

**TRADEMARK ASSIGNMENT**

Electronic Version v1.1  
 Stylesheet Version v1.1

SUBMISSION TYPE:	NEW ASSIGNMENT		
NATURE OF CONVEYANCE:	ASSIGNS THE ENTIRE INTEREST AND THE GOODWILL		
<b>CONVEYING PARTY DATA</b>			
Name	Formerly	Execution Date	Entity Type
Ranbaxy Pharmaceuticals Inc.		02/26/2004	CORPORATION: INDIA
<b>RECEIVING PARTY DATA</b>			
Name:	Pedinol Pharmacal Inc.		
Street Address:	30 Banfi Plaza North		
City:	Farmingdale		
State/Country:	NEW YORK		
Postal Code:	11735		
Entity Type:	CORPORATION: NEW YORK		
<b>PROPERTY NUMBERS Total: 1</b>			
Property Type	Number	Word Mark	
Registration Number:	974831	NALFON	
<b>CORRESPONDENCE DATA</b>			
Fax Number:	(631)694-5154		
	<i>Correspondence will be sent via US Mail when the fax attempt is unsuccessful.</i>		
Phone:	631-293-9500		
Email:	lmoore@pedinol.com		
Correspondent Name:	Lance T. Moore		
Address Line 1:	30 Banfi Plaza North		
Address Line 4:	Farmingdale, NEW YORK 11735		
NAME OF SUBMITTER:	Lance T. Moore		
Signature:	/Lance T. Moore/		
Date:	05/23/2005		

OP \$40.00 974831

Total Attachments: 24  
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PRODUCT PURCHASE AGREEMENT

This Product Purchase Agreement (the "Agreement") is dated as of February 26, 2004, between Pedinol Pharmacal, Inc., a New York corporation having its principal offices located at 30 Banfi Plaza North, Farmingdale, New York 11735, ("Purchaser") and Ranbaxy Pharmaceuticals Inc., a Florida corporation having its principal offices located at 4801 Executive Park Court, Suite 100, Jacksonville, FL 32216, ("Seller").

RECITALS

1. Seller owns the Product Assets (as defined below).
2. Purchaser desires to acquire, and Seller is willing to transfer, the Product Assets as provided herein.
3. Seller desires to manufacture for Purchaser the Product (as defined below) and Purchaser desires to purchase the Product from Seller.
4. In consideration of the foregoing premises and of the mutual covenants and obligations set forth herein, the parties hereto agree as follows:

ARTICLE 1

DEFINITIONS

- 1.1 "AB Rated Product" shall mean, with respect to a particular dosage strength of the Product, a product with an approved drug application that contains adequate scientific evidence establishing through in vitro or in vivo studies the bioequivalence of such product to the Product.
- 1.2 "Affiliates" shall mean, with respect to any party, any person or entity which, directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with, such party. A person or entity shall be deemed to control a corporation (or other entity) if such person or entity possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such corporation (or other entity) whether through the ownership of voting securities, by contract or otherwise.
- 1.3 "API" shall mean the active pharmaceutical ingredient fenoprofen calcium.
- 1.4 "Commercial Sale" means the sale of the Product by Purchaser or its Affiliates to an un-Affiliated third party, as evidenced by the invoice, receipt, transfer document or the like of Purchaser or its Affiliates to such third-party.
- 1.5 "Drug Master File" shall mean the Drug Master File for manufacturing the API used to manufacture the Product, as filed with the FDA, as same may be amended from time to time.

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1.6 "**FDA**" shall mean the United States Food and Drug Administration, and any successor agency thereto.

1.7 "**NDA**" shall mean the New Drug Application filed with the FDA relating to Nalfon.

1.8 "**Net Sales**" means the total gross sales (number of units shipped times the invoice price per unit) of the Product to third parties representing sales invoiced by Pedinol, its Affiliates or any third-party designee of such parties, less deductions for the following, to the extent actually paid or allowed:

(a) tariffs, duties, sales and excise taxes paid or allowed by a selling party and any other governmental charges imposed upon the sale of the Product;

(b) normal and customary trade, quantity and cash discounts and other incentives actually allowed with respect to such sales;

(c) allowances, chargebacks and credits to third parties on account of rejected, damaged, defective, outdated, returned, withdrawn or recalled Product or on account of chargebacks, refunds, rebates or retroactive price reductions affecting the Product; and

(d) amounts due to third parties on account of rebate payments, including, without limitation, Medicaid rebates.

Sales between Pedinol and its Affiliates shall be excluded from the calculation of Net Sales, but Net Sales shall include the first Commercial Sale to third parties by Pedinol or such Affiliate. Where the Product is sold by Pedinol or an Affiliate (i) as one of a number of items without a separate price, or (ii) the consideration for the Product shall include any non-cash element, then the Net Sales price applicable to any such transaction shall be deemed to be Pedinol's average Net Sales price for the applicable quantity of the Product at that time.

1.9 "**Patents**" shall mean those United States patents relating solely to the Product, as further set forth on Schedule 1(a) attached hereto, and any patent applications, extensions, registrations, confirmations, reissues, renewals, re-examinations or continuations-in-part of such patents.

1.10 "**Product**" shall mean fenoprofen calcium USP for oral administration in such dosage strengths as set forth on Schedule 1(b) attached hereto.

1.11 "**Product Assets**" shall mean the Product Intellectual Property, the Regulatory Dossiers, and the Trademarks.

1.12 "**Product Intellectual Property**" shall mean all of Seller's rights, existing as of the date hereof in and to all confidential or proprietary information, trade secrets, trade names, trademarks, copyrights, patent rights, research and results thereof, technology, know-how, discoveries, records of inventions (whether or not patentable), developments, improvements, techniques, data, methods, processes, instructions, formulae, recipes, drawings and specifications relating solely to the research, development, manufacture, use and registration of the Product and

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the API, including, without limitation, the Patents and the Trademarks; provided, however, that notwithstanding the foregoing, Product Intellectual Property shall not include the Drug Master File.

1.13 "**Product NDA**" shall mean NDA No. 17-604 as filed with the FDA for the Product.

1.14 "**Purchase Price**" shall have the meaning set forth in Section 3.1 herein.

1.15 "**Regulatory Dossiers**" shall mean all of Seller's United States registrations, permits, licenses, authorizations, approvals, presentations, notifications or filings (together with all applications therefor), which are filed with or granted by the FDA, and which are required to make, use, market, offer for sale and sell the Product, including without limitation, the Product NDA and any supporting data, studies or documents thereto; provided, however, that notwithstanding the foregoing, Regulatory Dossiers shall not include the Drug Master File.

1.16 "**Trademarks**" shall mean all of Seller's United States rights, title and interests in and to those trademarks relating solely to the Product, as further set forth on Schedule 1(c) attached hereto.

## ARTICLE 2

### TRANSFER OF PRODUCT ASSETS

2.1 **Transfer of Product Assets**. Seller does hereby sell, convey, transfer, assign and deliver to Purchaser all of Seller's rights, title and interests in and to the Product Assets, free and clear of all claims, liens, pledges, encumbrances, mortgages, taxes, and equities of any kind whatsoever. In order to further perfect and evidence Purchaser's interest in the Product Assets (including, without limitation, the Product Intellectual Property), Seller shall execute and deliver such instruments or documents as provided in this Article 2.

2.2 **Assignment and Conveyance of Product, Product NDA, Regulatory Dossiers and Product Intellectual Property**. Simultaneously with the execution hereof, Seller is executing a Bill of Sale in the form attached hereto as Exhibit A in favor of Purchaser pursuant to which Seller sells, conveys, transfers, assigns and delivers to Purchaser all of Seller's rights, title and interest in and to the Product, the Product NDA, the Regulatory Dossiers and the Product Intellectual Property.

2.3 **Assignment of Patents**. Simultaneously with the execution hereof, Seller is executing an Assignment of Patents in favor of Purchaser in the form attached hereto as Exhibit B pursuant to which Seller sells, conveys, transfers, assigns and delivers to Purchaser all of Seller's United States rights, title and interest in and to the Patents.

2.4 **Assignment of Trademarks**. Simultaneously with the execution hereof, Seller is executing an Assignment of Trademarks in favor of Purchaser in the form attached hereto as Exhibit C pursuant to which Seller sells, conveys, transfers, assigns and delivers to Purchaser all of Seller's United States rights, title and interest in and to the Trademarks.

2.5 **Delivery of Know-How**. Subsequent to the date hereof, Seller shall promptly furnish to Purchaser all original copies of documents in the possession or control of Seller that embody the Product Intellectual Property. <sup>ATA</sup>

2.6 **Delivery of Regulatory Dossiers.** Promptly following the date hereof, Seller shall promptly furnish to Purchaser originals (Seller will retain copies) of all Regulatory Dossiers, and all files, records and data (including all those in electronic or digital form) in the possession or control of Seller or its Affiliates that relate to the Product and/or the API. At Purchaser's reasonable request, Seller shall provide to the FDA or other applicable regulatory agencies any assignments, consents or other documents necessary to transfer the ownership of the Regulatory Dossiers to Purchaser.

2.7 **Governmental Filings.** Promptly following the date hereof, Seller shall submit to the FDA the information required of a former owner pursuant to 21 C.F.R. § 314.72 with respect to the NDA, and Purchaser shall submit to the FDA the information required of a new owner pursuant to 21 C.F.R. § 314.72 with respect to the Product NDA.

2.8 **Further Assurances.** Seller shall, and shall cause its Affiliates to, execute and deliver all other documents and instruments of conveyance, transfer or assignment and take all other actions reasonably requested by Purchaser to effect the sale and transfer to Purchaser of the Product Assets in accordance with this Agreement.

### ARTICLE 3

#### PAYMENTS, OTHER AGREEMENTS

3.1 **Purchase Price.** As consideration for the sale, transfer and assignment of the Product Assets, the Purchaser shall pay to Seller the following (the "Purchase Price"):

3.1.1 One Hundred Thousand Dollars (\$100,000) payable upon the filing with the FDA for approval of (i) the relocation of the manufacturing site for the Product to Ohm's facility, and (ii) Seller, its Affiliate or a third party designee as an approved source of the API, by Seller;

3.1.2 Three Hundred Thousand Dollars (\$300,000) payable to Seller in four (4) equal installments of Seventy-Five Thousand Dollars (\$75,000) commencing ninety (90) days following the date of filing with the FDA for approval of (i) the relocation of the manufacturing site for the Product to Ohm's facility, and (ii) Seller, its Affiliate or a third party designee as an approved source of the API, and payable on the first business day of each calendar quarter thereafter until fully paid. These payments shall specifically reimburse Seller for costs associated with the relocation of the manufacturing site for the Product to Seller or its Affiliate as outlined in Section 4.2 below (For the avoidance of doubt, if the date of the filing for FDA approval, as described directly above, occurs on October 1, 2003, then the first payment under this Section 3.1.2 shall occur on January 1, 2004, the second payment shall be paid on April 1, 2004, the third payment shall be paid on July 1, 2004, and the final payment shall be paid on October 1, 2004); and

3.1.3 One Hundred Thousand Dollars (\$100,000) payable within thirty (30) days after the later to occur of: (i) Seller's receipt of FDA approval of the relocation of the manufacturing site for the Product to Seller or its Affiliate, and (ii) Seller's receipt of FDA approval of an alternative supplier of the API (which may be Seller, its Affiliates or a third party).

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3.2 **Supply Agreement.** Concurrently with the execution of the Agreement herewith, Seller shall cause its Affiliate, Ohm Laboratories, Inc. ("Ohm") to enter into a manufacturing and supply agreement with Purchaser in the form attached as Exhibit D hereto (the "Manufacturing and Supply Agreement") for Ohm's exclusive supply of the Product for a minimum term of five (5) years.

3.3 **Existing Inventory of Product.**

(a) Purchaser hereby grants to Seller a non-exclusive license in the Product Intellectual Property to allow Seller or any Affiliate to sell any inventory of the Product existing in its possession as of the date hereof, under the name and labeling of Seller. During the period in which Seller is entitled to sell the Product pursuant to this Section 3.3, Seller shall follow its normal and customary sales policies, and shall not engage in any sales practice not consistent with sales made in the ordinary course of business. In consideration therefor, Seller agrees that (i) Purchaser may accept from Purchaser's customers or distributors valid returns of any such Product sold by Seller and grant such customers or distributors refunds or credits for the purchase price thereof in accordance with Purchaser's normal practice with respect to other products sold by Purchaser; (ii) Purchaser may destroy any such returned Product, and (iii) within thirty (30) days of receipt of an invoice from Purchaser, such invoice to be provided by Purchaser to Seller on or about the tenth (10<sup>th</sup>) business day of each calendar quarter, Seller shall pay to Purchaser, the amount invoiced which reflects the aggregate amount of such refunds or credits granted by Purchaser during such recently completed calendar quarter; provided, further, that Purchaser shall maintain (i) a record of all returns to Purchaser of Product sold by Seller, and (ii) the aggregate amounts of all refunds or credits granted for a period of one (1) year from the date such refund or credit was granted by Purchaser.

(b) Upon the first sale of commercial Product by Purchaser, Seller and its Affiliates shall cease the sale of Product pursuant to this Section 3.3, and Seller or its Affiliates shall destroy any remaining inventory at Seller's expense.

ARTICLE 4

DEVELOPMENT

4.1 **Regulatory Matters.** Pursuant to Section 2.1, upon the execution of this Agreement and all documents and instruments related hereto, the ownership of the Product NDA and the Regulatory Dossiers shall be transferred to Purchaser. Subsequent to the date hereof, Purchaser shall be responsible for fulfilling any and all regulatory requirements with respect to the Product that are imposed as the owner thereof including, without limitation, the filing of documents and payment of fees to the FDA and other applicable regulatory agencies; provided, however, that Seller shall file all documents required to be filed by it as Seller, at its cost and expense, to the FDA and other applicable regulatory agencies in connection with the assignment, transfer and conveyance to Purchaser of the Product, the Patents, the Trademarks, the Regulatory Dossiers and the Product NDA.

4.2 **Manufacturing Site Transfer; API Source.** Notwithstanding Section 4.1 above, Seller agrees to use commercially reasonable efforts and diligence to obtain FDA approval (i) for the relocation of the manufacturing site for the Product to Ohm's facility as described in Section 3.1.3 above, and (ii) of Seller, its Affiliate or a third party designee as an approved source of the API, including, without limitation, the timely preparation and submission of stability studies and such other information and data as may be required or otherwise requested by the FDA. Seller shall be <sup>ATA</sup>

solely responsible for preparing all necessary filings and submissions and paying all costs and expenses related to obtaining FDA approval of Seller or its Affiliate as the manufacturer of the Product and FDA approval of Seller, its Affiliate or a third party as an approved source of the API. Seller shall notify Purchaser on or about April 15, 2004 of Seller's status of completion of the required FDA submissions and filings as described above, and Purchaser shall have fifteen (15) days to notify Seller of its desire to review such submissions. In the event Purchaser notifies Seller of its desire to review Seller's FDA submissions described in this Section 4.2, then Purchaser and Seller shall arrange for Purchaser to review such submissions on seven (7) days advance notice, provided, that Purchaser shall not delay the filing or submission by Seller unless Purchaser has identified material deficiencies in such filings or submissions which could reasonably cause a delay in Seller receiving FDA approval of Seller or its Affiliate as the manufacturer of the Product, or FDA approval of Seller, its Affiliate or a third party as an approved source of the API. Attached hereto as Exhibit E is a projected timeline for the FDA approvals described in this Section 4.2. The parties agree to adjust such projected timeline, from time to time, as may be necessary to reflect events occurring during the FDA approval process.

## ARTICLE 5

### MARKETING; ROYALTIES

5.1 **Marketing.** (a) Purchaser shall control and make all decisions regarding the strategy and tactics of marketing, selling and otherwise commercializing of the Product, including, without limitation, the method of sales and distribution, organization and management of sales and marketing and other terms and conditions for such sales and marketing of the Product, and shall exercise commercially reasonable efforts in such regard. Notwithstanding the foregoing, Purchaser, either itself or through its Affiliates or third-party designees, shall market, promote, distribute and sell the Product in a manner consistent with which it markets other Purchaser products of comparable market size and to the extent commercially reasonable in light of the size of the market for prescription products for the management of mild to moderate pain and potential market for the Product, including, without limitation, the potential gross profit to be derived from the sale of the Product, the competitive environment for the Product and the marketing costs associated with selling the Product, all as may be determined by Purchaser in its reasonable discretion.

(b) Purchaser shall promote, distribute, market, advertise and sell the Product in compliance with all material applicable laws and regulations and with the Product NDA or other regulatory guidelines.

5.2. **Royalties.** (a) As additional consideration for the sale, transfer and assignment of the Product Assets, Purchaser shall pay to Seller a royalty of six percent (6%) of Net Sales of the Product during the five (5) years commencing with the first Commercial Sale of the Product. Purchaser's obligation to pay Seller royalties pursuant to this Section 5.2 shall commence upon the first Commercial Sale of the Product by Purchaser or its Affiliates.

(b) Within forty-five (45) days after the last day of the calendar quarter following the first Commercial Sale of the Product, and within forty-five (45) calendar days following the last day of each subsequent calendar quarter during the Term, Purchaser shall furnish to Seller a written report setting forth for such calendar quarter (i) Purchaser's Net Sales of the Products, (ii) as to the first such written report only, the date of Purchaser's first Commercial Sale of the Product, (iii) the <sup>ATA</sup>



royalties for such quarter, including all items used in calculating such royalties, and (iv) the exchange rate, if any, used in calculating the royalties. Purchaser shall remit to Seller at the time of the provision of Purchaser's report, the payment of Seller's royalty for such recently completed calendar quarter. Such reports shall be subject to the provisions of Section 5.3 below. All such reports shall constitute Confidential Information subject to the Confidentiality obligations of Article 7.

(c) All amounts due to Seller shall be payable in United States Dollars. In the event the Product is sold for monies other than United States Dollars, the earned royalties will first be determined in the foreign currency of the country in which the Product was sold and then converted into equivalent United States Dollars. The exchange rate will be the United States Dollar exchange rate quoted in The Wall Street Journal on the last day of the most recently completed calendar quarter.

(d) Notwithstanding the foregoing in this Section 5.2, in the event of the commercialization of an AB Rated Product by a third party subsequent to the first Commercial Sale of the Product, then the royalty payable by Purchaser shall be as follows for such dosage strength of the Product in which an AB Rated Product has been commercialized:

(i) Upon the entry and commercialization of the first (1<sup>st</sup>) AB Rated Product, the royalty payable by Purchaser to Seller for such dosage strength of the Product shall be reduced to four percent (4%) of Net Sales of the dosage strength of the Product; and

(ii) Upon the entry of and commercialization of the second (2<sup>nd</sup>) AB Rated Product, the royalty payable by Purchaser to Seller for such dosage strength of the Product shall be reduced to two percent (2%) of Net Sales of the dosage strength of the Product provided, further, that in no event shall the royalty payable by Purchaser to Seller with respect to such dosage to which an AB Rated Product has been commercialized be reduced below two percent (2%) during the period such royalty is payable pursuant to this Section 5.2.

**5.3 Seller's Audit Rights.** Purchaser shall maintain, and Purchaser shall require its Affiliates to maintain, at their respective offices, accurate and complete books and records of the Purchaser Net Sales and the royalties payable to Seller, in such form and in such reasonable detail, as to enable Purchaser and its Affiliates to verify the Purchaser Net Sales and the royalties payable to Seller. Upon the written request of Seller, but in no event more than once each calendar year, Purchaser shall permit an independent certified public accounting firm or consultant selected by Seller and reasonably acceptable to Purchaser to have access during normal business hours to such of the records of Purchaser as may be reasonably necessary to verify the accuracy of Purchaser's payments of the royalties made hereunder for any calendar year ending not more than two (2) full years prior to the date of such request. The accounting firm shall disclose to Seller only whether such payments are correct and not the specific details concerning any discrepancies. If such accounting firm concludes that there are discrepancies in the reporting or calculation of the royalties, such accounting firm shall recalculate such amount and Purchaser shall pay any additional sums underpaid to Seller within thirty (30) calendar days of such redetermination. Fees and expenses charged by such accounting firm shall be paid by Seller. However, if the audit discloses that the royalties paid to Seller for the Products was underpaid during the audit period by more than ten percent (10%), then Purchaser shall pay the reasonable fees and expenses charged by the accounting firm.

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ARTICLE 6

REPRESENTATIONS, WARRANTIES AND COVENANTS

6.1 **Seller Representations and Warranties.** Seller represents and warrants as of the date hereof, as follows:

6.1.1 **Corporate Authority.** Seller is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware. Seller has the power and authority to own and transfer the Product Assets as provided herein. Seller has the power and authority to execute and deliver this Agreement, as well as any instruments to be executed and delivered by it pursuant hereto, and to consummate the transactions contemplated hereby. All acts required to be taken by or on the part of Seller (corporate or otherwise) to authorize the execution, delivery and performance of this Agreement have been duly and properly taken and this Agreement has been duly and promptly executed and delivered by Seller and constitutes the legal, valid and binding obligation of Seller, except as enforcement may be limited by applicable bankruptcy, insolvency, reorganization and moratorium laws and other laws of general application affecting enforcement of creditors' rights generally.

6.1.2 **Title.** Seller is the sole owner of the Product Assets, and Seller has good and marketable title to each of the Product Assets free from any liens or encumbrances. Upon consummation of the transactions contemplated hereby, good and marketable title to each of the Product Assets shall be vested in Purchaser. The Product Assets constitute the entire right, title and interest owned by Seller relating to the Product.

6.1.3 **No Conflict.** The execution, delivery and performance of this Agreement by Seller will not result in the creation of any lien or encumbrance on any of the Product Assets, or violate, conflict with or result in a breach of or constitute a default (or an event with which the giving of notice, lapse of time or both, would become a default), under the charter documents of Seller, any agreement, contract or instrument to which Seller is a party or to which its assets may be bound or affected, or, any order or decree of any court, administrative agency or governmental authority. No approval, authorization, consent or other order or action of or filing with or providing notice to any court, administrative agency, governmental authority or any other third party is required for the execution, delivery or performance of Seller under this Agreement.

6.1.4 **Litigation.** There is no pending, or to its knowledge, threatened, litigation that would reasonably be expected to affect adversely its right and ability to perform its obligations under this Agreement.

6.1.5. **Product Intellectual Property.**

(a) **Schedule 1(a)** represents a complete and accurate list of all Patents owned by Seller related to the Product;

(b) The Patents are currently in compliance with all filing and maintenance requirements; including, without limitation, payment of all filing, examination and maintenance fees;

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(c) To Seller's knowledge, the Patent is not involved in any interference, reissue, reexamination or opposition proceeding;

(d) To Seller's knowledge (i) the Patent has not been challenged or threatened, and (ii) the Patent nor Product has not been alleged to infringe any patent or proprietary right of another person;

(e) Schedule 1(c) represents a complete and accurate list of all Trademarks owned by Seller related to the Product;

(f) The Trademarks have been registered with the United States Patent and Trademark Office, are in compliance with all formal filing and maintenance requirements, and are valid and enforceable;

(g) To the Seller's knowledge (i) the Trademarks are not subject to any opposition, invalidation or cancellation proceedings, and (ii) no such action is threatened with respect to any of the Trademarks;

(h) To the Seller's knowledge the Trademarks have not been challenged or threatened, or alleged to infringe any trade name, trademark or service mark of any other person

(i) Schedule 1(d) represents a complete and accurate list of all NDAs owned by Seller related to the Product;

(j) The NDA is validly registered and on file with the FDA, and is in compliance with all formal filing and maintenance requirements, and is valid and enforceable.

6.1.6 **DISCLAIMERS.** EXCEPT AS EXPRESSLY SET FORTH IN ARTICLE 6, SELLER MAKES NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, EXPRESS OR IMPLIED, WITH RESPECT TO THE PRODUCT, PATENTS, TRADEMARKS, PRODUCT NDA, REGULATORY DOSSIERS AND PRODUCT INTELLECTUAL PROPERTY, INCLUDING, WITHOUT LIMITATION, ANY REPRESENTATION OR WARRANTY WITH RESPECT TO THE DESIGN, COMPLIANCE WITH SPECIFICATIONS, QUALITY NOR CONDITION OF THE PRODUCT, OR ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

6.2 **Purchaser Representations and Warranties.** Purchaser represents and warrants as of the date hereof as follows:

6.2.1 **Corporate Authority.** Purchaser is a corporation duly organized, validly existing and in good standing under the laws of the State of New York. Purchaser has the power and authority to own and use the Product Assets as provided herein. Purchaser has the power and authority to execute and deliver this Agreement, as well as any instruments to be executed and delivered by it pursuant hereto, and to consummate the transactions contemplated hereby. All acts required to be taken by or on the part of Purchaser (corporate or otherwise) to authorize the execution, delivery and performance of this Agreement have been duly and properly taken and this Agreement has been duly and promptly executed and delivered by Purchaser and constitutes a legal, valid and binding obligation of Purchaser, except as enforcement may be limited by applicable <sup>ATA</sup>

bankruptcy, insolvency, reorganization and moratorium laws and other laws of general application affecting enforcement of creditors' rights generally.

6.2.2 **No Conflict**. The execution, delivery and performance of this Agreement by Purchaser will not violate, conflict with or result in a breach of or constitute a default (or event with which the giving of notice, lapse of time or both, would become a default), under any order or decree of any court, administrative agency or governmental authority, the charter documents of Purchaser or any agreement, contract or any other instrument to which Purchaser or any other Affiliate is a party or to which its or their assets or property may be bound or affected. No approval, authorization, consent or other order or action of or filing with or providing notice to any court, administrative agency, governmental authority or any other third party is required for the execution, delivery or performance of Purchaser under this Agreement.

6.2.3 **Litigation**. There is no pending, or to its knowledge threatened, litigation that would reasonably be expected to affect adversely its right and ability to perform its obligations under this Agreement.

## ARTICLE 7

### CONFIDENTIALITY

7.1 **Protection of Confidential Information**. Purchaser and Seller shall:

(a) not disclose any confidential and proprietary information of the other to third parties except to: (i) government authorities; or (ii) such party's Affiliates, consultants or actual or potential contract manufacturers, licensees, distributors, purchasers, joint ventures, clinical investigators or other persons having bona fide business relations with such party, in each case pursuant to a non-disclosure commitment; and

(b) take such precautions as it normally takes with its own confidential and proprietary information to prevent disclosure to third parties of any confidential and proprietary information (except as contemplated above).

7.2 **Exceptions**. No party shall be obligated to maintain confidentiality under this Article with respect to any information that:

(a) at the time of disclosure is or thereafter becomes available to the general public other than by breach of this Article by such party;

(b) is obtained by such party from a third-party source who is not breaching a commitment of confidentiality to the other party to this Agreement by disclosing such information to such first party; or

(c) is required to be disclosed pursuant to law to protect such party's interest or in connection with any litigation, investigation or regulatory proceeding, or as otherwise required by law. *MA*

## ARTICLE 8

### INDEMNITY

8.1 **Indemnity Obligations.** Each party shall indemnify and hold harmless the other party hereto and its Affiliates, successors and permitted assigns (and the respective officers, directors, stockholders, partners and employees of each) from and against any and all losses, liabilities, claims, actions, proceedings, damages and expenses arising out of (i) the breach or inaccuracy of any representation or warranty made by a party herein, (ii) the breach of any covenant or agreement made by such party herein, or (iii) the negligence or willful misconduct of such party, or their respective Affiliates, or any of their respective officers, directors, agents or employees; provided, that Seller's indemnity obligations with respect to the breach or inaccuracy of its representations and warranties shall not exceed the Purchase Price.

8.2 **Indemnification.** If a party intends to claim indemnification under this Article 8 (the "Indemnified Party"), it shall notify the party against whom indemnification is sought (the "Indemnifying Party") promptly in writing of any action, claim or liability in respect of which the Indemnified Party believes it is entitled to claim indemnification, provided that the failure to give such timely notice shall not release the Indemnifying Party from any liability to the Indemnified Party except to the extent the Indemnifying Party is prejudiced thereby. The Indemnifying Party shall have the right, by notice to the Indemnified Party, to assume the defense of any third party action or claim which may give rise to indemnification hereunder. If the Indemnifying Party so assumes such defense, the Indemnified Party may participate therein through counsel of its choice, but at the sole cost of the Indemnified Party.

8.3 **Exclusion of Warranties.** Except as expressly provided in this Agreement, neither party makes any representation or warranty to the other, whether expressed or implied, either in fact or by operation of law, by statute, or otherwise, and both parties specifically disclaim any and all implied or statutory warranties including, without limitation, any warranty of merchantability or warranty of fitness for a particular purpose.

8.4 **DISCLAIMER.** NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY CONSEQUENTIAL, INCIDENTAL OR INDIRECT DAMAGES OR EXPENSES, INCLUDING DAMAGES FOR LOST PROFITS, LOSS OF OPPORTUNITY OR USE OF ANY KIND, SUFFERED BY THE OTHER PARTY, WHETHER IN CONTRACT, TORT OR OTHERWISE.

## ARTICLE 9

### MISCELLANEOUS

9.1 **Independent Contractors.** This Agreement does not constitute Purchaser as the agent or legal representative of Seller, nor does it constitute Seller as the agent or legal representative of Purchaser. Neither Purchaser nor Seller shall have any right or authority to assume or create any obligation or responsibility or vicarious liability, express or implied, on behalf of or in the name of the other, or to bind the other in any manner.

9.2 **Notices.** All notices or other communications given pursuant hereto by one party hereto to the other party shall be in writing and deemed given (a) when delivered by messenger, (b)

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when sent by telecopier, (with receipt confirmed), (c) when received by the addressee, if sent by Express Mail, Federal Express or other express delivery service (receipt requested), or (d) five days after being mailed in the U.S., first-class postage prepaid, registered or certified, in each case to the appropriate addresses and telecopier numbers set forth below (or to such other addresses and telecopier numbers as a party may designate as to itself by notice to the other party):

If to Purchaser, to it at:

Pedinol Pharmacal, Inc.  
30 Banfi Plaza North  
Farmingdale, New York 11735  
Attention: Gary Strauss, Executive Vice President  
Telecopier No.: 631-293-7359

If to Seller, to it at:

Ranbaxy Pharmaceuticals Inc.  
4801 Executive Park Court, Suite 100  
Jacksonville, FL 32216  
Attention: James Meehan, Vice President  
Telecopier No.: 904-296-2917

With copies to:

St. John & Wayne, L.L.C.  
Two Penn Plaza  
Newark, New Jersey 07105  
Attention: John P. Reilly, Esq.  
Telecopier No. (973) 491-3555

9.3 **Force Majeure.** Neither party shall be responsible or liable to the other hereunder for failure or delay in performance of this Agreement due to any war, fire, accident or other casualty, or any labor disturbance, or act of God or the public enemy, or governmental action or any other contingency beyond such party's reasonable control. In the event of the applicability of this Section, the party affected by such force majeure shall use reasonable efforts, consistent with good business judgment, to eliminate, cure and overcome any of such causes and resume performance of its obligations.

9.4 **Successors and Assigns.** Neither party may assign this Agreement or assign or delegate its duties hereunder without the prior written consent of the other party. Notwithstanding the foregoing, Pedinol is entitled to assign the rights to the NDA and the Product Assets without the consent of Ranbaxy, in the event that it sells these assets to another party, although Pedinol will remain solely responsible for royalty payments pursuant to Section 5.2 of this agreement. All of the terms and provisions of this Agreement shall be binding upon and inure to the benefit of and be enforceable by the parties hereto and their respective successors and assigns.

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9.5 **Amendment.** This Agreement may be amended only by written agreement of the parties hereto.

9.6 **Waiver.** The failure of a party to insist upon strict adherence to any term of this Agreement on any occasion shall not be considered a waiver of that or any other term hereof or deprive that party of the right thereafter to insist upon strict adherence to that term or any other term of this Agreement. Any waiver must be in writing and be signed by the party against whom the waiver is asserted.

9.7 **Further Actions.** Each party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be reasonably necessary or appropriate in order to carry out the purpose and intent of this Agreement.

9.8 **Governing Law, Dispute Resolution, Arbitration.** This Agreement shall be governed by, and construed in accordance with, the laws of the State of New Jersey and the United States, as though made and to be fully performed therein without regard to conflicts of laws principles thereof.

The parties shall initially attempt in good faith to resolve any significant controversy, claim, allegation of breach or dispute arising out of or relating to this Agreement (hereinafter collectively referred to as a "Dispute") through negotiations between senior executives of Purchaser and Seller. If the Dispute is not resolved within thirty (30) days (or such other period of time mutually agreed upon by the parties) of notice of the Dispute (the "Executive Resolution Period"), then the parties agree to submit the Dispute to arbitration as provided herein. Unless otherwise mutually agreed by the parties, only if the Dispute is not resolved through negotiations as set forth herein, may a party resort to arbitration.

All Disputes relating in any way to this Agreement shall be resolved exclusively through arbitration conducted in accordance with the Commercial Arbitration Rules of the American Arbitration Association as then in effect. In the event either party demands arbitration, it shall do so within thirty (30) days after the expiration of the Executive Resolution Period (or any mutually agreed extension) and shall include a request that such arbitration be held within thirty (30) days of such demand. The arbitration hearing shall be held as soon as practicable. The arbitration hearing shall be held in New York City, New York and shall be before a single arbitrator selected by the parties in accordance with the Commercial Arbitration Rules of the American Arbitration Association pursuant to its rules on selection of arbitrators. The arbitrator shall render a formal, binding non-appealable resolution and award on each issue as expeditiously as possible but not more than ten (10) business days after the hearing. In any arbitration, the prevailing party shall be entitled to reimbursement of its reasonable attorneys fees and the parties shall use all reasonable efforts to keep arbitration costs to a minimum.

9.9 **Attorneys' Fees.** Each party shall bear its own legal fees incurred in connection with the transaction that is contemplated hereby, provided, however, that if either party to this Agreement seeks to enforce its rights under this Agreement by legal proceedings or otherwise, the non-prevailing party shall pay all costs and expenses incurred by the prevailing party, including, without limitation, reasonable attorneys' fees.

9.10 **Severability.** To the extent permitted by applicable law, any term or provision of this Agreement which is invalid or unenforceable will be ineffective to the extent of such invalidity

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or unenforceability without rendering invalid or unenforceable the remaining rights of the Person intended to be benefited by such term or provision or any other provisions of this Agreement.

9.11 **Entire Agreement.** This Agreement, the Manufacturing and Supply Agreement and all other agreements, certificates, documents and instruments contemplated hereby or thereby (in each case including any Exhibits or Schedules attached hereto or thereto), contains the sole and entire agreement and understanding of the parties hereto and their respective Affiliates and representatives related to the subject matter hereof and supersedes all oral or written agreements concerning the subject matter made prior to the date of this Agreement. There are no agreements, covenants or undertakings with respect to the subject matter of this Agreement or the other agreements, documents, certificates or instruments referred to in this Section 8.11 other than those expressly set forth or referred to herein or therein and no representations or warranties of any kind or nature whatsoever, express or implied, are made or shall be deemed to be made herein by the parties hereto except those expressly made in this Agreement and such other agreements, documents, certificates and instruments.

9.12 **Counterparts.** This Agreement may be executed in one or more counterparts, which may be either an original or facsimile signature, each of which shall be deemed an original but all of which shall be deemed one and the same agreement.

9.13 **Public Announcements.** Except to the extent disclosure may be required by applicable law or the rules or regulations of any stock exchange on which such party's stock is traded, neither party shall issue or make any public announcement or press release, or otherwise make any public statement, with respect to this Agreement without obtaining the other party's approval, which approval shall not be unreasonably withheld or delayed. In the event a party determines that applicable law or the rules or regulations of any stock exchange on which such party's stock is listed requires such a disclosure, it shall provide the other party a copy of the intended disclosure and provide such party a reasonable opportunity to comment on such disclosure. <sup>ATA</sup>

[SIGNATURE PAGE TO FOLLOW]



IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their  
duly authorized representatives as of the day and year first indicated above. *ATA*

RANBAXY PHARMACEUTICALS INC.

By: *James J. Meehan*  
Name: JAMES F MEEHAN  
Title: VICE PRESIDENT

PEDINOL PHARMACAL, INC.

By: *Gary Strauss*  
Name: GARY STRAUSS  
Title: Executive Vice President

BILL OF SALE

KNOW ALL MEN BY THESE PRESENTS, that in accordance with the Product Purchase Agreement of even date herewith (the "Purchase Agreement") by and between RANBAXY PHARMACEUTICALS INC., a Florida corporation having an address at 4801 Executive Park Court, Suite 100, Jacksonville, FL 32216 ("Seller") and PEDINOL PHARMACAL, INC., a New York corporation having an address at 30 Banfi Plaza North, Farmingdale, New York 11735 (the "Buyer"), for good and valuable consideration as recited in the Purchase Agreement, the receipt and adequacy of which is hereby acknowledged, Seller hereby sells, assigns, transfers, conveys and sets over to the Buyer, its successors and assigns, good, valid and marketable title, and all of Seller's rights, title, and interest in the Product Assets as such term is defined in the Purchase Agreement.

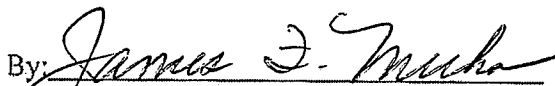
Seller hereby warrants and covenants that this Bill of Sale and the other related documents of assignment and transfer are effective to transfer, assign to and vest in the Buyer, good, valid and marketable title and all of Seller's right, title and interest in and to the Product Assets.

Seller hereby covenants that, from time to time, after delivery of this instrument, at the Buyer's request, and without further consideration, it will do, execute, acknowledge and deliver or cause to be done, executed, acknowledged and delivered, all such further acts, conveyances, transfers, assignments, powers of attorney and assurances as may be required to more effectively convey, transfer and vest in Buyer and put Buyer in possession of the Product Assets transferred and conveyed hereunder.

Capitalized terms used herein without definition shall have the meanings provided therefor in the Purchase Agreement.

IN WITNESS WHEREOF, Seller has caused this Bill of Sale to be executed this 26<sup>th</sup> day of February, 2004. *AKA*

RANBAXY PHARMACEUTICALS INC.

By:   
Name: James Meehan  
Title: Vice President

## ASSIGNMENT OF TRADEMARKS

This Assignment is being made this *26<sup>th</sup>* day of February, 2004 by and between RANBAXY PHARMACEUTICALS INC., a corporation organized and existing under the laws of the State of Florida having a place of business at 4801 Executive Park Court, Suite 100, Jacksonville, FL 32216 (the "Assignor") and PEDINOL PHARMACAL INC., a corporation organized and existing under the laws of the State of New York having a place of business at 30 Banfi Plaza North, Farmingdale, New York 11735 (the "Assignee"). Capitalized terms used but not defined in this Assignment shall have the same meanings as set forth in the Product Purchase Agreement (the "Purchase Agreement") between the Assignor and the Assignee executed concurrently with this Assignment.

WHEREAS, Assignor represents and warrants that it is the sole owner by Assignment of the entire right, title and interest in and to the trademark NALFON, and U.S. Trademark Reg. No. 974831, issued December 18, 1973 (the "Trademark"); and

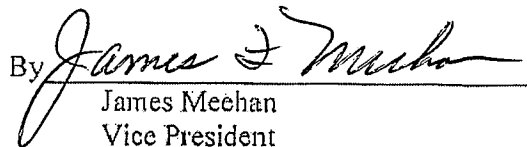
WHEREAS, Assignee is purchasing all of Assignor's United States right, title and interest in and to the Trademark pursuant to the Purchase Agreement;

NOW, THEREFORE, for good and valuable consideration, the receipt of which is hereby acknowledged, Assignor does hereby sell, assign, transfer and convey to Assignee its entire United States right, title and interest in and to the Trademark NALFON, its U.S. Registration No. 974831, and all good will symbolized by and associated with the Trademark as used, all income, royalties, and payments now or hereafter due or payable in respect thereto, and all causes of action in law or equity, for past, present or future infringement based upon the Trademark. Assignor further agrees to execute all papers and to perform such other acts as Assignee may deem necessary to secure to it the rights hereby assigned.

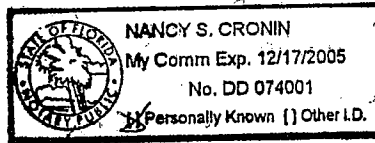
TO HAVE AND TO HOLD by the Assignee and its successors and assigns, as fully and entirely as the same would have been held and enjoyed by the Assignor had this sale and assignment not been made.

IN WITNESS WHEREOF, Assignor has caused this Assignment to be executed by its duly authorized officer on the date first above written.

AAA  
RANBAXY PHARMACEUTICALS INC.

By   
James Meehan  
Vice President

STATE OF FLORIDA )  
 ) SS.:  
COUNTY OF DUVAL )



On this 26<sup>th</sup> day of February, 2004, James Meehan personally came before me and acknowledged under oath, to my satisfaction, that:

- (c) this person signed, sealed and delivered the foregoing instrument as the Vice President of **RANBAXY PHARMACEUTICALS INC.**, a Florida corporation; and
- (d) this document was signed and delivered by **RANBAXY PHARMACEUTICALS INC.** as its voluntary act and deed by virtue of authority from its directors.

Nancy S. Cronin  
Notary Public

Schedule 1(c)

Trademarks ATA

United States Trademark

Nalfon

United States Registration Number

Reg. No. 974831

United States Registration Date

December 18, 1973

**AMENDMENT TO PRODUCT PURCHASE AGREEMENT**

This Amendment to the Product Purchase Agreement dated as of February 26, 2004 (the "Agreement") by and between **PEDINOL PHARMACAL, INC.**, having offices located at 30 Banfi Plaza North, Farmingdale, New York 11735 ("Purchaser") and **RANBAXY PHARMACEUTICALS INC.**, a Florida corporation, with its principle offices located at 4801 Executive Park Court, Jacksonville, Florida ("Seller"), is made as of this 3<sup>rd</sup> day of ~~April~~ <sup>May</sup> 2004 (the "Amendment"). Seller and Purchaser are sometimes herein referred to individually as a "Party" and collectively as the "Parties".

Unless otherwise defined herein, capitalized terms used in this Amendment shall have the meanings provided to such terms in the Agreement.

The following sets forth the background for this Amendment:

**WHEREAS**, pursuant to the Agreement, Seller sold, conveyed and transferred all of its right, title and interest in the Product Assets (as defined therein), including, without limitation, the Product, Product NDA, Regulatory Dossiers and Product Intellectual Property (as defined therein); and

**WHEREAS**, the Parties desire to amend the Agreement to allow for the retention by Seller of the Product NDA, Regulatory Dossiers and the Product Intellectual Property, excluding the Patents and Trademarks, as they were assigned by the Seller to Purchaser upon execution of the Agreement (hereinafter referred to as the "Remaining Product Intellectual Property), until such time as Seller receives approval from the FDA of (i) the relocation of manufacturing site for

the Product to the manufacturing facility of Seller's Affiliate, Ohm Laboratories, Inc. ("Ohm"), and (ii) Seller, its Affiliates or a third party designee as an approved source of the API.

NOW, THEREFORE, in consideration of the mutual promises, covenants and agreements hereinafter set forth, the Parties hereby agree as follows:

Section 1. Amendments to the Product Purchase Agreement.

The Product Purchase Agreement is hereby amended as follows:

A. **ARTICLE 2 – TRANSFER OF PRODUCT ASSETS** is hereby amended as follows:

**2.1 Transfer of Product Assets.** is hereby deleted in its entirety and replaced with the following:

"Except for the Product NDA, Regulatory Dossiers and the Remaining Product Intellectual Property, which shall be subject to Sections 2.2 and 4.1 below, Seller does hereby sell, convey, transfer, assign and deliver to Purchaser all of Seller's rights, title and interests in and to the Product Assets, free and clear of all claims, liens, pledges, encumbrances, mortgages, taxes, and equities of any kind whatsoever. In order to further perfect and evidence Purchaser's interest in the Product Assets (including, without limitation, the Product Intellectual Property), Seller shall execute and deliver such instruments or documents as provided in this Article 2."

**2.2 Assignment and Conveyance of Product, Product NDA, Regulatory Dossiers and Product Intellectual Property.** is hereby deleted in its entirety and replaced with the following:

"Upon receipt by Seller of approval from the FDA of (i) the relocation of manufacturing site for the Product to Ohm's facility, and (ii) Seller, its Affiliate or a third party designee as an approved source of the API, Seller shall execute a Bill of Sale in the form attached hereto as Exhibit A in favor of Purchaser pursuant to which Seller shall sell, convey, transfer, assign and deliver to Purchaser all of Seller's rights, title and interest in and to the Product, the Product NDA, the Regulatory Dossiers and the Remaining Product Intellectual Property. Notwithstanding the foregoing, Seller covenants that until such time as Seller receives the FDA approvals as provided in this Section 2.2, Seller shall not enter into any other license or conveyance agreements, other than with Purchaser, related to the Product."

**2.5 Delivery of Know-How.** is hereby deleted in its entirety and replaced with the following:

“Subsequent to the receipt by Seller of approval from the FDA of (i) the relocation of manufacturing site for the Product to Ohm’s facility, and (ii) Seller, its Affiliate or a third party designee as an approved source of the API, Seller shall promptly furnish to Purchaser all original copies in the possession or control of Seller that embody the Remaining Product Intellectual Property.”

**2.6 Delivery of Regulatory Dossiers.** is hereby deleted in its entirety and replaced with the following:

“Promptly following the receipt by Seller of approval from the FDA of (i) the relocation of manufacturing site for the Product to Ohm’s facility, and (ii) Seller, its Affiliate or a third party designee as an approved source of the API, Seller shall promptly furnish to Purchaser originals (Seller will retain copies) of all Regulatory Dossiers, and all files, records and data (including all those in electronic or digital form) in the possession or control of Seller or its Affiliates that relate to the Product and/or the API. At Purchaser’s reasonable request, Seller shall provide to the FDA or other applicable regulatory agencies any assignments, consents or other documents necessary to transfer the ownership of the Regulatory Dossiers to Purchaser.”

**2.7 Governmental Filings.** is hereby deleted in its entirety and replaced with the following:

“Promptly following the receipt by Seller of approval from the FDA of (i) the relocation of manufacturing site for the Product to Ohm’s facility, and (ii) Seller, its Affiliate or a third party designee as an approved source of the API, Seller shall submit to the FDA the information required of a former owner pursuant to 21 C.F.R. § 314.72 with respect to the NDA, and Purchaser shall submit to the FDA the information required of a new owner pursuant to 21 C.F.R. § 314.72 with respect to the Product NDA.”

**B. ARTICLE 4 – DEVELOPMENT** is hereby amended as follows:

**4.1 Regulatory Matters.** is hereby deleted in its entirety and replaced with the following:

“Pursuant to Section 2.1, following receipt by Seller of FDA approval of (i) the relocation of manufacturing site for the Product to Ohm’s facility, and (ii) Seller, its Affiliate or a third party designee as an approved source of the API, the ownership of the Product NDA, the Regulatory Dossiers and the Remaining Product Intellectual Property shall be transferred to Purchaser. Subsequent to the receipt by Seller of FDA approval of (i) the relocation of manufacturing site for the Product to Ohm’s facility, and (ii) Seller, its Affiliate or a third party designee as approved source of the API, Purchaser shall be responsible for fulfilling any and all regulatory requirements with respect to the Product that are imposed as the owner thereof including, without limitation, the filing of documents and payment of fees to the FDA and other applicable regulatory agencies; provided, however, that Seller shall file all documents required to be filed by it as Seller, at its cost and expense, to the FDA and other applicable regulatory agencies in



connection with the assignment, transfer and conveyance to Purchaser of the Product, the Patents, the Trademarks, the Regulatory Dossiers and the Product NDA.”

Section 2. No Further Amendments. Except as expressly provided in this Amendment, the Agreement shall remain unmodified and in full force and effect.

Section 3. Governing Law. This Amendment shall be governed by the laws of the State of New Jersey, as such laws are applied to contracts entered into and to be performed within such state as though made and to be fully performed therein without regard to conflict of laws principles.

Section 4. Counterparts. This Amendment may be executed in facsimile counterparts, each of which is hereby agreed to have the legal binding effect of an original signature. The Parties hereto agree to forward the original signatures by overnight mail to the other Party upon execution.

**[SIGNATURE PAGE ON NEXT PAGE]**

IN WITNESS WHEREOF, the parties have caused this Amendment to be executed by their duly authorized representatives as of the day and year first indicated above:

**RANBAXY PHARMACEUTICALS INC.**

By: James J. Mechan  
Name: James Mechan  
Title: Vice President - Sales & Marketing

**PEDINOL PHARMACAL, INC.**

By: Gary Strauss  
Name: Gary Strauss  
Title: Executive VP