



3279 5 AUG 18 P2:22

July 8, 2005

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

AUG - 4

Pharmavite Reference: 1061P30 AB

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):  
For Cardiovascular Health  
Inflammation Defense™ also contains powerful antioxidants Vitamin D and Grape Seed Extract, to help support your body's immune system by reducing oxidative stress. Oxidative stress from free radicals and other environmental factors such as pollution causes the body to respond by increasing inflammation. Antioxidants reduce the oxidative response to allow the body to maintain a normal level of inflammatory balance.

Selenium, an essential trace mineral, activates the body's natural antioxidant system to naturally fight oxidative stress and increased inflammation.

Vitamin D – Emerging science now shows the critical role Vitamin D plays in immune health and normal inflammatory response.

According to emerging science, chronic, excessive levels of arterial inflammation may be at the center of challenges to cardiovascular health. Inflammation Defense which helps the body maintain a normal inflammatory balance. This combination product features ingredients that may provide a synergistic solution for consumers.

This powerful new product offers a safe, natural approach to heart and artery health.

97S 0162

LET

16513

Pharmavite LLC • P.O. Box 9606 • Mission Hills, CA 91346-9606 • 818/221-6200 • 800/423-2405  
Deliveries Only: 8510 Balboa Blvd., Northridge, CA 91325

05-4868



Re: 1061P30AB  
July 8, 2005  
Page 2

- (3) Name of the dietary ingredient (s):  
Fish oil  
Vitamin D  
Selenium  
Grape seed extract
- (4) Name of the dietary supplement(s):  
Inflammation Defense or products containing fish oil 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, Target, TruNature, Walgreens.

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

Sincerely,

David Kropp  
Director, Regulatory Affairs

cc. P. Bolar