



PHARMAVITE

April 29, 2005

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OPS: 9/15/14

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

MAY - 5 2005

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):  
Pantesin® works by reducing the body's production of cholesterol and triglycerides in the liver.
- (3) Name of the dietary ingredient(s):  
Pantethine (also known as Pantesin®)
- (4) Name of the dietary supplement(s):  
Pantethine 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.

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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,

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David Kropp  
Director, Regulatory Affairs

cc. P. Bolar