



**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

February 28, 2001

74889

MAR - 5 2001

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.
30-Day Notice under 403(r)(6) of DSHEA

Dear Madam/Sir:

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 Edgewood, Maryland.

As required by 21 CFR §101.93(a)(2) Nutramax Laboratories submits the following information:

- (i) The name and address of the manufacturer of the dietary supplement that bears the statements:

Nutramax Laboratories, Inc.
2208 Lakeside Boulevard
Edgewood, Maryland 21040

- (ii) The text of the statements that are being made are as follows:

“Advanced Memory Enhancing Dietary Supplement”

“Helps overcome mild memory loss.”

*“Contains cerebral phospholipids and docosahexaenoic acid (DHA), two key nutrients essential **for** optimal memory function.”*

H:\leg\Regulatory\Senior Moment 30 Day Notice ver3 022801.doc 9750162

LET 7428

“To maintain memory function.”

“To enhance memory function.”

“Senior Moment™ is rich in the same phospholipids in the same combination as found in your brain.”

“Phospholipids are fats that are essential to the healthy structure of cell membranes in the brain.. Senior Moment™ contains the same combination of phospholipids found in optimally functioning brains.”

“DHA is an essential fatty acid present in brain phospholipids. It enhances the benefit of the cerebral phospholipids found in Senior Moment™. Additionally, DHA provides further protection against the breakdown of the brain's cellular structure and supports optimal memory function.”

“Nutrients called phospholipids are important in maintaining the cell membrane structure required for this activity. Cell membranes require specific types of phospholipids in specific combinations. Nerve cells require a unique combination of phospholipids to maintain optimum nerve, brain and memory performance.”

“Aging, stress, and diet can lead to brain cell membranes becoming rigid and less permeable. This change in cell membrane structure decreases the efficiency of brain function and memory. This process is accelerated by a diet lacking in the specific phospholipids and fatty acids necessary to keep the brain's chemical messengers and impulses working at their highest level.”

“Scientific research indicates that supplementation with the brain-specific phospholipids and DHA found in Senior Moment™ can compensate for aging, stress and diet-related deficits in these phospholipids. Senior Moment- is specifically designed to restore these deficits.”

“... Senior Moment™ actually supplies specific nutrients (phospholipids and DHA) the brain requires for optimal memory function. The combination of cerebral phospholipids and DHA found in Senior Moment™ is capable of passing through the brain's protective barrier. There, these compounds enter the brain and become incorporated into the cell membrane, thus restoring brain cell activity and performance.”

*“Cerebral Phospholipids – Components **of** brain cell membranes; maintains **and** restores cell **membrane** structure.”*

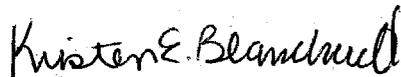
*“DHA – An essential **fatty** acid and **a** key component of phospholipids that enhances the benefit of cerebral phospholipids. Provide further protection against the breakdown of the brain's cellular structure.”*

- (iii) The dietary ingredients that are **the** subject of the statements are the combination of cerebral phospholipids from standardized porcine extract and docosahexaenoic acid (DHA).
- (iv) The statements appear on the labeling of the dietary supplement marketed under the brand name Senior Moment TM.

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,



Kristen E. Blanchard
Director, Legal & Regulatory Affairs