavite Reference: 1147P30AC

Dear Sir or Madam:

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act and Section 101.93 of FDA's regulations, we hereby notify you that we are using the following statement(s):

- (1) Name and address of manufacturer:
Pharmavite LLC, PO Box 9606, Mission Hills, CA 91346
- (2) Text of the statement(s):
Provides essential nutrients for people taking arthritis medication

Through extensive research, Nature Made science experts have identified essential nutrients helpful when taking certain arthritis prescription medications.

Vitamin C

Studies show that people taking Anti-inflammatory medications to treat arthritis may benefit from taking Vitamin C which is essential in maintaining healthy cartilage and joints.

Folic Acid

Some experts recommend that people taking anti-inflammatories such as NSAIDs and medications containing aspirin take additional folic acid.

Vitamin D

People with osteoarthritis may have lower blood levels of vitamin D. Vitamin D helps the body absorb and maintain adequate levels of calcium.



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If you take prescriptions, take Rx Essentials
People taking prescription medications may be more likely to have reduced levels of certain nutrients-low nutrient levels may lead to problems down the road. That's why Nature Made examined numerous clinical studies to create the Rx Essentials line of products formulated to provide essential nutrients when taking prescription medications.

Rx Essentials replenishes and supplies key nutrients that may be at reduced levels when taking prescriptions.

- (3) Name of the dietary ingredient(s):
Vitamin C
Vitamin D
Folic Acid
- (4) Name of the dietary supplement(s):
Rx Essentials or products containing the above ingredients as a single ingredient or in combination with other ingredients

The above statement(s) may be used in one or more of the following brands of products: B.J.'s Wholesale, Kirkland Signature, Nature Made, Nature's Resource, Nutri Plus, Olay, Spring Valley, TruNature, Walgreens.

We certify the information in this notice is complete and accurate, and we have substantiation that the above statement(s) is truthful and not misleading.

Sincerely,

Paul Bolar
Vice President
Regulatory Affairs



PHARMAVITE

September 12, 2007

Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740



Pharmavite Reference: 1145P30AC

Dear Sir or Madam:

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act and Section 101.93 of FDA's regulations, we hereby notify you that we are using the following statement(s):

- (1) Name and address of manufacturer:
Pharmavite LLC, PO Box 9606, Mission Hills, CA 91346
- (2) Text of the statement(s):
Provides essential nutrients for people taking antidepressant medication

Through extensive research, Nature Made science experts have identified essential nutrients helpful when taking certain antidepressant prescription medications.

Folic Acid, Vitamins B and D

Studies show that people suffering from depression may have lower blood levels of B6, B12, Folic Acid and Vitamin D which are essential in maintaining emotional well being.

If you take prescriptions, take Rx Essentials

People taking prescription medications may be more likely to have reduced levels of certain nutrients-low nutrient levels may lead to problems down the road.

That's why Nature Made examined numerous clinical studies to create the Rx Essentials line of products formulated to provide essential nutrients when taking prescription medications.

Some scientific studies suggest that lower levels of these nutrients may lead to low energy, low mood and muscle discomfort.

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Rx Essentials replenishes and supplies key nutrients that may be at reduced levels when taking prescriptions.

- (3) Name of the dietary ingredient(s):
Vitamin D
Vitamin B6
Folic Acid
Vitamin B12
- (4) Name of the dietary supplement(s):
Rx Essentials or products containing the above ingredients as a single ingredient or in combination with other ingredients

The above statement(s) may be used in one or more of the following brands of products: B.J.'s Wholesale, Kirkland Signature, Nature Made, Nature's Resource, Nutri Plus, Olay, Spring Valley, TruNature, Walgreens.

We certify the information in this notice is complete and accurate, and we have substantiation that the above statement(s) is truthful and not misleading.

Sincerely,

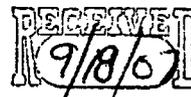
Paul Bolar
Vice President
Regulatory Affairs



PHARMAVITE

September 12, 2007

Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740



Pharmavite Reference: 1143P30AB

Dear Sir or Madam:

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act and Section 101.93 of FDA's regulations, we hereby notify you that we are using the following statement(s):

- (1) Name and address of manufacturer:
Pharmavite LLC, PO Box 9606, Mission Hills, CA 91346
- (2) Text of the statement(s):
Provides essential nutrients for people taking cholesterol medication

Through extensive research, Nature Made science experts have identified essential nutrients helpful when taking certain cholesterol prescription medications.

CoQ10

Studies have shown that people taking Statin cholesterol medications may have lower blood levels of CoQ10, an essential antioxidant clinically shown to support normal heart function.

B Vitamins and Folic Acid

Elevated homocysteine levels may affect heart health. Vitamin B6, B12 and Folic Acid may reduce homocysteine levels which is important in maintaining a healthy heart.

If you take prescriptions, take Rx Essentials

People taking prescription medications may be more likely to have reduced levels of certain nutrients-low nutrient levels may lead to problems down the road. That's why Nature Made examined numerous clinical studies to create the Rx Essentials line of products formulated to provide essential nutrients when taking

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prescription medications.

Some scientific studies suggest that low levels of CoQ10 over time may lead to body aches and low energy.

Rx Essentials replenishes and supplies key nutrients that may be at reduced levels when taking prescriptions.

- (3) Name of the dietary ingredient(s):
Vitamin B6
Folic Acid
Vitamin B12
Coenzyme Q-10
- (4) Name of the dietary supplement(s):
Rx Essentials or products containing the above ingredients as a single ingredient or in combination with other ingredients

The above statement(s) may be used in one or more of the following brands of products: B.J.'s Wholesale, Kirkland Signature, Nature Made, Nature's Resource, Nutri Plus, Olay, Spring Valley, TruNature, Walgreens.

We certify the information in this notice is complete and accurate, and we have substantiation that the above statement(s) is truthful and not misleading.

Sincerely,

Paul Bolar
Vice President
Regulatory Affairs



PHARMAVITE

September 12, 2007

Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740



Pharmavite Reference: 1144P30AB

Dear Sir or Madam:

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act and Section 101.93 of FDA's regulations, we hereby notify you that we are using the following statement(s):

- (1) Name and address of manufacturer:
Pharmavite LLC, PO Box 9606, Mission Hills, CA 91346
- (2) Text of the statement(s):
Provides essential nutrients for people taking heartburn & acid reflux medication

Through extensive research, Nature Made science experts have identified essential nutrients helpful when taking certain heartburn and acid reflux prescription medications.

B Vitamins and Folic Acid

Studies show that people taking Heartburn or Acid Reflux medications over time may have decreased absorption of vitamin B12. Vitamin B6, B12 and Folic Acid may reduce homocysteine levels which may help in maintaining bone health.

Calcium and Vitamin D

Studies also show that taking Acid Reflux or Heartburn medications overtime may lead to decreased absorption of calcium which along with vitamin D is critical for the formation and maintenance of strong bones.

If you take prescriptions, take Rx Essentials

People taking prescription medications may be more likely to have reduced levels of certain nutrients-low nutrient levels may lead to problems down the road. That's why Nature Made examined numerous clinical studies to create the Rx

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Essentials line of products formulated to provide essential nutrients when taking prescription medications.

Some scientific studies suggest that low levels of these nutrients over time may affect bone health and lead to low energy.

Rx Essentials replenishes and supplies key nutrients that may be at reduced levels when taking prescriptions.

(3) Name of the dietary ingredient(s):

Vitamin D
Vitamin B6
Folic Acid
Vitamin B12
Calcium

(4) Name of the dietary supplement(s):

Rx Essentials or products containing the above ingredients as a single ingredient or in combination with other ingredients

The above statement(s) may be used in one or more of the following brands of products: B.J.'s Wholesale, Kirkland Signature, Nature Made, Nature's Resource, Nutri Plus, Olay, Spring Valley, TruNature, Walgreens.

We certify the information in this notice is complete and accurate, and we have substantiation that the above statement(s) is truthful and not misleading.

Sincerely,

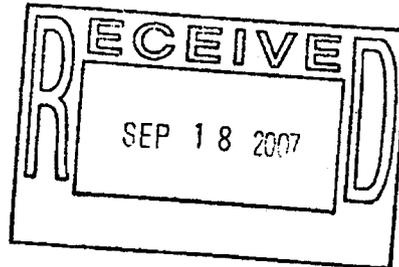
Paul Bolar
Vice President
Regulatory Affairs



PHARMAVITE

September 12, 2007

Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740



Pharmavite Reference: 1148P30AC

Dear Sir or Madam:

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act and Section 101.93 of FDA's regulations, we hereby notify you that we are using the following statement(s):

- (1) Name and address of manufacturer:
Pharmavite LLC, PO Box 9606, Mission Hills, CA 91346
- (2) Text of the statement(s):
Provides essential nutrients for people taking diabetes medication

Through extensive research, Nature Made science experts have identified essential nutrients helpful when taking certain diabetes prescription medications.

B Vitamins and Folic Acid

Studies show that people who take Diabetes medications containing metformin may have lower levels of vitamin B12 and Folic Acid. Vitamin B6, B12 and Folic Acid may reduce homocysteine levels, which is important in maintaining a healthy heart.

If you take prescriptions, take Rx Essentials

People taking prescription medications may be more likely to have reduced levels of certain nutrients-low nutrient levels may lead to problems down the road. That's why Nature Made examined numerous clinical studies to create the Rx Essentials line of products formulated to provide essential nutrients when taking prescription medications.

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Rx Essentials replenishes and supplies key nutrients that may be at reduced levels when taking prescriptions.

- (3) Name of the dietary ingredient(s):
Vitamin B6
Folic Acid
Vitamin B12
- (4) Name of the dietary supplement(s):
Rx Essentials or products containing the above ingredients as a single ingredient or in combination with other ingredients

The above statement(s) may be used in one or more of the following brands of products: B.J.'s Wholesale, Kirkland Signature, Nature Made, Nature's Resource, Nutri Plus, Olay, Spring Valley, TruNature, Walgreens.

We certify the information in this notice is complete and accurate, and we have substantiation that the above statement(s) is truthful and not misleading.

Sincerely,

Paul Bolar
Vice President
Regulatory Affairs