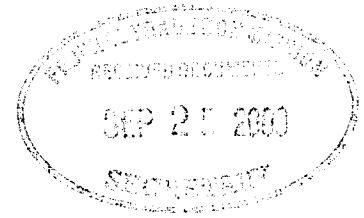


**UNITED STATES OF AMERICA  
BEFORE FEDERAL TRADE COMMISSION**



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

**COMPLAINT COUNSEL'S FIRST REQUESTS FOR ADMISSIONS  
TO RESPONDENT ANDRX CORPORATION**

Pursuant to Federal Trade Commission ("FTC") Rules of Practice for Adjudicative Proceedings § 3.32, Complaint counsel submit these requests for admissions to respondent Andrx Corporation. Andrx is requested to respond, in writing, to the following requests for admissions within twenty (20) days after service hereof.

**DEFINITIONS**

1. "ANDA" means an Abbreviated New Drug Application filed with the FDA pursuant to 21 U.S.C. § 355(j).
2. "ANDA 75-984" means the Abbreviated New Drug Application filed with the FDA by Faulding pursuant to 21 U.S.C. § 355(j) for a generic bioequivalent version of Cardizem CD.

3. “ANDA 75-1169” means the Abbreviated New Drug Application filed with the FDA by Biovail pursuant to 21 U.S.C. § 355(j) for a generic bioequivalent version of Cardizem CD.

4. “Andrx” means Andrx Pharmaceuticals, Inc., 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.

5. “Andrx’s Original Formulation” means ANDA 74-752 filed by Andrx with the FDA pursuant to 21 U.S.C. § 355(j) on September 22, 1995 and amended on April 4, 1996, for a generic or bioequivalent version of Cardizem CD.

6. “Andrx’s Reformulated Product” means the formulation of Andrx’s generic Cardizem CD product which was approved for sale by the FDA on or around June 8, 1999 pursuant to a supplement to ANDA 74-752 filed by Andrx on September 11, 1998.

7. “API” means active pharmaceutical ingredient.

8. “Biovail” means Biovail Corporation, 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.

9. “Cardizem CD” means the diltiazem formulation sold under that trademark.

10. “Cartia XT” means the diltiazem formulated sold by Andrx under that trademark.

11. “District Court” means the U.S. District Court for the Southern District of Florida.

12. “Faulding” means Faulding Inc., 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.

13. “FDA” means the United States Food and Drug Administration, including without limitation its employees, scientists, technicians, agents, examiners and laboratories.

14. “Final Judgement” means a final and unappealable order or judgement as that phrase is defined in paragraph 8.A. of the HMR/Andrx Stipulation and Agreement.

15. “First Filer” means the applicant submitting the first substantially complete ANDA for a listed drug with a Paragraph IV certification to any patent in the Orange Book for the listed drug.

16. “Hatch-Waxman Amendments” means the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417), adding section 505(j) to the Food Drug and Cosmetics Act (21 U.S.C. § 355(j)(5)).

17. “Hoechst” and “HMR” means Hoechst Marion Roussel, Inc., its predecessors, including without limitations Hoechst Inc. and Marion Merrell Dow Inc., and the officers, directors, employees, partners, subsidiaries, corporate parents, affiliates and divisions of each of the foregoing.

18. “HMR/Andrx Patent Infringement Litigation” means *Hoechst Marion Roussel, Inc. et al. v. Andrx Pharmaceuticals, Inc.*, Case No. 96-06121-Civ-Roettger (S.D. Fla.).

19. “HMR/Andrx Stipulation and Agreement” means the agreement between Hoechst Marion Roussel, Inc., Carderm Capital, L.P. and Andrx Pharmaceuticals entered into on or about September 24, 1997.

20. “HMR/Andrx Stipulation and Order” means the agreement entered into between Hoechst and Andrx on or about June 8, 1999 which resolved the Patent Infringement Litigation and terminated the HMR/Andrx Stipulation and Agreement.

21. “Orange Book” means the FDA publication entitled Approved Drug Products with Therapeutical Equivalence Evaluations.

22. “Paragraph IV Certification” means the certification made to the FDA pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

23. “584 Patent” means U.S. Patent No. 5,470,584 issued by the U.S. Patent and Trademark Office on November 28, 1995.

24. “180-day Exclusivity Period” means the period of time established by section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j) *et seq.*).

## REQUESTS FOR ADMISSIONS

### Interstate Commerce

**Request No. 1:** Admit that Andrx markets and sells pharmaceutical products, including Cartia XT in the United States.

**Request No. 2:** Admit that Andrx’s pharmaceutical products, including Cartia XT, are sold to consumers in states other than the state in which the products are manufactured.

**Request No. 3:** Admit that the HMR/Andrx Stipulation and Agreement occurred in, or affected, interstate commerce.

**FDA Regulations**

**Request No. 4:** Admit that a pharmaceutical manufacturer must file an ANDA with the FDA to receive FDA approval to market a generic product that is AB-rated to a brand-name product listed in the Orange Book.

**Request No. 5:** Admit that the FDA takes, on average, 12 to 18 months to review and approve an ANDA.

**Request No. 6:** Admit that a First Filer is eligible for the 180-day Exclusivity Period.

**Request No. 7:** Admit that a First Filer can relinquish its eligibility to the 180-day Exclusivity Period.

**Request No. 8:** Admit that the FDA is prohibited from approving another generic version of the branded product until either (1) the First Filer's 180-day Exclusivity Period has elapsed, or (2) the First Filer relinquishes its eligibility to the 180-day Exclusivity Period.

**Request No. 9:** Admit that if a First Filer relinquishes its eligibility to the 180-day Exclusivity Period, the FDA may grant final approval to another generic version of the branded product.

**Request No. 10:** Admit that Andrx was the First Filer for a generic version of Cardizem CD.

**Request No. 11:** Admit that Andrx, as the First Filer for a generic version of Cardizem CD, was eligible for the 180-day Exclusivity Period.

**The Patent Infringement Litigation**

**Request No. 12:** Admit that on December 19, 1995, Andrx submitted to the FDA a certification stating that Andrx's Original Formulation did not infringe the patents listed in the Orange Book for Cardizem CD.

**Request No. 13:** Admit that Andrx sent Hoechst notification of its December 19, 1995 patent certification to the FDA stating that Andrx's Original Formulation did not infringe the patents listed in the Orange Book for Cardizem CD.

**Request No. 14:** Admit that on January 17, 1996, Andrx submitted to the FDA an amended certification stating that Andrx's Original Formulation did not infringe the patents listed in the Orange Book for Cardizem CD, including the '584 patent.

**Request No. 15:** Admit that Andrx sent Hoechst notification of its January 17, 1996 amended patent certification to the FDA stating that Original Formulation did not infringe the patents listed in the Orange Book for Cardizem CD, including the '584 patent.

**Request No. 16:** Admit that in the HMR/Andrx Patent Infringement Litigation, Andrx took the position in papers filed with the District Court, including Andrx's Answer (dated February 20, 1996) and Andrx's Motion for Summary Judgment on the Issue of Non-Infringement and Memorandum in Support thereof (dated December 12, 1996) that Andrx's Original Formulation did not infringe the patents listed in the Orange Book for Cardizem CD, including the '584 patent.

**Request No. 17:** Admit that in the HMR/Andrx Patent Infringement Litigation, Andrx never took the position in papers filed with the District Court that Andrx's Original Formulation infringed the patents listed in the Orange Book for Cardizem CD, including the '584 patent.

**Request No. 18:** Admit that in the HMR/Andrx Patent Infringement Litigation, Andrx took the position in its counterclaims filed with the District Court on February 20, 1996 that Hoechst's filing of the HMR/Andrx Patent Infringement Litigation would result in the delay in the FDA's approval of Andrx's Original Formulation.

**Request No. 19:** Admit that in the HMR/Andrx Patent Infringement Litigation, Andrx took the position in its counterclaims filed with the District Court on February 20, 1996 that Hoechst's filing of the HMR/Andrx Patent Infringement Litigation would result in the delay of the introduction of Andrx's Original Formulation.

**Request No. 20:** Admit that in the HMR/Andrx Patent Infringement Litigation, Andrx took the position in its counterclaims filed with the District Court on February 20, 1996 that Hoechst's filing of the HMR/Andrx Patent Infringement Litigation would cause Andrx to miss or be precluded from up to 30 months of sales of Andrx's Original Formulation.

**Request No. 21:** Admit that in the HMR/Andrx Patent Infringement Litigation, Andrx never took the position that Andrx's Original Formulation infringed the '584 Patent.

**Request No. 22:** Admit that in the HMR/Andrx Patent Infringement Litigation, Andrx never took the position that any of its generic versions of Cardizem CD infringed the '584 Patent.

**Request No. 23:** Admit that the '584 Patent is a continuation of U.S. Patent No. 5,439,689 issued August 8, 1995.

**Request No. 24:** Admit that U.S. Patent No. 5,439,689 issued August 8, 1995, is a continuation of U.S. Patent No. 5,286,497 issued February 15, 1994.

**Request No. 25:** Admit that the specification of the '584 Patent is substantially identical to the specification of U.S. Patent No. 5,439,689.

**Request No. 26:** Admit that the specification of the '584 Patent is substantially identical to the specification of U.S. Patent No. 5,286,497.

**Request No. 27:** Admit that the specification of U.S. Patent No. 5,439,689 satisfies the requirements of 35 U.S.C. § 112 with regard to the claims of the '584 Patent.

**Request No. 28:** Admit that the specification of U.S. Patent No. 5,286,497 satisfies the requirements of 35 U.S.C. § 112 with regard to the claims of the '584 Patent.

**Request No. 29:** Admit that the specification of U.S. Patent No. 5,439,689 teaches one of ordinary skill in the art of the invention claimed in the '584 Patent how to practice the claimed invention.

**Request No. 30:** Admit that the specification of U.S. Patent No. 5,286,497 teaches one of ordinary skill in the art of the invention claimed in the '584 Patent how to practice the claimed invention.

**Request No. 31:** Admit that FDA regulations require that any drug sold pursuant to an approved ANDA satisfy the specification of the ANDA.

**Request No. 32:** Admit that the District Court made no finding that Andrx's Original Formulation infringed the '584 patent.



**Request No. 33:** Admit that the District Court made no finding that Andrx's Original Formulation was substantially likely to infringe the '584 patent.

**Request No. 34:** Admit that no federal district court has found that Andrx's Original Formulation infringed the '584 patent.

**Request No. 35:** Admit that no federal district court has found that Andrx's Original Formulation was substantially likely to infringe the '584 patent.

**Request No. 36:** Admit that in the HMR/Andrx Patent Infringement Litigation, Andrx took the position in its counterclaims filed with the District Court on February 20, 1996, that diltiazem is the relevant product market for purposes of the antitrust laws of the United States.

**Request No. 37:** Admit that in the HMR/Andrx Patent Infringement Litigation, Andrx took the position in its counterclaims filed with the District Court on February 20, 1996, that the sustained release (once-a day) form of diltiazem is a relevant product sub-market for purposes of the antitrust laws of the United States.

**Request No. 38:** Admit that in the HMR/Andrx Patent Infringement Litigation, Andrx took the position in its counterclaims filed with the District Court on February 20, 1996, that the United States is the relevant geographic market with respect to the relevant product market and relevant product sub-market for purposes of the antitrust laws of the United States.

**HMR/Andrx Stipulation and Agreement**

**Request No. 39:** Admit that in July 1997, representatives of Hoechst and Andrx met to discuss a possible agreement relating to the HMR/Andrx Patent Infringement Litigation.

**Request No. 40:** Admit that the first draft of the HMR/Andrx Stipulation and Agreement was prepared in July 1997.

**Request No. 41:** Admit that the HMR/Andrx Stipulation and Agreement was executed on September 24, 1997.

**Request No. 42:** Admit that the HMR/Andrx Stipulation and Agreement was negotiated over the course of nearly two months.

**Request No. 43:** Admit that during the negotiation of the HMR/Andrx Stipulation and Agreement, Hoechst and Andrx exchanged at least 40 drafts of the HMR/Andrx Stipulation and Agreement.

**Request No. 44:** Admit that the language “other bioequivalent or generic versions of Cardizem CD” first appears in paragraph 2 of the HMR/Andrx Stipulation and Agreement in a August 15, 1997 draft, Bates stamped 1584-1600.

**Request No. 45:** Admit that Hoechst was responsible for inserting the language “other bioequivalent or generic versions of Cardizem CD” into paragraph 2 of the August 15, 1997 draft of the HMR/Andrx Stipulation and Agreement, Bates stamped 1584-1600.

**Request No. 46:** Admit that the language “other bioequivalent or generic versions of Cardizem CD” is crossed out in paragraph 2 of the August 26, 1997 draft of the HMR/Andrx Stipulation and Agreement, Bates stamped 1512-23.

**Request No. 47:** Admit that Andrx was responsible for crossing out the language “other bioequivalent or generic versions of Cardizem CD” from paragraph 2 of the August 26, 1997 draft of the HMR/Andrx Stipulation and Agreement, Bates stamped 1512-23.

**Request No. 48:** Admit that the language “other bioequivalent or generic versions of Cardizem CD” appears in paragraph 2 of the September 3, 1997 draft of the HMR/Andrx Stipulation and Agreement, Bates stamped 1487-98.

**Request No. 49:** Admit that Hoechst was responsible for inserting the language “other bioequivalent or generic versions of Cardizem CD” into paragraph 2 of the September 3, 1997 draft of the HMR/Andrx Stipulation and Agreement, Bates stamped 1487-98.

**Request No. 50:** Admit that Andrx received FDA tentative approval for Andrx’s Original Formulation on September 17, 1997.

**Request No. 51:** Admit that the HMR/Andrx Stipulation and Agreement was entered into eight days after Andrx received FDA tentative approval for Andrx’s Original Formulation.

**Request No. 52:** Admit that Andrx could not receive final FDA approval to market Andrx’s Original Formulation until after the termination of the 30-month Hatch-Waxman statutory injunction.

**Request No. 53:** Admit that the 30-month Hatch-Waxman statutory injunction for Andrx’s Original Formulation expired in July 1998.

**Request No. 54:** Admit that Hoechst and Andrx entered into the HMR/Andrx Stipulation and Agreement more than 8 months before Andrx received final FDA approval to market Andrx’s Original Formulation.

**Request No. 55:** Admit that under the HMR/Andrx Stipulation and Agreement, Andrx agreed not to commence the sale of any “bioequivalent or generic version of Cardizem CD in the United States directly or indirectly” until the earlier of: (1) the date that Final

Judgment was entered in the Patent Infringement Litigation; (2) the date that Andrx obtained a license from HMR pursuant to paragraphs 5, 6, or 7 of the HMR/Andrx Stipulation and Agreement; or (3) the date that Andrx received notice that HMR had decided to market or license a third party to market a generic version of Cardizem CD.

**Request No. 56:** Admit that, on July 9, 1998, Andrx received final FDA approval for Andrx's Original Formulation.

**Request No. 57:** Admit that, as of July 9, 1998, FDA law and regulations permitted Andrx to begin the commercial sale of Andrx's Original Formulation.

**Request No. 58:** Admit that Andrx did not begin the commercial sale of Andrx's Original Formulation on July 9, 1998.

**Request No. 59:** Admit that, as of July 9, 1998, Hoechst became obligated to make payments of \$10 million per quarter to Andrx under the terms of the HMR/Andrx Stipulation and Agreement.

**Request No. 60:** Admit that Andrx did not begin the commercial sale of any generic version of Cardizem CD until after Hoechst and Andrx terminated the HMR/Andrx Stipulation and Agreement.

**Request No. 61:** Admit that under Paragraph 8.B.i. of the HMR/Andrx Stipulation and Agreement, if Andrx breached the terms of the HMR/Andrx Stipulation and Agreement: (1) the HMR/Andrx Stipulation and Agreement would terminate; (2) Andrx would not receive any further \$10 million payments from Hoechst; and (3) Andrx would be required to repay to Hoechst all payments made to Andrx by Hoechst under the HMR/Andrx Stipulation and Agreement.

**Request No. 62:** Admit that in the event Andrx commenced the sale of any “bioequivalent or generic version of Cardizem CD” in the United States while the HMR/Andrx Stipulation and Agreement was in effect: (1) the HMR/Andrx Stipulation and Agreement would terminate; (2) Andrx would not receive any further \$10 million payments from Hoechst; and (3) Andrx would be required to repay to Hoechst all payments made to Andrx by Hoechst under the HMR/Andrx Stipulation and Agreement.

**Request No. 63:** Admit that under the HMR/Andrx Stipulation and Agreement, the phrase “bioequivalent or generic version of Cardizem CD” applied to products that infringed the ‘584 Patent.

**Request No. 64:** Admit that under the HMR/Andrx Stipulation and Agreement, the phrase “bioequivalent or generic version of Cardizem CD” applied to products that did not infringe the ‘584 Patent.

**Request No. 65:** Admit that under the HMR/Andrx Stipulation and Agreement, the phrase “bioequivalent or generic version of Cardizem CD” applied to Andrx’s Reformulated Product.

**Request No. 66:** Admit that under the HMR/Andrx Stipulation and Agreement, Andrx agreed not to relinquish or otherwise compromise any rights accruing under its ANDA.

**Request No. 67:** Admit that under the HMR/Andrx Stipulation and Agreement, the phrase “any rights accruing under [Andrx’s] ANDA” included any rights Andrx had to a 180-day Exclusivity Period.

**Request No. 68:** Admit that in the event Andrx relinquished or otherwise compromised any rights accruing under ANDA 74-752 while the HMR/Andrx Stipulation and

Agreement was in effect: (1) the HMR/Andrx Stipulation and Agreement would terminate; (2) Andrx would not receive any further \$10 million payments from Hoechst; and (3) Andrx would be required to repay to Hoechst all payments made to Andrx by Hoechst under the HMR/Andrx Stipulation and Agreement.

**Request No. 69:** Admit that in the event Andrx relinquished or otherwise compromised its 180-day Exclusivity Period while the HMR/Andrx Stipulation and Agreement was in effect: (1) the HMR/Andrx Stipulation and Agreement would terminate; (2) Andrx would not receive any further \$10 million payments from Hoechst; and (3) Andrx would be required to repay to Hoechst all payments made to Andrx by Hoechst under the HMR/Andrx Stipulation and Agreement.

**Request No. 70:** Admit that under the HMR/Andrx Stipulation and Agreement, Hoechst granted Andrx an option to acquire a license to all intellectual property owned by Hoechst that Andrx would need to sell, market, and distribute a generic formulation of Cardizem CD in the United States (“Hoechst’s Intellectual Property”).

**Request No. 71:** Admit that under the HMR/Andrx Stipulation and Agreement, Andrx could not exercise its option to acquire a license to Hoechst’s Intellectual Property until after either: (1) eighteen months after final FDA approval of Andrx’s product – January 9, 2000; (2) 30 days after Hoechst provides notice to Andrx that it intended to license its intellectual property to another generic manufacturer or to market its version of generic Cardizem CD; or (3) if Andrx lost the HMR/Andrx Patent Infringement Litigation.

**Request No. 72:** Admit that under the HMR/Andrx Stipulation and Agreement, in the event that Andrx lost the HMR/Andrx Patent Infringement Litigation, Andrx could choose to exercise the option to acquire a license to Hoechst's Intellectual Property.

**Request No. 73:** Admit that under the HMR/Andrx Stipulation and Agreement, in the event that Andrx lost the HMR/Andrx Patent Infringement Suit, Andrx could choose not to exercise the option to acquire a license to Hoechst's Intellectual Property.

**Request No. 74:** Admit that under the HMR/Andrx Stipulation and Agreement, in the event that Andrx lost the HMR/Andrx Patent Infringement Suit and Andrx chose not to exercise the option to acquire a license to Hoechst's Intellectual Property, Andrx would keep all of the payments made to it by Hoechst.

**Request No. 75:** Admit that under Paragraph 4 of the HMR/Andrx Stipulation and Agreement, Hoechst agreed to pay Andrx \$10 million a quarter for the period from Andrx's receipt of final FDA approval for Andrx's Original Formulation through the duration of the HMR/Andrx Stipulation and Agreement.

**Request No. 76:** Admit that the quarterly payments from Hoechst to Andrx pursuant to Paragraph 4 of the HMR/Andrx Stipulation and Agreement began on the date Andrx received approval from the FDA to market Andrx's Original Formulation.

**Request No. 77:** Admit that Hoechst's payments to Andrx of \$10 million a quarter were to be made regardless of the outcome of the HMR/Andrx Patent Infringement Litigation.

**Request No. 78:** Admit that under the HMR/Andrx Stipulation and Agreement, Hoechst made a \$10 million payment to Andrx on July 9, 1998.

**Request No. 79:** Admit that under the HMR/Andrx Stipulation and Agreement, Hoechst made a \$10 million payment to Andrx on October 1, 1998.

**Request No. 80:** Admit that under the HMR/Andrx Stipulation and Agreement, Hoechst made a \$10 million payment to Andrx on January 4, 1999.

**Request No. 81:** Admit that under the HMR/Andrx Stipulation and Agreement, Hoechst made a \$10 million payment to Andrx on April 1, 1999.

**Request No. 82:** Admit that under the HMR/Andrx Stipulation and Agreement, in the event that Andrx lost the HMR/Andrx Patent Infringement Litigation, Andrx did not have to refund any of the \$10 million a quarter paid to it by Hoechst.

**Request No. 83:** Admit that under the HMR/Andrx Stipulation and Agreement, in the event that Andrx won the patent litigation, Hoechst would pay Andrx an additional \$60 million a year for the period from Andrx's receipt of final FDA approval for its Original Formulation through the duration of the HMR/Andrx Stipulation and Agreement.

**Request No. 84:** Admit that Hoechst did not file with the District Court a motion for a preliminary injunction in the HMR/Andrx Patent Infringement Action.

**Request No. 85:** Admit that the HMR/Andrx Stipulation and Agreement was not presented to the District Court for approval.

**Request No. 86:** Admit that the District Court did not approve the HMR/Andrx Stipulation and Agreement.

**Request No. 87:** Admit that the HMR/Andrx Stipulation and Agreement was not presented to any federal district court for approval.



**Request No. 88:** Admit that the HMR/Andrx Stipulation and Agreement was not approved by any federal district court.

**Request No. 89:** Admit that under the HMR/Andrx Stipulation and Agreement, Hoechst paid to Andrx approximately \$89.83 million.

**Request No. 90:** Admit that Andrx disclosed publicly in September 1997 that it had entered into the HMR/Andrx Stipulation and Agreement.

**Request No. 91:** Admit that Andrx did not disclose publicly in September 1997 the terms of the HMR/Andrx Stipulation and Agreement.

**Request No. 92:** Admit that Andrx did not disclose publicly in September 1997 the actual text of the HMR/Andrx Stipulation and Agreement.

**Request No. 93:** Admit that Andrx has never disclosed publicly the terms of the HMR/Andrx Stipulation and Agreement.

**Request No. 94:** Admit that Andrx has never disclosed publicly the actual text of the HMR/Andrx Stipulation and Agreement.

**Request No. 95:** Admit that during the time between the execution of the HMR/Andrx Stipulation and Agreement in September 1997, and the termination of the agreement in June 1999, Hoechst had net U.S. sales of roughly \$1.3 billion for Cardizem CD.

**Request No. 96:** Admit that at the time Andrx entered into the HMR/Andrx Stipulation and Agreement, Andrx believed that it would receive FDA approval for Andrx's Original Formulation upon expiration of the 30 month Hatch-Waxman waiting period in July 1998.

**Request No. 97:** Admit that at the time Andrx entered into the HMR/Andrx Stipulation and Agreement, Andrx believed that Faulding would receive tentative FDA approval of ANDA 75-984 prior to Final Judgement in the HMR/Andrx Patent Infringement Litigation.

**Request No. 98:** Admit that at the time Andrx entered into the HMR/Andrx Stipulation and Agreement, Andrx was uncertain as to whether or not Faulding would receive tentative FDA approval of ANDA 75-984 prior to Final Judgement in the HMR/Andrx Patent Infringement Litigation.

**Request No. 99:** Admit that at the time Andrx entered into the HMR/Andrx Stipulation and Agreement, Andrx believed that Biovail would receive tentative FDA approval to market a generic version of Cardizem CD prior to Final Judgement in the HMR/Andrx Patent Infringement Litigation.

**Request No. 100:** Admit that at the time Andrx entered into the HMR/Andrx Stipulation and Agreement, Andrx was uncertain as to whether or not Biovail would receive tentative FDA approval to market a generic version of Cardizem CD prior to Final Judgment in the HMR/Andrx Patent Infringement Litigation.

**Request No. 101:** Admit that Andrx took the position in its complaint in *Andrx v. Friedman*, Civ. No. 98-0099 (D.D.C.) that it was likely that the FDA would find Biovail's generic version of Cardizem CD approveable prior to Final Judgement in the HMR/Andrx Patent Infringement Litigation.

**Andrx's Reformulated Product**

**Request No. 102:** Admit that on June 8, 1999, Hoechst and Andrx entered into the HMR/Andrx Stipulation and Order.

**Request No. 103:** Admit that the HMR/Andrx Stipulation and Order terminated the HMR/Andrx Stipulation and Agreement.

**Request No. 104:** Admit that under the HMR/Andrx Stipulation and Order, Hoechst agreed that it would not institute or prosecute any action alleging patent infringement with respect to Andrx's Reformulated Product, so long as the Reformulated Product's SR2 beads release on average not less than 68% of the total amount of diltiazem after 18 hours when tested in the U.S. Pharmacopeia XXII Type 2 apparatus using 900 ml of 0.1 HCL at 37 degrees C and a paddle speed of 100 rpm.

**Request No. 105:** Admit that Hoechst has not initiated or prosecuted any action alleging patent infringement with respect to Andrx's Reformulated Product.

**Request No. 106:** Admit that Hoechst does not have a good faith basis for initiating or prosecuting a patent infringement action with respect to Andrx's Reformulated Product so long as Andrx's Reformulated Product's SR2 beads release on average not less than 68% of the total amount of diltiazem after 18 hours when tested in the U.S. Pharmacopeia XXII Type 2 apparatus using 900 ml of 0.1 HCL at 37 degrees C and a paddle speed of 100 rpm.

**Request No. 107:** Admit that in May 1999 Federal Trade Commission (FTC) staff discussed with Andrx an outline for a proposed consent order relating to the FTC's investigation of Hoechst and Andrx, FTC File No. 981-0368.

**Request No. 108:** Admit that Hoechst and Andrx reached an agreement in principle on the HMR/Andrx Stipulation and Order less than 3 weeks after the FTC staff discussed with Andrx an outline for a proposed consent order relating to the FTC's investigation of Hoechst and Andrx, FTC File No. 981-0368.

**Request No. 109:** Admit that the terms of the HMR/Andrx Stipulation and Order entered into by Hoechst and Andrx reflected at least some of the same terms proposed by the FTC's staff when the FTC staff discussed a proposed consent order relating to the FTC's investigation of Hoechst and Andrx, FTC File No. 981-0368.

**Request No. 110:** Admit that if Andrx and Hoechst had not entered into the HMR/Andrx Stipulation and Order, under the terms of the HMR/Andrx Stipulation and Agreement, Andrx would not have been permitted to commence the commercial sale of Andrx's Reformulated Product.

**Request No. 111:** Admit that if Andrx and Hoechst had not entered into the HMR/Andrx Stipulation and Order, under the terms of HMR/Andrx Stipulation and Agreement, Andrx would have had to repay Hoechst all amounts previously paid if it had commenced the commercial sale of Andrx's Reformulated Product.

**Request No. 112:** Admit that Hoechst's outside legal counsel James M. Spears believed that Hoechst and Andrx should enter into the HMR/Andrx Stipulation and Order because he understood that the FTC wanted the HMR/Andrx Stipulation and Agreement "ended in no uncertain terms."

## **Biovail**

**Request No. 113:** Admit that Biovail filed ANDA 75-1169 for a generic version of Cardizem CD on April 21, 1997.

**Request No. 114:** Admit that as part of ANDA 75-1169, Biovail submitted to the FDA a Paragraph IV Certification stating that its generic Cardizem CD product did not infringe the patents listed in the Orange Book for Cardizem CD.

**Request No. 115:** Admit that Hoechst did not sue Biovail for patent infringement concerning the generic Cardizem CD product that was the subject of Biovail's ANDA 75-1169.

## **Faulding**

**Request No. 116:** Admit that Faulding filed its application for a generic version of Cardizem CD, ANDA 75-984, on October 11, 1996.

**Request No. 117:** Admit that as part of ANDA 75-984, Faulding submitted to the FDA a Paragraph IV Certification stating that its generic Cardizem CD product did not infringe the patents listed in the Orange Book for Cardizem CD.

**Request No. 118:** Admit that on January 31, 1997, Hoechst filed a patent infringement action in the District of New Jersey, alleging that Faulding's generic product infringed U.S. Patent No. 5,439,689.

**Request No. 119:** Admit that the January 31, 1997 complaint filed by Hoechst against Faulding in the patent infringement action in the District of New Jersey did not allege that Faulding's generic product that is the subject of ANDA 75-984 infringed the '584 patent.

**Request No. 120:** Admit that Hoechst has not initiated or prosecuted a patent infringement claim alleging that Faulding's generic product that is the subject of ANDA 75-984 infringed the '584 patent.

**Request No. 121:** Admit that sales of Faulding's generic Cardizem CD product commenced on December 21, 1999.

**Calcium Channel Blocker Products**

**Request No. 122:** Admit that Cardizem CD was first sold in the United States in January 1992.

**Request No. 123:** Admit that Cardene SR was first sold in the United States in March 1992.

**Request No. 124:** Admit that Dilacor XR was first sold in the United States in June 1992.

**Request No. 125:** Admit that Norvasc was first sold in the United States in September 1992.

**Request No. 126:** Admit that Adalat CC was first sold in the United States in July 1993.

**Request No. 127:** Admit that Sular was first sold in the United States in January 1996.

**Request No. 128:** Admit that Tiazac was first sold in the United States in January 1996.

**Request No. 129:** Admit that Covera HS was first sold in the United States in May 1996.

**Request No. 130:** Admit that Dynacirc CR was first sold in the United States in December 1996.

**Request No. 131:** Admit that Verelan PM was first sold in the United States in March 1999.

**Other**

**Request No. 132:** Admit that on January 31, 1996, Hoechst and Carderm filed the HMR/Andrx Patent Infringement Litigation against Andrx in the Southern District of Florida.

**Request No. 133:** Admit that on April 4, 1996, Andrx filed with the FDA an amendment to its ANDA No. 74-752.

**Request No. 134:** Admit that Andrx's April 4, 1996 amendment to ANDA No. 74-752 added an additional dissolution specification for the SR2 beads which requires that each lot of the SR2 beads release not less than 55% of the total amount of diltiazem after 18 hours when tested in the U.S. Pharmacopeia XXII Type 2 apparatus using 900 ml of 0.1 HCL at 37 degrees C and a paddle speed of 100 rpm.

**Request No. 135:** Admit that on September 11, 1998, Andrx filed a supplement to its ANDA No. 74-752, which sought to add a small amount of a new ingredient to the SR2 bead coating and to change the dissolution specification for the SR2 bead to "not less than 65% of the total diltiazem after 18 hours."

**Request No. 136:** Admit that on October 7, 1998, Andrx notified Hoechst that it had filed a supplement to its approved ANDA No. 74-752.

**Request No. 137:** Admit that on January 8, 1999, Hoechst informed Andrx that FDA regulations required Andrx to provide Hoechst with a new Paragraph IV Certification that Andrx's Reformulated Product does not infringe the patents listed in the Orange Book for Cardizem CD.

**Request No. 138:** Admit that on January 19, 1999, Andrx informed Hoechst that it did not believe it was required to provide a new Paragraph IV Certification with respect to the Andrx's Reformulated Product.

**Request No. 139:** Admit that on January 15, 1999, Hoechst wrote to the FDA suggesting that Andrx was required to file a new Paragraph IV Certification for Andrx's Reformulated Product.

**Request No. 140:** Admit that on February 3, 1999, Andrx provided a Paragraph IV Certification to the FDA stating that Andrx's Reformulated Product did not infringe the patents listed in the Orange Book for Cardizem CD, including the '584 patent.

**Request No. 141:** Admit that Andrx purchases micronized diltiazem HCL API from Plantex USA, Inc.

**Request No. 142:** Admit that Andrx used micronized diltiazem HCL API in manufacturing Andrx's Original Formulation.

**Request No. 143:** Admit that Andrx uses micronized diltiazem HCL API in manufacturing Cartia XT.

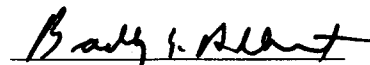


**Request No. 144:** Admit that Andrx advertising and promotional materials for Cartia XT explicitly mention Cardizem CD.

**Request No. 145:** Admit that Andrx advertising and promotional materials for Cartia XT do not explicitly mention any prescription drug other than Cardizem CD.

**Request No. 146:** Admit that Andrx is a corporation within the meaning of Section 4 of the Federal Trade Commission Act.

Respectfully Submitted,



Markus H. Meier  
Bradley S. Albert  
Robin Moore

Counsel Supporting the Complaint

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

Dated: September 25, 2000

## CERTIFICATE OF SERVICE

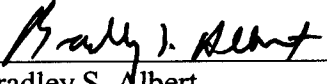
I, Bradley S. Albert, hereby certify that on September 25, 2000, I caused a copy of Complaint Counsel's First Requests for Admissions to Respondent Andrx Corporation to be served upon the following persons via facsimile and overnight delivery.

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Bradley S. Albert  
Counsel Supporting the Complaint