UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of	
NATURAL ORGANICS, INC., a corporation, and	Docket No. 9294
GERALD A. KESSLER, individually and as an officer of the corporation.	The Honorable James P. Timony Chief Administrative Law Judge

MOTION OF THE UNITED STATES FOOD AND DRUG ADMINISTRATION TO QUASH SUBPOENA SERVED BY NATURAL ORGANICS, INC.

Pursuant to § 3.34(c) of the Federal Trade Commission's Rules of Practice, 16 C.F.R. § 3.34(c), nonparty United States Food and Drug Administration respectfully moves to quash the subpoena duces tecum served on it by Natural Organics, Inc., in this proceeding. The grounds for this motion are set forth in the accompanying Memorandum.

Dated: March 7, 2001

Respectfully Submitted,

MARGARET JANE PORTER
CHIEF COUNSEL

By: _____

Michael M. Levy, Jr.
Assistant Chief Counsel for Enforcement
U.S. Food and Drug Administration
5600 Fishers Lane, GCF-1
Rockville, Maryland 20857
(301) 827-1142
Attorney for the United States
Food and Drug Administration

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of	)	
	)	Docket No. 9294
NATURAL ORGANICS, INC.,	)	
a corporation, and	)	The Honorable
	)	James P. Timony
GERALD A. KESSLER,	)	Chief Administrative Law Judge
individually and as an officer	)	
of the corporation.	)	
	)	
	)	

MEMORANDUM OF THE UNITED STATES FOOD AND DRUG ADMINISTRATION IN SUPPORT OF ITS MOTION TO QUASH SUBPOENA SERVED BY NATURAL ORGANICS, INC.

Pursuant to § 3.34(c) of the Federal Trade Commission's ("FTC") Rules of Practice, 16 C.F.R. § 3.34(c), nonparty United States Food and Drug Administration ("FDA") respectfully moves to quash the subpoena duces tecum served on it by Natural Organics, Inc. ("Natural Organics"), served on February 26, 2001. FDA regulations provide that any request for FDA records made by a subpoena duces tecum shall be declined and handled pursuant to the procedures governing public disclosure established in 21 C.F.R. Part 20. Furthermore, as demonstrated below, the subpoena seeks documents without making the requisite showing pursuant to § 3.36 of FTC's Rules of Practice and is overly burdensome. Accordingly, the subpoena should be quashed.

FACTS

On February 26, 2001, Natural Organics served David Read from the Center for Drug Evaluation and Research ("CDER") with a subpoena duces tecum containing twenty

specifications for documents. The documents requested include: (1) all documents related to David Read's FDA job classification or classifications sufficient to show his titles and responsibilities within the FDA during the period 1962 through 2001; (2) all documents relating to the NAS/NRC review of Deaner Tablets or deanol; (3) all documents relating to CDER or FDA's review of the efficacy of Deaner Tablets or deanol; (4) all documents relating to FDA Notice DESI 9366; (5) all documents concerning the FDA Notice of Withdrawal of Approval of New Drug Application for Deanol Acetamindobenzoate; and (6) all documents concerning products identical, related, or similar to Deaner Tablets, or that contain deanol.[1]

On March 5, 2001, and March 7, 2001, Michael M. Levy, Jr., the undersigned counsel for FDA, spoke with Paul L. Ferrari, counsel for Natural Organics, regarding FDA's objections to Natural Organics' subpoena. FDA and Natural Organics were unable to reach an agreement resolving FDA's objections to Natural Organics' subpoena. *See* Statement of Michael M. Levy, Jr., accompanying this motion.

ARGUMENT

FDA, like most federal agencies, has promulgated regulations under the authority of 5 U.S.C. § 301 and 21 U.S.C. § 371(a) that govern the production of records. FDA's document disclosure regulations are set forth in 21 C.F.R. Part 20. In particular, 21 C.F.R.

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[1] *See* Subpoena Duces Tecum Served by Natural Organics, Exhibit 1. Category 1 covers Request No. 1; Category 2 covers Request Nos. 2-5; Category 3 covers Request Nos. 6-9; Category 4 covers Request Nos. 10-11; Category 5 covers Request Nos. 13-17; Category 6 covers Request Nos. 18-20.

§ 20.2 designates the procedures that must be followed by an FDA employee who receives a subpoena duces tecum.[2] As directed by 21 C.F.R. § 20.2, FDA declines to produce the records pursuant to Natural Organics' subpoena. This reason should be sufficient grounds alone for quashing the subpoena. *See In the Matter of Hoechst Marion Roussel, Inc.*, Dkt. No. 9293, 2000 FTC LEXIS 149 at *2-4 (Oct. 2, 2000) (Order Granting Motions by United States Food and Drug Administration to Quash Subpoenas Served by Aventis Pharmaceuticals, Inc., and Andrx Corporation) (subpoena duces tecum quashed on basis of 21 C.F.R. Part 20; FTC Rules of Practice do not override FDA's own regulations governing document disclosure).

Natural Organics has not attempted to obtain the documents listed in its subpoena through the procedures outlined in 21 C.F.R. Part 20. Should Natural Organics consent to receipt of documents pursuant to the procedures established in Part 20, FDA will produce records consistent with those procedures.

2/ 21 C.F.R. § 20.2 provides:

> (a) Any request for records of the Food and Drug Administration, whether it be by letter or by a subpoena duces tecum or by any other writing, shall be handled pursuant to the procedures established in subpart B of this part, and shall comply with the rules governing public disclosure established in parts C, D, E, and F of this part and in other regulations cross-referenced in § 20.100(c).
>
> (b) Whenever a subpoena duces tecum, in appropriate form, has been lawfully served upon an officer or employee of the Food and Drug Administration commanding the production of any record, such officer or employee shall appear in response thereto, respectfully decline to produce the record on the ground that it is prohibited by this section, and state that the production of the record(s) involved will be handled by the procedures established in this part.

Alternatively, the subpoena should be quashed because Natural Organics has failed to make the requisite showing under FTC regulations. Section 3.36 of the FTC's Rules of Practice require that an application for a subpoena for records of governmental agencies other than the FTC contain a specific showing that:

> (1) the material sought is reasonable in scope;
>
> (2) if for 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.

As discussed above, the information sought by Natural Organics could be reasonably obtained by other means. Natural Organics could request the documents under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. *See In the Matter of Sonic Technology Products, Inc.*, Dkt. No. D-9252, 1992 FTC LEXIS 188 at *1 (July 28, 1992) (Order Denying Respondents' Application for Subpoena Duces Tecum) (subpoena duces tecum on sister agency denied where information could be obtained through FOIA). Provided the documents are releasable under FOIA and FDA's regulations governing release of CDER documents, they would be produced accordingly. Further, several of the documents requested by Natural Organics could be obtained from the companies that submitted them to CDER. Natural Organics could obtain most information concerning the New Drug Application ("NDA") file submitted in 1958 by Riker Laboratories, Inc., for Deaner Tablets, from Riker itself. Thus, Natural Organics has failed to show that it could not reasonably obtain the information sought in the subpoena by other means.

Moreover, Natural Organics' subpoena is not reasonable in scope. In addition to a multitude of other requests, the subpoena seeks an entire NDA file submitted in 1958 by Riker for Deaner Tablets. This NDA from forty-three years ago is no longer on site at CDER, but is instead housed at a Federal Records warehouse. Simply retrieving the NDA file from Federal Records would require several weeks. CDER would then need to redact the NDA to comply with 21 C.F.R. § 314.430, the regulation governing the availability for public disclosure of data and information in NDA files. Weeks, if not months, of CDER staff time would be required to complete this task. *See Weinberger v. Hynson, Westcott and Dunning, Inc.*, 412 U.S. 609, 624 (1973) (NDA files "contained about 30 volumes, a stack 10 to 12 feet high; and some contained as many as 400 volumes of data"). This burden on limited agency resources is in gross imbalance to CDER's extremely limited role in this case. CDER's only participation in this case is the proposed testimony of a CDER employee, David Read, as a fact witness to explain FDA's role in the regulation of deanol. The subpoena, therefore, is not reasonable in scope.

The use of limited CDER resources on this unreasonable request would be particularly meaningless and irrelevant to the case at hand, given the limited scope of the proposed testimony of David Read. Section 3.31(b)(1) references § 3.31(c)(1), which limits discovery "to the extent that it may be reasonably expected to yield information relevant . . . to the defenses of any respondent." *See In re Exxon Corp.*, 95 F.T.C. 919, 1980 FTC Lexis 64 at *8 (June 30, 1980) (Interlocutory Order) ("If a party requests information of another government agency, the administrative law judge shall carefully

consider the relevance of the requested information and its availability through other means."); *see also In re Automotive Breakthrough Sciences, Inc.*, Dkt. No. 9275, 1996 FTC Lexis 286 at *1-2 (June 19, 1996) (Order Denying Motion for Issuance of Subpoena Duces Tecum). FTC plans to call David Read as a fact witness for the sole purpose of explaining FDA's involvement in the regulation of deanol in FDA's Drug Efficacy Study Implementation ("DESI") proceeding. The information in the NDA file would not provide relevant information to defending against testimony on this issue. Any information pertinent to Read's testimony would be in CDER's DESI file, not the NDA file.[3] Natural Organics' inclusion of the NDA file is likely a fishing expedition to uncover information on the efficacy of deanol, one of the active ingredients in Natural Organics' product, Pedi-Active A.D.D. Read will not testify as to the efficacy of deanol or Pedi-Active A.D.D. FTC has a medical expert, Dr. L. Eugene Arnold, to opine on efficacy.[4] Thus, because Natural Organics' Subpoena Duces Tecum seeks documents that do not concern the testimony of David Read, it is in large part irrelevant.

---

[3] FDA does not consider the production of the DESI file to be unreasonable or irrelevant and plans to release it pursuant to FOIA and FDA regulations. The production of the NDA file, however, would be both unreasonable and irrelevant.

[4] The irrelevance of Natural Organics' subpoena is discussed in detail in Complaint Counsel's Answer to Respondents' Motions for the Issuance of Subpoenas to David T. Read and to the U.S. Food and Drug Administration, dated February 7, 2001.

CONCLUSION

For the foregoing reasons, FDA respectfully requests that its motion be granted.

Dated: March 7, 2001

Respectfully Submitted,

MARGARET JANE PORTER
CHIEF COUNSEL

By: _____

Michael M. Levy, Jr.
Assistant Chief Counsel for Enforcement
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5600 Fishers Lane, GCF-1
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UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of	)	
	)	Docket No. 9294
NATURAL ORGANICS, INC.,	)	
a corporation, and	)	The Honorable
	)	James P. Timony
GERALD A. KESSLER,	)	Chief Administrative Law Judge
individually and as an officer	)	
of the corporation.	)	
	)	
	)	

STATEMENT OF MICHAEL M. LEVY, JR., PURSUANT TO RULE 3.22(F) OF THE FEDERAL TRADE COMMISSION'S RULES OF PRACTICE

I am an attorney with the Office of Chief Counsel for the United States Food and Drug Administration and submit this statement pursuant to Rule 3.22(f) of the Federal Trade Commission's Rules of Practice, 16 C.F.R. § 3.22(f), in connection with the Motion of the United States Food and Drug Administration to Quash Subpoena Served by Natural Organics, Inc. On March 5, 2001, and March 7, 2001, I spoke four times with Paul L. Ferrari, counsel for Natural Organics, in good faith to resolve by agreement the issues raised by FDA's Motion to Quash. During those conversations, we were unable to reach agreement resolving the objections to the subpoena.

Dated: March 7, 2001

Respectfully Submitted,

Michael M. Levy, Jr.
Assistant Chief Counsel for Enforcement
U.S. Food and Drug Administration
5600 Fishers Lane, GCF-1
Rockville, Maryland 20857

(301) 827-1142
Attorney for the United States
Food and Drug Administration

CERTIFICATE OF SERVICE

I, Michael M. Levy, Jr., hereby certify that on March 7, 2001, I caused a copy of the Motion of the United States Food and Drug Administration to Quash Subpoena Served by Natural Organics, Inc., the Memorandum of the United States Food and Drug Administration in Support of its Motion to Quash Subpoena Served by Natural Organics, Inc., and all exhibits thereto to be served upon the following persons by Federal Express:

Hon. James P. Timony
Chief Administrative Law Judge
Federal Trade Commission
Room H-112
600 Pennsylvania Avenue, NW
Washington, DC 20580

Donald S. Clark, Secretary
Federal Trade Commission
Room 172
600 Pennsylvania Avenue, NW
Washington, DC 20580

Dean Graybill, Esq.
Western Region
Federal Trade Commission
901 Market Street, Suite 570
San Francisco, CA 94130

John R. Fleder, Esq.
Paul L. Ferrari, Esq.
Hyman, Phelps, and McNamara, P.C.
700 Thirteenth St., N.W.
Washington, DC 20005-5929

Michael M. Levy, Jr.

Exhibit 1

Subpoena Duces Tecum Served by Natural Organics, Inc., on David Read on February 26, 2001

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ANNE MARIE MURPHY *
PAUL L. FERRARI
JEFFREY N. WASSERSTEIN
BRIAN J. MALKIN

*NOT ADMITTED IN DC

FACSIMILE TRANSMITTAL SHEET

FROM:	Paul L. Ferrari	**DATE:**	February 26, 2001
TO:	David T. Read Supervisory Regulatory Counsel CDER / Food & Drug Administration	**FAX NO.:**	301-827-0951

NO. OF PAGES (including this page) : 17

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*NOT ADMITTED IN DC

February 23, 2001

BY FACSIMILE AND MAIL

David T. Read, Esq.
Supervisory Regulatory Counsel
Center for Drug Evaluation and Research
U.S. Food and Drug Administration (HFD-007)
1451 Rockville Pike, Room 6027
Rockville, MD 20852

Dear Mr. Read:

I have attached a courtesy copy of the subpoena duces tecum that we served on the Center for Drug Evaluation and Research ("CDER") today. The subpoena duces tecum demands certain documents that are related to your proposed testimony in the case presently before Administrative Law Judge James P. Timony of the U.S. Federal Trade Commission, captioned as In the Matter of Natural Organics, Inc. and Gerald A. Kessler, Docket No. 9294.

We have set March 26, 2001 as the date by which CDER must respond with the requested documents, but we hope that the Center will provide the documents in advance of that date. I would like to arrange a date for taking your deposition, and will call you as soon as we know when we are likely to receive all responsive documents from CDER. Once we agree on a date for your deposition, we will issue a subpoena ad testificandum to you.

Sincerely,

Paul L. Ferrari

Paul L. Ferrari

PLF/vam
Enclosure
cc: Matthew D. Gold, Esq.,
Federal Trade Commission, Western Region

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* NOT ADMITTED IN DC

February 23, 2001

BY FACSIMILE AND CERTIFIED MAIL

Janet Woodcock, M.D.
Director, Center for Drug Evaluation and Research
U.S. Food and Drug Administration (HFD-1)
1451 Rockville Pike, Room 6027
Rockville, MD 20852

Dear Dr. Woodcock:

Attached please find a subpoena duces tecum for certain documents from the Center for Drug Evaluation and Research ("CDER").

The subpoena has been issued by order of Administrative Law Judge James P. Timony of the Federal Trade Commission ("FTC") pursuant to a motion filed by the Respondents in an FTC case captioned as In the Matter of Natural Organics, Inc. and Gerald A. Kessler, Docket No. 9294. The FTC will call David T. Read, Esq., Supervisory Regulatory Counsel for CDER, as a witness in the case. The subpoena requests documents that are related to Mr. Read's testimony.

Thank you for your consideration.

Sincerely,

Paul L. Ferrari

Paul L. Ferrari

PLF/vam
Enclosure
cc: David T. Read, Esq., CDER, FDA
Matthew D. Gold, Esq., FTC, Western Region

SUBPOENA DUCES TECUM

Issued Pursuant to Rule 3.34(b), 16 C.F.R. § 3.34(b)(1997)

1. TO	2. FROM
Center for Drug Evaluation and Research U.S. Food and Drug Administration	UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

This subpoena requires you to produce and permit inspection and copying of designated books, documents (as defined in Rule 3.34(b)), or tangible things - or to permit inspection of premises - at the date and time specified in Item 5, at the request of Counsel listed in Item 9, in the proceeding described in Item 6.

3. PLACE OF PRODUCTION OR INSPECTION	4. MATERIAL WILL BE PRODUCED TO
Hyman, Phelps & McNamara, P.C. 700 Thirteenth Street, N.W. Suite 1200 Washington, D.C. 20005	John R. Fleder, Esq.
	5. DATE AND TIME OF PRODUCTION OR INSPECTION March 26, 2001 10:00 a.m. [See restriction in attached Order, clause 2g.]

6. SUBJECT OF PROCEEDING

In the Matter of Natural Orgranics, Inc., and Gerald A. Kessler, Docket No. 9294

7. MATERIAL TO BE PRODUCED

See Attached Document Specifications

[See restrictions on specifications in attached Order, clauses 2a-2g.]

8. ADMINISTRATIVE LAW JUDGE	9. COUNSEL REQUESTING SUBPOENA
The Honorable James P. Timony Federal Trade Commission Washington, D.C. 20580	Paul L. Ferrari Counsel for Respondents Natural Organics, Inc. and Gerald A. Kessler

DATE ISSUED	SECRETARY'S SIGNATURE
February 22, 2001	Donald S. Clark

GENERAL INSTRUCTIONS

APPEARANCE

The delivery of this subpoena to you by any method prescribed by the Commission's Rules of Practice is legal service and may subject you to a penalty imposed by law for failure to comply.

MOTION TO LIMIT OR QUASH

The Commission's Rules of Practice require that any motion to limit or quash this subpoena be filed within the earlier of 10 days after service or the time for compliance. The original and ten copies of the petition must be filed with the Secretary of the Federal Trade Commission, accompanied by an affidavit of service of the document upon counsel listed in Item 9, and upon all other parties prescribed by the Rules of Practice.

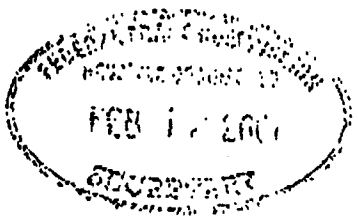
TRAVEL EXPENSES

The Commission's Rules of Practice require that fees and mileage be paid by the party that requested your appearance. You should present your claim to counsel listed in Item 9 for payment. If you are permanently or temporarily living somewhere other than the address on this subpoena and it would require excessive travel for you to appear, you must get prior approval from counsel listed in Item 9.

This subpoena does not require approval by OMB under the Paperwork Reduction Act of 1980.

FTC Form 70-8 (rev. 1/97)

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 IN PART, AND DENYING IN PART, RESPONDENTS' MOTIONS FOR THE ISSUANCE OF SUBPOENAS TO DAVID T. READ AND THE U.S. FOOD AND DRUG ADMINISTRATION

Respondents on January 16, 2001, served two motions for subpoenas. One proposed subpoena requested Mr. David Read of the Food and Drug Administration ("FDA") to appear for a deposition on February 21, 2001. The second subpoena directed FDA's Center for Drug Evaluation and Research to produce documents by February 16, 2001. Complaint counsel opposed the latter request on the grounds (1) that the proposed return date gave insufficient time for the FDA to exercise its motion-to-quash rights and to produce documents, (2) that certain document requests were excessively broad in scope, and (3) that Respondents did not carry their burden under § 3.36(b)(3) of showing that key documents "cannot reasonably be obtained by other means."

Complaint Counsel challenges the scope and relevancy of certain proposed document requests to the FDA regarding its actions on Riker Laboratories' "Deaner Tablets," a product asserted to include an ingredient similar to one in Respondents' product, and its actions on other products. Complaint counsel asserts that Respondents have a right to reasonable discovery regarding FDA's actions on Deaner Tablets and products having similar ingredients, but that Specifications 21 - 27 in particular are excessive in scope relative to the purposes for which the FDA evidence is offered. Having considered Respondents' and Complaint counsel's arguments, IT IS HEREBY ORDERED:

1. That 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 is GRANTED, on the condition that Respondents shall defer the deposition to a later date within the discovery cutoff; and

2. That 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 is hereby GRANTED IN PART AND DENIED IN PART, as follows:

a. Specification 1 will be restricted to a request for documents sufficient to show Mr. Read's titles and responsibilities within the FDA;

b. Specifications 10, 12, and 15 shall be restricted to request documents sufficient to show those persons who exercised substantial authority in the evaluation and approval of the FDA actions specified therein;

c. Specifications 2, 5, 8, 11, 13, and 16 shall be restricted to requesting documents sufficient to show the basis for the specified FDA actions, including dissenting views of those with substantial decision-making authority;

d. The document request will omit specifications 21 - 27 (requests relating to FDA actions on products not containing deanol);

e. The subpoena shall specifically exclude requests for documents already in Respondents' possession by virtue of previous FOIA requests to the FDA;

f. Instruction #12 regarding information that the FDA must provide with respect to withheld documents shall be modified to conform with § 3.38A of the Commission's Rules; and

g. The subpoena shall give the FDA a minimum of 30 days to respond to the subpoena.

James P. Timony
Administrative Law Judge

Dated: February 12, 2001

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 therefore shall include writings, drawings, graphs, charts, handwritten notes, film, photographs, audio and video recordings, and any such representations stored on a computer, a computer disk, CD-ROM, magnetic or electronic tape, or any other means of electronic storage, and other data compilations from which information can be obtained in machine-readable form (translated, if necessary, into reasonably usable form by the person subject to the subpoena).

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 Supervisory 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 subpoena 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 subpoena 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.

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.

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 requires a search of all documents in the possession, custody, or control of CDER, 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, pursuant to § 3.38A of the Commission Rules, CDER is to list such documents by request number and to provide the following information:

(a) the type of the document or item withheld;

(b) the title (if any) of the document;

(c) the specific subject matter of the document;

(d) the date of the document;

(e) the identity, including names, addresses, positions, and organizations, of all authors;

(f) the identity, including names, addresses, positions, and organizations, of all recipients;

(g) the privilege claimed and the specific grounds for claiming that the document is privileged;

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

14. This subpoena specifically excludes requests for documents already in the Respondents' possession by virtue of a Freedom of Information Act request to FDA

made on Nov. 3, 1998, by Bass & Ullman, Respondents' previous counsel, for documents related to Docket Nos. FDC-D556 and 82N006.

16. CDER shall respond to this subpoena in full no later than 30 calendar days from the delivery of the subpoena to the FDA.

SPECIFICATIONS

1. All documents related to David T. Read's FDA job classification or classifications sufficient to show his titles and responsibilities within FDA during the period 1962 through 2001.

2. All documents, including but not limited to notes, minutes, memoranda, communications, and drafts, sufficient to show the basis for the NAS/NRC Panel's review of, and conclusions regarding, the efficacy of Deaner Tablets or deanol, including all documents containing dissenting views of any person who had substantial decision-making authority.

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, sufficient to show the basis for CDER's review, evaluation, or analysis of the NAS/NRC

Panel's deanol reports, including all documents containing dissenting views of any person who had substantial decision-making authority.

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, sufficient to show the basis for 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), including all documents containing dissenting views of any person who had substantial decision-making authority.

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 exercised substantial authority in drafting, reviewing, or approving 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 sufficient to show the basis for FDA Notice DESI 9366, published in the Federal Register of May 15, 1970 (35 Fed. Reg. 7616), including all documents containing dissenting views of any person who had substantial decision-making authority

12. All documents sufficient to identify all persons who exercised substantial authority in drafting, reviewing, or approving 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, sufficient to show the basis for 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), including all documents containing dissenting views of any person who had substantial decision-making authority.

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 exercised substantial authority in drafting, reviewing, or approving 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 sufficient to show the basis for 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), including all documents containing dissenting views of any person who had substantial decision-making authority.

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.