UNITED STATES OF AMERICA
BEFORE THE 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

RESPONDENTS' STATEMENT OF THE CASE

INTRODUCTION

Respondents Natural Organics, Inc. ("Natural Organics") and Gerald A. Kessler submit this Statement of the Case, reporting on compliance with discovery and settlement negotiations, and identifying the legal and factual matters to be decided by the Administrative Law Judge.

This case involves the advertising of a dietary supplement product sold by a reputable company with an established history of legal and regulatory compliance. The Federal Trade Commission (FTC) has alleged that Natural Organics and Gerald A. Kessler disseminated, or caused to be disseminated, advertising containing claims for a dietary supplement that lacked a reasonable basis of substantiation, and that the Respondents engaged in unfair or deceptive acts or practices and the making of false

advertisements in violation of Sections 5(a) and 12 of the Federal Trade Commission Act (FTC Act).

At issue in this proceeding are four advertisements for the product "Pedi-Active A.D.D.," a dietary supplement manufactured and distributed by Natural Organics. The advertisements are attached to the Complaint as Exhibits A, B, C, and D, and, except for Exhibit C (which has been modified), continue to be disseminated. Respondents will demonstrate at the Hearing that they possessed a reasonable basis of substantiation to support the claims made for the dietary supplement Pedi-Active A.D.D., at the time the claims were disseminated. In so demonstrating, Respondents will also show that Complaint Counsel are applying an incorrect standard to the substantiation requirement for a dietary supplement effectiveness claim, and are mistaken in their apparent efforts to hold Pedi-Active A.D.D. to a drug standard of proof.

Factual Background

Natural Organics was founded in 1972 by Gerald A. Kessler. The company manufactures dietary supplements for retail sale to consumers through health food stores. Natural Organics' corporate headquarters is located at 548 Broadhollow Road, Melville, New York. Natural Organics employs 260 people. During its almost thirty year history, Natural Organics has not been the subject of any other federal governmental proceeding alleging any violation of the law. In fact, Natural Organics has been a leader in setting quality standards for the dietary supplement industry and has taken a conservative approach in the advertising and promotion of its products.

Mr. Kessler founded Natural Organics out of a keen desire to provide consumers with access to high quality dietary supplements and accurate information concerning the health-related benefits of such products, when used as part of a healthy lifestyle. Mr. Kessler was instrumental in the passage of the Dietary Supplement Health and Education Act of 1994 ("DSHEA") (Pub. L. No. 103-417, 108 Stat. 4325 (1994)), which amended the Federal Food, Drug, and Cosmetic Act ("FDC Act") to create a legal framework for the regulation of dietary supplements in place of the previous ad hoc regulatory policy.

For approximately twenty-nine years, and until his untimely death, Milton A. Bass acted as legal counsel to Respondents. Mr. Bass was a prominent food and drug and FTC lawyer who began practicing law in New York in 1948. During the course of his professional career, spanning some fifty years, Mr. Bass routinely represented many dietary supplement companies and offered legal advice concerning compliance with the FDC Act and the FTC Act. Mr. Bass was a well-known expert in the natural foods/dietary supplement industry, both testifying before Congress and litigating in the courts and before administrative agencies. He was instrumental in the passage of the 1976 amendments to the FDC Act, which curtailed FDA's ability to impose arbitrary restrictions on dietary supplements, and the passage of DSHEA, which further amended the FDC Act to create a legal definition for a "dietary supplement" product. Mr. Bass was also an experienced lawyer in the regulation of prescription and non-prescription drugs. At the time of his death, Mr. Bass was rated by Martindale-Hubbell as a lawyer

with "very high to preeminent legal ability and very high ethical standards," as established by confidential opinions from members of the Bar.[1]

In his long-standing capacity as counsel to Respondents, Mr. Bass provided legal advice to Natural Organics concerning the labeling and advertising of dietary supplements sold by the company. With regard to Pedi-Active A.D.D., Respondents determined that the use in dietary supplement labeling of structure-function claims authorized by DSHEA required legal approval by Mr. Bass prior to the use of the claims. Respondents employed the same policy with respect to the dissemination of the Pedi-Active A.D.D. advertisements at issue in this case to determine compliance with the FTC Act. Jim Gibbons, Natural Organics' Vice President, Research and Development, was primarily responsible for ensuring that proposed claims for the labeling and advertising of dietary supplements sold by Natural Organics were subject to legal review by Mr. Bass prior to their dissemination. Mr. Bass approved the claims made in these advertisements prior to their dissemination.

This case arose out of an access letter issued by the FTC staff on May 21, 1997. Respondents' former counsel, Mr. Bass, engaged in discussions with the FTC staff and provided to the FTC a significant amount of scientific evidence that Natural Organics had in its files that collectively substantiated advertising claims for Pedi-Active A.D.D. The parties were unable to reach a settlement.

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[1] Martindale-Hubbell Lawyer Locator at http://lawyers.martindale.com/Executable/location.php3 (2001).

On August 9, 2000, the Commission issued the Complaint against Natural Organics and Gerald A. Kessler, the Chief Executive Officer and sole owner of Natural Organics. On October 18, 2000, due to the sudden death of Respondents' former counsel, Mr. Bass, Administrative Law Judge (ALJ) James P. Timony granted Respondents a sixty-day stay in the proceedings to locate new counsel and to allow new counsel to become familiar with the matter. Respondents' current counsel, Hyman, Phelps & McNamara, P.C., entered its notice of appearance in this matter on December 1, 2000.

Discovery

As Respondents' new counsel, we readily agreed to Complaint Counsel's proposed modified Discovery and Trial Schedule (Amended Schedule) notwithstanding our unfamiliarity with the case and the need to address numerous critical tasks in an unnaturally compressed period of time. Under the Amended Schedule, discovery is scheduled to close on April 13, 2001. On March 20-22, 2001, Complaint Counsel indicated they would like to postpone the close of discovery, without postponing the Hearing, which is scheduled to begin on June 19, 2001. Respondents' counsel cannot agree to an extension of the discovery period without a postponement of the Hearing date.

Disputes have arisen between Counsel for Respondents and Complaint Counsel concerning the proper scope of discovery and the relevancy of information sought. Some disputes have been resolved by agreement of the parties. Other discovery issues are being negotiated; still others have been the subject of Motions filed with the ALJ.

Respondents' Counsel have made fact witnesses available for deposition. The depositions of five Natural Organics' employees were taken without subpoenas by Complaint Counsel during February 14 to 16, 2001. Respondents also made Gerald Kessler available during the same week, and on March 6, 2001. Complaint Counsel canceled the deposition, the afternoon before it was to occur and, on March 6, 2001, served a subpoena on Respondent Gerald Kessler. On March 19, 2001, Respondents filed a Motion to Quash the Subpoena served on Gerald A. Kessler.

Complaint Counsel has also deposed a raw materials supplier of 2-dimethylaminoethanol (DMAE), one of the ingredients in Pedi-Active A.D.D. Respondents have agreed to Complaint Counsel's requests for depositions of other potential fact witnesses.

On October 3, 2000, Complaint Counsel served upon Respondents' former counsel a Subpoena Duces Tecum containing fifty specifications, to which Respondents replied on January 12 and February 7, 2001 in accordance with the Amended Scheduling Order. Respondents intend to comply fully with the ALJ's Order on Complaint Counsel's Motion to Compel Discovery, issued on March 15, 2001.

Respondents have served one set of interrogatories and a request for production of documents on Complaint Counsel. Respondents find Complaint Counsel's responses to be deficient and will likely file a Motion to Compel, if an agreement with Complaint Counsel regarding these deficiencies cannot be reached.

Respondents intend to depose the three fact and expert witnesses named by Complaint Counsel in this proceeding. Regarding the one fact witness identified by

Complaint Counsel, David T. Read, Supervisory Regulatory Counsel for the FDA's Center for Drug Evaluation and Research (CDER), Respondents seek relevant documents from the FDA, prior to the deposition. A Motion for issuance of subpoenas on FDA was filed on January 26, 2001. On February 12, 2001, the ALJ granted in part, and denied in part, access to the documents, authorizing parts or all of twenty of the twenty-seven specifications sought by Respondents. On March 7, 2001, the FDA filed a Motion to Quash Respondents' Subpoena Duces Tecum. Respondents filed an answer to FDA's Motion to Quash on March 19, 2001.

On March 23, 2001, the date on which revised witnesses lists are to be exchanged by the parties, Respondents will again identify Robert Ullman, Esquire, former law partner of Mr. Bass, as a fact witness. Respondents do not know whether Complaint Counsel will attempt to add additional fact or expert witnesses. Respondents understand that Complaint Counsel intend to depose all of Respondents' expert witnesses in person. The parties are discussing a mutually acceptable deposition schedule.

Factual and Legal Issues to be Decided by the ALJ

Meaning of the Advertisements at Issue

As an initial matter, Your Honor will be asked to ascertain the meaning of the advertisements attached to the Complaint as Exhibits A, B, C, and D and the claims contained therein. The Complaint alleges that 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 [Attention Deficit/Hyperactivity Disorder];

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

E. treat or mitigate ADHD or its symptoms.

An advertisement is deemed to convey a claim if consumers acting reasonably under the circumstances would interpret the advertisement to contain that message. In the Matter of Thompson Medical, Co., 104 F.T.C. 648, 1984 FTC LEXIS 6 at *310 (1984); In the Matter of Cliffdale Associates, Inc., 103 F.T.C. 110, 1984 FTC LEXIS 71 at *104-05. The FTC has concluded that it can address claims that are either express or implied. Thompson Medical at *310. Express claims are ones that unequivocally state the representation at issue. Id. Implied claims are any other claim. Id.

Your Honor has previously ruled, in denying Complaint Counsel's Motion for Partial Summary Decision, that the challenged advertisements do not contain express claims that Pedi-Active A.D.D. will treat or mitigate ADHD or its symptoms; will improve the attention span and the scholastic performance of children who suffer from ADHD; or will improve the attention span and the scholastic performance of children who have difficulty focusing on school work. Order Denying Complaint Counsel's Motion for Partial Summary Decision (Jan. 30, 2001) (Denial of Partial Summary Decision).

Implied claims are, for obvious reasons, more difficult to discern than express claims. Thompson Medical at *311-*312. In evaluating advertisements, the Commission employs two techniques to determine whether implied claims are made – reviewing direct evidence from the advertisement itself, and relying on extrinsic evidence as to what consumers reasonably believe the advertisement to be saying. Id.; Denial of Partial Summary Decision at 3. The Commission has stated that the most useful form of extrinsic evidence is consumer surveys showing what consumers believe the advertisements claim. Thompson Medical at *311-*312.

As Your Honor has previously ruled in the Denial of Partial Summary Decision, and as one of Respondents' expert witnesses, Dr. Ivan Preston, will testify, Respondents did not make any express claims relating to ADHD in the advertising pieces. Moreover, direct evidence of implied claims in the advertising pieces is also lacking. Dr. Preston is eminently qualified to offer an expert opinion regarding what claims are present in advertisements. Dr. Preston has testified or consulted for the Commission regarding advertising claims on at least seven occasions, in addition to the numerous articles he has written regarding advertising regulation by the Commission.

Complaint Counsel has not proffered any consumer surveys – clearly the best type of extrinsic evidence to determine what consumers might reasonably interpret an advertisement to mean. The absence of this extrinsic evidence in a case such as this is striking, particularly since the advertisements at issue are couched in qualified terms, such as "maybe," "sometimes," "many," "can be." Nor are these qualifiers in small print; one of the advertisements notes in large font that "If yelling, begging and pleading

doesn't get your child to do their homework, *maybe* this will." Exhibit A to the Complaint (emphasis added). The other qualifiers appear in the body of the text.

Substantiation of Claims

The Complaint alleges that Respondents did not rely upon a reasonable basis of substantiation to support advertising claims and, therefore, engaged in unfair or deceptive acts or practices. At the Hearing, Respondents will present evidence demonstrating that the claims were substantiated by a reasonable basis of scientific data at the time the claims were made, that the claims and scientific data were reviewed and approved by experienced FTC legal counsel, and that Complaint Counsel will not meet their heavy burden of proof on this issue.

Advertising containing objective product claims must be supported by a reasonable basis of substantiation, while advertising containing a claim that the product is supported by scientific data must have substantiation to the level claimed. See Thompson Medical, at *366; FTC Dietary Supplements Advertising Guide for Industry (1998) ("FTC Guide") at 2.

When, as in this proceeding, an advertisement does not specify a particular level of substantiation for a claim, the Court must determine whether the advertiser possessed, at the time the claim was made, a "reasonable basis" for making the claim. In re Pfizer, 81 F.T.C. 23 (1972); In the Matter of Removatron Int'l Corp., 111 F.T.C. 206, 306 n.20 (1988), aff'd, 884 F.2d 1489 (1st Cir. 1989). According to the FTC, substantiation of a health-related claim for a dietary supplement product requires "competent and reliable scientific evidence." FTC Guide at 6. Such evidence has been defined to 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." Id.

The FTC has emphasized that the "reasonable basis" standard is flexible and must be assessed on a case-by-case basis in light of a number of factors, including: the type of claim, the nature of the product, the consequences of a false claim, the benefits of a truthful claim, the cost of developing substantiation, and the amount of substantiation that experts in the relevant field believe is appropriate. FTC Guide at 6; Removatron, at 306 n.20.

Further, in assessing an advertiser's scientific support, the FTC considers the studies and the views of the experts relied upon by the advertiser, as well as experts retained by Complaint Counsel. Letter from Robert Pitofsky, Chairman, Federal Trade Commission, to the Honorable Dan Burton, Chairman, Committee on Government Reform, 2 (June 14, 2000) ("Burton letter"). As Chairman Pitofsky noted in the Burton letter, "the central question is whether the evidence relied on demonstrates that the product works as claimed." Id. at 2-3. Although the FTC has stated with regard to dietary supplements that "well-controlled human studies" are the most reliable form of evidence, the FTC has also recognized that other types of relevant studies can provide sufficient evidence of substantiation and that clinical studies are not required by law. FTC Guide at 6-10.

Respondents will present substantial testimony that the scientific data in Respondents' possession was more than sufficient to constitute a reasonable basis on which to make the claims in the advertisements for Pedi-Active A.D.D. To that end, Respondents have identified a number of eminently qualified scientific experts with varying backgrounds and areas of expertise who are prepared to testify at the Hearing that representations made for Pedi-Active A.D.D. are supported by a reasonable basis of substantiation, based on these experts' review of scientific materials provided by Respondents' counsel, and their general scientific knowledge and expertise in their fields. The diversity among Respondents' expert witnesses is reflected in the array of disciplines represented, including: nutritional biochemistry and neuroscience; cellular and developmental biology; child and general psychiatry; pediatric, allergy, and preventive medicine; clinical psychology; physiology; pharmacology, neuropharmacology, and pharmacokinetics.

Included among Respondents' scientific expert witnesses are eight medical doctors, four of whom have used either one or both of the dietary ingredients contained in Pedi-Active A.D.D. (i.e., 2-dimethylaminoethanol (DMAE) and phosphatidylserine-enriched lecithin, including related phospholipids) in addressing the behavioral manifestations associated with ADHD, such as inability to focus and difficulty in learning. DMAE and phospholipids are naturally occurring nutrients found in the food supply, in animals, and in the human body, including the brain. DMAE, a biochemical that is closely related to choline, can increase choline in the brain, which is an essential nutrient linked to biochemical processes that specifically support learning, attention and

behavioral control. Phosphatidylserine and other phospholipids are present in every living organism. Phosphatidylserine is concentrated in the human brain (at far higher levels than occur elsewhere), and is essential for facilitating the chemical transmitter systems for acetylcholine and dopamine, both of which are centrally involved in processes regarding attention, learning, and memory. The safety of these ingredients is well established. In short, the experience of clinicians using nutritional supplementation to improve such conditions in children will corroborate the clinical and other scientific evidence relied upon by Respondents to substantiate claims for Pedi-Active A.D.D.

In addition to proffering expert testimony regarding Respondents' substantiating evidence, Respondents' highly qualified experts will offer testimony concerning the controversial nature of ADHD itself. Respondents' experts will establish that there is a sound scientific basis to support the proposition that what is identified in the Diagnostic and Statistical Manual of Mental Disorders, IV (DSM-IV) as a "disorder" is, as the DSM-IV makes clear, more properly understood as a cluster of symptoms with no common biological origin that are generally identified by subjective measures, including observations of teachers and parents.

Respondents' scientific experts will also offer testimony concerning the biochemical bases by which DMAE and phosphatidylserine, along with related phospholipids, affect brain chemistry and the relative composition of biochemicals found in the brain, particularly in areas of the brain that affect attention and learning.

In assessing the level of substantiation that would constitute a reasonable basis for a dietary supplement claim, Complaint Counsel are attempting to apply the wrong

standard: that is, Complaint Counsel are trying to hold a dietary supplement product to a drug standard. As explained below, Respondents will present the expert testimony of Eugene I. Lambert, a preeminent food and drug lawyer, to testify to the appropriate legal standard that should be applied regarding the substantiation of advertising claims for the dietary supplement Pedi-Active A.D.D.

Under the FDC Act, new drugs, i.e., those drugs not generally recognized as safe and effective, or that are so recognized, but have not been marketed for a material time or extent since that recognition, may not be marketed until the sponsor of the new drug proves the safety and effectiveness for any use for the new drug. 21 U.S.C. § 321(p). Proof of safety and effectiveness is shown through "substantial evidence," which is defined as comprising of "adequate and well controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved . . . ." 21 U.S.C. § 355(d). Under most circumstances, FDA requires two adequate and well-controlled studies to approve a new drug. However, the standards for drug approvals have become more flexible in recent years and the Food and Drug Administration Modernization Act of 1997 ("FDAMA") authorizes FDA to approve products on the basis of a single qualified clinical investigation. 21 U.S.C. § 355(d).

Concerned that FDA was regulating dietary supplements as drugs, Congress determined that dietary supplements should be regulated differently. DSHEA amended the FDC Act to expressly permit in dietary supplement labeling certain types of health-related claims called "statements of nutritional support," (commonly known as

"structure-function claims") without premarket approval from the FDA. 21 U.S.C. § 343(r)(6); 21 C.F.R. § 101.93(f). In general, such claims may describe the role and documented mechanism of a dietary ingredient or supplement intended to affect the structure or function of the body and overall well-being. Structure-function claims in dietary supplement labeling may require only post-use notification to FDA, and are subject to the requirement that the responsible company has "substantiation that such statement is truthful and not misleading." 21 U.S.C. § 343(r)(6)(B). In addition to the general requirement that structure-function claims in dietary supplement labeling be notified to FDA, the claim must bear the following statement: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." 21 U.S.C. § 343(r)(6)(C). Unlike drug products, there is no requirement that the claims be substantiated with adequate and well-controlled studies. 21 U.S.C. § 343(r)(6).

Pursuant to section 343(r)(6), on October 21, 1997, Natural Organics submitted a claims notification to FDA for the Pedi-Active A.D.D. dietary supplement and Pedi-Active Spray (that is, for the ingredients (2-dimethylaminoethanol bitartrate (DMAE) and phosphatidylserine-enriched lecithin concentrate (LECI-PS®)) for the label statement "Nutritional Support for the Active Child." In more than three years, the company has not received any objection from FDA regarding the claim for these products.

Significantly, in passing the DSHEA (by unanimous consent in both the Senate and House), Congress specifically found that "the Federal Government should not take any actions to impose unreasonable regulatory barriers in limiting or slowing the flow of

safe products and accurate information to consumers;" and that "legislative action that protects the right of access of consumers to safe dietary supplements is necessary in order to promote wellness." Pub. L. No. 103-417, 108 Stat. 4325-26 (1994). Notwithstanding the clear and unambiguous action by Congress to treat dietary supplements differently than drugs, Complaint Counsel have sought to find a way to import the drug standards into the dietary supplement context.[2]

In fact, the Bureau of Consumer Protection (Bureau) has stated that dietary supplements are "not held to any set of federal standards for quality or purity."[3] This statement is patently false. Dietary supplements are statutorily regulated under the FDC Act, in the exact manner determined by Congress when it enacted DSHEA. This statement illustrates the Bureau's unwillingness to accept the Congressional mandate for the regulation of dietary supplement products.

Proof that Complaint Counsel have confused the requirements for the substantiation of dietary supplement claims with the requirements for approval of new drugs is exemplified by the fact that Complaint Counsel's sole fact witness is David Read, an FDA employee in the Center for Drug Evaluation and Research. Mr. Read is expected to testify for Complaint Counsel about FDA's review of a drug product called "Deaner," which was used to treat childhood behavior and learning problems, and

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2 There are no allegations, by either Complaint Counsel or FDA that Pedi-Active A.D.D. is unsafe.

3 Bureau of Consumer Protection, Federal Trade Commission, Promotions for Kids' Dietary Supplements Leave Sour Taste, FTC Consumer Feature (May 2000), at http://www.ftc.gov/bcp/conline/features/kidsupp.htm.

contained as its active component DMAE, one of the ingredients in Pedi-Active A.D.D. Further, it is anticipated that Mr. Read will testify that FDA approval for Deaner tablets was revoked because the data were insufficient to demonstrate drug efficacy pursuant to the 1962 amendments to the FDC Act.

The problem for Complaint Counsel is that a dietary supplement manufacturer may possess substantiation for structure-function claims even if the data are insufficient to show efficacy as a drug. Complaint Counsel are apparently trying to take action against a dietary supplement product that FDA is not permitted to take on its own because of the applicable standards under DSHEA. FDA recognizes that under DSHEA, substantiation for dietary supplements, unlike drugs, does not require product-specific clinical trials. Nevertheless, Complaint Counsel are attempting to regulate Pedi-Active A.D.D. as a drug by requiring such adequate and well-controlled clinical trials.

Instead, as Respondents will demonstrate at the Hearing, the proper standard to be applied is "sound scientific evidence," which, as the FTC states in the advertising guide to the dietary supplement industry, "provides flexibility in the precise amount and type of support necessary." FTC Guide at 24. According to the Guide, the level of substantiation required for dietary supplement claims is not based on a "fixed formula" concerning the number or type of studies required. The guiding principle concerning the amount and type of evidence sufficient to support a claim is what "experts in the relevant area of study would generally consider to be adequate." Id. at 10. Respondents' claims for Pedi-Active A.D.D. easily meet these substantiation standards.

Scope of the Remedy

Although Respondents are confident that Complaint Counsel will fall short of meeting their heavy burden to prove that the advertisements at issue violated Section 5 of the FTC Act, Respondents will nevertheless address here the relief that the Commission may obtain if Complaint Counsel meets its burden. The Commission has stated that an "advertiser's good faith efforts to comply with the competent and reliable scientific evidence standard are a consideration in determining what action, if any, is appropriate." Burton letter at 3. Respondents will present substantial and unrefuted evidence that they made good faith efforts to comply with the FTC Act.

In particular, we will focus on the proposed Order included in the Complaint, and address the scope of the "fencing-in" provision contained therein.

Paragraph III of the proposed Order states:

> 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.

Respondents will show that any broad fencing-in provision is unwarranted. In order to justify multi-product, or other broad fencing-in provisions, the FTC must consider: (1) the deliberateness and seriousness of Respondents' actions; (2) the ease of

transferability of the practice to other products and practices; and (3) Respondents' past history of unlawful conduct. In the Matter of Metagenics, Inc., 1996 FTC LEXIS 459 at *168 (1996) (citing FTC v. Colgate-Palmolive Co., 380 U.S. 374 (1965); Sears, Roebuck & Co. v. FTC, 676 F.2d 385, 390 (9th Cir. 1982); and Standard Oil Co. v. FTC, 577 F.2d 653, 662 (9th Cir. 1978)).

First, as noted above, the scientific evidence Respondents possessed provided an overwhelming basis on which to make the claims in the advertisements. Clearly, any possible violation of the FTC Act that may have occurred was inadvertent. Respondents acted in good faith in relying on the review of each of the advertisements by Respondents' experienced food and drug and FTC counsel, Milton Bass. Mr. Bass had more than fifty years of experience representing the dietary supplement industry in regulatory and litigation matters involving FDA and FTC, and was well-qualified to render legal opinions regarding advertising claims.

Nor was any violation serious. Unlike the "parade of horribles" addressed in the FTC Guide that many unscrupulous advertisers engage in, Respondents' advertisements do not contain claims that famous people endorsed the product; the product is approved by a government agency; the product is supported by government sponsored research; hundreds or thousands of children have benefited; or that the efficacy of the product is scientifically proven.

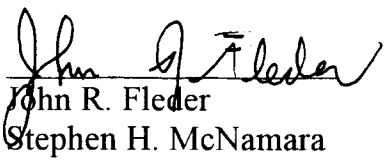
As Dr. Preston will testify, the challenged claims and practices are not easily transferable to other products. The claims generally focus on "active children" and include details regarding homework and school, or are so product-specific that they

cannot be readily transferred to other products. These claims are not easily transferable to most, if not all, of Respondents' other products.

Finally, Respondents do not have a history of unlawful conduct. This is the first time Respondents have been challenged by any of the federal agencies responsible for regulating dietary supplements. Although Respondents do not believe a fencing-in provision is legally warranted, if your Honor disagrees, any fencing-in provision should be narrow.

Dated: March 23, 2001

Respectfully submitted,



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CERTIFICATE OF SERVICE

I hereby certify that on this twenty-third day of March 2001 a copy of the foregoing Respondents' Statement of the Case was served by facsimile transmittal and first-class mail, postage prepaid, on the following parties:

Matthew D. Gold, Esq.
Kerry O'Brien, Esq.
Dean Graybill, Esq.
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901 Market Street, Suite 570
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and two copies were hand delivered to :

Judge James P. Timony
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