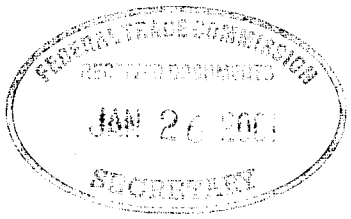
UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION



In the Matter of NATURAL ORGANICS, INC., a corporation, and GERALD A. KESSLER, individually and as an officer of the corporation.	)	Docket No. 9294

RESPONDENTS' MOTION FOR ISSUANCE OF A SUBPOENA AD TESTIFICANDUM FOR THE APPEARANCE FOR DEPOSITION OF DAVID T. READ, SUPERVISORY REGULATORY COUNSEL FOR THE CENTER FOR DRUG EVALUATION AND RESEARCH OF THE U.S. FOOD AND DRUG ADMINISTRATION

Pursuant to § 3.34 and § 3.36 of the Federal Trade Commission Rules of Practice, 16 C.F.R. §§ 3.34, 3.36, Respondents Natural Organics, Inc. and Gerald A. Kessler hereby move for an Order authorizing the issuance of a subpoena ad testificandum for the appearance for deposition of David T. Read, Supervisory Regulatory Counsel for the Center for Drug Evaluation and Research of the U.S. Food and Drug Administration ("FDA"). Respondents request that Mr. Read be ordered to appear for deposition on February 21, 2001, at 9:00 a.m. at the offices of Hyman, Phelps & McNamara PC, 700 Thirteenth Street, N.W., Suite 1200, Washington, D.C. 20005.

On January 8, 2001, Complaint Counsel provided notice that it contemplates calling Mr. Read as a fact witness to testify as to FDA's regulation of a product containing deanol that was marketed prior to June 23, 1983, by Riker Laboratories, Inc. under an approved new drug application. Deanol, whose chemical name is 2-dimethylaminoethanol, is one of the ingredients in the dietary supplement products marketed by the Respondents, whose advertising is the subject of this proceeding.

Complaint Counsel has agreed to allow Respondents to depose Mr. Read on February 21, 2001. Nevertheless, Respondents request that a subpoena ad testificandum be issued as a protective measure in order to ensure that they will be able to take Mr. Read's deposition should circumstances change.

The bases of this motion are set forth in the accompanying Memorandum in Support of Motions for the Issuance of a Subpoena Ad Testificandum for the Appearance of David T. Read and of a Subpoena Duces Tecum to the Center for Drug Evaluation and Research of the U.S. Food and Drug Administration. As a courtesy, Respondents have served a copy of this motion on Mr. Read at the Center for Drug Evaluation and Research.

Dated: January 26, 2001

Respectfully Submitted,

John R. Fleder
Stephen H. McNamara
A. Wes Siegner
Holly M. Bayne
HYMAN, PHELPS & MCNAMARA, P.C.
700 13th Street, N.W.
Suite 1200
Washington, D.C. 20005
(202) 737-5600
(202) 737-9329 (FAX)

Attorneys for Respondents
Natural Organics, Inc. and Gerald A. Kessler

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

RESPONDENTS' MOTION
FOR THE ISSUANCE OF A SUBPOENA DUCES TECUM
TO THE CENTER FOR DRUG EVALUATION AND RESEARCH
OF THE U.S. FOOD AND DRUG ADMINISTRATION

Pursuant to § 3.36 of the Federal Trade Commission Rules of Practice, 16 C.F.R. § 3.36, Respondents Natural Organics, Inc. and Gerald A. Kessler hereby move for an Order authorizing the issuance of a subpoena duces tecum to the Center for Drug Evaluation and Research of the U.S. Food and Drug Administration ("FDA") calling for the production of those categories of documents identified in the appended subpoena (see Attachment A). The Respondents require the documents to prepare for a deposition that is scheduled for February 21, 2001, of an FDA representative who has been identified by Complaint Counsel as a fact witness. Respondents request that the Center for Drug Evaluation and Research be ordered to respond to the subpoena duces tecum by February 16, 2001, which is five days before the scheduled deposition. Complaint Counsel has

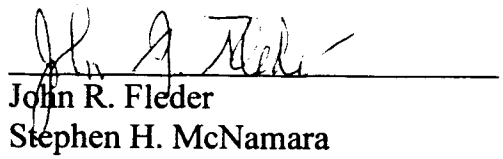
indicated that it will not oppose a deposition of the witness. However, Complaint Counsel has not seen or commented on this subpoena duces tecum.

On January 8, 2001, Complaint Counsel provided notice that it contemplates calling David T. Read, Supervisory Regulatory Counsel with the Center for Drug Evaluation and Research at FDA, as a fact witness to testify as to FDA's regulation of a product containing deanol that was marketed prior to June 23, 1983, by Riker Laboratories, Inc. under an approved new drug application. Deanol, whose chemical name is 2-dimethylaminoethanol, is one of the ingredients in the dietary supplement products marketed by the Respondents, whose advertising is the subject of this proceeding.

The bases of this motion are set forth in the accompanying Memorandum in Support of Motions for the Issuance of a Subpoena Ad Testificandum for the Appearance of David T. Read and of a Subpoena Duces Tecum to the Center for Drug Evaluation and Research of the U.S. Food and Drug Administration. Respondents have served a copy of this Motion on Mr. Read at the Center for Drug Evaluation and Research.

Dated: January 26, 2001

Respectfully Submitted,



John R. Fleder
Stephen H. McNamara
A. Wes Siegner
Holly M. Bayne
HYMAN, PHELPS & MCNAMARA, P.C.
700 13th Street, N.W.
Suite 1200
Washington, D.C. 20005
(202) 737-5600
(202) 737-9329 (FAX)

Attorneys for Respondents
Natural Organics, Inc. and Gerald A. Kessler

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

RESPONDENTS' MEMORANDUM IN SUPPORT OF MOTIONS FOR THE ISSUANCE OF A SUBPOENA AD TESTIFICANDUM FOR THE APPEARANCE OF DAVID T. READ FOR DEPOSITION AND OF A SUBPOENA DUCES TECUM TO THE CENTER FOR DRUG EVALUATION AND RESEARCH OF THE U.S. FOOD AND DRUG ADMINISTRATION

Pursuant to § 3.36 of the Federal Trade Commission ("FTC") Rules of Practice, 16 C.F.R. § 3.36, Respondents Natural Organics, Inc. and Gerald A. Kessler submit this Memorandum in Support of Motions for the Issuance of a Subpoena Ad Testificandum for the Appearance of David T. Read for Deposition and of a Subpoena Duces Tecum to the Center for Drug Evaluation and Research ("CDER") of the U.S. Food and Drug Administration ("FDA").

ARGUMENT

Respondents Should Be Permitted To Seek The Appearance of David T. Read Via Subpoena Ad Testificandum And To Seek The Requested Documents From CDER Via A Subpoena Duces Tecum Because Complaint Counsel Has Identified Mr. Read As A Fact Witness Who Will Provide Testimony In This Case And CDER Is The Custodian Of All Documents Relevant To Mr. Read's Testimony.

Section 3.36 of the FTC's Rules of Practice expressly authorizes the issuance of subpoenas ad testificandum and duces tecum upon other governmental agencies in the context of an FTC administrative proceeding. 16 C.F.R. § 3.36(a). Subpoenas directed to other governmental agencies must satisfy the following three-part showing:

1. the material sought is reasonable in scope;

2. if for the purposes of discovery, the material falls within the limits of discovery under § 3.31(b)(1); and

3. the information or material sought cannot reasonably be obtained by other means.

16 C.F.R. § 3.36(b). Section 3.31(b)(1) of the FTC Rules of Practice references § 3.31(c)(1), which limits discovery "to the extent that it may be reasonably expected to yield information relevant to the allegations of the complaint, to the proposed relief, or to the defenses of any respondent." 16 C.F.R. § 3.31(c)(1).

Respondents' proposed subpoenas satisfy these criteria. On January 8, 2001, Complaint Counsel provided notice that it contemplates calling David T. Read, Supervisory Regulatory Counsel with CDER as a fact witness in this proceeding. Complaint Counsel has represented that Mr. Read will testify about FDA's regulation of

Deaner Tablets, a drug product containing deanol that was lawfully marketed by Riker Laboratories, Inc. ("Riker") before June 23, 1983. According to FDA, as stated in Complaint Counsel's proposed stipulations, Riker marketed Deaner Tablets with the following labeled indications:[1]

1. Learning problems -- learning in deficit of that usually associated with apparent level of intelligence, including I.Q. Reading difficulties. Shortened attention span.

2. Behavior problems -- hyperkinetic behavior problem syndrome characterized by distractibility, motor disinhibition, dissociation, and perseveration.

3. Or, as more frequently encountered, hyperkinetic behavior and learning disorders incorporating varying combinations of both of the above. Under-achievers. Reading and speech difficulties. Impaired motor coordination. Hyperactive, impulsive/compulsive behavior, often described as asocial, antisocial, delinquent, stimulus-governed.

The chemical name for deanol, which is also known as deanol acetamindobenzoate or DMAE, is 2-dimethylaminoethanol. DMAE is one of the ingredients in the dietary supplement products that are marketed by the Respondents and whose advertising is the subject of this proceeding.

On January 17, 2001, Complaint Counsel elaborated on Mr. Read's proposed testimony by proposing stipulations.[2] The Respondents have not agreed to the stipulations. Complaint Counsel, through the proposed stipulations, represents that Mr.

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[1] Complaint Counsel's Proposed Stipulations, January 17, 2001, appended as Attachment A.

[2] See Attachment A.

Read will testify on a broad range of subjects, including: (1) that FDA approved an NDA for Riker's Deaner Tablets in 1958 exclusively on the basis of its safety for use under the conditions prescribed, recommended, or suggested in the product's labeling; (2) that an expert panel of the National Academy of Sciences/National Research Council Drug Efficacy Study Group ("NAS/NRC Panel") reviewed the Deaner Tablets product for efficacy pursuant to the requirements of the 1962 Kefauver-Harris Drug Amendments to the Federal Food, Drug, and Cosmetic Act of 1938; (3) that the NAS/NRC Panel concluded that the Deaner Tablets product was only "possibly effective" and that in 1970 FDA agreed with this assessment; (4) that in response to the NAS/NRC Panel's conclusion and FDA's concurrence, Riker submitted deanol studies to FDA; (5) that FDA determined that the deanol studies were insufficient to establish the efficacy of Deaner Tablets; (6) that after considering the available evidence, FDA concluded that the Deaner Tablets product is not effective for its intended use; and (7) that as a result, in 1983 FDA denied Riker a hearing on the matter and withdrew its approval of the NDA for Deaner Tablets.

Although Complaint Counsel has not stated this directly, the clear inferences that Complaint Counsel can be expected to attempt to draw from Mr. Read's testimony are: (1) that FDA has determined that deanol is not effective in the treatment or mitigation of symptoms now commonly associated with Attention Deficit Disorder/Attention Deficit Hyperactivity Disorder ("ADD/ADHD"); (2) that FDA's prior determination concerning the lack of effectiveness for deanol, and the subsequent withdrawal of Riker's NDA for

Deaner Tablets, is relevant to the issue of a related performance claim for a dietary supplement containing DMAE (i.e., deanol); and, further (3) that any product that contains deanol and is intended for the treatment, mitigation, or to otherwise affect ADD/ADHD or its symptoms must have an approved new drug application before it can be marketed lawfully.

Insofar as the FTC has expressly relied upon FDA's determination concerning deanol to assert that Respondents' advertising claims for dietary supplement products containing DMAE are not supported by credible scientific evidence, it is imperative that Respondents be allowed to obtain from FDA all documents related to the agency's regulation of Riker's Deaner Tablets and of any other products containing deanol as an active ingredient. Respondents must have access to these documents in order to assess the significance, rigorousness, and applicability of the deanol studies and of the NAS/NRC Panel and FDA's analysis of the studies, and to rebut any inferences that Complaint Counsel might seek to draw from FDA's regulation of a product containing deanol nearly twenty years ago. Similarly, Respondents must be able to depose Mr. Read in advance of any testimony that he might give in this proceeding in order to understand and probe the parameters of his likely testimony.

The documents requested in the Respondents' subpoena duces tecum,[3] and the

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[3] Respondents' proposed subpoena duces tecum is appended as Attachment B. Respondents have not provided a completed subpoena duces tecum form for the signature of the Secretary of the FTC because they were unsuccessful in their attempts to obtain the form from the Secretary's office.

deposition of Mr. Read sought in their subpoena ad testificandum, are directly relevant to the allegations raised in the FTC's compliant, to Complaint Counsel's prosecution of this case, and to the Respondents' prospective defenses. The Respondents' document requests also are drafted with particularity, are extremely focused, and will only require FDA to search for responsive documents in discrete, easily identifiable files at the agency. The first category of documents listed in the subpoena duces tecum is limited to discovery of materials related to the positions that Mr. Read held at FDA for the period during which the agency considered the efficacy of deanol. The second through sixth categories of documents requested in the subpoena are limited to documents related to the NAS/NRC Panel's evaluation of the efficacy of Deaner Tablets, and of FDA's analysis of the NAS/NRC Panel's conclusions. The seventh through ninth categories of documents are limited to those related to FDA's analysis of deanol studies submitted to the agency by Riker. The tenth through seventeenth categories of documents are limited to those related to the Federal Register notices through which FDA regulated the Deaner Tablets product. The eighteenth through twentieth categories are limited to documents related to any other products containing deanol that FDA might have regulated. Finally, the twenty-first through twenty-seventh categories are limited to documents that are probative of the program under which FDA determined the efficacy of Riker's Deaner Tablets product, and of the agency's contemporaneous understanding of ADD/ADHD.

Finally, Respondents' subpoena requests are appropriate because the information sought therein cannot be obtained by any other means.[4] Complaint Counsel has represented that Mr. Read was integrally involved in FDA's regulation of the Deaner Tablets product, and Respondents have no way of ascertaining the exact parameters of his knowledge and likely testimony absent an opportunity to depose him. The FDA, not surprisingly, is the custodian of the documents requested in the Respondents' subpoena duces tecum. The testimony that Complaint Counsel seeks to elicit from Mr. Read involves a drug product that was regulated almost 20 years ago in an environment that preceded passage of the Dietary Supplement Health and Education Act. If documents exists that will allow Respondents to rebut or otherwise refute Mr. Read's testimony and any inferences that the Complaint Counsel may seek to derive from that testimony, they will be found in the files of the FDA.

CONCLUSION

For the foregoing reasons, Respondents respectfully request that their Motions for the Issuance of a Subpoena Ad Testificandum for the Appearance of David T. Read for Deposition and of a Subpoena Duces Tecum to the Center for Drug Evaluation and Research of the U.S. Food and Drug Administration be granted in all respects.

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[4] Respondents theoretically could seek to secure the documents covered by the proposed subpoena duces tecum through Freedom of Information Act requests. However, Respondents have not pursued this avenue because they have no reasonable hope of receiving the documents in advance of Mr. Read's scheduled deposition, given the current backlog of pending Freedom of Information requests at FDA.

Dated: January 26, 2001

Respectfully Submitted

John R. Fleder
Stephen H. McNamara
A. Wes Siegner
Holly M. Bayne
HYMAN, PHELPS & MCNAMARA, P.C.
700 13th Street, N.W.
Suite 1200
Washington, D.C. 20005
(202) 737-5600
(202) 737-9329 (FAX)

Attorneys for Respondents
Natural Organics, Inc. and Gerald A. Kessler

ATTACHMENT A

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WESTERN REGION

901 Market Street, Suite 570
San Francisco, CA 94103-1768
Voice: (415) 356-5276
Fax: (415) 356-5242

Matthew D. Gold
Attorney

January 17, 2001

VIA FACSIMILE

John R. Fleder, Esq.
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W.
Washington, D.C. 20005-5929

Re: Natural Organics, Inc., *et al.*
Docket No. 9294

Dear Mr. Fleder:

As I stated in my letter of January 8, 2001, complaint counsel contemplate calling David T. Read, Supervisory Regulatory Counsel with the Center for Drug Evaluation and Research at the FDA, as a fact witness. We intend to use Mr. Read for the limited purpose of explaining the FDA's involvement in the regulation of deanol.

As I have repeatedly stated, I do not anticipate that Mr. Read's testimony will be either extensive or controversial. Accordingly, we have prepared the attached set of stipulations that we hope can obviate the need for Mr. Read's testimony. These stipulations constitute the sum and substance of Mr. Read's intended testimony.

Please note that we are proffering Mr. Read as a fact witness. He is not a scientist, and is therefore not competent to testify regarding the merits of any purported substantiation materials.

Please call me once you have had a chance to review the proposed stipulations.

Very truly yours,

Matthew D. Gold

Matthew D. Gold

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

TO: The Honorable James P. Timony
Chief Administrative Law Judge

Complaint counsel and counsel for respondents agree and stipulate as follows:

FDA DRUG REGULATORY HISTORY

1. In 1938, Congress passed the Federal Food, Drug, and Cosmetic Act ("FDCA") of 1938, which among other things, required drug manufacturers to show that new drugs were safe before marketing them. Before marketing a new drug, a manufacturer had to perform studies to demonstrate the safety of the drug and submit these studies to the Food and Drug Administration ("FDA") as part of a new drug application ("NDA"). Prior to passage of the FDCA of 1938, drug marketers did not obtain approval from the FDA before marketing their products.

2. In 1962, the Kefauver-Harris Drug Amendments to the FDCA ("1962 Amendments") were passed to ensure drug efficacy and greater drug safety. Among other things, the 1962 Amendments required a drug manufacturer to submit to the FDA, as part of the NDA for a new drug, substantial evidence of the effectiveness of the new drug for which the NDA was submitted. Moreover, the law was retroactive in its effect. That is, manufacturers were required to submit evidence of, and the FDA had to review, the efficacy of all drugs that had been approved on the basis of only safety between 1938 and 1962.

3. Under the 1962 Amendments, manufacturers were given two years to develop sustantial evidence of effectiveness. To aid FDA in its task of fulfilling the statutory mandate to review the effectiveness of the thousands of drugs approved between 1938 and 1962, the FDA contracted with the National Academy of Sciences/National Research Council (NAS/NRC) to convene panels of experts to review available material relating to the efficacy of these drugs. This large undertaking by the NAS/NRC was known as the Drug Efficacy Study. The 30 panels convened

had six members each, and were formed on the basis of organ systems and categories of disease. One such panel was the Panel on Psychiatric Drugs.

FDA AND DEANER TABLETS

4. In 1958, the FDA approved the application (NDA 11-417) of Riker Laboratories, Inc., for Deaner Tablets. Deaner contained as its only labeled active ingredient deanol (2-dimethylaminoethanol) as the para-acetamidobenzoic acid salt. The 1958 approval of NDA 11-417 indicates that Riker had submitted sufficient evidence on which the FDA could base a finding that Deaner was safe for use under the conditions prescribed, recommended or suggested in the labeling Riker proposed in the NDA. This 1958 approval in no way consititutes any finding by FDA with respect to Deaner's efficacy.

5. Because Riker's NDA for Deaner Tablets had been approved prior to 1962, Deaner was among the thousands of drug products on the market that the FDA was required to review for efficacy as a result of the 1962 Amendments.

6. The NAS/NRC expert panel that was assigned Deaner Tablets was the Panel on Psychiatric Drugs.

7. The Panel on Psychiatric Drugs reviewed all available material to determine whether there was substantial evidence of the effectiveness of Deaner Tablets for any of its labeled indications. The Panel reviewed the following labeled indications for Deaner Tablets:

a. Learning problems -- learning in deficit of that usually associated with apparent level of intelligence, including I.Q. Reading difficulties. Shortened attention span.

b. Behavior problems -- hyperkinetic behavior problem syndrome characterized by distractibility, motor disinhibition, dissociation, and perseveration.

c. Or, as more frequently encountered, hyperkinetic behavior and learning disorders incorporating varying combinations of both of the above. Under-achievers. Reading and speech difficulties. Impaired motor coordination. Hyperactive, impulsive/compulsive behavior, often described as asocial, antisocial, delinquent, stimulus-governed.

8. In a notice (DESI 9366) published in the Federal Register of May 15, 1970 (35 Fed. Reg. 7616), the FDA evaluated and concurred in reports received from the NAS/NRC's Panel on Psychiatric Drugs, and concluded that Deaner Tablets was possibly effective for its labeled indications. (The NAS/NRC rating system categorized drugs as "effective," "effective but," "probably effective," "possibly effective," or "ineffective.")

9. In response to the 1970 Federal Register notice, Riker submitted three complete studies on Deaner Tablets. Those studies were: (a) Oettinger, L., "A Double-Blind Study of

Dimethylaminoethanol (Deaner) and Placebo in Children with Minimal Brain Dysfunction," unpublished, 1971 (Riker Number 546-054); (b) Duncan, C., "Double-Blind Study of the Effects of Deaner (2-Dimethylaminoethanol) and Placebo on the Attention Span of Children with the Hyperkinetic Syndrome," unpublished, 1971 ((Riker Number 546-055); and (c) Lewis, J. A., and R. Young, "Deanol and Methylphenidate in Minimal Brain Dysfunction," Clinical Pharmacology and Therapeutics, 17(5):534-40, 1975 (Riker Number 546-056). Partial results of a fourth study (Riker Number 546-057) were submitted. (Full results were submitted later, and the study was published: Coleman, N., P. Dexheimer, A. DiMascio, W. Redman, and R. Finnerty, "Deanol in the Treatment of Hyperkinetic Children," Psychosomatics, 17:69-72, 1976.)

10. In a Federal Register notice published on January 8, 1975 (40 Fed. Reg. 1533), the Director of the Bureau of Drugs (later the National Center for Drugs and Biologics, and now the Center for Drug Evaluation and Research) evaluated those four studies and concluded that they did not constitute substantial evidence of effectiveness. Accordingly, the Director proposed to withdraw approval of the NDA for Deaner Tablets and offered Riker an opportunity for a hearing.

11. On February 3, 1975, Riker requested a hearing, and on March 5, 1975, submitted the material on which it relied to justify a hearing.

12. On July 19, 1982, having reviewed the material in Riker's 1975 hearing request, finding that it did not constitute substantial evidence of effectiveness, and concluding that summary judgment was appropriate (21 CFR 314.200(g)(3)), the Director of the National Center for Drugs and Biologics provided Riker an opportunity to comment on a proposed summary judgment order denying a hearing and withdrawing approval of Deaner Tablets.

13. On September 14, 1982, Riker responded to the proposed order by submitting the results of a 1975 study, "Deanol vs. Placebo in Hyperactive Children," by James A. Lewis and Barbara S. Lewis, in which the investigators found no significant differences between Deaner and placebo. With respect to the proposed summary judgment order, Riker did not dispute the FDA's criticisms of the data previously submitted, but maintained without explanation that the data were not afforded an adequate and fair medical review.

14. In 1983, the Commissioner of Food and Drugs denied Riker's request for a hearing and withdrew approval of the NDA for Deaner Tablets. After reviewing each of the studies that Riker submitted, the Commissioner concluded that the drug lacked substantial evidence of effectiveness for its labeled indications. See FDA, "Deanol Acetamidobenzoate; Withdrawal of Approval of New Drug Application," 48 Fed. Reg. 23307 (May 24, 1983) (attached). This order became effective June 23, 1983.

15. Since June 23, 1983, it has been illegal to distribute a drug product containing deanol in interstate commerce without an approved new drug application.

16. The FDA has never approved as effective any drug product containing deanol.

STIPULATED AND AGREED:

Matthew D. Gold
Kerry O'Brien
Federal Trade Commission
901 Market Street, Suite 570
San Francisco, CA 94103
(415) 356-5276
(415) 356-5244 (FAX)

Complaint Counsel

John R. Fleder
Stephen H. McNamara
A. Wes Siegner
Holly M. Bayne
Hyman, Phelps & McNamara, P.C.
700 13th Street, N.W., Suite 1200
Washington, D.C. 20005
(202) 737-5600
(202) 737-9329 (FAX)

Counsel for Respondents

ATTACHMENT B

DEFINITIONS

1. The term "communication" shall mean any written or oral disclosure, transfer, or exchange of information or opinion, however made.

2. The term "document," "documents" or "documentation" shall have the meaning ascribed to them by 16 C.F.R. § 3.34(b), and shall also include, without limitation, originals, masters and every copy of writings and printed, typed and other graphic or photographic matter, including microfilm of any kind or nature, recordings (tape, diskette or other) of oral communications, other data compilations and every other tangible thing from which information can be obtained, including, without limitation, magnetic or electronic media, in the possession, custody or control of complainant or any present or former officer, employees or agents thereof, or known by complainant to exist. The term "document" or "documents" shall include, without limiting the generality of the foregoing, all computer files, electronic mail, letters, telegrams, teletypes, correspondence, contracts, agreements, notes to the files, notebooks, reports, memoranda, mechanical and electronic sound recordings or transcripts thereof, blueprints, flow sheets, formal or information drawings or diagrams, calendar or diary entries, memoranda of telephone or personal conversations of meetings or conferences, studies, reports, interoffice communications, price lists, bulletins, circulars, statements, manuals, summaries of compilations, minutes of meetings, maps, charts, graphs, order papers, articles, announcements, books, catalogs, records, tables, books of account, ledgers, vouchers, canceled checks, invoices or bills. A draft or non-identical copy is a separate document within the meaning of this term.

3. The term "CDER," "you" or "your" shall mean the Center for Drug Evaluation and Research of the United States Food and Drug Administration ("FDA"), including without limitation its predecessors, units or sub-units however named, employees, scientists, technicians, agents, examiners, laboratories, consultants, special government employees, and any other persons acting or purporting to act on its behalf.

4. "David T. Read" shall mean Mr. David T. Read, presently Regulatory Counsel with the Center for Drug Evaluation and Research at FDA.

5. The term "Riker" shall mean Riker Laboratories, Inc., formerly located at 19901 Nordhoff Street, Northridge, CA 91324, and currently located at 3M Center, St. Paul, MN 55144-1000.

6. The term "NDA" shall mean new drug application.

7. The terms "deanol" and "deanol acetamindobenzoate" shall mean the substance whose chemical name is 2-dimethylaminoethanol.

8. The term "Deaner Tablets" shall mean the drug product containing deanol that was formerly marketed by Riker Laboratories, Inc. and that FDA approved as NDA 11-417 in 1958.

9. The terms "NAS/NRC Panel on Psychiatric Drugs," "NAS/NRC Panel," and "the Panel" shall mean the National Academy of Sciences/National Research Council Drug Efficacy Study Group's expert panel assigned the task of reviewing the efficacy of Deaner Tablets or deanol.

10. The term "deanol reports" shall mean reports issued by the NAS/NRC Panel on Psychiatric Drugs pursuant to its review of the efficacy of Deaner Tablets or deanol.

11. The term "person" includes any natural person, corporate entity, sole proprietorship, partnership, association, governmental entity, trust, or other entity or organization.

12. The term "relate" shall mean concerns, refers to, describes, forms the basis for, evidences or constitutes, and the term "relating" shall mean concerning, referring to, describing, evidencing or constituting.

13. The connectives "and" and "or" shall be construed either disjunctively or conjunctively as necessary to bring within the scope of the discovery request all responses that might otherwise be construed to be outside of its scope.

14. The term "all" shall be construed as all and each, and the term "each" shall be construed as all and each. The terms "a," "an," and "any" include "all," and vice versa.

15. The use of the singular form of any word includes the plural, and vice versa whenever appropriate to bring within the scope of this request any documents or things that might otherwise be construed to be outside its scope.

16. The use of the masculine gender includes the feminine gender and vice versa.

INSTRUCTIONS

1. Produce each responsive document in its entirety by including all attachments and all pages, regardless of whether they directly related to the specified subject matter. Submit any appendix, table, or other attachment by either physically attaching it to the responsive document or clearly marking it to indicate the responsive document to which it corresponds. Do not mask, cut, expunge, edit, or delete any responsive document or portion thereof in any manner.

2. Unless otherwise specified, the time period applicable to the documents demanded in the Specifications shall not be limited and all documents responsive to each request, regardless of dates or time periods involved, should be provided. If the response to any request is different for different periods within the relevant time period, provide a complete response for each separate time period.

3. The Specifications are continuing in nature. If, after producing documents, CDER obtains or becomes aware of any further documents, or information responsive to these Specifications, CDER is required to produce to Respondents such additional documents or to provide Respondents with such additional information.

4. Respondents may request the production of additional documents at a later time. Accordingly, you should suspend any routine procedures for document destruction and take other measures to prevent the destruction of documents that are in any way relevant to this case during its pendency, irrespective of whether you believe that such documents are protected from discovery by privilege or otherwise.

5. The Specifications cover documents in your possession, custody or control, wherever the documents are located. Compliance with the Specifications require a search of all documents in the possession, custody, or control of the CDER's current or former officers, directors, employees, agents, or representatives, whether or not such documents are on the premises of CDER. If any person is unwilling to have his or her files searched, or is unwilling to produce responsive documents, CDER must provide counsel serving this request with the following information as to each such person: his or her name, address, telephone number, and relationship to CDER.

6. If any requested documents cannot be produced in full, produce the remainder.

7. In addition to hard-copy documents, the search will include all of CDER's electronically stored data. Sources of such data include, but are not limited to, the following:

(a) Desktop personal computers ("PCs") and workstations; PCs, workstations, minicomputers and mainframes used as file servers, application servers, or mail servers; laptops, notebooks, hand-held devices and other portable computers available for shared use; and home computers used for work related purposes;

(b) Backup disks and tapes, archive disks and tapes, and other forms of offline storage, whether stored onsite with the computer used to generate them, stored offsite in another facility or stored offsite by a third-party, such as in a disaster recovery center; and

(c) Computers and related offline storage used by agents, consultants, and other persons as defined herein, which may include persons who are not employees of CDER or who do not work on CDER's premises.

8. CDER will submit all documents, including electronically-stored documents, in hard copy. In addition to the hard copies, CDER will submit the electronically-stored documents in machine-readable form.

9. All documents submitted shall be clearly and precisely identified as to the Specification or Specifications to which it is responsive. Each document shall be submitted in its entirety even if only a portion of the document is responsive to a Specification.

10. The source and location of each responsive document shall be designated, including the person from whom it was obtained. Responsive documents from each person's files shall be produced together, in file folders or with other enclosures that segregate the files by request number. If a document is responsive to more than one request, it shall be produced in response to the request to which it is primarily responsive.

11. When instructed to submit documents sufficient to identify a person, submit documents sufficient to show the following information:

(a) full name;

(b) current business address and telephone number (or current residence if business address is unavailable);

(c) current title, job description and classification, and employment status; and

(d) any other title and job description and classification during the relevant time period.

12. In the event that CDER withholds any document on the basis that it is privileged, subject to work-product immunity, or is otherwise excludable from disclosure,

CDER is to list such documents by request number and to provide the following information:

(a) the identity of the authors;

(b) the identity of all recipients;

(c) the date of the document;

(d) the title (if any) and subject matter or purpose of the document;

(e) the number of pages contained in the document;

(f) the identify of any attachments or appendices to the document;

(g) the privilege claimed;

(h) the nature of the relationship between the authors and counsel with sufficient particularity to sustain the asserted privilege;

(i) whether direct quotes or paraphrases of advice from counsel were identified;

(j) whether such quotes could be redacted, leaving non-privileged information; and,

(k) any other information necessary to reveal the basis upon which the document is withheld to provide Respondents with sufficient information to determine whether the stated basis for withholding the document is proper.

13. All objections to these Specifications, or to any individual Specification, must be raised by the return date or are waived.

14. If any document responsive to the Specifications once existed but has been destroyed, lost, discarded or is otherwise not available for production, the recipient shall identify in writing each such document, including the date of the document's creation, a description of the document's subject matter, the name and address of each person who

prepared, received, viewed, or had possession, custody or control of the document or otherwise had knowledge of its subject matter, and a statement of the circumstances under which the document was destroyed, lost, discarded or why such document is otherwise not available for production.

SPECIFICATIONS

1. All documents related to David T. Read's FDA job classification or classifications during the period 1962 through 2001.

2. All documents, including but not limited to notes, minutes, memoranda, communications, and drafts, related to the NAS/NRC Panel's review of the efficacy of Deaner Tablets or deanol.

3. All documents sufficient to identify all persons who were members of, or otherwise related to, the NAS/NRC Panel during the period when the Panel evaluated the efficacy of Deaner Tablets or deanol.

4. All documents sufficient to identify all persons who reviewed, evaluated, or analyzed the NAS/NRC Panel's deanol reports for, or on behalf of, CDER or FDA.

5. All documents, including but not limited to memoranda, communications, and drafts of reports and of Federal Register notices, authored by any person, including but not limited to CDER or FDA medical officers, other clinicians, or statisticians, related to CDER's review, evaluation, or analysis of the NAS/NRC Panel's deanol reports.

6. All documents related to deanol, including but not limited to scientific studies and data, that CDER or FDA received from any person other than the NAS/NRC Panel and reviewed pursuant to its evaluation of the efficacy of Deaner Tablets or deanol.

7. The following studies and data submitted by Riker to FDA pursuant to CDER's evaluation of the efficacy of Deaner Tablets:

(a) Oettinger, L., "A Double-Blind Study of Dimethylaminoethanol (Deaner) and Placebo in Children with Minimal Brain Dysfunction," unpublished, 1971 (Riker Number 546-054);

(b) Duncan, D., "Double-Blind Study of the Effects of Deaner (2-Dimethylaminoethanol) and Placebo on the Attention Span of Children with the Hyperkinetic Syndrome, unpublished, 1971 (Riker Number 546-055);

(c) Data on neurological involuntary movements, such as Dopa-induced dyskinesias, tardive dyskinesias, and Huntington's chorea as referenced in Paragraph E of the FDA Notice of Withdrawal of Approval of New Drug Application for Deanol Acetamindo-benzoate, published in the Federal Register of May 24, 1983 (48 Fed. Reg. 23307);

(d) Studies and data on the influence of 2-dimethylaminoethanol on the level of acetylcholine in the brains of mice as referenced in Paragraph E of the FDA Notice of Withdrawal of Approval of New Drug Application for Deanol Acetamindobenzoate, published in the Federal Register of May 24, 1983 (48 Fed. Reg. 23307); and

(e) Studies and data on the suppressant effects of two stimulants on the growth of hyperactive children as referenced in Paragraph E of the FDA Notice of Withdrawal of Approval of New Drug Application for Deanol Acetamindobenzoate, published in the Federal Register of May 24, 1983 (48 Fed. Reg. 23307).

8. All documents, including but not limited to notes, reports, communications, and drafts authored by CDER or FDA medical officers, other clinicians, statisticians, or other persons, related to CDER's evaluation of any study related to the efficacy of Deaner Tablets or deanol, including but not limited to those studies submitted by Riker to CDER.

9. All communications, correspondences, and documents sent to CDER or FDA by Riker, or received by Riker from CDER or FDA, related to CDER's review of the efficacy of Deaner Tablets or deanol.

10. All documents sufficient to identify all persons who drafted, reviewed, or approved FDA Notice DESI 9366, published in the Federal Register of May 15, 1970 (35 Fed. Reg. 7616).

11. All documents, including but not limited to notes, communications, and drafts authored by CDER or FDA medical officers, other clinicians, statisticians, or other persons, related to FDA Notice DESI 9366, published in the Federal Register of May 15, 1970 (35 Fed. Reg. 7616).

12. All documents sufficient to identify all persons who drafted, reviewed, or approved FDA Notice of Opportunity for Hearing on Proposal to Withdraw Approval of New Drug Application for Deanol Acetamindobenzoate, published in the Federal Register of January 8, 1975 (40 Fed. Reg. 1533).

13. All documents, including but not limited to notes, communications, and drafts authored by CDER or FDA medical officers, other clinicians, statisticians, or other persons, related to FDA Notice of Opportunity for Hearing on Proposal to Withdraw Approval of New Drug Application for Deanol Acetamindobenzoate, published in the Federal Register of January 8, 1975 (40 Fed. Reg. 1533).

14. All documents that the authors of FDA Notice of Opportunity for Hearing on Proposal to Withdraw Approval of New Drug Application for Deanol Acetamindobenzoate, published in the Federal Register of January 8, 1975 (40 Fed. Reg.

1533), relied upon in reaching the conclusion that the clinical data submitted by Riker failed to prove the effectiveness of the Deaner Tablets product, and that FDA approval for the product should be withdrawn

15. All documents sufficient to identify all persons who drafted, reviewed, or approved FDA Notice of Withdrawal of Approval of New Drug Application for Deanol Acetamindobenzoate, published in the Federal Register of May 24, 1983 (48 Fed. Reg. 23307).

16. All documents, including but not limited to notes, communications, and drafts authored by FDA medical officers, other clinicians, statisticians, or other persons related to FDA Notice of Withdrawal of Approval of New Drug Application for Deanol Acetamindobenzoate, published in the Federal Register of May 24, 1983 (48 Fed. Reg. 23307).

17. All documents that the authors of FDA Notice of Withdrawal of Approval of New Drug Application for Deanol Acetamindobenzoate, published in the Federal Register of May 24, 1983 (48 Fed. Reg. 23307), relied upon in deciding to withdraw FDA's approval for Riker's Deaner Tablets product.

18. All documents sufficient to identify any product known to FDA that is identical, related, or similar to Deaner Tablets, or that contains deanol as an active ingredient.

19. All documents related to any product that is identical, related, or similar to Deaner Tablets, or that contains deanol as an active ingredient, including but not limited

to any documents that might have been submitted to FDA pursuant to an NDA or an investigational new drug application.

20. All documents related to any FDA evaluation of efficacy of any product other than Deaner Tablets that contain deanol.

21. All document sufficient to identify the number and names of the drugs that were reviewed by CDER for each year from 1960 through 1983 under the Drug Efficacy Study Implementation ("DESI") program, and the number of FDA reviewers assigned to the DESI procedure for each of those years.

22. All documents sufficient to identify the number and names of the drugs reviewed under the DESI program for which CDER withdrew FDA's approval for each of the years from 1962 through 1983.

23. All documents sufficient to identify the number and names of the drugs reviewed under the DESI program for which CDER did not withdraw FDA's approval for each of the years from 1962 through 1983.

24. All documents that were available to CDER for the period 1962 through 1983 that related to the indications identified in the labeling for Riker's Deaner Tablets product.

25. All documents available to CDER during the period 1962 through 1983 related to designing and analyzing studies to measure the efficacy of products labeled for indications identical or similar to those identified in the labeling for the Riker's Deaner Tablets product.

26. All documents related to products known to CDER during the period 1962 through 1983 whose intended use was identical or similar to that of Riker's Deaner Tablets product as determined by the indications identified in the labeling for the Deaner Tablets product.

27. All documents related to CDER's review of Ritalin for Attention Deficit Disorder/Attention Deficit Hyperactivity Disorder or any similar neurological disorder, up to and through 2000.

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

ORDER GRANTING RESPONDENTS' MOTIONS FOR THE ISSUANCE OF A SUBPOENA AD TESTIFICANDUM FOR THE APPEARANCE OF DAVID T. READ FOR DEPOSITION AND OF A SUBPOENA DUCES TECUM TO THE CENTER FOR DRUG EVALUATION AND RESEARCH OF THE U.S. FOOD AND DRUG ADMINISTRATION

On January 26, 2001, pursuant to Federal Trade Commission Rule 3.36, 16 C.F.R. § 3.36, Respondents Natural Organics, Inc., and Gerald A. Kessler filed a Motion for an Order authorizing the issuance of a subpoena ad testificandum for the appearance of David T. Read, and a Motion for an Order authorizing the issuance of a subpoena duces tecum to the Center for Drug Evaluation and Research of the U.S. Food and Drug Administration.

Respondents' Motions are GRANTED.

Pursuant to Federal Trade Commission Rule 3.34, 16 C.F.R. § 3.34, in the event that the Center for Drug Evaluation and Research of the Food and Drug Administration seeks to limit or quash the subpoena, it shall have ten days after receipt of the Respondents' Motion to file any such Motion.

ORDERED:

JAMES P. TIMONY
Administrative Law Judge

Dated: _____, 2001

CERTIFICATE OF SERVICE

I hereby certify that on this twenty-sixth day of January 2001, a copy of the foregoing Respondents' Motion for the Issuance of a Subpoena Ad Testificandum for the Appearance of David T. Read for Deposition, Motion for the Issuance of a Subpoena Duces Tecum to the Center for Drug Evaluation and Research of the U.S. Food and Drug Administration, and Memorandum in Support of the Motions, was served by facsimile and by Federal Express on:

Matthew D. Gold
Kerry O'Brien
Jeffrey A. Klurfeld
Federal Trade Commission
901 Market Street, Suite 570
San Francisco, CA 94103-1768,

by facsimile and first-class mail, postage prepaid, on:

David T. Read
Supervisory Regulatory Counsel
Center for Drug Evaluation and Research, HFD-007
U.S. Food and Drug Administration
1451 Rockville Pike, Room 3047
Rockville, MD 20852

and two courtesy copies of the aforegoing materials were hand delivered to :

Judge James P. Timony
Adminstrative Law Judge
c/o Victoria C. Arthaud, Esq.
Attorney Advisor to Judge Timony
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580.

Paul L. Ferrari