# UNITED STATES OF AMERICA BEFORE FEDERAL TRADE COMMISSION

JUN 7 2000

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

### MOTION OF BIOVAIL CORPORATION, EUGENE N. MELNYK AND KENNETH C. CANCELLARA TO QUASH SUBPOENAS ISSUED BY ANDRX CORPORATION AND MEMORANDUM IN SUPPORT

Upon the accompanying Declaration of Kenneth C. Cancellara, executed on June 7, 2000, and the supporting memorandum of law, Biovail Corporation ("Biovail"), a Canadian corporation, its Chariman, Eugene N. Melnyk, a citizen of Barbados and its General Counsel, Kenneth C. Cancellara, a citizen of Canada, hereby move for an order pursuant to section 3.34(c) of the Code of Federal Regulations quashing the subpoenas duces tecum and ad testificandum dated May 12, 2000 directed to them by Andrx Corporation for failure to follow, in violation of the FTC Act, Canadian procedures governing service of process in a United States proceeding within the sovereign territory of Canada and for failure to personally serve Mr. Melnyk.

The subpoenas issued in this proceeding by Andrx Corporation were simply dropped off at Biovail's offices in suburban Toronto without any apparent effort by Andrx to

follow any of the procedures of the FTC Act which mandate compliance with the requirements of Canadian and international law to serve process in a United States proceeding within the sovereign territory of Canada. Because Andrx did not obtain the letters rogatory required to confer this Commission's jurisdiction over people who are not citizens of the United States and were not served with process within the United States, the Subpoenas are not effective and the command stated in the subpoenas for these witnesses to appear in this proceeding is null and void. (See Point I below.)

In addition, the subpoena delivered to Biovail addressed to Biovail's Chairman, Eugene N. Melnyk, was not personally served, as required. Mr. Melnyk does not work at Biovail's offices in Mississauga, Ontario where the subpoenas were delivered. Mr. Melnyk is a citizen of Barbados, and he maintains his principal place of business there. Accordingly, under Rule 45, Fed. R. Civ. P., which Andrx is required to follow in serving the subpoenas, *FTC v. Compagnie de Saint-Gobain-Pont-A-Mousson*, 636 F.2d 1300, 1323 (D.C. Cir. 1980), Andrx's attempt to serve the subpoena by delivering it to Biovail's offices in Mississauga would have been ineffective, even if Andrx had followed the proper procedure by obtaining letters rogatory to serve process within Canada (which it did not). For this additional reasons, the subpoena directed to Mr. Melnyk must be quashed. (*See* Point II *below*.)

### **STATEMENT OF FACTS**

On or about May 18, 2000, Kenneth C. Cancellara, Senior Vice President and General Counsel to Biovail, was handed a copy of subpoenas duces tecum and ad testificandum dated May 12, 2000, issued in this proceeding by Andrx Corporation (the "Subpoenas"), by a man appearing at Biovail's offices in Mississauga, Ontario. (Cancellara Dec. ¶1). The Subpoenas were directed at Biovail, a corporation organized and existing under the laws of Canada, Mr.

Cancellara, a Canadian citizen, and Eugene N. Melnyk, a citizen of Barbados and were made returnable on June 13, 2000 in Toronto, Ontario. The Subpoenas are Exhibit 1 to the Cancellara Declaration.

### POINT I

# ANDRX DID NOT FOLLOW THE PROCEDURES REQUIRED TO CONFER THIS COMMISSION'S JURISDICTION OVER FOREIGN CITIZENS ON FOREIGN TERRITORY

Delivering a piece of paper to a foreign citizen on foreign territory is ineffective to confer the jurisdiction of this Commission over those foreign citizens because the D.C. Circuit has held that the Commission must utilize established channels of international judicial assistance prior to serving a subpoena upon a foreign individual in a foreign territory. FTC v. Compagnie De Saint-Gobain-Pont-A-Mousson, 636 F.2d 1300 (D.C. Cir. 1980). Accordingly, Andrx's delivery of subpoenas to Biovail's Canadian headquarters without first enlisting the judicial power and authority of the appropriate Canadian court renders those subpoenas ineffective, and requires that the subpoenas be quashed by this Commission.

At issue in *De-Saint-Gobin* was the validity of an investigatory subpoena issued by the Commission and sent by registered mail to the De-Saint-Gobain de Saint-Gobain-Pont-a-Mousson ("SGPM"), a French holding company headquartered in Paris. *Id.* at 1304-05. The District Court held that the FTC could validly serve subpoenas upon foreign nationals in a foreign territory by registered mail without offending principles of international law and foreign sovereignty. *Id.* at 1306. The Court of Appeals reversed and held that the method of service chosen by the FTC substantially interfered with foreign autonomy and principles of international law dictating that American tribunals should resort to established procedures for judicial

assistance under foreign procedure prior to serving foreign nationals in a foreign territory. *Id.* at 1317.

In holding that the FTC subpoena issued to foreign individuals on foreign soil violated fundamental principles of international law, the Court of Appeals determined that delivery of an FTC subpoena upon a witness "carries with it the full array of American judicial power." *Id.* at 1312. The mere service of this compulsory process "constitutes an exercise of one nation's sovereignty within the territory of another sovereign. Such an exercise constitutes a violation of international law." *Id.* at 1313. The Court cautioned that such service is maximally intrusive upon a foreign nation's sovereignty where officials of the local state are not given advance warning and "without initial request for or prior resort to established channels of international judicial assistance...." *Id.* Furthermore, the Court of Appeals determined that an appropriate reading of congressional intent underlying the FTC Act with respect to acceptable methods of subpoena service would require that an agency attempt subpoena service "through established diplomatic channels or procedures authorized by international convention." *Id.* at 1323.

Here, Andrx's mere delivery of the subpoenas to Biovail in Canada without prior resort to established Canadian procedures for judicial assistance clearly violates, and is obnoxious to, fundamental principles of international law. Canadian authorities have established procedures to assist U.S. tribunals and litigants in obtaining testimony and documents for use in American proceedings. *See* Ú.S. DEP'T OF STATE, JUDICIAL ASSISTANCE IN CANADA, WWACSEUR 681 (1996) (hereinafter referred to as "STATE DEP'T PUBLICATION").

Under these Canadian procedures, American tribunals or litigants seeking to compel the testimony of a witness or the production of documents must obtain the evidence they seek by a letter rogatory/letter of request to the appropriate Canadian court. STATE DEP'T PUBLICATION at 7. With the assistance of a Canadian lawyer, American parties to a proceeding may apply for an order under Section 43 of the Canada Evidence Act, R.S.C., c. E-10, s. 40, or under Section 60 of the Ontario Evidence Act, R.S.O, c. E.23, s. 60, which empowers the Canadian Court to compel the testimony or production of documentary evidence pursuant to a letter of request from an American court or tribunal.

Rather than following these procedures for securing its requested evidence in Canada, Andrx seeks to circumvent Canadian authority and autonomy by delivering the Subpoenas to Biovail's Canadian offices without any notice to or action by any Canadian court or authority. This procedure is improper and ineffective. As shown, Andrx is first required to obtain — but has not obtained — a letter of request, and to follow the appropriate procedures to obtain the requested evidence. Due to its failure to follow the proper procedures, Andrx's Subpoenas are an invalid infringement of Canadian sovereignty under general principles of international law, and they must therefore be quashed.

### **POINT II**

### THE SUBPOENA WAS NOT SERVED PERSONALLY ON MR. MELNYK

Andrx's subpoena directed to Mr. Melnyk is also invalid because he was not personally served. The D.C. Circuit has clearly determined that considerations of foreign sovereignty dictate that service of FTC or agency subpoenas abroad must comply with "all

customary and legitimate methods of service of compulsory process commonly employed by American courts and administrative tribunals." See FTC vs. Compaigne De Saint-Gobain-Pont-A-Mousson, 636 F.2d 1300, 1323 (D.C. Cir. 1980) (holding that service of an FTC subpoena by registered mail and not personally on a foreign national on foreign soil conflicted with international law and foreign sovereignty.) The De-Saint-Gobain Court determined that an appropriate reading of congressional intent underlying the enactment of the FTC Act imposes the personal service requirement of Federal Rule of Civil Procedure 45¹ upon all FTC issued subpoenas served on foreign nationals in a foreign jurisdiction. The Court reasoned that it could not imagine "that when Congress enacted the FTC Act in 1914 it could have intended an administrative agency such as the FTC to procure witnesses and documents from abroad by means which no civil litigant had ever been able to employ within the borders of the United States." Id. at 1324.

Mr. Melnyk was never personally served by Andrx with the subpoenas bearing his name. Rather, the subpoena bearing Mr. Melnyk's name was provided by a process server on behalf of Andrx to Mr. Cancellara at Biovail's offices in Mississauga, Ontario. Thus, under *De-Saint-Gobain*, any purported service against Mr. Melnyk, other than direct personal service, is invalid. Any holding to the contrary would result in the absurd proposition that U.S.

Rule 45(b)(1), Fed. R. Civ. P., governs the service of subpoenas. Rule 45(b)(1) specifically provides that "a subpoena may be served by any person who is not a party and is not less that 18 years of age. Service of a subpoena upon a person named therein shall be made by delivering a copy thereof to such person and, if the person's attendance is commanded, by tendering to that person the fees for one day's attendance and the mileage allowed by law. When the subpoena is issued on behalf of the United States or an officer or agency thereof, fees and mileage need not be tendered. Prior notice of any commanded production of documents and things or inspection of premises before trial shall be served on each party in the manner prescribed by Rule 5(b)." FED. R. CIV. P. 45(b)(1).

administrative agencies may dismiss principles of international sovereignty and procure the testimony of foreign nationals on foreign soil by less rigorous means that a civil litigant may employ in the United States.

### **CONCLUSION**

For the reasons set forth above, Biovail Corporation International, Kenneth C. Cancellara and Eugene N. Melnyk respectfully request that the Commission quash the Subpoenas that Andrx directed to them.

Dated: June 7, 2000

### PROSKAUER ROSE LLP

Ronald S. Rauchberg

Francis D. Landrey

John Siegal

Stefanie S. Kraus

1585 Broadway

New York, NY 10036-8299

(212) 969-3342

Attorneys for Biovail

Corporation International, Eugene N.

Melnyk and Kenneth C. Cancellara

O'MELVENY & MYERS LLP

David T. Beddow

Neil K. Gilman

555 13th Street, N.W.

Washington, D.C. 20004-1109

Attorneys for Biovail

Corporation International, Eugene N.

Melnyk and Kenneth C. Cancellara

### 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

# STATEMENT OF FRANCIS D. LANDREY PURSUANT TO SECTION 3.22(F) OF THE CODE OF FEDERAL REGULATIONS

I am Senior Counsel with Proskauer Rose LLP, counsel for Biovail Corporation ("Biovail") and submit this statement pursuant to the provisions of section 3.22(f) of the Code of Federal Regulations in connection with the motion of Biovail to quash the subpoenas dated May 12, 2000, directed to Biovail, Kenneth Cancellara and Eugene Melnyk. Over the past several weeks, I and my colleague, John Siegal, have engaged in several discussions with Louis M. Solomon and Hal Shaftel of Solomon, Zauderer, Ellenhorn, Frischer & Sharp, counsel for Andrx Pharmaceuticals, Inc. ("Andrx") in a good faith effort to resolve by agreement the issues raised by Biovail's Motion to Quash. During those conversations we were unable to reach agreement with counsel for Andrx resolving the objections to the subpoenas.

Dated: June 7, 2000

Francis D. Landrey

### **CERTIFICATE OF SERVICE**

I, Neil K. Gilman, hereby certify that on June 7, 2000, I caused a copy of the Motion Of Biovail Corporation, Eugene N. Melnyk And Kenneth C. Cancellara To Quash Subpoenas Issued by Andrx Corporation to be served upon the following persons by hand:

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

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

Markus M. Meier, Esq. Federal Trade Commission Room 3114 601 Pennsylvania Ave., N.W. Washington, DC 20580

And upon the following persons by overnight mail:

James M. Spears, Esq. Shook, Hardy & Bacon, L.L.P. 801 Pennsylvania Avenue, N.W. Suite 800 Washington, DC 20004

Peter O. Safir, Esq. Kleinfeld, Kaplan & Becker 1140 19<sup>th</sup> St., N.W. Washington, DC 20036 Louis M. Solomon, Esq. Colin A. Underwood, Esq. Solomon, Zauderer, Ellenhorn, Frischer & Sharp 45 Rockefeller Plaza New York, NY 10111

Neil K. Gilman

# 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

DECLARATION IN SUPPORT OF MOTION BY BIOVAIL CORPORATION, EUGENE N. MELNYK AND KENNETH C. CANCELLARA TO QUASH SUBPOENAS SERVED BY ANDRX CORPORATION

### KENNETH C. CANCELLARA, hereby declares:

- 1. I am a citizen of Canada where I am employed as Senior Vice President and General Counsel of Biovail Corporation ("Biovail"), a corporation organized and existing under the laws of Canada with its principal place of business located in Canada at 2488 Dunwin Drive, Mississauga, Ontario. I make this affidavit in support of the motion by Biovail, its Chairman Eugene N. Melnyk, a citizen of Barbados, and me to quash subpoenas, dated May 12, 2000, issued in this proceeding by Andrx Corporation ("Andrx"), copies of which are annexed hereto as Exhibit 1 (the "Subpoenas").
- 2. On or about May 18, 2000, a man appeared at Biovail's offices in Mississauga, Ontario. I was summoned to the front desk and the man handed me the Subpoenas. They were not accompanied by any process issued by any Canadian court, nor were they accompanied by any paper demonstrating that the man delivering the Subpoenas, or those on

whose behalf he was acting, had taken any step to seek the authorization of or otherwise obtain the consent or jurisdiction of any agency or office of the governments of Canada or Ontario.

I declare under penalty of perjury under the laws of the United States of America

that the foregoing is true and correct. Executed on June 7, 2000.

KENNETH C. CANCELLARA



# SUBPOENA AD TESTIFICANDUM

Issued Pursuant to Rule 3.34(a)(1), 16 C.F.R. § 3.34(a)(1) (1997)

1 10

Biovail Corporation International.

by Eugene N. Melnyk

2488 Dunwin Drive, Mississauga, Ontario L5L 1J9

2. FROM

UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

This subpoend requires you to appear and give testimony, at the date and time specified in Item 5, at the request of Counsel listed in Item 8, in the proceeding described in Item 6.

3. PLACE OF HEARING

Victory Verbatim Reporting Services
T-D Bank Tower, Toronto-Dominion Centre
66 Wellington Street West, Suite 3320
Toronto, Ontario M5K 1H6

4. YOUR APPEARANCE WILL BE BEFORE

Respondent, Andrx Corporation (at Deposition)

5. DATE AND TIME OF HEARING OR DEPOSITION

June 13, 2000 10:00 a.m.

6 -- SUBJECT OF PROCEEDING

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

7. ADMINISTRATIVE LAW JUDGE

Federal Trade Commission Washington, D.C. 20580

عددهم وبالشريق وبالجداد الأسام وجران

The Honorable D. Michael Chappell

8. COUNSEL REQUESTING SUBPOENA

Solomon, Zauderer, Ellenhorn, Frischer & Sharp

45 Rockefeller Plaza

New York, NY 10111

Counsel for the Respondent, Andrx Corporation

DATE ISSUED .....

SECRET ARY'S SIGNATURE

MAY 1 2 2000

GENERAL INSTRUCTIONS

### **APPEARANCE**

The delivery of this subpoend 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 subpoend 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 recerd Trade Commission, accompanied by an afficult of service of the apartment upon counsel listed in Item 8, 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 dam to Counsel listed in Item 8 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 8.

This subpoena does not require approval by OMB under the Paperwork Reduction Act of 1980.



### SUBPOENA DUCES TECUM

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

1. 10

Biovail Corporation International.

2. FROM

by Eugene N. Melnyk

2488 Dunwin Drive, Mississauga, Ontario L5L 1J9

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

Victory Verbatim Reporting Services
T-D Bank Tower, Toronto-Dominion Centre
66 Wellington Street West, Suite 3320
Toronto, Ontario M5K 1H6

4. MATERIAL WILL BE PRODUCED TO

Respondent, Andrx Corporation (at Deposition)

5. DATE AND TIME OF PRODUCTION OR INSPECTION

June 13, 2000 10:00 a.m.

6. SUBJECT OF PROCEEDING

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

7. MATERIAL TO BE PRODUCED

SEE EXHIBIT A

8. ADMINISTRATIVE LAW JUDGE

The Honorable D. Michael Chappell

Federal Trade Commission Washington, D.C. 20580

9. COUNSEL REQUESTING SUBPOENA

Solomon, Zauderer, Ellenhorn, Frischer & Sharp 45 Rockefeller Plaza

New York, NY 10111

Counsel for the Respondent, Andrx Corporation

DATE ISSUED

SECRETARY'S SIGNATURE

MAY 1 2 2000

Donald & Clark

GENERAL INSTRUCTIONS

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### APPEARANCE

The delivery of this subpoend to you by any method prescribed by the Commission's Rules of Practice is legal service and may subject you to a pendty imposed by law for fallure to comply.

#### MOTION TO LIMIT OR QUASH

The Commission's Rules of Practice require that any motion to limit or quash this subpoend be filed within the earlier of 10 days after service or the time for compliance. The original and ten copies of the petition must be filed with the Secretary of the Federal Trade Commission, accompanied by an officiality of service of the document upon counsel listed in Item 9, and upon all other parties prescribed by the Rules of Practice.

#### TRAVEL EXPENSES

The Commission's Rules of Practice require that fees and mileage be paid by the party that requested your appearance. You should present your dain to counsel listed in Item 9 for payment. If you are permanently or temporally tiving 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**

### **DEFINITIONS AND INSTRUCTIONS**

- 1. As used here, the term "Biovail" shall refer to Biovail International Corporation, and each of its predecessors, successors, groups, divisions, subsidiaries and affiliates and each of their present or former officers, directors, employees, agents, consultants (including public relations consultants and Anne George, John Grimaldi, Michael Sitrick, Steven Seiler or Sitrick and Company), controlling shareholders (and any entity controlled by any such controlling shareholder) or other person acting for or on behalf of any of them.
- 2. As used herein, the term "Andrx" shall refer to Andrx Pharmaceuticals, Inc. 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.
- 3. As used herein, the term "HMR" 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 share-holders (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, the term "Proskauer" shall refer to Proskauer Rose LLP, including its partners, employees, agents, consultants or other person action for or on behalf of any of them.
- 5. As used herein, the term "Teva" shall refer to Teva Pharmaceutical Industries, Ltd. and each of its predecessors, successors, groups, divisions, subsidiaries

(including without limitation Teva Pharmaceuticals USA) and affiliates and each of their present or former officers, directors, employees, agents, consultants, 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 "Elan" shall refer to Elan Corporation, plc and each of its predecessors, successors, groups, divisions, subsidiaries and affiliates and each of their present or former officers, directors, employees, agents, consultants, 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 "Mylan" shall refer to Mylan Laboratories, Inc. and each of its predecessors, successors, groups, divisions, subsidiaries and affiliates and each of their present or former officers, directors, employees, agents, consultants, controlling shareholders (and any entity controlled by any such controlling shareholder) or other person acting for or on behalf of any of them.
- 8. As used herein, the term "Forest" shall refer to Forest Laboratories, Inc. and each of its predecessors, successors, groups, divisions, subsidiaries and affiliates and each of their present or former officers, directors, employees, agents, consultants, controlling shareholders (and any entity controlled by any such controlling shareholder) or other person acting for or on behalf of any of them.
- 9. As used herein, the term "Direct Purchaser" shall refer to a purchaser who buys Cardizem® CD directly from HMR.
- 10. As used herein, the term "Indirect Purchaser" shall refer to a purchaser who buys Cardizem CD from a source other then HMR, whether a wholesaler, retailer or some other source.

- 11. As used herein, the term "Substitute Cardiovascular Drug" shall mean any branded and/or generic drug which you understand some persons use or may use as a substitute in whole or in part for, or in lieu of, Cardizem® CD, including but not limited to therapeutic class.
- 12. As used herein, the term "person" shall mean any natural person, firm, partnership, corporation, incorporated association, organization, joint venture, cooperative, governmental body or other form of legal entity.
- limitation, writings and printed matter of every kind and description, correspondence, memoranda, agreements, contracts, photographs, drawings, notes, records (tape, disc or other) or any communication, statements, invoices, purchase orders, records of hearings, reports of decisions of state or federal governmental agencies, telegrams, summaries or records of telephone conversations, summaries of records of personal interviews, diaries, graphs, reports, notebooks, note charts, plans, sketches, maps, summaries or records of meetings or conferences, summaries or reports of investigations or negotiations opinions or reports of consultants, motion picture film, brochures, pamphlets, advertisements circulars, press releases, drafts marginal comments appearing on any document, microfilm, microfiche, computer printouts, programs, tapes, cassettes, disks, magnetic drums, and punch cards, all data stored in computer banks, all nonidentical copies of any item listed above and all other writings of any kind.
- 14. The word "communication" or "communications" as used herein means any effort to convey information, whether written or oral, recorded or unrecorded, including, but not limited to: (a) speeches and lectures, (b) statements, (c) monologues, (d) dialogues, (e) telephone conversations and conferences, (f) discussions, (g) confer-

- ences, (h) debates, (i) arguments, (j) discourses, (k) interviews, (l) conversations, (m) consultations, and (n) information conveyed through documents.
- 15. As used herein, the term "concerning" means related to, referring to, describing, evidencing or constituting.
- 16. Unless otherwise stated, each paragraph or subparagraph herein shall be construed independently and without reference to any other paragraph or subparagraph for purpose of limitation.
- leged, work product or otherwise protected from disclosure, identify such information by its subject matter and state the nature and basis for any such claim of privilege, work product or other ground for nondisclosure. As to any such document, state: (a) the reason for withholding it or other information relating to it; (b) the author of the documents; (c) each individual to whom the original or a copy of the document was sent; (d) the date of the documents or oral communication; (e) the general subject matter of the document; and (f) any additional information on which you base your claims of privilege. Any part of an answer to which you do not claim privilege or work product should be given in full.
- 18. Unless otherwise stated, the use of a verb in any tense shall be construed as the use of the verb in all other tenses as necessary to bring within the scope of the document requests that which might otherwise be construed outside its scope.
- 19. As used herein, the singular includes the plural and vice versa; the words "and" and "or" shall be both conjunctive and disjunctive; the word "all" means "any and all"; the word "any" means "any and all"; the word "including" means "including without limitation"; the word "he" or any other masculine pronoun includes any individual regardless of sex.

- 20. In the event that any document required to be identified or produced has been destroyed, lost, discarded or otherwise disposed of, any such document is to be identified as completely as possible, including, without limitation, the following information: date of disposal, manner of disposal, reason for disposal, person authorizing the disposal and person disposing of the document.
- 21. Unless otherwise indicated, the time period covered by these interrogatories and document requests is from January 1, 1995 to date.
- 22. Whenever a document request, in whole or in part, calls for documents already supplied by Biovail in answer to a similar document request served in this action, you need not repeat information already supplied, provided that you clearly indicate in your answer to the document request (a) the portion of the document request for which the information called for has already been supplied by Biovail, and (b) the specific document request (or subpart thereof) in answer to which Biovail has already supplied the requested documents.

### **SPECIFIC REQUESTS FOR DOCUMENTS**

- 1. All documents Biovail produced in the action captioned <u>Biovail Corporation International v. Hoechst Aktiengesselschaft, et al.</u>, N.J. No. 98-1434 (MTB)(SRC).
- 2. All documents concerning regulatory approval, or the absence thereof, from any governmental agency, department or organization in the United States, Canada or elsewhere, including any employee, agent or representative thereof, in connection with Biovail manufacturing, developing, producing, licensing, marketing or selling any Substitute Cardiovascular Drug or diltiazem, including but not limited to any New Drug Application (NDA) or Abbreviated NDA (ANDA).

- 3. All documents concerning any communications between Biovail and any Direct Purchaser or Indirect Purchaser of Cardizem® CD, concerning (i) HMR; (ii)

  Andrx; (iii) Cardizem® CD; and/or (iv) Cartia XT.
- 4. All documents concerning any communications between Biovail and any potential manufacturer of a generic version of Cardizem<sup>®</sup> CD, including but not limited to Faulding Inc., concerning (i) HMR; (ii) Cardizem<sup>®</sup> CD; (iii) Andrx; and/or (iv) Cartia XT.
- 5. All documents concerning any communications between, on the one hand, Biovail (including its attorneys, public relations contractors (Anne George, John Grimaldi, Michael Sitrick, Steven Seiler, or Sitrick and Company) or other representatives and, on the other hand, any law firm, including but not limited to Lowey, Dannenberg, Benporad & Selinger, P.C., Berman, Devaleno, Pease & Tabacco, Boies & Schiller, LLP, Niewald, Waldeck & Brown, P.C., Aronovitz & Associates, P.A., Garwin, Bronzaft, Gerstein & Fisher, L.L.P., Calvin, Richardson & Verner, concerning (i) HMR; (ii) Andrx; (iii) Cardizem CD; and/or (iv) Cartia XT.
- 6. All documents concerning any purported agreement(s) between Andrx and HMR, including, but not limited to, any documents concerning the negotiation, execution, and/or modification of any such agreement(s).
- 7. All documents concerning Andrx's generic version of Cardizem® CD (Cartia XT).
- 8. All documents concerning any business relationship or proposed business relationship between Biovail and HMR.
- 9. All documents concerning meetings of the Board of Management, Board of Directors, or Managing Directors of Biovail at which any of the following

subjects were raised, discussed or included on the agenda: (i) Cardizem® CD; (ii) potential, actual or past competition for Cardizem® CD in North America or Canada; (iii)

Andrx; and (iv) litigation or governmental investigation concerning generic competition for Substitute Cardiovascular Drugs.

- 10. All communications between Biovail and the FTC concerning: (i)
  HMR; (ii) Andrx; (iii) any purported agreements between HMR and Andrx; (iv) Cardizem® CD; (v) Andrx's generic version of Cardizem® CD or any other generic version of Cardizem® CD; (vi) the market for Cardizem® CD; or (vii) the 100-day exclusivity period or the Mova decision.
- 11. All documents concerning George Cary (or his law firm), including, without limitation, diameters constituting or communications between George Cary (or anyone else at his law firm) and the FTC with respect to (i) HMR; (ii) Andrx; (iii) Cardizem® CD; and/or (iv) Caria XT.
- 12. All studies, market analyses or other documents concerning any market or submarket for Substitute Cardiovascular Drugs, including, without limitation, those analyses concerning the impact of a generic Cardizem® CD.
- 13. All documents concerning Biovail's actual or anticipated sales, revenues, royalties, or other payments or income from or based on Biovail's actual or planned generic version of Cardizem<sup>®</sup> CD.
- 14. All documents concerning Biovail's actual or anticipated prices or its policies or practices for setting, marketing or determining prices for Biovail's actual or planned generic version of Cardizem® CD.

- 15. All documents concerning any proposals or plans by Biovail with respect to the actual or anticipated commencement of commercial marketing of Biovail's generic version of Cardizem® CD.
- 16. All documents concerning communications with Sitrick and Company, or any principals, employees, or agents thereof, concerning Cardizem® CD or HMR or Andrx.
- 17. Any agreements ever operative between Biovail and Teva and/or any affiliated entities concerning in whole or in part Cardizem® CD or any generic version thereof.
- 18. All documents and communications concerning any agreements ever operative between Biovail and Teva and/or any affiliated entities concerning in whole or in part Cardizem<sup>®</sup> CD or any generic version thereof.
- 19. Any operative agreements between Biovail and Elan and/or any affiliated entities concerning in whole or in part Adalat or any generic version thereof.
- 20. All documents and communications concerning any operative agreements between Biovail and Elan and/or any affiliated entities concerning in whole or in part Adalat or any generic version thereof.
- 21. Any operative agreements between Biovail and Mylan and/or any affiliated entities concerning in whole or in part Verelan or any generic version thereof.
- 22. All documents and communications concerning any operative agreements between Biovail and Mylan and/or any affiliated entities concerning in whole or in part Verelan or any generic version thereof.
- 23. Any operative agreement between Biovail and Forest and/or any affiliated entities concerning Tiazac or any generic version thereof.

- 24. All documents and communications concerning any operative agreement between Biovail and Forest and/or any affiliated entities concerning Tiazac or any generic version thereof.
- 25. All documents concerning any agreement or arrangement, concerning which you are aware, involving an innovator or brand name pharmaceutical company, and a generic company, that marketed any form of:
  - (a) payment from the brand name company to the generic company; or
  - (b) licensing and/or royalty arrangements between the brand name company and the generic company.
- 26. All documents concerning any investigation by or on behalf of the FTC or any other governmental entity concerning Andrx and/or HMR.



## SUBPOENA AD TESTIFICANDUM

Issued Pursuant to Rule 3.34(a)(1), 16 C.F.R. § 3.34(a)(1) (1997)

1 10

### Biovail Corporation International,

by one or more officers, directors, or managing agents, or other persons who consent to testify on its behalf, knowledgeable about the subject matter of this proceeding and the subject matter of the documents requested by this subpoena.

2488 Dunwin Drive, Mississauga, Ontario L5L 1J9

2. FROM

# UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

This subpoena requires you to appear and give testimony, at the date and time specified in Item 5, at the request of Counsel listed in Item 8, in the proceeding described in Item 6.

3. PLACE OF HEARING

Victory Verbatim Reporting Services
T-D Bank Tower, Toronto-Dominion Centre
66 Wellington Street West, Shife 3320
Toronto, Ontario M5K 1H6

4. YOUR APPEARANCE WILL BE BEFORE

Respondent, Andrx Corporation (at Deposition)

5 DATE AND TIME OF HEARING OF DEPOSITION

June 12, 2000 10:00 a.m.

6-SUBJECT-OF-PROCEEDING----

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

7. ADMINISTRATIVE-LAW JUDGE - -

The Honorable D. Michael Chappell

Federal Trade Commission Washington, D.C. 20580

ACHIER TO ALIVER ALVINE TREE.

8. COUNSEL-REQUESTING SUBPOENA ....

Solomon, Zauderer, Ellenhorn, Frischer & Sharp 45 Rockefeller Plaza

New York, NY 10111

Counsel for the Respondent, Andrx Corporation

DATE ISSUED

SECRETARY'S SIGNATURE

MAY 1 2 2000

TITLEOS OF PEARING

Donald & Clark
GENERAL INSTRUCTIONS

### **APPEARANCE**

The delivery of this subpoend to you by any method presalibed by the Commission's Rules of Practice is legal service and may subject you to a pendty 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 auash this subpoend 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 Searchary of the Federal Trade Commission, accompanied by an affidavit of service of the abaument upon counsel listed in Item 8, 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 adam to Counsel listed in Item 8 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 8.

This subpoena does not require approval by CMB under the Paperwork Reduction Act of 1980.



### SUBPOENA DUCES TECUM

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

1. 10

Biovail Corporation International,

by one or more officers, directors, or managing agents, or other persons who consent to testify on its behalf, knowledgeable about the subject matter of this proceeding and the subject matter of the documents requested by this subpoena.

2488 Dunwin Drive, Mississauga, Ontario L5L 1J9

2. FROM

# UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

This subpoend 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

Victory Verbatim Reporting Services
T-D Bank Tower, Toronto-Dominion Centre
66 Wellington Street West, Suite 3320
Toronto, Ontario M5K 1H6

- 4. MATERIAL WILL BE PRODUCED TO Respondent, Andrx Corporation (at Deposition)
- 5. DATE AND TIME OF PRODUCTION OR INSPECTION
  - June 12, 2000 10:00 a.m.

6. SUBJECT OF PROCEEDING

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

7. MATERIAL TO BE PRODUCED

SEE EXHIBIT A

8. ADMINISTRATIVE LAW JUDGE

The Honorable D. Michael Chappell

Federal Trade Commission Washington, D.C. 20580

9. COUNSEL REQUESTING SUBPOENA

Solomon, Zauderer, Ellenhorn, Frischer & Sharp 45 Rockefeller Plaza

New York, NY 10111

Counsel for the Respondent, Andrx Corporation

DATE ISSUED

SECRETARY'S SIGNATURE

MAY 1 2 2000

nald Clark

GENERAL INSTRUCTIONS

### APPEARANCE

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This subpoena does not require approval by CMB under the Paperwork Reduction Act of 1980.

### EXHIBIT A

### **DEFINITIONS AND INSTRUCTIONS**

- 1. As used here, the term "Biovail" shall refer to Biovail International Corporation, and each of its predecessors, successors, groups, divisions, subsidiaries and affiliates and each of their present or former officers, directors, employees, agents, consultants (including public relations consultants and Anne George, John Grimaldi, Michael Sitrick, Steven Seiler or Sitrick and Company), controlling shareholders (and any entity controlled by any such controlling shareholder) or other person acting for or on behalf of any of them.
- 2. As used herein, the term "Andrx" shall refer to Andrx Pharmaceuticals, Inc. 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.
- 3. As used herein, the term "HMR" 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 share-holders (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, the term "Proskauer" shall refer to Proskauer Rose
  LLP, including its partners, employees, agents, consultants or other person action for or
  on behalf of any of them.
- 5. As used herein, the term "Teva" shall refer to Teva Pharmaceutical Industries, Ltd. and each of its predecessors, successors, groups, divisions, subsidiaries

(including without limitation Teva Pharmaceuticals USA) and affiliates and each of their present or former officers, directors, employees, agents, consultants, controlling share-holders (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 "Elan" shall refer to Elan Corporation, plc and each of its predecessors, successors, groups, divisions, subsidiaries and affiliates and each of their present or former officers, directors, employees, agents, consultants, 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 "Mylan" shall refer to Mylan Laboratories, Inc. and each of its predecessors, successors, groups, divisions, subsidiaries and affiliates and each of their present or former officers, directors, employees, agents, consultants, controlling shareholders (and any entity controlled by any such controlling shareholder) or other person acting for or on behalf of any of them.
- 8. As used herein, the term "Forest" shall refer to Forest Laboratories, Inc. and each of its predecessors, successors, groups, divisions, subsidiaries and affiliates and each of their present or former officers, directors, employees, agents, consultants, controlling shareholders (and any entity controlled by any such controlling shareholder) or other person acting for or on behalf of any of them.
- 9. As used herein, the term "Direct Purchaser" shall refer to a purchaser who buys Cardizem® CD directly from HMR.
- 10. As used herein, the term "Indirect Purchaser" shall refer to a purchaser who buys Cardizem CD from a source other then HMR, whether a wholesaler, retailer or some other source.

- 11. As used herein, the term "Substitute Cardiovascular Drug" shall mean any branded and/or generic drug which you understand some persons use or may use as a substitute in whole or in part for, or in lieu of, Cardizem® CD, including but not limited to therapeutic class.
- 12. As used herein, the term "person" shall mean any natural person, firm, partnership, corporation, incorporated association, organization, joint venture, cooperative, governmental body or other form of legal entity.
- limitation, writings and printed matter of every kind and description, correspondence, memoranda, agreements, contracts, photographs, drawings, notes, records (tape, disc or other) or any communication, statements, invoices, purchase orders, records of hearings, reports of decisions of state or federal governmental agencies, telegrams, summaries or records of telephone conversations, summaries of records of personal interviews, diaries, graphs, reports, notebooks, note charts, plans, sketches, maps, summaries or records of meetings or conferences, summaries or reports of investigations or negotiations opinions or reports of consultants, motion picture film, brochures, pamphlets, advertisements circulars, press releases, drafts marginal comments appearing on any document, microfilm, microfiche, computer printouts, programs, tapes, cassettes, disks, magnetic drums, and punch cards, all data stored in computer banks, all nonidentical copies of any item listed above and all other writings of any kind.
- 14. The word "communication" or "communications" as used herein means any effort to convey information, whether written or oral, recorded or unrecorded, including, but not limited to: (a) speeches and lectures, (b) statements, (c) monologues, (d) dialogues, (e) telephone conversations and conferences, (f) discussions, (g) confer-

- ences, (h) debates, (i) arguments, (j) discourses, (k) interviews, (l) conversations, (m) consultations, and (n) information conveyed through documents.
- 15. As used herein, the term "concerning" means related to, referring to, describing, evidencing or constituting.
- 16. Unless otherwise stated, each paragraph or subparagraph herein shall be construed independently and without reference to any other paragraph or subparagraph for purpose of limitation.
- 17. If it is claimed that any document responsive to any request is privileged, work product or otherwise protected from disclosure, identify such information by its subject matter and state the nature and basis for any such claim of privilege, work product or other ground for nondisclosure. As to any such document, state: (a) the reason for withholding it or other information relating to it; (b) the author of the documents; (c) each individual to whom the original or a copy of the document was sent; (d) the date of the documents or oral communication; (e) the general subject matter of the document, and (f) any additional information on which you base your claims of privilege. Any part of an answer to which you do not claim privilege or work product should be given in full.
- 18. Unless otherwise stated, the use of a verb in any tense shall be construed as the use of the verb in all other tenses as necessary to bring within the scope of the document requests that which might otherwise be construed outside its scope.
- 19. As used herein, the singular includes the plural and vice versa; the words "and" and "or" shall be both conjunctive and disjunctive; the word "all" means "any and all"; the word "any" means "any and all"; the word "including" means "including without limitation"; the word "he" or any other masculine pronoun includes any individual regardless of sex.

- 20. In the event that any document required to be identified or produced has been destroyed, lost, discarded or otherwise disposed of, any such document is to be identified as completely as possible, including, without limitation, the following information: date of disposal, manner of disposal, reason for disposal, person authorizing the disposal and person disposing of the document.
- 21. Unless otherwise indicated, the time period covered by these interrogatories and document requests is from January 1, 1995 to date.
- 22. Whenever a document request, in whole or in part, calls for documents already supplied by Biovail in answer to a similar document request served in this action, you need not repeat information already supplied, provided that you clearly indicate in your answer to the document request (a) the portion of the document request for which the information called for has already been supplied by Biovail, and (b) the specific document request (or subpart thereof) in answer to which Biovail has already supplied the requested documents.

### SPECIFIC REQUESTS FOR DOCUMENTS

- 1. All documents Biovail produced in the action captioned <u>Biovail Corporation International v. Hoechst Aktiengesselschaft, et al.</u>, N.J. No. 98-1434 (MTB)(SRC).
- 2. All documents concerning regulatory approval, or the absence thereof, from any governmental agency, department or organization in the United States, Canada or elsewhere, including any employee, agent or representative thereof, in connection with Biovail manufacturing, developing, producing, licensing, marketing or selling any Substitute Cardiovascular Drug or diltiazem, including but not limited to any New Drug Application (NDA) or Abbreviated NDA (ANDA).

- 3. All documents concerning any communications between Biovail and any Direct Purchaser or Indirect Purchaser of Cardizem® CD, concerning (i) HMR; (ii) Andrx, (iii) Cardizem® CD; and/or (iv) Cartia XT.
- 4. All documents concerning any communications between Biovail and any potential manufacturer of a generic version of Cardizem® CD, including but not limited to Faulding Inc., concerning (i) HMR; (ii) Cardizem® CD; (iii) Andrx, and/or (iv) Cartia XT.
- 5. All documents concerning any communications between, on the one hand, Biovail (including its attorneys, public relations contractors (Anne George, John Grimaldi, Michael Sitrick, Steven Seiler, or Sitrick and Company) or other representatives and, on the other hand, any law firm, including but not limited to Lowey, Dannenberg, Benporad & Selinger, P.C., Berman, Devaleno, Pease & Tabacco, Boies & Schiller, LLP, Niewald, Waldeck & Brown, P.C., Aronovitz & Associates, P.A., Garwin, Bronzaft, Gerstein & Fisher, L.L.P., Calvin, Richardson & Verner, concerning (i) HMR; (ii) Andrx; (iii) Cardizem® CD; and/or (iv) Cartia XT.
- 6. All documents concerning any purported agreement(s) between Andrx and HMR, including, but not limited to, any documents concerning the negotiation, execution, and/or modification of any such agreement(s).
- 7. All documents concerning Andrx's generic version of Cardizem® CD (Cartia XT).
- 8. All'documents concerning any business relationship or proposed business relationship between Biovail and HMR.
- 9. All documents concerning meetings of the Board of Management, Board of Directors, or Managing Directors of Biovail at which any of the following

subjects were raised, discussed or included on the agenda: (i) Cardizem® CD; (ii) potential, actual or past competition for Cardizem® CD in North America or Canada; (iii)

Andrx; and (iv) litigation or governmental investigation concerning generic competition for Substitute Cardiovascular Drugs.

- 10. All communications between Biovail and the FTC concerning: (i)
  HMR; (ii) Andrx; (iii) any purported agreements between HMR and Andrx; (iv) Cardizem® CD; (v) Andrx's generic version of Cardizem® CD or any other generic version of Cardizem® CD; (vi) the market for Cardizem® CD; or (vii) the 100-day exclusivity period or the Mova decision.
- 11. All documents concerning George Cary (or his law firm), including, without limitation, diameters constituting or communications between George Cary (or anyone else at his law firm) and the FTC with respect to (i) HMR; (ii) Andrx; (iii) Cardizem® CD; and/or (iv) Caria XT.
- 12. All studies, market analyses or other documents concerning any market or submarket for Substitute Cardiovascular Drugs, including, without limitation, those analyses concerning the impact of a generic Cardizem<sup>®</sup> CD.
- 13. All documents concerning Biovail's actual or anticipated sales, revenues, royalties, or other payments or income from or based on Biovail's actual or planned generic version of Cardizem® CD.
- 14. All documents concerning Biovail's actual or anticipated prices or its policies or practices for setting, marketing or determining prices for Biovail's actual or planned generic version of Cardizem® CD.

- 15. All documents concerning any proposals or plans by Biovail with respect to the actual or anticipated commencement of commercial marketing of Biovail's generic version of Cardizem® CD.
- 16. All documents concerning communications with Sitrick and Company, or any principals, employees, or agents thereof, concerning Cardizem® CD or HMR or Andrx.
- 17. Any agreements ever operative between Biovail and Teva and/or any affiliated entities concerning in whole or in part Cardizem® CD or any generic version thereof.
- 18. All documents and communications concerning any agreements ever operative between Biovail and Teva and/or any affiliated entities concerning in whole or in part Cardizem<sup>®</sup> CD or any generic version thereof.
- 19. Any operative agreements between Biovail and Elan and/or any affiliated entities concerning in whole or in part Adalat or any generic version thereof.
- 20. All documents and communications concerning any operative agreements between Biovail and Elan and/or any affiliated entities concerning in whole or in part Adalat or any generic version thereof.
- 21. Any operative agreements between Biovail and Mylan and/or any affiliated entities concerning in whole or in part Verelan or any generic version thereof.
- 22. All documents and communications concerning any operative agreements between Biovail and Mylan and/or any affiliated entities concerning in whole or in part Verelan or any generic version thereof.
- 23. Any operative agreement between Biovail and Forest and/or any affiliated entities concerning Tiazac or any generic version thereof.

- 24. All documents and communications concerning any operative agreement between Biovail and Forest and/or any affiliated entities concerning Tiazac or any generic version thereof.
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  - (a) payment from the brand name company to the generic company; or
  - (b) licensing and/or royalty arrangements between the brand name company and the generic company.
- 26. All documents concerning any investigation by or on behalf of the FTC or any other governmental entity concerning Andrx and/or HMR.



## SUBPOENA AD TESTIFICANDUM

Issued Pursuant to Rule 3.34(a)(1), 16 C.F.R. § 3.34(a)(1) (1997)

1 TC

Biovail Corporation International,

by Kenneth C. Cancellara

2488 Dunwin Drive, Mississauga, Ontario L5L 1J9

2. FROM

UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

This subpoena requires you to appear and give testimony, at the date and time specified in Item 5, at the request of Counsel listed in Item 8, in the proceeding described in Item 6.

3. PLACE OF HEARING

Victory Verbatim Reporting Services
T-D Bank Tower, Toronto-Dominion Centre
66 Wellington Street West, Shife 3320
Toronto, Ontario, M5K 1H6

4. YOUR APPEARANCE WILL BE BEFORE

Respondent, Andrx Corporation (at Deposition)

5. DATE AND TIME OF HEARING OR DEPOSITION

June 14, 2000 10:00 a.m.

6. SUBJECT-OF PROCEEDING

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

7. ADMINISTRATIVE LAW JUDGE

The Honorable D. Michael Chappell

Federal Trade Commission Washington, D.C. 20580 8. COUNSEL REQUESTING SUBPOENA

Solomon, Zauderer, Ellenhorn, Frischer & Sharp

45 Rockefeller Plaza

New York, NY 10111

Counsel for the Respondent, Andrx Corporation

DATE ISSUED

SECRETARY'S SIGNATURE -----

MAY 1 2 2000

GENERAL INSTRUCTIONS

### **APPEARANCE**

The delivery of this subpoend 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 subpoema be filed within the earlier of 10 days after service or the time for compliance. The original land ten copies of the petition must be filed with the Secretary of the Federal Trade Commission, accompanied by an affidavit of service of the abaument upon counsel listed in Item 8, and upon all other parties prescribed by the Rules of Practice.

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This subpoena does not require approval by CMB under the Paperwork Reduction Act of 1980.



### SUBPOENA DUCES TECUM

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

. IC

Biovail Corporation International.

by Kenneth C. Cancellara

2488 Dunwin Drive, Mississauga, Ontario L5L 1J9

2. FROM

UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

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3. PLACE OF PRODUCTION OR INSPECTION

Victory Verbatim Reporting Services
T-D Bank Tower, Toronto-Dominion Centre
66 Wellington Street West, Suite 3320
Toronto, Ontario M5K 1H6

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June 14, 2000 10:00 a.m.

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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

New York, NY 10111

Counsel for the Respondent, Andrx Corporation

DATE ISSUED

SECRETARY'S SIGNATURE

MAY 1 2 2000

Donald & Clark

GENERAL INSTRUCTIONS

### APPEARANCE

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FTC Form 70-8 (rev. 1/97)

### **EXHIBIT A**

### **DEFINITIONS AND INSTRUCTIONS**

- 1. As used here, the term "Biovail" shall refer to Biovail International Corporation, and each of its predecessors, successors, groups, divisions, subsidiaries and affiliates and each of their present or former officers, directors, employees, agents, consultants (including public relations consultants and Anne George, John Grimaldi, Michael Sitrick, Steven Seiler or Sitrick and Company), controlling shareholders (and any entity controlled by any such controlling shareholder) or other person acting for or on behalf of any of them.
- 2. As used herein, the term "Andrx" shall refer to Andrx Pharmaceuticals, Inc. 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.
- 3. As used herein, the term "HMR" 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.
- 4. As used herein, the term "Proskauer" shall refer to Proskauer Rose LLP, including its partners, employees, agents, consultants or other person action for or on behalf of any of them.
- 5. As used herein, the term "Teva" shall refer to Teva Pharmaceutical Industries, Ltd. and each of its predecessors, successors, groups, divisions, subsidiaries

(including without limitation Teva Pharmaceuticals USA) and affiliates and each of their present or former officers, directors, employees, agents, consultants, 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 "Elan" shall refer to Elan Corporation, plc and each of its predecessors, successors, groups, divisions, subsidiaries and affiliates and each of their present or former officers, directors, employees, agents, consultants, 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 "Mylan" shall refer to Mylan Laboratories, Inc. and each of its predecessors, successors, groups, divisions, subsidiaries and affiliates and each of their present or former officers, directors, employees, agents, consultants, controlling shareholders (and any entity controlled by any such controlling shareholder) or other person acting for or on behalf of any of them.
- 8. As used herein, the term "Forest" shall refer to Forest Laboratories,
  Inc. and each of its predecessors, successors, groups, divisions, subsidiaries and affiliates
  and each of their present or former officers, directors, employees, agents, consultants,
  controlling shareholders (and any entity controlled by any such controlling shareholder)
  or other person acting for or on behalf of any of them.
- 9. As used herein, the term "Direct Purchaser" shall refer to a purchaser who buys Cardizem® CD directly from HMR.
- 10. As used herein, the term "Indirect Purchaser" shall refer to a purchaser who buys Cardizem<sup>®</sup> CD from a source other then HMR, whether a wholesaler, retailer or some other source.

- 11. As used herein, the term "Substitute Cardiovascular Drug" shall mean any branded and/or generic drug which you understand some persons use or may use as a substitute in whole or in part for, or in lieu of, Cardizem® CD, including but not limited to therapeutic class.
- 12. As used herein, the term "person" shall mean any natural person, firm, partnership, corporation, incorporated association, organization, joint venture, cooperative, governmental body or other form of legal entity.
- limitation, writings and printed matter of every kind and description, correspondence, memoranda, agreements, contracts, photographs, drawings, notes, records (tape, disc or other) or any communication, statements, invoices, purchase orders, records of hearings, reports of decisions of state or federal governmental agencies, telegrams, summaries or records of telephone conversations, summaries of records of personal interviews, diaries, graphs, reports, notebooks, note charts, plans, sketches, maps, summaries or records of meetings or conferences, summaries or reports of investigations or negotiations opinions or reports of consultants, motion picture film, brochures, pamphlets, advertisements circulars, press releases, drafts marginal comments appearing on any document, microfilm, microfiche, computer printouts, programs, tapes, cassettes, disks, magnetic drums, and punch cards, all data stored in computer banks, all nonidentical copies of any item listed above and all other writings of any kind.
- 14. The word "communication" or "communications" as used herein means any effort to convey information, whether written or oral, recorded or unrecorded, including, but not limited to: (a) speeches and lectures, (b) statements, (c) monologues, (d) dialogues, (e) telephone conversations and conferences, (f) discussions, (g) confer-

- ences, (h) debates, (i) arguments, (j) discourses, (k) interviews, (l) conversations, (m) consultations, and (n) information conveyed through documents.
- 15. As used herein, the term "concerning" means related to, referring to, describing, evidencing or constituting.
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- 17. If it is claimed that any document responsive to any request is privileged, work product or otherwise protected from disclosure, identify such information by its subject matter and state the nature and basis for any such claim of privilege, work product or other ground for nondisclosure. As to any such document, state: (a) the reason for withholding it or other information relating to it; (b) the author of the documents; (c) each individual to whom the original or a copy of the document was sent; (d) the date of the documents or oral communication; (e) the general subject matter of the document; and (f) any additional information on which you base your claims of privilege. Any part of an answer to which you do not claim privilege or work product should be given in full.
- 18. Unless otherwise stated, the use of a verb in any tense shall be construed as the use of the verb in all other tenses as necessary to bring within the scope of the document requests that which might otherwise be construed outside its scope.
- 19. As used herein, the singular includes the plural and vice versa; the words "and" and "or" shall be both conjunctive and disjunctive; the word "all" means "any and all"; the word "any" means "any and all"; the word "including" means "including without limitation"; the word "he" or any other masculine pronoun includes any individual regardless of sex.

- 20. In the event that any document required to be identified or produced has been destroyed, lost, discarded or otherwise disposed of, any such document is to be identified as completely as possible, including, without limitation, the following information: date of disposal, manner of disposal, reason for disposal, person authorizing the disposal and person disposing of the document.
- 21. Unless otherwise indicated, the time period covered by these interrogatories and document requests is from January 1, 1995 to date.
- 22. Whenever a document request, in whole or in part, calls for documents already supplied by Biovail in answer to a similar document request served in this action, you need not repeat information already supplied, provided that you clearly indicate in your answer to the document request (a) the portion of the document request for which the information called for has already been supplied by Biovail, and (b) the specific document request (or subpart thereof) in answer to which Biovail has already supplied the requested documents.

### SPECIFIC REQUESTS FOR DOCUMENTS

- 1. All documents Biovail produced in the action captioned <u>Biovail Corporation International v. Hoechst Aktiengesselschaft</u>, et al., N.J. No. 98-1434 (MTB)(SRC).
- 2. All documents concerning regulatory approval, or the absence thereof, from any governmental agency, department or organization in the United States, Canada or elsewhere, including any employee, agent or representative thereof, in connection with Biovail manufacturing, developing, producing, licensing, marketing or selling any Substitute Cardiovascular Drug or diltiazem, including but not limited to any New Drug Application (NDA) or Abbreviated NDA (ANDA).

- 3. All documents concerning any communications between Biovail and any Direct Purchaser or Indirect Purchaser of Cardizem® CD, concerning (i) HMR; (ii) Andrx; (iii) Cardizem® CD; and/or (iv) Cartia XT.
- 4. All documents concerning any communications between Biovail and any potential manufacturer of a generic version of Cardizem® CD, including but not limited to Faulding Inc., concerning (i) HMR; (ii) Cardizem® CD; (iii) Andrx; and/or (iv) Cartia XT.
- 5. All documents concerning any communications between, on the one hand, Biovail (including its attorneys, public relations contractors (Anne George, John Grimaldi, Michael Sitrick, Steven Seiler, or Sitrick and Company) or other representatives and, on the other hand, any law firm, including but not limited to Lowey, Dannenberg, Benporad & Selinger, P.C., Berman, Devaleno, Pease & Tabacco, Boies & Schiller, LLP, Niewald, Waldeck & Brown, P.C., Aronovitz & Associates, P.A., Garwin, Bronzaft, Gerstein & Fisher, L.L.P., Calvin, Richardson & Verner, concerning (i) HMR; (ii) Andrx; (iii) Cardizem® CD; and/or (iv) Cartia XT.
- 6. All documents concerning any purported agreement(s) between Andrx and HMR, including, but not limited to, any documents concerning the negotiation, execution, and/or modification of any such agreement(s).
- 7. All documents concerning Andrx's generic version of Cardizem® CD (Cartia XT).
- 8. All documents concerning any business relationship or proposed business relationship between Biovail and HMR.
- 9. All documents concerning meetings of the Board of Management, Board of Directors, or Managing Directors of Biovail at which any of the following

subjects were raised, discussed or included on the agenda: (i) Cardizem® CD; (ii) potential, actual or past competition for Cardizem® CD in North America or Canada; (iii)

Andrx; and (iv) litigation or governmental investigation concerning generic competition for Substitute Cardiovascular Drugs.

- 10. All communications between Biovail and the FTC concerning: (i)
  HMR; (ii) Andrx; (iii) any purported agreements between HMR and Andrx; (iv) Cardizem® CD; (v) Andrx's generic version of Cardizem® CD or any other generic version of Cardizem® CD; (vi) the market for Cardizem® CD; or (vii) the 100-day exclusivity period or the Mova decision.
- 11. All documents concerning George Cary (or his law firm), including, without limitation, diameters constituting or communications between George Cary (or anyone else at his law firm) and the FTC with respect to (i) HMR; (ii) Andrx; (iii) Cardizem® CD; and/or (iv) Caria XT.
- 12. All studies, market analyses or other documents concerning any market or submarket for Substitute Cardiovascular Drugs, including, without limitation, those analyses concerning the impact of a generic Cardizem® CD.
- 13. All documents concerning Biovail's actual or anticipated sales, revenues, royalties, or other payments or income from or based on Biovail's actual or planned generic version of Cardizem® CD.
- 14. All documents concerning Biovail's actual or anticipated prices or its policies or practices for setting, marketing or determining prices for Biovail's actual or planned generic version of Cardizem® CD.

- 15. All documents concerning any proposals or plans by Biovail with respect to the actual or anticipated commencement of commercial marketing of Biovail's generic version of Cardizem® CD.
- 16. All documents concerning communications with Sitrick and Company, or any principals, employees, or agents thereof, concerning Cardizem® CD or HMR or Andrx.
- 17. Any agreements ever operative between Biovail and Teva and/or any affiliated entities concerning in whole or in part Cardizem® CD or any generic version thereof.
- 18. All documents and communications concerning any agreements ever operative between Biovail and Teva and/or any affiliated entities concerning in whole or in part Cardizem<sup>®</sup> CD or any generic version thereof.
- 19. Any operative agreements between Biovail and Elan and/or any affiliated entities concerning in whole or in part Adalat or any generic version thereof.
- 20. All documents and communications concerning any operative agreements between Biovail and Elan and/or any affiliated entities concerning in whole or in part Adalat or any generic version thereof.
- 21. Any operative agreements between Biovail and Mylan and/or any affiliated entities concerning in whole or in part Verelan or any generic version thereof.
- 22. All documents and communications concerning any operative agreements between Biovail and Mylan and/or any affiliated entities concerning in whole or in part Verelan or any generic version thereof.
- 23. Any operative agreement between Biovail and Forest and/or any affiliated entities concerning Tiazac or any general version thereof.

- 24. All documents and communications concerning any operative agreement between Biovail and Forest and/or any affiliated entities concerning Tiazac or any generic version thereof.
- 25. All documents concerning any agreement or arrangement, concerning which you are aware, involving an innovator or brand name pharmaceutical company, and a generic company, that marketed any form of:
  - (a) payment from the brand name company to the generic company; or
  - (b) licensing and/or royalty arrangements between the brand name company and the generic company.
- 26. All documents concerning any investigation by or on behalf of the FTC or any other governmental entity concerning Andrx and/or HMR.