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.	)	
	)	

RESPONDENTS' ANSWER TO MOTION OF THE UNITED STATES FOOD AND DRUG ADMINISTRATION TO QUASH SUBPOENA DUCES TECUM

Complaint Counsel in this matter have indicated they will call David T. Read, Supervisory Regulatory Counsel for the Food and Drug Administration's ("FDA's") Center for Drug Evaluation and Research, as a witness to testify about FDA's regulation of deanol.[1] In fact, Mr. Read is Complaint Counsel's only fact witness for the whole case. As a result, on January 26, 2001, Respondents served proposed subpoenas on Complaint Counsel, seeking both testimony from Mr. Read and documents from FDA. We served courtesy copies on Mr. Read at the same time. Respondents orally requested Complaint Counsel to obtain FDA's cooperation so that the deposition could be completed well before discovery closes.

---

[1] Deanol, which is also known as 2-dimethylaminoethanol or DMAE, is one of the ingredients in Respondents' Pedi-Active A.D.D. dietary supplement product, the subject of this action.

On February 7, 2001, Complaint Counsel responded to our Motion; FDA remained silent. On February 12, 2001, Your Honor granted in part, and denied in part, access to the documents Respondents sought. Your Honor adopted many of Complaint Counsel's "relevance" objections to the subpoena but granted the Motion and authorized parts or all of twenty of the twenty-seven specifications we had sought.

Indeed, based on Complaint Counsel's objection to many of the specifications, Your Honor may well have believed (as we did) that Complaint Counsel had filed its Response in consultation with, and considering the views of, its sister agency, FDA. FDA employs Mr. Read and has allowed him to testify as a witness for Complaint Counsel. Instead, FDA decided to take a second bite of the apple by waiting until Respondents served the subpoenas on February 26, 2001, before raising the objections discussed below.[2]

On March 7, 2001, the FDA filed a Motion to Quash Respondents' subpoena duces tecum.[3] FDA asserts that its regulations state that any request for records made by subpoena must be handled by the agency's Freedom of Information ("FOI") staff. Motion at 2-3. FDA also argues that quashing the subpoena is appropriate because the requested documents are reasonably available by other means, and the subpoena is

---

[2] Respondents did not serve the subpoenas immediately after issuance of Your Honor's Order, in part because we were unable to immediately secure signed subpoenas from the FTC Office of the Secretary. Respondents appreciate Complaint Counsel's assistance in eventually securing the subpoenas.

[3] As an initial matter, it should be noted that FDA's Motion appears to be defective insofar as it fails to include a proposed Order.

neither reasonable in scope nor limited to requests for relevant information. Motion at 4-6.

Contrary to FDA's belated and largely unsupported assertions, the FDA regulations that provide for the handling of subpoenas are not applicable in the instant case, the requested documents are not reasonably available by other sources, and the subpoena is reasonable in scope and seeks only relevant information. For these reasons, FDA's Motion to Quash should be denied.

ARGUMENT

FDA asserts that the subpoena should be quashed because the agency must follow its document disclosure regulations as set forth in 21 C.F.R. Part 20. In fact, FDA has conceded in other litigation that these rules are controlling only when the United States is not a party to the action. See In re United States Bioscience Sec. Litig., 150 F.R.D. 80, 81 (E.D. Pa. 1993). This position – notably different than FDA's position in its Motion – is consistent with an unbroken line of cases originating with United States ex rel. Touhy v. Ragen, 340 U.S. 462 (1951), in which the courts have recognized the ability of federal agencies to promulgate regulations restricting their employees from testifying or producing documents in litigation in which the government is not a party. Indeed, the case law is consistent that these "Touhy regulations" are inapplicable in matters in which the government is a party to the litigation. See, e.g., Exxon Shipping Co. v. United States Dep't of Interior, 34 F.3d 774, 776 n.4 (9th Cir. 1994); Boron Oil Co. v. Downie, 873 F.2d 67, 69-70 (4th Cir. 1989); United States ex rel. Roby v. Boeing Co., 189 F.R.D. 512, 517 (S.D. Ohio 1999) ("it is well established that the Government, as a litigant, is bound

by the rules of discovery to the same extent as any other litigant. . . . Thus, fundamental fairness dictates that the Touhy regulations should not apply where the Government is a party to the litigation [citations omitted]"); Alexander v. Federal Bureau of Investigation, 186 F.R.D. 66, 70-71 (D.D.C. 1998); In re Travelstead, 212 B.R. 505, 510 (Bankr. D. Md. 1997) ("While the validity of such housekeeping regulations has been previously approved by various courts, no court has held that a governmental agency is authorized to refuse to provide nonprivileged discovery where it is a party to the litigation").

More specifically, courts have permitted discovery against FDA when the government was a party to litigation. See In re Kessler, 100 F.3d 1015 (D.C. Cir. 1996) (permitting deposition of FDA Commissioner in lawsuit against FDA); Metrex Research Corp. v. United States, 151 F.R.D. 122, 124 (D. Colo. 1993) (permitting depositions of FDA employees notwithstanding 21 C.F.R. § 20.1; "When discovery of FDA personnel is relevant in civil litigation, it can be ordered despite the regulation").[4] Thus, contrary to FDA's bald assertion that the regulations at 21 C.F.R. Part 20 are controlling, well-established case law makes clear that FDA's Touhy regulations do not apply where, as here, the government is a party to the action.

Further, contrary to the impression left by FDA's Motion, the agency is not an innocent bystander that is being pulled unwillingly into this proceeding. Rather, FDA

---

[4] Cf. Connaught Lab., Inc. v. SmithKline Beecham, 7 F. Supp. 2d 477 (D. Del. 1998) (denying motions to quash subpoenas against FDA in private patent litigation), appeal dismissed for lack of jurisdiction, 165 F.3d 1368 (Fed. Cir. 1999); In re Biosciences Litig., 150 F.R.D. 80, 81 (E.D. Pa. 1993) (permitting discovery against FDA notwithstanding 21 C.F.R. Part 20, in private securities litigation).

voluntarily agreed to provide Mr. Read to testify on Complaint Counsel's behalf as their sole fact witness in this matter. FDA should not be heard to say that it is permitted under its regulations to treat a subpoena duces tecum properly issued by Your Honor as a FOI request. Cf. Alexander, supra. ("The case presently before this court is not one in which private litigants seek to drag a witness employed by the federal government or one of its agencies into court to offer some testimony on a particular party's behalf. . . . [I]n the instant case, the litigation originated in federal court and the United States voluntarily substituted itself for [the individual] defendants" emphasis added). Further, it is inequitable to allow FDA to testify voluntarily in this matter at the same time it is withholding relevant, non-privileged material from Respondents and forcing Respondents into the murky quagmire that is FDA's FOI process.

In the context of civil litigation instituted by the government, courts have held that the plaintiff government agency subject to civil discovery demands is defined as both the agency that is directly responsible for commencing the litigation, and includes all other interested federal executive agencies. United States v. Am. Tel. & Tel. Co., 461 F. Supp. 1314, 1332-35 (D.D.C. 1978) (citing cases). The logic of this is inescapable. Where, as here, federal agencies have regulatory jurisdiction over the matter, they are considered to be interested parties, and thus subject to the same discovery requirements as the agency that is litigating the matter. FDA regulates dietary supplements. Moreover, it has voluntarily agreed to appear in this matter on Complaint Counsel's behalf. FDA cannot aid Complaint Counsel by providing an employee to testify, and then hide behind its Touhy regulations, claiming all the while that it is merely a bystander to this litigation.

In the context of criminal cases, courts have similarly held that the government may not withhold documents requested through discovery that either the prosecutor or other federal agencies that have assisted in the investigation possess. Here, FDA is obviously deeply involved in Complaint Counsel's prosecution of this matter. See United States v. Wood, 57 F.3d 733, 737 (9th Cir. 1995) (FDA, "the agency charged with administration of the statute, which has consulted with the prosecutor in the steps leading to prosecutions, is to be considered as part of the prosecution in determining what information must be made available to the defendant charged with the violation of that statue. The government cannot with its right hand say it has nothing while its left hand holds what is of value"); United States v. Bryan, 868 F.2d 1032, 1035 (9th Cir. 1989); United States v. La Rouche Campaign, 695 F. Supp 1265, 1280 (D. Mass. 1988) (government counsel must search, inter alia, for documents, "that are maintained by any other government agency that has participated in or assisted in the investigation or prosecution of the charges that are the subject of this trial, or any related potential charges").

Proof that FDA is cooperating with Complaint Counsel is apparent: First, FDA is voluntarily providing Mr. Read to testify on Complaint Counsel's behalf, and second, counsel for FDA has stated what he believes will be the scope and substance of Mr. Read's testimony, information he likely garnered from discussions with Complaint

Counsel. FDA is not an unwitting and unwilling participant in this matter, but rather an integral part of Complaint Counsel's team.[5]

FDA also argues that the subpoena should be quashed because the Respondents have failed to make the requisite showing under Section 3.36 of the FTC's Rules of Practice. Motion at 4-5. The agency asserts that the materials sought by Respondents can be reasonably obtained by other means, are not reasonable in scope, and are not relevant.

Of course, this argument ignores Your Honor's findings on this subject. In its Answer to Respondents' Motion for Issuance of Subpoenas to David T. Read and to the FDA, Complaint Counsel set forth arguments that were substantially similar to the ones that FDA is making now. Exhibit A at 6-9. Your Honor carefully balanced the arguments then, and ruled that the materials sought by Respondents could not be reasonably obtained by other means, and removed provisions from the subpoena that Your Honor deemed to be unreasonable in scope or irrelevant.

Your Honor's previous ruling aside, the arguments that FDA makes in its Motion are without merit. First, it is patently obvious that the information requested by the Respondents' subpoena cannot reasonably be obtained by other means. FDA baldly asserts that the subpoena is improper because the Respondents could theoretically secure

---

[5] FDA has cited only one FTC decision in which its Touhy regulations were held to preclude discovery in litigation. See In the Matter of Hoechst Marion Roussel, Inc. 2000 FTC LEXIS 149 (2000) (Chappell, ALJ). This decision is plainly inapposite. It is Respondent's understanding that, unlike the present matter, FDA personnel were not scheduled to testify on Complaint Counsel's behalf. This decision is thus factually distinct, and irrelevant to the present analysis.

the requested document through the FOI Act. Motion at 4. Discovery closes on April 13, 2001. Respondents have deferred taking Mr. Read's deposition solely because we need the subpoenaed documents for the deposition. Clearly, FDA's effort to treat the subpoena as a FOI request is a thinly veiled effort to avoid producing the documents.

Also, the FOI Act argument flies in the face of Your Honor's rejection of the same argument made over twenty years ago. In the Matter of Exxon Corp., Your Honor ruled that the FTC's Rules of Practice on subpoenas to government agencies do not require "final agency and final court determinations on FOIA requests as prerequisites to allowing formal discovery to respondent in adjudicative proceedings." 1980 FTC LEXIS 121, *11 (Feb. 8, 1980) (Order Ruling on Respondents' Motion for Subpoenas Duces Tecum and Preservation of Documents). Your Honor also noted that "not all potentially relevant documents will be available through FOIA," and that "an extended line of cases hold that FOIA was not intended to be a discovery tool [citations omitted]." Id. at *11-*13. The Respondents in this case should also be spared the "delay which resort to the FOIA machinery would engender, and [should be] afford[ed] . . . access to all discoverable material, regardless of whether such are available through the FOIA." Id. at *15.

Moreover, the case that FDA cites in its Motion in support of its FOI Act argument actually proves Respondents' point. Judge Parker concluded In the Matter of Sonic Technology Products, Inc. that the respondents could reasonably obtain the necessary information through the FOI Act after the federal agency's FOI officer had informed the respondents that the documents would be divulged four months before the

scheduled hearing. 1992 FTC LEXIS 188 at *1 (July 28, 1992). Judge Parker determined that the FOI Act was a reasonable alternative to a subpoena because the respondents would possess the materials sufficiently in advance so as to "not prejudice their ability to prepare for trial." Id. In the instant case, Respondents would be badly prejudiced. They have no hope that FDA could produce all or most of the responsive documents pursuant to a FOI request before April 13, 2001, the deadline for the close of discovery in this case, and the date by which Respondents must depose Mr. Read. FDA's FOI Office is notoriously understaffed, and requests routinely languish for months and even years.

FDA has known that Respondents need all documents relevant to Mr. Read's testimony since January 26, 2001, the day Mr. Read received a courtesy copy of Respondents' Motion for the issuance of subpoenas. Nearly two months have passed, and Respondents still do not have all of the necessary documents. Counsel for FDA states in its Motion that the FDA does not consider the production of documents related to its regulation of deanol in its Drug Efficacy Study Implementation ("DESI") proceeding to be unreasonable.[6] Motion at 6, fn. 3. Respondents received these

---

[6] FDA approved a New Drug Application in 1958 for a deanol product submitted by Riker Laboratories, Inc. ("Deaner NDA") pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA") of 1938. The FDCA of 1938, among other things, required drug manufacturers to show that new drugs were safe before marketing them. In 1962, Congress passed the Kefauver-Harris Drug Amendments to the FDCA ("1962 Amendments") to ensure efficacy and greater drug safety. Pursuant to the 1962 Amendments, manufacturers of already-approved drugs were required to provide FDA with evidence of effectiveness. FDA then reviewed the new efficacy data in an undertaking that was known as the Drug Efficacy Study.

documents on March 16, 2001. See Exhibit B. This response, however, contains a fraction of the information requested of FDA by Respondents' subpoena, and provides no indication of whether FDA will produce the additional documents, and if so, whether such production will be made before the Hearing. Moreover, FDA's Motion is deficient insofar as it fails to address any of the specifications of Respondents' subpoena other than those involving the Deaner NDA or DESI materials.

FDA also suggests that Respondents could reasonably obtain some of the documents covered by the subpoena directly from the company that submitted them to FDA more than forty years ago. Motion at 4. This assertion is absurd. The FDA, not that company, voluntarily entered the case. It is incredulous that FDA would assert it is reasonable for Respondents to seek 43-year-old documents from a disinterested, corporate third-party. FDA's assertion also badly misses the point that it has no idea whether that company even has those documents. In short, Respondents served their subpoena on FDA because they have no other reasonable alternative.

Next, FDA argues that the subpoena should be quashed because it is not reasonable in scope. Motion at 5. This argument again ignores the fact that Your Honor already ruled that the subpoena as issued is reasonable in scope. The agency takes issue with the fact that Respondents have asked for the Deaner NDA. Motion at 5. FDA insinuates that the Deaner NDA is enormous. It also complains that it would need weeks, if not months, to retrieve the documents from storage and to redact them prior to release. Id. FDA's protestations of unreasonableness, however, must be steeply discounted by the fact that there is no evidence that the agency has even bothered to look at the NDA to

determine the amount of work actually involved in retrieving and redacting if for release. Nor is it clear that FDA adequately investigated whether the NDA file could be retrieved on an expedited basis.

Moreover, if FDA now finds itself pressed for time, it is only because the agency affirmatively chose not to act earlier. Complaint Counsel identified Mr. Read as a witness on January 8, 2001. Respondents served Mr. Read with a copy of their Motion for the issuance of subpoenas to FDA on January 26, 2001. The Motion contained the subpoena specification demanding the release of the Deaner NDA. It is fundamentally unfair for FDA to argue that it is unreasonable to expect it to produce the relevant documents on a timely basis given that the agency sat on its hands for more than seven weeks.

Finally, FDA argues that the subpoena should be quashed because the Deaner NDA is irrelevant, given the scope of Mr. Read's likely testimony. Motion at 6. The agency states that Complaint Counsel will call Mr. Read to testify for the purpose of explaining FDA's involvement in the regulation of deanol in the agency's DESI proceeding. However, FDA has mischaracterized the scope of Mr. Read's direct testimony and ignores Respondents' right to supplement that testimony with cross-examination. According to Complaint Counsel, Mr. Read's testimony will "help explain why FDA's earlier approval of Deaner Tablets," i.e., the Deaner NDA, "signified no judgment as to the efficacy of deanol in treating ADHD." Exhibit A at 5. Because Mr. Read's testimony will address the significance of FDA's approval of the Deaner NDA, Respondents' subpoena for documents from the Deaner NDA is relevant, appropriate,

and necessary if Respondents are to have any meaningful hope of cross-examining Mr. Read at the Hearing. Complaint Counsel opened the door and FDA cannot now slam it shut.

CONCLUSION

For the foregoing reasons, Respondents respectfully request that FDA be compelled to respond to the subpoena duces tecum, and that FDA's Motion to Quash be denied.

Dated: March 19, 2001.

Respectfully submitted,

By: _____

John R. Fleder
Stephen H. McNamara
A. Wes Siegner, Jr.
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.
Gerald A. Kessler

EXHIBIT A

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

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

---

[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,

Dean Graybill /LJD

Matthew D. Gold (415) 356-5276
Kerry O'Brien (415) 356-5289
Dean Graybill (415) 356-5224
Linda K. Badger (415) 356-5275

Complaint Counsel
Western Region
Federal Trade Commission
901 Market Street, Suite 570
San Francisco, CA 94103

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:

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

Dean Graybill /LJD

Matthew D. Gold
Kerry O'Brien
Dean C. Graybill
Linda K. Badger

EXHIBIT B

**LETTER FROM MICHAEL M. LEVY, JR., ESQ.,
ASSISTANT CHIEF COUNSEL FOR ENFORCEMENT, FDA
TO PAUL L. FERRARI, ESQ., HYMAN, PHELPS & MCNAMARA, P.C.,
COUNSEL FOR RESPONDENTS (MARCH 15, 2001)**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the General Counsel

Office of the Chief Counsel
Food and Drug Administration
5600 Fishers Lane, GCF-1
Rockville, MD 20857

March 15, 2001

VIA FEDERAL EXPRESS
Paul L. Ferrari, Esq.
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W.
Suite 1200
Washington, D.C. 20005-5929

Re: In the Matter of Natural Organics, Inc., Docket No. 9294 (FTC)

Dear Mr. Ferrari:

I am enclosing documents responsive to the subpoena duces tecum you served on David Read from the Center for Drug Evaluation and Research on January 26, 2001. As we discussed in our phone conversations on March 5 and March 7, 2001, the agency has treated the subpoena as a request under the Freedom of Information Act. The enclosed documents are the contents of the DESI file for Deaner tablets. No redactions were made.

If you have any questions, please call me at (301) 827-5087.

Sincerely,

Michael M. Levy, Jr.
Assistant Chief Counsel for
Enforcement

attachments

cc w/o attachments: Dean Graybill, FTC

CERTIFICATE OF SERVICE

I hereby certify that on this nineteenth day of March 2001 copies of the foregoing Respondents' Answer to the United States Food and Drug Administration's Motion to Quash Subpoena Served by Natural Organics, Inc. were served by facsimile transmittal and first-class mail, postage prepaid, on the following parties:

Matthew D. Gold, Esq.
Kerry O'Brien, Esq.
Dean Graybill, Esq.
Federal Trade Commission
901 Market Street, Suite 570
San Francisco, CA 94103,

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

and two copies were hand delivered to :

Judge James P. Timony
Administrative Law Judge
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580.

John R. Fleder