

50740

February 11, 1997

Elizabeth A. Yetley, Ph.D., Acting Director  
Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street, S.W.  
Washington, D.C. 20204

0021 '97 SEP 19 P1:28

Re: Nutramax Laboratories, Inc.  
First Amended Notification of Use of a Statement of  
Nutritional Support

Dear Dr. Yetley:

By letter, dated January 21, 1997, Nutramax Laboratories, Inc. ("Nutramax") provided you with notice pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994 codified at 21 USC § 343(r)(6) that it is making a statement of nutritional support for its dietary supplement marketed under the brand name Cosamin®, ("Notice"). A copy of the Notice is enclosed for your convenience.

Nutramax wishes to amend the Notice to correct two (2) minor stylistic oversights and by moving the reference to hyaluronic acid from the discussion of Chondroitin Sulfate to the statement of mechanics in relation to Glucosamine HCL. This move is being made to more accurately reflect current scientific research.

The amendments to the Notice all appear in Section 2. Cosamin® composition and statement of mechanics by which ingredients act to maintain bodily function and are highlighted below for your convenience:

Cosamin® is a patented combination of dietary ingredients of unparalleled purity and each has its own primary function in connective tissues synthesis. Studies reported the following chondrometabolic effects:

Glucosamine HCL - In addition to being the main substrate for the biosynthesis of glycosaminoglycans and hyaluronic acid, the primary function of glucosamine is to stimulate the secretion of glycosaminoglycans in the articular cartilage. It was also found to provide natural protection against the cartilage-damaging effects of some NSAIDs.

certified Mail

975-0162

LET 534

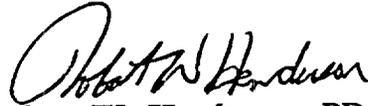
Elizabeth A. Yetley, Ph.D., Acting Director  
Office of Special Nutritionals (HFS-450)  
February 11, 1997  
Page 2

**Chondroitin Sulfate** - In addition to being the major glycosaminoglycans found in cartilage, its primary function is to inhibit degradative enzymes. **Degradative enzymes contribute to cartilage breakdown.**

**Manganese** - In addition to being a necessary cofactor in the body for the biosynthesis of glycosaminoglycans, it was found to have a superoxide dismutase-like activity and to work as a cofactor for mitochondrial superoxide dismutase **in the body.**

If you have any questions regarding this amendment, please contact us. Two (2) copies of the amendment are enclosed.

Sincerely,



Robert W. Henderson, PD  
President

cc: Dr. Robert J. Moore  
Senior Regulatory Scientist