



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

DEC 28 1999

1624 '00 JAN -4 P2 04

Mr. Robert W. Henderson
President
Nutramax Laboratories, Inc.
2208 Lakeside Boulevard
Edgewood, Maryland 21040

Dear Mr. Henderson:

This is in response to your letter of December 14, 1999 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Nutramax Laboratories, Inc. is making the following statement, among others, for the product "Cosamin:"

"Scientifically proven to reduce joint discomfort"

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The claims that you are making for this product suggest that it is intended to treat, prevent, or mitigate disease, in that it is intended to treat, prevent, or mitigate joint disorders. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

975-0163

LET 319

Page 2 - Mr. Robert W. Henderson

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Baltimore District Office, Compliance Branch, HFR-MA240

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (r/f, file)

HFS-450 (r/f, file)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-605

HFV-229 (Benz)

GCF-1 (Barnett, Nickerson, Dorsey)

f/t:rjm:HFS-456:12/27/99:68495.adv:disc43



68495

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

December 14, 1999



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.
*Third 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 amended notifications were filed on February 11, 1997 and November 2, 1998.

Since the original notification and amendments 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 third 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 HCl, sodium chondroitin sulfate, and manganese ascorbate.

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

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Elizabeth A. Yetley, Ph.D.
Director, Office of Special Nutritionals (HFS-450)
December 14, 1999
Page 2

1. The text of the statements that are being made are as follows:

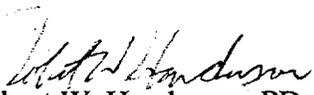
"Scientifically proven to reduce joint discomfort."

2. The dietary ingredients that are the subject of the statements are the combination of glucosamine HCl, sodium chondroitin sulfate and manganese ascorbate.
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,


Robert W. Henderson, PD
President