



UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of

NATURAL ORGANICS, INC., a corporation, and
GERALD A. KESSLER, individually and as an officer of the corporation.

DOCKET NO. 9294

COMPLAINT

The Federal Trade Commission, having reason to believe that Natural Organics, Inc., a corporation, and Gerald A. Kessler, individually and as an officer 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:

1. Respondent Natural Organics, Inc. is a New York corporation with its principal office or place of business at 548 Broadhollow Road, Melville, New York 11747-3708. Natural Organics, Inc., does business as "Nature's Plus."
2. Respondent Gerald A. Kessler is an officer of the corporate respondent. Individually or in concert with others, he formulates, directs, or controls the policies, acts, or practices of the corporation, including the acts or practices alleged in this complaint. His principal office or place of business is the same as that of Natural Organics, Inc.
3. Respondents have manufactured, advertised, labeled, offered for sale, sold, and distributed products to the public, including "Pedi-Active A.D.D." Pedi-Active A.D.D. is a "food" and/or "drug" within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.
4. Pedi-Active A.D.D. is targeted to parents of children with Attention Deficit/Hyperactivity Disorder ("ADHD"). As defined in the American Psychiatric Association, Diagnostic and Statistical Manual of Mental Disorders, (4th ed. 1994), ADHD is a widely-recognized developmental disorder of childhood characterized by a persistent pattern of inattention and/or hyperactivity-impulsiveness that is more frequent and severe than is typically observed in individuals at a comparable level of development. A prior edition of the American Psychiatric Association's Manual referred to this disorder as Attention Deficit Disorder, or "ADD." For this reason, the terms ADHD and ADD are often used interchangeably.
5. The acts and practices of respondents alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.
6. Respondents have disseminated or have caused to be disseminated advertisements for Pedi-Active A.D.D., including but not necessarily limited to the attached Exhibits A through D. These advertisements contain the following statements and depictions:

A. Print Advertisement for Pedi-Active A.D.D. (Exhibit A):

"If yelling, begging and pleading doesn't get your child to do their

homework, maybe this will.

[picture of child who is holding a pen and apparently focusing on his work is shown next to a bottle of Pedi-Active A.D.D.]

REPORT CARD. *Not working up to capabilities. Has difficulty paying attention. Does not follow instructions. Does not work well with others.*

In many cases children will score very high on I.Q. tests. Still, they do not perform as well in school as their parents and teachers know they can. The problem is often not their intelligence, but the child's inability to remain focused. A skill which is essential for success in the classroom and beyond.

Nature's Plus has approached the problems of the active child from a nutritional perspective. Pedi-Active A.D.D.TM, a formula which combines phosphatidylserine, DMAE and activated soy phosphatides in a state-of-the-art nutritional supplement. Each incredibly delicious, mixed berry flavor, chewable tablet supplies a complete profile of the most advanced neuronutrients available.

Isn't your child worth the best nutritional support science has to offer?

...."

B. Brochure for Pedi-Active A.D.D. (Exhibit B):**"NUTRITIONAL SUPPORT FOR THE ACTIVE CHILD**

[picture of very young child holding teddy bear is shown]

ADVANCED DIETARY DELIVERY SYSTEM

PEDI-ACTIVE A.D.D.

Phosphatidylserine DMAE Complex

[report card depicted showing poor to satisfactory performance]

Not working up to capabilities.

Has difficulty paying attention.

Does not follow instructions.

Does not work well with others.

In many cases children will score very high on I.Q. tests. Still, they do not perform as well in school as their parents and teachers know they can. The problem is often not their intelligence, but the child's inability to remain focused. A skill which is essential for success in the classroom and beyond.

Nature's Plus has approached the problems of the active child from a nutritional perspective. Introducing **Pedi-Active A.D.D.**, a precisely calibrated formula designed for the active child. Each incredibly delicious,

chewable tablet supplies a complete profile of the most advanced neuronutrients available, including a diversified combination of phosphatidylserine, DMAE and activated soy phosphatides, such as phosphatidylcholine. **Pedi-Active A.D.D.** is a state-of-the-art nutritional supplement that naturally complements an active child's delicate system.

Isn't your child worth the best nutritional support science has to offer?

[bottle of Pedi-Active A.D.D. is depicted]

...."

C. Letter Sent To Consumers Who Inquire About Pedi-Active A.D.D. (Exhibit C):

"....

Dear [consumer's name]:

Thank you for your interest in **Pedi-Active A.D.D.** from Nature's Plus. We know that sometimes yelling, pleading and begging your child to [sic] their homework just isn't enough. Research has shown that many of the problems [sic] a child who is hyperactive or suffering from Attention Deficit Disorder can be related to improper nutrition. What your child needs is a nutritional supplement that supplies a complete profile of the most advanced neuronutrients available to help your child live up to their full potential. Each delicious mixed berry flavored chewable tablet combines phosphatidylserine, DMAE and activated soy phosphatides to provide the nutritional support your active child needs.

....

Sincerely,
[signature]
Gerald Kessler
Founder, Nature's Plus

[coupons for Pedi-Active A.D.D. and another product are attached to bottom of letter]"

D. Natural Organics' World Wide Web Advertisement for Pedi-Active A.D.D. (Exhibit D):

"Pedi-Active A.D.D. Chewables

...."

7. Through the means described in Paragraph 6, respondents have represented, expressly or by implication, that Pedi-Active A.D.D. will:

A. improve the attention span of children who have difficulty focusing on school work;

B. improve the scholastic performance of children who have difficulty focusing on

school work;

C. improve the attention span of children who suffer from ADHD;

D. improve the scholastic performance of children who suffer from ADHD; and

E. treat or mitigate ADHD or its symptoms.

8. Through the means described in Paragraph 6, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 7, at the time the representations were made.

9. In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 7, at the time the representations were made. Therefore, the representation set forth in Paragraph 8 was, and is, false or misleading.

10. The acts and practices of respondents 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.

NOTICE

Proceedings on the charges asserted against the respondents named in this complaint will be held before an Administrative Law Judge (ALJ) of the Federal Trade Commission, under Part 3 of the Commission's Rules of Practice, 16 C.F.R. Part 3. A copy of Part 3 of the Rules is enclosed with this complaint.

You are notified that the opportunity is afforded you to file with the Commission an answer to this complaint on or before the twentieth (20th) day after service of it upon you. An answer in which the allegations of the complaint are contested shall contain a concise statement of the facts constituting each ground of defense; and specific admission, denial, or explanation of each fact alleged in the complaint or, if you are without knowledge thereof, a statement to that effect. Allegations of the complaint not thus answered shall be deemed to have been admitted.

If you elect not to contest the allegations of fact set forth in the complaint, the answer shall consist of a statement that you admit all of the material allegations to be true. Such an answer shall constitute a waiver of hearings as to the facts alleged in the complaint, and together with the complaint will provide a record basis on which the ALJ shall file an initial decision containing appropriate findings and conclusions and an appropriate order disposing of the proceeding. In such answer you may, however, reserve the right to submit proposed findings and conclusions and the right to appeal the initial decision to the Commission under Section 3.52 of the Commission's Rules of Practice for Adjudicative Proceedings.

Failure to answer within the time above provided shall be deemed to constitute a waiver of your right to appear and contest the allegations of the complaint and shall authorize the ALJ, without further notice to you, to find the facts to be as alleged in the complaint and to enter an initial decision containing such findings, appropriate conclusions and order.

The ALJ will schedule an initial prehearing scheduling conference to be held not later than 7 days after the last answer is filed by any party named as a respondent in the

complaint. Unless otherwise directed by the ALJ, the scheduling conference and further proceedings will take place at the Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. Rule 3.21(a) requires a meeting of the parties' counsel as early as practicable before the prehearing scheduling conference, and Rule 3.31(b) obligates counsel for each party, within 5 days of receiving a respondent's answer, to make certain initial disclosures without awaiting a formal discovery request.

Notice is hereby given to each of the respondents named in this complaint that a hearing before the ALJ on the charges set forth in this complaint will begin on April 9, 2001, at 10:00 A.M., or such other date and time as determined by the ALJ, in Room 532, Federal Trade Commission Building, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. At the hearing, you will have the right under the Federal Trade Commission Act to appear and show cause why an order should not be entered requiring you to cease and desist from the violations of law charged in this complaint.

The following is the form of order which the Commission has reason to believe should issue if the facts are found to be as alleged in the complaint. If, however, the Commission should conclude from record facts developed in any adjudicative proceedings in this matter that the proposed order provisions might be inadequate to fully protect the consuming public, the Commission may order such other relief as it finds necessary or appropriate, including corrective advertising or other affirmative disclosure.

Moreover, the Commission has reason to believe that, if the facts are found as alleged in the complaint, it may be necessary and appropriate for the Commission to seek relief to redress injury to consumers, or other persons, partnerships or corporations, in the form of restitution and refunds for past, present, and future consumers and such other types of relief as are set forth in Section 19(b) of the Federal Trade Commission Act. The Commission will determine whether to apply to a court for such relief on the basis of the adjudicative proceedings in this matter and such other factors as are relevant to consider the necessity and appropriateness of such action.

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. "Substantially similar product" shall mean any product that is substantially similar in ingredients, composition, and properties.
3. "ADHD" shall mean Attention Deficit/Hyperactivity Disorder, as defined in American Psychiatric Association, Diagnostic and Statistical Manual of Mental Disorders, (4th ed. 1994).
4. Unless otherwise specified, "respondents" shall mean Natural Organics, Inc., a corporation, its successors and assigns and its officers; Gerald A. Kessler, individually and as an officer of the corporation; and each of the above's agents, representatives, and

employees.

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 respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Pedi-Active A.D.D. or any other food, drug, or dietary supplement, 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, that such product:

- A. will improve the attention span of children who have difficulty focusing on school work;
- B. will improve the scholastic performance of children who have difficulty focusing on school work;
- C. will improve the attention span of children who suffer from ADHD;
- D. will improve the scholastic performance of children who suffer from ADHD; or
- E. can treat or mitigate ADHD or its symptoms;

unless, at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

II.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Pedi-Active A.D.D. or any substantially similar product in or affecting commerce, shall not use the name "A.D.D." or any other name that represents expressly or by implication, that the product can treat or mitigate ADHD or its symptoms unless, at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

III.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, 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, 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, about the health benefits, performance, or efficacy of such product, unless, at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

IV.

Nothing in this order shall prohibit respondents 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.

V.

Nothing in this order shall prohibit respondents 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.

VI.

IT IS FURTHER ORDERED that respondent Natural Organics, Inc., and its successors and assigns, and respondent Gerald A. Kessler 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 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.

VII.

IT IS FURTHER ORDERED that respondent Natural Organics, Inc., and its successors and assigns, and respondent Gerald A. Kessler 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 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. Respondents 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. Respondents shall maintain and upon request make available to the Federal Trade Commission for inspection and copying a copy of each signed statement acknowledging receipt of the order.

VIII.

IT IS FURTHER ORDERED that respondent Natural Organics, Inc. 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.

IX.

IT IS FURTHER ORDERED that respondent Gerald A. Kessler, for a period of ten (10) years after the date of issuance of this order, shall notify the Commission of the discontinuance of his current business or employment, or of his affiliation with any new business or employment. The notice shall include respondent's new business address and telephone number and a description of the nature of the business or employment and his duties and responsibilities. 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.

X.

IT IS FURTHER ORDERED that respondent Natural Organics, Inc., and its successors and assigns, and respondent Gerald A. Kessler 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 they have complied with this order.

XI.

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.

IN WITNESS WHEREOF, the Federal Trade Commission has caused this complaint to be signed by its Secretary and its official seal to be hereto affixed at Washington, D.C. this ninth day of August, 2000.

By the Commission.

Donald S. Clark
Secretary

SEAL:

