

In the Matter of Efamol Nutraceuticals Inc. (2000)

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Case: In the Matter of Efamol Nutraceuticals Inc. (2000)

Subject Category: Consent Order

Agency Involved: FTC

Complaint Synopsis: Efamol manufactured and distributed products that it claimed could treat ADHD in children. The FTC claimed that Efamol did not have any reliable scientific evidence to back up its claims.

Consent Details: Efamol claimed that two of its products could treat ADHD symptoms in children by managing fatty acid deficiencies. The FTC filed a complaint alleging that reliable scientific evidence did not exist that supported such a claim, in violation of the Federal Trade Commission Act. Efamol agreed to cease advertising that its products were effective at treating ADHD unless it could produce competent and reliable evidence that supported the company's claim. In exchange for the voluntary cessation of the subject advertising, the FTC agreed to withdraw its complaint.

Practical Importance to Business of MLM/Direct Sales/Direct Selling/Network Marketing/Party Plan/Multilevel Marketing: The FTC takes health efficacy claims very seriously, and aggressively peruses those that are not, in the FTC's opinion, properly founded on reliable and competent scientific support.

In the Matter of Efamol Nutraceuticals Inc. (2000) , File No. 992 3027 : Efamol claimed that two of its products could treat ADHD symptoms in children by managing fatty acid deficiencies. The FTC filed a complaint alleging that reliable scientific evidence did not exist that supported such a claim, in violation of the Federal Trade Commission Act. Efamol agreed to cease advertising that its products were effective at treating ADHD unless it could produce competent and reliable evidence that supported the company's claim. In exchange for the voluntary cessation of the subject advertising, the FTC agreed to withdraw its complaint.

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Consent Agreement

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

In the Matter of

EFAMOL NUTRACEUTICALS, INC., a corporation.

FILE NO. 992 3027

AGREEMENT CONTAINING CONSENT ORDER

The Federal Trade Commission has conducted an investigation of certain acts and practices of Efamol Nutraceuticals, Inc., a corporation ("proposed respondent"). Proposed respondent, having been represented by counsel, is willing to enter into an agreement containing a consent order resolving the allegations contained in the attached draft complaint. Therefore,

IT IS HEREBY AGREED by and between Efamol Nutraceuticals, Inc., by its duly authorized officers, and counsel for the Federal Trade Commission that:

1. Respondent Efamol Nutraceuticals, Inc. ("Efamol"), is a Delaware corporation with its principal office or place of business at 23 Dry Dock Avenue, 2nd Floor, Boston, Massachusetts 02210.
2. Proposed respondent admits all the jurisdictional facts set forth in the draft complaint.
3. Proposed respondent waives:
 - a. Any further procedural steps;
 - b. The requirement that the Commission's decision contain a statement of findings of fact and conclusions of law; and
 - c. All rights to seek judicial review or otherwise to challenge or contest the validity of the order entered pursuant to this agreement.

4. This agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this agreement is accepted by the Commission, it, together with the draft complaint, will be placed on the public record for a period of thirty (30) days and information about it publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify proposed respondent, in which event it will take such action as it may consider appropriate, or issue and serve its complaint (in such form as the circumstances may require) and decision in disposition of the proceeding.

5. This agreement is for settlement purposes only and does not constitute an admission by proposed respondent that the law has been violated as alleged in the draft complaint, or that the facts as alleged in the draft complaint, other than the jurisdictional facts, are true.

6. This agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of Section 2.34 of the Commission's Rules, the Commission may, without further notice to proposed respondent, (1) issue its complaint corresponding in form and substance with the attached draft complaint and its decision containing the following order in disposition of the proceeding, and (2) make information about it public. When so entered, the order shall have the same force and effect and may be altered, modified, or set aside in the same manner and within the same time provided by statute for other orders. The order shall become final upon service. Delivery of the complaint and the decision and order to proposed respondent by any means specified in Section 4.4 of the Commission's Rules shall constitute service. Proposed respondent waives any right it may have to any other manner of service. The complaint may be used in construing the terms of the order. No agreement, understanding, representation, or interpretation not contained in the order or in the agreement may be used to vary or contradict the terms of the order.

7. Proposed respondent has read the draft complaint and consent order. It understands that it may be liable for civil penalties in the amount provided by law and other appropriate relief for each violation of the order after it becomes final.

ORDER

DEFINITIONS

For the 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 have 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 Efamol Nutraceuticals, Inc., its successors and assigns and its officers, agents, representatives and employees.
3. "Drug" shall mean as defined in Section 15 of the Federal Trade Commission Act, 15 U.S.C. § 55.
4. "Food" shall mean as defined in Section 15 of the Federal Trade Commission Act, 15 U.S.C. § 55.
5. "Commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

I.

IT IS ORDERED that respondent, directly or through any corporation, partnership, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of "Efalex," "Efalex Focus," or any food, drug or dietary supplement, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, that:

A. Such product can cure, prevent, treat or mitigate Attention Deficit Disorder, Attention Deficit Hyperactivity Disorder, or their symptoms;

B. Such product is effective in reducing attention and behavioral problems;

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, partnership, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any food, drug or dietary supplement that contains essential fatty acids, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, about the health benefits, efficacy or safety of such product, unless, at the time the representation is made, respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation.

III.

Nothing in this order shall prohibit respondent from making any representation for any drug that is permitted in labeling for such drug under any tentative final or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration.

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, 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;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in its 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, and its successors and assigns, shall, for a period of five (5) years from the date of service of this order, 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 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, and its successors and assigns, shall notify the Commission at least thirty (30) days prior to any change in the corporation 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, Washington, D.C. 20580.

VIII.

IT IS FURTHER ORDERED that respondent, and its successors and assigns, shall, within sixty (60) days after 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 it has complied with this order.

IX.

This order will terminate twenty (20) years from the date of its issuance, 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 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.

Signed this ___ day of ___, 2000.

EFAMOL NUTRACEUTICALS, INC.

By:

President

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