

In the Matter of

NATURAL ORGANICS, INC.
a corporation, and

NAULI GABRIELIANUS, INC.

)
)
)
)
Docket No. 9294

individually and as an officer
of the corporation

RESPONDENTS' STATEMENT OF THE CASE

INTRODUCTION

Respondents Natural Organics, Inc. ("Natural Organics") and Gerald A. Kessler
and factual matters to be decided by the negotiations, and identifying the legal

Administrative Law Judge.

This case involves the advertising of a dietary supplement product sold by respondents
Federal Trade Commission (FTC) has alleged that Natural Organics and Gerald A.
for a Kessler disseminated, or caused to be disseminated, advertising containing claims

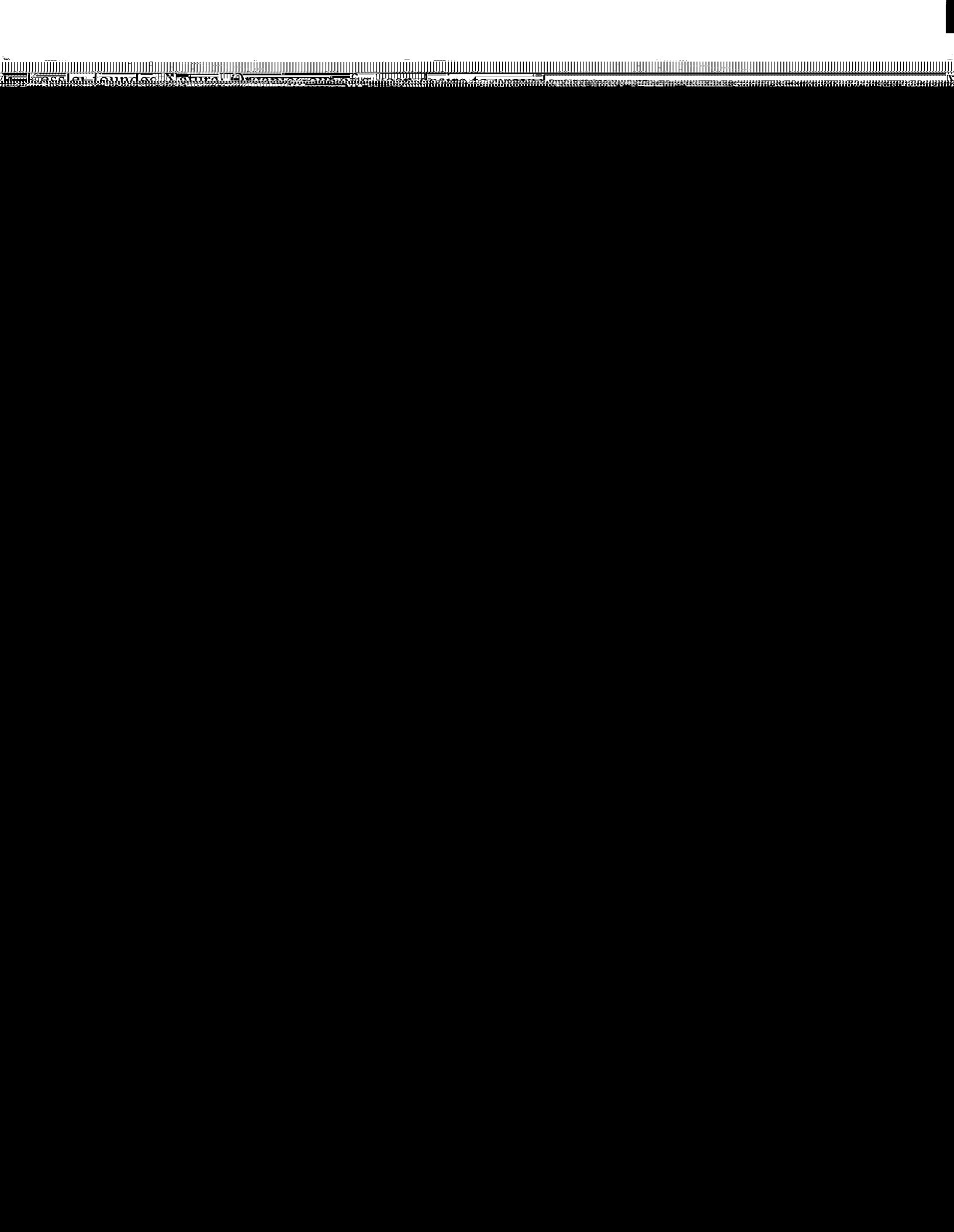
Respondent's

(FC Act)

(F

Product: Pedit-Active

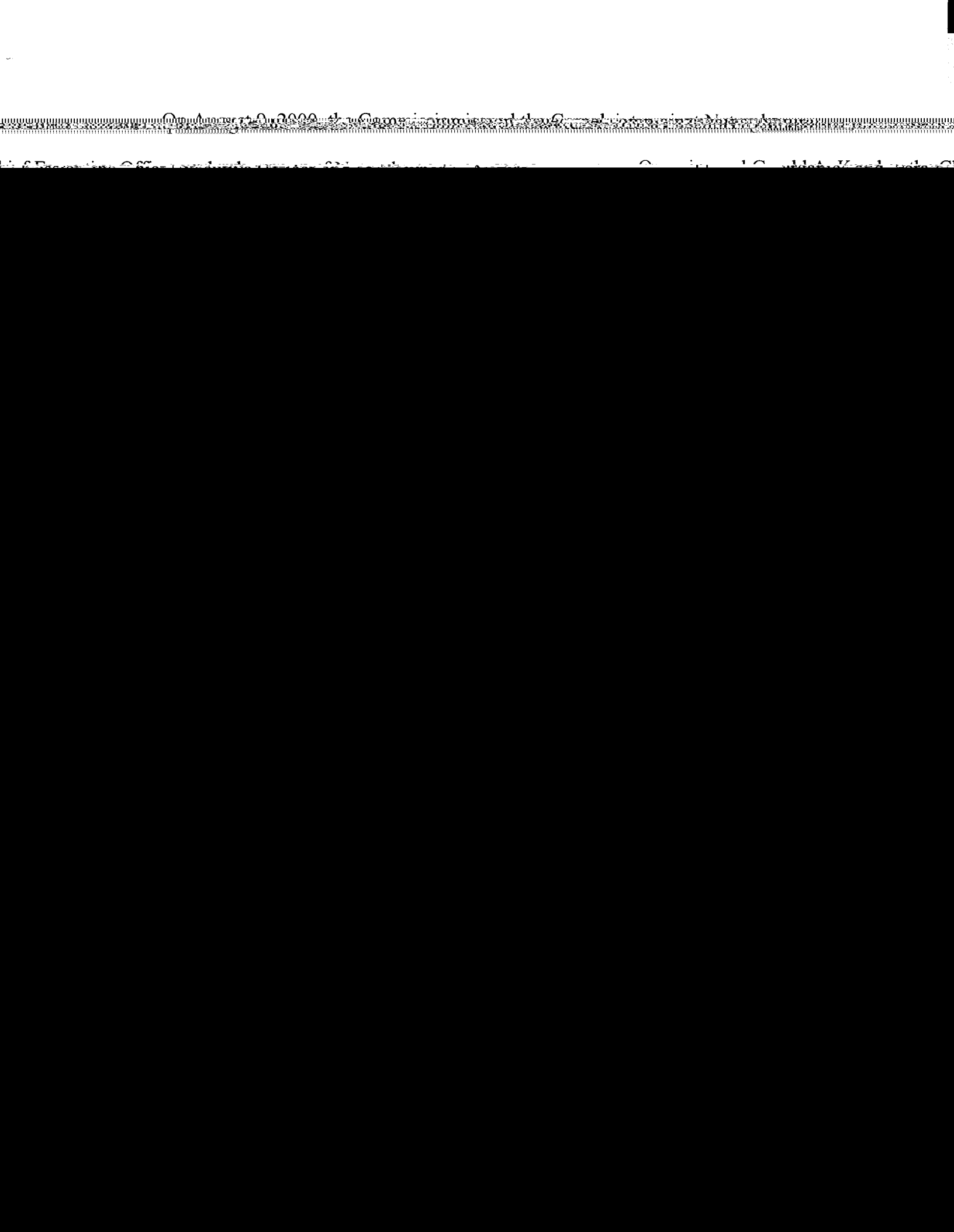
At issue in this proceeding are four advertisements for the prod



with "very high to preeminent legal ability and very high ethical standards" as

published by the National Commission on the Causes and Prevention of Errors

Joseph P. ... M. B. ... D. H. ... In the law center ...



Respondents' Counsel have made fact witnesses available for deposition. The

depositions of five Natural Organics employees were taken

on March 6, 2001. Respondent's Counsel also obtained a deposition of

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position. A Motion for issuance of subpoenas on FDA was filed from the FDA, prior to the deposition.

February 12, 2001, the ALJ entered in part and decided the motion filed on January 26, 2001. On

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Motion to Quash on March 19, 2001

On March 19, 2001, Respondent filed a Motion to Quash the subpoenas issued on February 12, 2001.

Respondent's Motion to Quash is based on the grounds that the subpoenas are overly broad and unduly burdensome.

Respondent argues that the subpoenas seek information that is not relevant to the issues in this case.

Respondent also argues that the subpoenas are unduly burdensome because they require the production of a large volume of documents.

Respondent's Motion to Quash is denied. The ALJ finds that the subpoenas are relevant and not unduly burdensome.

The parties are directed to bring a mutually acceptable schedule for the deposition.

Factual and Legal Issues to be Decided by the ALJ

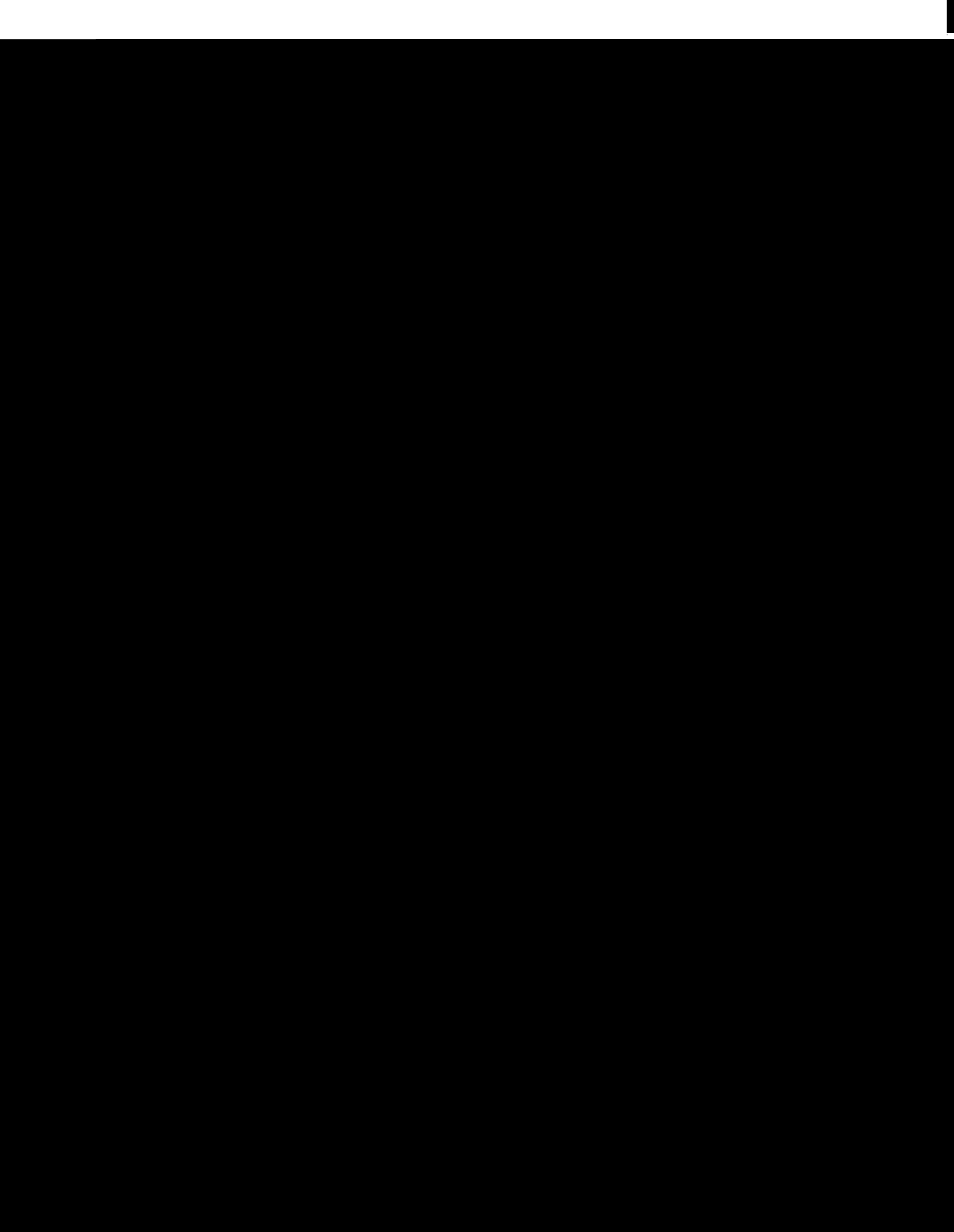
D. improve the scholastic performance of children with
focusing on school work;

Deficit/Hyperactivity Disorder];

D. improve the scholastic performance of children with
and

E. treat or mitigate ADHD or its symptoms

advertisement is deemed to convey a claim if consumers act reasonably



and reliable results. ic.

The FTC has emphasized that the “market” has been analyzed in a “reasonable” manner.

has assessed each case on a case-by-case basis in light of a number of factors, including the nature

of the market, the nature of the product,

Respondents' possession was more than sufficient to constitute a violation of the law, which to make the claims in the advertisement for Daily Active is a D. B. 2. The advertisement is not a true and accurate representation of the product.

which to make the claims in the advertisement for Daily Active is a D. B. 2. The advertisement is not a true and accurate representation of the product.

Respondents have identified a number of eminent, qualified, and experienced individuals who have used the product and have provided their names and contact information to the respondents.

Phenethylamine and other amphetamine-like substances - behavioral control
of aggression, anxiety, and depression. The role of the organism in the control of

systems for acetylcholine and dopamine, both of which are centrally involved in

processed, regarding attention, learning, and memory.

experience of children with attention deficit disorder (ADD) is well established. In short, the

such children will contribute to the clinical and educational to improve such conditions.

combine parameters for a better understanding of the evidence relied on
to proffering expert testimony regarding Respondents' substantiation. In addition

"structure function claims") without reciting the structure, material, or acts of the prior art.

3(f) In general, such claims may describe the role and function of the element, and the element's relationship to other elements, and may include the name of the element, the name of the element's parent, and the name of the element's child. § 343(r)(6); 21 C.F.R. § 101.9

claims that describe the role and function of the element, and the element's relationship to other elements, and may include the name of the element, the name of the element's parent, and the name of the element's child.

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to consumers? and that "safe products and accurate information" are essential to a free market.

protects the rights of consumers of agricultural products.

the clear and unambiguous action by Congress to create a distinct and separate agency

into the dairy supplement context.

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Although dependent on the quality of the data, the results are

transferability of the practice to other products and practices; and (2) Respondents' next

CERTIFICATE OF SERVICE

...hereby
...statement of the case was served by

Matthew L. Gordon, Esq.

Nery E. Sten, Esq.
Dean Graybill, Esq.

Federal Trade Commission

901 Market Street, Suite 570
San Francisco, CA 94102

Two copies were hand delivered to

Judge James P. Timony
Administrative Law Judge

Federal Trade Commission
600 Pennsylvania Avenue, N.W.

[Handwritten Signature]

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