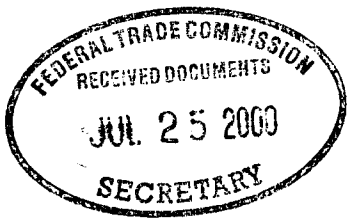
UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION



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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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]

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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,

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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

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

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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 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:

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Federal Trade Commission
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600 Pennsylvania Ave., N.W.
Washington, D.C. 20580

Richard Feinstein
Federal Trade Commission
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Hon. D. Michael Chappell
Administrative Law Judge
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Peter D. Bernstein