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



TO: The Honorable D. Michael Chappell Administrative Law Judge

COMPLAINT COUNSEL'S MEMORANDUM IN OPPOSITION TO HOECHST'S MOTION FOR THE ISSUANCE OF A SUBPOENA TO THE FOOD AND DRUG ADMINISTRATION

Hoechst's proposed subpoena to the FDA should be denied in its entirety because it seeks information either that Andrx already has requested from the FDA or that is being – or has been – produced to Hoechst by the FTC and other third parties. Section 3.36 of the FTC's Rules of Practice permit the issuance of subpoenas upon other governmental agencies only if, among other things, a specific showing is made that "the information and material sought cannot reasonably be obtained by other means." The Commission has consistently held that, in order to meet this standard, the requesting party is required to affirmatively show that the information it seeks by

¹ See 16 C.F.R. § 3.36(b)(3).

subpoena from governmental agencies can be obtained only from these agencies.² Since Hoechst has not, and cannot, make such a showing here, its motion should be denied in its entirety. As detailed below, each of Hoechst's proposed requests can be – and are being – obtained from non-governmental parties.

First, Hoechst can obtain the same information that it seeks from the FDA in Request No. 1 from its co-respondent Andrx, who already has issued to the FDA the same request:

Hoechst Proposed	L
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.

Andrx Request

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.

The FDA should not be compelled to respond for a second time to the same request – especially given that the agency is now negotiating with Andrx the documents it will produce in response to this request. Forcing the FDA to respond to Hoechst's request would require that the agency renegotiate the same request with yet another respondent here.³

² See, In re Automotive Breakthrough Sciences, Inc., Dkt. No. 9275, 1996 FTC Lexis 286 at *2, (June 19, 1996) (Order Denying Motion for Issuance of Subpoenas Duces Tecum); Exxon Corp., 95 F.T.C. 919, 922 (1980) (Interlocutory Order); Volkswagen of America, Dkt. No. 9154, (Jan. 19, 1982), slip op. at 2 (Order Denying Motion Requesting Subpoena Duces Tecum); Schering Corp., Dkt. No. 9232, (Oct. 16, 1990) (Order Denying Authorization to Serve Subpoena of Government Agency).

³ Hoechst and Andrx's failure to coordinate their discovery on the FDA is systematic of how the respondents are generally conducting third-party discovery. Not once have Hoechst and Andrx jointly issued a document request. Rather, the respondents have repeatedly issued separate, but similar, document requests to third parties, unnecessarily burdening these companies and unnecessarily complicating third-party discovery.

Second, Request No. 2 seeks documents concerning the FTC's comments on the FDA's proposed rule on 180-day generic drug exclusivity. Hoechst requested the same information from us,⁴ and we have produced all of our non-privileged documents. Hoechst should not be allowed to turn to another government agency to seek exactly the same non-privileged information.

Third, Requests Nos. 3 and 4 seek "documents which reflect the date of submission, filing, tentative approval and final approval" of Faulding's and Andrx's ANDAs. Again, this information is readily available from other sources. Hoechst certainly can ask its co-respondent Andrx for information relating to Andrx's ANDA, and information concerning Faulding's ANDA is easily obtainable – and has already been requested by Andrx – from Faulding.⁵

Finally, Request No. 5 seeks "documents concerning the development of Probucol for prevention of restenosis after corchary angioplasty." Probucol is a Hoechst product for which it holds an approved New Drug Application. Shortly after Biovail filed an ANDA to market a generic version of Cardizem CD, Hoechst offered to pay Biovail millions of dollars, ostensibly to complete the development of Probucol for a new indication (the prevention of restenosis). This offer was contingent upon Biovail agreeing not to market a generic Cardizem CD for several years. The only relevance of Probucol to this proceeding (if any) is whether Hoechst's offer to pay Biovail a substantial sum to develop the product was (1) a sham to cover-up a proposed agreement to delay Biovail's introduction of a generic Cardizem CD, or (2) a legitimate joint-

⁴ See Hoechst's Second Request for the Production of Documents to the FTC, specification 42 (attached as Exhibit 1).

⁵ See Andrx's Request for the Production of Documents to Faulding, specifications 5, 25, and 26 (attached as Exhibit 2).

development agreement. Discovery related to this issue comes from Hoechst's own documents or can be obtained – and has been requested by Hoechst ⁶ – from Biovail. To the extent Hoechst's request seeks additional information from the FDA relating to Probucol, such information is irrelevant.⁷

* * * * *

For the reasons discussed above, Hoechst's Motion for the Issuance of a Subpoena to the Food and Drug Administration should be denied in its entirety.

Respectfully Submitted,

Markus H. Meier Bradley S. Albert Daniel A. Kotchen

Robin Moore

Counsel Supporting the Complaint

Bureau of Competition Federal Trade Commission Washington, D.C. 20580

Dated: August 1, 2000

⁶ See Hoechst's First Document Production Request to Biovail Corp., specifications 27 – 32 (attached as Exhibit 3)

⁷ As the Commission has made clear, Your Honor "should 'carefully consider the relevance of the requested materials' when discovery is sought by another federal agency." *Automotive Breakthrough Sciences, Inc.*, 1996 FTC Lexis at *1 (quoting *Exxon Corp.*, 95 F.T.C. at 922).

CERTIFICATE OF SERVICE

I, Daniel A. Kotchen, hereby certify that on August 1, 2000, I caused a copy of Complaint Counsel's Memorandum in Opposition to Hoechst's Motion for the Issuance of a Subpoena to the Food and Drug Administration (including the attachments to the memorandum) to be served upon the following persons either (1) by hand or (2) by facsimile and Federal Express:

Hon. D. Michael Chappell Administrative Law Judge Federal Trade Commission Room 104 600 Pennsylvania Ave., N.W. Washington, D.C. 20580 Louis M. Solomon, Esq. Solomon, Zauderer, Ellenhorn, Frischer & Sharp 45 Rockefeller Plaza New York, NY 10111

James M. Spears, Esq. Shook, Hardy & Bacon, L.L.P. 600 14th Street, N.W. Suite 800 Washington, D.C. 20005-2004 Peter O. Safir, Esq. Kleinfeld, Kaplan and Becker 1140 19th St., N.W Washington, D.C. 20036

Daniel A. Kotchen

EXHIBIT ONE

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 <u>Hoechst AG</u>; <u>Proposed Consent</u>
 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

EXHIBIT TWO

T.

SUBPOENA DUCES TECUM

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

1 10

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.

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 SOLOMON, ZAUDERER, ELLENHORN, FRISCHER & SHARP 45 Rockefeller Plaza New York, NY 10111 or at such other location as is mutually

4. MATERIAL WILL BE PRODUCED TO

Respondent - Andrx Corporation

5. DATE AND TIME OF PRODUCTION OR INSPECTION

July 24, 2000 at 10:30 a.m.

6. SUBJECT OF PROCEEDING

agreed upon.

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 Andry

DATE ISSUED

SECRETARY'S SIGNATURE

MAY 1 2 2000

rald & 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 ederal Trade Commission, accompanied by an fidovit of service of the abaument upon counsel and in Item 9, and upon all other parties prescribed are 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 CMB 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 XTTM, 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 XTTM.

- 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

- the commercial market of each bioequivalent or generic version of Cardizem® CD;
- (c) 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;
- (d) for each of the first three years following the projected or anticipated introduction or sale of bioequivalent or generic version of Cardizem® CD:
 - 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;
 - (iv) the Company's projected or anticipated lost annual revenues and profits.
- 8. 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, 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 XTTM, 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 XTTM

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

- 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 XTTM.
- 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.
- 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.
- 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.
- 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 XTTM, 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.
- As used herein, "Cartia XTTM" 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.

- As used herein, the terms "document" or "documents" or 13. "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.

- 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 THREE



SUBPOENA DUCES TECUM

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

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

2. FROM

UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

New York, NY 10019

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

- 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

SECRET ARY'S SIGNATURE

17 2000

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 Searctary of the Federal Trade Commission, accompanied by an afficiavit of service of the aboument 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 adding 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 subpoend 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:

- 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:

- 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 Probacol.

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;
- 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.

REOUEST 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:

- 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 Andra'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.
- 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.

- 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.
- 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.
- As used herein, "person" includes any natural person, corporate entity, sole proprietorship, partnership, association, governmental entity, or trust.
- 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.
- 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.
- 27. 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.
- 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.
- 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.

SHOOK, HARDY & BACON L.L.P.

James M. Spears

Paul S. Schleifman

D. Edward Wilson, Jr.

Peter D. Bernstein

60014th Street, N.W.

Washington, D.C. 20005-2004

202-783-8400

Attorneys for Respondent Hoechst Marion Roussel, Inc.

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