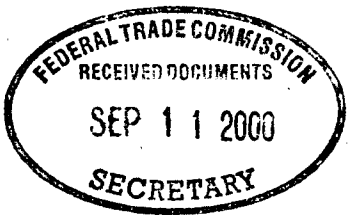
UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION



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

MEMORANDUM IN OPPOSITION TO THE MOTION OF THE UNITED STATES FOOD AND DRUG ADMINISTRATION TO QUASH SUBPOENA SERVED BY RESPONDENT AVENTIS PHARMACEUTICALS, INC.

Pursuant to Rule 3.22 of the Federal Trade Commission's ("FTC")Rules of Practice, Respondent Aventis Pharmaceuticals Inc. ("Aventis"), formerly known as Hoechst Marion Roussel, Inc. ("HMR"), submits this Memorandum in Opposition to the Motion of the United States Food and Drug Administration ("FDA") to Quash Subpoena Served by Aventis Pharmaceuticals, Inc. This Opposition first addresses the FDA's broad arguments that it is, somehow, exempt from complying with the subpoena and then focuses on each of the specific document requests contained in the subpoena. A draft Order denying the FDA's motion and mandating prompt compliance with the subpoena is attached.

I. BACKGROUND

On August 8, 2000, the Court authorized issuance of a subpoena *duces tecum* to the FDA based upon Aventis' motion under Rule 3.36 of the FTC's Rules of Practice.[1] 16 C.F.R. § 3.36. Aventis served the subpoena on the FDA the following day and delivered a courtesy copy of the subpoena along with a letter to the General Counsel of the FDA.[2] In the letter, Aventis informed the FDA that it need not produce documents which it might produce in response to the Andrx subpoena. On August 11, 2000, FDA filed a motion to quash a subpoena *duces tecum* issued by Andrx.

On August 16,2000, counsel for Aventis contacted FDA's counsel, Ms. Claudia Zuckerman, to begin "meet and confer" discussions.[3] Notwithstanding the filing of FDA's motion to quash the Andrx subpoena, Aventis hoped it would be able to reach partial agreement with the FDA in order to limit the matters necessary for review by the Court. Toward this end, substantive calls were held with the FDA on August 17, 2000 and again on August 22, 2000.[4]

The meet and confer process was abruptly halted when, on August 25, 2000, the FDA filed its Motion to Quash Subpoena Served by Aventis Pharmaceuticals, Inc. As discussed below, discussions were ongoing regarding several issues, including the potential use of the FDA's Freedom of Information Act ("FOIA") regulations to obtain a portion of the materials and the public

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1 See exhibits D and E to the Declaration of Peter D. Bernstein (the "Bernstein Declaration") accompanying this memorandum.

2 See exhibit F to the Bernstein Declaration.

3 See Bernstein Declaration, ¶ 2.

4 See Bernstein Declaration, ¶¶ 3, 4 and 5.

availability of other materials. Mr. Bernstein placed two calls to Ms. Zuckerman on August 24, 2000 which have yet to be returned.[5]

II. SECTION 3.36 OF THE FTC'S RULES OF PRACTICE

In its motion for the issuance of a subpoena *duces tecum* to the FDA, Aventis specifically met the requisite showing pursuant to Section 3.36 of the FTC's Rules of Practice.[6] As discussed in that motion, subpoenas directed to other governmental agencies must satisfy the following tripartite showing:

> (1) the material sought is reasonable in scope;
> (2) if for the purposes of discovery, the material falls within the limits of discovery under §3.31(b)(1); and
> (3) the information and material sought cannot reasonably be obtained by other means.

16 C.F.R. §3.36(b).

Aventis demonstrated that the materials it seeks from the FDA are relevant to one or more of the central issues in this proceeding. First, Aventis' proposed requests were narrowly drawn and only required the FDA to search for responsive documents in discrete files at the agency. Second, each request only sought information relevant to the dispute in this case.[7] Finally, since Aventis already collected all of the publicly available documents, the specific limited documents

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5 See Bernstein Declaration, ¶ 6.

6 See exhibit D to the Bernstein Declaration. The relevancy of each request was also reviewed with the FDA during the meet and confer process. See Bernstein Declaration, ¶ 3.

7 Like discovery under the Federal Rules of Civil Procedure, the standard for determining relevancy in Part III litigation is quite broad. *R.R. Donnelley & Sons Co.*, Docket No. 9243, 1991 FTC LEXIS 268, at *1 (June 6, 1991) (denying third party's motion to quash or limit subpoena, and rejecting relevance argument in light of the "broad scope of discovery in Commission proceedings."). Commission Rule 3.31(c) makes clear that a party to an adjudicative proceeding "may obtain discovery to the extent that it may be reasonably expected to yield information relevant to the allegations of the complaint, to the proposed relief, or to the defenses of any respondent." 16 C.F.R. § 3.31(c)(1).

requested by the subpoena made the FDA the most expeditious and only source for Aventis to secure the desired information.

III. DISCOVERY FROM THE FDA

The FDA claims Aventis is entitled to the agency no discovery from it even though the FTC's alleged the FDA is responsible for the approval of generic pharmaceuticals products and the FDA was specifically involved in the evaluation and ultimate approval of the generic applications filed by Andrx, Faulding and Biovail.[8] The FDA's position is that the documents sought are not relevant; could be obtained from other persons or entities; FDA personnel had better things to do than respond to discovery requests; to the extent FDA documents are responsive, the only non-privileged ones are available publicly; and FDA would not produce a log of withheld documents.[9] The allegations of the Complaint, however, along with the affirmative defenses raised by Aventis, necessitate seeking documents from the FDA concerning third-party applications and the FDA's regulatory process.

The FDA, relying on the regulations found in 21 C.F.R. Part 20, asserts it will neither disclose responsive documents nor provide a log of documents withheld based on claims of privilege. A cursory examination of Part 20 reveals that the regulations are specifically limited to information available for public disclosure under FOIA. In effect, FDA attempts to decline all outside discovery and attemps to force Aventis into the black hole of the FDA's FOIA system.

Aventis has taken more than adequate steps to obtain the needed information from public sources and the FDA. Aventis has collected all of the publicly available materials through

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8 See Complaint, ¶¶ 8 through 11 and 17, 19, 20, 27 and 28.

9 See Bernstein Declaration, ¶ 3.

use of the FDA website and physical searches at the FDA Records Branch. Under the FDA's procedures, however, no other documents may be produced (including a log of withheld documents and any redactions made by the agency), without a court order. Absent some sort of expedited process -- that the FDA declined to describe[10] -- discovery from the FDA would, in all likelihood, occur outside the previously scheduled discovery deadline. When talks were terminated by the FDA and the Motion to Quash was filed, all hope of utilizing such process effectively disappeared.[11]

The remaining issue is whether the FDA has an obligation to produce responsive non-public documents and provide a log of documents withheld on the basis of privilege. Rather than discuss the production of documents, the FDA seeks to impose FOIA on every scrap of paper within the agency's possession. FDA asserts that other than materials available for production under FOIA, there is no other means for production. This position is contrary to the FDA's own regulations, which clearly envision the production of the types of materials sought by the subpoena where required by Court order. The regulations state:

> Records of the Food and Drug Administration which the Commissioner has determined are not available for public disclosure, either in the form of a regulation published or cross-referenced in this part or by a written determination pursuant to the procedure established in Sec. 20.44, shall nevertheless be made available for public disclosure in compliance with a final court order requiring such disclosure.

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10 During the meet and confer process, the FDA suggested utilizing an expedited FOIA procedure to collect publicly available documents for certain of the requests contained in the subpoena and agreed to provide information concerning this process to Aventis' counsel. See Bernstein Declaration, ¶ 5. It was clear that the FDA (1) did not intend to produce materials responsive to all of the requests; (2) materials produced under the FOIA procedures would be redacted by FDA employees; and (3) no "privilege log" would be produced. Nonetheless, counsel for Aventis requested information relating to issues of timing and scope of the "expedited" FOIA process in order to see if the scope of the outstanding issues might be narrowed. Aventis was awaiting the receipt of this information when the FDA unilaterally terminated discussions and filed its Motion to Quash.

11 As Aventis collected the publically available documents, they did not make a formal request under 21 C.F.R. Part 20. The subpoena was never intended to be a substitute for a FOIA request to the FDA. In fact, the FTC's Rule of Practice 3.36 specifically states that "No application for records pursuant to. . . the Freedom of Information Act may be filed with the Administrative Law Judge."

21 CFR Sec. 20.83(a). The FDA fails to acknowledge that materials are available outside of the FOIA process where a court, such as this one, orders production..

Additionally, the FDA never made an offer to produce documents should Aventis consent to receipt of such documents pursuant to 21 C.F.R. Part 20.[12] In fact, the early discussions made clear that in order to utilize the FDA FOIA procedures, the FDA required Aventis to withdraw its subpoena in its entirety. By withdrawing its subpoena, Aventis would relinquish its right to seek redress from the Court should an impasse be reached regarding the scope and timing of production. Instead, Aventis would be left to the FOIA proceedings, ensuring that no responsive documents would be produced in a timely fashion should Aventis disagree with the FDA's unilateral decisions to withhold or redact responsive information.

IV. SPECIFIC REQUESTS

A cursory review of the specific requests reveals the relevancy of those requests and the inability of Aventis to obtain those documents through other means. The FDA should be ordered to produce documents responsive to these requests without further delay. Of course, as discussed below, the FDA retains the ability to withhold documents on the grounds that the materials are privileged.

Request No. 1: All documents concerning any ANDA and NDA submitted by Biovail for the manufacture and production of a pharmaceutical product that is the bioequivalent of Cardizem® CD, excluding the ANDA and NDA themselves. This request includes, by way of example, but is not limited to:

(a) all communications between the FDA and Biovail;

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[12] See Bernstein Declaration, ¶ 5.

(b) all communications between the FDA and any person, including but not limited to any reports from and correspondence with external consultants, relating to the issues raised in the Andrx citizen petition; and

(c) all FDA analyses and communications, including but not limited to bioequivalence issues raised in the review of any ANDA and NDA submitted by Biovail for the manufacture and production of a pharmaceutical product that is the bioequivalent of Cardizem® CD and documentation reflecting medical review of clinical studies contained in any NDA submitted by Biovail for the manufacture and production of a pharmaceutical product that is the bioequivalent of Cardizem® CD.

Discussion: A major, critical question posed by this case is whether, but for the Stipulation and Agreement, either of the other two generic applicants (Faulding or Biovail) could have entered the market earlier than Andrx did with a non-infringing generic version of Cardizem® CD. For this reason, documents in the FDA's possession relating to the status of Biovail's applications for generic Cardizem® CD bear directly on whether they could have reached the market with a non-infringing generic product prior to the introduction of the Andrx product. Aventis has reason to believe that the FDA's files will show that flaws in Biovail's application, coupled with the complexity of the bioequivalency issues raised by Biovail's application, caused the FDA's approval of Biovail's application to issue months after the non-infringing version of Andrx's product reached the market.

The FDA declines to produce the requested materials responsive to Request 1(a) based on a misguided belief that the materials are available from Biovail and that the commercial sensitivity of such documents restricts the release of such documents. The FDA is wrong.

While Biovail agreed to provide Aventis access to materials that were produced in unrelated litigation in New Jersey, there are serious questions regarding the updating of that production.[13] These and other issues regarding the subpoena issued to Biovail remain unresolved.

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[13] The updating of the Biovail documents remains one of the open issues in the New Jersey litigation.

It is inconceivable that Aventis would be limited to obtaining historical documents concerning the FDA process surrounding Biovail's applications directly from Biovail. Biovail is clearly a party-in-interest and allowing it to select documents for production would place Aventis at a severe disadvantage. Thus, absent Biovail's cooperation, the FDA is the only source for the updated communications.

The FDA states that the materials requested are commercial sensitivity and that Biovail is in the best position to make decisions regarding the release of the communications. This ignores the fact that Aventis explained to the FDA during the meet and confer that Aventis has requested these materials from the FDA in response to Biovail's failure to complete its discovery obligations. As Biovail has already given consent to production of a subset of related documents under the Second Amended Protective Order Governing Discovery Materials, there is no reason that Biovail would not consent to FDA release of communications, nor is there any indication that the FDA has sought such consent. As explained above, Aventis will be placed at a serious disadvantage should Biovail be in a position to cherry-pick materials available for Aventis to present its defense. As such, the FDA should be ordered to produce all communications between the FDA and Biovail.

As to Request 1(b), the FDA states that materials regarding the Andrx citizens petition are publicly available. While this is true for a portion of the requested documents, Aventis has reason to believe that there are materials that are responsive to the request that do not appear on the public record.

Aventis has obtained all of the documents that appear on the public docket at the FDA. However, the request goes further, in seeking "all communications between the FDA and any person, including but not limited to any reports from and correspondence with external consultants." Other than those comments that have found their way to the public docket, Aventis wishes to

confirm that there were no other comments or communications regarding the citizen petition.[14] In addition, the public docket would not contain documents exchanged with external consultants. Should the FDA wish to object to the production of such documents on grounds of deliberative process privilege, the proper procedure concerning the invocation of this privilege, discussed below, should be followed.

The FDA also refuses to produce documents responsive to Request 1(c) related to bioequivalence issues raised by Biovail's applications based on relevancy objections. As explained in the Motion for Issuance of the subpoena, these documents are clearly relevant to issues raised in Complaint and potential defenses of respondents.[15]

The FDA is the only source for this information. For example, the FDA reviewers' opinions are central to whether the FDA would consider approval of Biovail's product based on the bioequivalency issues. As discussed below, the FDA retains the ability to withhold these documents provided that the privilege has been properly invoked and the withheld documents appear on a log.

> **Request No. 2:** All documents concerning comments submitted to FDA by the FTC relating to FDA's proposed rule on 180-day generic drug exclusivity for ANDAs, including but not limited to any communication between the FDA and the FTC or any other person, and internal FDA communications.

Discussion: The FDA declines to produce documents relating to FTC's comments on FDA's proposed 180-day generic drug exclusivity rule. The FDA claims that these materials are privileged and that the FTC has already produced such materials.

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14 Should the FDA certify that the documents on the public record represent the totality of documents responsive to this request, Aventis would withdraw this portion of the subpoena *duces tecum*.

15 The standard of relevancy is quite broad under the FTC's Rules of Practice. See footnote 7, supra.

To date, the FTC has not produced materials other than comments that were publicly available from the FTC website. The request is broader in that it calls for the production of communications (1) between the agencies and (2) internal considerations related to the FTC's comments on the 180-day generic drug exclusivity rule. Communications of this type would include documents concerning review panels, advisory committees or speeches and comments by FDA personnel.

These documents are clearly relevant as the FTC asked FDA for relief similar to proposed relief in our case. In both instances, the FTC has asked all patent litigation settlement agreements and agreements related to the filing of an ANDA application be filed with the FDA prior to being finalized. While the FDA has yet to publicly comment, Aventis has reason to believe there will be FDA analysis of the FTC's proposed relief.

There is nothing more central to the prosecution of this case than the relief sought by the Complaint. As, this relief was suggested to the relevant regulatory agency, it is absolutely imperative to know how the FDA reacted to the position put forward by the FTC. Again, should the FDA wish to object to the production of such documents on grounds of deliberative process privilege, the proper procedure concerning the invocation of this privilege and a log of withheld documents are discussed below.

> **Request No. 3:** All documents which reflect the date of submission, filing, tentative approval and final approval of the ANDA submitted by Faulding for the manufacture and production of a pharmaceutical product that is the bioequivalent of Cardizem® CD, excluding the ANDA itself.

Discussion: The FDA stated that Aventis should seek documents related to the submission, filing, tentative approval and final approval of the ANDA submitted by Faulding directly from Faulding. While Andrx has issued a subpoena to Faulding requesting similar information, Aventis has not.

Based on the discussions during the meet and confer process, Aventis was able to obtain a majority of these documents from the FDA website. However, Aventis continues to seek the letter from FDA to Faulding reflecting the date the application was accepted for filing by the FDA. This letter is not available on the FDA website and is important in terms of the various triggering dates contained in the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq. This letter should be publicly available from the FDA. The production of this letter was one of the open topics of discussion when the FDA terminated the meet and confer process. Aventis will withdraw this request if the FDA provides the missing letter and authenticates the letter and the other documents obtained from the website.

Request No. 4: All documents which reflect the date of submission, filing, tentative approval and final approval of Andrx's ANDA for the manufacture and production of a pharmaceutical product that is the bioequivalent of Cardizem® CD and any supplement thereto, excluding the ANDA and supplement themselves.

Discussion: The FDA stated that Aventis should seek documents related to the submission, filing, tentative approval and final approval of the ANDA submitted by Andrx directly from Andrx. While Aventis has requested such documents from Andrx, there are issues of authenticity that would easily be resolved were the materials produced directly from the FDA.

Based on the discussions during the meet and confer process, Aventis was able to obtain a majority of these documents from the FDA website. However, Aventis continues to seek the letter from FDA to Andrx reflecting the date the application was accepted for filing by the FDA and the correspondence from the FDA related to the acceptance and approval of the supplement to the Andrx ANDA for the product that is currently on the market. These letters are not avialbe on the FDA website and are important in terms of the various triggering dates contained in the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq.

Again, these letters should be publicly available from the FDA. The production of these documents were also being discussed when the meet and confer process was aborted. Aventis will withdraw this request if the FDA provides the missing letters and authenticates the correspondence and the other documents obtained from the website.

> **Request No. 5:** All documents concerning development of Probucol for prevention of restenosis after coronary angioplasty, including but not limited to communications between the FDA and any person and any analysis, other evaluation or test regarding such development.

Discussion: The FDA refuses to produce these documents based on relevancy objections and states that Aventis sought the responsive documents from Biovail.

As part of Commission's effort to demonstrate anticompetitive conduct, paragraph 21 of the Complaint details meetings between HMRI and Biovail relating to Probucol.[16] At the time of these meetings, Aventis and others were interested in obtaining a new indication for Probucol for prevention of restenosis after coronary angioplasty. Aventis believes the FDA began a review process concerning the new indication and any guidance FDA offered would be relevant to the decision-making process of whether to continue development of the new indication. There is documentary evidence concerning at least one meeting between personnel from Aventis' predecessor and the FDA relating to Probucol.

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[16] Paragraph 21 of the Complaint states

> Despite the terms of the General Release and Covenant Not to Sue, representatives of Hoechst MRI met with Biovail in early August 1997, ostensibly to discuss resolution of a potential claim of Hoechst MRI against Biovail for patent infringement relating to Biovail's generic version of Cardizem CD, as well as to discuss development of a new indication or use for the drug Probucol, a product for which Hoechst MRI held an approved NDA but which was not then being marketed or sold. During the course of these meetings, Hoechst MRI offered to pay Biovail a substantial amount of money to complete testing and the FDA approval process for a new Probucol indication. This offer was contingent on Biovail's agreeing to refrain from entering the market with a bioequivalent or generic version of Cardizem CD until at least July 1999.

In addition, FDA materials concerning development of Probucol for the treatment of restinosis will substantiate the legitimacy of Aventis's efforts to secure Biovail as a development partner in advancing the new indication for Probucol. Ultimately, it was the FDA's review and comments that dictated Aventis' decision regarding its continued pursuit for the development of Probucol. Finally, complaint counsel recently deposed both an officer and counsel for the key company that was intimately involved in the development of Probucol.

While Aventis has requested certain materials from Biovail regarding its involvement in the development of the new indication for Probucol, the materials sought by the subpoena to the FDA are different in nature. Biovail, acting independently of Aventis, was working to secure a collaboration agreement with the small Canadian company that had done some of the preliminary development for the new indication. These documents will not be in the FDA's files.

The FDA will possess documents relating to meetings, reviews and evaluations that would not have been made available to any of the companies involved in the development process. Again, should the FDA wish to claim privilege for these materials, the procedures for proper invocation and the necessary log must be observed.

V. WITHHELD DOCUMENTS

The FDA has taken the position that a majority of documents responsive to the subpoena would be withheld on grounds of deliberative process privilege yet it has refused to produce a log of withheld documents. Under the FDA FOIA scheme there is no procedure to obtain a log of withheld documents. As the Court pointed out in its Order on Motions to Compel Discovery From Complaint Counsel Filed by Andrx and by Aventis dated August 18, 2000, "[t]he deliberative process privilege is a qualified privilege and can be overcome where there is a sufficient showing of need." (citation omitted). Once the government satisfies its initial burden of demonstrating that

the privilege applies, the Court will balance the discovering party's need for the materials and the interest in accurate fact-finding against the government's interest in non-disclosure. *See FTC v. Warner Communications Inc.*, 742 F.2d 1156, 1161 (9th Cir. 1984).

The Court, citing *Landry v. FDIC*, explained that in order to assert the deliberative process privilege, the agency is required to: (1) make a formal claim of privilege by the head of the department having control over the requested information; (2) assert the privilege based on actual personal consideration by that official; and (3) provide a detailed specification of the information for which the privilege is claimed, with an explanation why it properly falls within the scope of the privilege. 204 F.3d 1125, 1135 (D.C. Cir. 2000). These procedural requirements have yet to be met.

Had the FDA met the procedural benchmarks, Aventis was prepared to demonstrate the need for these materials.[17] However, it is impossible for Aventis to challenge the FDA's ability to protect such documents absent the agency providing a log of withheld documents. Commission Rule 3.38A requires a person withholding responsive materials to provide a detailed log of the items withheld if requested by the original request. For each item withheld, the log must include "the type, title, specific subject matter, and date of the item; the names, addresses, positions, and organizations of all authors and recipients of the item; and the specific grounds for claiming that the item is privileged." 16 C.F.R. 3.38A

The FDA should be ordered to produce a log of documents withheld on the basis of deliberative process or any other claims of privilege. Aventis reserves the right to return to the Court

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[17] Among the factors to be considered in making this determination are: (1) the relevance of the evidence; (2) the availability of other evidence; (3) the government's role in the litigation; and (4) the extent to which disclosure would hinder frank and independent discussion regarding contemplated policies and decisions. *Warner, 742* F.2d at 1161. As discussed throughout this memorandum, many of the issues raised by the FDA subpoena are central to the issues raised by the Complaint in this case.

to seek production of any and all materials for which the FDA asserts the deliberative process or any other privilege.

The application of the FDA regulatory scheme in the manner proposed would seriously curtail the ability to obtain useful discovery from the FDA. The FDA's statement that since the agency has declined to produce documents pursuant to the Aventis subpoena, "[t]his reason should be sufficient grounds alone for quashing the subpoena" is entirely inconsistent with both the FTC and FDA regulations. Reading the regulations in this manner eliminates the need for 16 C.F.R. § 3.36, which specifically allows for discovery of governmental agencies other than the FTC in the context of Part III litigation. This reading is particularly absurd where the FDA regulations specifically contemplate receiving subpoenas (21 C.F.R. § 20.2(b)) and providing materials outside of both publicly and non-publicly available documents when ordered by a court. (21 C.F.R. § 20.83). Based on the proper showing under 16 C.F.R. § 3.36, the FDA should be compelled by order of the Court to produce responsive documents and a log of all documents withheld based upon claims of privilege.

CONCLUSION

For the foregoing reasons, the Aventis respectfully request that the Motion of the United States Food and Drug Administration to Quash Subpoena Served by Aventis Pharmaceuticals, Inc., be denied in all respects that the FDA be compelled to respond to the subpoena *duces tecum* in its entirety, including proper invocation of any privileges claims and providing a proper log of withheld documents.

Dated: September 11, 2000

Respectfully Submitted,

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UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

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

ORDER DENYING MOTION OF THE UNITED STATES FOOD AND DRUG ADMINISTRATION TO QUASH SUBPOENA SERVED BY RESPONDENT AVENTIS PHARMACEUTICALS, INC.

On August 25, 2000, the United States Food and Drug Administration ("FDA") filed a motion to quash subpoena served by Respondent Aventis Pharmaceuticals, Inc. ("Aventis"). Aventis filed a memorandum in opposition on September 11, 2000. FDA's motion is DENIED.

IT IS HEREBY ORDERED that the FDA produce any documents responsive to the subpoena, produce a log of withheld documents and comply with the procedures for the invocation of any applicable privileges.

ORDERED:

D. Michael Chappell
Administrative Law Judge

Date: September __, 2000

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

In the Matter of **Hoechst Marion Roussel, Inc., et al.,** **Respondents.**	Docket No. 9293

CERTIFICATE OF SERVICE

I, Peter D. Bernstein, hereby certify that on September 11, 2000, a copy of Memorandum in Opposition to the Motion of The United States Food and Drug Administration to Quash Subpoena Served by Respondent Aventis Pharmaceuticals, Inc. was served upon the following persons by hand delivery and/or Federal Express as follows:

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Federal Trade Commission
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Hon. D. Michael Chappell
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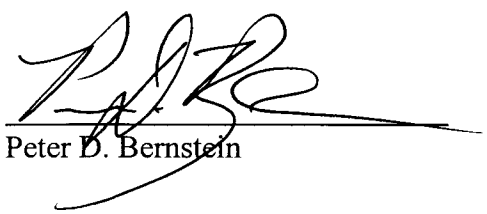


Peter D. Bernstein

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

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

DECLARATION OF PETER D. BERNSTEIN IN SUPPORT OF MEMORANDUM IN OPPOSITION TO THE MOTION OF THE UNITED STATES FOOD AND DRUG ADMINISTRATION TO QUASH SUBPOENA SERVED BY RESPONDENT AVENTIS PHARMACEUTICALS, INC.

I, Peter D. Bernstein, pursuant to 28 U.S.C. § 1746, declare as follows,:

1. I am associated with the firm of Shook Hardy & Bacon LLP, counsel for respondent Aventis Pharmaceuticals, Inc. ("Aventis").

2. On August 16, 2000, D. Edward Wilson, also of this firm, and I left a message for Claudia Zuckerman, an attorney with the Office of Chief Counsel for the United States Food and Drug Administration ("FDA") regarding the subpoena *duces tecum* served on the FDA by Aventis on August 9, 2000. This call was the first step in initiating a meet and confer process.

3. Ms. Zuckerman returned this call on August 17, 2000. At that time, Ms. Zuckerman requested that Aventis withdraw its subpoena. Ms. Zuckerman expressed only an interest in helping Aventis to compile the documents available through public means. Mr. Wilson and I explained the significance and relevancy of each item requested by the subpoena. We read from the FTC's Complaint and offered to provide a copy of it to Ms. Zuckerman. We discussed the production of

a log for documents for which a claim of privilege was being made by Ms. Zuckerman. At the end of the call Ms. Zuckerman stated that the FDA's position was that the documents sought were not relevant; could be obtained from other persons or entities; FDA personnel had better things to do than respond to discovery requests; to the extent FDA documents were responsive, the only non-privileged ones were available publicly; and FDA would not produce a log of withheld documents. She also said she would not change her position on these issues. Nonetheless, she agreed to continue discussions.

4. Mr. Wilson and I spoke with Ms. Zuckerman again on August 17, 2000. We agreed that the FDA's ability to file a motion to quash or limit in a timely manner would not be impeded by our meet and confer discussions. A letter, attached hereto as Exhibit A, was ultimately agreed upon and sent to Ms. Zuckerman on August 18, 2000.

5. On August 22, 2000, we again spoke with Ms. Zuckerman in detail regarding the specific requests. We informed Ms. Zuckerman that we had located some responsive material through the FDA's public sources, and narrowed the request to exclude these documents. Ms. Zuckerman informed us of the possibility of utilizing an expedited FOIA request for the remaining publicly available materials. We asked Ms. Zuckerman what this would entail and she stated that she would obtain that information before our next call. She also informed us that we would need to withdraw the subpoena before she would consent to such a procedure. At no time during this or any other call did Ms. Zuckerman offer that "[s]hould Aventis consent to receipt of documents pursuant to the procedures established in Part 20, FDA will produce records accordingly."

6. On August 24, 2000, I left a message for Ms. Zuckerman in the morning to follow-up on our call of August 22, 2000. Prior to receiving a reply, I received a letter from counsel for Andrx concerning the timing of their reply to the FDA's Motion to Quash. This letter, annexed hereto as Exhibit B, suggested that "Earlier today, the FDA had indicated to counsel for HMR that it would be making a similar motion to quash HMR's subpoena." I understood that this letter had been forwarded to Ms. Zuckerman and I communicated to counsel for Andrx that such language was premature in that meet and confer discussions were ongoing. I left another message for Ms. Zuckerman explaining that it was our position that discussions were still ongoing. Counsel for Andrx then issued a second letter, annexed hereto as Exhibit C, that clarified that this was the case. Ms. Zuckerman has not returned either of my calls from August 24, 2000 and the FDA, by Ms. Zuckerman's hand, filed the instant Motion to Quash on August 25, 2000.

7. Annexed hereto as Exhibit D is a copy of Motion for an Order Approving the Issuance of a Subpoena *Duces Tecum* to the United States Food and Drug Administration, dated July 25, 2000.

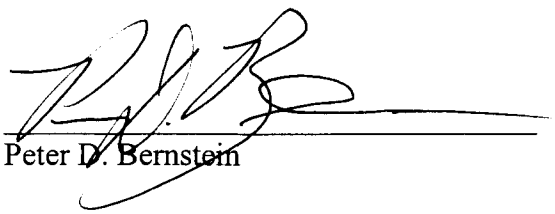
8. Annexed hereto as Exhibit E is a copy of Order Granting Respondent Aventis' Motion for the Issuance of a Subpoena *Duces Tecum* to the United States Food and Drug Administration, dated August 8, 2000.

9. Annexed hereto as Exhibit F is a copy of the letter from Peter D. Bernstein to Margaret Jane Porter, General Counsel of the FDA (including attachments), dated August 9, 2000.

I declare under penalty of perjury that the foregoing is true and correct.

Executed in Washington, D.C., on September 11, 2000

Respectfully Submitted,



Peter D. Bernstein

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August 18, 2000

VIA FACSIMILE (301)480-2255

Claudia Zuckerman, Esq.
United States Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Re: In re Hoechst Marion Roussel, Inc. et al., FTC Docket No. 9293

Dear Ms. Zuckerman:

Thank you for taking the time to discuss the subpoena *duces tecum* issued to the Food & Drug Administration ("FDA") with Ed Wilson and me. As you know, this firm represents Aventis Pharmaceuticals, Inc., formerly known as Hoechst Marion Roussel, Inc. ("HMRI"), in the above referenced administrative proceeding before the U.S. Federal Trade Commission ("FTC").

This letter confirms that with regard to the subpoena, we will examine documents available through the FDA's web site and public docket documents, as you suggested, with the intent of obtaining documents there which will satisfy requests numbers 3 & 4 of the subpoena. In addition, we will search for other documents available on the FDA's web site and public docket with the purpose of being able to provide you with a letter narrowing the scope of our requests, particularly request number 1. Also with respect to request number 1, we will await further discussions with you concerning the option of submitting a Freedom of Information Act request that will satisfy request number 1(a). At the same time, we understand that documents responsive to requests numbers 2 & 5 are not likely to be available publically and electronically from the FDA. From our conversation, it appears that, at the present time, we disagree as to the FDA's obligation to produce documents responsive to these requests.

In order to facilitate further discussion of these matters, HMRI and FDA agree that the deadline for FDA to file a motion to quash or limit the subpoena is extended until five business days after delivery, by fax or other means, of a letter to the FDA informing it of HMRI's lack of agreement to an FDA decision concerning production under the subpoena. FDA, however, remains free to file a motion with the Administrative Law Judge at any time prior to that deadline.

Please contact me should you have any questions regarding with this letter. Ed Wilson and I look forward to working with you.

Sincerely,

Peter D. Bernstein

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WRITER'S DIRECT DIAL

(212) 424-0755

August 24, 2000

VIA FACSIMILE

The Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
Room 104
600 Pennsylvania Avenue
Washington, D.C. 20580

Re: In the Matter of Hoechst Marion Roussel, Inc., et a.,
FTC Docket No. 9293

Dear Judge Chappell:

We write on behalf of respondent Andrx Corporation ("Andrx"). As the Court may recall, both Andrx and Aventis Pharmaceuticals, Inc., formerly Hoechst Marion Roussel, Inc. ("HMR"), obtained orders authorizing subpoenas directed to the U.S. Food and Drug Administration, which were served on the FDA. The FDA has raised precisely the same objections to both subpoenas, and has taken the position, as to both, that it need not produce a single document nor a privilege log. HMR brought this exact issue to the Court's attention in its letter dated August 21, 2000.

On August 10, 2000, the FDA moved to quash the subpoena *duces tecum* served by Andrx. Andrx's response to that motion is presently due on Monday, August 28, 2000. Earlier today, the FDA indicated to counsel for HMR that it would be making a similar motion to quash HMR's subpoena.

Because the bases for opposing these two motions to quash are largely duplicative, it would be more efficient for the Court and all the parties if Andrx and HMR filed a coordinated set of responsive papers. HMR's counsel consents to this process. In

order to effectuate this coordination, we respectfully request that both parties' submissions be due fifteen days after service by the FDA of its motion to quash the HMR subpoena.

We apologize for burdening the Court with this ministerial issue, but FDA's counsel has refused our request to stipulate to the proposed schedule.

Please let us know if we can provide anything further.

Respectfully,

SOLOMON, ZAUDERER, ELLENHORN,
FRISCHER & SHARP

By: Hal S. Shaftel

Hal S. Shaftel
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Counsel for Respondent Andrx Corp.

cc: All counsel

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WRITER'S DIRECT DIAL

(212) 424-0755

August 24, 2000

VIA FACSIMILE

The Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
Room 104
600 Pennsylvania Avenue
Washington, D.C. 20580

Re: In the Matter of Hoechst Marion Roussel, Inc., et a.,
FTC Docket No. 9293

Dear Judge Chappell:

We write as a follow up to our prior letter of today, which related to discovery disputes with the FDA. We have learned that discussions between co-respondent Hoechst and counsel for the FDA are ongoing. We therefore continue to hope that those discussions can resolve or at least narrow the disputes between respondents and the FDA. In the event, however, that the discussions are not successful and motion practice with respect to Hoechst's subpoena on the FDA ensues, respondents continue to believe that the sensible course is to coordinate the motion practice. In that way, the common and overlapping issues pertaining to Andrx's and Hoechst's respective subpoenas on the FDA can be addressed in a coordinated fashion. In the meantime as the discussions continue, we will continue to seek the FDA's consent to proceeding in such a manner.

Respectfully,

Hal S. Shaftel

Hal S. Shaftel

HSS:se
cc: All Counsel of Record
Counsel for the FDA

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

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

RESPONDENT AVENTIS PHARMACEUTICALS, INC.
MOTION FOR THE ISSUANCE OF A SUBPOENA DUCES TECUM TO THE FOOD AND DRUG ADMINISTRATION

Pursuant to § 3.36 of the Federal Trade Commission's Rules of Practice, Respondent Aventis Pharmaceuticals, Inc. ("Aventis") hereby moves for an Order authorizing the issuance of a subpoena duces tecum to the United States Food and Drug Administration ("FDA") calling for the production of those categories of documents identified in Exhibit 1 to the accompanying Declaration of Peter D. Bernstein. Carderm Capital L.P. and Andrx Corporation have indicated that they consent to the motion. Complaint Counsel has indicated that it will oppose this motion.

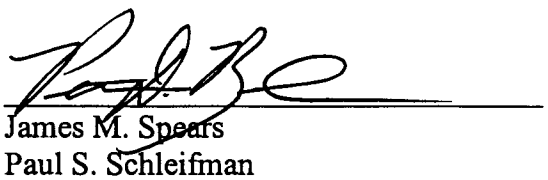
On July 5, 2000, this Court granted a motion by Andrx corporation for an order authorizing the issuance of a subpoena duces tecum to the FDA that called for a portion of the documents requested in Aventis' proposed subpoena *duces tecum* to the FDA. The requests should not be construed in a manner that would make them duplicative of the Andrx subpoena

and indeed, to the extent that documents have been requested by or produced in response to the Andrx subpoena, the FDA need not produce those documents again to Aventis.

The bases of this motion are set forth in the accompanying Memorandum in Support of Motion for the Issuance of a Subpoena *Duces Tecum* to the Food and Drug Administration.

Dated: July 25, 2000

Respectfully Submitted,



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Attorneys for Respondent
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UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

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

**RESPONDENT AVENTIS PHARMACEUTICALS, INC.
MEMORANDUM IN SUPPORT OF MOTION FOR THE
ISSUANCE OF A SUBPOENA DUCES TECUM
TO THE FOOD AND DRUG ADMINISTRATION**

Pursuant to § 3.36 of the FTC's Procedures and Rules of Practice, Respondent Aventis Pharmaceuticals Inc. ("Aventis"), formerly known as Hoechst Marion Roussel, Inc. ("HMR") submits this memorandum in support of its motion for an order approving the issuance of a subpoena *duces tecum* to the United States Food and Drug Administration ("FDA").[1] Carderm Capital L.P. and Andrx Corporation have indicated that they consent to the motion. Complaint Counsel has indicated that it will oppose this motion.[2]

---

1 A proposed schedule identifying those categories of documents that Aventis seeks from the FDA is annexed as Exhibit 1 to the accompanying Declaration of Peter D. Bernstein. (the "Bernstein Declaration").

2 See ¶ 4 of the Bernstein Declaration.

On July 5, 2000, this Court granted a motion by Andrx Corporation for an order authorizing the issuance of a subpoena *duces tecum* to the FDA that called for a small portion of the documents requested in Aventis' proposed subpoena *duces tecum* to the FDA. The requests should not be construed in a manner that would make them duplicative of the Andrx subpoena. To the extent that documents have been requested by or produced in response to the Andrx subpoena, Aventis will coordinate the sharing of those materials with FDA and Andrx.

ARGUMENT

BECAUSE THE FDA IS CENTRAL TO THE PHARMACEUTICAL APPROVAL PROCESS AT ISSUE IN THIS CASE, AVENTIS SHOULD BE PERMITTED TO SEEK THE DISCOVERY OF RELEVANT DOCUMENTS FROM THE AGENCY.

Section 3.36 of the FTC's Rules of Practice expressly authorizes the issuance of subpoenas upon other governmental agencies in the context of an FTC administrative proceeding. See 16 C.F.R. §3.36(a). Subpoenas directed to other governmental agencies must satisfy the following tripartite showing:

> (1) the material sought is reasonable in scope;
> (2) if for the purposes of discovery, the material falls within the limits of discovery under §3.31(b)(1); and
> (3) the information and material sought cannot reasonably be obtained by other means.

16 C.F.R. §3.36(b).

Aventis' proposed subpoena is narrowly drawn and satisfies these criteria. The information Aventis seeks from the FDA is relevant to one or more of the central issues in this proceeding. The first, third and fourth requests seek documents relating to the applications filed by Biovail Corporation International ("Biovail"), Faulding, Inc. ("Faulding"), and Andrx Corporation ("Andrx"). The gravamen of Complaint Counsel's case is that the Stipulation and Agreement had the "purpose and effect" of "injuring competition and consumers" by delaying the "entry of a generic version of Cardizem® CD." (Complaint, ¶¶ 29, 30). Aventis believes that

the record will show that the Stipulation and Agreement did not delay the entry of any non-infringing, generic version of Cardizem® CD and that Andrx's non-infringing generic version of the product was offered for sale on the date that FDA approval for that product was obtained. The only remaining question is -- but for the Stipulation and Agreement, could either of the other two generic applicants (Faulding or Biovail) have entered the market earlier than Andrx did with a non-infringing generic version of Cardizem® CD. For this reason, documents in the FDA's possession relating to the status of other applications for generic Cardizem® CD bear directly on whether these applicants could have reached the market with a non-infringing generic product prior to the introduction of the Andrx product. Aventis has reason to believe that the FDA's files will show that neither product could have entered the market earlier and that flaws in Biovail's application, coupled with the complexity of the bioequivalency issues raised by Biovail's application, caused the FDA's approval of Biovail's application to issue months after the non-infringing version of Andrx's product reached the market.

The first request to the FDA seeks documents relating to the FDA review of the Biovail applications for a product that is the bioequivalent of Cardizem® CD. Specifically, subparts (b) and (c) seek materials related to the issues raised by the Andrx citizens petition, which questioned the bioequivalence of the Biovail products, and the FDA analyses relating to issued of bioequivalence and clinical studies. These documents were not specifically requested by the Andrx subpoena.

The second request seeks documents relating to comments submitted by the United States Federal Trade Commission ("FTC") to FDA Docket No. 85N-0214 relating to FDA's proposed rule on 180-day generic drug exclusivity for ANDAs (64 Fed.Reg. 42873 (Aug. 6, 1999)). In its comments, the FTC suggested that the FDA require that patent litigation

agreements between branded companies and ANDA applicants and agreements related to the filing of an ANDA by a potential applicant be filed confidentially with the FDA and be accessible to the FTC so that the FTC may be aware of any possible anticompetitive issues "in a timely manner." The notification urged by the FTC in the FDA regulatory action is virtually identical to the "Prior Notification" relief sought, in part, in this action. (Complaint, Notice of Contemplated Relief, ¶¶ 3, 4). Accordingly, the FDA's assessment of whether imposition of this extra-statutory review mechanism is consistent with Hatch-Waxman or will facilitate the entry of non-infringing generic products to the market, is critical to the issue of whether the relief sought by Complaint Counsel is appropriate and otherwise consistent with federal law. These documents were not requested in the Andrx subpoena.

The third and fourth requests only seek documents which reflect the date of submission, filing, tentative approval and final approval of Andrx and Faulding ANDAs for the manufacture and production of a pharmaceutical product that is the bioequivalent of Cardizem® CD. The Andrx subpoena had sought a broad category of information regarding these applications, but did not contain specific requests for the submission, filing and approval dates. As stated above, the information requested by the third and fourth requests will show that no product could have entered the market earlier than non-infringing version of Andrx's product.

The fifth request seeks documents related to Probucol, a product that was subject to an approved NDA held by Aventis. While the product is not currently marketed in the U.S., Aventis and others were interested in obtaining a new indication for Probucol for prevention of restenosis after coronary angioplasty. Aventis believes that the FDA had numerous discussions with various persons regarding development of Probucol. In fact, it appears the FDA began a review process concerning the new indication and any guidance FDA offered would be relevant

to the decision-making process of whether to continue development of the new indication. In addition, FDA materials concerning this development will substantiate the legitimacy of Aventis's efforts to secure Biovail as a development partner in advancing the new indication for Probucol. Finally, complaint counsel recently served a subpoena on counsel for one of the companies intimately involved in the development of Probucol. Again, these documents were not requested in the Andrx subpoena.

While complaint counsel has expressed a view that requests 1, 3 and 4 are duplicative of the requests in the Andrx subpoena to the FDA and that Aventis should have coordinated with Andrx to include requests 2 and 5 in the Andrx subpoena, these are not proper grounds to oppose this motion.[3] The requests should not be construed in a manner that would make them duplicative of the Andrx subpoena. As explained above, these requests are narrowly focused to elicit a limited number of materials not specifically requested in the Andrx subpoena. Indeed, to the extent that documents have been requested by or produced in response to the Andrx subpoena, the FDA need not produce those documents again to Aventis. Simply because the Andrx subpoena requested a broader category of materials that might potentially overlap should not prevent the issuance of the requested subpoena.

Complaint counsel's argument that Aventis' proposed requests should have coordinated with the Andrx subpoena in order to alleviate any burden on the FDA of having to respond to two subpoenas is not supported by the facts and regulations surrounding this case. Based on the expedited schedule required under the Federal Trade Commission's Rules of Practice, the tight time frame does not always allow for the coordination of discovery. In addition, there is no support for the notion that discovery must be conducted in a manner that

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[3] See ¶ 4 of the Bernstein Declaration.

would limit the issuance of one subpoena to a non-party. This would place an undue burden on the parties to the action as there would be no room for any follow-up discovery should the initial subpoena response indicate that additional discovery is warranted. Requiring coordination would also place the parties at a disadvantage, as each parties discovery needs differ. Aventis does not intend for this subpoena to burden the FDA. Accordingly, it has limited its discovery to those issues necessary for the prosecution of this action.

Aventis' proposed requests are narrowly drawn, and will only require the FDA to search for responsive documents in discrete files at the agency. Given the nature of the documents requested, subpoenaing the FDA will be by far the most expeditious (if not the only) method for Aventis to secure the desired information.

CONCLUSION

For the foregoing reasons, Aventis respectfully request that its motion be granted in all respects.

Dated: July 25, 2000

Respectfully Submitted,

James M. Spears
Paul S. Schleifman
D. Edward Wilson, Jr.
Peter D. Bernstein
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Attorneys for Respondent
Aventis Pharmaceuticals, Inc.

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

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

DECLARATION OF PETER D. BERNSTEIN IN SUPPORT OF RESPONDENT AVENTIS PHARMACEUTICALS, INC. MOTION FOR THE ISSUANCE OF A SUBPOENA DUCES TECUM TO THE FOOD AND DRUG ADMINISTRATION

I, Peter D. Bernstein, pursuant to 28 U.S.C. § 1746, declare as follows,:

1. I am associated with the firm of Shook Hardy & Bacon LLP, counsel for respondent Aventis Pharmaceuticals, Inc. ("Aventis"). I submit this declaration: (a) to place before the Court a schedule of those documents Aventis seeks from the FDA; and (b) to apprise the Court that Aventis sought consent of the other parties prior to the filing of this motion.

2. Annexed hereto as Exhibit A is a copy of "Schedule A," which identifies those categories of documents Aventis seeks from the United States Food and Drug Administration.

3. Stacy Ehrlich, counsel for Carderm Capital L.P., and Hal Shaftel, counsel for Andrx Corporation, have consented to the motion.

4. On July 24, 2000, I spoke with Bradley Albert, a Commission attorney serving as complaint counsel. I provided Mr. Albert with a draft copy of Exhibit A. We discussed whether complaint counsel would consent to the filing of this motion. Mr. Albert stated that complaint counsel would oppose the motion based on the theory that requests 1, 3 and 4 are duplicative of the requests in the Andrx subpoena to the FDA and that requests 2 and 5 should have been included in the Andrx subpoena to the FDA in order to alleviate the burden of FDA having to respond to two subpoenas. We were not able to resolve our differences with respect to this issue.

I declare under penalty of perjury that the foregoing is true and correct.

Executed in Washington, D.C., on July 25, 2000

Respectfully Submitted,

Peter D. Bernstein

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

SCHEDULE "A"

In the Matter of	)	
	)	Docket No. 9293
Hoechst Marion Roussel, Inc., et al.,	)	
	)	
Respondents	)	

AVENTIS PHARMACEUTICALS, INC.
SUBPOENA DUCES TECUM TO THE
FOOD AND DRUG ADMINISTRATION

Respondent Aventis Pharmaceuticals, Inc, formerly known as Hoechst Marion Roussel, Inc., pursuant to the Federal Trade Commission's Rules of Practice for Adjudicative Proceedings, 16 C.F.R. § 3.36, requests that the U.S. Food and Drug Administration (hereinafter referred to as "FDA") produce documents and other things for inspection and copying, within 10 days, in response to the Document Requests set forth below, and in accordance with the Definitions and Instructions following thereafter, at the offices of Shook, Hardy & Bacon, L.L.P., 600 14th Street, N.W., Washington, D.C. 20005, or such location as may be mutually agreed upon.

DOCUMENTS REQUESTS

Request No. 1: All documents concerning any ANDA and NDA submitted by Biovail for the manufacture and production of a pharmaceutical product that is the bioequivalent of Cardizem® CD, excluding the ANDA and NDA themselves. This request includes, by way of example, but is not limited to:

(a) all communications between the FDA and Biovail;

(b) all communications between the FDA and any person, including but not limited to any reports from and correspondence with external consultants, relating to the issues raised in the Andrx citizen petition; and

(c) all FDA analyses and communications, including but not limited to bioequivalence issues raised in the review of any ANDA and NDA submitted by Biovail for the manufacture and production of a pharmaceutical product that is the bioequivalent of Cardizem® CD and documentation reflecting medical review of clinical studies contained in any NDA submitted by Biovail for the manufacture and production of a pharmaceutical product that is the bioequivalent of Cardizem® CD.

Request No. 2: All documents concerning comments submitted to FDA by the FTC relating to FDA's proposed rule on 180-day generic drug exclusivity for ANDAs, including but not limited to any communication between the FDA and the FTC or any other person, and internal FDA communications.

Request No. 3: All documents which reflect the date of submission, filing, tentative approval and final approval of the ANDA submitted by Faulding for the manufacture and production of a pharmaceutical product that is the bioequivalent of Cardizem® CD, excluding the ANDA itself.

Request No. 4: All documents which reflect the date of submission, filing, tentative approval and final approval of Andrx's ANDA for the manufacture and production of a pharmaceutical product that is the bioequivalent of Cardizem® CD and any supplement thereto, excluding the ANDA and supplement themselves.

Request No. 5: All documents concerning development of Probucol for prevention of restenosis after coronary angioplasty, including but not limited to communications between the FDA and any person and any analysis, other evaluation or test regarding such development.

DEFINITIONS AND INSTRUCTIONS

1. As used herein, the term"Biovail" means Biovail Corporation International and any of its parents, subsidiaries, affiliates, divisions, employees, officers, directors, agents, lawyers, representatives, predecessors or successors. The term "Biovail" specifically includes Biovail's outside counsel, Cleary Gottlieb Steen & Hamilton.

2. As used herein, the term"Faulding" means Faulding, Inc. and any of its parents, subsidiaries, affiliates, divisions, employees, officers, directors, agents, lawyers, representatives, predecessors or successors.

3. As used herein, the term"Andrx" means Andrx Corporation, and any of its parents, subsidiaries, affiliates, divisions, employees, officers, directors, agents, representatives, predecessors or successors.

4. As used herein, the term"FDA" means the Federal Food and Drug Administration and its divisions, agents, representatives, predecessors or successors.

5. As used herein, the term"NDA" means a New Drug Application submitted to the FDA for approval for the manufacture and marketing of a pharmaceutical product.

6. As used herein, the term"ANDA" means an Abbreviated New Drug Application submitted to the FDA for approval for the manufacture and marketing of a pharmaceutical product that is the "bioequivalent" of an FDA approved, brand name pharmaceutical product.

7. As used herein, the term"FTC" means the Federal Trade Commission and its divisions, agents, representatives, predecessors or successors.

8. As used herein, the term"Andrx citizen petition" shall refer to FDA Docket No. 98P-0145.

9. As used herein, the term"FDA's proposed rule on 180-day generic drug exclusivity for ANDAs" shall refer to the rule published at 64 Fed. Reg. 42873 (Aug. 6, 1999) and identified by FDA Docket No. 85N-0214.

10. As used herein, the term s "document" or "documents" or "documentation" include these terms as defined by 16 C.F.R. § 3.34(b) and, in addition, the original or drafts or any kind of written, printed, recorded or graphic matter or sound reproduction, however produced or reproduced, whether sent or received or neither, and all copies thereof which are different in any way from the original (whether by notation, indication of copies sent or received or otherwise) regardless of whether designated "Confidential," "Privileged" or otherwise and including, but not limited to, any correspondence, paper, book, account, drawing, agreement, contract, e-mail, handwritten notes, invoice, memorandum, telegram, object, opinion, purchase order, report, records, transcript, summary, study, survey recording of any telephone or other conversation, interviews or notes of any conference. The terms "document" or "documents" shall also include data stored, maintained or organized electronically or magnetically or through computer equipment, translated, if necessary, by you into reasonably usable form, and film impressions, magnetic tape and sound or mechanical productions of any kind or nature whatsoever.

11. As used herein, the term "person" shall refer to any natural persons, firm, company, syndicate, group, pool, joint venture, partnership, trust, estate, corporation, or other form or organization or legal entity.

12. As used herein, the term"concern" and "concerning" mean relating to, referring to, describing, evidencing, or constituting.

13. As used herein, the terms "and" and "or" include both the conjunctive and disjunctive, as necessary, to bring within the scope of this request all responses that might otherwise be construed to be outside of its scope.

14. As used herein, the terms "any" "all" and "each" each shall be construed to mean "any, all and each".

15. The use of a singular form of any word includes the plural, and vice-versa.

16. The terms "include" and "including" are used for illustration and not by way of limitation.

17. Except for privileged materials, produce each responsive document in its entirety by including all attachments and all pages, regardless of whether they directly relate 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. Except for privileged material, do not mask, cut, expunge, edit, or delete any responsive document or portion thereof in any manner.

18. If any documents that are responsive to the document requests herein are withheld from production, furnish a list of all such documents withheld. Said list shall contain a complete description of each document, including: (i) the type, date, and number of pages of the document; (ii) its title (if any); (iii) a general description of its subject matter; (iv) the identity of any attachments or appendices to the document; (v) the name and identification of each person to whom it is addressed; (vi) the name and identification of each person who received a copy thereof; (vii) the name and identification of the persons or person by whom it was written or

generated; (viii) its present custodian; (ix) the ground or grounds upon which it is being withheld.

19. In the event that any document called for by this document request has been destroyed or discarded, please identify each such document by stating: (i) any addresser and addressee; (ii) the addressees of any indicated or blind copies; (iii) the type, date, subject matter and number of pages of the document; (iv) a description of any attachment or appendices to the document; (v) the names and identification of all persons to whom the document was distributed, shown or explained; (vi) the date when it was destroyed or discarded, and the manner in which it was destroyed or discarded; and (vii) the names and identification of the persons authorizing and carrying out such destruction or discarding.

20. Unless otherwise indicated, this subpoena calls for the production of documents that were created or utilized during, or otherwise concern, the period from January 1993 through and including the date of production.

Dated: July 25, 2000

James M. Spears
Paul S. Schleifman
D. Edward Wilson, Jr.
Peter D. Bernstein
SHOOK HARDY & BACON, LLP
600 Fourteenth Street, N.W., Suite 800
Washington, D.C. 20005-2004
(202) 783-8400

Attorneys for Respondent
Aventis Pharmaceuticals, Inc.

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

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

ORDER GRANTING RESPONDENT AVENTIS PHARMACEUTICALS, INC. MOTION FOR THE ISSUANCE OF A SUBPOENA DUCES TECUM TO THE FOOD AND DRUG ADMINISTRATION

On July 25, 2000, pursuant to Commission Rule 3.36, Respondent Aventis Pharmaceuticals, Inc. filed a motion for an order authorizing the issuance of a subpoena duces tecum to the United States Food and Drug Administration (FDA). Respondent's motion is GRANTED.

Pursuant to Rule 3.34, in the event that the FDA seeds to limit or quash the subpoena, the FDA shall have ten days after service of the subpoena or the time for compliance therewith to file any such motion.

Aventis shall serve a copy of this order on the Food and Drug Administration at the time it serves the subpoena.

ORDERED:

D. Michael Chappell
Administrative Law Judge

Date: July __, 2000

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

In the Matter of **Hoechst Marion Roussel, Inc., et al.,** **Respondents.**	Docket No. 9293

CERTIFICATE OF SERVICE

I, Peter D. Bernstein, hereby certify that on July 25, 2000, a copy of the Motion of Aventis Pharmaceuticals, Inc. for an Order authorizing the issuance of a subpoena duces tecum to the United States Food and Drug Administration was served upon the following persons by hand delivery and/or Federal Express as follows:

Donald S. Clark, Secretary
Federal Trade Commission
Room 172
600 Pennsylvania Ave., N.W.
Washington, D.C. 20580

Richard Feinstein
Federal Trade Commission
Room 3114
601 Pennsylvania Ave., N.W.
Washington, D.C. 20580

Hon. D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
Room 104
600 Pennsylvania Ave., N.W.
Washington, D.C. 20580

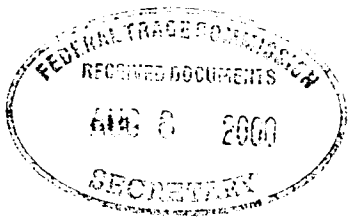
Markus Meier
Federal Trade Commission
Room 3017
601 Pennsylvania Ave., N.W.
Washington, D.C. 20580

Louis M. Solomon [By FedEx]
Solomon, Zauderer, Ellenhorn,
Frischer & Sharp
45 Rockefeller Plaza
New York, NY 10111

Peter O. Safir
Kleinfeld, Kaplan and Becker
1140 19th St., N.W.
Washington, D.C. 20036

Peter D. Bernstein

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION



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

ORDER GRANTING RESPONDENT AVENTIS' MOTION FOR THE ISSUANCE OF A SUBPOENA DUCES TECUM TO THE FOOD AND DRUG ADMINISTRATION

On July 25, 2000, pursuant to Commission Rule 3.36, Respondent Aventis Pharmaceuticals Inc. ("Aventis") filed a motion for an order authorizing the issuance of a subpoena *duces tecum* to the United States Food and Drug Administration. The other respondents consented to the motion. Complaint Counsel filed an opposition to the motion on August 1, 2000. Respondent's motion is GRANTED.

Pursuant to Rule 3.34, in the event that the Food and Drug Administration (FDA) seeks to limit or quash the subpoena, the FDA shall have ten days after service of the subpoena or the time for compliance therewith to file any such motion.

Aventis shall serve a copy of this order on the FDA at the time it serves the subpoena.

ORDERED:

D. Michael Chappell
Administrative Law Judge

Date: August 8, 2000

LAW OFFICES

SHOOK, HARDY & BACON L.L.P.

KANSAS CITY
OVERLAND PARK
HOUSTON
SAN FRANCISCO
MIAMI

HAMILTON SQUARE
600 14TH STREET, NW, SUITE 800
WASHINGTON, D.C. 20005-2004
TELEPHONE (202) 783-8400 ▮ FACSIMILE (202) 783-4211

LONDON
ZURICH
GENEVA
MELBOURNE
BUENOS AIRES

Peter D. Bernstein
(202) 662-4858
pbernstein@shb.com

August 9, 2000

VIA FEDERAL EXPRESS

Margaret Jane Porter, Esq.
General Counsel
United States Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Re: In re Hoechst Marion Roussel, Inc. et al., FTC Docket No. 9293

Dear Ms. Porter:

This firm represents Aventis Pharmaceuticals, Inc., formerly known as Hoechst Marion Roussel, Inc. ("Aventis"), in the above referenced administrative proceeding before the U.S. Federal Trade Commission ("FTC").

Attached please find a courtesy copy of a subpoena *duces tecum* issued in connection with this proceeding and an order, dated August 9, 2000, issued by Administrative Law Judge D. Michael Chappell authorizing the issuance on this subpoena to the FDA. A separate copy of this document is being served upon FDA in accordance with the FTC's Rules of Practice. Pursuant to the subpoena, responsive documents are to be produced on or before August 29, 2000. Also attached is a copy of the Protective Order entered in this proceeding.

On July 6, 2000, Andrx Corporation ("Andrx") issued a subpoena *duces tecum* to the FDA that called for a small portion of the documents requested in Aventis' subpoena *duces tecum*. The requests in the Aventis subpoena should not be construed in a manner that would make them duplicative of the Andrx subpoena. To the extent that documents have been requested by or produced in response to the Andrx subpoena, Aventis will coordinate the sharing of those materials with the FDA and Andrx.

Please contact me should you have any questions regarding compliance with this subpoena.

Sincerely,

Peter D. Bernstein

encl.

SUBPOENA DUCES TECUM

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

1. TO

United States Food & Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

2. FROM

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

Shook, Hardy & Bacon L.L.P.
600 14th Street, N.W., Suite 800
Washington, DC 20005-2004

4. MATERIAL WILL BE PRODUCED TO

Shook, Hardy & Bacon L.L.P.
Attn: D. Edward Wilson, Counsel for Hoechst Marion Roussel, Inc.

5. DATE AND TIME OF PRODUCTION OR INSPECTION

August 29, 2000 at 10:00 a.m.

6. SUBJECT OF PROCEEDING

In the matter of Hoechst Marion Roussel, Inc., et al.

7. MATERIAL TO BE PRODUCED

See Exhibit "A" attached hereto

8. ADMINISTRATIVE LAW JUDGE

The Honorable D. Michael Chappell

Federal Trade Commission
Washington, D.C. 20580

9. COUNSEL REQUESTING SUBPOENA

Shook, Hardy & Bacon L.L.P
James M. Spears
D. Edward Wilson
Peter D. Bernstein
Counsel for Hoechst Marion Roussel

DATE ISSUED

MAY 11 2000

SECRETARY'S SIGNATURE

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.

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

EXHIBIT "A"

In the Matter of	)	
	)	Docket No. 9293
Hoechst Marion Roussel, Inc., et al.,	)	
	)	
Respondents	)	

AVENTIS PHARMACEUTICALS, INC.
SUBPOENA DUCES TECUM TO THE
FOOD AND DRUG ADMINISTRATION

Respondent Aventis Pharmaceuticals, Inc, formerly known as Hoechst Marion Roussel, Inc., pursuant to the Federal Trade Commission's Rules of Practice for Adjudicative Proceedings, 16 C.F.R. § 3.36, requests that the U.S. Food and Drug Administration (hereinafter referred to as "FDA") produce documents and other things for inspection and copying, within 20 days, in response to the Document Requests set forth below, and in accordance with the Definitions and Instructions following thereafter, at the offices of Shook, Hardy & Bacon, L.L.P., 600 14th Street, N.W., Washington, D.C. 20005, or such location as may be mutually agreed upon.

DOCUMENTS REQUESTS

Request No. 1: All documents concerning any ANDA and NDA submitted by Biovail for the manufacture and production of a pharmaceutical product that is the bioequivalent of Cardizem® CD, excluding the ANDA and NDA themselves. This request includes, by way of example, but is not limited to:

(a) all communications between the FDA and Biovail;

(b) all communications between the FDA and any person, including but not limited to any reports from and correspondence with external consultants, relating to the issues raised in the Andrx citizen petition; and

(c) all FDA analyses and communications, including but not limited to bioequivalence issues raised in the review of any ANDA and NDA submitted by Biovail for the manufacture and production of a pharmaceutical product that is the bioequivalent of Cardizem® CD and documentation reflecting medical review of clinical studies contained in any NDA submitted by Biovail for the manufacture and production of a pharmaceutical product that is the bioequivalent of Cardizem® CD.

Request No. 2: All documents concerning comments submitted to FDA by the FTC relating to FDA's proposed rule on 180-day generic drug exclusivity for ANDAs, including but not limited to any communication between the FDA and the FTC or any other person, and internal FDA communications.

Request No. 3: All documents which reflect the date of submission, filing, tentative approval and final approval of the ANDA submitted by Faulding for the manufacture and production of a pharmaceutical product that is the bioequivalent of Cardizem® CD, excluding the ANDA itself.

Request No. 4: All documents which reflect the date of submission, filing, tentative approval and final approval of Andrx's ANDA for the manufacture and production of a pharmaceutical product that is the bioequivalent of Cardizem® CD and any supplement thereto, excluding the ANDA and supplement themselves.

Request No. 5: All documents concerning development of Probucol for prevention of restenosis after coronary angioplasty, including but not limited to communications between the FDA and any person and any analysis, other evaluation or test regarding such development.

DEFINITIONS AND INSTRUCTIONS

1. As used herein, the term"Biovail" means Biovail Corporation International and any of its parents, subsidiaries, affiliates, divisions, employees, officers, directors, agents, lawyers, representatives, predecessors or successors. The term "Biovail" specifically includes Biovail's outside counsel, Cleary Gottlieb Steen & Hamilton.

2. As used herein, the term"Faulding" means Faulding, Inc. and any of its parents, subsidiaries, affiliates, divisions, employees, officers, directors, agents, lawyers, representatives, predecessors or successors.

3. As used herein, the term"Andrx" means Andrx Corporation, and any of its parents, subsidiaries, affiliates, divisions, employees, officers, directors, agents, representatives, predecessors or successors.

4. As used herein, the term"FDA" means the Federal Food and Drug Administration and its divisions, agents, representatives, predecessors or successors.

5. As used herein, the term"NDA" means a New Drug Application submitted to the FDA for approval for the manufacture and marketing of a pharmaceutical product.

6. As used herein, the term"ANDA" means an Abbreviated New Drug Application submitted to the FDA for approval for the manufacture and marketing of a pharmaceutical product that is the "bioequivalent" of an FDA approved, brand name pharmaceutical product.

7. As used herein, the term"FTC" means the Federal Trade Commission and its divisions, agents, representatives, predecessors or successors.

8. As used herein, the term"Andrx citizen petition" shall refer to FDA Docket No. 98P-0145.

9. As used herein, the term"FDA's proposed rule on 180-day generic drug exclusivity for ANDAs" shall refer to the rule published at 64 Fed. Reg. 42873 (Aug. 6, 1999) and identified by FDA Docket No. 85N-0214.

10. As used herein, the term s "document" or "documents" or "documentation" include these terms as defined by 16 C.F.R. § 3.34(b) and, in addition, the original or drafts or any kind of written, printed, recorded or graphic matter or sound reproduction, however produced or reproduced, whether sent or received or neither, and all copies thereof which are different in any way from the original (whether by notation, indication of copies sent or received or otherwise) regardless of whether designated "Confidential," "Privileged" or otherwise and including, but not limited to, any correspondence, paper, book, account, drawing, agreement, contract, e-mail, handwritten notes, invoice, memorandum, telegram, object, opinion, purchase order, report, records, transcript, summary, study, survey recording of any telephone or other conversation, interviews or notes of any conference. The terms "document" or "documents" shall also include data stored, maintained or organized electronically or magnetically or through computer equipment, translated, if necessary, by you into reasonably usable form, and film impressions, magnetic tape and sound or mechanical productions of any kind or nature whatsoever.

11. As used herein, the term "person" shall refer to any natural persons, firm, company, syndicate, group, pool, joint venture, partnership, trust, estate, corporation, or other form or organization or legal entity.

12. As used herein, the term"concern" and "concerning" mean relating to, referring to, describing, evidencing, or constituting.

13. As used herein, the terms "and" and "or" include both the conjunctive and disjunctive, as necessary, to bring within the scope of this request all responses that might otherwise be construed to be outside of its scope.

14. As used herein, the terms "any" "all" and "each" each shall be construed to mean "any, all and each".

15. The use of a singular form of any word includes the plural, and vice-versa.

16. The terms "include" and "including" are used for illustration and not by way of limitation.

17. Except for privileged materials, produce each responsive document in its entirety by including all attachments and all pages, regardless of whether they directly relate 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. Except for privileged material, do not mask, cut, expunge, edit, or delete any responsive document or portion thereof in any manner.

18. If any documents that are responsive to the document requests herein are withheld from production, furnish a list of all such documents withheld. Said list shall contain a complete description of each document, including: (i) the type, date, and number of pages of the document; (ii) its title (if any); (iii) a general description of its subject matter; (iv) the identity of any attachments or appendices to the document; (v) the name and identification of each person to whom it is addressed; (vi) the name and identification of each person who received a copy thereof; (vii) the name and identification of the persons or person by whom it was written or

generated; (viii) its present custodian; (ix) the ground or grounds upon which it is being withheld.

19. In the event that any document called for by this document request has been destroyed or discarded, please identify each such document by stating: (i) any addresser and addressee; (ii) the addressees of any indicated or blind copies; (iii) the type, date, subject matter and number of pages of the document; (iv) a description of any attachment or appendices to the document; (v) the names and identification of all persons to whom the document was distributed, shown or explained; (vi) the date when it was destroyed or discarded, and the manner in which it was destroyed or discarded; and (vii) the names and identification of the persons authorizing and carrying out such destruction or discarding.

20. Unless otherwise indicated, this subpoena calls for the production of documents that were created or utilized during, or otherwise concern, the period from January 1993 through and including the date of production.

Dated: August 9, 2000

James M. Spears
Paul S. Schleifman
D. Edward Wilson, Jr.
Peter D. Bernstein
SHOOK HARDY & BACON, LLP
600 Fourteenth Street, N.W., Suite 800
Washington, D.C. 20005-2004
(202) 783-8400

Attorneys for Respondent
Aventis Pharmaceuticals, Inc.

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

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

ORDER GRANTING RESPONDENT AVENTIS' MOTION FOR THE ISSUANCE OF A SUBPOENA DUCES TECUM TO THE FOOD AND DRUG ADMINISTRATION

On July 25, 2000, pursuant to Commission Rule 3.36, Respondent Aventis Pharmaceuticals Inc. ("Aventis") filed a motion for an order authorizing the issuance of a subpoena *duces tecum* to the United States Food and Drug Administration. The other respondents consented to the motion. Complaint Counsel filed an opposition to the motion on August 1, 2000. Respondent's motion is GRANTED.

Pursuant to Rule 3.34, in the event that the Food and Drug Administration (FDA) seeks to limit or quash the subpoena, the FDA shall have ten days after service of the subpoena or the time for compliance therewith to file any such motion.

Aventis shall serve a copy of this order on the FDA at the time it serves the subpoena.

ORDERED:

D. Michael Chappell
Administrative Law Judge

Date: August 8, 2000

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

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

ORDER GRANTING CONSENT MOTION TO AMEND AND REISSUE PROTECTIVE ORDER

IT IS HEREBY ORDERED that the Consent Motion to Amend and Reissue Protective Order Governing Discovery Material, filed July 24, 2000, is hereby GRANTED.

D. Michael Chappell
Administrative Law Judge

Date: August 7, 2000

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

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

SECOND AMENDED PROTECTIVE ORDER GOVERNING DISCOVERY MATERIAL

For the purpose of protecting the interests of the parties and third parties in the above-captioned matter (the "Matter") against improper use and disclosure of confidential information submitted or produced in connection with this Matter:

IT IS HEREBY ORDERED THAT this Protective Order Governing Confidential Material ("Protective Order") shall govern the handling of all Discovery Material, as hereafter defined.

DEFINITIONS

1. "Matter" means the matter captioned *In the Matter of Hoechst Marion Roussel, Inc., Carderm Capital L.P., and Andrx Corporation,* Docket Number 9293, pending before the Federal Trade Commission, and all subsequent appellate or other review proceedings related thereto.

2. "Commission" or "FTC" means the Federal Trade Commission, or any of its employees, agents, attorneys, and all other persons acting or purporting to act on its behalf,

excluding persons retained as consultants or experts for purposes of this Matter.

3. "HMR" means Aventis Pharmaceuticals Inc., formerly known as Hoechst Marion Roussel, Inc., a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at Parsippany, New Jersey.

4. "Carderm" means Carderm Capital L.P., a limited partnership organized, existing, and doing business under and by virtue of the laws of the Delaware, with its office and principal place of business located at Hamilton, Bermuda.

5. "Andrx" means Andrx Corporation, a corporation organized, existing, and doing business under and by virtue of the laws of the State of Florida, with its office and principal place of business located at Fort Lauderdale, Florida.

6. "Party" means either the FTC, HMR, Carderm or Andrx.

7. "Respondents" means HMR, Carderm and Andrx.

8. "Outside Counsel" means the law firm(s) that is/are counsel of record for Respondents in this Matter and its/their associated attorneys; persons regularly employed by such law firm(s) (including legal assistants, clerical staff, and information management personnel) and temporary personnel retained by such law firm(s) to perform legal or clerical duties, or to provide logistical litigation support with regard to this Matter; provided that any attorney associated with Outside Counsel shall not be a director, officer or employee of Respondents. The term Outside Counsel does not include persons retained as consultants or experts for the purposes of this Matter.

9. "Producing Party" means a Party or Third Party that produced or intends to

produce Confidential Discovery Material to any of the Parties. For purposes of Confidential Discovery Material of a Third Party that either is in the possession, custody or control of the FTC or has been produced by the FTC in this Matter, the Producing Party shall mean the Third Party that originally provided the Confidential Discovery Material to the FTC. The Producing Party shall also mean the FTC for purposes of any document or material prepared by, or on behalf of the FTC.

10. "Third Party" means any natural person, partnership, corporation, association, or other legal entity not named as a party to this Matter -- including without limitation Biovail Corporation ("Biovail") and Faulding Inc. ("Faulding") -- and their employees, directors, officers, attorneys and agents.

11. "Expert/Consultant" means experts or other persons who are retained to assist complaint counsel or Respondents' counsel in preparation for trial or to give testimony at trial.

12. "Document" means the complete original or a true, correct and complete copy and any non-identical copies of any written or graphic matter, no matter how produced, recorded, stored or reproduced, including, but not limited to, any writing, letter, envelope, telegraph meeting minute, memorandum statement, affidavit, declaration, book, record, survey, map, study, handwritten note, working paper, chart, index, tabulation, graph, tape, data sheet, data processing card, printout, microfilm, index, computer readable media or other electronically stored data, appointment book, diary, diary entry, calendar, desk pad, telephone message slip, note of interview or communication or any other data compilation, including all drafts of all such documents. "Document" also includes every writing, drawing, graph, chart, photograph, phono

record, tape and other data compilations from which information can be obtained, and includes all drafts and all copies of every such writing or record that contain any commentary, notes, or marking whatsoever not appearing on the original.

13. "Discovery Material" includes without limitation deposition testimony, deposition exhibits, interrogatory responses, admissions, affidavits, declarations, documents produced pursuant to compulsory process or voluntarily in lieu thereof, and any other documents or information produced or given to one Party by another Party or by a Third Party in connection with discovery in this Matter.

14. "Confidential Discovery Material" means all Discovery Material that is designated by a Producing Party as confidential and that is covered by Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. § 46(f), and Commission Rule of Practice § 4.10(a)(2), 16 C.F.R. § 4.10(a)(2); submitted to the FTC pursuant to the Hart-Scott-Rodino Antitrust Improvements Act of 1976, 15 U.S.C. § 18a, or formal interpretations or rules promulgated thereunder, 16 C.F.R. Part 800; or Section 26(c)(7) of the Federal Rules of Civil Procedure and precedents thereunder. Confidential Discovery Material shall include non-public commercial information, the disclosure of which to Respondent or Third Parties would cause substantial commercial harm or personal embarrassment to the disclosing party. The following is a non-exhaustive list of examples of information that likely will qualify for treatment as Confidential Discovery Material: strategic plans (involving pricing, marketing, research and development, product roadmaps, corporate alliances, or mergers and acquisitions) that have not been fully implemented or revealed to the public; trade secrets; customer-specific evaluations or data (e.g., prices, volumes, or revenues); personnel files and evaluations; information subject to

confidentiality or non-disclosure agreements; proprietary technical or engineering information; proprietary financial data or projections; and proprietary consumer, customer or market research or analyses applicable to current or future market conditions, the disclosure of which could reveal Confidential Discovery Material.

TERMS AND CONDITIONS OF PROTECTIVE ORDER

1. Discovery Material, or information derived therefrom, shall be used solely by the Parties for purposes of this Matter, and shall not be used for any other purpose, including without limitation any business or commercial purpose. The Parties, in conducting discovery from Third Parties, shall attach to such discovery requests a copy of this Protective Order and a cover letter that will apprise such Third Parties of their rights hereunder.

2. This paragraph concerns the designation of material as "Confidential" and "Restricted Confidential, Attorney Eyes Only."

(a) Designation of Documents as CONFIDENTIAL - FTC Docket No. 9293.

Discovery Material may be designated as Confidential Discovery Material by Producing Parties by placing on or affixing, in such manner as will not interfere with the legibility thereof, the notation "CONFIDENTIAL - FTC Docket No. 9293" (or other similar notation containing a reference to this Matter) to the first page of a document containing such Confidential Discovery Material, or, by Parties by instructing the court reporter to denote each page of a transcript containing such Confidential Discovery Material as "Confidential." Such designations shall be made within fourteen (14) days from the initial production or deposition and constitute a good-faith representation by counsel for the Party or Third Party making the

designations that the document constitutes or contains "Confidential Discovery Material."

(b) Designation of Documents as "RESTRICTED CONFIDENTIAL, ATTORNEY EYES ONLY"

In order to permit Producing Parties to provide additional protection for a limited number of documents which contain highly sensitive commercial information, Producing Parties may designate documents as "Restricted Confidential, Attorney Eyes Only" by placing on or affixing such legend on each page of the document. It is anticipated that documents to be designated Restricted Confidential, Attorney Eyes Only may include certain marketing plans, sales forecasts, business plans, the financial terms of contracts, operating plans, pricing and cost data, price terms, analyses of pricing or competition information, and personnel information, and that this particularly restrictive designation is to be utilized for a limited number of documents. Documents designated Restricted Confidential, Attorney Eyes Only shall not be disclosed to the individuals designated under paragraph 5, hereof, and shall not be disclosed to Experts/Consultants (paragraph 4(c), hereof) and to witnesses or deponents at trial or deposition (paragraph 4(d) hereof), in each instance who are officers, directors, or employees of pharmaceutical companies except in accordance with subsection (c) of this paragraph 2. In all other respects, Restricted Confidential, Attorney Eyes Only material shall be treated as Confidential Discovery Material and all references in this Protective Order and in the exhibit hereto to Confidential Discovery Material shall include documents designated Restricted Confidential, Attorney Eyes Only.

(c) Disclosure to Experts/Consultants, Deponents or Witnesses in Each Instance Who Are Officers, Directors, or Employees of Pharmaceutical Companies

If any Party desires to disclose Restricted Confidential, Attorney Eyes Only material to any Expert/Consultant, deponent or witness in each instance who is an officer, director, or employee of a pharmaceutical company ("the individual"), the disclosing Party shall notify the Producing Party of its desire to disclose such material. Such notice shall identify the specific individual to whom the Restricted Confidential, Attorney Eyes Only material is to be disclosed. Such identification shall include, but not be limited to, the full name and professional address and/or affiliation of the proposed individual. The Producing Party may object to the disclosure of the Restricted Confidential, Attorney Eyes Only material within five (5) business days of receiving notice of an intent to disclose the Restricted Confidential, Attorney Eyes Only material to an individual by providing the disclosing Party with a written statement of the reasons for the objection. If the Producing Party timely objects, the disclosing Party shall not disclose the Restricted Confidential, Attorney Eyes Only material to the identified individual, absent a written agreement with the Producing Party, order of the Administrative Law Judge or ruling on appeal. The Producing Party lodging an objection and the disclosing Party shall meet and confer in good faith in an attempt to determine the terms of disclosure to the identified individual. If at the end of five (5) business days of negotiating the parties have not resolved their differences or if counsel determine in good faith that negotiations have failed, the disclosing Party may make written application to the Administrative Law Judge as provided by paragraph 7(c) of this Protective Order. If the Producing Party does not object to the disclosure of Restricted Confidential, Attorney Eyes Only material to the Expert/Consultant within five (5) business days,

the disclosing Party may disclose the Restricted Confidential, Attorney Eyes Only material to the identified individual.

(d) Disputes Concerning Designation or Disclosure of Restricted Confidential, Attorney Eyes Only Material

Disputes concerning the designation or disclosure of Restricted Confidential, Attorney Eyes Only material shall be resolved in accordance with the provisions of paragraph 7.

(e) No Presumption or Inference

No presumption or other inference shall be drawn that material designated Restricted Confidential, Attorney Eyes Only is entitled to the protections of this paragraph.

(f) Due Process Savings Clause

Nothing herein shall be used to argue that a Party's right to attend the trial of, or other proceedings in, this matter is affected in any way by the designation of material as Restricted Confidential, Attorney Eyes Only.

3. To the extent any such material is made part of this proceeding, all documents heretofore obtained by compulsory process or voluntarily from any Party or Third Party, regardless of whether designated confidential by the Party or Third Party, and transcripts of any investigational hearings, interviews and depositions, which were obtained during the pre-complaint stage of this Matter shall be treated as Confidential Discovery Material. Material previously produced by Respondents or a Third Party, and designated as "Confidential," regardless of whether such materials have been marked in accordance with paragraph 2 above, shall be treated as Confidential Discovery Material as provided herein. The material referred to in this paragraph shall only be available for use in this proceeding once an independent basis has

been demonstrated for such use.

4. Confidential Discovery Material shall not, directly or indirectly, be disclosed or otherwise provided to anyone except, in accordance with paragraphs 5 and 6, to:

(a) complaint counsel and the Commission, as permitted by the Commission's Rules of Practice;

(b) Outside Counsel;

(c) Experts/Consultants;

(d) witnesses or deponents at trial or deposition;

(e) the Administrative Law Judge and personnel assisting him;

(f) court reporters and deposition transcript reporters;

(g) judges and other court personnel of any court having jurisdiction over any appeal proceedings involving this Matter; and

(h) any author or recipient of Confidential Discovery Material (as indicated on the face of the document, record or material), and any individual who was in the direct chain of supervision of the author at the time the Confidential Discovery Material was created or received.

5. In addition to the above-designated persons, certain named designated individuals and in-house counsel not to exceed two attorneys per corporate party who do not have day to day business responsibilities shall be provided with access on the condition that each such in-house counsel or designated executive signs a declaration in the form attached hereto as Exhibit "A," which is incorporated herein by reference. For Respondent Carderm, the designated individual is Stephan Petri. For Respondent HMR, the designated individual is Edward Stratemeier, Vice President and General Counsel. For Respondent Andrx, the designated

individual is Scott Lodin, Vice President and General Counsel.

6. Confidential Discovery Material shall not, directly or indirectly, be disclosed or otherwise provided to an Expert/Consultant unless such Expert/Consultant agrees in writing:

(a) to maintain such Confidential Discovery Material in separate locked room(s) or locked cabinet(s) when such Confidential Discovery Material is not being reviewed;

(b) to return such Confidential Discovery Material to complaint counsel or Respondent's Outside Counsel, as appropriate, upon the conclusion of the Expert/Consultant's assignment or retention or the conclusion of this Matter;

(c) to not disclose such Confidential Discovery Material to anyone, except as permitted by the Protective Order; and

(d) to use such Confidential Discovery Material and the information contained therein solely for the purpose of rendering consulting services to a Party to this Matter, including providing testimony in judicial or administrative proceedings arising out of this Matter.

7. This paragraph governs the procedures for the following specified disclosures and challenges to designations of confidentiality.

(a) Disclosure to Experts

If any Party desires to disclose Confidential Discovery Material to any expert who may testify, who is not an FTC employee, and who may have interests in the pharmaceutical industry beyond their employment as an expert in this Matter, the disclosing Party shall notify the Producing Party of its desire to disclose such material. Such notice shall identify the specific expert who may testify to whom the Confidential Discovery Material is to be disclosed. Such identification shall include, but not be limited to, the full name and professional

address and/or affiliation of the proposed expert who may testify, and a current curriculum vitae of such expert identifying all other present and prior employers and/or firms in the pharmaceutical industry for which or on behalf of which the identified expert has been employed or done consulting work in the preceding four (4) years. The Producing Party may object to the disclosure of the Confidential Discovery Material within five (5) business days of receiving notice of an intent to disclose the Confidential Discovery Material to the identified expert by providing the disclosing Party with a written statement of the reasons for the objection. If the Producing Party timely objects, the disclosing Party shall not disclose the Confidential Discovery Material to the identified expert, absent a written agreement with the Producing Party or order of the Administrative Law Judge. The Producing Party lodging an objection and the disclosing Party shall meet and confer in good faith in an attempt to determine the terms of disclosure to the identified expert. If at the end of five (5) business days of negotiating the parties have not resolved their differences or if counsel determine in good faith that negotiations have failed, the disclosing Party may make written application to the Administrative Law Judge as provided by paragraph 7(c) of this Protective Order. If the Producing Party does not object to the disclosure of Confidential Discovery Material to the identified expert within five (5) business days, the disclosing Party may disclose the Confidential Discovery Material to the identified expert.

(b) Challenges to Confidentiality Designations

If any Party seeks to challenge a Producing Party's designation of material as Confidential Discovery Material or any other restriction contained within this Protective Order, the challenging Party shall notify the Producing Party and all Parties of the challenge to such designation. Such notice shall identify with specificity (i.e., by document control numbers,

deposition transcript page and line reference, or other means sufficient to locate easily such materials) the designation being challenged. The Producing Party may preserve its designation within five (5) business days of receiving notice of the confidentiality challenge by providing the challenging Party and all Parties with a written statement of the reasons for the designation. If the Producing Party timely preserves its rights, the Parties shall continue to treat the challenged material as Confidential Discovery Material, absent a written agreement with the Producing Party or order of the Administrative Law Judge. The Producing Party preserving its rights and the challenging Party shall meet and confer in good faith in an attempt to negotiate changes to any challenged designation. If at the end of five (5) business days of negotiating the parties have not resolved their differences or if counsel determine in good faith that negotiations have failed, the challenging Party may make written application to the Administrative Law Judge as provided by paragraph 7(c) of this Protective Order. If the Producing Party does not preserve its rights within five (5) business days, the challenging Party may alter the designation as contained in the notice. The challenging Party shall notify the Producing Party and the other Party of any changes in confidentiality designations.

Regardless of confidential designation, copies of published magazine or newspaper articles, and excerpts from published books and public documents filed with the Securities and Exchange Commission may be used by any Party without reference to the procedures of this subparagraph.

(c) Resolution of Disclosure or Confidentiality Disputes

If negotiations under subparagraphs 7(a)-(b) of this Protective Order have failed to resolve the issues, a Party seeking to disclose Confidential Discovery Material or challenging a confidentiality designation or any other restriction contained within this Protective Order may make written application to the Administrative Law Judge for relief. Such application shall be served on the Producing Party and the other Party, and be accompanied by a certification that the meet and confer obligations of this paragraph have been met, but that good faith negotiations have failed to resolve outstanding issues. The Producing Party and any other Party shall have five (5) business days to respond to the application, which time may be extended by the Administrative Law Judge. While an application is pending, the Parties shall maintain the pre-application status of the Confidential Discovery Material. Nothing in this Protective Order shall create a presumption or alter the burden of persuading the Administrative Law Judge of the propriety of a requested disclosure or change in designation.

8. Confidential Discovery Material shall not be disclosed to any person described in subparagraphs 4(b), 4(c) and 4(d) and paragraph 5 of this Protective Order until such person has executed and transmitted to Respondent's counsel or complaint counsel, as the case may be, a declaration or declarations, as applicable, in the form attached hereto as Exhibit "A," which is incorporated herein by reference. Respondents' counsel and complaint counsel shall maintain a file of all such declarations for the duration of the litigation. Confidential Discovery Material shall not be copied or reproduced for use in this Matter except to the extent such copying or reproduction is reasonably necessary to the conduct of this Matter, and all such copies or reproductions shall be subject to the terms of this Protective Order. If the duplication process

by which copies or reproductions of Confidential Discovery Material are made does not preserve the confidentiality designations that appear on the original documents, all such copies or reproductions shall be stamped "CONFIDENTIAL - FTC Docket No. 9293."

9. The Parties shall not be obligated to challenge the propriety of any designation or treatment of information as confidential and the failure to do so promptly shall not preclude any subsequent objection to such designation or treatment, or any motion seeking permission to disclose such material to persons not referred to in paragraphs 4 and 5 above. If Confidential Discovery Material is produced without the legend attached, such document shall be treated as Confidential from the time the Producing Party advises complaint counsel and Respondents' counsel in writing that such material should be so designated and provides all the Parties with an appropriately labeled replacement. The Parties shall return promptly or destroy the unmarked documents.

10. If the FTC: (a) receives a discovery request that may require the disclosure by it of a Third Party's Confidential Discovery Material; or (b) intends to or is required to disclose, voluntarily or involuntarily, a Third Party's Confidential Discovery Material (whether or not such disclosure is in response to a discovery request), the FTC promptly shall notify the Third Party of either receipt of such request or its intention to disclose such material. Such notification shall be in writing and, if not otherwise done, sent for receipt by the Third Party at least five (5) business days before production, and shall include a copy of this Protective Order and a cover letter that will apprise the Third Party of its rights hereunder.

11. If anyone receives a discovery request in another proceeding that may require the disclosure of a Producing Party's Confidential Discovery Material, the subpoena

recipient promptly shall notify the Producing Party of receipt of such request. Such notification shall be in writing and, if not otherwise done, sent for receipt by the Producing Party at least five (5) business days before production, and shall include a copy of this Protective Order and a cover letter that will apprise the Producing Party of its rights hereunder. The Producing Party shall be solely responsible for asserting any objection to the requested production. Nothing herein shall be construed as requiring the subpoena recipient or anyone else covered by this Order to challenge or appeal any such order requiring production of Confidential Discovery Material, or to subject itself to any penalties for noncompliance with any such order, or to seek any relief from the Administrative Law Judge or the Commission.

12. This Order governs the disclosure of information during the course of discovery and does not constitute an *in camera* order as provided in Section 3.45 of the Commission's Rules of Practice ("Rule"), 16 C.F.R. § 3.45.

13. *In camera* provisions

(a) The Commission's Rules of Practice require that material may not be withheld from the public record unless it falls within the scope of an order by the Administrative Law Judge that such material, or portions thereof, be placed *in camera*. 16 C.F.R. § 3.45(b) and (d). To comply with this rule, the Party seeking to introduce into evidence by filing a pleading, an exhibit thereto, or otherwise placing on the record Confidential Discovery Material ("filing Party") must first obtain an order by the Administrative Law Judge that such information has been granted *in camera* status.

An application for *in camera* treatment must: (1) specifically identify or describe the materials for which *in camera* treatment is sought; (2) provide reasons for granting such

materials *in camera* status; (3) specify the time period for which *in camera* treatment is sought for each document; and (4) attach as exhibits to the application the documents containing the specific information for which *in camera* treatment is sought.

A blanket *in camera* order for an entire pleading is contrary to public policy and will not be granted. The parties must specifically identify the portions of a pleading, document, deposition transcript, or exhibit for which *in camera* treatment is sought. Entire documents or exhibits will rarely, if ever, be eligible for *in camera* treatment. The parties are reminded that Rule 3.45 places the burden of showing that public disclosure will likely result in a clearly defined, serious injury upon the person requesting *in camera* treatment. In addition, to sustain the burden of proof, an application must be supported by proper evidence, such as affidavits, to support all factual issues. *See* 16 C.F.R. § 3.43.

(b) The Scheduling Order requires the parties to file motions to request *in camera* treatment of materials marked confidential pursuant to a protective order no later than September 1, 2000.

A Party that has produced materials or information that it reasonably expects to include in a pleading, motion, exhibit or other paper to be filed with the Secretary ("pleading") and that it believes meets the standards for *in camera* treatment must file a motion with the Administrative Law Judge to request *in camera* treatment of such materials no later than September 1, 2000.

A Party that has received materials or information from another Party or a Third Party that it reasonably expects to include in a pleading must provide the opposing Party or Third Party with a list of such materials no later than August 18, 2000. A Third Party shall be provided

with a copy of this Order along with such list. This list will not be filed with the Secretary's Office, but must be served on the Administrative Law Judge.

(c) If any Party seeks to file a pleading or attachment thereto which includes its own Confidential Discovery Material which has not previously been granted *in camera* status, and the Party seeks to prevent its own materials or information from being placed on the public record, at least 10 days prior to filing such pleading, -- unless it is impracticable (e.g., when filing a response or reply brief) in which case at least 5 days prior to filing such pleading -- the Party shall make an application to the Administrative Law Judge to request that such materials or information be treated as *in camera* information.

If any Party seeks to file a pleading or attachment thereto which includes another Party's or Third Party's Confidential Discovery Material which has not previously been granted *in camera* status, the filing Party must notify the Producing Party at least 14 days prior to such proposed filing -- unless it is impracticable (e.g., when filing a response or reply brief). If 14 days advance notice cannot be provided, the Producing Party must be notified as soon as possible and prior to the time of introduction of such documents or information. The Producing Party shall have 7 days from the date of notice to make an application to the Administrative Law Judge to request that such materials be treated as *in camera* information. The parties shall not file pleadings or attachments thereto that contain another Party's or Third Party's Confidential Discovery Material unless the Party seeking to introduce such material has first obtained an *in camera* order or certifies that the Producing Party has been given notice prior to the introduction of such material, and, in the case of Third Parties, has also been given a copy of this Order.

(d) The parties are cautioned that compliance with this Order will require them

to submit applications for *in camera* treatment in advance of filing motions which include confidential materials and that deadlines for filing motions attaching confidential materials will not be extended for failure to file applications for *in camera* treatment in a timely manner. The parties are further cautioned that it is rarely necessary to attach confidential information in support of pleadings. Absent strict adherence to these procedures, pleadings should be composed in a manner which sufficiently apprises the Court of the matter at issue and which does not identify or disclose any confidential information. Failure to comply with these procedures may result in pleadings or portions thereof being stricken from the record.

(e) Should any party seek to introduce into evidence at the trial of this case or any pretrial hearing Confidential Discovery Material which has not previously been granted *in camera* status, the evidence will not be disclosed or admitted into evidence until the Producing Party has had the opportunity to seek *in camera* treatment. The party seeking to introduce such evidence must demonstrate good cause for not previously obtaining an *in camera* order. If the Producing Party is a Third Party, the Party seeking to introduce or disclose such evidence must provide notice to the Third Party within 3 days of the date on which the evidence was sought to be introduced or disclosed. The Producing Third Party shall have 7 days from the date of notice to make an application to the Administrative Law Judge to request that such materials be treated as *in camera* information.

14. Nothing in this Protective Order shall be construed to conflict with the provisions of Sections 6, 10, and 21 of the Federal Trade Commission Act, 15 U.S.C. §§ 46, 50,

57b-2, or with Rules 3.22, 3.45 or 4.11(b)-(e), 16 C.F.R. §§ 3.22, 3.45 and 4.11(b)-(e).[1] Any Party or Producing Party may move at any time for, treatment *in camera* of any Confidential Discovery Material or any portion of the proceedings in this Matter to the extent necessary for proper disposition of the Matter.

15. At the conclusion of this Matter, Respondent's counsel shall return to the Producing Party, or destroy, all originals and copies of documents and all notes, memoranda, or other papers containing Confidential Discovery Material which have not been made part of the public record in this Matter. Complaint counsel shall dispose of all documents in accordance with Rule 4.12, 16 C.F.R. § 4.12.

16. The provisions of this Protective Order, insofar as they restrict the communication and use of Confidential Discovery Material shall, without written permission of the Producing Party or further order of the Administrative Law Judge hearing this Matter, continue to be binding after the conclusion of this Matter.

17. This Protective Order shall not apply to the disclosure by a Producing Party or its Counsel of such Producing Party's Confidential Discovery Material to such Producing Party's employees, agents, former employees, board members, directors, and officers.

18. The production or disclosure of any Discovery Material made after entry of this Protective Order which a Producing Party claims was inadvertent and should not have been produced or disclosed because of a privilege will not automatically be deemed to be a waiver of

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[1] The right of the Administrative Law Judge, the Commission, and reviewing courts to disclose information afforded *in camera* treatment or Confidential Discovery Material, to the extent necessary for proper disposition of the proceeding, is specifically reserved pursuant to Rule 3.45, 16 C.F.R. § 3.45.

any privilege to which the Producing Party would have been entitled had the privileged Discovery Material not inadvertently been produced or disclosed. In the event of such claimed inadvertent production or disclosure, the following procedures shall be followed:

(a) The Producing Party may request the return of any such Discovery Material within twenty (20) days of discovering that it was inadvertently produced or disclosed (or inadvertently produced or disclosed without redacting the privileged content). A request for the return of any Discovery Material shall identify the specific Discovery Material and the basis for asserting that the specific Discovery Material (or portions thereof) is subject to the attorney-client privilege or the work product doctrine and the date of discovery that there had been an inadvertent production or disclosure.

(b) If a Producing Party requests the return, pursuant to this paragraph, of any such Discovery Material from another Party, the Party to whom the request is made shall return immediately to the Producing Party all copies of the Discovery Material within its possession, custody, or control – including all copies in the possession of experts, consultants, or others to whom the Discovery Material was provided – unless the Party asked to return the Discovery Material in good faith reasonably believes that the Discovery Material is not privileged. Such good faith belief shall be based on either (i) a facial review of the Discovery Material, or (ii) the inadequacy of any explanations provided by the Producing Party, and shall not be based on an argument that production or disclosure of the Discovery Material waived any privilege. In the event that only portions of the Discovery Material contain privileged subject matter, the Producing Party shall substitute a redacted version of the Discovery Material at the time of making the request for the return of the requested Discovery Material.

(c) Should the Party contesting the request to return the Discovery Material pursuant to this paragraph decline to return the Discovery Material, the Producing Party seeking return of the Discovery Material may thereafter move for an order compelling the return of the Discovery Material. In any such motion, the Producing Party shall have the burden of showing that the Discovery Material is privileged and that the production was inadvertent.

19. Entry of the foregoing Protective Order is without prejudice to the right of the Parties or Third Parties to apply for further protective orders or for modification of any provision of this Protective Order.

ORDERED:

D. Michael Chappell
Administrative Law Judge

Dated: August 7, 2000

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

EXHIBIT A

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

DECLARATION CONCERNING PROTECTIVE ORDER GOVERNING DISCOVERY MATERIAL

I, [NAME], hereby declare and certify the following to be true:

1. [Statement of employment]

2. I have read the "Protective Order Governing Discovery Material" ("Protective Order") issued by Administrative Law Judge D. Michael Chappell on April 28, 2000, in connection with the above captioned matter. I understand the restrictions on my use of any Confidential Discovery Material (as this term is used in the Protective Order) in this action and I agree to abide by the Protective Order.

3. I understand that the restrictions on my use of such Confidential Discovery Material include:

   a. that I will use such Confidential Discovery Material only for the purposes of preparing for this proceedings, and hearing(s) and any appeal of this proceeding and for no other purpose;

   b. that I will not disclose such Confidential Discovery Material to anyone, except as permitted by the Protective Order; and

c. that upon the termination of my participation in this proceeding I will promptly return all Confidential Discovery Material, and all notes, memoranda, or other papers containing Confidential Discovery Material, to complaint counsel or respondent's counsel, as appropriate.

[4. I understand that if I am receiving Confidential Discovery Material as an Expert/Consultant, as that term is defined in this Protective Order, the restrictions on my use of Confidential Discovery Material also include the duty and obligation:

a. to maintain such Confidential Discovery Material in separate locked room(s) or locked cabinet(s) when such Confidential Discovery Material is not being reviewed;

b. to return such Confidential Discovery Material to complaint counsel or Respondent's Outside Counsel, as appropriate, upon the conclusion of my assignment or retention; and

c. to use such Confidential Discovery Material and the information contained therein solely for the purpose of rendering consulting services to a Party to this Matter, including providing testimony in judicial or administrative proceedings arising out of this Matter.]

5. I am fully aware that, pursuant to Section 3.42(h) of the Commission's Rules of Practice, 16 C.F.R. § 3.42(h), my failure to comply with the terms of the Protective Order may constitute contempt of the Commission and may subject me to sanctions imposed by the Commission.

_____ Date: _____

Full Name [Typed or Printed]

_____

Signature