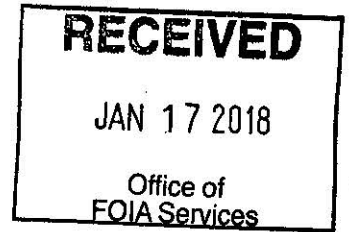


18-01985-E

January 17 2018

US Securities & Exchange Commission  
Office of FOIA and Privacy Act Operations  
100 F Street, NE Mail Stop 5100  
Washington, DC 20549-5100



Dear FOIA Office:

Under the Freedom of Information Act (FOIA), please send a copy of the following: **A copy of:**

**Exhibit: 10.84 to the form 10-Q filed by ANDRX CORP /DE/ on August 9, 2004** In the event confidential treatment has not expired provide the specific date for which confidential treatment is still in effect. I do not need a copy of the order. We authorize up to \$61.00 in processing fees.

Thank You,

**Paul D'Souza**  
Editor - Deals

**Clarivate Analytics** Friars House, 160 Blackfriars Road London, UK SE1 8EZ  
Phone: +44-2074334789  
[paul.dsouza@clarivate.com](mailto:paul.dsouza@clarivate.com)



UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
STATION PLACE  
100 F STREET, NE  
WASHINGTON, DC 20549-2465

Office of FOIA Services

January 23, 2018

Mr. Paul DSouza  
Clarivate Analytics  
160 Blackfriars Road  
London, 1U SE18EZ

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552  
Request No. 18-01985-E

Dear Mr. DSouza:

This letter is in response to your request, dated and received in this office on January 17, 2018, for information regarding Exhibit 10.84 to the form 10-Q filed by Andrx Corp /DE/ on August 9, 2004.

The search for responsive records has resulted in the retrieval of thirty three pages of records that may be responsive to your request. They are being provided to you with this letter.

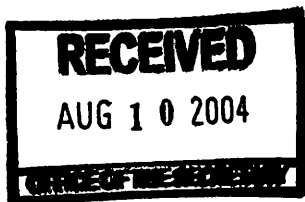
If you have any questions, please contact me at moodyd@sec.gov or (202) 551-8355. You may also contact me at [foiapa@sec.gov](mailto:foiapa@sec.gov) or (202) 551-7900. You also have the right to seek assistance from Aaron Taylor as a FOIA Public Liaison or contact the Office of Government Information Services (OGIS) for dispute resolution services. OGIS can be reached at 1-877-684-6448 or [Archives.gov](http://Archives.gov) or via e-mail at [ogis@nara.gov](mailto:ogis@nara.gov).

Sincerely,

A handwritten signature in cursive script that reads "Denise R. Moody".

Denise R. Moody  
FOIA Research Specialist

Enclosures



Supply and Distribution Agreement

THIS SUPPLY AND DISTRIBUTION AGREEMENT is effective as of the 24th day of November, 2003, between Pfizer Inc., a corporation organized and existing under the Laws of Delaware and having its principal office at 235 East 42<sup>nd</sup> Street, New York, New York 10017 (hereinafter referred to as "**Pfizer**") and Andrx Corporation, a corporation organized and existing under the Laws of Delaware and having its principal office at 2915 Weston Road, Weston, Florida 33331 (hereinafter called "**Distributor**").

WITNESSETH

WHEREAS, Pfizer and its Affiliates are seeking NDA Approval (as defined below) of the Product (as defined below);

WHEREAS, Pfizer wishes to appoint Distributor as its exclusive distributor for the Product in the United States of America, including its territories and possessions (hereinafter referred to as the "**Territory**"), and Distributor is willing to accept such appointment in accordance with and subject to the terms and conditions hereinafter appearing.

NOW, THEREFORE, in consideration of the premises and mutual covenants herein contained, the parties hereto agree as follows:

ARTICLE I  
DEFINITIONS

*Section 1.01. Definitions.* As used in this Agreement, the following capitalized terms shall have the following meanings:

"**Adjusted Detailing Requirement**" has the meaning set forth in *Section 7.01(c)*.

"**Adverse Drug Experience Report**" means any oral, written or electronically transmitted report of any "adverse drug experience" (as defined in the FD&C Act, including, but not limited to, 21 C.F.R. 314.80 or 312.32), associated with the use of doxazosin mesylate (including the Product).

"**ALZA**" has the meaning set forth in *Section 11.02(a)*.

"**ANDA**" means an "abbreviated new drug application" (as defined in Section 201(aa) of the FD&C Act).

"**Affiliate**" means any Person that directly or indirectly controls, is controlled by or is under common control with Pfizer or Distributor, as the case may be, but only for so long as said control shall continue. As used herein, the term "control" means possession of the power to direct or cause the direction of the management and policies of a Person whether by contract or

## CONFIDENTIAL TREATMENT

otherwise. For the avoidance of doubt, neither Pfizer, on the one hand, nor Distributor, on the other hand, shall be considered an Affiliate of the other.

“**CGMP**” means current good manufacturing practices as defined in Title 21 of the C.F.R. Parts 210 et seq., as amended from time to time.

“**Code**” means the Code on Interactions with Healthcare Professionals promulgated by the Pharmaceutical Research and Manufacturers of America (PhRMA), the American Medical Association Guidelines on Gifts to Physicians and the Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers, as any of the foregoing may be amended from time to time.

“**Commercially Reasonable Efforts**” means the efforts that a party shall use in carrying out its obligations under this Agreement, which efforts, except as provided herein, shall be the same as those efforts a party would use with respect to its own pharmaceutical products which are of similar importance to the Products taking into account market potential, past performance, economic return and competitive market conditions in the therapeutic area, all as measured by the facts and circumstances at the time such efforts are due.

“**COA**” has the meaning set forth in Section 9.08(a).

“**Competing Product**” has the meaning set forth in Section 2.02(a).

“**Confidential Information**” means, with respect to any party (the “disclosing party”), any information relating to the disclosing party, the Product or the disclosing party’s business (including, but not limited, to technical information, research, personnel, financial, marketing, strategic or other information) that is disclosed in writing to the other party (“receiving party”) in the course of the parties’ negotiation of or performance under this Agreement (it being understood that if any information is disclosed verbally, in order for that information to be considered “Confidential Information,” the disclosing party must notify the receiving party in writing that the information is “Confidential Information” within thirty (30) days after disclosure), but shall not include information that: (a) the receiving party knew, owned or controlled prior to receipt from the disclosing party; (b) is or becomes public through no fault of the receiving party or any Affiliate thereof; (c) is developed by the receiving party independent of any disclosure from the disclosing party or (d) the receiving party obtains from a third party not under a confidentiality obligation to the disclosing party.

“**Contract Year**” means each twelve (12) month-period commencing on the date of NDA Approval and each anniversary of the date of NDA Approval.

“**Covered Activity**” has the meaning set forth in Section 10.03(c)(i).

“**DDMAC**” has the meaning set forth in *Section 9.02*.

“**Distributor**” has the meaning set forth in the recitals hereto.

“**Distributor Logo**” has the meaning set forth in *Section 11.01(b)*.

## CONFIDENTIAL TREATMENT

“**FD&C Act**” has the meaning set forth in *Section 7.03(g)*:

“**FDA**” has the meaning set forth in *Section 7.03(g)*.

“**Firm Order**” means a firm, binding, written order for Product, specifying quantities and delivery schedules. Firm Orders must be in full lot size quantities as described in Exhibit A, provided, however, if FDA permits printing on 4mg and 8mg Systems that is identical to the printing permitted on 4mg and 8mg Systems outside the Territory, Launch Date Firm Order and the Firm Orders submitted during the first six (6) months after launch may be in half lot sizes for 4mg and/or 8mg Systems.

“**Force Majeure**” means any event beyond the reasonable control of a party or its Affiliates and whose effect such Person could not reasonably have avoided, including, but not limited to, acts of God, fires, floods, wars, acts of terrorism, sabotage, strike, change of Laws. Any party asserting its inability to perform any obligation hereunder for any such contingency shall promptly notify the other party of the existence of such contingency and shall use Commercially Reasonable Efforts to commence its performance of such obligation as soon as commercially practicable.

“**Governmental or Regulatory Authority**” means any court, tribunal, arbitrator, agency, commission, official or other instrumentality of any federal, state, county, city or other political subdivision, domestic or foreign, including, but not limited to, the FDA.

“**Indemnified Party**” has the meaning set forth in *Section 15.04*.

“**Indemnifying Party**” has the meaning set forth in *Section 15.04*.

“**Independent Accountant**” has the meaning set forth in *Section 6.01*.

“**Indirect Losses**” means any damages or other losses involving, but only to the extent of, any loss of profits, diminution in value, or incidental, indirect, consequential, special or punitive damages.

“**Laws**” means all laws, statutes, rules, regulations, ordinances, Codes, and other pronouncements having the effect of law of any government or Governmental or Regulatory Authority.

“**Losses**” means any and all claims, liabilities, losses, damages, fees, penalties, judgments, awards, interest, costs and expenses (including, but not limited to, reasonable attorneys’ fees and expenses) owed directly to either party to this Agreement or any Affiliate thereof. Notwithstanding the foregoing, Losses shall not include Indirect Losses.

“**Marketing Plan**” has the meaning set forth in *Section 7.02(a)*.

“**Minimum Detailing Requirement**” has the meaning set forth in *Section 7.01(a)*.

“**MSDS**” has the meaning set forth in *Section 9.08(a)*.

## CONFIDENTIAL TREATMENT

“**NDA**” means Pfizer’s FDA New Drug Application 21-269 and any supplements thereto.

“**NDA Approval**” means Pfizer’s receipt of FDA approval of the NDA with manufacturing specifications either (i) the same as will be provided in Pfizer’s response to the FDA regarding the NDA or (ii) otherwise acceptable to Pfizer as determined in its sole discretion, provided that Pfizer gives Distributor notice of such acceptance within thirty (30) days of receipt of such FDA final marketing approval (in which case NDA Approval shall be deemed to be received at the time of Pfizer giving such notice).

“**Net Sales**” means the aggregate gross sales of the Product by Distributor and its Affiliates in the Territory when received by customer, *minus*: (i) trade, quantity and cash discounts actually taken or accrued; (ii) excise and sales taxes paid or accrued; and (iii) amounts for rejections, rebates and chargebacks actually taken, allowed or accrued, all as determined in accordance with Distributor’s books and records, which are maintained under U.S. generally accepted accounting principles. Notwithstanding anything herein to the contrary, returns shall not decrease Net Sales, and the costs of any returns shall be for the account of Distributor.

“**PDMA**” has the meaning set forth in Section 3.08(c).

“**Per System Fee**” has the meaning set forth in *Section 5.03*.

“**Person**” means any natural person, corporation, partnership, joint venture, trust, proprietorship or other entity or organization.

“**Pfizer**” has the meaning set forth in the recitals hereto.

“**Proceedings**” means claims, suits, actions, investigations or proceedings.

“**Product**” means prescription pharmaceutical forms (4mg and 8mg) of Cardura® XL (doxazosin mesylate) extended release tablets.

“**Product Liability Claim**” shall mean any third party Proceedings involving any actual or alleged death or bodily injury arising out of or resulting from the use of the Product sold in the Territory.

“**Promotional Materials**” has the meaning set forth in *Section 7.03(a)*.

“**Serious Adverse Drug Experience Report**” means any Adverse Drug Experience Report that involves an adverse drug experience or any other event which would constitute a “serious” adverse drug experience under the FD&C Act, including, but not limited to, 21 C.F.R 314.80 or 312.32.

“**Shortfall Contract Year**” has the meaning set forth in Section 7.01(c).

“**Shortfall Details**” has the meaning set forth in Section 7.01(c).

## CONFIDENTIAL TREATMENT

“**Specifications**” shall mean all product, regulatory, manufacturing, quality control and quality assurance procedures, processes, standard instructions and specifications comprising the NDA Approval.

“**State**” has the meaning set forth in *Section 7.03(c)*.

“**Supply Failure Notice**” shall have the meaning set forth in Section 3.05(b).

“**System**” shall mean a 4mg or 8mg extended-release tablet of the Product.

“**Term**” has the meaning set forth in *Section 13.01*.

“**Territory**” has the meaning set forth in the recitals hereto.

“**Trademark**” has the meaning set forth in *Section 11.01(a)*.

### ARTICLE II APPOINTMENT - EXCLUSIVE DISTRIBUTOR

*Section 2.01. Appointment.* Pfizer hereby appoints Distributor as its exclusive Distributor in the Territory during the Term of this Agreement to buy and resell for Distributor’s own account, to solicit orders for, to distribute, detail and promote the Product. Distributor hereby accepts such appointment in accordance with the terms of this Agreement.

*Section 2.02.* (a) Pfizer shall notify Distributor upon the receipt of any notice of (i) an AB rated ANDA for a Cardura® XL product or (ii) an application described in Section 505(b)(2) of the FD&C Act for a doxazosin mesylate extended release product relating to Cardura® XL (in either case, a “Competing Product”). Thereafter, the parties shall jointly monitor the FDA approval process for the Competing Product(s). Prior to the anticipated date of FDA approval of a Competing Product, Pfizer shall determine if it desires to have its Product compete in the Territory with the Competing Product as a generic or other non-branded product in the Territory, and shall notify Distributor, in writing, of such determination. Except as set forth in Section 2.02(b) below, if Pfizer desires to have the Product sold as a generic or non-branded doxazosin mesylate extended release product in the Territory, Pfizer will agree to allow Distributor to become Pfizer’s exclusive distributor for Pfizer’s generic or non-branded product in the Territory (the “Option”) on terms substantially similar to those set forth in the form of the Agreement attached hereto as Exhibit B, which will allow Distributor to launch such Product into the Territory either simultaneously with or shortly after the launch of the Competing Product, and provides for a transfer price to be paid to Pfizer of sixty-seven and one-half percent (67-½%) of net sales (as such term is to be defined in the generic agreement) for an initial term of three (3) years. The Option may be exercised and accepted by Distributor by providing Pfizer with written notice of such exercise and acceptance, together with an executed counterpart of the signature page to the form of Agreement attached hereto as Exhibit B, within ten (10) days of the date of its receipt of Pfizer’s Option notice to Distributor pursuant to the preceding sentence. If such documents are not received by Pfizer within such time period, then the Option shall be deemed to have not been exercised and accepted and shall lapse at the expiration of such time period.

## CONFIDENTIAL TREATMENT

(b) Notwithstanding the provisions of subsection (a) above, Distributor shall not have the Option described in subsection (a) above if (x) a Person files an application for a Competing Product and (y) ALZA or Pfizer, in its sole discretion, brings a Proceeding against such Person and resolves such Proceeding by, among other things, granting to such Person the exclusive right to sell and distribute Pfizer's non-branded doxazosin mesylate extended release product in the Territory.

### ARTICLE III ORDERS AND MANUFACTURE OF PRODUCT

*Section 3.01. Orders and Terms of Sale.* Distributor and its Affiliates shall have the sole and exclusive right and authority to: (i) receive, accept and fill orders for the Product; (ii) control invoicing, order processing and collection of accounts receivable for Product sales; (iii) record Product sales in their books of account; (iv) establish and modify the commercial terms and conditions with respect to the sale and distribution of the Product, including the price at which the Product will be sold and whether any discounts, rebates or other deductions should be made, paid or allowed; and (v) enter into discount or rebate contracts for the Product with managed care entities (including PBMs, HMOs and other managed care businesses) or other purchasers or reimbursers of the Product, in each case subject to applicable Laws.

*Section 3.02. Misdirected Orders.* If, for any reason, Pfizer receives written orders for the purchase of the Product in the Territory, Pfizer shall forward such orders to Distributor as soon as practicable.

#### *Section 3.03. Manufacturing and Forecasts.*

(a) Pfizer and its Affiliates shall have the sole and exclusive authority and responsibility for the manufacture of the Product. Distributor shall not be permitted to manufacture, nor shall it acquire any rights to any know-how or technical information with respect to the manufacture, of the Product.

(b) Pfizer will provide to Distributor quantities of 4mg and 8mg Systems of Product (both commercial quantities and samples) set forth as the "Launch Date Firm Order" in Exhibit A as soon as practicable following the date of the NDA Approval. In addition, Distributor's first two (2)-year rolling forecast of orders for 4mg and 8mg Systems (both commercial quantities and samples) also is set forth in Exhibit A. On or before three (3) months prior to the start of each calendar quarter, Distributor shall provide to Pfizer a rolling quarterly forecast of its anticipated 4mg and 8mg Product requirements for the following two (2) Contract Years. In addition, at least three (3) months prior to the start of each calendar quarter, Distributor will provide Pfizer with a Firm Order for each of the 4mg and 8mg Systems of Product for such quarter (listing separately commercial quantities and samples), which must be no less than 85% (subject to the minimum purchase amounts below), or greater than 115% of the amount forecast in the most recent prior rolling forecast. Notwithstanding the foregoing, Distributor shall not be required to meet these requirements for the calendar quarter immediately following the calendar quarter in which a Competing Product enters the market.

## CONFIDENTIAL TREATMENT

(c) Distributor shall purchase hereunder the following minimum aggregate commercial quantities of 4mg and 8mg Systems of Product in each Contract Year:

1st Contract Year:	28.2 million
2nd Contract Year:	73.4 million
3rd Contract Year:	102.0 million

If in any Contract Year Distributor orders at least the minimum aggregate commercial quantities for such year as set forth above and Pfizer fails to deliver such minimum aggregate commercial quantities, Distributor shall be relieved of its obligation in such Contract Year solely to the extent by which Pfizer's deliveries are less than such minimum aggregate commercial quantities. In addition, if (x) a Person files an application for a Competing Product and (y) ALZA or Pfizer, in its sole discretion, brings a Proceeding against such Person and resolves such Proceeding by, among other things, granting to such Person the exclusive right to sell and distribute Pfizer's non-branded doxazosin mesylate extended release product in the Territory prior to the end of the 3rd Contract Year and (z) such Person commences commercial sales of the Competing Product prior to the end of the 3rd Contract Year, then Distributor shall be relieved of its minimum purchase obligations on a pro rata basis for the Contract Year which the commercial sale of the Competing Product commences and for all subsequent Contract Years.

*Section 3.04. Acceptance of Orders.* Distributor shall submit Firm Orders to Pfizer against the forecasts via facsimile transmission or e-mail, and Pfizer shall confirm all of Distributor's Firm Orders by facsimile transmission or e-mail within seven (7) days after receipt of such Firm Orders.

*Section 3.05. Supply Obligations.* (a) All of Pfizer's obligations to supply quantities of the Product pursuant to *Section 3.03* shall be contingent upon its receipt of NDA Approval. Thereafter, notwithstanding anything herein to the contrary, Pfizer shall use its Commercially Reasonable Efforts to supply the Product, having expiration dating of at least eighteen (18) months at the time of delivery to Distributor, in sufficient quantities to meet all demands for the Product in the Territory in accordance with the then current Firm Order and the procedures set forth in *Section 3.03*.

(b) Pfizer shall deliver Product to Distributor pursuant to Purchase Orders no later than ten (10) days after Distributor's requested delivery dates. Pfizer shall promptly notify Distributor in writing if for any reason Pfizer has reason to believe that it will be unable to supply on a timely basis (in accordance with Pfizer's normal and customary practices) the quantities of Product ordered pursuant to *Section 3.03* above (a "Supply Failure Notice").

(c) If Pfizer has delivered a Supply Failure Notice to Distributor pursuant to subsection (b), then Pfizer will as soon as practicable after the delivery of the Supply Failure Notice, supply Distributor pursuant to the provisions of the following sentence until such time Pfizer is once again capable of supplying the quantities of Product ordered by Distributor. Unless such supply failure principally results from Force Majeure, raw material unavailability or product recall, during the period Pfizer is incapable of supplying all of Distributor's requirements for the Product, the amount of Product to be delivered to Distributor will be at least equal to the product of (x) and (y), with (x) being all of Pfizer's output of its branded and generic extended-

release doxazosin mesylate pharmaceutical product at its Brooklyn, New York manufacturing plant during such time (and/or at any other facility at which Pfizer, in its discretion, manufactures such products) and (y) being a fraction, the numerator of which shall be the forward twelve months rolling forecast for the period beginning on the date Distributor received the Supply Failure Notice and the denominator of which is the aggregate number of units of its branded and generic extended-release doxazosin mesylate pharmaceutical product forecasted to be produced by Pfizer for consumption on a worldwide basis during that same twelve (12) month period.

(d) If, as a result of Pfizer's failure to fill one or more Firm Orders for a continued period of ninety (90) days or more past a scheduled delivery date(s) -- unless such supply failure principally results from Force Majeure, raw material unavailability or product recall -- there is a "stock out" of the Product at the wholesaler level, as evidenced by contemporaneous backorders from all three (3) major wholesalers (Cardinal Health, Inc., McKesson Corporation, AmerisourceBergen Corporation and their successors), the Per System Fee shall be reduced to \$0.55 for the quantities of Product covered by such Firm Orders and delivered by Pfizer subsequent to ninety (90) days following the scheduled delivery date. Additionally, Pfizer acknowledges that in connection with such a supply failure, it may be necessary to replenish sample forecasts. Notwithstanding the foregoing, Distributor will not be entitled to the benefits of this Section 3.05(d) if, at the time it placed the first Firm Order which was not filled during any applicable period, it was not in compliance with the provisions of Section 5.04. If, following Pfizer's failure to supply Product, Distributor receives backorders from any of the three major wholesalers, Distributor promptly shall so inform Pfizer in writing and, in connection therewith, also certify in writing as to its compliance with Section 5.04 as set forth in this subsection (d).

(e) For the avoidance of doubt, it is understood that Pfizer's obligations to expend its Commercially Reasonable Efforts pursuant to Section 3.05(a) shall not require Pfizer to expand manufacturing capacity at its plant in Brooklyn, New York (where the Product is to be manufactured), materially interfere with its existing commitments to third parties to produce products at its plant in Brooklyn, New York, nor to license, contract or otherwise arrange for any other plants to manufacture the Product.

(f) Except as set forth in Section 3.05(d), Distributor's sole remedy in the event Pfizer fails to supply Product in accordance with Firm Orders furnished to Pfizer in accordance with the terms of this Agreement shall be to bring suit to recover its Losses in the event of a breach of Section 3.05(c) (if and to the extent Pfizer fails to comply with its obligations thereunder and Distributor is damaged by reason of its resulting inability and failure to fill bona fide customer orders). Distributor hereby waives any and all other claims (including, without limitation, claims of breach of contract) and remedies (including the remedy of termination of this Agreement) that it might otherwise have available to it upon Pfizer's failure to supply the quantities of Product ordered by Distributor hereunder on a timely basis.

*Section 3.06. Delivery and Title.* Each shipment of Product will be shipped to a single destination designated by Distributor. Title and risk of loss or damage to Product for each shipment shall pass from Pfizer to Distributor at the shipping dock at Pfizer's plant in Brooklyn, New York, F.O.B.

## CONFIDENTIAL TREATMENT

*Section 3.07. Manufacture in Compliance with Specifications.* Pfizer will manufacture, package, label, store and ship the Product in accordance with the Specifications set forth in the NDA as such NDA may be amended from time to time and, as to tablet printing designation and label copy, in accordance with Distributor's reasonable instructions to Pfizer. Pfizer shall promptly advise Distributor of any new instructions or specifications required by the FDA or the FFDCa. In the event Pfizer cannot reasonably manufacture Product in accordance with Distributor's instructions and the Specifications, Pfizer shall so advise Distributor.

*Section 3.08. Samples.* (a) Following launch of the Product and in support of Distributor's promotional activities hereunder, Pfizer shall provide Distributor with Product samples as set forth in Section 3.03 above.

(b) The price for each Product sample initially shall be \$0.15 per System. The price of Product samples shall be adjusted effective as of each January 1st following NDA Approval by such percentage increase in the Producer Price Index as published by the United States Department of Labor, Bureau of Labor Statistics (the "PPI") over the immediately preceding 12 month period. The price adjustment under this Section 3.08(b) shall be notified to Distributor not later than June 30th of each year and shall be retroactively effective to January 1st of that same year and shall apply to all firm orders for samples received on or after said January 1st. In the event that Pfizer fails to provide notice of any PPI increase by June 30th of a given year, any such increase shall only be effective as of the date such notice is actually given and shall only apply to Firm Orders received on or after such date. If the PPI is not available for any period, the most similar available index shall be used.

(c) Distributor shall store and distribute samples in full compliance, and otherwise fully comply, with all applicable Laws, including the requirements of the Prescription Drug Marketing Act of 1987, as amended (the "PDMA"). Distributor will maintain those records required by the PDMA and all other Laws with respect to the Product samples. Distributor shall be responsible for the filing of any necessary reports to FDA in connection with the PDMA with respect to the samples allocated to it. Section 3.06 shall be applicable to samples.

### ARTICLE IV THIRD PARTY OFFERS OR RE-SALE OUTSIDE THE TERRITORY

*Section 4.01. Third Party Offers.* Distributor shall purchase the Product only from Pfizer or Pfizer's Affiliates and shall report to Pfizer any offers by third parties to supply the Product or any other pharmaceutical products purporting to be products of Pfizer to Distributor for sale in the Territory or elsewhere.

*Section 4.02. Resale Outside the Territory.* Distributor shall not solicit orders for, nor resell, distribute or promote the Product outside of the Territory or to any purchaser or distributee that Distributor anticipates, or reasonably should anticipate, intends to utilize, resell, distribute or promote the Product outside the Territory.

*Section 4.03. Indemnification.* Distributor shall indemnify Pfizer and its Affiliates from and against any and all Losses arising from the re-sale of the Product outside the Territory or re-export of the Product from the Territory.

# CONFIDENTIAL TREATMENT

## ARTICLE V TERMS OF PAYMENT

*Section 5.01. Up Front Fee.* Distributor shall pay Pfizer an up-front, non-creditable fee of ten million dollars (\$10,000,000) on the date hereof, which will be refunded only if this Agreement is terminated by Pfizer pursuant to *Section 13.02(a)* or Distributor pursuant to *Section 13.03(a)*.

*Section 5.02. NDA Approval Fee.* Distributor shall pay Pfizer a non-creditable fee of twenty-five million dollars (\$25,000,000) within thirty (30) days of Distributor receiving notice from Pfizer that it has received NDA Approval, provided that the approved Product meets all or substantially all of the criteria for each claim set forth on Attachment I hereto and Pfizer complies with all conditions associated with NDA Approval. The twenty-five million dollar (\$25,000,000) fee will be nonrefundable.

*Section 5.03. Per System Fee.* (a) The Per System Fee shall be equal to \$0.75 per 4mg and 8mg System for commercial sale by Distributor and \$0.15 per 4mg and 8mg System to be used by Distributor as samples. Payment will be due and owing by Distributor within one hundred thirty-five (135) days after the date of invoice with respect to the first delivery of Product made pursuant to the Launch Date Firm Order and all other deliveries of Product made within sixty (60) days after such first delivery. Payments will be due and owing within one hundred twenty (120) days after the date of invoice in respect of all subsequent deliveries of Product (i.e., in respect of all deliveries of Product scheduled to be made subsequent to the 60th day after the initial delivery of Product). The Per System Fee shall be adjusted pursuant to Section 7.01(c).

(b) In the event that the quotient obtained by dividing Net Sales by the number of commercial Systems sold (the “**Net Sales Per System**”) in any calendar quarter experiences an independently verifiable decrease of at least twenty-five percent (25%) from the previous calendar quarter as a result of Extraordinary Market Events (as hereinafter defined), the parties shall in good faith attempt to determine a new reduced Per System Fee for the Products available for commercial sale. In the absence of such agreement, the Per System Fee, effective as of the start of the calendar quarter following which the Net Sales Per System experienced the requisite decrease, shall be reduced by a percentage equal to the Net Sales Per System percentage decreases from the previous calendar quarter as a result of the Extraordinary Market Events. Extraordinary Market Events shall be limited to (i) reductions (in a calendar quarter from the previous calendar quarter) in the Federal Supply Schedule (FSS) (or any successor schedule that will reflect the effective price paid for brand pharmaceuticals by governmental programs taking into account the manufacturer rebates received by States and/or other governmental entities) of each of the five (5) (or if there is not five (5) such products, such lower number) highest selling branded products (by volume) at such time (excluding the Product), indicated for benign prostatic hyperplasia (BPH), and/or (ii) governmentally required changes in the rebates, discounts, allowances, reimbursements or other changes, such as price controls, in the manner in which pharmaceutical products are presently sold to customers, including but not limited to the broader non-state or federal markets or the amounts required to be paid to state and/or other governmental agencies, such as the Department of Veteran Affairs. The reduction of twenty-five percent (25%) in the Net Sales Per System to Distributor may result from either (i) or (ii) or a

## CONFIDENTIAL TREATMENT

combination of (i) and (ii) in such quarter from the previous calendar quarter, provided however, that if the cause of the price reduction is reflected in both (i) and (ii), only one of such reductions shall be included when determining whether the twenty five percent (25%) threshold has been met. Published sources such as the FSS or the Medicaid Rebate Net Price program (in the case of clause (ii)) or data generated by third party vendors such as IMS Health or NDC Health (in the case of clause (i)), may serve as an independently verifiable source. Distributor may so exercise its right to a price reduction pursuant to this subsection (b) no more than once during the Term. If there is a reduction of the Per System Fee pursuant to this subsection (b) and there are subsequent increases in the Net Sales Per System received by Distributor during the Term, then the Per System Fee shall be proportionately increased upon each subsequent increase in Net Sales Per System, but not above \$0.75 per System, subject to increase pursuant to the provisions of Section 7.01(c).

(c) In the event Distributor believes that the provisions of this subsection (b) are applicable, it will promptly inform Pfizer in writing of its belief and furnish Pfizer calculations of the Net Sales Per System for the applicable calendar quarters, along with copies of the published sources which support such belief. In addition, following any reduction of the Per System Fee pursuant to this subsection (b), Distributor shall promptly notify Pfizer of any subsequent increase in the amount it charges Per System during the Term.

*Section 5.04. Minimum Inventory.* During the Term, at all times from and after the date of the initial delivery to be made pursuant to the Launch Date Firm Order, Distributor will keep on hand inventories of the Product that will be sufficient to meet two (2) months demand from customers for the Product based upon Distributor's good faith estimates of future sales. At the end of each calendar month, Distributor will determine and provide Pfizer with the quantities of each system of the Product sold by Distributor during such calendar month. Additionally, Distributor will provide Pfizer with ending inventory quantities at the end of each calendar month. Such information will be set forth in a report furnished by the Distributor to Pfizer within forty-five (45) days after each calendar month.

*Section 5.05. Manner of Payments.* All sums due under this Agreement shall be payable in United States dollars by bank wire transfer of immediately available funds to such bank account(s) as Pfizer shall designate.

*Section 5.06. Interest on Late Payments.* If Distributor shall fail to make a timely payment pursuant to this *ARTICLE V*, interest shall accrue on the past due amount at a rate equal to the prime rate effective for the date such payment is due, as published in the Wall Street Journal, +2% effective for the first date on which the payment was delinquent for up to thirty (30) days such payment is delinquent, then +4% thereafter, and calculated through and including the date of payment on the basis of 360-day years.

## ARTICLE VI RECORDS AND AUDIT RIGHTS

## CONFIDENTIAL TREATMENT

*Section 6.01.* For each Contract Year, Distributor shall keep such records of details as are necessary to determine accurately the number of details performed by Distributor pursuant to *Section 7.01* below. Such records shall be retained by Distributor and shall be made available only for inspection, review and audit, at any time during the applicable Contract Year and for three years thereafter, at the request and, except as provided below, expense of Pfizer, by a nationally recognized independent certified public accountant with expertise in the pharmaceutical industry that is selected by Pfizer and reasonably acceptable to Distributor (the “**Independent Accountant**”) for the sole purpose of verifying the number of details performed by Distributor pursuant to this Agreement. Distributor acknowledges and agrees that KPMG is suitable to serve as the Independent Accountant. Such audits may not be performed more than twice per Contract Year. The Independent Accountant shall not reveal to Pfizer the details of such review, except for such information as is required to be disclosed under this Agreement, and shall be subject to confidentiality obligations consistent with the provisions of *Section 14.01* hereof. The Independent Accountant shall prepare a report of its findings and conclusions, which report shall be final and binding on the parties hereto. All costs and expenses related to such audit shall be borne by Pfizer; *provided* that if the number of details performed by Distributor varies by 5% or more than the number reported by Distributor, Distributor shall pay such costs and expenses within forty-five (45) days after it receives an invoice from Pfizer regarding the same.

### ARTICLE VII PROMOTIONAL ACTIVITIES AND MATERIALS

*Section 7.01. Marketing, Promotional and Detailing Efforts.*

(a) Distributor shall deploy such of its sales forces and other resources to market, promote and detail the Product in the Territory in accordance with the terms of this Agreement and the then current Marketing Plan. In conducting such marketing, promotion and detailing, Distributor shall use its reasonable commercial efforts and diligence, consistent with accepted pharmaceutical industry business practices and in compliance with all applicable Laws. Distributor shall perform a minimum of 500,000 self-reported details per Contract Year (or proportional amount thereof in the event of a partial Contract Year) (the “Minimum Detailing Requirement”). Notwithstanding the preceding sentence, if Pfizer fails to supply Product ordered by Distributor in accordance with the provisions of this Agreement and such failure makes it not commercially feasible for Distributor to fulfill the Minimum Detailing Requirement, then Distributor shall be relieved of its obligation during the period of the supply failure solely to the extent of the number of details below the Minimum Detailing Requirement that Distributor was not able to perform by reason of Pfizer’s failure to supply. In addition, Distributor’s obligation to perform the Minimum Detailing Requirement shall be suspended for Contract Years beginning after the date of launch of a Competing Product (with Distributor’s obligation for the Contract Year in which such launch occurs pro rated pursuant to the provisions above). All details performed by or on behalf of Distributor hereunder shall be performed by Distributor’s own sales representatives, and Distributor shall not use any contract sales force for such purpose unless approved by Pfizer in advance.

## CONFIDENTIAL TREATMENT

(b) Distributor shall bear all of the costs and expenses incurred in connection with its marketing, promotional and detailing efforts, including, but not limited to, the costs and expenses of its sales representatives.

(c) In the event in any Contract Year (a "Shortfall Contract Year"), Distributor performs less than 100% of its Minimum Detailing Requirement, Distributor shall be required to perform a number of details in addition to the Minimum Detailing Requirement during the following Contract Year equal to the shortfall of details in such Shortfall Contract Year (such details, "Shortfall Details"; and such requirement equal to the Minimum Detailing Requirement plus the Shortfall Details, the "Adjusted Detailing Requirement"). In the event that in the Contract Year following a Shortfall Contract Year the Distributor performs less than 100% of the Adjusted Detailing Requirement, the Per System Fee, beginning as a retroactive adjustment for such following Contract Year and carrying forward for the remainder of the Term of this Agreement, shall be increased by a percentage equal to one minus a fraction multiplied by 100, where the numerator is the actual number of details performed in such following Contract Year and the denominator is the Adjusted Detailing Requirement in such following Contract Year, provided, however, that the percentage increase in respect of any one Contract Year may not exceed 10%. The Per System Fee may be increased, on a cumulative basis, in accordance with the above process as many times as Distributor fails to perform 100% of the Adjusted Detailing Requirement. In the event that in any Contract Year Distributor performs less than 90% of its Minimum Detailing Requirement or Adjusted Detailing Requirement (as the case may be), Distributor shall be in material breach of this Agreement entitling Pfizer to exercise its right of termination pursuant to Section 13.02(f) (for these purposes, the thirty (30)-day notice and cure period set forth in such Section 13.02(f) shall not be applicable).

### *Section 7.02. Marketing Plans.*

(a) Distributor shall be responsible for developing a comprehensive and detailed annual plan and budget for the marketing, promotion and detailing of the Product in the Territory (the "**Marketing Plan**") for each Contract Year. Distributor's initial draft Marketing Plan for the first Contract Year is attached hereto as Exhibit C, and subsequent Marketing Plans shall be submitted by the Distributor to Pfizer no later than February 28, 2004 for the first Contract Year, and no later than sixty (60) days prior to the start of each subsequent calendar year. Pfizer shall have the right to comment on the Marketing Plan, and Distributor shall make changes to such plan as may be reasonably requested by Pfizer.

(b) Subject to the provisions of this Agreement, each Marketing Plan shall describe in reasonable detail how the Product is to be promoted and detailed in the Territory during the Contract Year to which that Marketing Plan relates and shall consist of:

- (i) a situation and competitive analysis;
- (ii) a discussion of key growth drivers for the Product;
- (iii) sales and unit forecast for the coming Contract Year;
- (iv) specific detailing and promotional strategies related to the Product;
- (v) the number of details to be performed, subject to the Minimum Detailing Requirement;
- (vi) the positioning of the Product;

## CONFIDENTIAL TREATMENT

- (vii) the promotional, advertising and educational programs to be undertaken by the Distributor;
- (viii) the number of sales representatives and field force allocation;
- (ix) the targeting of physicians and institutions;
- (x) the training programs to be conducted; and
- (xi) the marketing expense and medical education budget.

### *Section 7.03. Marketing, Advertising, Promotional and Educational Materials.*

(a) Distributor shall create and develop marketing, advertising, promotional, educational and communication materials for the Product for distribution to third parties (including medical professionals) and to Distributor's sales force (the "**Promotional Materials**") consistent with the terms of the final Marketing Plans.

(b) Subject to the terms of this Section and *Section 11.01*, Distributor shall own all right, title and interest in and to any Promotional Materials, including all applicable copyrights and trademarks. Distributor hereby grants Pfizer a non-exclusive, perpetual royalty-free license, with the right to sublicense to its Affiliates, to display, reproduce, distribute and use Distributor's Promotional Materials outside the Territory, subject to applicable Laws.

(c) Distributor shall be responsible for filing and maintaining all documentation and other information as required by each and every state and locality ("**State**") for the purpose of listing the Product on each State's formulary or other similar authority, and for obtaining such other approvals as may be necessary to sell the Product in the Territory, at its expense. Distributor will pay Medicaid and other applicable rebates required by Laws or contract.

(d) Distributor shall bear all costs and expenses incurred in connection with creating, producing, distributing, publishing and otherwise using the Promotional Materials.

(e) Distributor covenants that no claims or representations in respect of the Product or doxazosin mesylate or the characteristics thereof shall be made by or on behalf of it (by members of its sales force or otherwise) that do not comply with FDA-approved labeling of the Product or that are not otherwise in compliance with all applicable Laws and will not take any action that, in the reasonable opinion of Pfizer, either dilutes the Cardura® XL trademark or may cause damage to Pfizer's sale of doxazosin mesylate (including the Product) outside the Territory or to Pfizer's reputation, and Pfizer shall have the reasonable right to require that Distributor withdraw or change any Promotional Materials if any of the foregoing claims or representations are made or actions are taken.

(f) During the Term, Pfizer will not sponsor exhibits or booths at meetings and symposia directed at promotion of the Product in the Territory. Distributor will not sponsor exhibits or booths at meetings and symposia directed at promotion of the Product outside the Territory. To the extent Pfizer sponsors booths or symposia within the Territory directed at activities outside of the Territory and Distributor sponsors booths or symposia outside the Territory directed at activities within the Territory, the parties agree to meet in good faith to coordinate potential overlapping activities.

## CONFIDENTIAL TREATMENT

(g) The parties agree that, subject to the requirements of the Federal Food, Drug and Cosmetic Act, as amended from time to time, and all applicable regulations thereunder (the “**FD&C Act**”) and any required approval of the United States Food and Drug Administration (the “**FDA**”), the name of Pfizer or Pfizer’s Affiliate shall not appear on any Promotional Materials used or distributed in the Territory under this Agreement.

(h) Distributor shall not conduct any clinical or non-clinical studies involving the Product or sponsor any publications concerning the Product without the prior written approval of Pfizer, which shall not be unreasonably withheld.

(i) Within two months following the execution of this Agreement, Pfizer shall provide Distributor with access to appropriate personnel experienced with the marketing of doxazosin mesylate in order to transfer to Distributor marketing and reasonably related information that would be beneficial to Distributor’s promotion of the Product, in such place as mutually agreed. Notwithstanding the foregoing, Pfizer shall not be required to provide such representatives for a total of more than sixteen (16) person hours during such period.

*Section 7.04. Labeling.* The parties agree that, subject to the requirements of the FD&C Act and any required approval of the FDA, the name of Pfizer or Pfizer’s Affiliate, on the one hand, and the name of Distributor, on the other hand, shall be given similar exposure and prominence on all created or manufactured Product package inserts and packaging used or distributed in the Territory under this Agreement; *provided* that if only one name is permitted by applicable Laws, it shall be the name of Pfizer or Pfizer’s Affiliate. Pfizer shall provide Distributor with a copy of all labeling content changes Pfizer has made to the Product sold in the Territory no later than ten (10) days after any such change is introduced to the market.

### ARTICLE VIII TRAINING

*Section 8.01. Training Program and Materials.* Distributor shall be responsible for the training of the Distributor’s sales representatives and for developing training materials for use in connection therewith. Distributor shall bear all of the costs and expenses of implementing and producing its training program and materials. Distributor’s training programs for its sales representatives will include training to comply with all applicable Laws.

### ARTICLE IX REGULATORY MATTERS

*Section 9.01. Regulatory and Legal Matters.*

(a) Except as otherwise provided in this Section 9.01, Pfizer and its Affiliates shall have the sole authority and responsibility to obtain and maintain any FDA or other Governmental or Regulatory Authority approvals with respect to the Product and Pfizer and/or its Affiliates shall own all such approvals. Pfizer shall provide Distributor with copies of all final submissions that are intended to change or modify the packaging, label or labeling for, or the indications of, the Product. Except as provided in this Section 9.01, Distributor shall not file any document with the FDA or any other Governmental or Regulatory Authority relating to the Product, and

## CONFIDENTIAL TREATMENT

will not take any action in respect of any complaint, communication or report, in each case without Pfizer's prior consent.

(b) In the event the FDA requires that additional studies (clinical or non-clinical), or additional pharmacokinetic or manufacturing data be provided as a condition to approval or as a requirement following approval, Pfizer agrees that it shall use its Commercially Reasonable Efforts to undertake such studies at its expense.

(c) Subject to *Section 9.03(b)* below, in the event Distributor desires to file for additional indications or a change in label with the FDA following NDA Approval, the parties shall meet in good faith for the purpose of coming to a mutually agreeable approach to such filings.

*Section 9.02. Communication with Regulatory Authorities.* Except in relation to activities relating to the FDA's Division of Drug Marketing, Advertising and Communications ("DDMAC") pursuant to *Section 9.03(b)* below, Distributor shall not, without the consent of Pfizer which shall not be unreasonably withheld or delayed or unless so required by Law (and then only pursuant to the terms of this *Section 9.02*), correspond or communicate with the FDA or with any other Governmental or Regulatory Authority (including Adverse Drug Experience Reports and Serious Adverse Drug Experience Reports to the FDA and/or other Governmental or Regulatory Authorities), whether within the Territory or otherwise, concerning the Product or doxazosin mesylate generally or otherwise take any action concerning any authorization or permission under which the Product is sold or any application for the same. Furthermore, Distributor shall, immediately upon receipt of any communication from the FDA or from any other Governmental or Regulatory Authority relating to the Product or doxazosin mesylate generally, forward a copy or description of the same to Pfizer and respond to all inquiries by Pfizer relating thereto. If Distributor is advised by its counsel that it must communicate with the FDA or with any other Governmental or Regulatory Authority, then Distributor shall so advise Pfizer immediately and, unless prohibited by Law, provide Pfizer in advance with a copy of any proposed written communication with the FDA or any other Governmental or Regulatory Authority, and shall comply with any and all reasonable directions of Pfizer concerning any meeting or written or oral communication with the FDA or any other Governmental or Regulatory Authority.

*Section 9.03. Labeling and Promotional Materials.*

(a) Pfizer and its Affiliates shall have the sole authority and responsibility to seek and/or obtain any necessary FDA approvals of any label, labeling, package inserts and packaging used in connection with the Product, and for determining whether the same requires FDA approval.

(b) Following NDA Approval, Distributor shall be solely responsible for submission of all Promotional Materials as required by Law to DDMAC, including, but not limited to, submission of each Form 2253 to the FDA. In addition, Distributor agrees to seek pre-clearance from DDMAC with respect to all Promotional Materials to be used on launch of the Product. Distributor will be the designated recipient of all DDMAC correspondence, and agrees to be solely responsible for responding to, and complying with, all FDA inquiries, Notices of

## CONFIDENTIAL TREATMENT

Violation, Warning Letters and other actions of FDA related to promotional activities. In addition, Distributor will immediately notify Pfizer of any Proceedings (threatened or pending), involving potential or actual violations of Law by Distributor related to the Product. Except with respect to the Form 2253, Distributor agrees that it will promptly provide to Pfizer copies of all submissions to and correspondence to and from the FDA and any Proceedings related to the Product pursuant to this Section, and Pfizer shall have the right, but not the obligation, to comment on such submissions and correspondence, and Distributor shall make such changes to any such communications and submissions to the FDA and take such actions in respect thereof as may be reasonably requested by Pfizer.

(c) Following execution of this Agreement, Pfizer shall continue to own the NDA, and will use its Commercially Reasonable Efforts to obtain NDA Approval. Pfizer may file, but shall not be required to file, any additional New Drug Applications or supplemental New Drug Applications with respect to the Product. Pfizer agrees that it will provide to Distributor copies of correspondence to and from the FDA related to the Product, except to the extent such correspondence relates to any proprietary manufacturing data.

*Section 9.04. Complaints.* Distributor shall refer any complaints which it receives concerning the Product or doxazosin mesylate in general to Pfizer within five (5) business days after Distributor's receipt of the same; *provided* that all complaints concerning suspected or actual Product tampering, damage, contamination or mix-up (*e.g.*, wrong ingredients or incorrect labeling) shall be delivered to Pfizer within one (1) business day of Distributor's receipt of the same. Distributor shall not take any other action in respect of any such complaint without Pfizer's consent, unless otherwise required by Law.

*Section 9.05. Regulatory Information.* Subject to the terms of *Section 9.02* above, each party agrees to provide the other party with all reasonable assistance and take all actions reasonably requested by the other party that are necessary or desirable to enable the other party to comply with any Law under the FD&C Act applicable to the Product or doxazosin mesylate in general, including, but not limited to, Pfizer meeting its reporting and other obligations to: (i) maintain and update any New Drug Applications for the Product; and (ii) report Adverse Drug Experience Reports and Serious Adverse Drug Experience Reports to the FDA and/or other Governmental or Regulatory Authorities. Such assistance and actions shall include, among other things, keeping the other party informed, commencing within two (2) business days of notification of any action by, or notification or other information which it receives (directly or indirectly) from, the FDA or any other Governmental or Regulatory Authority which (a) raises any material concerns regarding the safety or efficacy of the Product, (b) indicates or suggests a potential material liability for either party to third parties arising in connection with the Product or (c) is reasonably likely to lead to field alert report, recall or market withdrawal of the Product; *provided* that neither party shall be obliged to disclose information in breach of any contractual restriction.

*Section 9.06. Adverse Drug Experience Reports.*

## CONFIDENTIAL TREATMENT

(a) Pfizer shall have sole responsibility for evaluation of, and, as required by the FD&C Act and FDA regulations, for reporting of adverse drug experiences to, the FDA. In order to fulfill this obligation, Distributor shall notify Pfizer of all Adverse Drug Experience reports as defined in 21 C.F.R. Section 314.80(a), within two (2) business days after such report becomes known to Distributor.

(b) Subject to *Section 9.02* above, (i) Distributor shall not disclose any information concerning Adverse Drug Experience Reports or Serious Adverse Drug Experience Reports to any Person or Governmental or Regulatory Authority without Pfizer's prior consent and (ii) Pfizer and its Affiliates shall have the sole discretion to determine whether any complaint, Adverse Drug Experience Report or Serious Adverse Drug Experience Report must be reported to the FDA or any other Governmental or Regulatory Authority or any other Person.

(c) Within ten (10) business days after submission, Pfizer shall provide Distributor with copies of all fifteen (15) day "Alert Reports" relating to the Product and submitted to the FDA in accordance with 21 C.F.R. 314.80(c)(1). Within ten (ten) business days after submission, Pfizer shall provide Distributor with copies of all periodic adverse drug experience reports relating to the Product and submitted in accordance with 21 C.F.R. 314.80(c)(2).

(d) Distributor will train its field force to handle Adverse Drug Experience Reports and Serious Adverse Drug Experience Reports in a manner consistent with Pfizer's practices (including, but not limited to, instruction in using Pfizer's toll-free number for such reports).

(e) Within sixty (60) days from execution of this Agreement, Distributor and Pfizer shall enter into such other agreements as are reasonably necessary to ensure that satisfactory systems and procedures are in place to effect the effective exchange of safety and other medical information between the two parties as necessary to fulfill all applicable legal and regulatory requirements.

*Section 9.07. Recalls Or Other Corrective Action.* Pfizer and its Affiliates shall have the sole authority and responsibility to make all decisions with respect to any recall, market withdrawal or any other corrective action related to the Product. Pfizer shall promptly notify Distributor of any such recall, mandatory withdrawal or other corrective action regarding the Product in the Territory. If a corrective action is due to Pfizer's negligence, willful misconduct or breach of this Agreement, Pfizer shall reimburse Distributor for the Per System Fee paid by Distributor pursuant to *Section 5.03* hereof for any orders of the Product subject to such corrective action (other than orders that have been resold by, and not returned to, Distributor), all of the reasonable costs and expenses actually incurred by Distributor in connection with such corrective action, including, but not limited to, costs of retrieving Product already delivered to customers, costs and expenses Distributor is required to pay for notification, shipping and handling charges, and such other costs as may be reasonably related to the corrective action. If a corrective action is due to Distributor's negligence, willful misconduct or breach of this Agreement, Distributor shall remain responsible for the Per System Fee paid by Distributor pursuant to *Section 5.03* hereof for any orders of the Product subject to such corrective action and shall reimburse Pfizer for all the reasonable costs and expenses described above actually incurred by Pfizer in connection with such corrective action, including administration of the recall and such other actual costs as may be reasonably related to the corrective action. If a

## CONFIDENTIAL TREATMENT

corrective action results from a cause other than the negligence, willful misconduct or breach of this Agreement of or by Distributor or Pfizer, the parties hereto shall share equally, all of the costs of the corrective action, including the Per System Fee paid by Distributor pursuant to *Section 5.03* hereof for any orders of the Product subject to such corrective action (other than orders that have been resold by, and not returned to, Distributor). Prior to any reimbursements pursuant to this Section, the party claiming any reimbursement shall provide the other party with reasonably acceptable documentation of all reimbursable costs and expenses. Neither party will be liable to the other for Indirect Losses in connection with any corrective action undertaken pursuant to this Section.

### *Section 9.08. Product Testing/Inspection.*

(a) Pfizer shall perform quality assurance testing with respect to the Products sold hereunder, including stability testing, so that the Products conform with the Specifications. Pfizer shall provide to Distributor a certificate for the Product describing the Product, product number, lot number and expiration date, the physical, chemical, biological or other testing results and specifications relating to the Product and certifying that the Product meets the Specifications to Distributor in the form of a Certificate of Analysis (hereinafter "COA"). Pfizer will also provide Distributor with Material Safety Data Sheets (hereinafter "MSDS") as required for the Products, and updates of same as necessary.

(b) Distributor shall have a period of thirty (30) days from the later of (a) the date of Distributor's receipt of the Products in accordance with Article III hereof, or (b) the date of Distributor's receipt of the COA's applicable to such Product, to inspect any shipment of a Product to determine whether such shipment conforms to the Specifications. If Distributor determines that a Product does not conform to the Specifications, it shall notify Pfizer, immediately, if possible, but no later than seven (7) business days after determining a Product does not conform to the Specifications. Distributor's failure to notify Pfizer within the stipulated period will be deemed, for purposes of this Agreement, as Distributor's acceptance of such shipment and shall constitute a waiver of any claims Distributor may have against Pfizer with respect to such shipment subject, however, to Distributor's right to reject such Product for latent defects discovered by Distributor or Distributor's customer(s) after such stipulated period has expired. If Pfizer agrees that a Product does not conform to the Specifications, Distributor shall return the non-conforming Product to Pfizer, at a location designated by Pfizer and at Pfizer's expense. Pfizer, at no expense to Distributor, shall use Commercially Reasonable Efforts to replace any non-conforming Product within the shortest possible time.

(c) In the event Pfizer does not agree with Distributor's determination that a Product fails to meet Specifications, the Parties shall, in good faith, attempt to resolve such dispute. In the event the Parties cannot resolve said dispute among themselves they may submit the matter to an independent third party testing laboratory agreeable to both Distributor and Pfizer for a binding opinion. The expenses of obtaining the binding opinion shall be equally shared by Distributor and Pfizer. In the event that the Parties do not agree to submit the dispute to a testing laboratory, the Parties shall remain free to pursue any legal, equitable or administrative remedies to which they may be entitled.

## CONFIDENTIAL TREATMENT

(d) Distributor will permit Pfizer's personnel, upon reasonable notice, to visit at reasonable intervals, and for reasonable durations during regular business hours, any facility used by Distributor for the storage and distribution of the Product and will allow such personnel to review and make copies of any relevant records in connection therewith.

### ARTICLE X REPRESENTATIONS, COVENANTS AND WARRANTIES

*Section 10.01. Pfizer Representations and Warranties.* Pfizer hereby represents and warrants to Distributor as follows:

(a) The execution, delivery and performance by Pfizer of this Agreement and the consummation of the transactions contemplated hereby are within Pfizer's corporate powers and have been duly authorized by all necessary corporate action on the part of Pfizer. This Agreement constitutes a legal, valid and binding obligation of Pfizer, enforceable against Pfizer in accordance with its terms;

(b) As of the date hereof, the execution, delivery and performance of this Agreement by Pfizer will not violate in any material respect any Laws or any order of any Governmental or Regulatory Authority;

(c) As of the date hereof, none of the execution, delivery or performance of this Agreement by Pfizer requires Pfizer to obtain any permits, authorizations or consents from any Governmental or Regulatory Authority (except for FDA approval of the Product), and such execution, delivery and performance will not result in a material breach of or give rise to any termination of any material agreement or contract to which Pfizer may be a party and which relates to the Product in the Territory and, except for FDA approval of the Product, Pfizer has, and will maintain throughout the term of this Agreement all permits, licenses, representations and all forms of governmental authorization and approval as required by law in order for Pfizer to execute, deliver and perform its obligations hereunder; and

(d) Except as set forth in this *Section 10.01*, Pfizer gives no other warranty, express or implied.

*Section 10.02. Distributor Representations and Warranties.* Distributor hereby represents and warrants to Pfizer as follows:

(a) The execution, delivery and performance by Distributor of this Agreement and the consummation of the transactions contemplated hereby are within Distributor's corporate powers and have been duly authorized by all necessary corporate action on the part of Distributor. This Agreement constitutes a legal, valid and binding obligation of Distributor, enforceable against Distributor in accordance with its terms. Distributor is properly registered, licensed and qualified, and has all requisite power and authority under its organizational documents and in accordance with the Laws of the Territory to act as Pfizer's distributor, and to conduct its business and perform its obligations hereunder and, during the Term of this Agreement and any extensions thereof, it shall take all action as may be required and necessary to obtain and keep

## CONFIDENTIAL TREATMENT

current any governmental licenses, permits, registrations and approvals that are necessary or advisable for it to carry out its activities hereunder;

(b) As of the date hereof, the execution, delivery and performance of this Agreement by Distributor will not violate in any material respect any Laws or any order of any Governmental or Regulatory Authority; and

(c) As of the date hereof, none of the execution, delivery or performance of this Agreement by Distributor requires Distributor to obtain any permits, authorizations or consents from any Governmental or Regulatory Authority, and such execution, delivery and performance will not result in a material breach of or give rise to any termination of any material agreement or contract to which Distributor may be a party and which relates to the Product in the Territory.

*Section 10.03. Pfizer Covenants.* Pfizer covenants and agrees that:

(a) Pfizer shall carry out, or shall cause its Affiliates to carry out, the manufacturing of the Product and Pfizer's other obligations and activities hereunder in all material respects in accordance with (i) the terms of this Agreement; (ii) accepted pharmaceutical industry practices; (iii) current good manufacturing practices set forth in Title 21 of the C.F.R. Parts 210 and 211, as amended from time to time, and other FDA regulations and guidelines issued under 21 C.F.R. 10.90 relating to the manufacture, processing, testing, packing and storage of drug products regulated by the FDA; (iv) the Specifications; and (v) all applicable Laws, including, but not limited to, those Laws regarding the handling, storage, transportation, generation and disposal of waste and regulated substances; and

(b) The Product to be delivered by Pfizer or its Affiliates to Distributor will not, at the time of shipment by or on behalf of Pfizer, in any material respect be misbranded or adulterated under the terms of the FD&C Act.

(c) (i) During the Term, Pfizer agrees that, except as contemplated hereby in Section 2.02(b), it shall not, and it shall cause its subsidiaries not to, engage in, own, manage, operate or control any business that manufactures, markets, sells or licenses a doxazosin mesylate extended release product (a "Covered Activity"); provided, however, that it shall not be deemed to be a violation of this subsection for Pfizer or any of its subsidiaries to (A) invest in or own any debt securities or other debt obligations; (B) invest in any third Person (including any corporation or mutual or other fund) which invests in, manages or operates a Covered Activity, so long as Pfizer's or any of its subsidiary's investment is less than 20% of the outstanding ownership interest in such third Person and Pfizer and its subsidiaries do not control or conduct such third Person or Covered Activity; (C) invest in, own an interest in, or acquire all or a majority of the stock or assets of any Person which is not "engaged primarily in a Covered Activity" (as hereinafter defined); (D) invest in securities having less than 10% of the outstanding voting power of any Person, the securities of which are publicly traded or listed on any securities exchange or automated quotation system; (E) invest in any Person after the date hereof to the extent that Pfizer or a subsidiary had, directly or indirectly, acquired, or had a right to acquire, such interest prior to the date of this Agreement; or (F) own any equity interests through any employee benefit plan or pension plan. For purposes of this subsection, "engaged primarily in a Covered Activity" shall mean that greater than 50% of the aggregate net revenue derived during

## CONFIDENTIAL TREATMENT

the last complete fiscal year of such Person (calculated on a consolidated basis) is derived from the Covered Activity. Each investment or acquisition made by Pfizer or its subsidiaries which is subject to the provisions of this Section 10.03(c) must be permissible hereunder at the time of such investment; provided, however, that any such investment which was permissible when made cannot thereafter be the basis of a claim of violation of this Section 10.03(c).

(ii) Notwithstanding anything to the contrary contained in subsection (c)(i) of this Section 10.03, Pfizer and its subsidiaries shall not be deemed to have violated the restrictions contained in Section 10.03(c)(i) in the event that Pfizer or a subsidiary acquires (by purchase of stock or assets, merger or otherwise) or invests in any Person engaged primarily in a Covered Activity; provided, however, that Pfizer or such subsidiary thereafter enters into a definitive agreement to divest such Covered Activity within 12 months from the date of purchase of such Person so as to be in compliance with Section 10.03(c)(i).

(iii) During the Term, neither Party shall, directly or indirectly, induce or attempt to induce any employee of the other Party with whom such Party has interacted in the performance of this Agreement, to accept employment with the other Party, except that nothing in this sentence shall restrict or preclude the rights of either Party to make generalized searches for employees by the use of advertisements in the media (including trade media) or by engaging search firms to engage in searches that are not targeted or focused on the employees of the other Party.

### *Section 10.04. Distributor Covenant.*

(a) Distributor shall carry out the distribution, detailing, promotion and marketing of the Product and its other obligations and activities hereunder in all material respects in accordance with (i) the terms of this Agreement, (ii) accepted pharmaceutical industry practices and (iii) all applicable Laws.

(b) The Product to be Distributed by the Distributor to unaffiliated third parties will not, at the time of such shipment, in any material respect be misbranded or adulterated under the terms of the FD&C Act.

## ARTICLE XI INTELLECTUAL PROPERTY

### *Section 11.01. Intellectual Property.*

(a) The Product shall initially be promoted and sold in the Territory under the Cardura<sup>®</sup> XL trademark (U.S. Trademark Registration No. 1,360,101) owned by Pfizer (the "**Trademark**").

(b) Pfizer hereby grants Distributor a non-exclusive, royalty-free license, with the right to further sublicense solely to its Affiliates, to use the Trademark in the Territory in connection with this Agreement, including, but not limited to, Promotional Materials, and promoting and detailing the Product. Upon termination or expiration of this Agreement, Distributor shall discontinue all use of the Trademark. Except for the licenses granted in this

## CONFIDENTIAL TREATMENT

Section, Distributor shall not have or acquire any ownership, proprietary or property right or other interest in the Trademark, any other trademarks, its related goodwill, nor in any patents, know-how, technical information or in any copyright owned or otherwise held by Pfizer or any of its Affiliates and relating to the Product.

(c) Distributor owns the Distributor logo set forth on Exhibit D attached hereto (the “**Distributor Logo**”). Distributor hereby grants Pfizer and its Affiliates a non-exclusive royalty-free license to use the Distributor Logo in the Territory on labeling, package inserts and packaging materials for Product, all Promotional Materials and any other materials used in connection with the performance of this Agreement during the Term hereof. Distributor shall have the right to approve the design, color and specifications of the Distributor Logo itself on all materials used in connection with this Agreement. After the expiration or termination of this Agreement, Pfizer shall not create or produce any materials bearing the Distributor Logo. Except as provided in this Section, Pfizer shall have no rights under this Agreement in or to the Distributor Logo or the goodwill pertaining thereto and agrees that upon termination or expiration of this Agreement, except for the period specified above, it shall discontinue all use of the Distributor Logo. All uses of the Distributor Logo inure solely to Distributor’s benefit.

### *Section 11.02. Patent and Trademark Infringement.*

(a) Each party shall promptly notify the other party upon its becoming aware of (i) any infringement in the Territory by any Person of any patent, the Trademark, the Distributor Logo or any copyrights relating to the Product and (ii) any patent or trademark infringement action brought against such party or any of its Affiliates with respect to the Product. Except for trademark infringement of the Distributor Logo, and subject to the rights of ALZA Corporation (“ALZA”) pursuant to the License Agreement between ALZA and Pfizer, dated October 8, 1987. Pfizer shall have the sole and absolute discretion whether or not to bring suit to enjoin, prohibit, or retard any third party infringement; *provided* that if Pfizer becomes aware that a third party has either filed a certification under Section 505(b)(2)(A)(iv) of the FD&C Act for the Product or an ANDA with the FDA for the Product, subject to the rights of ALZA, Pfizer shall use reasonable efforts to consult with Distributor prior to deciding (in Pfizer’s sole and absolute discretion) whether to exercise its rights provided under Law, including the FD&C Act. Pfizer shall be solely responsible for all out-of-pocket expenses incurred in connection with such infringement suits and shall have the sole right to any recoveries made thereunder, subject to the rights of ALZA. Distributor shall, at Pfizer’s request and expense, cooperate fully in such suits or actions. Distributor shall have the sole discretion whether or not to bring suit to enjoin, prohibit, or retard any third party infringement of the Distributor Logo in connection with the Product. Distributor shall be solely responsible for all out-of-pocket expenses incurred in connection with such infringement suits and shall have sole rights to any recoveries made thereunder. Pfizer shall, at Distributor’s request and expense, cooperate fully in such suits or actions.

(b) Each party shall promptly notify the other party upon receipt of any communications from Governmental or Regulatory Authorities in the Territory with respect to the Trademark or any patents or copyrights relating to the Product.

# CONFIDENTIAL TREATMENT

## ARTICLE XII INFORMATION CONCERNING THE PRODUCT

*Section 12.01. Ownership.* Distributor shall not represent to any third party that it has any proprietary or property right or other interest in the Product, doxazosin mesylate or in the Trademark or any patents or copyrights relating to the Product, except for such rights granted to Distributor under this Agreement.

*Section 12.02. Medical Inquiries.* Distributor shall have sole responsibility for responding to all medical questions or inquiries from members of the medical and paramedical professions and consumers relating to the Product. However, Distributor shall comply with the directions and policies which Pfizer may reasonably formulate concerning responses to be made to medical questions or inquiries from members of the medical and paramedical professions and consumers regarding the Product, including, but not limited to, forms of response letters, and shall, if so requested by Pfizer, provide Pfizer with details of inquiries received and responses given.

# CONFIDENTIAL TREATMENT

## ARTICLE XIII TERM AND TERMINATION

*Section 13.01. Term.* (a) The term of this Agreement (herein referred to as the “**Term**”) shall commence on the date first set forth above and shall continue for an initial period of five (5) years from the date of NDA Approval. Thereafter, this Agreement may be renewed on a year to year basis upon mutual written consent of both parties. Pfizer shall give Andrx written notice no later than six (6) months prior to the expiration of the Term (or any renewal period) as to its intent to renew or terminate this Agreement; provided, however, that if no such notice is given, this Agreement shall not renew and shall terminate at its then scheduled termination date. Distributor shall give Pfizer written notice no later than thirty (30) days following Pfizer’s renewal notice whether it agrees to extend the Term.

(b) If, as of the expiration of the initial five (5) year Term, a Competing Product is not being sold in the marketplace and Pfizer continues to manufacture the Product following such expiration and sells and distributes the Product in the Territory either directly or through a person other than Distributor, then Distributor shall receive a residual compensation payment equal to twenty-five (25%) of the difference between (i) the Net Sales received by Distributor in respect of Product sold during the last twelve (12) months of the Term and (ii) the aggregate Per System Fee paid to Pfizer for such Product during such twelve (12) month period. The residual compensation payment shall be made, if due, to Distributor in four equal quarterly installments within ten (10) days after each quarter during the year immediately following expiration of the Term. Notwithstanding the foregoing, such installments will cease for the then current calendar quarter and for any of the remaining calendar quarters, in such year in the event Distributor or any third party commences sale of a Competing Product in the Territory within twelve (12) months of the expiration of the Term.

(c) At such time that Pfizer fails to give notice to renew or the parties otherwise do not agree to renew the Term, at such time Distributor’s obligation to maintain the Minimum Inventory pursuant to Section 5.04 shall be of no further force and effect. Moreover, following the termination date, at Pfizer’s option, Distributor shall be permitted to either continue to sell off its remaining inventory to third parties or be authorized to return said inventory to Pfizer at the Per System Fee.

*Section 13.02. Termination by Pfizer.* Notwithstanding anything contained herein, Pfizer may immediately terminate this Agreement prior to the expiration of the Term or any renewal thereof, by giving written notice given to Distributor upon the occurrence of one or more of the following events, which for all purposes, shall be deemed to be and shall be treated as just cause for such termination:

- (a) In the event that:
  - (i) NDA Approval is not obtained prior to December 31, 2004;

## CONFIDENTIAL TREATMENT

- (ii) FDA approval of the NDA is received with manufacturing specifications which differ from Pfizer's response to the FDA regarding the NDA and Pfizer provides notice to Distributor that it will not manufacture the Product with such specifications;
- (b) In the event that regulatory authorities in the United States of America withdraw marketing approval of the Product;
- (c) In the event that Distributor fails to purchase the minimum quantities of Product in any of the first three (3) Contract Years;
- (d) In the event that with respect to its promotional, educational or detailing activities of the Product, the Distributor (i) receives any Warning Letter from the FDA and fails to use Commercially Reasonable Efforts to remedy same and satisfactorily resolve the matters raised in such letter within a reasonable time, or is subject to a criminal indictment or is otherwise formally accused by any Governmental or Regulatory Authority with a violation of Law or (ii) is otherwise engaged in a pattern of conduct resulting in multiple Notices of Violation from the FDA or inquiries from the FDA or other Governmental or Regulatory Authorities.
- (e) In the event manufacture, distribution or sale of the Product in the Territory contravenes any Law; provided that it shall not terminate in the event manufacture, distribution or sale can be brought into compliance with Law within a reasonable time;
- (f) In the event of a material breach by Distributor of the terms and conditions hereof and a failure to cure such breach within thirty (30) days of receipt of written notice by Distributor;
- (g) In the event of bankruptcy, receivership, liquidation or insolvency of Distributor or in the event that any valid similar actions or proceedings are instituted by, on behalf of or against Distributor;
- (h) Upon any assignment or attempted assignment (whether by contract, operation of Law or otherwise) by Distributor of any interest in this Agreement without Pfizer's prior written consent;
- (i) Upon the unauthorized solicitation of sales of the Product outside of the Territory by Distributor or the unauthorized sales of the Product outside the Territory by Distributor, other than isolated situations involving sales of non-material quantities of Product; and
- (j) In the event that it becomes physically or legally impossible or commercially impracticable for either party to perform its obligations by virtue of Force Majeure pursuant to *Section 16.05* hereof.

It is agreed that Distributor shall immediately advise Pfizer in writing of the occurrence of any event specified in this Article, provided that the giving of such notice shall not be a condition precedent to the exercise of Pfizer of its rights hereunder.

*Section 13.03. Termination by Distributor.* Notwithstanding anything contained herein, Distributor may terminate this Agreement prior to the expiration of the Term or any renewal

## CONFIDENTIAL TREATMENT

thereof, by giving three (3) months' written notice to Pfizer upon the occurrence of one or more of the following events (provided, however, that upon the occurrence of the event in *Section 13.03(a)*, Distributor may immediately terminate this Agreement), which for all purposes, shall be deemed to be and shall be treated as just cause for such termination:

(a) In the event NDA Approval is not obtained prior to December 31, 2004, or if the NDA Approval does not meet all or substantially all of the criteria for each claim set forth on Attachment I hereto;

(b) In the event that regulatory authorities in the United States of America withdraw marketing approval of the Product;

(c) In the event manufacture, distribution or sale of the Product contravenes any Law; provided that it shall not terminate in the event manufacture, distribution or sale can be brought into compliance with Law within a reasonable time;

(d) Except as provided in this Agreement (including, without limitation, in Section 3.05(f) hereof), in the event of a material breach by Pfizer of the terms and conditions hereof and a failure to cure such breach within thirty (30) days of receipt of written notice by Pfizer; and

(e) In the event that it becomes physically or legally impossible or commercially impracticable for either party to perform its obligation by virtue of Force Majeure pursuant to and under the terms described in *Section 16.05* hereof.

It is agreed that Pfizer will immediately advise Distributor in writing of the occurrence of any event specified in this Article, provided that the giving of such notice shall not be a condition precedent to the exercise of Distributor of its rights hereunder.

### *Section 13.04. Effects of Termination.*

(a) Except as otherwise provided herein, any termination of this Agreement shall not release either party from any obligation to pay to the other party any sums due under *ARTICLE V* in connection with activities completed on or before the date of such termination, but no further sums shall be payable under *ARTICLE V*; provided that such termination shall be without prejudice to any remedies which either party may then have hereunder or at Law.

(b) The provisions of *Section 14.01* and *ARTICLE XV*, *Section 16.01* and this *Section 13.04* shall survive the expiration or termination hereof indefinitely. The obligations of the parties set forth in *Section 9.02*, *Section 9.04*, *Section 9.05* and *Section 9.03(a)* shall survive the expiration or termination hereof for the shelf life of the items containing the Distributor Logo in accordance with *Section 11.01(c)*. The provisions of *ARTICLE V* shall survive the termination hereof in accordance with their terms.

(c) Subject to the terms of *Section 14.01*, within thirty (30) days after the expiration or termination of this Agreement, (i) Distributor shall return to Pfizer all Promotional Materials, Marketing Plans, reports and all other tangible Confidential Information provided to, or based upon Confidential Information provided to, Distributor by or on behalf of Pfizer and (ii) Pfizer

## CONFIDENTIAL TREATMENT

shall return to Distributor all tangible Confidential Information provided to, or based upon Confidential Information provided to, Pfizer by or on behalf of Distributor.

### ARTICLE XIV CONFIDENTIALITY AND PRESS RELEASES

*Section 14.01. Confidentiality.* For a period of five (5) years following termination of this Agreement, each party shall hold in confidence and use only in furtherance of its rights and obligations under this Agreement all Confidential Information that it acquires from the other party pursuant to this Agreement, unless (i) the disclosing party consents to the receiving party's disclosure or use or (ii) disclosure of the disclosing party's Confidential Information by the receiving party is required by order of any Governmental or Regulatory Authority, in which event the receiving party will notify the disclosing party of that order as soon as practicable, shall use reasonable efforts (at the disclosing party's expense) to obtain a protective order covering the Confidential Information and shall disclose only such Confidential Information that its legal counsel determines is legally required. Each party shall make Confidential Information that it acquires from the other party pursuant to this Agreement available only to those of its Affiliates, directors, officers, employees, consultants, advisors or representatives who need to have access thereto for the purposes of this Agreement and who are bound by an obligation of confidentiality consistent with the provisions herein.

*Section 14.02. Press Releases.* Except as required by any Governmental or Regulatory Authority, neither party shall make any press release or other public announcement or other disclosure to third parties (other than its advisors) relating to the Agreement or the transactions described herein without the prior written consent of the other party.

### ARTICLE XV INDEMNIFICATION

*Section 15.01. Indemnification by Distributor.* Distributor agrees to indemnify, protect, defend and hold Pfizer and its directors, officers, employees and agents harmless from and against any Losses that they may incur at any time arising out of (i) Distributor's breach of this Agreement or of any warranty made by Distributor to Pfizer in this Agreement or (ii) Distributor's promotional, marketing, advertising, detailing and educational activities and from its storage, handling and distribution of the Product supplied to it by Pfizer.

*Section 15.02. Indemnification by Pfizer.* Pfizer agrees to indemnify, protect, defend and hold Distributor and its directors, officers, employees and agents harmless from and against any Losses that they may incur at any time arising out of (i) Pfizer's breach of this Agreement or of any warranty made by Pfizer to Distributor in this Agreement or (ii) Pfizer's supply of damaged or defective Product that does not meet the Specifications authorized under the NDA Approval, provided, however, that Distributor shall not be indemnified under this Section (i) for any individual third party claims involving Losses of less than \$500,000 and (ii) unless and until the aggregate amount of all third party claims involving Losses of \$500,000 or more exceeds \$20,000,000, in which event Pfizer shall be liable only for such indemnified aggregate Losses in excess of \$20,000,000. In addition, Pfizer shall not be liable to, or be required to indemnify, Distributor under this Section for an aggregate amount of Losses exceeding the total amount of

## CONFIDENTIAL TREATMENT

payments made by Distributor to Pfizer pursuant to *ARTICLE V* of this Agreement. Except with respect to Product Liability Claims, Distributor acknowledges and agrees that the provisions of this Section 15.02 and other applicable provisions of this *ARTICLE XV* shall be the sole and exclusive remedy of Distributor in respect of any third party claim made against Distributor.

*Section 15.03. Joint Indemnification.* *Section 15.01* and *Section 15.02* notwithstanding, if the Losses arising from any Product Liability Claim are a result of Pfizer's negligence, willful misconduct or a breach of this Agreement, Pfizer shall bear responsibility for all the Losses arising under such Product Liability Claim. If the Losses arising from any Product Liability Claim are a result of Distributor's negligence, willful misconduct or a breach of this Agreement, Distributor shall bear responsibility for all the Losses arising under such Product Liability Claim. If the Losses arising from any Product Liability Claim are not a result of either Party's negligence, willful misconduct or a breach of this Agreement, the Parties shall share the Losses equally. Upon receipt of any such Product Liability Claim, each party promptly will notify the other party in writing of such Product Liability Claim. Pfizer shall have the right to defend against and control the defense and settlement of such Product Liability Claim, provided that (a) Pfizer (i) shall assume the conduct of such defense within thirty (30) days of notice of such claim or suit and (ii) shall not compromise or settle such claim or suit without the written approval of Distributor to the extent such claim or suit involves equitable or non-monetary relief legally binding upon Distributor or forces Distributor to take any action (but in all other instances shall consult with Distributor prior to settlement, if practical), and (b) Distributor shall have the right to participate in the defense of such claim or suit at its own expense. Distributor shall not compromise or settle such claim or suit or make any admissions concerning such claim or suit (unless required by applicable Law) without the prior written approval of Pfizer.

*Section 15.04. Procedures.* The party seeking indemnification under this *ARTICLE XV* (the "**Indemnified Party**") agrees to give prompt notice to the party against whom indemnity is sought (the "**Indemnifying Party**") of the assertion or commencement of any Proceeding in respect of which indemnity may be sought under such Section and will provide the Indemnifying Party such information with respect thereto that the Indemnifying Party may reasonably request. The failure to give such notice shall relieve the Indemnifying Party of any liability hereunder only to the extent that the Indemnifying Party has suffered actual prejudice thereby. Except as provided in *Section 15.03* above, the Indemnifying Party shall have the right to participate in and control the defense of any such action, suit or proceeding at its own expense. The Indemnified Party shall, if requested by the Indemnifying Party, cooperate in all reasonable respects in such defense. The Indemnified Party shall be entitled at its own expense to participate in such defense and to employ separate counsel for such purpose. The Indemnifying Party shall not be liable under this *ARTICLE XV* for any settlement effected without its consent of any Proceeding in respect of which indemnity may be sought hereunder. No party to this Agreement shall enter into any compromise or settlement which commits the other party to take, or to forbear to take, any action without the other party's prior written consent.

*Section 15.05. Insurance Proceeds; Taxes.* Any indemnification hereunder shall be made net of any insurance proceeds recovered or recoverable by the Indemnified Party from third parties and net of any net tax benefits attributable to such Losses. If, following the payment to the Indemnified Party of any amount under this *ARTICLE XV*, such Indemnified Party recovers any insurance proceeds in respect of the claim for which such indemnification payment was

## CONFIDENTIAL TREATMENT

made, the Indemnified Party shall promptly pay an amount equal to the amount of such proceeds (but not exceeding the amount of such indemnification payment) to the Indemnifying Party.

*Section 15.06. Limitation on Liability.* Notwithstanding anything to the contrary contained herein, indemnification hereunder only shall include liability for any Indirect Losses to the extent the Indemnified Party pays such amount to a third party in respect of a claim of such third party. Except as expressly provided in the preceding sentence, no party to this Agreement shall be liable to or otherwise responsible to any other party hereto or, as applicable, Pfizer or Distributor for Indirect Losses that arise out of or relate to this Agreement or the performance or breach hereof.

### ARTICLE XVI MISCELLANEOUS

*Section 16.01. Choice of Law; Jurisdiction.* This Agreement shall be governed by and construed exclusively in accordance with the law of the State of New York, without regard to the conflicts of law rules of such state. With respect to any Proceeding relating to this Agreement, each party hereto irrevocably (i) agrees and consents to be subject to the exclusive jurisdiction of the United States District Court for the Southern District of New York or any New York State court sitting in New York City and (ii) waives any objection which it may have at any time to the laying of venue of any Proceeding brought in any such court, waives any claim that such Proceeding has been brought in an inconvenient forum and further waives the right to object, with respect to such Proceeding, that such court does not have any jurisdiction over such party.

*Section 16.02. Independent Contractor.* It is expressly agreed that Distributor is an independent contractor and has no authority to act for or on behalf of Pfizer or Pfizer's Affiliates or to bind Pfizer or its Affiliates to any contract or in any other manner commit Pfizer or its Affiliates or make warranties for Pfizer or its Affiliates in any way without the prior express written approval of Pfizer, except as may be otherwise provided herein. Further, nothing contained herein shall constitute an agency, a partnership or a joint venture between the parties hereto.

*Section 16.03. Notices.* All notices or other communications hereunder shall be deemed sufficient if given in writing, mailed registered mail (return receipt requested), postage paid, or by facsimile (confirmed by such registered mail) or by courier addressed to the appropriate party at the address set forth below, or at such other place as such party may designate in writing to the other party.

## CONFIDENTIAL TREATMENT

If to Pfizer:

PFIZER INC.  
235 East 42<sup>nd</sup> Street  
New York, New York 10017  
Attn: Jeffrey Kindler, Esq.  
Senior Vice President and General Counsel  
Telephone No. (212) 733-4935  
Facsimile No. (212) 808-8924

If to Distributor:

ANDRX CORPORATION  
4955 Orange Drive  
Davie, Florida 33314  
Attn: Scott Lodin, Esq.  
Executive Vice President and General Counsel

All such notices shall be effective five (5) days following the date of mailing.

*Section 16.04. Intentionally omitted*

*Section 16.05. Force Majeure.* No party shall be liable for delay in performing or failure to perform obligations hereunder (in no event to include the obligation to pay money), and no party shall be deemed in breach of its obligations hereunder (in no event to include the obligation to pay money), if such failure or delay is due to any event of Force Majeure. If such failure or delay exceeds ninety (90) consecutive days and would otherwise be a material breach of this Agreement, the party without the obligation to perform may terminate this Agreement upon fifteen (15) days' prior notice, provided that at the time of serving notice the event of Force Majeure persists.

*Section 16.06. Severability.* Whenever possible, each provision of this Agreement shall be interpreted in such a manner as to be effective and valid under applicable Law, but if any provision of this Agreement is held to be prohibited by or invalid under applicable Law, such provision shall be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement.

*Section 16.07. Headings.* The headings used in this Agreement have been inserted for convenience of reference only and do not define or limit the provisions hereof.

*Section 16.08. Amendments and Waivers.*

(a) Any provision of this Agreement may be amended or waived if, but only if, such amendment or waiver is in writing and is signed, in the case of an amendment, by each party to

## CONFIDENTIAL TREATMENT

this Agreement, or in the case of a waiver, by the party against whom the waiver is to be effective.

(b) No failure or delay by any party in exercising any right, power or privilege hereunder shall operate as a waiver thereof nor shall any single or partial exercise thereof preclude any other or further exercise thereof or the exercise of any other right, power or privilege. Except to the extent specifically provided herein, the rights and remedies herein provided shall be cumulative and not exclusive of any rights or remedies provided by Law.

*Section 16.09. Entire Agreement.* This Agreement (including the Exhibits and Schedules attached hereto) constitutes the entire agreement between the parties hereto with respect to the subject matter hereof and supersedes all previous agreements, whether written or oral, with respect to such subject matter.

*Section 16.10. Third Party Beneficiaries.* None of the provisions of this Agreement shall be for the benefit of or enforceable by any third party, including, but not limited to, any creditor of either party hereto. No such third party shall obtain any right under any provision of this Agreement or shall by reasons of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against either party hereto.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, this Agreement has been executed by a duly authorized officer of each party as of the date first above written.

PFIZER INC.

By: \_\_\_\_\_  
Name:  
Title:

ANDRX CORPORATION

By: \_\_\_\_\_  
Name:  
Title: