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BY: \_\_\_\_\_

February 13, 2002

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

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 Corporation, PO Box 9606, Mission Hills, CA 91346
- (2) Text of the statement(s):

Don't Let Your Joints Hold You Captive...

Set your body free with TripleFlex

Comfort Flexibility Mobility  
GLUCOSAMINE CHONDROITIN PLUS MSM

Experience TripleFlexibility  
Nature Made® TripleFlex  
Triple Action For Your Joints!

Improve the health of your sore, stiff joints with the triple-action power of TripleFlex. TripleFlex is specially formulated with the key nutrients your joints need to promote flexibility, joint comfort and an active, independent lifestyle.

What's in TripleFlex? Maximum Strength TripleFlex contains glucosamine, chondroitin, and methylsulfonylmethane (MSM), nutrients that have been clinically shown to restore cartilage and improve mobility.

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## The Importance of Joint Health

Everyone wants to keep their bodies flexible, mobile and pain-free for as much of their life as possible. With TripleFlex, you can help your body do that.

How? Throughout life our bodies rebuild and regenerate cartilage. But aging and joint stress lead to joint cartilage deterioration. As we age, our bodies produce less glucosamine and chondroitin, two key components that maintain joint cartilage. In addition, joint stress caused by repetitive motion, overexertion, obesity and athletic activity can add to joint discomfort and immobility. That's where TripleFlex comes in. TripleFlex replenishes these key nutrients and helps nourish and rebuild your cartilage, promoting joint health.

Who can benefit from TripleFlex?

TripleFlex benefits individuals of all ages seeking to maintain an active lifestyle.

Those with occasional joint stiffness and soreness

The weekend warrior or sport enthusiast

Persons whose activities include repetitive motions

Mature adults seeking to delay cartilage breakdown that can occur with age

## The Power of Three

Here's a closer look at the three TripleFlex ingredients that work together to actively support joint health and mobility by rebuilding and maintaining cartilage.

Glucosamine, a form of amino sugar, is produced naturally in the body and found mainly in cartilage. Glucosamine declines with age, leading to thinning of cartilage. Supplementing your diet with glucosamine stimulates the formation of cartilage thereby increasing joint comfort and flexibility.

Chondroitin, is a natural substance found in the body. Chondroitin inhibits the enzymes that breakdown cartilage by creating a water-filled, shock-absorbing space within the tissue. This helps relieve joint stress and contributes to its resilience.

Methylsulfonylmethane (MSM) is a naturally-occurring sulfur compound found in all living organisms. MSM is necessary for the body's synthesis of collagen and softening of connective tissue. MSM contains supportive properties and, when combined with Glucosamine, enhances relief from joint discomfort. MSM is present in the body in small amounts



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You can also find it in fresh foods such as meat, fish, fruits, vegetables and grains. But, when foods are processed, MSM is destroyed. This is why we need a dietary supplement like TripleFlex.

TripleFlex™, for all your joints... hands, wrists, knees, back, neck, hips, ankles, and feet!

#### Backed By Clinical Support

According to a recent Journal of the American Medical Association (JAMA) report, trials of glucosamine and chondroitin were demonstrated to provide moderate to large effects for improving joint health function.

A recent, double-blind, placebo-controlled study published in the Lancet, a well-respected British medical journal, reported that long term use of glucosamine can help maintain joint structure and promote healthy joints.

A study conducted by the Oregon Health Sciences University compared the effectiveness of MSM with a popular alternative product. The study found that both products effectively reduced joint discomfort and immobility.

- (3) Name of the dietary ingredient(s) if not provided in the text of the statement:  
Glucosamine (from glucosamine hydrochloride)  
Chondroitin (from sodium chondroitin sulfate)  
Methylsulfonylmethane
  
- (4) Name of the dietary supplement:  
TripleFlex  
Glucosamine  
Chondroitin  
plus MSM

The above statement(s) may be used in one or more of the following brands of products: AAFES, B.J.'s Wholesale, CVS, Duane Reade, Kirkland Signature, Jogmate, Nature Made, Nature's Resource, Optimize, Spring Valley, 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,

David Kropp  
Acting Director, Regulatory and Consumer Affairs