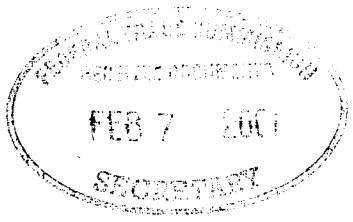
UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION



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

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

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

Respondents have filed two motions for subpoenas, one for Mr. David Read of the FDA to be deposed on February 21 and another for the FDA to respond to 27 document specifications by February 16. Complaint counsel had agreed to the February 21st deposition date and do not oppose that motion. However, Complaint counsel do oppose Respondents' motion for document subpoenas as currently crafted -- (1) The proposed document production date of February 16th gives the FDA literally no time to respond if it exercises any of its rights to object under the Commission's Rules;[1] (2) Many of Respondents' 27 requests are clearly excessive in scope; and

[1] Respondents served their motion on January 26th. Even if Your Honor approved their motion immediately (February 7th), the FDA would have until at least February 17th to file a motion to quash pursuant to § 3.34(c) of the Commission Rules. The alternative of producing documents on the day of the deposition also would leave just four days for Your Honor to resolve all motion-to-quash issues and for the FDA then to complete all its discovery.

(3) Respondents have not adequately demonstrated under § 3.36(b)(3) of the Commission Rules that key documents "cannot reasonably be obtained by other means." Respondents' previous counsel already had obtained core documents from the FDA in an earlier FOIA request.

Complaint counsel has discussed these issues with Respondents' counsel, and the parties have arrived at a partial solution. First, Respondents' counsel agrees that the February 21st deposition date, if Complaint counsel or the FDA pose objections to document discovery, would leave a very short time for Your Honor and the parties to resolve all issues and complete document production. Respondents' counsel has stated that they will not insist on going forward with the deposition on February 21st in that event, on the further assurance that Mr. Read will be made available for deposition at a later date. Complaint counsel agrees that deferring Mr. Read's deposition is in the interest of all the parties for the above reasons, and also based on our belief that Respondents' Motion at the outset failed to give the FDA adequate time to exercise its rights and also respond to permitted discovery.

Second, Respondents' counsel has agreed to modify its proposed subpoena request to omit requests for documents already in their possession by virtue of the earlier FOIA request. Complaint counsel had confirmed with FDA staff that Bass & Ullman, Respondents' prior counsel, had made an FOIA request to the FDA on November 3, 1998 for documents relating to docket nos. FDC-D556 and 82N006. These dockets concern the FDA's review of a Riker Laboratories product called "Deaner Tablets," the principal subject of Respondents' Motions. Respondents' counsel has located this file and offered to give Complaint counsel a copy.

That said, Complaint counsel still oppose Respondents' Motion for a Subpoena Duces Tecum to the extent that it requests unrealistic production dates and is overbroad. Below, we

briefly summarize the relevance of the FDA actions to this case and set forth objections to particular aspects of Respondents' Motion. We do not purport to address the FDA's possible objections to particular specifications on the grounds of privilege, burden, or other matters affecting that agency's interest.

Background on the FDA's Actions and Their Relevance

The Complaint alleges that Natural Organics has claimed in its advertising that "Pedi-Active A.D.D.," among other things, will improve the attention span and scholastic performance of children who have difficulty focusing on school work; will improve the attention span of children who suffer from Attention Deficit/Hyperactivity Disorder ("ADHD", also commonly referred to as "ADD"); will improve the scholastic performance of children who suffer from ADHD; and will treat or mitigate ADHD or its symptoms. The Commission, to prevail, must prove, *inter alia*, that Natural Organics made the claims cited in the complaint and that Natural Organics "did not possess and rely upon a reasonable basis that substantiated the representations," as those terms are construed in FTC doctrine (Complaint ¶¶ 7 - 9).

At trial, Complaint Counsel's principal proof on the substantiation question will be the expert testimony of Dr. L. Eugene Arnold of Ohio State University. Dr. Arnold is perhaps the pre-eminent authority in the world on alternative treatments for ADHD. He has reviewed in depth Respondents' claimed substantiation and other relevant material, and has concluded that Natural Organics lacks reasonable basis for the claims cited in the Complaint.

The FDA has not taken public action with respect to Pedi-Active A.D.D., and Complaint counsel will not contend at trial that the FDA has made any conclusions about the efficacy of Natural Organics' product. Nor will Complaint counsel contend that the FDA's actions on

similar products, without more, have established that Natural Organics lacks reasonable basis for its claims under the FTC Act. Nevertheless, the FDA's actions with respect to one similar product -- Riker Laboratories' "Deaner Tablets" -- are relevant to certain aspects of both Respondents' and the FTC's case.

Riker Laboratories in the 1950's labeled its Deaner Tablets as treating hyperkinetic behavior problem syndrome (as ADHD or ADD was then known) and as helping to mitigate many of the same conditions that Natural Organics refers to in its advertising. Riker's product contained as its sole active ingredient a substance closely related to DMAE, a major constituent of Natural Organics' Pedi-Active A.D.D. product.[2] The FDA's actions on Riker's product can be briefly summarized (see Attachment A to Respondents' Motions):

– The FDA in 1958 had approved Deaner Tablets as a drug that could be lawfully marketed. However, the FDA Act at that time only required the FDA to evaluate safety, not efficacy. Accordingly, the FDA's approval at that time signified nothing as to the efficacy of Riker's product.

-- The 1962 Amendments to the FDA Act required the FDA to review thousands of previously-approved drugs for efficacy, including Riker's product. This larger undertaking was referred to the "Drug Efficacy Study."

-- The FDA in a 1970 Federal Register Notice concurred with a Panel on Psychiatric Drugs

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[2] Deaner Tablets contained as its only labeled active ingredient deanol (2-dimethylaminoethanol) as the para-acetamidobenzoic acid salt. Natural Organics' product contains DMAE (2-dimethylamino-ethanol bitartrate) in suggested daily dosages of 400 mg; phosphatidylserine (PS)(80 mg); Phosphatidylcholine (PC)(80 mg); Cephalin (phosphatidylethanolamine)(12 mg); Phospoinositides (6 mg); and various fatty acids in lesser amounts.

that Deaner Tablets was only "possibly" effective (meaning not *proven* "ineffective," but also not proven "probably effective, "effective but," or "effective.") Riker Laboratories submitted four complete or partial studies.

– The FDA, having evaluated those four studies, announced in a 1975 Federal Register notice that the studies did not constitute substantial basis for Riker's claims under FDA Act standards. Riker requested a hearing and submitted further material.

-- In 1982, the FDA's National Center for Drugs and Biologics announced in the Federal Register that the newly submitted material also did not constitute substantial basis for Riker's claims and granted summary judgment. Riker objected and requested a further hearing. The FDA denied the request and withdrew approval for Deaner Tablets in 1983.

Complaint counsel recognize that there are distinctions between Pedi-Active ADD and Deaner Tablets, and also that FDA may have evaluated the Deaner product under a stricter standard than is applicable in FTC law. As stated previously, Dr. Arnold's testimony will be the centerpiece of our case. However, Complaint counsel believes that FDA's actions, as summarized by Mr. Read and the underlying public documents, are relevant in several respects. First, Respondents -- having no controlled tests regarding the efficacy of Pedi-Active A.D.D. themselves – rely upon the Riker submissions to the FDA as part of their own substantiation case. Thus, the FDA's actions require explanation. Second, the FDA's actions also establish that Natural Organics had ample notice that its claims may be unsubstantiated. Third, the materials help explain why FDA's earlier approval of Deaner Tablets signified no judgment as to the efficacy of deanol in treating ADHD. Fourth, is the simple fact that the FDA, after lengthy

review of a similar product, made conclusions that are consistent with and in no way undermine Dr. Arnold's conclusions regarding the efficacy of Pedi-Active A.D.D.

This does not purport to be an exhaustive list of relevant purposes. However, Complaint counsel can state that we do *not* intend to use the FDA materials for certain purposes cited by Respondents -- (1) "that FDA has determined that deanol is not effective" (the FDA only having determined that Riker lacked proof of its efficacy), and (2) "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." Respondents' Memorandum, at 4 - 5. That is a matter of FDA law, and Complaint counsel do not purport to litigate the question.

Objections to Certain Document Requests

We believe that the foregoing perspective on how the FDA evidence "fits' in this case has implications with respect to the proper scope of Respondents' discovery requests. On the one hand, the foregoing suggests that Respondents certainly should have the right to obtain the materials upon which the FDA relied in making its conclusions regarding Deaner Tablets, subject to privilege and other concerns. On the other hand, this is not an instance where Complaint counsel are offering the FDA as its expert or claiming that the FDA's actions constitute conclusive proof that Respondents lack basis for their efficacy claims. This suggests that there should be some constraint on Respondents engaging in a fishing expedition on matters of entirely speculative value (*e.g.*, every note, memo, or draft pertaining to Ritalin "up to and through 2000"). The relevance of materials requested of another agency must be "carefully considered" before subpoena authority is granted. *Exxon Corp.* 95 F.T.C. 919, 922 (1980) (Interlocutory

Order); *accord*, *North American Phillips Corp.*, D. 9209 (Order Denying Request for Documents Relating to Expert Testimony, Timony, ALJ, December 18, 1987).

Specifically, we oppose Respondents' Motion in the following respects.

General Objections

1. **Time for Production:** As stated previously, we object to the time frame set for document production by the FDA. The FDA must be granted 10 days to file a motion to quash, as necessary, pursuant to § 3.34(c) of the Commission Rules. The FDA also should be given a reasonable period of time thereafter to produce the documents.

2. **Requests for Identification of All Persons who "Drafted, Reviewed, or Approved":** A number of specifications request that the FDA produce documents sufficient to identify who "drafted, reviewed, or approved" various FDA pronouncements (*see*, Specifications 10, 12, 15). We recognize that Respondents may wish to identify key officials who were involved in the decision. However, the request that the FDA search for documents showing all persons who touched documents at the most preliminary stages is excessive relative to the purposes for which the FDA actions are offered.

3. **Requests for "All notes, communications, and drafts":** For the same reason, it seems excessive to request "all notes, communications, and drafts" of all persons "related to" those pronouncements in this instance. (Specifications 2, 5, 8, 11, 13, 16)

4. **Instructions regarding Withheld Materials**: Instruction #12 states that the FDA, if it wishes to withhold documents on the basis of privilege or otherwise, must provide a litany of information that exceeds the specific requirements of § 3.38A of the Commission's Rules (*e.g.*, "whether direct quotes or paraphrases of advice from counsel

were identified," Instruction #12(i)).

Objections to Specific Document Requests

Complaint counsel, as stated previously, believes that Respondents have a right to obtain information upon which the FDA based its decisions regarding Deaner Tablets. With the above caveats, we therefore have not objected to the thrust of Respondents requests in Specifications 2 - 20.

Specification 1

Respondents do not need "All documents related to David T. Read's job classification" from 1962 to 2001 to conduct his deposition.

Specifications 21 - 27

We submit that Specifications 21 - 27 go far afield, relative to the purposes for which the FDA evidence is offered. Respondents already stretch the bounds of relevancy in requesting that the FDA search its files for all documents regarding "deanol" products *other* than Riker's product (Specifications 18 - 20), but we do not oppose that request. However, we submit that Respondents should not be permitted to engage in wholesale discovery of FDA files regarding products that do not even contain the ingredients in Pedi-Active ADD. To support this broad-ranging request, Respondents offer nothing more than the assertion that the documents "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." Respondents' Memorandum, at 6. We submit that a subpoena to a third party agency for such broad and potentially burdensome discovery requires much higher justification. Accordingly, we believe that the following specifications should be stricken:

21. "All documents 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 identified in the labeling for 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."

Accordingly, Complaint counsel respectfully requests that Respondents' Motions be granted in part, and denied in part, as set forth in the attached proposed Order.

Respectfully submitted,

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Dated: February 7, 2001

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.	)	

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 and Respondents have narrowed the disputed issues by agreeing that it may be necessary to defer Mr. Read's deposition in order to resolve discovery disputes and then obtain permitted document production before the deposition. Respondents' counsel also has agreed to modify its document subpoena to avoid requests for documents previously obtained in FOIA requests to the FDA.

The remaining issues concern the scope and relevancy of certain proposed document requests to the FDA regarding its actions on Riker Laboratories' "Deaner Tablets," a product that includes an ingredient similar to one in Respondents' product, and its actions on other products. Complaint counsel assert 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, and mindful of the Commission's directive that the relevance of materials requested of another agency must be

"carefully considered" before subpoena authority is granted, *Exxon Corp.* 95 F.T.C. 919, 922 (1980)(Interlocutory Order), IT IS HEREBY ORDERED:

1. That Respondents' Motion for Issuance of a Supboena 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 person 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.

Dated: _____, 2001

_____
James P. Timony
Administrative Law Judge

CERTIFICATE OF SERVICE

This certifies that a copy of 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, was served by facsimile and overnight courier on February 7, 2001, on the following:

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