UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

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

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

Pursuant to § 3.34(c) of the Federal Trade Commission's Rules of Practice, 16 C.F.R. § 3.34(c), nonparty United States Food and Drug Administration respectfully moves to quash the subpoena duces tecum served on it by Aventis Pharmaceuticals, Inc. (formerly Hoechst Marion Roussell, Inc.), in this proceeding. The grounds for this motion are set forth in the accompanying Memorandum.

Dated: August 25, 2000

Respectfully Submitted,

MARGARET JANE PORTER
CHIEF COUNSEL

By: Claudia Zuckerman

Claudia J. Zuckerman
Assistant Chief Counsel
U.S. Food and Drug Administration
5600 Fishers Lane, GCF-1
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Attorney for the United States
Food and Drug Administration

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

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

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

Pursuant to § 3.34(c) of the Federal Trade Commission's ("FTC") Rules of Practice, 16 C.F.R. § 3.34(c), nonparty United States Food and Drug Administration ("FDA") respectfully moves to quash the subpoena duces tecum served on it by Aventis Pharmaceuticals, Inc. ("Aventis"), served on August 10, 2000. FDA regulations provide that FDA denies a request for FDA records made by a subpoena duces tecum and handles the production of such records by procedures established in 21 C.F.R. Part 20. Furthermore, as demonstrated below, the subpoena seeks documents without making the requisite showing pursuant to § 3.36 of FTC's Rules of Practice. Accordingly, the subpoena should be quashed.

FACTS

Aventis seeks the following from FDA: (1) documents relating to drug applications of three manufacturers, Biovail, Faulding, and Andrx, for a bioequivalent Cardizem CD;

(2) internal FDA communications and communications between FDA and any third-party regarding FDA's proposed 180-day generic drug exclusivity rule; (3) documents concerning the development of Aventis's drug, Probucol, for a new indication.[1]

This is the second subpoena that FDA has received in connection with this proceeding. On July 7, 2000, Andrx served a subpoena duces tecum on FDA. *See* Subpoena Duces Tecum Served by Andrx on FDA, Exhibit 2. On August 11, 2000, FDA filed a motion to quash Andrx's subpoena. *See* Motion of the United States Food and Drug Administration to Quash Subpoena Served by Andrx Corporation, Exhibit 3.

On August 11, 2000, Aventis was served with FDA's Memorandum supporting its motion to quash Andrx's subpoena. On August 17, 2000, and then again on August 22, 2000, Claudia J. Zuckerman, the undersigned counsel for FDA, spoke with D. Edward Wilson and Peter D. Bernstein, counsel for Aventis, regarding FDA's objections to Aventis's subpoena. With a minor exception, FDA and Aventis were unable to reach agreement resolving the objections.[2] *See* Statement of Claudia J. Zuckerman, accompanying this motion.

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[1] *See* Subpoena Duces Tecum Served by Aventis, Exhibit 1. Category 1 covers Request Nos. 1, 3, and 4; Category 2 covers Request No. 2; and Category 3 covers Request No. 5.

[2] Despite Andrx's counsels' contention to the contrary in the first of two letters dated August 24, 2000, to Your Honor, the undersigned FDA counsel did not refuse to stipulate to a proposed schedule that "both parties' submissions [opposing FDA's motions to quash the subpoenas] be due fifteen days after service by the FDA of its motion to quash the [Aventis] subpoena." Prior to FDA counsel's receipt of that letter, FDA counsel was unaware of the existence of such a proposal.

ARGUMENT

FDA, like most federal agencies, has promulgated regulations under the authority of 5 U.S.C. § 301 and 21 U.S.C. § 371(a) that govern the production of records. FDA's document disclosure regulations are set forth in 21 C.F.R. Part 20. In particular, 21 C.F.R. § 20.2 designates the procedures that must be followed by an FDA employee who receives a subpoena duces tecum.[3] As directed by 21 C.F.R. § 20.2, FDA declines to produce the records pursuant to Aventis's subpoena. This reason should be sufficient grounds alone for quashing the subpoena.

Aventis has not even attempted to submit a request for FDA documents pursuant to 21 C.F.R. Part 20. Should Aventis consent to receipt of documents pursuant to the procedures established in Part 20, FDA will produce records accordingly.

Alternatively, the subpoena should be quashed because Aventis has failed to make the requisite showing under FTC regulations. Section 3.36 of the FTC's Rules of Practice require that an application for a subpoena for records of governmental agencies other than the FTC contain a specific showing that:

(1) the material sought is reasonable in scope;

[3/] 21 C.F.R. § 20.2(b) provides:

> Whenever a subpoena duces tecum, in appropriate form, has been lawfully served upon an officer or employee of the Food and Drug Administration commanding the production of any record, such officer or employee shall appear in response thereto, respectfully decline to produce the record on the ground that it is prohibited by this section, and state that the production of the record(s) involved will be handled by the procedures established in this part.

(2) if for purposes of discovery, the material falls within the limits of discovery under § 3.31(b)(1) . . .; and

(3) the information or material sought cannot reasonably be obtained by other means.

Section 3.31(b)(1) references § 3.31(c)(1), which limits discovery "to the extent that it may be reasonably expected to yield information relevant . . . to the defenses of any respondent." *See In re Exxon Corp.*, 95 F.T.C. 919, 1980 FTC Lexis 64 at *8 (June 30, 1980) (Interlocutory Order) ("If a party requests information of another government agency, the administrative law judge shall carefully consider the relevance of the requested information and its availability through other means."); *see also In re Automotive Breakthrough Sciences, Inc.*, Dkt. No. 9275, 1996 FTC Lexis 286 at *1-2 (June 19, 1996) (Order Denying Motion for Issuance of Subpoena Duces Tecum).

A. Aventis's Request Nos. 1(a), 1(b), 3, 4

Aventis has not made a specific showing pursuant to § 3.36 of FTC's Rules of Practice that "the information or material sought cannot reasonably be obtained by other means," with respect to: (1) communications between FDA and Biovail regarding Biovail's drug applications (Request No. 1(a)); (2) communications between FDA and any third party relating to issues raised in Andrx's citizen petition (Request No. 1(b)); and (3) documents reflecting the filing dates for Faulding's and Andrx's drug applications and documents reflecting the approval date for Andrx's supplement (Request Nos. 3, 4).

As discussed below, Aventis has the ability to get documents relating to drug companies' drug applications from the companies themselves. Because Aventis has other

means to reasonably obtain the information it seeks on other companies' drug applications, there is no need for Aventis to burden a government agency with such requests. Also as discussed below, documents requested in Request No. 1(b) are publicly available and easily accessible to Aventis.

Communications between FDA and Biovail regarding Biovail's application – Given the extreme commercial sensitivity of certain information contained in drug applications and in correspondence with FDA relating to the applications, a drug company, such as Biovail, is itself in the best position to make decisions regarding, and arrangements for, the release of its own documents.

Documents reflecting certain application dates – The documents reflecting filing and approval dates for Faulding's and Andrx's applications are easily obtainable from the companies themselves. Aventis can certainly ask its co-respondent, Andrx, for information relating to Andrx's application as well as for information relating to Faulding's application.[4]

Communications about Andrx's citizen petition – Third-party communications regarding issues Andrx raised in its citizen petition are publicly available from the public docket FDA established when Andrx's citizen petition was filed.

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[4] Andrx has already requested information from Faulding regarding Faulding's application. *See* Subpoena Duces Tecum Served by Andrx on Faulding, Exhibit 4, specifications 5, 25, and 26.

B. Aventis's Request No. 1(c)

With respect to FDA's internal documents regarding Biovail's applications, Aventis has not made a specific showing pursuant to § 3.36 of FTC's Rules of Practice that "the material falls within the limits of discovery under § 3.31(b)(1)." Such FDA internal documents are not relevant nor are they likely to lead to information relevant to Aventis's defenses. Aventis's defenses appear to rest on its contention that no application's approval was delayed as a result of the agreement between Aventis and Andrx because no generic drug application was otherwise ready for approval during the pendency of the agreement. Even it the Court were to accept the merit of such a defense, FDA has no internal documents that are relevant to that defense. Where an application has a significant deficiency that delays or precludes approval, such deficiency is communicated in writing to the applicant. Aventis can obtain those communications, if relevant, from the application sponsors who received them and need not seek them from a nonparty government entity. Those correspondences and the issues surrounding them have been discussed above. Additional predecisional documents that reflect the agency's deliberative process and individual reviewers' opinions regarding the nature of an application's deficiencies will neither bolster nor undercut the argument that competitor applications were otherwise not ready for approval during the pendency of the agreement. Moreover, even if Aventis could establish the relevance of predecisional agency documents, such documents are covered by the deliberative process privilege.

Disclosure of intra-agency deliberations and advice is injurious to the federal government's decision-making functions because it tends to inhibit the frank and candid discussion necessary to effective government. *National Labor Relations Bd. v. Sears, Roebuck & Co.*, 421 U.S. 132, 149-51 (1975). It is beyond dispute that such internal government communications are protected by the deliberative process privilege. *Carl Zeiss Stiftung v. V.E.B. Carl Zeiss, Jena*, 40 F.R.D. 318, 324 (D.D.C. 1966), *aff'd*, 384 F.2d 979 (D.C. Cir.), *cert. denied*, 389 U.S. 952 (1967). Such privilege from disclosure exists for agency materials that are (1) pre-decisional and (2) deliberative in nature, i.e., that contain opinions, recommendations, or advice about agency decisions. *See e.g., Access Reports v. Department of Justice*, 926 F.2d 1192, 1194 (D.C. Cir. 1991). If disclosure of such communications would chill the frank expression and discussion of ideas necessary to enable the government to operate, such information is protected by the privilege. *Sears, Roebuck & Co.*, 421 U.S. at 149-51; *Access Reports*, 926 F.2d at 1195, 1196; *Carl Zeiss Stiftung*, 40 F.R.D. at 324.

To overcome the privilege, Aventis must demonstrate that there are compelling circumstances necessitating the release of this information that outweigh the adverse effects upon FDA and the public that would inevitably flow from disclosing FDA's deliberations. *See In re Champion Spark Plug Co.*, Dkt. No. 9141,1980 FTC Lexis 200 *10-11 (December 16, 1980) (Order Granting, In Part, Motion To Quash Access Order). Given that Aventis can obtain the documents containing the decisions that were ultimately made during the review process (including letters detailing application deficiencies, if any)

through other means, and that the internal agency decisionmaking process that led to the identification of the deficiencies is, at best, only marginally relevant to Aventis's defense, there are no compelling circumstances here to justify release of internal predecisional documents.

C. Aventis's Request No. 2

FDA's internal communications relating to FTC's comments on FDA's proposed 180-day generic drug exclusivity rule are also privileged documents.[5] FDA's proposed rule has not been finalized. FDA is in the process of considering and responding to the comments on its proposal as the Administrative Procedure Act requires. FDA's response to all of the comments submitted to the proposed rule will be available to the public when FDA publishes the Final Rule in the Federal Register. Releasing FDA's internal documents considering the comments prior to publication of the Final Rule will short-circuit FDA's administrative process. Such a release will jeopardize the free exchange of ideas that is essential to agency decisionmaking and that the deliberative process privilege is designed to protect. Again, Aventis has not shown compelling circumstances to justify release of this information.

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[5] Also as part of Request No. 2, Aventis has requested communications between FDA and FTC relating to FDA's proposed 180-day generic drug exclusivity rule. Aventis has already requested from FTC those same communications. *See* Aventis's Second Request for Production of Documents, Exhibit 5, specification 42. FTC has already produced all non-privileged, responsive documents. There is no need for Aventis to burden a nonparty with such a request when it already has such documents in its possession.

D. Aventis's Request No. 5

Aventis has failed to explain to FDA how the documents concerning the development of Aventis's drug, Probucol, for prevention of restenosis after coronary angioplasty are relevant to the instant proceeding that concerns Aventis's Stipulation and Agreement with Andrx over generic Cardizem CD. FDA, therefore, believes that Aventis has failed to make the requisite showing of relevance required by FTC's Rules of Practice. Moreover, Aventis has already requested documents regarding Probucol from Biovail,[6] and, therefore, Aventis's request to FDA appears to be duplicative.

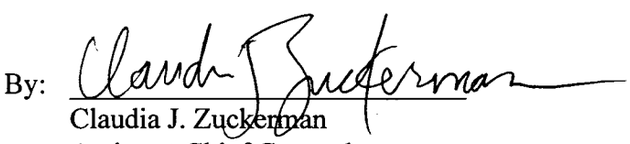
CONCLUSION

For the foregoing reasons, FDA respectfully requests that its motion be granted.

Dated: August 25, 2000

Respectfully Submitted,

MARGARET JANE PORTER
CHIEF COUNSEL

By: 

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Attorney for the United States
Food and Drug Administration

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[6] *See* Subpoena Duces Tecum Served by Aventis on Biovail, Exhibit 6, specifications 27-32.

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

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

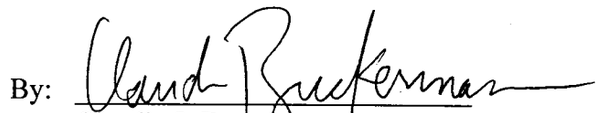
STATEMENT OF CLAUDIA J. ZUCKERMAN PURSUANT TO RULE 3.22(F) OF THE FEDERAL TRADE COMMISSION'S RULES OF PRACTICE

I am an attorney with the Office of Chief Counsel for the United States Food and Drug Administration and submit this statement pursuant to Rule 3.22(f) of the Federal Trade Commission's Rules of Practice, 16 C.F.R. § 3.22(f), in connection with the Motion of the United States Food and Drug Administration to Quash Subpoena Served by Aventis Pharmaceuticals, Inc. On August 17, 2000, and August 22, 2000, I spoke with Peter D. Bernstein and D. Edward Wilson, counsel for Aventis, in good faith to resolve by agreement the issues raised by FDA's Motion to Quash. During those conversations, we were unable to reach agreement resolving the objections to the subpoena, with the exception of an agreement on documents relating to submission, tentative, and final approval dates of Faulding's and Andrx's applications (but not including any approval letter of Andrx's supplement).

Dated: August 25, 2000

Respectfully Submitted,

MARGARET JANE PORTER
CHIEF COUNSEL

By: 

Claudia J. Zuckerman
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U.S. Food and Drug Administration
5600 Fishers Lane, GCF-1
Rockville, Maryland 20857
(301) 827-1147
Attorney for the United States
Food and Drug Administration

CERTIFICATE OF SERVICE

I, Sandra K. Pixley, hereby certify that on August 25, 2000, I caused a copy of the Memorandum of the United States Food and Drug Administration in Support of its Motion to Quash Subpoena Served by Aventis Pharmaceuticals, Inc., to be served upon the following persons by Federal Express:

Hon. D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
Room 104
600 Pennsylvania Avenue, NW
Washington, DC 20580

Donald S. Clark, Secretary
Federal Trade Commission
Room 172
600 Pennsylvania Avenue, NW
Washington, DC 20580

Richard Feinstein, Esq.
Markus H. Meier, Esq.
Daniel Kotchen, Esq.
Federal Trade Commission
Room 3114
601 Pennsylvania Avenue, NW
Washington, DC 20580

James M. Spears, Esq.
Shook, Hardy & Bacon, L.L.P
600 14th Street, NW
Suite 800
Washington, DC 20005

Peter O. Safir, Esq.
Kleinfeld, Kaplan and Becker
1140 19th Street, NW
Washington, DC 20036

Louis M. Solomon, Esq.
Solomon, Zauderer, Ellenhorn,
Frischer & Sharp
45 Rockefeller Plaza
New York, NY 10111

Sandra K. Pixley

EXHIBIT I

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.

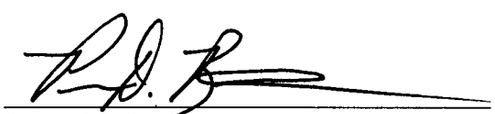
18. If any documents that are responsive to the document requests herein are withheld from production, furnish a list of all such documents withheld. Said list shall contain a complete description of each document, including: (i) the type, date, and number of pages of the document; (ii) its title (if 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.

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,	)	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

EXHIBIT II

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, D.C. 20005

4. MATERIAL WILL BE PRODUCED TO

Solomon, Zauderer, Ellenhorn, Frischer & Sharp
Counsel for Respondent Andrx Corporation

5. DATE AND TIME OF PRODUCTION OR INSPECTION

July 31, 2000
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

8. ADMINISTRATIVE LAW JUDGE

The Honorable D. Michael Chappell

Federal Trade Commission
Washington, D.C. 20580

9. COUNSEL REQUESTING SUBPOENA

Solomon, Zauderer, Ellenhorn, Frischer & Sharp
45 Rockefeller Plaza, 7th Floor
New York, New York 10111

Attorneys for Respondent Andrx

DATE ISSUED

JUN 29 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.

EXHIBIT "A"

Documents Requested

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; and

    b) All communications between the FDA and any third party; and

    c) All responsive internal FDA documents.

2. All documents concerning 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. This request includes, by way of example, but is not limited to:

    a) All communications between the FDA and Faulding.

    b) All communications between the FDA and any third party; and

    c) All responsive internal FDA documents.

3) All communications between the FDA and any other party (excluding Andrx) concerning Andrx's ANDA for the manufacture and production of a pharmaceutical product that is the bioequivalent of Cardizem® CD. This request includes, by way of example, but is not limited to:

    a) All communications between the FDA and the FTC concerning Andrx's ANDA; and

b) All documents concerning the FDA's decision to grant approval for Andrx's ANDA, including Andrx's reformulated product approved by the FDA on June 9, 1999 .

Definitions and Instructions

a. "Andrx" means Andrx Corporation, and any of its parents, subsidiaries, affiliates, divisions, employees, officers, directors, agents, representatives, predecessors or successors.

b. "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.

c. "Faulding" means Faulding, Inc. and any of its parents, subsidiaries, affiliates, divisions, employees, officers, directors, agents, lawyers, representatives, predecessors or successors.

d. "FDA" means the Federal Food and Drug Administration and its divisions, agents, representatives, predecessors or successors.

e. "FTC" means the Federal Trade Commission, and its divisions (including its enforcement divisions), bureaus (including its Bureau of Competition), agents, representatives, predecessors or successors

f. "NDA" means a New Drug Application submitted to the FDA for approval for the manufacture and marketing of a pharmaceutical product.

g. "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.

h. The terms "document" and "documents" are used in their broadest sense, to the full extent permitted by the Federal Rules of Civil Procedure to mean , without limitation, any original written, recorded, filmed, or graphic matter of every type and description, whether produced or reproduced on paper, cards, tapes, film, electronic facsimile, computer storage disks, tapes, or devices, or any other media, and each copy of such writing, record, film, or graphic matter that is different in any way from the original or where such copy contains any commentary or notation whatsoever that does not appear on the original whether by interlineation, receipt stamp notation, inclusion of comments or notations, or otherwise and drafts. Documents specifically include, by way of illustration, but not by way of limitation, all letters, notes, diaries, E-mails, reports, studies, charts, graphs, memoranda, instruments, minutes, ledgers, records, recordings, tapes, microfilm, photographs, correspondence, telegrams, diaries, bookkeeping entries, financial statements, tax returns, checks, check stubs, notebook statements, affidavits, agreements, applications, books, pamphlets, periodicals, appointment calendars and work papers.

i. "Concern" and "concerning" mean relating to, referring to, describing, evidencing, or constituting.

j. 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.

k. The terms "any" "all" and "each" each shall be construed to mean "any, all and each".

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

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

n. 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.

o. 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.

p. 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.

q. This subpoena should be construed as not calling for the production of any documents prepared, authored, created, submitted or filed by Andrx.

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 ANDRX'S MOTION FOR THE ISSUANCE OF A SUBPOENA DUCES TECUM TO THE FOOD AND DRUG ADMINISTRATION

On June 12, 2000, pursuant to Commission Rule 3.36, Respondent Andrx Corporation 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 and Complaint Counsel did not oppose the motion. 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.

Andrx 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 5, 2000

EXHIBIT III

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

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

MOTION OF THE UNITED STATES FOOD AND DRUG ADMINISTRATION TO QUASH SUBPOENA SERVED BY ANDRX CORPORATION

Pursuant to § 3.34(c) of the Federal Trade Commission's Rules of Practice, 16 C.F.R. § 3.34(c), nonparty United States Food and Drug Administration respectfully moves to quash the subpoena duces tecum served on it by Andrx Corporation in this proceeding. The grounds for this motion are set forth in the accompanying Memorandum.

Dated: August 10, 2000

Respectfully Submitted,

MARGARET JANE PORTER
CHIEF COUNSEL

By: _____
Claudia J. Zuckerman
Assistant Chief Counsel
U.S. Food and Drug Administration
5600 Fishers Lane, GCF-1
Rockville, Maryland 20857
(301) 827-1147
Attorney for the United States
Food and Drug Administration

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

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

MEMORANDUM OF THE UNITED STATES FOOD AND DRUG ADMINISTRATION IN SUPPORT OF ITS MOTION TO QUASH SUBPOENA SERVED BY ANDRX CORPORATION

Pursuant to § 3.34(c) of the Federal Trade Commission's ("FTC") Rules of Practice, 16 C.F.R. § 3.34(c), nonparty United States Food and Drug Administration ("FDA") respectfully moves to quash the subpoena duces tecum served on it by Andrx Corporation ("Andrx"), dated June 26, 2000, and served on July 7, 2000. As demonstrated below, the subpoena seeks documents without making the requisite showing pursuant to § 3.36 of FTC's Rules of Practice. Accordingly, the subpoena should be quashed.

FACTS

The documents Andrx seeks from FDA fall into three categories: (1) communications between FDA and two drug companies, Biovail and Faulding, regarding each company's respective drug applications ("Category 1"); (2) FDA's internal documents regarding Biovail's and Faulding's applications ("Category 2"); and (3) communications

between FDA and any "third party" regarding Biovail's, Faulding's, or Andrx's applications, explicitly including communications between FDA and FTC regarding Andrx's drug application ("Category 3").[1]

On July 14, 2000, Claudia J. Zuckerman, the undersigned counsel for FDA, and Jonathan D. Lupkin, counsel for Andrx, agreed to a narrowing of the subpoena as well as an extension of time until August 15, 2000, to produce documents responsive to the narrowed request. Declaration of Claudia J. Zuckerman ("Zuckerman Decl."), ¶ 2. During that telephone conversation, Ms. Zuckerman stated that the documents requested were subject to certain statutes and privileges that may prevent release of information such as trade secret, confidential commercial, and deliberative process information. *Id.* at ¶ 3. Moreover, the narrowed request did not include an agreement by FDA to produce communications between FDA and FTC. *See id.* at ¶ 4.

At the time that Ms. Zuckerman agreed that FDA would produce responsive documents subject to certain statutes and privileges, Ms. Zuckerman was unaware that documents in Category 1 had already been, or were in the process of being, obtained by Andrx through other means. *See* Zuckerman Decl., ¶¶ 5, 6. Since the July 14, 2000, conversation between Ms. Zuckerman and Mr. Lupkin, Ms. Zuckerman learned from Francis D. Landrey, Biovail's counsel, that Biovail, in another proceeding, already

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[1] *See* Subpoena Duces Tecum (attached as Exhibit 1). Category 1 covers Request Nos. 1(a) and 2(a); Category 2 covers Request Nos. 1(c) and 2(c); and Category 3 covers Request Nos. 1(b), 2(b), and 3.

a request. Moreover, given the extreme commercial sensitivity of information contained in the drug applications and in correspondence with FDA relating to the applications, drug companies themselves are in the best position to make agreements regarding the release of their own documents.

With respect to communications between FDA and FTC regarding Andrx's application, Andrx, if it has not already done so, can request such documents from FTC. There is no need for Andrx to burden a nonparty with such a request when it can reasonably obtain the documents from a party to the proceeding.

With respect to FDA's internal documents, Andrx has not made a specific showing pursuant to § 3.36 of FTC's Rules of Practice that "the material falls within the limits of discovery under § 3.31(b)(1)." FDA's internal documents concerning Biovail's and Faulding's drug applications are not relevant nor are they likely to lead to information relevant to Andrx's defenses. Andrx's defenses appear to rest on its contention that no application's approval was delayed as a result of the agreement between Andrx and Hoechst because no generic drug application was otherwise ready for approval during the pendency of the agreement. Even it the Court were to accept the merit of such a defense, FDA has no internal documents that are relevant to that defense. Where an application has a significant deficiency that delays or precludes approval, such deficiency is communicated in writing to the applicant. Andrx can obtain those communications, if relevant, from the application sponsors who received them and need not seek them from a nonparty government entity. Those correspondences and the issues surrounding them have been

discussed above. Additional predecisional documents that reflect the agency's deliberative process and individual reviewers' opinions regarding the nature of an application's deficiencies will neither bolster nor undercut the argument that competitor applications were otherwise not ready for approval during the pendency of the agreement.

Moreover, even if Andrx could establish the relevance of predecisional agency documents, such documents are covered by the deliberative process privilege. The deliberative process privilege protects documents from disclosure unless there are compelling circumstances that necessitate their release. *See In re Champion Spark Plug Co.*, Dkt. No. 9141,1980 FTC Lexis 200 *10-11 (December 16, 1980) (Order Granting, In Part, Motion To Quash Access Order). Given that Andrx can obtain the documents containing the decisions that were ultimately made during the review process (including letters detailing application deficiencies, if any) through other means, and that the internal agency decisionmaking process that led to the identification of the deficiencies is, at best, only marginally relevant to Andrx's defense, there are no compelling circumstances here to justify release of internal predecisional documents.

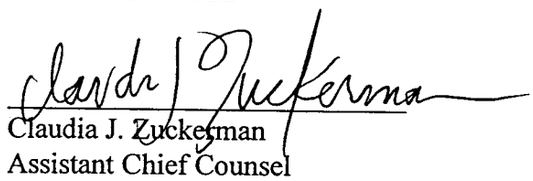
CONCLUSION

For the foregoing reasons, FDA respectfully requests that its motion be granted.

Dated: August 10, 2000

Respectfully Submitted,

MARGARET JANE PORTER
CHIEF COUNSEL

By: 

Claudia J. Zuckerman
Assistant Chief Counsel
U.S. Food and Drug Administration
5600 Fishers Lane, GCF-1
Rockville, Maryland 20857
(301) 827-1147
Attorney for the United States
Food and Drug Administration

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

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

STATEMENT OF CLAUDIA J. ZUCKERMAN PURSUANT TO RULE 3.22(F) OF THE FEDERAL TRADE COMMISSION'S RULES OF PRACTICE

I am an attorney with the Office of Chief Counsel for the United States Food and Drug Administration and submit this statement pursuant to Rule 3.22(f) of the Federal Trade Commission's Rules of Practice, 16 C.F.R. § 3.22(f), in connection with the Motion of the United States Food and Drug Administration to Quash Subpoena Served by Andrx Corporation dated June 26, 2000. I have discussed with Jonathan D. Lupkin (on July 31, 2000, and August 1, 2000) and Hal S. Shaftel (on August 1, 2000) of Solomon, Zauderer, Ellenhorn, Frischer & Sharp, counsel for Andrx, in good faith to resolve by agreement the issues raised by FDA's Motion to Quash. During those conversations, we were unable to reach agreement resolving the objections to the subpoena.

Dated: August 10, 2000

Respectfully Submitted,

MARGARET JANE PORTER
CHIEF COUNSEL

By: Claudia Zuckerman

Claudia J. Zuckerman
Assistant Chief Counsel
U.S. Food and Drug Administration
5600 Fishers Lane, GCF-1
Rockville, Maryland 20857
(301) 827-1147
Attorney for the United States
Food and Drug Administration

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

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

DECLARATION IN SUPPORT OF MOTION OF THE UNITED STATES FOOD AND DRUG ADMINISTRATION TO QUASH SUBPOENA SERVED BY ANDRX CORPORATION

CLAUDIA J. ZUCKERMAN, a member in good standing of the Bar of the State of Maryland, declares:

1. I am an assistant chief counsel in the Office of Chief Counsel, United States Food and Drug Administration ("FDA"), a nonparty to the above-captioned proceeding. I make this declaration in support of FDA's motion to quash the subpoena (the "Subpoena"), dated June 26, 2000, issued in this proceeding by Andrx Corporation ("Andrx").

2. On July 14, 2000, I had a telephone conversation with Jonathan D. Lupkin, of Solomon, Zauderer, Ellenhorn, Frischer & Sharp ("Solomon Zauderer"), counsel for Andrx, with respect to the Subpoena. We agreed to a narrowing of the subpoena as well as an extension of time for production of documents. August 15, 2000, is the agreed-upon deadline for production of certain documents responsive to the subpoena, as narrowed.

3. During the July 14, 2000, conversation with Mr. Lupkin, I stated that the documents requested were subject to certain statutes and privileges that may prevent release of information such as trade secrets, confidential commercial information, and internal agency deliberations.

4. During the July 14, 2000 conversation with Mr. Lupkin, I did not agree to produce communications between FDA and FTC.

5. On July 25, 2000, I had a telephone conversation with Francis D. Landrey of Proskauer Rose LLP, counsel for Biovail Corporation. It was during that conversation that I learned that Biovail had produced documents relating to its drug application in another proceeding and that Andrx had copies of those documents.

6. On August 1, 2000, I had a telephone conversation with Hal S. Shaftel of Solomon Zauderer, counsel for Andrx. It was during that conversation that I learned that Andrx had served a subpoena in this proceeding on Faulding, requesting substantially the same documents about Faulding's application that Andrx was seeking from FDA.

7. During the August 1, 2000, conversation with Mr. Shaftel, he stated that he would have more information by August 4, 2000, as to whether Andrx would continue to seek documents from FDA regarding communications between FDA and Biovail and between FDA and Faulding about each company's respective applications.

8. As of the close of business on August 9, 2000, I have not had any communications with Mr. Shaftel, Mr. Lupkin, or any other counsel for Andrx, subsequent to the August 1, 2000, telephone conversation.

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

Executed on August 10, 2000.

CLAUDIA J. ZUCKERMAN

EXHIBIT IV

SUBPOENA DUCES TECUM

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

1. TO	2. FROM
Faulding, Inc. By one or more officers, directors, or managing agents, or other persons who consent to testify on its behalf concerning the subject matter of this action and/or of the subject matter of the documents described in Exhibit A 200 Elmora Ave. Elizabeth, NJ	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	4. MATERIAL WILL BE PRODUCED TO
SOLOMON, ZAUDERER, ELLENHORN, FRISCHER & SHARP 45 Rockefeller Plaza New York, NY 10111 or at such other location as is mutually agreed upon.	Respondent – Andrx Corporation
	5. DATE AND TIME OF PRODUCTION OR INSPECTION July 24, 2000 at 10:30 a.m.

6. SUBJECT OF PROCEEDING

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

7. MATERIAL TO BE PRODUCED

See Exhibit A

8. ADMINISTRATIVE LAW JUDGE	9. COUNSEL REQUESTING SUBPOENA
The Honorable D. Michael Chappell Federal Trade Commission Washington, D.C. 20580	Solomon, Zauderer, Ellenhorn, Frischer & Sharp 45 Rockefeller Plaza, 7th Floor New York, New York 10111 Attorneys for Respondent Andrx

DATE ISSUED	SECRETARY'S SIGNATURE
MAY 12 2000	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.

EXHIBIT A

1. All documents relating to marketing cardiovascular pharmaceutical products to any of the following other entities: Pfizer, Merck & Company, Zeneca Pharm (now Astra Zeneca), Andrx, HMRI, Novartis RX, Abbott Pharm Prods, Mylan, Parke-Davis, Key Pharmaceutical, Astra Pharm L.P., Bayer Pharm, Searle, Watson Lab, Zenith Goldline, and Forest Pharmaceutical, including but not limited to sales plans and budgets, sales forecasts, marketing and pricing strategies, brochures and sales materials of any kind.

2. All documents which relate to the effect of bioequivalent or generic versions of pioneer pharmaceutical products on the market for those pioneer pharmaceutical products.

3. All documents which relate to the actual or potential effect on competition with, or on sales, prices or market share for the Company's cardiovascular pharmaceutical products by any actual or potential prescription or non-prescription drugs for the treatment of hypertension and angina.

4. All documents which relate to the actual or potential effect on competition with, or on sales, prices or market share for the Company's cardiovascular pharmaceutical products by Cardizem® CD, Cartia XT™, or a bioequivalent or generic version of Cardizem® CD.

5. All documents filed with, or being prepared for submission to, the Food and Drug Administration relating to any person's approved or pending application for cardiovascular pharmaceutical products, or any other product which the Company believes competes with Cardizem® CD or Cartia XT™.

6. All documents relating to the following sales and marketing information:

(a) annual (and, for the current year, monthly) sales (in units), revenue, and profit information for each stock keeping unit relating to the sale of each of the Company's cardiovascular pharmaceutical products;

(b) prices, pricing plans, pricing policies, pricing forecasts, pricing strategies, and pricing decisions for each of the Company's cardiovascular pharmaceutical products;

(c) projected or anticipated prices, sales (in units), revenues, and profits for each stock keeping unit relating to the sale of each of the Company's cardiovascular pharmaceutical products;

(d) strategic and marketing plans for each of the Company's cardiovascular pharmaceutical products; and,

(e) promotional materials of any kind, including but not limited to brochures, print advertisements, transcripts of electronic media advertisement.

7. All documents relating to the introduction or sale of bioequivalent or generic versions of Cardizem® CD by any person, including, but not limited to:

(a) attempts to introduce a bioequivalent or generic version of Cardizem® CD to the commercial market;

(b) the historical projections or anticipated dates of entry into

distributed;

(c) sales returns in units and dollars;

(d) cost of goods sold in dollars;

(e) gross and net profit in dollars;

(f) sales, promotion, or marketing expenses;

(g) the list price and wholesale acquisition cost;

(h) product returns in units and dollars; and

(i) rebates, credits, allowances, charge backs, and any other adjustment to price.

9. All data and reports, including but not limited to data and reports provided by third-party vendors such as IMS, that reflect the sales of any cardiovascular pharmaceutical product and any analysis that might consider: (1) the extent to which these products compete against each other and compete against Cardizem® CD, Cartia XT™, and other sustained release diltiazem products; (2) the extent to which sales of the products respond to/or are affected by variations in price or manufacturer discounts, rebates, credits or other price adjustments; and (3) the extent to which sales of the products respond to changes in the manner in which they are listed in formularies maintained by third-party payors, insurers and other health care providers.

10. All documents which reflect in any way standards of care for the treatment of hypertension and/or angina through the use of cardiovascular pharmaceutical products.

11. All documents sufficient to show the name and chemical entity of all products which the Company believes competes with Cardizem® CD or Cartia XT™

For each product, produce documents sufficient to explain why the Company believes that product competes with Cardizem® CD or Cartia XT™.

12. All documents sufficient to show the name and chemical entity of all products which the Company believes competes with the company's cardiovascular pharmaceutical products. For each product, produce documents sufficient to explain why the company believes that product competes with the company's cardiovascular pharmaceutical products.

13. All documents which reflect, in any way, the substitutability or exchangeability of any actual or potential cardiovascular pharmaceutical product for Cardizem® CD or Cartia XT™.

14. All documents which reflect, in any way, the substitutability of any cardiovascular pharmaceutical product for any other cardiovascular pharmaceutical product.

15. All documents which relate in any way to programs, campaigns or activities undertaken by you which are designed to encourage the use or substitution of any cardiovascular pharmaceutical product for any other cardiovascular pharmaceutical product.

16. All documents relating to agreements or contracts between you and any of the following other entities: Pfizer, Merck & Company, Zeneca Pharm (now Astra Zeneca), Andrx, HMRI, Novartis RX, Abbott Pharm Prods, Mylan, Parke-Davis, Key Pharmaceutical, Astra Pharm L.P., Bayer Pharm, Searle, Watson Lab, Zenith Goldline, and Forest Pharmaceutical, concerning or relating to cardiovascular pharmaceutical products.

17. All documents that relate in any way to the negotiation of contracts or other agreements regarding discounts, rebates, credits, allowances, charge backs and other price adjustments between you and any of the following other entities: Pfizer, Merck & Company, Zeneca Pharm (now Astra Zeneca), Andrx, HMRI, Novartis RX, Abbott Pharm Prods, Mylan, Parke-Davis, Key Pharmaceutical, Astra Pharm L.P., Bayer Pharm, Searle, Watson Lab, Zenith Goldline, and Forest Pharmaceutical, with regard to cardiovascular pharmaceutical products.

18. All documents relating to agreements or contracts between you and any of the following other entities: Pfizer, Merck & Company, Zeneca Pharm (now Astra Zeneca), Andrx, HMRI, Novartis RX, Abbott Pharm Prods, Mylan, Parke-Davis, Key Pharmaceutical, Astra Pharm L.P., Bayer Pharm, Searle, Watson Lab, Zenith Goldline, and Forest Pharmaceutical, with regard to cardiovascular pharmaceutical products.

19. All documents that relate in any way to the negotiation of contracts or other agreements regarding discounts, rebates, credits, allowances, charge backs and other price adjustments between you and any of the following other entities: Pfizer, Merck & Company, Zeneca Pharm (now Astra Zeneca), Andrx, HMRI, Novartis RX, Abbott Pharm Prods, Mylan, Parke-Davis, Key Pharmaceutical, Astra Pharm L.P., Bayer Pharm, Searle, Watson Lab, Zenith Goldline, and Forest Pharmaceutical, with regard to cardiovascular pharmaceutical products.

20. All documents sufficient to identify the individual(s) (by name, address, position and date) who supervise the negotiation of contracts and/or agreements between you and any of the following other entities: Pfizer, Merck & Company, Zeneca

Pharm (now Astra Zeneca), Andrx, HMRI, Novartis RX, Abbott Pharm Prods, Mylan, Parke-Davis, Key Pharmaceutical, Astra Pharm L.P., Bayer Pharm, Searle, Watson Lab, Zenith Goldline, and Forest Pharmaceutical, with regard to cardiovascular pharmaceutical products.

21. All documents concerning your company and Andrx, HMRI, Faulding, Biovail, Cardizem® CD or Cartia XT™, any diltiazem product or FTC File No. 981-0368.

22. All documents produced to the FTC by the company in connection with the Section 5 investigation of the Stipulation and Agreement, FTC File No. 981-0368.

23. All communications and documents which relate to communications between the Company and the FTC (including without limitation documents provided by the Company to the FTC and transcripts of testimony before the FTC), concerning FTC File No. 981-0368.

24. All communications with the FTC regarding request for information, including but not limited to subpoenas and civil investigative demands received from the FTC and all documents and all communications transmitting responses or modifying the requests.

25. All other documents produced to the FTC or FDA by the Company relating to HMRI, Andrx, Biovail, Faulding, Cardizem® CD, Cartia XT™ or diltiazem products.

26. All other communications and documents which relate to communications between the Company and the FTC or FDA (including without

limitation documents provided by the Company to the FTC or FDA and transcripts of testimony before the FTC or FDA) relating to HMRI, Andrx, Biovail, Faulding or diltiazem products.

27. All documents maintained by the Company with respect to FTC File No. 981-0368.

28. All documents maintained by the Company with respect to FTC Docket No. 9293, "Hoechst-Andrx Generic Cardizem," Complaint issued March 16, 2000.

29. All communications between the Company and FTC with respect to FTC Docket No. 9293, "Hoechst-Andrx Generic Cardizem,"Complaint issued March 16, 2000.

30. All documents sufficient to identify each settlement or partial settlement of patent litigation, concerning which your Company is aware, involving an innovator or brand name pharmaceutical company, and a generic company, that involved any form of:

(a) payment from the brand name company to the generic company; or

(b) licensing and/or royalty arrangement between the brand name company and the generic company.

31. All operative agreements involved in the settlements or partial settlements referenced in Request No. 30 above, together with any analyses of any such agreements.

32. Copies of all Licensing Agreements and Joint Development Agreements to which your Company is or was a party, that involved any form of:

(a) payment from the brand name company to the generic company; or

(b) licensing and/or royalty arrangement between the brand name company and the generic company.

33. For the production of a generic version of Cardizem CD at all times between January 1, 1998 to the present, documents sufficient to reflect the quantity of raw materials, whether active ingredients or otherwise, in your company's possession, custody, or control, or the possession, custody or control of those manufacturing the product.

34. Documents sufficient to reflect your company's manufacturing capacity to produce a generic version of Cardizem CD at all times between January 1, 1998 to the present.

35. Documents sufficient to reflect your inventory or stockpile of active or other ingredients a generic version of Cardizem CD at all times between January 1, 1998 to the present.

36. Documents sufficient to reflect the back orders for your company's generic version of Cardizem CD at all times between January 1, 1998 to the present.

DEFINITIONS AND INSTRUCTIONS

1. To the extent any of the foregoing requests are duplicative in whole, or in part, with requests previously served by another Respondent on your company, Andrx is not seeking materials already made available in this proceeding.

2. Unless otherwise stated, the requests herein refer to the time period of January 1, 1992 through present.

3. As used herein, the words "you" or "your," "your Company," or "the Company" shall mean the individual and/or entity to whom this subpoena was directed, and each of its predecessors, successors, groups, divisions, subsidiaries and affiliates and each of your present or former officers, directors, employees, agents, controlling shareholders (and any entity controlled by any such controlling shareholder) or other person acting for or on behalf of any of them.

4. As used herein, "Andrx" shall mean the Respondent Andrx Corporation, and each of its predecessors, successors, groups, divisions, subsidiaries and affiliates and each of their present or former officers, directors, employees, agents, controlling shareholders (and any entity controlled by any such controlling shareholder) or other person acting for or on behalf of any of them.

5. As used herein, the term "HMRI" shall mean Hoeschst Marion Roussel and each of its predecessors, successors, groups, divisions, subsidiaries and affiliates and each of their present or former officers, directors, employees, agents, controlling shareholders (and any entity controlled by any such controlling shareholder) or other person acting for or on behalf of any of them.

6. As used herein, the term "other entities" shall mean Pfizer, Merck & Company, Zeneca Pharm (now Astra Zeneca), Andrx, Hoechst, Novartis RX, Abbott Pharm Prods, Mylan, Parke-Davis, Key Pharmaceutical, Astra Pharm L.P., Bayer Pharm, Searle, Watson Lab, Zenith Goldline, and Forest Pharmaceutical and each of their predecessors, successors, groups, divisions, subsidiaries and affiliates and each of their

present or former officers, directors, employees, agents, controlling shareholders (and any entity controlled by any such controlling shareholder) or other person acting for or on behalf of any of them.

7. As used herein, the term "payor" means any entity with which you have a contractual or other relationship setting the terms by which prescription pharmaceutical products are provided to members pursuant to plans, including, without limitation, insurance companies, pharmaceutical benefit companies, and managed care organizations.

8. As used herein, the term "formulary" means a list of prescription pharmaceutical products generally covered under a health or prescription benefit plan subject to applicable limits and conditions. For the purposes of this document request, the term "formulary" excludes pharmaceutical products in classifications other than "cardiovascular pharmaceutical products" but includes all descriptive material, including but not limited to operating guidelines, definitions and lists of abbreviations.

9. As used herein, "cardiovascular pharmaceutical products" means the products within code 31000 of the IMS Uniform System of Classification.

10. As used herein, "Cardizem® CD" means the diltiazem formulation sold under this name.

11. As used herein, "Cartia XT™" means the diltiazem formulation sold under this name.

12. As used herein, "person" means all employees, individuals, and entities, including but not limited to corporations, associations, companies, partnerships, joint ventures, trusts and estates.

13. As used herein, the terms "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.

14. 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.

15. As used herein, the words "describe" or "relates to" or "relating to"

or "regarding" or equivalent language shall mean constituting, reflecting, respecting, supporting, contradicting, referring to, stating, describing, recording, noting, containing, monitoring, studying, analyzing, discussing, evaluating or relevant to.

16. As used herein, the connectives "and" and "or" shall be construed either disjunctively or conjunctively as necessary to bring within the scope of the discovery request all responses that might otherwise be construed to be outside of its scope.

17. As used herein, the term "communication" means every manner of transmitting or receiving information, opinions, and thoughts whether orally or in writing.

18. As used herein, the term "health benefit plan" refers to any plan which you operate or administer which provides for the payment or reimbursement of health care related expenses.

19. As used herein, the term "prescription benefit plan" refers to any plan which you operate or administer, either solely or in conjunction with another entity, which provides for the payment of or reimbursement for pharmaceutical products dispensed pursuant to doctors' prescriptions.

20. As used herein, the term "plan" or "plans" refers jointly to the health benefit plan and prescription benefit plan.

21. As used herein, the term "group" refers to an employer or other entity that purchases insurance or benefits under a health benefit plan and/or prescription benefit plan.

22. As used herein, the term "members" refers to individuals who are enrolled in and eligible to receive benefits through a health benefit plan and/or

prescription benefit plan.

23. As used herein, the term "pharmacy" refers to any entity, including mail order vendors and other retailers, which dispenses pharmaceutical products pursuant to doctors' prescriptions. When a pharmacy has more than one retail location or outlet, please answer the document request for each location separately.

24. As used herein, the term "substitutability" refers to the degree to which doctors, patients, pharmacies, wholesalers, PBMs, and/or health benefit plans shift purchases between or among pharmaceutical products based on considerations including, but not limited to, cost, efficacy, and side effects.

25. The response to each document production request is to be numbered in a manner consistent with these requests and is to be preceded by the specific request.

26. If any form of privilege or immunity is claimed as a ground for withholding a response, submit a written statement that describes the factual basis of the purported privilege or claim of immunity in sufficient detail to permit the court to adjudicate the validity of the claim.

EXHIBIT V

UNITED STATES OF AMERICA
BEFORE 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'S SECOND REQUEST FOR THE PRODUCTION OF DOCUMENTS

Pursuant to Federal Trade Commission ("FTC") Rules of Practice for Adjudicative Proceedings ("Rule of Practice") § 3.37, Respondent Aventis Pharmaceuticals, Inc., formerly known as Hoechst Marion Roussel, Inc., by counsel, submits these requests for production of documents to the FTC. Respondent requests that the FTC begin producing documents or things responsive to these requests, within its possession, custody or control, within twenty (20) business days for inspection and copying by counsel for respondent at the offices of Shook, Hardy & Bacon LLP, 600 14th Street, N.W., Suite 800, Washington, D.C. 20005, in accordance with the Instructions set forth below.

INSTRUCTIONS AND DEFINITIONS

As used herein, "agreement" means any oral or written contract, arrangement or understanding, whether formal or informal, between two or more persons, together with modifications or amendments thereto.

1. As used herein, "ANDA" means an Abbreviated New Drug Application filed with the FDA pursuant to 21 U.S.C. § 355(j), including but not limited to the original application and any supplements thereto.

2. As used herein, "Andrx" means Andrx Pharmaceuticals, Inc., and its predecessors, successors, assigns and present and/or former affiliates and subsidiaries and any of its respective officers, directors, employees, agents, attorneys, representatives, economic consultants, lobbyists, public relations consultants or any person acting or purporting to act on its behalf.

3. As used herein, "Biovail" shall refer to Biovail Corporation with its principal place of business in Mississauga, Ontario, Canada, and its predecessors, successors, assigns and present and/or former affiliates and subsidiaries and any of its respective officers, directors, employees, agents, attorneys, representatives, economic consultants, lobbyists, public relations consultants or any person acting or purporting to act on its behalf.

4. As used herein, "cardiovascular pharmaceutical products" means the products within code 31000 of the IMS Uniform System of Classification.

5. As used herein, "Cardizem® CD" means the diltiazem product sold under that trademark.

6. As used herein, "Compliance Investigation" means FTC File No. 971-0055.

7. As used herein, "Consent Order" means Hoechst AG; Proposed Consent Agreement with Analysis to Aid Public Comment, 60 Fed.Reg. 49609 (1995).

8. As used herein, "diltiazem product" means any pharmaceutical product containing diltiazem and/or its salts including diltiazem hydrochloride as an active pharmaceutical ingredients.

9. As used herein, "document" or "documents" shall include, without limitation, originals, masters and every copy of writings and printed, typed and other graphic or photographic matter, including microfilm of any kind or nature, recordings (tape, diskette or other) of oral communications, other data compilations and every other tangible thing from which information can be obtained, including, without limitation, magnetic or electronic media, in the possession, custody or control of plaintiff or any present or former officer, employees or agents thereof, or known by plaintiff to exist. The term "document" or "documents" shall include, without limiting the generality of the foregoing, all computer files, electronic mail, letters, telegrams, teletypes, correspondence, contracts, agreements, notes to the files, notebooks, reports, memoranda, mechanical and electronic sound recordings or transcripts thereof, blueprints, flow sheets, formal or information drawings or diagrams, calendar or diary entries, memoranda of telephone or personal conversations of meetings or conferences, studies, reports, interoffice communications, price lists, bulletins, circulars, statements, manuals, summaries of compilations, minutes of meetings, maps, charts, graphs, order papers, articles, announcements, books, catalogs, records, tables, books of account, ledgers, vouchers, canceled checks, invoices or bills. A draft or nonidentical copy is a separate document within the meaning of this term.

10. As used herein, "Faulding" means Faulding Inc. and its predecessors, successors, assigns and present and/or former affiliates and subsidiaries and any of its respective officers, directors, employees, agents, attorneys, representatives, economic consultants, lobbyists, public relations consultants or any person acting or purporting to act on its behalf.

11. As used herein, "FDA" means the United States Food and Drug Administration, including without limitation its employees, scientists, technicians, agents, examiners, laboratories, consultants and special governmental employees.

12. As used herein, "FTC" means the United States Federal Trade Commission, including without limitations its employees, investigators, agents, consultants and special governmental employees.

13. As used herein, "formulary" means a list of prescription medications covered under a pharmacy benefit plan maintained by a governmental entity or third-party payor.

14. As used herein, "HMR" means Hoechst Marion Roussel, Inc., its successors, predecessors and the officers, directors, employees, partners, subsidiaries, corporate parents, affiliates and divisions of each of the foregoing.

15. As used herein, "Hoechst/Andrx Investigation" means Hoechst Marion Roussel, Inc. and Andrx Corporation, FTC File No. 981-0368; Andrx-Hoechst Generic Cardizem, FTC Docket No. 9293; and Hoechst A.G./Watson Pharmaceuticals, Inc., FTC File No. 981-0006 as it pertains to the Stipulation and Agreement between Hoechst Marion Roussel, Inc. and Andrx Corporation.

16. As used herein, "Hoechst/Biovail Rights Agreement" means the Rights Agreement between Biovail and Hoechst Roussel Pharmaceuticals, Inc. dated as of June 30, 1993.

17. As used herein, "Hoechst/Biovail Settlement Agreement" means the Settlement Agreement and Release between Biovail, Hoechst A.G., Hoechst Roussel Pharmaceuticals, Inc., Marion Merrill Dow and Carderm Capital, L.P. dated April 28, 1995.

18. As used herein, "Hoechst/MMD Merger" means the acquisition by Hoechst A.G. of Marion Merrell Dow Inc., FTC File No. 951-0090, as it relates to the Hoechst/Biovail Settlement Agreement.

19. As used herein, "NDA" means a New Drug Application filed with the FDA pursuant to 21 U.S.C. § 355(b), including but not limited to the original application and any supplements thereto.

20. As used herein, "person" includes any natural person, corporate entity, sole proprietorship, partnership, association, governmental entity, or trust.

21. As used herein, "Probucol Negotiations" means the discussions occurring after July 1997 between HMR and Biovail relating to development of new indications for Probucol and any related or contemporaneous discussions, which included, but are not limited to, settlement negotiations.

22. As used herein, "relate" means concerns, refers to, describes, forms the basis for, evidences or constitutes, and the term "relating" means concerning, referring to, describing, evidencing or constituting.

23. As used herein, "Stipulation and Agreement" means that agreement between Hoechst Marion Roussel, Inc., Carderm Capital, L.P. and Andrx Pharmaceuticals entered into on or about September 26, 1997.

24. As used herein, "Stipulation and Order" means that agreement between Hoechst Marion Roussel, Inc., Carderm Capital, L.P. and Andrx Pharmaceuticals entered into on or about June 8, 1999.

25. As used herein, "Third Parties" means any person that is not a named party in FTC File No. 981-0368 or FTC Docket No. 9293 and includes, but is not limited to Biovail,

Faulding, Quatro Scientific Inc., Teva Pharmaceuticals and their respective officers, directors, employees, agents, attorneys, representatives, economic consultants, lobbyists, public relations consultants or any person acting or purporting to act on their behalf.

26. The connectives "and" and "or" shall be construed either disjunctively or conjunctively as necessary to bring within the scope of the discovery request all responses that might otherwise be construed to be outside of its scope.

27. The term "all" shall be construed as all and each, and the term "each" shall be construed as all and each.

28. The use of the singular form of any word includes the plural, and vice versa.

29. 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.

30. Unless otherwise stated, the scope of this request is from January 1, 1993 through the present and is continuing in nature. If, after producing documents, the FTC obtains or becomes aware of any further documents, or information responsive to this request for production of documents, the FTC is required to produce to HMR such additional documents and/or to provide HMR with such additional information.

31. Compliance with this document request requires a search of all documents in the possession, custody, or control of the FTC's current or former officers, directors, employees, agents, or representatives, whether or not such documents are on the premises of the FTC. If any

person is unwilling to have his or her files searched, or is unwilling to produce responsive documents, the FTC must provide counsel serving this request with the following information as to each such person: his or her name, address, telephone number, and relationship to the FTC.

This subpoena covers documents in your possession, custody or control, wherever the documents are located.

32. If any requested documents cannot be produced in full, produce the remainder and state whatever information, knowledge, or belief the FTC has concerning the unproduced portion.

33. In addition to hard-copy documents, the search will include all the FTC's electronically stored data. Sources of such data include, but are not limited to, the following:

(a) Desktop personal computers ("PCs") and workstations; PCs, workstations, minicomputers and mainframes used as file servers, application servers, or mail servers; laptops, notebooks, hand-held devices and other portable computers available for shared use; and home computers used for work related purposes;

(b) Backup disks and tapes, archive disks and tapes, and other forms of offline storage, whether stored onsite with the computer used to generate them, stored offsite in another facility or stored offsite by a third-party, such as in a disaster recovery center; and

(c) Computers and related offline storage used by agents, consultants, and other persons as defined herein, which may include persons who are not employees of the FTC or who do not work on FTC premises.

34. The FTC will submit all documents, including electronically-stored documents, in hard copy. In addition to the hard copies, the FTC will submit the electronically-stored documents in machine readable form.

35. The source and location of each responsive document shall be designated, including the person from which it was obtained. Responsive documents from each person's files shall be produced together, in file folders or with other enclosures that segregate the files by

request number. If a document is responsive to more than one request, it shall be produced in response to the request to which it is primarily responsive. An index of responsive documents is requested in hard copy and machine-readable form identifying for each document produced: (1) the identification and consecutive control number; (2) the numbered request(s) to which it is responsive; (3) the person from whom the document was obtained; and (4) for documents generated by the recipient, the person and/or file name or number from which it was obtained.

36. In the event that the FTC withholds any document on the basis that it is privileged, subject to work-product immunity, or is otherwise excludable from discovery, the FTC is requested to list such documents by request number and to provide the following information:

(a) the identity of the authors;

(b) the identity of all recipients;

(c) the date of the document;

(d) the subject matter or purpose of the document or report;

(e) the nature of the relationship between the authors and counsel with sufficient particularity to sustain the asserted privilege;

(f) whether direct quotes or paraphrases of advice from counsel were identified;

(g) whether such quotes could be redacted, leaving non-privileged information; and,

(h) any other information necessary to reveal the basis upon which the document is withheld to provide HMR with sufficient information to determine whether the stated basis for withholding the document is proper.

37. If any document responsive to these requests once existed but has been destroyed, lost, discarded or is otherwise not available for production, the recipient shall identify in writing each such document, including the date of the document's creation, a description of the

document's subject matter, the name and address of each person who prepared, received, viewed, or had possession, custody or control of the document or otherwise had knowledge of its subject matter, and a statement of the circumstances under which the document was destroyed, lost, discarded or why such document is otherwise not available for production.

38. If the FTC has produced documents to HMR responsive to this request as part of the Third Party materials collected during the course of the pre-complaint investigation of this matter, FTC File No. 981-0368, those documents need not be produced again, provided that the FTC clearly indicates in its answers to the document request the location within the Third Party materials where responsive information resides.

39. If the FTC believes documents responsive to this request originated from HMR, the FTC need not produce those documents, provided that the FTC provides the location within the HMR materials where responsive information resides.

DOCUMENT REQUESTS

Request No. 1: All documents submitted to the FTC voluntarily or through compulsory process by any Third Party in connection with or relating in any manner to the Hoechst/Andrx Investigation.

Request No. 2: All transcripts of all depositions, investigational hearings, or formal, informal or sworn statements, including all exhibits thereto, taken by the FTC of or from Third Parties in connection with or relating in any manner to the Hoechst/Andrx Investigation.

Request No. 3: All statements, including but not limited to responses to interrogatories, responses to civil investigative demands and subpoenas, statements, memoranda and white papers, and affidavits and declarations provided to the FTC by Third Parties in connection with or relating in any manner to the Hoechst/Andrx Investigation.

Request No. 4: All communications, including but not limited to letters, notes, documents relating to telephonic communications or meetings, electronic mail messages or voice mail messages, between the FTC and any Third Party in connection with or relating in any manner to the Hoechst/Andrx Investigation.

Request No. 5: All documents sufficient to identify each person with whom the FTC communicated in connection with or relating in any manner to the Hoechst/Andrx Investigation.

Request No. 6: All documents reflecting statements made by third parties in meetings, interviews, or other communications with the FTC in connection with or relating in any manner to the Hoechst/Andrx Investigation.

Request No. 7: All civil investigative demands, subpoenas or other formal or informal requests for materials and information issued by the FTC to Third Parties in connection with or relating in any manner to the Hoechst/Andrx Investigation.

Request No. 8: All documents submitted to the FTC, voluntarily or through compulsory process, by any Third Party relating in any manner to the negotiation, operation or termination of the Hoechst/Biovail Rights Agreement or the Hoechst/Biovail Settlement Agreement, including but not limited to documents submitted during the course of the Compliance Investigation or the Hoechst/MMD Merger.

Request No. 9: All transcripts of all depositions, investigational hearings, or formal, informal or sworn statements, including all exhibits thereto, taken by the FTC of or from Third Parties in connection with or relating in any manner to the negotiation, operation, interpretation or termination of the Hoechst/Biovail Rights Agreement or the Hoechst/Biovail Settlement Agreement, including but not limited to documents submitted during the course of the Compliance Investigation or the Hoechst/MMD Merger.

Request No. 10: All statements, including but not limited to responses to interrogatories, responses to civil investigative demands and subpoenas, statements, memoranda and white papers, and affidavits and declarations, provided to the FTC by Third Parties in connection with or relating in any manner to the negotiation, operation, interpretation or termination of the Hoechst/Biovail Rights Agreement or the Hoechst/Biovail Settlement Agreement, including but not limited to documents submitted during the course of the Compliance Investigation or the Hoechst/MMD Merger.

Request No. 11: All communications, including but not limited to letters, notes, documents relating to telephonic communications or meetings, electronic mail messages or voice mail messages, between the FTC and any Third Party in connection with or relating in any manner to the negotiation, operation, interpretation or termination of the Hoechst/Biovail Rights Agreement or the Hoechst/Biovail Settlement Agreement, including but not limited to documents submitted during the course of the Compliance Investigation or the Hoechst/MMD Merger.

Request No. 12: All documents sufficient to identify each person with whom the FTC communicated in connection with or relating in any manner to the negotiation, operation, interpretation or termination of the Hoechst/Biovail Rights Agreement or the Hoechst/Biovail Settlement Agreement, including but not limited to documents submitted during the course of the Compliance Investigation or the Hoechst/MMD Merger.

Request No. 13: All documents reflecting statements made by Third Parties in meetings, interviews, or other communications with the FTC in connection with or relating in any manner to the negotiation, operation, interpretation or termination of the Hoechst/Biovail Rights Agreement or the Hoechst/Biovail Settlement Agreement, including but not limited to

documents submitted during the course of the Compliance Investigation or the Hoechst/MMD Merger.

Request No. 14: All documents submitted to the FTC, voluntarily or through compulsory process, by any Third Party in connection with or relating in any manner to the Probucol Negotiations.

Request No. 15: All transcripts of all depositions, investigational hearings, or formal, informal or sworn statements, including all exhibits thereto, taken by the FTC of or from Third Parties in connection with or relating in any manner to the Probucol Negotiations.

Request No. 16: All statements, including but not limited to responses to interrogatories, responses to civil investigative demands and subpoenas, statements, memoranda and white papers, and affidavits and declarations, provided to the FTC by Third Parties in connection with or relating in any manner to the Probucol Negotiations

Request No. 17: All communications, including but not limited to letters, notes, documents relating to telephonic communications or meetings, electronic mail messages or voice mail messages, between the FTC and any Third Party in connection with or relating in any manner to the Probucol Negotiations.

Request No. 18: All documents sufficient to identify each person with whom the FTC communicated in connection with or relating in any manner to the Probucol Negotiations.

Request No. 19: All documents reflecting statements made by Third Parties in meetings, interviews, or other communications with the FTC in connection with or relating in any manner to the Probucol Negotiations.

Request No. 20: All documents, transcripts of all depositions, investigational hearings, statements, submissions or other communications between the FTC and Andrx Pharmaceuticals, Inc. in connection with or relating in any manner to the Hoechst/Andrx Investigation.

Request No. 21: All documents, transcripts, statements, submissions or other communications between the FTC and Biovail in connection with or relating in any manner to the Hoechst/Andrx Investigation, the Hoechst/Biovail Rights Agreement, the Hoechst/Biovail Settlement Agreement, the Probucol Negotiations, or the Hoechst/MMD Merger.

Request No. 22: All documents reflecting statements made by Biovail in connection with or relating in any manner to the Hoechst/Andrx Investigation, the Hoechst/Biovail Rights Agreement, the Hoechst/Biovail Settlement Agreement, the Probucol Negotiations, or the Hoechst/MMD Merger.

Request No. 23: All documents including but not limited to the marketing documents, sales plans and budgets, sales forecasts, marketing and pricing strategies of any pharmaceutical manufacturer that relate to the sales, marketing or promotion of any cardiovascular pharmaceutical product which may have been provided to or received by the FTC in connection with the Hoechst/Andrx Investigation or any other Commission proceeding, investigation or enforcement action.

Request No. 24: All documents reflecting the sales of any cardiovascular pharmaceutical product and all documents reflecting any measure of the sale, price, revenues and profits of each cardiovascular pharmaceutical product, including but not limited to:

(a) gross and net sales to all customers in units and dollars;

(b) gross number and dollar value of promotional sample units distributed;

(c) sales returns in units and dollars;

(d) cost of goods sold in dollars;

(e) gross and net profit in dollars;

(f) sales, promotion, or marketing expenses;

(g) the list price and wholesale acquisition cost;

(h) product returns in units and dollars; and

(i) rebates, credits, allowances, chargebacks, and any other adjustment to price.

Request No. 25: All data and reports, including but not limited to data and reports provided by third-party vendors such as IMS, that reflect the sales of any cardiovascular pharmaceutical product and any analysis that might consider: (1) the extent to which these products compete against each other and compete against Cardizem® CD and other sustained release diltiazem products; (2) the extent to which sales of the products respond to/or are affected by variations in price or manufacturer discounts, rebates, credits or other price adjustments; and (3) the extent to which sales of the products respond to changes in the manner in which they are listed in formularies maintained by third-party payors, insurers and other health care providers.

Request No. 26: All documents which reflect in any way standards of care for the treatment of hypertension and/or angina through the use of cardiovascular pharmaceutical products.

Request No. 27: All documents which reflect, in any way, the substitutability of any cardiovascular pharmaceutical product for any other cardiovascular pharmaceutical product.

Request No. 28: All documents sufficient to identify the government entities or third-party payors who maintain prescription pharmaceutical formularies and with whom the FTC communicated in connection with or relating in any manner to the Hoechst/Andrx Investigation.

Request No. 29: All documents which relate in any manner to the categories into which prescription pharmaceutical products are grouped in formularies, including categories of drug types and categories used for determining co-payments or reimbursement amounts for individual participants and/or payments to pharmacies.

Request No. 30: All documents which describe any process or criteria used to determine the pharmaceutical products to be included in any formulary.

Request No. 31: All documents which reflect in any manner the policies or criteria for making any initial classification in formularies as well as any reclassification of any previously classified pharmaceutical product in subsequent formulary listings.

Request No. 32: All documents which describe the formularies in which Cardizem® CD has been listed, including but not limited formularies identifying all categories in which Cardizem® CD has been listed, as well as the other pharmaceutical products included in each categories so described.

Request No. 33: All documents which relate in any way to programs, campaigns or activities undertaken by governmental entities and/or third-party payors which are designed to encourage the use or substitution of any cardiovascular pharmaceutical product for any other cardiovascular pharmaceutical product.

Request No. 34: All documents which relate in any way to the reimbursements paid by any governmental entity or third-party payor for cardiovascular pharmaceutical products.

Request No. 35: All documents that relate in any way to the negotiation of contracts or other agreements regarding discounts, rebates, credits, allowances, chargebacks and other price adjustments between government entities or third party payors and any manufacturer or distributor of cardiovascular pharmaceutical products.

Request No. 36: All specimen pharmacy or prescription benefit policies or riders maintained by any government entities or third-party payors that apply to cardiovascular pharmaceutical products.

Request No. 37.: All documents relating in any manner to the Hoechst/Andrx Investigation given or transmitted to any FTC Commissioner by the Bureau of Competition or the Bureau of Economics.

Request No. 38: All documents, transcripts, statements, submissions or other communications between the FTC and any Third Party that relate to formularies or other prescription pharmaceutical benefit plans.

Request No. 39: All documents, transcripts, statements, submissions or other communications between the FTC and any other agency or instrumentality of the federal government, including but not limited to the FDA and the Congress, that relates in any manner to the Hoechst/Andrx Investigation; the negotiation, operation, interpretation or termination of the Hoechst/Biovail Rights Agreement or the Hoechst/Biovail Settlement Agreement; the Consent Order or the Probucol Negotiations.

Request No. 40: All documents, transcripts, statements, submissions or other communications between the FTC and any Third Party that may relate or pertain to the settlement or partial settlement of patent litigation involving an innovator or brand name pharmaceutical company, and a generic company, that involve any form of payment from the brand name company to the generic company, or any form of licensing and/or royalty arrangement between the brand name company and the generic company.

Request No. 41: All documents which relate in any manner to any allegations in the complaint issued in Andrx-Hoechst Generic Cardizem, FTC Docket No. 9293.

Request No. 42: All documents which relate to communications between the FTC and the FDA from January 1, 1995 to the present (including without limitation documents provided by the FTC to the FDA and transcripts of testimony before the FDA, and vice versa), concerning generic exclusivity, including, but not limited to, comments on Docket No. 98D-0481, Guidance on 180-Day Generic Drug Exclusivity.

Request No. 43: All documents which relate to communications between the FTC and any Third Party from January 1, 1995 to the present (including without limitation comments or documents provided by the FTC to the FDA and transcripts of testimony before the FDA, and vice versa), concerning generic exclusivity, including, but not limited to, comments on Docket No. 98D-0481, Guidance on 180-Day Generic Drug Exclusivity.

Request No. 44: All document or articles relating to descriptions, policy considerations, and discussions of legal and economic implications relating to the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman").

Request No. 45: All documents relating to communications between the FTC and the FDA on the status of, and the likely date of final FDA approval for, the application for the bioequivalent or generic version of Cardizem® CD filed by Andrx.

Request No. 46: All documents relating to communications between the FTC and any Third Party on the status of, and the likely date of final FDA approval for, the application for the bioequivalent or generic version of Cardizem® CD filed by Andrx.

Request No. 47: All documents relating to the product encompassed by Andrx's ANDA 74-752, including but not limited to documents obtained from the FDA, Andrx and/or any Third Party.

Request No. 48: All documents relating to communications between the FTC and the FDA on the status of, and the likely date of final FDA approval for, the application for the bioequivalent or generic version of Cardizem® CD filed by Faulding.

Request No. 49: All documents relating to communications between the FTC and any Third Party on the status of, and the likely date of final FDA approval for, the application for the bioequivalent or generic version of Cardizem® CD filed by Faulding.

Request No. 50: All documents relating to the product encompassed by Faulding's ANDA 79-984, including but not limited to documents obtained from the FDA, Faulding and/or any Third Party.

Request No. 51: All documents relating to communications between the FTC and the FDA on the status of, and the likely date of final FDA approval for, the applications for bioequivalent or generic versions of Cardizem® CD filed by Biovail.

Request No. 52: All documents relating to communications between the FTC and any Third Party on the status of, and the likely date of final FDA approval for, the applications for bioequivalent or generic versions of Cardizem® CD filed by Biovail.

Request No. 53: All documents relating to the product encompassed by Biovail's ANDA 75-116, including but not limited to documents obtained from the FDA, Biovail and/or any Third Party.

Request No. 54: All documents relating to the product encompassed by Biovail's NDA 20-939, including but not limited to documents obtained from the FDA, Biovail and/or any Third Party.

Request No. 55: All documents relating to communications between the FTC and the FDA concerning *Mova Pharmaceuticals Corp. v. Shalala*, 955 F.Supp. 128 (D.D.C. 1997), *Mova*

Pharmaceuticals Corp. v. Shalala, 140 F.3d 1060 (D.C. Cir. 1998), *Granutec, Inc. v. Shalala*, No. CA 97-485-5-BO (E.D.N.C. 1997), and/or *Granutec, Inc. v. Shalala*, 139 F.3d. 889, 1998 WL 153410 (4th Cir. 1998).

Request No. 56: All documents relating to communications between the FTC and any Third Party concerning *Mova Pharmaceuticals Corp. v. Shalala*, 955 F.Supp. 128 (D.D.C. 1997), *Mova Pharmaceuticals Corp. v. Shalala*, 140 F.3d 1060 (D.C. Cir. 1998), *Granutec, Inc. v. Shalala*, No. CA 97-485-5-BO (E.D.N.C. 1997), and/or *Granutec, Inc. v. Shalala*, 139 F.3d. 889, 1998 WL 153410 (4th Cir. 1998).

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 May 12, 2000, a copy of the Second Request for the Production of Documents of Respondent Aventis Pharmaceuticals, Inc., formerly known as Hoechst Marion Roussel, Inc., 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, Ellerhorn,
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

37009.1

EXHIBIT VI

SUBPOENA DUCES TECUM

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

1. TO Custodian of Records for:
Biovail Corporation
2488 Dunwin Drive
Mississauga, ON L5L 1J9
CAN
c/o C T Corporation
1633 Broadway
New York, NY 10019

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

June 26, 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 17 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
BEFORE THE FEDERAL TRADE COMMISSION

Exhibit A to Subpoena Duces Tecum

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

HMRI'S FIRST DOCUMENT PRODUCTION REQUEST
TO BIOVAIL CORPORATION

Respondent Hoechst Marion Roussel, Inc. ("HMRI"), pursuant to the Federal Trade Commission's Rules of Practice for Adjudicative Proceedings, 16 C.F.R. § 3.34(b), requests that Biovail Corporation (hereinafter referred to as "the company") 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.

DOCUMENT REQUESTS

REQUEST NO. 1: All documents produced to the FTC by the company in connection with the acquisition by Hoechst A.G. of Marion Merrell Dow Inc., FTC File No. 951-0090.

REQUEST NO. 2: All communications and documents which relate to communications between the company and the FTC (including without limitation documents provided by the company to the FTC and transcripts of testimony before the FTC), concerning FTC File No. 951-0090.

REQUEST NO. 3: All documents produced to the FTC by the company in connection with the sale of acquisition of the Rugby Group from Hoechst A.G. by Watson, FTC File No. 981-0006.

REQUEST NO. 4: All communications and documents which relate to communications between the company and the FTC (including without limitation documents provided by the company to the FTC and transcripts of testimony before the FTC), concerning FTC File No. 981-0006.

REQUEST NO. 5: All documents produced to the FTC by the company in connection with the compliance investigation, FTC File No. 971-0055.

REQUEST NO. 6: All communications and documents which relate to communications between the company and the FTC (including without limitation documents provided by the company to the FTC and transcripts of testimony before the FTC), concerning FTC File No. 971-0055.

REQUEST NO. 7: All documents produced to the FTC by the company in connection with the Section 5 investigation of the HMR/Andrx Stipulation and Agreement, FTC File No. 981-0368.

REQUEST NO. 8: All communications and documents which relate to communications between the company and the FTC (including without limitation documents provided by the company to the FTC and transcripts of testimony before the FTC), concerning FTC File No. 981-0368.

REQUEST NO. 9: All other communications and documents which relate to communications between the company and the FTC (including without limitation documents provided by the company to the FTC and transcripts of testimony before the FTC) relating to HMR, Faulding, Andrx or diltiazem products.

REQUEST NO. 10: All documents maintained by the company with respect to FTC investigations involving the company, HMR, Andrx, Faulding, or diltiazem products, including but not limited to FTC File No. 951-0090, FTC File No. 981-0006, FTC File No. 971-0055, and FTC File No. 981-0368.

REQUEST NO. 11: All documents maintained by the company with respect to FTC Docket No. 9293, "Hoechst-Andrx Generic Cardizem,"Complaint issued March 16, 2000.

REQUEST NO. 12: All communications between the company and FTC with respect to FTC Docket No. 9293, "Hoechst-Andrx Generic Cardizem,"Complaint issued March 16, 2000.

REQUEST NO. 13: All documents relating to communications between the company and the FDA on the status of, and the likely date of final FDA approval for, the company's applications for bioequivalent or generic versions of Cardizem® CD.

REQUEST NO. 14: All documents submitted by the company to the FDA in support of the ANDA 75-116 application for approval to market a generic version of Cardizem® CD including, but not limited to:

(a) all documents made part of the company's ANDA 75-116 submission to the FDA;

(b) all documents referenced in the company's ANDA 75-116 submission to the FDA; and,

(c) all documents submitted to the FDA in support of or related in any way to the company's ANDA 75-116 submission to the FDA.

REQUEST NO. 15: All documents the company either transmitted to or received from the FDA or any other government agency related to in any way to the company's ANDA 75-116 submission to the FDA, including but not limited to:

(a) all correspondence involving the company, the FDA and/or any other government agency related in any way to the company's ANDA 75-116 submission to the FDA;

(b) any approvable letter or deficiency letter or notice from any government agency, including but not limited to the FDA relating in any way to the company's ANDA 75-116; and,

(c) each document that concerns any approvable letter or deficiency letter or notice from any government agency, including but not limited to the FDA, relating in any way to ANDA 75-116.

REQUEST NO. 16: All documents prepared by the company or others related in any way to the diltiazem product that was the subject of the company's ANDA 75-116 submission to the FDA including, but not limited to, product monograph/labeling and promotional materials.

REQUEST NO. 17: All documents in the company's possession relating to the chemical, biological, pharmacological and pharmacokinetic properties of the product that was the subject of the company's ANDA 75-116 including, but not limited to:

(a) each document concerning studies or testing of any diltiazem bead or formulation in any way related to the company's ANDA 75-116 submission to the FDA including without limitation any solubility studies, studies or tests reflecting the influence of pH, dissolution tests or studies, stability tests or studies, and studies of or tests on the effects of coating on the beads, whether or not those studies or tests were used in the filing of an ANDA;

(b) all documents concerning the dissolution profile of the product that was the subject of the company's ANDA 75-116 submission to the FDA, whether or not those profiles were used in the filing of an ANDA;

(c) each document that concerns any test, analysis or evaluation performed by or on behalf of the company or known to the company concerning the properties, characteristics, design, activity, benefits or performance of the product that was the subject of the company's ANDA 75-116 submission to the FDA, whether or not those tests, analysis or evaluations were used in the filing of an ANDA; and,

(d) each document that concerns any preclinical or clinical test, including but not limited to, any bioavailability or dissolution test for the product that was the subject of the company's ANDA 75-116 submission to the FDA as well as any comparative data relating to any other delayed release diltiazem formulation, whether or not those tests were used in the filing of an ANDA.

REQUEST NO. 18: All documents which identify the formulation contained in ANDA 75-116.

REQUEST NO. 19: All documents submitted by the company to the FDA in support of its NDA 20-939 for approval to market a generic form of Cardizem® CD including, but not limited to:

(a) all documents made part of the company's NDA 20-939 submission to FDA;

(b) all documents referenced in the company's NDA 20-939 submission to the FDA; and,

(c) all documents submitted to the FDA in support of or related in any way to the company's NDA 20-939 submission to the FDA.

REQUEST NO. 20: All documents that the company either transmitted to or received from the FDA or any other government agency related in any way to the company's NDA 20-939 submission to the FDA, including but not limited to:

(a) all correspondence involving the company, the FDA and/or any other government agency related in any way to the company's NDA 20-939 submission to the FDA;

(b) any approvable letter or deficiency letter or notice from any government agency, including but not limited to the FDA relating in any way to the company's NDA 20-939; and,

(c) each document that concerns any approvable letter or deficiency letter or notice from any government agency, including but not limited to the FDA, relating in any way to the company's NDA 20-939 .

REQUEST NO. 21: All documents prepared by the company or others related in any way to the diltiazem product that was the subject of the company's NDA 20-939 submission to the FDA including, but not limited to, product monograph/labeling or promotional materials.

REQUEST NO. 22: All documents in the company's possession relating to the chemical, biological, pharmacological and pharmacokinetic properties of the product that was the subject of the company's NDA 20-939 including, but not limited to:

(a) each document concerning studies or testing of any diltiazem bead or formulation in any way related to the company's NDA 20-939 submission to the FDA including without limitation any solubility studies, studies or tests reflecting the influence of pH, dissolution tests or studies, stability tests or studies, and studies of or tests on the effects of coating on the beads, whether or not those studies or tests were used in the filing of an NDA;

(b) all documents concerning the dissolution profile of the product that was the subject of the company's NDA 20-939 submission to the FDA, whether or not those profiles were used in the filing of an NDA;

(c) each document that concerns any test, analysis or evaluation performed by or on behalf of the company or known to the company concerning the properties,

characteristics, design, activity, benefits or performance of the product that was the subject of the company's NDA 20-939 submission to the FDA, whether or not those tests, analysis or evaluations were used in the filing of an NDA; and,

(d) each document that concerns any preclinical or clinical test, including but not limited to, any bioavailability or dissolution test for the product that was the subject of the company's NDA 20-939 submission to the FDA as well as any comparative data relating to any other delayed release diltiazem formulation, whether or not those tests were used in the filing of an NDA.

REQUEST NO. 23: All documents which identify the formulation contained in NDA 20-939.

REQUEST NO. 24: All documents identifying officers, directors, employees, agents, attorneys, representatives, economic consultants, lobbyists, public relations consultants or any person acting or purporting to act on the company's behalf with regards to relations with HMR.

REQUEST NO. 25: All communications between the company and Quatro.

REQUEST NO. 26: All documents which relate to any agreements or proposed agreements between the company and Quatro.

REQUEST NO. 27: All communications between the company and any person relating to Probucol.

REQUEST NO. 28: All documents which relate to any agreements or proposed agreements between the company and any person relating to Probucol.

REQUEST NO. 29: All documents exchanged between the company and Quatro with respect to Probucol.

REQUEST NO. 30: All documents exchanged between the company and any other person with respect to Probucol.

REQUEST NO. 31: All documents reflecting pre-clinical or clinical testing or any other efforts by Quatro or the company to develop alternative indications for Probucol.

REQUEST NO. 32: All documents reflecting, concerning, mentioning, or relating to Probocol, including, but not limited to, correspondence, internal documents, internal memoranda, drafts, outlines, e-mails, projections, technical analyses, studies, strategic plans, marketing plans or business plans.

REQUEST NO. 33: All documents concerning all communications between the company and HMR relating to:

(a) the settlement or potential settlement of any disputes or litigation between the company and HMR;
(b) meetings between the company and HMR which took place from July 1997 through March 1998;
(c) Probucol;
(d) draft, proposed or executed confidentiality agreements, tolling agreements, and standstill agreements between the company and HMR.

REQUEST NO. 34: All correspondence or other communications between the company, including but not limited to officers, directors, employees, agents, attorneys, representatives, economic consultants, lobbyists, public relations consultants or any person acting or purporting to act on its behalf, and ABC News, the staff of 20/20 or any other news media.

REQUEST NO. 35: All documents or materials provided by the company, including but not limited to officers, directors, employees, agents, attorneys, representatives, economic consultants, lobbyists, public relations consultants or any person acting or purporting to act on its behalf, to ABC News, the staff of 20/20 or any other news media.

REQUEST NO. 36: All documents describing, recording or in any other way relating to correspondence or other communications between the company, including but not limited to officers, directors, employees, agents, attorneys, representatives, economic consultants, lobbyists, public relations consultants or any person acting or purporting to act on its behalf, and ABC News, the staff of 20/20 or any other news media.

REQUEST NO. 37: All tape recordings, transcripts or other purported verbatim records of the communications between the company, including but not limited to officers, directors, employees, agents, attorneys, representatives, economic consultants, lobbyists, public relations consultants or any person acting or purporting to act on its behalf, and ABC News, the staff of 20/20 or any other news media.

REQUEST NO. 38: All documents identifying officers, directors, employees, agents, attorneys, representatives, economic consultants, lobbyists, public relations consultants or any person acting or purporting to act on the company's behalf with regards to contacts with ABC News, the staff of 20/20 or any other news media.

REQUEST NO. 39: All documents which relate to the effect of bioequivalent or generic versions of Cardizem® CD on the market for Cardizem® CD or Tiazac.

REQUEST NO. 40: All documents which relate to the actual or potential effect on competition with, or on sales, prices or market share for Tiazac, Cardizem® CD or a bioequivalent or generic version of Cardizem® CD by any actual or potential prescription or non-prescription drugs for the treatment of hypertension and angina.

REQUEST NO. 41: All documents sufficient to show the name and chemical entity of all products which the company believes competes with Tiazac. For each product, produce documents sufficient to explain why the company believes that product competes with Tiazac.

REQUEST NO. 42: All documents sufficient to show the name and chemical entity of all products which the company believes competes with Cardizem® CD. For each product, produce documents sufficient to explain why the company believes that product competes with Cardizem® CD.

REQUEST NO. 43: All documents sufficient to show the name and chemical entity of all products which the company believes competes with the company's bioequivalent or generic version of Cardizem® CD. For each product, produce documents sufficient to explain why the company believes that product competes with the company's bioequivalent or generic version of Cardizem® CD.

REQUEST NO. 44: All documents which relate to the actual or potential effect on competition with, or on sales, prices or market share for a bioequivalent or generic version of Cardizem® CD by another a bioequivalent or generic version of Cardizem® CD.

REQUEST NO. 45: All documents filed with, or being prepared for submission to, the Food and Drug Administration relating to any person's approved or pending application for a diltiazem product, or any other product which the company believes competes with Cardizem® CD.

REQUEST NO. 46: All documents filed with, or being prepared for submission to, the Food and Drug Administration relating to any person's approved or pending application for a diltiazem product, or any other product which the company believes competes with Tiazac.

REQUEST NO. 47: All documents relating to the following sales and marketing information:

(a) annual (and, for the current year, monthly) sales (in units), revenue, and profit information for each stock keeping unit relating to the sale of Tiazac;
(b) prices, pricing plans, pricing policies, pricing forecasts, pricing strategies, and pricing decisions for Tiazac;
(c) projected or anticipated prices, sales (in units), revenues, and profits for each stock keeping unit relating to the sale of Tiazac; and
(d) strategic and marketing plans for Tiazac.

REQUEST NO. 48: All documents relating to the following sales and marketing information:

(a) annual (and, for the current year, monthly) sales (in units), revenue, and profit information for each stock keeping unit relating to the sale of the company's bioequivalent or generic versions of Cardizem® CD;
(b) prices, pricing plans, pricing policies, pricing forecasts, pricing strategies, and pricing decisions for the company's bioequivalent or generic versions of Cardizem® CD;
(c) projected or anticipated prices, sales (in units), revenues, and profits for each stock keeping unit relating to the sale of the company's bioequivalent or generic versions of Cardizem® CD;
(d) strategic and marketing plans for the company's bioequivalent or generic versions of Cardizem® CD;
(e) actual, projected or anticipated date of market introduction for the company's bioequivalent or generic versions of Cardizem® CD; and
(f) the actual, projected or anticipated annual market share, measured in terms of unit sales and revenues, of the company's bioequivalent or generic version of Cardizem® CD.

REQUEST NO. 49: All documents relating to the introduction or sale of bioequivalent or generic versions of Cardizem® CD by any person, including, but not limited to:

(a) attempts to introduce a bioequivalent or generic version of Cardizem® CD to the commercial market;
(b) any strategy, procedure, effort, or attempt considered or made by the company that had a purpose or effect of delaying or attempting to delay the market introduction of bioequivalent or generic versions of Cardizem® CD;

(c) the historical projections or anticipated dates of entry into the commercial market of each bioequivalent or generic version of Cardizem® CD;

(d) any analysis, study, projection, forecast, budget or plan on the affect of the introduction of a bioequivalent or generic version of Cardizem® CD on the company's sales, revenues or profits relating to Tiazac or other diltiazem products; and

(e) for each of the first three years following the projected or anticipated introduction or sale of bioequivalent or generic version of Cardizem® CD:

  (i) the projected or anticipated market share (measured in terms of unit sales and revenues) of the bioequivalent or generic version of Cardizem® CD;

  (ii) projected or anticipated price of the bioequivalent or generic version of Cardizem® CD;

  (iii) projected or anticipated price of Cardizem® CD; and

  (iv) the company's projected or anticipated lost annual revenues and profits.

REQUEST NO. 50: All documents identifying officers, directors, employees, agents, attorneys, representatives, economic consultants, lobbyists, public relations consultants or any person acting or purporting to act on the company's behalf with regards to regulatory approval, marketing and/or sales of the company's bioequivalent or generic versions of Cardizem® CD.

REQUEST NO. 51: All documents relating to the importance, significance or benefit generally of being the first company to file an ANDA with the FDA for the particular referenced drug.

REQUEST NO. 52: All documents concerning FDA procedure for filing an NDA for a bioequivalent or generic version of a referenced drug.

REQUEST NO. 53: All documents concerning the company's actual or anticipated sales, revenue, royalties, or other payments or income from or based on the company's actual or planned bioequivalent or generic version of Cardizem® CD.

REQUEST NO. 54: All documents concerning the company's actual or anticipated prices or its policies or practices for setting, marketing or determining prices for the company's actual or planned bioequivalent or generic version of Cardizem® CD.

REQUEST NO. 55: All documents concerning any proposal or plans by the company with respect to the actual or anticipated commencement of commercial marketing of the company's bioequivalent or generic version of Cardizem® CD.

REQUEST NO. 56: All documents relating to the decision by HMR not to file a patent infringement suit against the company for the company's certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii) regarding the company's bioequivalent or generic version of Cardizem® CD.

REQUEST NO. 57: All documents concerning Andrx Pharmaceuticals, Inc. v. Friedman et al., Civ. No. 98-0099 (JGP), in the United States District Court for the District of Columbia.

REQUEST NO. 58: All transcripts or other purported verbatim records of testimony given in any proceeding, lawsuit or other legal inquiring relating to bioequivalent or generic versions of Cardizem® CD, Tiazac, HMR, Cardizem® CD, Andrx or Faulding.

REQUEST NO. 59: All documents which relate to communications between the company and the FDA from January 1, 1995 to the present (including without limitation documents provided by the company to the FDA and transcripts of testimony before the FDA), concerning the Citizen Petition filed by Andrx on February 26, 1998, Docket No. 98P-0145.

REQUEST NO. 60: All documents which relate to communications between the company and the FDA from January 1, 1995 to the present (including without limitation documents

provided by the company to the FDA and transcripts of testimony before the FDA), concerning generic exclusivity, including, but not limited to, comments on Docket No. 98D-0481, Guidance on 180-Day Generic Drug Exclusivity.

REQUEST NO. 61: All documents which relate to communications between the company and the FDA from January 1, 1995 to the present (including without limitation documents provided by the company to the FDA and transcripts of testimony before the FDA), concerning the FDA citizen petition process, including, but not limited to, comments on Docket No. 99N-2497, Citizen Petition Process; Actions That Can Be Requested by Petition; Denials, Withdrawals, and Referrals for Other Administrative Action.

REQUEST NO. 62: All documents sufficient to show the names, business addresses, and business phone numbers of all agents or consultants retained by the company in any capacity relating to the development, manufacture, sale or marketing of diltiazem formulations.

REQUEST NO. 63: All documents which relate to any agreements, including, but not limited to proposed agreements, between or among Galephar and the company concerning diltiazem products existing, entered into or negotiated on or after October 1, 1990.

REQUEST NO. 64: All documents which relate to Galephar's development or Galephar's participation in the company's development of a bioequivalent or generic version of Cardizem® CD.

REQUEST NO. 65: All documents relating to the effect of the Stipulation and Agreement on the commercial introduction of a bioequivalent or generic version of Cardizem® CD.

REQUEST NO. 66: All documents the company produced, received, or disseminated in the context of communications with any governmental agency regarding the propriety or legality of the Stipulation and Agreement.

REQUEST NO. 67: All documents relating to the Stipulation and Agreement, including any discussions, communications, or negotiations concerning the Stipulation and Agreement.

REQUEST NO. 68: All documents which relate to any agreements, including, but not limited to, proposed agreements, between or among the company and Andrx concerning diltiazem products existing, entered into, negotiated or discussed on or after January 1, 1993.

REQUEST NO. 69: All documents describing, recording or in any other way relating to correspondence, meetings, potential meetings or communications between the company and Andrx concerning diltiazem products on or after January 1, 1993.

REQUEST NO. 70: All correspondence or other communications between the company and Andrx concerning diltiazem products.

REQUEST NO. 71: All documents describing, recording or in any way relating to discussions, meetings, strategies or communications between or among the company's present or former officers, directors, employees, agents, attorneys, representatives, economic consultants, lobbyists, public relations consultants or any person acting or purporting to act on its behalf concerning Andrx's generic diltiazem based product on or after January 1, 1993.

REQUEST NO. 72: Documents relating to any plans of, interest in, or efforts undertaken by the company for any acquisition, licensing, joint venture, alliance, or merger of any

kind with Andrx involving the research, development, manufacture, license or sale of any pharmaceutical product.

REQUEST NO. 73: All documents which relate to any agreements, including, but not limited to, proposed agreements, between or among the company and Faulding concerning diltiazem products existing, entered into, negotiated or discussed on or after January 1, 1993.

REQUEST NO. 74: All documents describing, recording or in any other way relating to correspondence, meetings, potential meetings or communications between the company and Faulding concerning diltiazem products on or after January 1, 1993.

REQUEST NO. 75: All correspondence or other communications between the company and Faulding concerning diltiazem products.

REQUEST NO. 76: All documents describing, recording or in any way relating to discussions, meetings, strategies or communications between or among the company's present or former officers, directors, employees, agents, attorneys, representatives, economic consultants, lobbyists, public relations consultants or any person acting or purporting to act on its behalf concerning Faulding's generic diltiazem based product on or after January 1, 1993.

REQUEST NO. 77: Documents relating to any plans of, interest in, or efforts undertaken by the company for any acquisition, licensing, joint venture, alliance, or merger of any kind with Faulding involving the research, development, manufacture, license or sale of any pharmaceutical product.

REQUEST NO. 78: All documents which relate to the substitutability of any actual or potential product for Cardizem® CD.

REQUEST NO. 79: All documents which relate to the substitutability of any actual or potential product for Tiazac.

REQUEST NO. 80: All documents which reflect, in any way, the substitutability of any cardiovascular pharmaceutical product for any other cardiovascular pharmaceutical product.

REQUEST NO. 81: All documents provided to or received from Forest Laboratories regarding the marketing and promotion of Tiazac in the United States.

REQUEST NO. 82: All documents provided to or received from TEVA regarding the marketing and promotion of diltiazem products in the United States.

REQUEST NO. 83: All documents which relate to any agreements, including, but not limited to proposed agreements, between or among TEVA and the company concerning diltiazem products existing, entered into or negotiated on or after January 1, 1993.

REQUEST NO. 84: All documents which relate to communications between the company and TEVA concerning attempts to purchase or otherwise acquire or obtain a right of reference to a toxicology package for diltiazem.

REQUEST NO. 85: All documents which relate to TEVA's participation on the company's development of a bioequivalent or generic version of Cardizem® CD.

DEFINITIONS AND INSTRUCTIONS

1. As used herein, "agreement" means any oral or written contract, arrangement or understanding, whether formal or informal, between two or more persons, together with modifications or amendments thereto.

2. As used herein, "ANDA" means an Abbreviated New Drug Application filed with the FDA pursuant to 21 U.S.C. § 355(j), including but not limited to the original application and any supplements thereto.

3. As used herein, "ANDA 75-116" means that Abbreviated New Drug Application submitted by the company to the United States Food and Drug Administration for approval to market a generic version of Cardizem® CD.

4. As used herein, "Andrx" means Andrx Pharmaceuticals, Inc., and its predecessors, successors, assigns and present and/or former affiliates and subsidiaries and any of its respective officers, directors, employees, agents, attorneys or any person acting or purporting to act on its behalf.

5. As used herein, "Cardizem® CD" means the diltiazem formulation sold under that trademark.

6. As used herein, "communication" means the transmittal of information (in the form of facts, ideas, inquiries, or otherwise), whether or not in written form.

7. As used herein, "company" shall refer to Biovail Corporation with its principal place of business in Mississauga, Ontario, Canada, and its predecessors, successors, assigns and present and/or former affiliates and subsidiaries and any of its respective officers, directors, employees, agents, attorneys, representatives, economic consultants, lobbyists, public relations consultants or any person acting or purporting to act on its behalf.

8. As used herein, "concerns" means relates to, refers to, describes, forms the basis for, evidences or constitutes, and the term "concerning" means relating to, referring to, describing, evidencing or constituting.

9. As used herein, "diltiazem product" means any pharmaceutical product containing diltiazem and/or its salts including diltiazem hydrochloride as an active pharmaceutical ingredients.

10. As used herein, "document" or "documents" shall include, without limitation, originals, masters and every copy of writings and printed, typed and other graphic or photographic matter, including microfilm of any kind or nature, recordings (tape, diskette or other) of oral communications, other data compilations and every other tangible thing from which information can be obtained, including, without limitation, magnetic or electronic media, in the possession, custody or control of the company or any present or former officer, employees or agents thereof, or known by the company to exist. The term "document" or "documents" shall include, without limiting the generality of the foregoing, all computer files, electronic mail, letters, telegrams, teletypes, correspondence, contracts, agreements, notes to the files, notebooks, reports, memoranda, mechanical and electronic sound recordings or transcripts thereof, blueprints, flow sheets, formal or information drawings or diagrams, calendar or diary entries, memoranda of telephone or personal conversations of meetings or conferences, studies, reports, interoffice communications, price lists, bulletins, circulars, statements, manuals, summaries of compilations, minutes of meetings, maps, charts, graphs, order papers, articles, announcements, books, catalogs, records, tables, books of

account, ledgers, vouchers, canceled checks, invoices or bills. A draft or nonidentical copy is a separate document within the meaning of this term.

11. As used herein, "Faulding" means Faulding Inc. and its predecessors, successors, assigns and present and/or former affiliates and subsidiaries and any of its respective officers, directors, employees, agents, attorneys or any person acting or purporting to act on its behalf.

12. As used herein, "FDA" means the United States Food and Drug Administration, including without limitation its employees, scientists, technicians, agents, examiners, laboratories, consultants and special governmental employees.

13. As used herein, "FTC" means the United States Federal Trade Commission, including without limitations its employees, investigators, agents, consultants and special governmental employees.

14. As used herein, "Forest" means Forest Laboratories Inc. and its predecessors, successors, assigns and present and/or former affiliates and subsidiaries and any of its respective officers, directors, employees, agents, attorneys or any person acting or purporting to act on its behalf.

15. As used herein, "Galephar" means Galephar P.R. Inc. and its predecessors, successors, assigns and present and/or former affiliates and subsidiaries and any of its respective officers, directors, employees, agents, attorneys or any person acting or purporting to act on its behalf.

16. As used herein, "HMR" means Hoechst Marion Roussel, Inc., its successors, predecessors, and the officers, directors, employees, partners, subsidiaries, corporate parents, affiliates and divisions of each of the foregoing.

17. As used herein, "Hoechst/Biovail Settlement Agreement" means the Settlement Agreement and Release between Biovail, Hoechst A.G., Hoechst Roussel Pharmaceuticals, Inc., Marion Merrill Dow Inc. and Carderm Capital, L.P. dated April 28, 1995.

18. As used herein, "NDA" means a New Drug Application filed with the FDA pursuant to 21 U.S.C. § 355(b), including but not limited to the original application and any supplements thereto.

19. As used herein, "NDA 20-939" means that New Drug Application submitted by the company to the United States Food and Drug Administration for approval to market a generic version of Cardizem® CD.

20. As used herein, "once-a-day diltiazem formulation" means any diltiazem formulation designed for once-a-day administration.

21. As used herein, "person" includes any natural person, corporate entity, sole proprietorship, partnership, association, governmental entity, or trust.

22. As used herein, "plan" means a proposal, recommendation or consideration, whether or not precisely formulated, finalized, authorized, or adopted.

23. As used herein, "Quatro" means Quatro Scientific Inc. and its predecessors, successors, assigns and present and/or former affiliates, including the Montreal Heart Institute and subsidiaries and any of its present and/or former officers, directors, employees, agents, attorneys or any person acting or purporting to act on its behalf.

24. As used herein, "relate" means concerns, refers to, describes, forms the basis for, evidences or constitutes, and the term "relating" means concerning, referring to, describing, evidencing or constituting.

25. As used herein, "Rights Agreement" means the Rights Agreement between Biovail Research Corporation and Hoechst-Roussel Pharmaceuticals, Inc., dated June 30, 1993.

26. As used herein, "sales" means net sales, i.e., total sales after deducting discounts, returns, allowances and excise taxes. "Sales" include sales wether manufactured by the company itself or purchased from sources outside the company and resold by the company in the same manufactured form as purchased.

27. As used herein, "Stipulation and Agreement" means that agreement between Hoechst Marion Roussel, Inc., Carderm Capital, L.P. and Andrx Pharmaceuticals entered into on or about September 26, 1997.

28. As used herein, "TEVA" means TEVA Pharmaceuticals USA and its predecessors, successors, assigns and present and/or former affiliates and subsidiaries and any of its respective officers, directors, employees, agents, attorneys or any person acting or purporting to act on its behalf.

29. As used herein, "Tiazac" means the diltiazem product sold under that trademark.

30. As used herein, "toxicology package" means the results of preclinical studies conducted in accordance with FDA guidelines to assess the safety of a particular compound. A toxicology package includes: studies of the toxicological effects of a drug as they relate to the drug's intended clinical uses; including, as appropriate, studies assessing the drug's acute, subacute, and chronic toxicity; carcinogenicity; studies of toxicities related to the drug's particular mode of administration or conditions of use; and, as appropriate, studies of the effects of the drug on reproduction and on the developing fetus.

31. As used herein, "Watson" means Watson Pharmaceuticals Inc. and its predecessors (including, without limitation, Circa Pharmaceuticals, Inc.), successors, assigns and present and/or former affiliates and subsidiaries and any of its respective officers, directors, employees, agents, attorneys or any person acting or purporting to act on its behalf.

32. The connectives "and" and "or" shall be construed either disjunctively or conjunctively as necessary to bring within the scope of the discovery request all responses that might otherwise be construed to be outside of its scope.

33. The term "all" shall be construed as all and each, and the term "each" shall be construed as all and each.

34. The use of the singular form of any word includes the plural, and vice versa.

35. Except for privileged materials, the company will 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. The company should 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, the company will not mask, cut expunge, edit, or delete any responsive document or portion thereof in any manner.

36. Unless otherwise stated, the scope of this request is from January 1, 1993 through the present and is continuing in. If, after producing documents, the company obtains or becomes aware of any further documents, or information responsive to this request for production of documents, the company is required to produce to HMR such additional documents and/or to provide HMR with such additional information.

37. Compliance with this subpoena requires a search of all documents in the possession, custody, or control of the company's officers, directors, employees, agents, or representatives, whether or not such documents are on the premises of the company. If any person is unwilling to have his or her files searched, or is unwilling to produce responsive documents, the company must provide counsel serving this request with the following information as to each such person: his or her name, address, telephone number, and relationship to the company.

38. If any requested documents cannot be produced in full, produce the remainder and state whatever information, knowledge, or belief the company has concerning the unproduced portion.

39. In addition to hard-copy documents, the search will include all the company's electronically stored data. Sources of such data include, but are not limited to, the following:

(a) Desktop personal computers ("PCs") and workstations; PCs, workstations, minicomputers and mainframes used as file servers, application servers, or mail servers; laptops, notebooks, hand-held devices and other portable computers available for shared use; and home computers used for work related purposes;

(b) Backup disks and tapes, archive disks and tapes, and other forms of offline storage, whether stored onsite with the computer used to generate them, stored offsite in another company facility or stored offsite by a third-party, such as in a disaster recovery center; and

(c) Computers and related offline storage used by agents, consultants, and other persons as defined herein, which may include persons who are not employees of the company or who do not work on company premises.

40. The company will submit all documents, including electronically-stored documents, in hard copy. In addition to the hard copies, the company will submit the electronically-stored documents.

41. The source and location of each responsive document shall be designated, including the corporate entity and/or person from which it was obtained. Responsive documents from each entity and or person's files shall be produced together, in file folders or with other enclosures that segregate the files by request number. If a document is responsive to more than one request, it shall be produced in response to the request to which it is primarily responsive. An index of responsive documents is requested in hard copy and machine-readable form identifying for each document produced: (1) the corporate identification and consecutive control number; (2) the numbered requested to which it is responsive; (3) the person from whom the document was obtained;

and (4) for documents generated by the recipient, the person and/or file name or number from which it was obtained.

42. In the event that the company withholds any document on the basis that it is privileged, subject to work-product immunity, or is otherwise excludable from discovery, the company is requested to list such documents by request number and to provide the following information:

(a) the identity of the authors;

(b) the identity of all recipients;

(c) the date of the document;

(d) the subject matter or purpose of the document or report;

(e) the nature of the relationship between the authors and counsel with sufficient particularity to sustain the asserted privilege;

(f) whether direct quotes or paraphrases of advice from counsel were identified;

(g) whether such quotes could be redacted, leaving non-privileged information; and,

(h) any other information necessary to reveal the basis upon which the document is withheld to provide HMR with sufficient information to determine whether the stated basis for withholding the document is proper.

43. If any document responsive to these requests once existed but has been destroyed, lost, discarded or is otherwise not available for production, the recipient shall identify in writing each such document, including the date of the document's creation, a description of the document's subject matter, the name and address of each person who prepared, received, viewed, or had possession, custody or control of the document or otherwise had knowledge of its subject

matter, and a statement of the circumstances under which the document was destroyed, lost, discarded or why such document is otherwise not available for production.

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