

Complaint

IN THE MATTER OF

NUTRAMAX LABORATORIES, INC.CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 AND SEC. 12 OF THE FEDERAL TRADE COMMISSION ACT*Docket C-4116; File No. 0323052**Complaint, August 27, 2004--Decision, August 27, 2004*

This consent order, among other things, requires Respondent Nutramax Laboratories, Inc., to possess competent and reliable scientific evidence substantiating any claims that Senior Moment -- a dietary supplement containing cerebral phospholipids and docosahexaenoic acid (DHA) -- or any substantially similar product prevents memory loss or restores lost memory function. The order also requires the respondent to possess competent and reliable scientific evidence substantiating any claims -- whether conveyed directly, or by implication through the use of the product name -- about the benefits, performance or efficacy of any food, drug, dietary supplement, device or service sold for human use or consumption for cognitive functions or processes, or the treatment, cure, mitigation, alleviation of the symptoms, prevention, or reduction in the risk of any related disease or disorder. In addition, the order prohibits the respondent from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test or study, in connection with the marketing or sale of any product or program for human cognitive function or processes.

Participants

For the Commission: *Shira D. Modell, Michael Ostheimer, Heather Hipsley, and Mary K. Engle.*

For the Respondent: *Michael Oliver, Bowie & Jensen, and Charles E. Buffon, Covington & Burling*

COMPLAINT

The Federal Trade Commission, having reason to believe that Nutramax Laboratories, Inc., a corporation, ("respondent"), has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

Complaint

1. Respondent Nutramax Laboratories, Inc. is a Maryland corporation with its principal office or place of business at 2208 Lakeside Boulevard, Edgewood, MD 21040.
2. Respondent has advertised, labeled, offered for sale, sold, and distributed the dietary supplement Senior Moment. According to the package label, Senior Moment contains cerebral phospholipids and docosahexaenoic acid (DHA).
3. Senior Moment is a “food” or “drug” within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.
4. The acts and practices of respondent alleged in this complaint has been in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act.
5. Respondent has disseminated or has caused to be disseminated advertisements for Senior Moment, including but not limited to the attached Exhibits A through F. These advertisements contain the following statements:
 - A. (Exhibit A: Television advertisement)

Opening	An envelope reading: “Happy Belated Birthday”
Visual:	
Accompanying	“I’m worried about her. She’s starting to
Voice Over:	forget things.”
Visual:	Mother & daughter having lunch at restaurant, birthday card is on the table (the mother’s voice provided the preceding voice-over)
Daughter:	“I can’t seem to remember anything these days.”
Mother:	“Oh Kathy, even younger adults forget things. Dad and I take this.”
Daughter:	“Senior Moment. I’m not a senior”
Mother:	“It’s for adults of all ages.”
Daughter:	“This isn’t one of the trendy herbal kind of . . .”

Complaint

Mother: “No, no, no. This is a nutritional supplement just for the brain. It helps us remember. And it’s safe.”

Daughter: “Well, thanks mom. With Senior Moment, I won’t miss your birthday next year.”

B. (Exhibit B: Radio advertisement)

Dr. Anna Marie: I’m sure this has happened to you. You try to recall a name and it’s right there on the tip of your tongue, but you just can’t remember it. As we get older, our memory seems to play tricks on us more and more. I’m Dr. Anna Marie. I’ve been a television medical reporter for over ten years, and I have exciting news about a new nutritional supplement specially formulated to enhance memory in adults of all ages. Don’t laugh, the name of the product is Senior Moment. It’s a serious product with a name that’s easy to remember. It’s not one of those trendy herbal products. Senior moment is truly the next generation in memory support. Senior Moment contains two brain-specific nutrients to help overcome mild memory loss. And what I like best? Senior moment is from the makers of CosaminDS, so you know it’s a safe, quality supplement. Don’t forget, try Senior Moment. Even the name is easy to remember.

C. (Exhibit C: Print advertisement)

NEW MEMORY ENHANCING SUPPLEMENT

“You don’t have to be a senior
to need SENIOR MOMENT!”

THE NEXT GENERATION IN MEMORY
ENHANCEMENT*

- ❖ Advanced formula -
Not an herbal product -
NO GINGKO
- ❖ Helps overcome mild

Complaint

memory loss*

- ❖ Contains a proprietary blend of brain specific nutrients
- ❖ For adults of all ages

. . .

*These statements have not been evaluated by the Food & Drug Administration.

This product is not intended to diagnose, treat, cure or prevent any disease.

D. (Exhibit D: Press Release)

**Nutramax Laboratories Compiles Studies Affirming
Efficacy of Senior Moment**

Edgewood, MD (May 16, 2002) - **Nutramax Laboratories** announced that it is reaffirming the efficacy of its **Senior Moment** product, a dietary supplement containing a proprietary blend of brain-specific nutrients shown to enhance memory, by making available a booklet of studies related to the product. . . .

The booklet, **CLINICAL AND SCIENTIFIC STUDIES SUPPORTING THE USE OF SENIOR MOMENT FOR MEMORY**, contains a summary of studies conducted to show that DHA and Cerebral Phospholipids, the two ingredients that comprise Senior Moment, have been proven to enhance memory.

E. (Exhibit E: Package label)

“You don’t have to be a senior
to need Senior Moment”

**SENIOR
MOMENT**
Dietary Supplement

Complaint

FOR
ADULTS OF
ALL AGESADVANCED MEMORY
ENHANCING FORMULA

- Contains a proprietary blend of brain-specific nutrients
- Helps overcome mild memory loss*

*These statements have not been evaluated by the Food & Drug Administration.

This product is not intended to diagnose, treat, cure or prevent any disease.

F. (Exhibit F: Package insert)

SENIOR MOMENT
ADVANCED MEMORY ENHANCING*
DIETARY SUPPLEMENT**What is Senior Moment?**

Senior Moment is a liquid filled capsule containing cerebral phospholipids and docosahexaenoic acid (DHA) taken once a day to help maintain memory function or taken more frequently, according to the directions provided, to help enhance memory function.* Senior Moment is rich in the same phospholipids in the same combination as found in your brain.

. . .

How did this happen?

Aging, stress, heredity, 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. . . .

Complaint

How can Senior Moment Help?

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.*

...

To maintain memory function, take 1 or 2 capsules daily, preferably in the morning.

To enhance memory function, intake can vary depending on individual needs and may be increased up to 6 capsules daily.

...

*These statements have not been evaluated by the Food & Drug Administration.

This product is not intended to diagnose, treat, cure or prevent any disease.

6. Through the means described in Paragraph 5, respondent has represented, expressly or by implication, that:

- (a) Senior Moment prevents memory loss in adults of all ages.
- (b) Senior Moment restores lost memory function in adults of all ages.

7. Through the means described in Paragraph 5, respondent has represented, expressly or by implication, that it possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 6, at the time the representations were made.

8. In truth and in fact, respondent did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 6, at the time the representations were made.

Complaint

Therefore, the representation set forth in Paragraph 7 was, and is, false or misleading.

9. Through the means described in Paragraph 5, respondent has represented, expressly or by implication, that scientific studies prove that Senior Moment restores lost memory function in adults of all ages.

10. In truth and in fact, scientific studies do not prove that Senior Moment restores lost memory function in adults of all ages. Therefore, the representation set forth in Paragraph 9 was, and is, false or misleading.

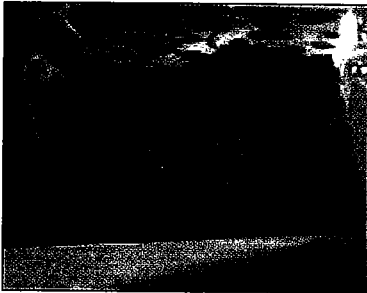
11. The acts and practices of respondent as alleged in this complaint constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

IN WITNESS WHEREOF, the Federal Trade Commission has caused its complaint to be signed by its Secretary and its official seal to be hereto affixed at Washington, D.C. this twenty-seventh day of August, 2004.



PRODUCT Senior Moment
MARKET San Francisco, CA
PROGRAM Eyewitness News At Noon
CODE # 030200530
TITLE Daughter Is Losing Memory/Costco

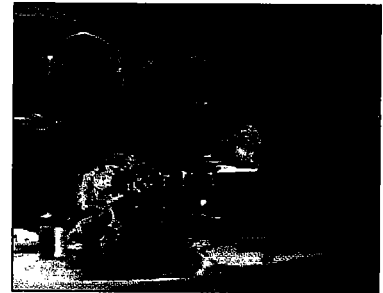
LENGTH 30
STATION KPIX
DATE 02/04/2003
TIME 12:10 PM
REV OF # 020407303



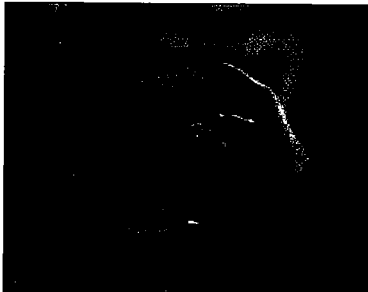
FEMALE (VO): I'm worried about her.
She's starting to forget things.



(MUSIC IN) (SFX: RESTAURANT IN)
KATHY: I can't seem to remember
anything these days.



WOMAN: Oh, Kathy. Even younger
adults forget things.



Dad and I take this. KATHY: Senior
Moment?



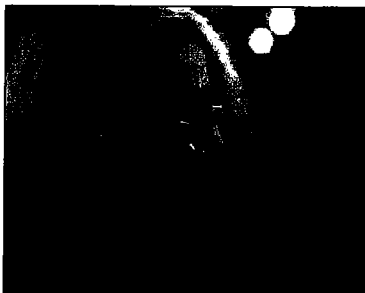
I'm not a senior.



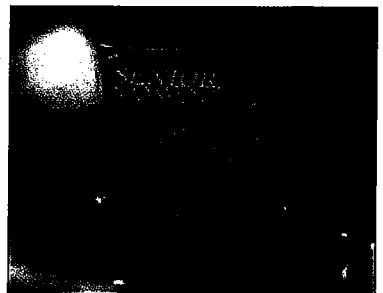
WOMAN: It's for adults of all ages.



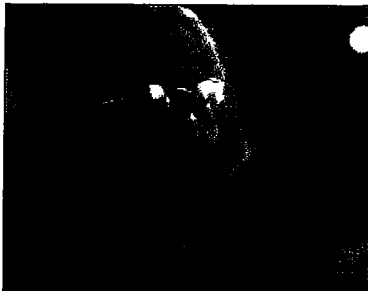
KATHY: This isn't one of those trendy,
herbal kind of--



WOMAN: No, no, no. This is a
nutritional supplement just for the brain.



It helps us remember



and it's safe.



KATHY: Well, thanks, Mom.



With Senior Moment, I won't miss your
birthday next year. WOMAN: Oh.
(SFX/MUSIC OUT)

Exhibit A

VIDEO ALSO AVAILABLE

Material supplied by VMS may be used for internal review, analysis or research only. Any editing, reproduction, publication, re-broadcasting, public showing or display for profit is forbidden and may violate copyright law.

330 West 42nd Street, New York, NY 10036 T 212 736 2010



TRANSCRIPT

DATE: SEPTEMBER 2, 2002
TIME: 6:34AM
STATION: WTOP-FM
LOCATION: WASHINGTON, D.C.
PRODUCT: SENIOR MOMENT / WALGREENS
LENGTH: :60
CODE: 0209-01597C

TITLE: DR. ANNA MARIE; REPORTER; WEB

DR. ANNA MARIE: I'm sure this has happened to you. You try to recall a name and it's right there on the tip of your tongue, but you just can't remember it. As we get older, our memory seems to play tricks on us more and more. I'm Dr. Anna Marie. I've been a television medical reporter for over ten years, and I have exciting news about a new nutritional supplement specially formulated to enhance memory in adults of all ages. Don't laugh, the name of the product is Senior Moment. It's a serious product with a name that's easy to remember. It's not one of those trendy herbal products. Senior Moment is truly the next generation in memory support. Senior Moment contains two brain-specific nutrients to help overcome mild memory loss. And what I like best? Senior Moment is from the makers of Cosamin DS, so you know it's a safe quality supplement. Don't forget, try Senior Moment. Even the name is easy to remember.

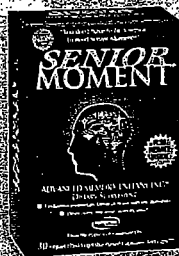
MALE ANNCR: Available at leading discount, drug and grocery stores. For more information, visit SeniorMoment.com. That's SeniorMoment.com.

###

Exhibit B

NEW MEMORY ENHANCING SUPPLEMENT

*"You don't have to be a senior
to need Senior Moment!"*



THE NEXT GENERATION IN MEMORY ENHANCEMENT*

- ◆ Advanced formula—
Not an herbal product—
NO GINKGO
- ◆ Helps overcome mild
memory loss*
- ◆ Contains a proprietary blend
of brain-specific nutrients
- ◆ For adults of all ages

From Nutramax Laboratories[®]
the makers of:
#1 Doctor Recommended Brand[®]
Glucosamine/Chondroitin Sulfate
Joint Health Supplement[®]

Cosamin[®] DS



U.S. Patent Nos. 5,344,405 and 5,507,335

*Source: Results published in the *Journal of Clinical Pharmacology* in April, 2000.
Clinical studies conducted by University of Maryland, 1999,
and Chondroitin and Glucosamine, 2000.



NUTRAMAX LABORATORIES, INC.
1-800-925-5187 • senior-moment.com • cosamin.com

*These statements have not been evaluated by the Food & Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

FOR IMMEDIATE RELEASE



Media Contact:

Megan Arts, 410-902-5036
marts@mgpr.com

Nutramax Laboratories Compiles Studies Affirming Efficacy of Senior Moment®

EDGEWOOD, Md. (May 16, 2002) – Nutramax Laboratories today announced that it is reaffirming the efficacy of its **Senior Moment®** product, a dietary supplement containing a proprietary blend of brain-specific nutrients shown to enhance memory, by making available a booklet of studies related to the product. Nutramax Laboratories is also the maker of CosaminDS, the No. 1 doctor-recommended glucosamine/chondroitin sulfate joint supplement*.

The booklet, **CLINICAL AND SCIENTIFIC STUDIES SUPPORTING THE USE OF SENIOR MOMENT® FOR MEMORY**, contains a summary of studies conducted to show that DHA and Cerebral Phospholipids, the two ingredients that comprise *Senior Moment*, have been proven to enhance memory. Nutramax lead researcher Chuck Filburn, PhD, who is the author of the fall 2000 *Journal of the American Nutraceutical Association* article that originally reviewed the studies, compiled the booklet.

The Cerebral Phospholipids and DHA unique to *Senior Moment* have been extensively tested in clinical and scientific studies for their effects on cognition and biochemical aspect of brain function. These studies have been published in such distinguished medical journals as:

- *Journal of the American College of Nutrition*
- *Journal of Neurochemistry*
- *American Journal of Clinical Nutrition*
- *Journal of Lipid Research*
- *Neurology*
- *Neurobiology of Aging*

"The Nutramax family stands behind the research that has gone into the development of all of our products," said pharmacist Robert W. Henderson, president and CEO of Nutramax Laboratories. "We feel that to truly tell the whole Senior Moment story, people have to know the research behind it."

The booklet is available free of charge to all interested parties including the news media, consumer groups and private individuals. To obtain a copy, please call 1-410-776-4000.

Nutramax Laboratories, based in Edgewood, Md., develops, manufactures and markets nutraceuticals for humans and companion animals. For more information about Senior Moment, visit www.senior-moment.com.

* Source: Survey conducted by *Orthopedics Today* of 1,000 Orthopedic Surgeons and Rheumatologists in April 2000 relating to glucosamine/chondroitin brands.

#

"You don't have to be a senior
to need Senior Moment®"

SENIOR MOMENT®

DIETARY SUPPLEMENT



FOR
ADULTS OF
ALL AGES

ADVANCED MEMORY
ENHANCING* FORMULA

- Contains a proprietary blend
of brain-specific nutrients
- Helps overcome mild memory loss*



From the makers of Cosamin® DS

75 Liquid-filled
Vegetable-based Capsules
(Indicaps™)

RECOMMENDATION:

To maintain normal memory function*, take 1 capsule daily.

For severe memory loss, consult your physician.

For complete product and dosage information, see package insert.

While there are no known interactions or side effects with Senior Moment®, if you have any condition that requires medical attention, you should always consult your physician before taking any drug or dietary supplement.

KEEP OUT OF REACH OF CHILDREN. KEEP IN A COOL, DRY PLACE.

Supplement Facts

Serving Size 1 Capsule

	Amount Per Capsule	
▲ Cerebral Phospholipids (from standardized porcine extract)	50mg	†
Docosahexaenoic Acid (DHA) (from standardized algal oil extract)	40mg	†

† Daily Value Not Established

Other ingredients: Sunflower oil, hydroxypropylmethylcellulose,
ascorbyl palmitate, tocopherols, water, propylene glycol, titanium dioxide color,
FD&C Red #3, FD&C Yellow #5, and FD&C Blue #1
Algal oil* from Martek Biosciences Corp.

* These statements have not been evaluated by the Food & Drug Administration.
This product is not intended to diagnose, treat, cure or prevent any disease.



NUTRAMAX LABORATORIES®, INC. EDGEWOOD, MARYLAND 21040
senior-moment.com • 1-800-925-5187

SENIOR MOMENT®

ADVANCED MEMORY ENHANCING*
DIETARY SUPPLEMENT

Exhibit F



What is *Senior Moment*?

Senior Moment is a liquid-filled capsule containing cerebral phospholipids and docosahexaenoic acid (DHA) taken once a day to help maintain memory function or taken more frequently, according to the directions provided, to help enhance memory function.* *Senior Moment* is rich in the same phospholipids in the same combination as found in your brain.



What are phospholipids and DHA?

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.

Why can't I remember things the way I used to?

There are many reasons why you may not remember things as well as you used to. This may be caused by aging, stress, and deficiencies in your diet. Young nerve and brain cell membranes are fluid and permeable, allowing chemical messengers and impulses to easily interact with the cells. This dynamic flow is responsible for efficient brain and 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.

How did this happen?

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.

How can *Senior Moment* help?

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.*

How is *Senior Moment* different from other supplements that are supposed to help memory loss?

Phospholipids from vegetable sources, including soy and several other dietary supplements, lack the specific compounds critical in regulating brain transmissions and function. Younger individuals may be able to convert the compounds from other sources into specific membrane structures the brain requires. However, older individuals benefit most when these compounds are provided directly in the supplement.

*These statements have not been evaluated by the Food & Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Exhibit F

Unlike some dietary supplements that claim to increase circulation in the brain, *Senior Moment* actually supplies specific nutrients (phospholipids and DHA) the brain requires for optimal memory function. The components of cerebral phospholipids and DHA found in *Senior Moment* are capable of passing through the brain's protective barrier. There, these compounds enter the brain and become incorporated into the cell membrane, thus helping brain cell activity and performance.*

Why is *Senior Moment* in a liquid-filled capsule?

Liquid-filled capsules represent a state-of-the-art technology in the dietary supplement industry. A tamper evident seal locks the capsule together. This prevents the leakage of liquid and oxidative damage to the active ingredients in *Senior Moment*. Nutramax Laboratories®, Inc. follows the manufacturing and quality control standards developed by the pharmaceutical industry.

Directions for Use:

- To help maintain memory function, take 1 or 2 capsules daily, preferably in the morning.
- To help enhance memory function, intake can vary depending on individual needs and may be increased up to 6 capsules daily.
- For severe memory loss, consult your physician.
- *Senior Moment* should be taken during the day; if taken prior to bedtime it may increase mental awareness and interfere with sleep in certain individuals.
- Research on the components indicates *Senior Moment* should be taken on a continual daily basis for maximum effect.

*Developed by the makers of Cosamin® DS,
the #1 Doctor Recommended brand of Glucosamine/Chondroitin Sulfate*
(Source: April 2000 survey by *Orthopedics Today* of 1,000 orthopedic surgeons and rheumatologists relating to glucosamine/chondroitin sulfate brands.)

Questions? Contact Nutramax Laboratories®, Inc. at 1-800-925-5187 or check the website:
www.senior-moment.com or www.nutramaxlabs.com.



2208 Lakeside Boulevard • Edgewood, Maryland 21040
1-800-925-5187 1-410-776-4000

*These statements have not been evaluated by the Food & Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Decision and Order

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondent named in the caption hereof, and the respondent having been furnished thereafter with a copy of a draft of complaint which the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge the respondent with violation of the Federal Trade Commission Act; and

The respondent, its attorneys, and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondent of all the jurisdictional facts set forth in the aforesaid draft complaint, a statement that the signing of the agreement is for settlement purposes only and does not constitute an admission by the respondent that the law has been violated as alleged in such complaint, or that the facts as alleged in such complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondent has violated the Act, and that complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of thirty (30) days, now in further conformity with the procedure prescribed in § 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings, and enters the following order:

1. Respondent Nutramax Laboratories, Inc., is a Maryland corporation with its principal office or place of business at 2208 Lakeside Boulevard, Edgewood, MD 21040.

Decision and Order

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondent, and the proceeding is in the public interest.

ORDER

DEFINITIONS

For purposes of this order, the following definitions shall apply:

1. “Competent and reliable scientific evidence” shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.
2. Unless otherwise specified, “respondent” shall mean Nutramax Laboratories, Inc., a corporation, its successors and assigns, and the officers, agents, representatives, and employees of each of the above, including, without limitation, any successor to, assignee of, lessee of or licensee of the Senior Moment trademark or the Senior Moment or any substantially similar product, under that trademarked name or any other name.
3. “Commerce” shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
4. “Endorsement” shall mean as defined in 16 C.F.R. § 255.0.
5. “Substantially similar product” shall mean any ingestible dietary supplement for human consumption with respect to cognitive functions or processes that contains the following ingredients: cerebral phospholipids or docosahexaenoic acid.
6. “Cognitive functions or processes” include all aspects of perception, thinking, reasoning and remembering, including, but

Decision and Order

not limited to, memory, learning, concentration, abstract thinking, language, visuospatial perception, and higher executive functions (planning, organizing and sequencing), but do not include emotional or mental states, including but not limited to, mood, nervousness, sadness, anxiety or depression.

I.

IT IS ORDERED that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the labeling, advertising, promotion, offering for sale, sale, or distribution of Senior Moment or any substantially similar product, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of endorsements or the product name:

- A. That the product or service prevents memory loss; or
- B. That the product or service restores lost memory function;

unless, at the time the representation is made, respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation.

II.

IT IS FURTHER ORDERED that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the labeling, advertising, promotion, offering for sale, sale, or distribution of Senior Moment or any food, drug, dietary supplement, device, or service, as “food” and “drug,” are defined in Section 15 of the Federal Trade Commission Act, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of endorsements or the product name, about the benefits, performance or efficacy of such product or service for cognitive functions or processes, or the treatment, cure, mitigation, alleviation of the symptoms, prevention, or reduction in the risk of

Decision and Order

any disease or disorder related thereto, unless, at the time the representation is made, respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation. PROVIDED, however, that this Paragraph shall apply only to products or services labeled, advertised, promoted, offered for sale, sold for use or distributed for consumption by or use on humans.

III.

IT IS FURTHER ORDERED that respondent, directly or through any partnership, corporation, subsidiary, division, or other device, in connection with the labeling, advertising, promotion, offering for sale, sale, or distribution of any product or program for human cognitive functions or processes, in or affecting commerce, shall not misrepresent, in any manner, directly or by implication, the existence, contents, validity, results, conclusions, or interpretations of any test or study.

IV.

Nothing in this order shall prohibit respondent from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.

V.

IT IS FURTHER ORDERED that respondent Nutramax Laboratories, Inc., and its successors and assigns, shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation including videotape recordings of all such broadcast advertisements;

Decision and Order

- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations or other evidence in their possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

VI.

IT IS FURTHER ORDERED that respondent Nutramax Laboratories, Inc., and its successors and assigns, shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having managerial responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondent shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

VII.

IT IS FURTHER ORDERED that respondent Nutramax Laboratories, Inc., and its successors and assigns, shall notify the Commission at least thirty (30) days prior to any proposed change in its corporate structure that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. Provided, however, that, with respect to any proposed change in the corporation about which respondent learns less than thirty (30)

Decision and Order

days prior to the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, NW, Washington, D.C. 20580.

VIII.

IT IS FURTHER ORDERED that respondent Nutramax Laboratories, Inc., and its successors and assigns, shall, within sixty (60) days from the date of service of this order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

IX.

This order will terminate on August 27, 2024, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; provided, however, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Provided further, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as

Decision and Order

though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

Analysis

Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission has accepted, subject to final approval, an agreement containing a consent order from Nutramax Laboratories, Inc. (“Nutramax”).

The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

This matter involves the advertising and promotion of Senior Moment, a dietary supplement containing cerebral phospholipids and docosahexaenoic acid (DHA). According to the FTC complaint, Nutramax represented that Senior Moment prevents memory loss and restores lost memory function in adults of all ages. The complaint alleges that the company failed to have substantiation for these claims. It further alleges that Nutramax falsely represented that scientific studies prove that Senior Moment restores lost memory function in adults of all ages.

The proposed consent order contains provisions designed to prevent Nutramax from engaging in similar acts and practices in the future.

Part I of the order requires Nutramax to have competent and reliable scientific evidence substantiating any claims that Senior Moment or any substantially similar product prevents memory loss or restores lost memory function.

Part II requires Nutramax to have competent and reliable scientific evidence substantiating any claims about the benefits, performance or efficacy of any food, drug, dietary supplement, device or service sold for human use or consumption for cognitive functions or processes, or the treatment, cure, mitigation,

Analysis

alleviation of the symptoms, prevention, or reduction in the risk of any related disease or disorder. Although the order does not prohibit the trade name “Senior Moment,” it does require the respondent to have competent and reliable scientific evidence to substantiate any covered claims conveyed directly or by implication through the use of the product name.

Part III prohibits any misrepresentation of the existence, contents, validity, results, conclusions, or interpretations of any test or study, in connection with the marketing or sale of any product or program for human cognitive function or processes.

Part IV permits any representation for any product that is permitted in labeling for such product pursuant to regulations promulgated by FDA pursuant to the Nutrition Labeling and Education Act of 1990.

Parts V through VIII of the order require Nutramax to keep copies of relevant advertisements and materials substantiating claims made in the advertisements; to provide copies of the order to certain of its personnel; to notify the Commission of changes in corporate structure; and to file compliance reports with the Commission. Part IX provides that the order will terminate after twenty (20) years under certain circumstances.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

Complaint

IN THE MATTER OF

PRINCE LIONHEART, INC.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 AND SEC. 12 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-4117; File No. 0323245

Complaint, September 1, 2004--Decision, September 1, 2004

This consent order, among other things, prohibits Respondents Prince Lionheart, Inc., and its president, Thomas E. McConnell, from representing that the “Love Bug” -- an electronic mosquito repellent device -- or any substantially similar product, (1) repels mosquitoes from a baby or any person; (2) is an effective alternative to the use of chemical products formulated to repel mosquitoes; or (3) protects babies or other persons against contracting the West Nile virus, unless the representation is true and the respondents possess competent and reliable scientific evidence that substantiates the representation. The order also prohibits unsubstantiated representations about the benefits, performance, or efficacy of any consumer electronic product. In addition, the order requires the respondents to send a letter, with a copy of the order, to any catalog company or other wholesale or retail seller to which respondents have sold the “Love Bug” since January 1, 2002.

Participants

For the Commission: *Carol Jennings, Robert M. Frisby, Elaine Kolish, Susan Braman and Jesse Leary.*

For the Respondents: *Thomas E. McConnell, pro se.*

COMPLAINT

The Federal Trade Commission, having reason to believe that Prince Lionheart, Inc., a corporation, and Thomas E. McConnell, individually and as President of the corporation (“respondents”), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges: