

Complaint

IN THE MATTER OF
EFAMOL NUTRACEUTICALS, INC.

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

Docket C-3958; File No. 9923027
Complaint, June 22, 2000--Decision, June 22, 2000

This consent order requires Respondent Efamol Nutraceuticals, Inc. to possess competent and reliable scientific evidence for any claim about the health benefits, efficacy or safety of any food, drug or dietary supplement that contains essential fatty acids. The order permits respondent to make drug claims that have been approved by the FDA pursuant to either a new drug application or a tentative final or final standard and to make claims that the FDA has approved pursuant to the Nutrition Labeling and Education Act of 1990.

Participants

For the Commission: *Matthew D. Gold, Linda K. Badger, Kerry O'Brien.*

For the Respondents: *Stephen H. McNamara and A. Wes Siegner, Jr., Hyman, Phelps & McNamara, P.C.*

COMPLAINT

The Federal Trade Commission, having reason to believe that Efamol Nutraceuticals, Inc. ("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:

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Respondent Efamol Nutraceuticals, Inc., is a Delaware corporation with its principal office or place of business at 23 Dry Dock Avenue, 2nd Floor, Boston, Massachusetts 02210.

Respondent has manufactured, advertised, labeled, offered for sale, sold, and distributed numerous dietary supplements to the public, all of which contain essential fatty acids. Included among respondent's products are "Efalex" and "Efalex Focus." Respondent has marketed Efalex and Efalex Focus to parents of children with Attention Deficit Disorder and Attention Deficit Hyperactivity Disorder ("ADD/ADHD"). Efalex and Efalex Focus are "foods" and/or "drugs," within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.

The acts and practices of respondent alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

Respondent has disseminated or has caused to be disseminated advertisements for Efalex and Efalex Focus, including but not necessarily limited to the attached Exhibits A through D. These advertisements contain the following statements and depictions:

A. "LONG-TERM SIDE EFFECTS MAY INCLUDE:
HUGGING YOUR MOM.

When your child is bouncing off the walls, hyper and aggressive, do you go crazy wishing he'd just let you love him? Efalex™ is a dietary supplement that manages fatty acid deficiency in ADD/ADHD. It's safe and gentle, and it's available today without a prescription. In capsules or liquid. Because hugging your mom is the best medicine of all. To find out more, call 1 888 EFAMOL 1 or visit www.efamol.com."

(Exhibit A, Print Advertisement).

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B. "FREAK

Why would anyone say such a thing? He's a beautiful kid. But sometimes beautiful kids suffer from really ugly attention and behavior problems. Luckily, Efalex™ is here. This safe, gentle, dietary supplement, now available in capsules or liquid, manages fatty acid deficiency in ADD/ADHD. Because he's not a monster, a demon, a weirdo. He's your child. Call 1 888 EFAMOL 1 or visit www.efamol.com."

(Exhibit B, Print Advertisement).

C. "You'd Try Anything to Help Your Child with ADHD. Try This.

Studies show that some children with Attention Deficit Hyperactivity Disorder (ADHD) have a fatty acid deficiency. This is because they have problems converting essential fatty acids into the long chain forms the body needs to maintain optimum eye and brain function.

Only Efalex provides the precise combination of these important fatty acids -- G.A., DHA, and AA -- to properly manage this deficiency.

Efalex has been used by thousands of children in the United Kingdom, other parts of Europe and Australia. Manufactured by Efamol, the world leader in fatty acid research, Efalex is a safe, gentle way to manage fatty acid deficiency.

Now Efalex is available at your local pharmacy in the vitamin/natural products section. For more

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information on fatty acid deficiency and ADHD, call 1-888-EFAMOL-1 or visit www.efamol.com.

Efamol. Better Science for Better Nutrition.”

(Exhibit C, Print Advertisement).

D. “Can you help him stay focused?

Today’s children are intelligent, creative and more talented than ever, yet some find it difficult to focus on even the most everyday tasks. What causes this problem remains a mystery.

Nutritional research conducted at a major American university may offer hope. Studies have shown that essential fatty acids may play a role in maintaining eye and brain function. New research has shown that these nutrients may be low in some of today’s overly active children.

More and more parents are finding out about Efalex™ Focus -- a new dietary supplement from Efamol Ltd., the world leader in essential fatty acid research.

Efalex™ Focus is a patented formula that provides an important balance of these fatty acids. It has been widely used in Europe and is now available in the U.S.

To learn more about Efalex™ Focus and essential fatty acids, or to locate a store near you, call 1-888-EFAMOL-1 or visit us at www.efamol.com.”

(Exhibit D, Print Advertisement).

Through the means described in Paragraph 4, respondent has represented, expressly or by implication, that:

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- A. Efalex and Efalex Focus can cure, prevent, treat or mitigate ADD/ADHD or its symptoms.
- B. Efalex and Efalex Focus are effective in reducing attention and behavioral problems.

Through the means described in Paragraph 4, respondent has represented, expressly or by implication, that it possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 5, at the time the representations were made.

In truth and in fact, respondent did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 5, at the time the representations were made. There are no studies showing that children suffering from ADD/ADHD can be effectively treated by supplementation with essential fatty acids. Respondent relied on studies that do not purport to establish a link between essential fatty acid supplementation and an effect on ADD/ADHD or its symptoms. Therefore, the representation set forth in Paragraph 6 was, and is, false or misleading.

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.

THEREFORE, the Federal Trade Commission this twenty-second day of June, 2000, has issued this complaint against respondent.

By the Commission.

Complaint Exhibits

Complaint Exhibits

LONG-TERM SIDE EFFECTS MAY INCLUDE:
HUGGING YOUR MOM.

When your child is bouncing off the walls, hyper and aggressive, do you go crazy wishing he'd just let you love him? Efalex™ is a dietary supplement that manages fatty acid deficiency in ADD/ADHD. It's safe and gentle, and it's available



today without a prescription, in capsules or liquid. Because hugging your mom is the best medicine of all. To find out more, call 1888 EFAMOL 1 or visit www.efamol.com



NOW AVAILABLE AT FOOD, DRUG, DISCOUNT AND HEALTH FOOD STORES EVERYWHERE

EXHIBIT A

Complaint Exhibits



Why would anyone say such a thing? He's a beautiful kid. But sometimes beautiful kids suffer from really ugly attention and behavior problems. Luckily, Efalex™ is here. This safe, gentle dietary supplement,



now available in capsules or liquid, manages fatty acid deficiency in ADD/ADHD. Because he's not a monster, a demon, a weirdo. He's your child. Call 1888 EFAMOL I or visit www.efamol.com



NOW AVAILABLE AT CVS PHARMACY, RITE AID, ECKERD AND OTHER FINE STORES

EXHIBIT B

Complaint Exhibits

Now available at Brooks, Mainwaring and MacArthur.

You'd Try Anything to Help Your Child with ADHD. Try This.

Studies show that some children with Attention Deficit Hyperactivity Disorder (ADHD) have a fatty acid deficiency. This is because they have problems converting essential fatty acids into the long chain forms the body needs to maintain optimum eye and brain function.

Only Efalex provides the precise combination of these important fatty acids - γ -CL A, DHA, and AA - to properly manage this deficiency. Efalex has been used by thousands of children in the United Kingdom, other parts of Europe and Australia. Manufactured by Elamol, Efalex is a safe, gentle way to manage fatty acid deficiency.

Now Efalex is available at your local pharmacy in the vitamin/natural products section. For more information on fatty acid deficiency and ADHD, call 1-888-ELAMOL or visit www.elamol.com.

Efalex
For the Dietary Management of Fatty Acid Deficiency in ADHD/ADHD
With DHA 60 CAPSULES

Efalex
Better Science for Better Nutrition.

EXHIBIT C

Complaint Exhibits

Can you help him stay focused?

Today's children are intelligent, creative, and more talented than ever, yet some find it difficult to focus on even the most everyday tasks. What causes this problem remains a mystery. Nutritional research conducted at a major American university may offer hope. Studies have shown that essential fatty acids may play a role in maintaining eye and brain function. New research has shown that these nutrients may be low in some of today's overly active children.

More and more parents are finding out about Efalex® Focus — a new dietary supplement from Efamol Ltd., the world leader in essential fatty acid research.

Efalex® Focus is a patented formula that provides an important balance of these fatty acids. It has been widely used in Europe and is now available in the U.S.

To learn more about Efalex® Focus and essential fatty acids, or to locate a store near you, call 1-888-EFALFEX-1 or visit us at www.efamol.com

Available at GNC and Fine Health Food Stores Everywhere

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

EXHIBIT D

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 Western Region proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondent with violation of the Federal Trade Commission Act; and

The respondent, its attorney, 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 of complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by 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 said 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 Efamol Nutraceuticals, Inc., is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business at 23 Dry Dock Avenue, 2nd Floor, Boston, Massachusetts 02210.

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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 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

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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.

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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

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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.

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IX.

This order will terminate twenty on June 22, 2020, 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.

By the Commission.

Analysis to Aid Public Comment

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 Efamol Nutraceuticals, Inc., ("Efamol"). Efamol is a marketer of dietary supplement products, all of which contain essential fatty acids.

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 alleged misleading representations for Efaless and Efaless Focus, two of Efamol's dietary supplement products. The advertisements claimed that these products can mitigate or cure the effects of Attention Deficit Disorder or Attention Deficit Hyperactivity Disorder ("ADD/ADHD").

The proposed complaint alleges that Efamol could not substantiate the following claims: (1) that Efaless and Efaless Focus can cure, prevent, treat or mitigate ADD/ADHD or its symptoms; and (2) that Efaless and Efaless Focus are effective in reducing attention and behavioral problems. Part I of the proposed order would address these misrepresentations by prohibiting Efamol from making the claims in the future unless it possesses and relies upon competent and reliable scientific evidence that substantiates the claim.

Part II of the proposed order requires Efamol to possess competent and reliable scientific evidence for any claim about the health benefits, efficacy or safety of any food, drug or dietary supplement that contains essential fatty acids. Because all of Efamol's products contain essential fatty acids, this provision would apply to the company's entire current product line.

Analysis to Aid Public Comment

Part III of the proposed order contains language permitting Efamol to make drug claims that have been approved by the FDA pursuant to either a new drug application or a tentative final or final standard. Part IV states that Efamol would be permitted to make claims that the FDA has approved pursuant to the Nutrition Labeling and Education Act of 1990.

Parts V-VII of the proposed order contain requirements that Efamol keep copies of relevant advertisements and materials substantiating claims made in the advertisements; provide copies of the order to certain of its current and future personnel; and notify the Commission of changes in the corporate structure that might affect compliance with the order. Part VIII requires Efamol to file one or more reports detailing compliance with the order. 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.

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IN THE MATTER OF

ZIM TEXTILE CORPORATION**CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT**

Docket C-3960; File No. 0023082
Complaint, June 29, 2000--Decision, June 29, 2000

This consent order prohibits Respondent Zim Textile Corporation from future violations of the Textile Fiber Products Identification Act and Commission rules and regulations, found at 16 C.F.R. Part 303, implementing the requirements of the statute.

Participants

For the Commission: *Carol Jennings, Stephen Ecklund, Elaine D. Kolish, and BE.*

For the Respondents: *Jerry P. Wiskin, Simons & Wiskin.*

COMPLAINT

The Federal Trade Commission, having reason to believe that Zim Textile Corporation (respondent) has violated the provisions of the Federal Trade Commission Act, 15 U.S.C. § 41 *et seq.* (FTC Act) and the Textile Fiber Products Identification Act, 15 U.S.C. § 70 *et seq.* (Textile Act), and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent is a New York corporation with its principal office or place of business at 300 Campus Drive, Suite E, Morganville, New Jersey 07751.
2. Respondent is a manufacturer and distributor of household textile products, including sheets and pillowcases. Respondent has manufactured, offered for sale, sold, and distributed textile products subject to the requirements of the Textile Act.