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UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

COMMISSIONERS: Deborah Platt Majoras, Chairman Mozelle W. Thompson Orson Swindle Thomas B. Leary Pamela Jones Harbour

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In the Matter of)	
)	DOCKET NO. C-4116
NUTRAMAX LABORATORIES, INC.,)	
a corporation.)	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.
- 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 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 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.

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;
- 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) 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; <u>provided</u>, <u>however</u>, 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.

<u>Provided further</u>, 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 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.

By the Commission.

Donald S. Clark Secretary

SEAL

ISSUED: August 27, 2004