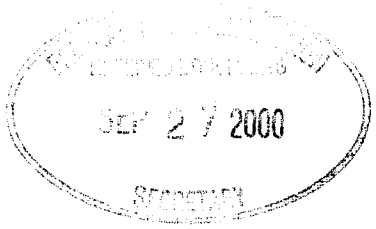


UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of	)	
	)	
HOECHST MARION ROUSSEL, INC.,	)	
a corporation,	)	
	)	
CARDERM CAPITAL L.P.,	)	Docket No. 9293
a limited partnership,	)	
and	)	The Honorable
ANDRX CORPORATION,	)	D. Michael Chappell
a corporation.	)	Administrative Law Judge
	)	

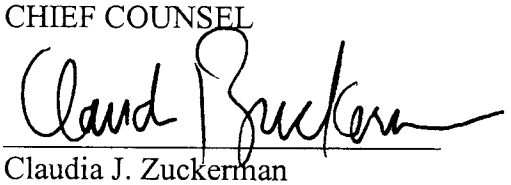
MOTION OF THE UNITED STATES FOOD AND DRUG ADMINISTRATION FOR LEAVE TO FILE A REPLY MEMORANDUM IN SUPPORT OF ITS MOTIONS TO QUASH SUBPOENAS SERVED BY AVENTIS PHARMACEUTICALS, INC., AND ANDRX CORPORATION

Pursuant to § 3.22(c) of the Federal Trade Commission Rules of Practice for Adjudicatory Proceedings, nonparty United States Food and Drug Administration respectfully requests leave to file the attached Reply Memorandum in Support of its Motions to Quash Subpoenas Served by Aventis Pharmaceuticals, Inc., and Andrx Corporation in this proceeding. Andrx served its Opposition on FDA on September 12, 2000. Aventis served its Opposition on FDA on September 20, 2000, nine days after it was filed. FDA respectfully requests the opportunity to address certain inaccuracies in both Oppositions and submits the attached reply memorandum to do so.

Dated: September 25, 2000.

Respectfully Submitted,

MARGARET JANE PORTER
CHIEF COUNSEL

By: 

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Food and Drug Administration

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of	)	
	)	
HOECHST MARION ROUSSEL, INC.,	)	
a corporation,	)	
	)	
CARDERM CAPITAL L.P.,	)	Docket No. 9293
a limited partnership,	)	
and	)	
ANDRX CORPORATION,	)	
a corporation.	)	
	)	

ORDER GRANTING LEAVE TO FILE REPLY MEMORANDUM
IN SUPPORT OF FDA'S MOTIONS TO QUASH SUBPOENAS SERVED
BY AVENTIS PHARMACEUTICALS, INC., AND ANDRX CORPORATION

IT IS HEREBY ORDERED that the United States Food and Drug Administration's Motion for Leave to file a Reply Memorandum in Support of its Motions to Quash Subpoenas Served by Aventis Pharmaceuticals, Inc., and Andrx Corporation is GRANTED.

D. Michael Chappell
Administrative Law Judge

Dated: September ___, 2000.

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of	)	
	)	
HOECHST MARION ROUSSEL, INC.,	)	
a corporation,	)	
	)	
CARDERM CAPITAL L.P.,	)	Docket No. 9293
a limited partnership,	)	
and	)	The Honorable
ANDRX CORPORATION,	)	D. Michael Chappell
a corporation.	)	Administrative Law Judge
	)	

REPLY MEMORANDUM IN SUPPORT OF FDA'S MOTIONS TO QUASH SUBPOENAS SERVED BY AVENTIS PHARMACEUTICALS, INC., AND ANDRX CORPORATION

Nonparty United States Food and Drug Administration (FDA) submits this memorandum in support of its Motion to Quash Subpoena Served by Aventis Pharmaceuticals, Inc. ("Aventis"), and its Motion to Quash Subpoena Served by Andrx Corporation ("Andrx") in this proceeding.

Production of Records Pursuant to FDA's Regulations

Pursuant to 21 C.F.R. § 20.2, an FDA officer or employee, upon being served a subpoena duces tecum, is required to decline production of records in response to the subpoena. Section 20.2 contemplates that, upon withdrawal of the subpoena, FDA would produce the records that had been requested by the subpoena according to procedures established in 21 C.F.R. Part 20. Part 20 contains FDA's Freedom of Information ("FOI") regulations.

FDA's policy on disclosure of FDA records is to make records available to the fullest extent possible, consistent with protecting privacy rights, property rights in trade secrets and confidential commercial information, and the agency's need to promote candid internal deliberations and pursue its regulatory activities without disruption. 21 C.F.R. § 20.20(a). Aventis and Andrx had, and still have, the opportunity to obtain FDA records pursuant to 21 C.F.R. Part 20.[1] Such records would be redacted for, among other things, trade secrets, confidential commercial information, and the agency's internal pre-decisional deliberations. The release of trade secrets or confidential commercial information would require, at a minimum, advance authorization of such release by the submitter of the information to the agency.

According to Aventis, FDA's regulations in 21 C.F.R. Part 20 do not require the withdrawal of a subpoena duces tecum prior to the production of records in accordance with Part 20. Aventis attempts to support its belief by citing to 21 C.F.R. § 20.83(a). Aventis, however, incorrectly interprets the limitations on exemptions listed in 21 C.F.R. Subpart E, specifically "disclosure required by court order." See 21 C.F.R. § 20.83. Agency documents responsive to a subpoena are not automatically made available by

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[1] Aventis appears to assert that it was not informed of its option to use the process in 21 C.F.R. Part 20 to obtain certain documents that it seeks from FDA. Aventis also claims that it was awaiting information from FDA regarding the option of withdrawing its subpoena and using an expedited "FOIA request." FDA, however, after initially describing the option to Aventis on August 17, 2000, which was confirmed in a letter dated August 18, 2000 (attached as Exhibit A to Aventis's Opposition), provided the requested information over the telephone to Aventis on August 22, 2000. Aventis expressed no further interest in using a FOIA request to obtain documents from the agency.

§ 20.83 to the person serving the subpoena. A subpoena is not a "final court order requiring . . . disclosure" as described in 21 C.F.R. § 20.83(a). If it were, then 21 C.F.R. § 20.2(b) (prohibiting the production of documents in response to a subpoena duces tecum) would be rendered a nullity, thus violating a basic tenet of statutory interpretation. Aventis and Andrx, therefore, should be required to follow FDA's procedures for obtaining documents before seeking relief from the Court.

Availability of Documents Through Other Means

Aventis argues that, if Biovail is uncooperative with Aventis's request for documents regarding Biovail's drug application, then FDA is the only source of certain information Aventis seeks.[2] Such an argument seems to skirt FTC's requirement that the material Aventis and Andrx seek through their respective subpoenas served on FDA "cannot reasonably be obtained by other means." See 16 C.F.R. § 3.36(b). If Aventis is having problems with Biovail's production of documents, then Aventis should address such problems with Biovail. There is no need for Aventis to burden a nonparty government agency with its inability to obtain documents from a "party-in-interest."

Relevancy of Certain FDA Documents

Aventis and Andrx misunderstand the nature of FDA's relevancy argument with respect to FDA internal communications about certain drug applications. Prior to a final agency decision, individual reviewers' opinions and deliberations regarding deficiencies of

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[2] Andrx makes a similar argument with respect to documents regarding Biovail's and Faulding's applications.

an application may be resolved or cured before a final determination. Those preliminary thoughts are not determinative of the existence or nonexistence of significant deficiencies that delay or preclude approval. The final agency decision, however, is relevant to that issue, and such decision is communicated in writing to the applicant. And therefore, the communication to the applicant is available to Aventis and Andrx from the applicant itself.

Producing a Privilege Log

Certain documents sought by Aventis and Andrx contain internal agency deliberations. Aventis and Andrx argue that FDA cannot move to quash any part of their subpoenas without submitting a privilege log of the documents the agency wishes to withhold on the ground that they are covered by the deliberative process privilege. Requiring FDA to produce a privilege log at this stage is premature.

The threshold requirements for asserting the deliberative process privilege are different for parties versus nonparties. Nonparty government agencies are permitted to make a general argument of privilege. See, e.g., In the Matter of Flowers Industries, Inc., 1981 FTC Lexis 117 *2 (September 11, 1981) ("When the privilege is raised by a third party to a broad request for discovery of documents in the custody of the third party, the description of the documents for which the privilege is asserted may be by general category."); In the Matter of Exxon Corporation, et al., 1980 FTC Lexis *7, 8 (December 4, 1980) (same). Under that standard, FDA has met its burden and should be permitted to rely on the assertions of privilege it has made in its Motions to Quash.

The Federal Trade Commission Rules of Practice, 16 C.F.R. § 3.38A, do not suggest a contrary result. Section 3.38A provides that, in response to a "subpoena or other request for production," a person withholding responsive material must submit a schedule of items withheld. Section 3.38A, however, does not appear to apply to subpoenas issued on government agencies (other than the Commission). That section makes explicit reference to subpoenas issued pursuant to § 3.34, as well as to interrogatories pursuant to § 3.35 and to requests for production or access pursuant to § 3.37. Section 3.34, however, does not authorize the issuance of subpoenas requiring the production of documents in the custody of an official or employee of a governmental agency other than the Commission. Such subpoenas are authorized only in accordance with § 3.36, which is not listed in § 3.38A. The requirement in § 3.38A for submitting a schedule of withheld documents, therefore, does not cover the subpoenas at issue here.

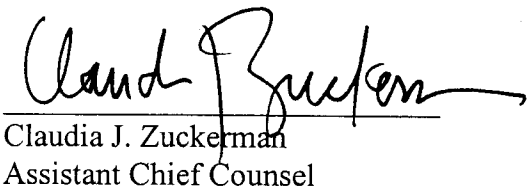
Conclusion

The respondents have made unreasonable and unnecessary demands on FDA, and FDA respectfully requests that its motions be granted.

Dated: September 25, 2000.

Respectfully Submitted,

MARGARET JANE PORTER
CHIEF COUNSEL

By: 

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CERTIFICATE OF SERVICE

I, Claudia J. Zuckerman, hereby certify that on September 25, 2000, I caused a copy of the Reply Memorandum in Support of Motions to Quash Subpoenas Served by Aventis Pharmaceuticals, Inc., and Andrx Corporation to be served upon the following persons by Federal Express:

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Administrative Law Judge
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Washington, DC 20580

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Federal Trade Commission
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