

The Nutraceutical Company

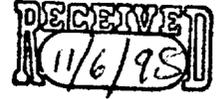
nutramax
LABORATORIES, INC.

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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

November 2, 1998



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

Re: Nutramax Laboratories, Inc.
*Second Amended Notification of Use
of Statement of Nutritional Support*

Dear Dr. Yetley:

This letter is being submitted pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994 codified at 21 U.S.C. §343(r)(6) by Nutramax Laboratories, Inc., located in Baltimore, Maryland. Nutramax Laboratories previously notified the Food and Drug Administration that it was making statements of nutritional support for its dietary supplement marketed under the brand name Cosamin[®]. This prior notification was filed on January 21, 1997, and an amended notification was filed on February 11, 1997.

Since the original notification and amendment were filed, Nutramax Laboratories has made some revisions to the wording of the Cosamin[®] labeling. Although the new wording is probably covered by the original notification and amendment, consistent with Nutramax Laboratories' commitment to assure full compliance with FDA laws and regulations, we are filing this second amendment notification with the revised text of these statements.

Cosamin[®] is sold as a broad-spectrum cartilage matrix/glycosaminoglycan enhancer. It is a patented combination of glucosamine HC, sodium chondroitin sulfate, and manganese ascorbate.

As required by 21 CFR §101.93, Nutramax Laboratories submits the following information:

TRH cc:C:\YETLEY.LTR-103098

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Elizabeth A. Yetley, Ph.D.
Director, Office of Special Nutritionals (HFS-450)
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1. The text of the statements that are being made are as follows:

"Enjoy freedom of movement and flexibility again."

"Cosamin[®] DS is the only oral cartilage modifying agent used in controlled studies."

"These compounds are not only structural building blocks of joint tissue, but also have a recognizable, reproducible effect on the metabolism of joint tissues."

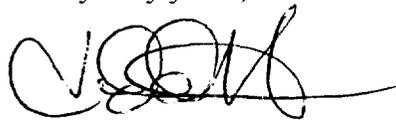
"Cosamin[®] DS can help by providing your body with the building blocks it needs to replenish and renew joint cartilage."

2. The dietary ingredients that are the subject of the statements are glucosamine HC and sodium chondroitin sulfate.
3. The statements appear on the labeling of the dietary supplement marketed under the brand name Cosamin[®].

I hereby certify that the information contained in this notice is complete and accurate, and that Nutramax Laboratories has substantiation that the statements in this notice are truthful and not misleading.

If you have any questions regarding this notification, please contact us.

Very truly yours,



Todd R. Henderson, D.V.M.
Vice President