Exhibit 10.36  
 AMENDED AND RESTATED  
MANUFACTURING AND SUPPLY AGREEMENT  
 THIS AMENDED AND RESTATED MANUFACTURING AND SUPPLY AGREEMENT (the “Agreement”) made as of January 1, 2004 (the “Effective Date”), by and between FIRST HORIZON PHARMACEUTICAL CORPORATION (“First Horizon”), a Delaware corporation, having offices at 0000 Xxxxxx Xxxx, Xxxxxxxxxx, Xxxxxxx, XXX, 00000, and PATHEON INC. (“Patheon”), a corporation existing under the laws of Canada having its registered office at 0000 Xxxxxxxxxxx Xxxx, Xxxxx 000, Xxxxxxxxxxx, Xxxxxxx, X0X 0X0.  
 WHEREAS Patheon and Sanofi-Synthelabo Inc. entered into a Manufacturing and Supply Agreement dated October 1, 1999, which was subsequently assigned by Sanofi-Synthelabo Inc. to First Horizon on August 20, 2001 (the “Original Agreement”); and  
 WHEREAS Patheon and First Horizon have decided to amend and restate the Original Agreement in order to add a new product and to revise certain of the existing terms as set forth herein;  
 NOW THEREFORE in consideration of the rights conferred and the obligations assumed herein, and intending to be legally bound, the parties hereby agree that the Original Agreement is amended and restated as follows:  
 1.0 INTERPRETATION  
 1.1 Definitions. The following terms shall, unless the context otherwise requires, have the following meanings, respectively:  
 “Active Materials” shall mean the materials listed on Exhibit A hereto.  
 “Affiliate” shall mean any Persons directly or indirectly controlling, controlled by, or under common control with such other Person at any time during the period for which the determination of affiliation is being made. For purposes of this definition, the term “controlled” (including the correlative meanings of the term “controlled by “and “under common control with”), as used with respect to any Person, shall mean the possession, directly or indirectly, of the power to direct or cause the direction of management policies of such Person whether through ownership of voting securities, by contract or otherwise.  
 “Client” shall mean First Horizon Pharmaceutical Corporation.  
 “Components” shall mean, collectively, all packaging components, raw materials and ingredients (including labels, product inserts and other labeling for the  
 \* Redacted text has been omitted and filed separtely pursuant to a request for confidential treatment.  
   
 Products), required to be used in order to produce the Products in accordance with the Specifications, including Active Materials, and “Component” means any one of the foregoing.  
 “Confidential Information” has the meaning given to the term “Information” in the Confidentiality Agreement between the parties dated as of March 12, 2002 (the “Confidentiality Agreement”).  
 “Deficiency Notice” shall have the meaning ascribed thereto in Subsection 2.6(a).  
 “FDA” shall mean the United States Food and Drug Administration.  
 “Firm Orders” shall have the meaning ascribed thereto in Section 3.2.  
 “GMPs” shall have the meaning ascribed thereto in Subsection 2.5(a).  
 “Inventory” shall mean all inventories of Components and work-in-process produced or held by Patheon in connection with the manufacture of the Products in accordance with the Specifications.  
 “Patheon” shall mean Patheon Inc.  
 “Patheon Manufacturing Requirements” shall have the meaning ascribed thereto in Subsection 2.5(a).  
 “Person” shall mean a natural person, a corporation, a partnership, a limited liability company, a trust, a joint venture, any governmental authority or any other entity or organization.  
 “Products” shall have the meaning ascribed thereto in Section 2.1.  
 “Quality Agreement” shall mean the quality agreement dated the date hereof between the parties hereto, a copy of which is attached as Exhibit D.  
 “Specifications” shall mean, collectively, (i) the product formulae, raw materials specifications, manufacturing process and packaging specifications for the Products, (ii) the quality control testing procedures and specifications for the Products, and (iii) the Client incoming inspection standards, all as provided or approved by Client in connection herewith.  
 1.2 Annual Quantity. In this Agreement for purposes of calculating the volume of product in a calendar year or any other period specified in this Agreement, references to “Products shipped and delivered” or “Products purchased” shall include Products ordered in conformity with the provisions of this Agreement for delivery within that calendar year, whether or not delivered, unless non-delivery is a result of the actions of Client.  
 \* Redacted text has been omitted and filed separtely pursuant to a request for confidential treatment.  
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 1.3 Exhibits. The following exhibits are attached hereto and are incorporated in and are deemed to be an integral part of this Agreement:  
 Exhibit A  
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Products  
Exhibit B  
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Facilities  
Exhibit C  
-  
Price List  
Exhibit D  
-  
Quality Agreement  
Exhibit E  
-  
Lot Numbering and Expiration Dates  
 1.4 Currency. All dollar amounts in this Agreement expressed in the lawful currency of the United Sates of America.  
 2.0 MANUFACTURE AND SUPPLY OF PRODUCTS  
 2.1 Manufacture. Patheon shall manufacture and sell to Client the products listed on Exhibit A hereto (the “Products”) at the prices listed on Exhibit C hereto (such prices being subject to adjustment in accordance with the terms hereof). The Products will be manufactured in the Patheon facilities listed in Exhibit B and any change to a different manufacturing facility shall be approved by the Client. Client shall purchase its entire requirement of Products for sale in the United States from Patheon pursuant to the terms of this Agreement, but the parties acknowledge that Client is not hereby or herein, including the references to volume in this Section 2.1, Article 9 and Exhibit C, giving any guarantee of annual volume of Product. If and when Client decides that it wishes to have Patheon manufacture the Product for countries in addition to the United States, the Client shall inform Patheon of any additional requirements related to such additional jurisdiction and any resulting increase in cost will be borne by the Client. The agreed additional costs and change over fees shall be set out in a written amendment to this Agreement.  
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 2.3 [Intentionally deleted.]  
 2.4 Packaging. It is agreed that the Products are to be supplied in bulk without packaging. Any references in this Agreement to Patheon performing packaging  
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 means packaging of bulk Product as opposed to finished Product. Client shall be responsible for all finished Product packaging, labels, product inserts and other labeling for the Products. Patheon’s name shall not appear on the label nor anywhere else on the Products unless required by a governmental authority or applicable laws or regulations.  
 2.5 Quality Control and Assurance.  
 (a) Patheon shall manufacture, package, test and ship the Products in accordance with (i) the current good manufacturing practices as described in Division 2 of Part C of the Food and Drug Regulations (Canada) and Parts 210 and 211 of Title 21 of the United States Code of Federal Regulations, together with the latest Health Canada and FDA guidance documents pertaining to manufacturing and quality control practices all as updated, amended and revised from time to time (collectively “GMPs”), and (ii) the Specifications. Patheon’s responsibilities and obligations described in the foregoing sentence are hereinafter referred to as the “Patheon Manufacturing Requirements”.  
 (b) Patheon shall perform the quality control and quality assurance testing specified in the Quality Agreement.  
 (c) If the Products as manufactured by Patheon do not satisfy Patheon’s quality control and quality assurance testing due to Patheon’s failure to produce the Products in accordance with the Patheon Manufacturing Requirements, Patheon shall, at its sole cost and expense, manufacture additional Products to replace such defective Products. In such circumstances, Client shall have no obligation to purchase or pay for any rejected Products.  
 (d) Notwithstanding any provisions of this Agreement to the contrary, the parties agree that Patheon shall not be liable or have any responsibility for any deficiencies in, or other liabilities associated with: (i) the formulae and procedures specified by Client; (ii) the safety (except to the extent due to the fault of Patheon as determined in accordance with the provisions of this Agreement), efficacy or marketability of the Products; (iii) distribution risk; (iv) Components, provided that any such deficiency was not reasonably discoverable using the test methods detailed in the Specifications and applying such test methods in accordance with GMP; or (v) services provided by third parties in connection with the packaging of the bulk Product.  
 (e) Each time Patheon ships Products to Client, it shall provide Client with a certificate of analysis that sets out the actual test results for each lot of Products and which certifies that the Products shipped to Client have been evaluated by Patheon’s Quality Control/Quality Assurance department and that the Products comply with the Patheon Manufacturing Requirements.  
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 Patheon shall not under any circumstances ship Non-Conforming Products (as defined in Section 2.6(a)) to Client.  
 2.6 Rejection of Products.  
 (a) Client shall inspect the Products manufactured by Patheon within thirty (30) business days after receipt at Client’s warehouse and shall give Patheon written notice (a “Deficiency Notice”) of all claims for (i) Products which do not conform to the Patheon Manufacturing Requirements or the tests results as shown on the certificate of analysis (such Products being referred to herein as “Non-Conforming Products”), or (ii) shortages in the amount of delivered Products, in each case prior to the expiry of such thirty (30) day period. Except as set out in Sections 4.2 and 4.3 below, Patheon shall have no liability for any deviations or shortages for which it has not received notice within such thirty (30) day period. Client shall return, at Patheon’s expense, any Non-Conforming Product. Cost and method of returned Non-Conforming Product disposal shall be Patheon’s responsibility.  
 (b) Upon receipt of a Deficiency Notice relating to claims under 2.6(a)(i) above, Patheon shall have 10 business days to notify Client in writing as to whether it agrees that the subject Products are Non-Conforming Products. If Client and Patheon fail to agree within 10 business days after Patheon’s notice to Client as to whether any Products identified in the Deficiency Notice are Non-Conforming Products, the parties shall mutually determine an independent laboratory to evaluate whether the Products are Non-Conforming Products. If such evaluation certifies that any Products are Non-Conforming Products, Client may have those Products replaced in the manner contemplated by Subsection 2.6(d).  
 (c) Claims for shortages set out in a Deficiency Notice delivered to Patheon pursuant to Subsection 2.6(a)(ii) shall be dealt with in accordance with normal commercial practices.  
 (d) All fees and disbursements incurred in connection with the independent determination by the laboratory as described in Section 2.6(b) above shall be borne by the party which determined incorrectly that the relevant Product was or was not a Non-Conforming Product. Within 15 days of the determination by the independent laboratory that the Product is a Non-Conforming Product, Patheon shall replace such returned Non-Conforming Product at its expense or if it is unable to make prompt replacement, shall either credit Client’s account or refund any payment made on the rejected Product, depending on Client’s account balance.  
 2.7 Stability Testing. Patheon shall conduct stability testing on the Products as required by GMPs and in accordance with the protocols approved by Client from time to time and executed by the Client and Patheon. The fee proposal for such  
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 stability testing shall be prepared by Patheon and approved by the Client, such approval to be evidenced by the Client’s execution of such proposal. Patheon shall not make any changes to these testing procedures without prior written approval from Client. In the event that any lot of Products fails stability testing, Patheon and Client shall jointly determine the proceedings and methods to be undertaken to investigate the causes of such failure, including which party shall bear the cost of such investigation. Patheon will provide any and all data and results relating to the stability testing upon request by Client. From time to time, Patheon shall, at the request of Client, also provide stability testing services with respect to products not manufactured by Patheon, the cost of such services to be agreed to between the parties prior to such services being undertaken.  
 3.0 ORDERS, DELIVERY, INVOICING AND PAYMENT  
 3.1 Yearly Forecast. On the execution of this Agreement, Client shall provide Patheon with a forecast of the volume of each Product required during the first year of this Agreement.  
 3.2 Orders/Forecasts. During the term of this Agreement, Client shall, on a monthly basis, submit to Patheon a 12 month rolling forecast that sets forth the total quantity of Product that the Client has ordered and expects to order from Patheon within the 12 month period. The first two months of such forecast are to be considered firm orders (the “Firm Orders”). Firm Orders in respect of batches of Product of not more than 24 per month will be accompanied by a purchase order for the Product to be produced and delivered to the Client on a date not less than 75 days from the date Patheon receives the purchase order. Each forecast and purchase order will be provided to Patheon no later than the 15th of each month. The parties shall mutually agree on an acceptable delivery schedule in the event the forecasted requirements exceed 24 batches.  
 In addition, in January and June of each year, the Client shall provide Patheon with a written non-binding three year forecast (broken down by quarters for the second and third years of the forecast) of the volume of each Product the Client then anticipates will be required to be produced and delivered to the Client during such three-year period.  
 3.3 Written Orders. The Firm Orders submitted to Patheon pursuant to Section 3.2 shall specify Client’s purchase order number, quantities by Product type, monthly delivery schedule and any other elements necessary to ensure the timely production and delivery of the Products. The quantities of Products ordered in such Firm Orders shall be firm and binding on Client and shall not be subject to reduction. Patheon shall provide written confirmation of receipt of Firm Orders to the Client within ten (10) calendar days of receipt thereof.  
 3.4 Reliance by Patheon. Client agrees that purchases may be made by Patheon of the Components to satisfy the production requirements for Firm Orders. In addition, the Client authorizes Patheon to purchase Components in order to satisfy  
 \* Redacted text has been omitted and filed separtely pursuant to a request for confidential treatment.  
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 the production requirements for Products for the first six months contemplated in the most recent forecast provided by the Client pursuant to Section 3.2, and agrees that Patheon may make such other purchases of Components to meet production requirements during such longer periods as may be agreed to in writing from time to time by the Client at the request of Patheon. In such circumstances, if such Components are not included in finished Products purchased by Client within six months after such purchases have been made (or such longer period as the parties may have agreed to), Client will pay to Patheon its costs thereof and, in the event such Components are incorporated into Products subsequently purchased by Client, Client will receive credit for any of such costs previously paid to Patheon by Client.  
 3.5 Minimum Orders. The Products to be manufactured and packaged by Patheon may only be ordered in quantities equal to or greater than the minimum order quantities specified in Exhibit C.  
 3.6 Late Shipments. Patheon agrees that time is of the essence of this Agreement. If Patheon becomes aware that it will not meet a scheduled delivery date, Patheon will promptly communicate this to Client. In the event of repeated late deliveries, Patheon and Client shall meet to determine a mutually satisfactory solution to this problem. If after such meetings, there are continued late deliveries, Client shall be entitled to treat same as a material breach of this Agreement and the provisions of Section 5.3(a) hereof shall apply and the time period specified in Section 5.3(a) shall commence.  
 3.7 Termination. If this Agreement expires or is terminated in whole or in part for any reason other than a default by Patheon as set out in subsection 5.3(a) or (b), Client shall (in addition to any other remedies Patheon may have in the event of default by Client):  
 (a) purchase, at Patheon’s cost, the Inventory applicable to the Products which were purchased, produced or maintained by Patheon in contemplation of filling Firm Orders, or in accordance with Section 3.4, prior to notice of termination being given. Client’s obligation under this section shall not exceed Patheon’s actual costs of Components and Inventory in order to manufacture a six month supply of Product based upon the most recent forecast unless the purchase of such Components and Inventory was authorized by the Client pursuant to Section 3.4;  
 (b) purchase all undelivered Products which were manufactured and/or packaged pursuant to a Firm Order, at the price in effect at the time the order was placed; and  
 (c) satisfy the purchase price payable pursuant to Patheon’s orders with suppliers of Components, or in accordance with Section 3.4, provided such orders were made by Patheon in reliance on Firm Orders.  
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 If this Agreement is terminated as a result of a default by Patheon, Client shall have the option to purchase such of the items referred to in (a), (b) and (c) above if it determines in its absolute discretion that the items can be used by it.  
 3.8 Specifications. All Components shall be purchased and tested by Patheon at Patheon’s expense in accordance with Patheon Manufacturing Requirements. Patheon will not change the Specifications used to manufacture, test, package and ship the Products without the written consent of Client. Amendments to Specifications requested by Client will only be implemented following a technical and cost review, subject to Client and Patheon reaching agreement as to price revisions necessitated by any such amendment in accordance with Section 3.9 below.  
 3.9 Change in Specifications.  
 (a) If Client requests a change in the Specifications which would result in an increase or decrease in Patheon’s costs for Components or would cause Patheon to incur other costs as a result of the change in Specifications, the parties shall discuss, each acting reasonably and based on satisfactory documentation provided by Patheon indicating the cause of the price change, what impact, if any, such change should have on the price of the Products and payment to Patheon of the related costs. If Client, acting reasonably, accepts a proposed price change, the proposed change in the Specifications shall be implemented, and the price change shall become effective only with respect to those orders of Products which are manufactured in accordance with the revised Specifications.  
 (b) Notwithstanding any change in the Specifications implemented in accordance with the terms of (a) above, Client agrees to purchase all Products manufactured by Patheon based upon any “old” Specifications at the then-current price for those Products. In addition, Client agrees to purchase, at Patheon’s cost, all Inventory, utilized under the “old” Specifications and purchased or maintained by Patheon in order to fill Firm written Orders to the extent that such Inventory can no longer be utilized under the revised Specifications. Open purchase orders for Components no longer required under any revised Specifications which were placed by Patheon with suppliers in order to fill Firm Orders or in accordance with Section 3.4 shall be cancelled where possible, and where such orders are not subject to cancellation without penalty, shall be assigned to and satisfied by Client.  
 (c) If a change in Specifications must be made by Client solely as a result of Patheon’s acts or omissions, the parties will meet to determine who will bear any costs arising from such change in the Specifications.  
 3.10 Shipments. Patheon shall ship and deliver the Products at Patheon’s premises at the facilities listed in Exhibit B to such Client locations as requested by Client and  
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 at Client’s expense. Client shall select the freight carrier used by Patheon to ship the Products and may monitor Patheon’s shipping/freight practices as they pertain to this Agreement. Risk of loss and title shall pass to Client upon delivery by Patheon to the freight carrier selected by Client at Patheon’s premises. For greater certainty, Patheon agrees that it will be responsible for preparation, on Client’s behalf and at Client’s expense, of all shipping documents, including customs formalities for export of the Products.  
 3.11 Invoices and Payment. Except as otherwise provided in this Agreement, Patheon shall charge Client for only those Products that are shipped to Client. Invoices shall be sent by fax or email to such fax number or email address as may be provided by the Client in writing from time to time. Patheon shall also submit to the Client, with each shipment of Products, a duplicate copy of the invoice covering such shipment. Each such invoice shall, to the extent applicable, identify the Client purchase order number, Product numbers, names and quantities, unit price, freight charges and the total amount to be remitted by Client. Client shall pay all such invoices within thirty (30) days of the date thereof.  
 3.12 Lot Numbering/Expiration Dates. Patheon shall make arrangements for and implement the imprinting of lot numbers, expiration dates, retest dates or “package-by” dates, as applicable, on each Product container as required by GMPs for each Product shipped. Such lot numbers and dates shall be affixed on the Products and/or on the shipping carton of each Product as is required by GMPs. The system used by Patheon for lot numbering and expiration dates is detailed on Exhibit E hereto. Except in circumstances constituting force majeure pursuant to Section 10.10 or an inability of Patheon to obtain Components due to no fault of Patheon or circumstances beyond Patheon’s reasonable control (including, without limitation, where Product is undergoing an investigation in respect of quality matters), Patheon shall take best efforts to ensure that Product shall have not less than 21 months remaining before expiration at the time of shipment of such Product by Patheon; provided, however, in the event that Product will have less than 21 months remaining before expiration at the time of shipment of such Product by Patheon, Patheon shall promptly notify the Client and Patheon and the Client shall endeavor to mutually agree on a resolution in respect of such shipment.  
 3.13 Technical Transfer Costs. In accordance with the terms of the Technical Transfer Proposal between the parties dated as of September 15, 2003, Patheon has agreed to absorb a portion of the technical transfer costs associated with transferring the Prenate Elite (Metafolin Formulation) to Patheon’s Niagara Region Operations facility, provided that the Client orders and pays for a minimum volume of ########## tablets of such Product within 24 months after the completion of the process validation batch of Prenate Elite (Metafolin Formulation). Notwithstanding any provision to the contrary in this Agreement, the parties agree that the Client will reimburse Patheon for the full amount of the technical transfer costs incurred by Patheon in the event that: (a) the Prenate Elite (Metafolin  
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 Formulation) Product, or any line extension thereof containing Metafolin, ceases to be produced by Patheon for any reason within 24 months after the completion of the process validation batch of such Product; or (b) a minimum volume of ########## tablets of the Prenate Elite (Metafolin Formulation) Product, or any line extension thereof containing Metafolin, is not ordered by the Client and paid for by the Client within 24 months after the completion of the process validation batch of such Product.  
 3.14 Risk Allocation of Metafolin. Client recognizes that certain financial risk exists in Patheon’s procurement of the Active Material Metafolin. If there is any loss of Metafolin due to reasons other than Patheon’s negligence or willful misconduct, then Client shall be solely liable for the cost of such loss of Metafolin; provided, however, that Patheon shall take reasonable actions to mitigate such losses. If there is any loss of Metafolin due to Patheon’s negligence or willful misconduct and Client fails to meet the minimum purchase volume of ########### tablets of Product during the calendar year, then Client shall be responsible for the cost of such loss of Metafolin to a maximum of ######## of that calendar year. If there is any loss of Metafolin due to Patheon’s negligence or willful misconduct and Client meets or exceeds the minimum purchase volume of ########## tablets of Prenate Elite Product during the calendar year, then Client shall be responsible for the cost of such loss of Metafolin to a maximum of ####### of that calendar year. Amounts owing from each party under this Section 3.14 shall be reconciled at the end of each calendar year.  
 4.0 CO-OPERATION  
 4.1 Records and Accounting by Patheon. Patheon shall keep records of the manufacture, testing and shipping of the Products, and retain samples of such Products in order to comply with applicable GMPs as well as to assist with resolving Product complaints and other similar investigations. Copies of such records and samples shall be made available to Client upon its request and shall be retained by Patheon and be available to Client for a period of one (1) year after the expiration dates of the packaged batch, or longer if required by law.  
 4.2 Product Recalls.  
 (a) Patheon and Client shall each maintain such records as may be necessary to permit a recall or a field correction of any of the Products delivered to Client or customers of Client, effected voluntarily or under a threat of, or a directive by, any governmental agency. Each party shall give notice within 24 hours by telephone (to be confirmed in writing) to the Director of Quality Control/Quality Assurance of the other party upon discovery that any Products should be recalled or corrected, or may be required to be recalled or corrected, and, each party upon receiving any such notice or upon any such discovery, shall cease and desist from further shipments of such Products in its possession or control until a decision has been made whether a recall or some other corrective action is necessary. The  
 \* Redacted text has been omitted and filed separtely pursuant to a request for confidential treatment.  
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 decision to initiate a recall or to take some other corrective action, if any, shall be made and implemented by Client. Patheon will co-operate as reasonably required by Client, having regard to all applicable laws and regulations. Each party shall co-operate with the other in developing any necessary recall plan, and the manner and extent of such plan shall be subject to prior consultation, which consultation shall not unreasonably delay such plan.  
 (b) To the extent that a recall results from, or arises out of, any breach by Patheon of the Patheon Manufacturing Requirements then (i) such recall and all reasonable expenses associated with the recall shall be made at Patheon’s cost and expense, and (ii) Patheon shall use its best efforts to replace the recalled Products with new Products within sixty (60) days from the date that Client notifies Patheon about the recalled Products. In the event that (i) Patheon is unable to replace the recalled Products within this sixty (60) day period (except where such inability results from a failure to receive the required Active Materials), or (ii) such new Products are also recalled or returned due to a breach by Patheon of the Patheon Manufacturing Requirements, then Client may request Patheon to reimburse Client for the purchase price that Client paid Patheon for the affected Products. In all other circumstances, recalls shall be made at Client’s cost and expense.  
 4.3 Product Returns. Client shall have the responsibility for handling customer returns of the Products. Patheon shall provide Client with such assistance as Client may reasonably need to handle such returns. To the extent that such return results from, or arises out of, any breach by Patheon of the Patheon Manufacturing Requirements, Patheon shall use all reasonable best efforts to replace the returned Products with new Products within sixty (60) days from the date that Client notifies Patheon about the returned Products or sooner if reasonably possible. In the event that (i) Patheon is unable to replace the returned Products within this sixty (60) day period or (ii) such new Products are also returned or recalled due to a breach by Patheon, then Client may request Patheon to reimburse Client the purchase price that Client paid Patheon for the affected Products. In all other circumstances, customer returns shall be made at Client’s cost and expense.  
 4.4 Audits.  
 (a) During the term of this Agreement, Client shall have the right, at Client’s sole cost and expense, during normal business hours and upon reasonable request and notice, to inspect the facilities, sanitation procedures and equipment used to manufacture, test and package the Products, provided, however, that there shall be no undue interference by Client’s representatives with the operations at Patheon’s facilities.  
 \* Redacted text has been omitted and filed separtely pursuant to a request for confidential treatment.  
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 (b) Client shall have the right, upon prior reasonable notice to Patheon and during normal business hours, to examine all technical records related to the Products (or to examine any portions of any technical records related to the Products, as the case may be) kept by Patheon and to request and receive reasonable samples of raw materials, packaging materials and finished Products.  
 (c) During the term of this Agreement, Patheon shall promptly notify Client of any inspections by the FDA, or any other federal, state, local or foreign government agency, of the facilities where the Products are manufactured and packaged, and shall thereupon furnish Client with copies of all reports, analyses and other documents (including responses to the FDA) relating to such inspections, where the inspections involve or may involve the Products, the Components of the Products or the manufacture of the Products. If such inspections are scheduled or conducted with advance notice, Patheon shall so advise Client and unless there is a legal prohibition against doing so, Client shall have the option to be present during the inspections. Duplicate samples of the Products given to government agencies and duplicates of the photographs taken during the inspection shall be provided to Client. Any Patheon correspondence relating to the Products shall be approved by Client prior to submission to any government agency.  
 (d) During the term of this Agreement, each party shall report promptly to the other any significant information it may receive concerning any defects, adverse reactions and unexpected side effects, if reasonably believed to be related to the Products.  
 (e) Patheon shall support the annual reporting requirements of Client under GMPs by providing Client with updated stability data for its ongoing studies for the Products.  
 4.5 Customer Questions and Complaints. Client shall have the sole responsibility for responding to questions and complaints from Client customers. Questions or complaints received by Patheon from Client customers shall be promptly referred to Client. Patheon shall co-operate as required to allow Client to resolve any customer questions and complaints. Such assistance shall include follow-up investigations including testing. In addition, within ten (10) business days from the date of request, or sooner if reasonably possible Patheon shall provide Client with all necessary information that will enable Client to respond properly to questions or complaints relating to the Products. Unless it is determined that the cause of any customer complaint resulted from a breach by Patheon of the Patheon Manufacturing Requirements or its representations in Section 6.2 hereof, all costs incurred in respect of this Section 4.5 shall be borne by Client.  
 \* Redacted text has been omitted and filed separtely pursuant to a request for confidential treatment.  
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 5.0 TERM, RENEWAL AND TERMINATION  
 5.1 Term. This Agreement shall become effective on the Effective Date hereof. Subject to any extension pursuant to Section 5.2, this Agreement shall expire five (5) years from the Effective Date hereof, unless terminated by one of the parties as provided herein.  
 5.2 Extension. This Agreement shall continue after the initial term for successive terms of one year unless either party gives written notice to the other party of its intention to terminate this Agreement at least three hundred and sixty-five (365) days prior to the end of the then current term.  
 5.3 Termination.  
 (a) Upon failure of either party to remedy its material breach of any of the obligations or provisions of this Agreement within forty-five (45) days following receipt of written notice of said breach, the aggrieved party shall have the right to terminate this Agreement immediately by written notice. For certainty, failure to purchase the minimum order quantities set forth in Exhibit C shall not constitute a breach of this Agreement.  
 (b) Either party at its sole option may immediately terminate this Agreement upon written notice, but without prior advance notice, to the other party in the event that (i) the other party is declared insolvent or bankrupt by a court of competent jurisdiction; (ii) a voluntary petition of bankruptcy is filed in any court of competent jurisdiction by such other party; or (iii) this Agreement is assigned by such other party for the benefit of creditors.  
 (c) Client may terminate this Agreement as to any Products upon thirty (30) days’ written notice in the event that any governmental agency takes any action, or raises any objection, that prevents Client from importing, exporting, purchasing or selling such Products.  
 (d) Any termination or expiration of this Agreement shall not affect any outstanding obligations or payments due hereunder prior to such termination or expiration, nor shall it prejudice any other remedies that the parties may have under this Agreement.  
 (e) Customer may terminate it’s obligation to purchase Product, by giving written notice to Patheon at least one hundred eighty (180) days prior to the effective date of such termination. Customer may not terminate this Agreement in accordance with this paragraph prior to the second anniversary date from the Effective Date.  
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 6.0 REPRESENTATIONS AND WARRANTIES  
 6.1 Authority. Each party represents and warrants that it has the full right and authority to enter into this Agreement, and that it is not aware of any impediment that would inhibit its ability to perform its obligations hereunder.  
 6.2 Patheon. Patheon represents and warrants that:  
 (i) the work it performs hereunder will be in accordance with Subsections 2.5(a) and (b);  
 (ii) the Products supplied to Client and the packaging and testing for the Products will comply in all respects with Patheon Manufacturing Requirements;  
 (iii) upon delivery, the Products will be free and clear from all liens and encumbrances, other than liens and encumbrances that are a result of actions taken by Client;  
 (iv) the Products will be manufactured at an FDA approved facility and in compliance with applicable regulatory requirements;  
 (v) the manufacture of the Products, other than the manufacture in accordance with the Specifications or the Client’s instructions, will not as a result solely of the acts or omissions of Patheon or Patheon’s agents, representatives or independent contractors infringe any valid rights of third parties; and  
 (vi) Products delivered to Client under this Agreement shall not, at the time of delivery, be adulterated or misbranded within the meaning of the Federal Food, Drug and Cosmetic Act, as amended, or within the meaning of any applicable law in which the definition of adulteration and misbranding is substantially the same as that contained in the Federal Food, Drug and Cosmetic Act, as such act and such laws are effective at the time of delivery.  
 PATHEON MAKES NO WARRANTY OF ANY KIND, EITHER EXPRESSED OR IMPLIED, BY FACT OR LAW, OTHER THAN THOSE EXPRESSLY SET FORTH IN THIS AGREEMENT. PATHEON MAKES NO WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR WARRANTY OF MERCHANTABILITY IN RESPECT OF THE CLIENT’S PRODUCT.  
 6.3 Client: Client represents and warrants that:  
 (i) the Specifications for each of the Products are its property or are licensed to it and that Client may lawfully disclose the Specifications to Patheon;  
 \* Redacted text has been omitted and filed separtely pursuant to a request for confidential treatment.  
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 (ii) any trademarks utilized in connection with any of the Products are its property or are licensed to it and may be lawfully used as directed by Client;  
 (iii) the Specifications for all Products conform to all applicable laws and regulations;  
 (iv) the Products if labeled and formulated in accordance with the Specifications will not infringe the valid intellectual property rights of any third party;  
 (v) the Specifications will not in and of themselves result in production of Products which are unfit for human consumption or adulterated or misbranded within the meaning of any applicable law;  
 (vi) the Products, if labeled and manufactured in accordance with the Specifications and in compliance with applicable GMPs (a) may be lawfully sold and distributed in every jurisdiction in which the Client markets such Products, (b) will be fit for the purpose intended, and (iii) will be safe for human consumption; and  
 (vii) the provision of the manufacturing service by Patheon in respect of any Product pursuant to this Agreement or use or other disposition of any Product by Patheon as may be required to perform its obligations under this Agreement does not and will not infringe any intellectual property rights of any third party.  
 7.0 INDEMNITY  
 7.1 Patheon. Subject to Sections 2.5(d) and 7.3, Patheon agrees to defend, indemnify and hold harmless Client, its Affiliates, officers, directors, employees and agents against any and all losses, damages, costs, claims, demands, judgments and liability of any kind (including attorneys’ fees) (collectively, “Liabilities”) arising out of or attributable to (i) Patheon’s breach of its representations or warranties under this Agreement or its obligation to manufacture, package, test and ship Products in accordance with the Patheon Manufacturing Requirements, or (ii) any negligent or wrongful act or omission on the part of Patheon, its employees, agents or representatives except, in each case, to the extent that any such Liabilities are due to the negligence or wrongful act(s) of Client, its Affiliates, officers, directors, employees or agents.  
 7.2 Client. Subject to Section 7.3, Client agrees to defend, indemnify and hold harmless Patheon, its Affiliates, officers, directors, employees and agents against any and all Liabilities arising out of or attributable to, (i) Client’s breach of its representations or warranties under this Agreement, or (ii) any negligent or wrongful act or omission on the part of Client, its Affiliates, officers, directors, employees, agents or representatives except, in each case, to the extent that any  
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 such Liabilities are due to the negligence or wrongful act(s) of Patheon, its officers, directors, employees or agents.  
 7.3 Consequential Damages. A party shall not be liable to the other party for that other party’s consequential damages, but for greater certainty nothing in this Section 7.3 shall limit the liability of a party under its indemnity of the other party in this Article 7 in respect of damages suffered by the other party which include consequential damages of a third party.  
 8.0 CONFIDENTIALITY  
 8.1 During and in furtherance of this Agreement, each of the parties hereto may disclose certain of its Confidential Information to the other party. The parties agree that for the term of this Agreement (including any renewals) and for a period of five years after the termination of this Agreement, such Confidential Information shall be subject to the terms of the Confidentiality Agreement, which terms are incorporated herein by reference.  
 9.0 PRICE  
 9.1 Annual Price Adjustments. The fees for the Products listed in Exhibit C during any period following the first anniversary of this Agreement shall be determined in accordance with the following:  
 (a) Annual Price Adjustment. On January 1st of each calendar year of this Agreement, Patheon shall be entitled to an adjustment to the fees (i) for manufacturing services in respect of the Products to reflect inflation, which adjustment shall be based on the increase in the Consumer Price Index, Canada (All Items) published by Statistics Canada in September of the then current year compared to the same month of the preceding year which shall not exceed four percent (4%) of the then current year’s costs associated with manufacturing services, unless the parties otherwise agree in writing; and (ii) for Component costs to pass on the actual amount of any increase or decrease in such costs. Such annual price increases shall be effective on January 1st of each calendar year.  
 (b) Annual Forecast. To the extent that Patheon determines that the projections contained in the Client’s most recent forecast provided in accordance with Section 3.2 necessitate that an adjustment be made to the fees in respect of any Product for such year, Patheon shall, within 30 days of receipt by Patheon of the yearly forecast, be entitled to request an appropriate price adjustment.  
 (c) Pricing Basis. The Client acknowledges that the fee in respect of a Product in any year is quoted based upon the minimum order quantity and minimum annual quantity per Product specified in Exhibit C or thereafter specified in the forecast provided pursuant to Section 9.1(b) for the year and is subject to change if the specified minimum order quantity and  
 \* Redacted text has been omitted and filed separtely pursuant to a request for confidential treatment.  
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 minimum annual quantity is not met. For greater certainty, if Patheon and the Client agree that the minimum order quantity in respect of a Product shall be reduced whether as a result of a decrease in minimum annual quantity or otherwise and, as a result of such reduction, Patheon’s fees for services relating to such Product increase on a per unit basis, then Patheon shall be entitled to an increase in the fee in respect of such Product by an amount sufficient to absorb such increase.  
 In connection with a fee adjustment pursuant to Section 9.1(a), Patheon shall deliver to the Client a revised Exhibit C and a statement outlining the percentage increase in the Consumer Price Index, Canada (All Items) upon which such fee adjustment is based. In connection with all fee adjustment requests pursuant to this Section 9.1(b) and 9.1(c), Patheon shall deliver to the Client a revised Exhibit C and such budgetary pricing information or other documentation reasonably sufficient to demonstrate that a fee adjustment is justified, provided that Patheon shall have no obligation to provide any supporting documents to the extent such documents are subject to obligations of confidentiality between Patheon and its suppliers. Upon delivery of such a request, each of the Client and Patheon shall forthwith use all reasonable efforts to agree on a revised fee in respect of each affected Product.  
 9.2 Mid-Year Price Adjustments. During any year of this Agreement, the fees set out in Exhibit C shall be subject to adjustment in accordance with the following:  
 (a) Volume Reduction. If at any time and from time to time Patheon determines, acting reasonably and based on the forecasts and Firm Orders received from the Client, that the current yearly run-rate volumes (including, without limitation, any permanent reductions in volumes) relating to a specific Product will constitute no more than 85% of the minimum annual quantities for that Product specified in Exhibit C hereto or, if applicable, any revised minimum annual quantity hereinafter agreed to by the parties, then Patheon shall be entitled to request an adjustment to the fee in respect of that Product to reflect the increased costs that Patheon will incur as a result of the reduced volumes.  
 (b) Extraordinary Increases in Component Costs. If at any time market conditions result in Patheon’s cost of Components being materially greater than normal forecasted increases, then Patheon shall be entitled to request an adjustment to the fee in respect of any affected Product to compensate it for such increased Component costs. For the purposes of this Section 9.2(b), changes materially greater than normal forecasted increases shall be considered to have occurred if: (i) the cost of a Component increases by 10% of the cost for that Component upon which the fee quote was based; or (ii) the aggregate cost for all Components required to manufacture a Product increases by 5% of the total Component costs for such Product upon which the fee quote was based. To the extent that fees have been previously adjusted pursuant to Section 9.1(a) or this Section 9.2(b) to  
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 reflect an increase in the cost of one or more Components, the adjustments provided for in (i) and (ii) above shall operate based on the costs attributed to such Component (or Components) at the time the last of such adjustments were made.  
 In connection with a fee adjustment request pursuant to this Section 9.2, Patheon shall deliver to the Client a revised Exhibit C and such budgetary pricing information, adjusted Component costs or other documentation reasonably sufficient to demonstrate that a fee adjustment is justified, provided that Patheon shall have no obligation to provide any supporting documents to the extent such documents are subject to obligations of confidentiality between Patheon and its suppliers. Upon delivery of such a request, each of the Client and Patheon shall forthwith use all reasonable efforts to agree on a revised fee in respect of each affected Product.  
 Notwithstanding anything to the contrary in Sections 9.1 and 9.2 hereof, Patheon shall not be entitled to a price increase pursuant to Section 9.1(a) to the extent that such price increase was reflected in a price increase already taken pursuant another provision of Section 9.1 or 9.2.  
 9.3 Tooling Costs. Client shall reimburse Patheon promptly upon request for any costs related to tablet press tooling and printing press change parts specific to the Prenate logo required for the production of the Products. These charges are to be approved by Client prior to incurring these costs.  
 10.0 MISCELLANEOUS  
 10.1 Product Discontinuation. During the term of this Agreement or any extension, Client shall provide at least six (6) months advance notice if it intends to no longer order a Product due to its discontinuance. In such event, Client shall have the right to terminate this Agreement as it relates to the discontinued Product and shall, subject to Sections 3.7 and 5.3(d), have no further liability hereunder in respect of such discontinued Product.  
 10.2 Compliance with Laws. Each party, in connection with its performance under this Agreement, shall comply with all applicable laws, rules, regulations, and orders including maintaining all insurance coverage required by state, federal, provincial or other applicable laws.  
 10.3 Permits. Patheon shall, at its own expense, obtain and maintain the necessary permits required for the manufacture, packaging and testing of the Products, provided that Patheon shall not be responsible for obtaining or maintaining any permits or other regulatory approvals in respect of the Products or the Specifications, which shall be the sole responsibility of Client.  
 10.4 Trademarks. Client and Patheon hereby acknowledge that neither party has, nor shall it acquire, any interest in any of the other party’s trademarks or trade names unless otherwise expressly agreed to in writing. The parties agree not to use any  
 \* Redacted text has been omitted and filed separtely pursuant to a request for confidential treatment.  
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 trademark or trade name of the other party, except as specifically authorized by the other party.  
 10.5 Reports. Patheon will on an annual basis supply Product data, including release test results, complaint test results, all investigations (in manufacturing, testing and storage), and the like, which Client reasonably requires in order to complete the Annual Product Review report that is required to be filed by Client with the FDA.  
 10.6 Insurance. Each party shall maintain comprehensive general liability insurance, including blanket contractual liability insurance covering the obligations of that party under this Agreement through the term of this Agreement and for five (5) years thereafter, which insurance shall afford limits of not less than $2,000,000 for each occurrence for bodily injury liability, personal injury liability, products liability, property damage liability, contractual liability and completed operations liability. If requested, each party will provide the other with a certificate of insurance evidencing the above and showing the name of the issuing company, the policy number, the effective date, the expiration date and the limits of liability. The insurance certificate shall further provide for a minimum of thirty (30) days written notice to the recipient of a cancellation of, or material change in, the insurance, subject to the insurer’s agreement to so state on the certificate.  
 10.7 Independent Contractors. The parties shall be deemed to be independent contractors, and this Agreement shall not be construed to create between Patheon and Client any other relationship such as, by way of example only, that of employer-employee, principal agent, joint-venturer, co-partners or any similar relationship, the existence of which is expressly denied by the parties hereto.  
 10.8 No Waiver. Each party’s failure to require the other party to comply with any provision of this Agreement shall not be deemed a waiver of such provision or any other provision of this Agreement.  
 10.9 Assignment. Patheon may not assign this Agreement or any of its rights or obligations hereunder except with the written consent of Client, such consent not to be unreasonably withheld, provided, however, that Patheon may arrange for subcontractors to perform specific testing services arising under this Agreement without the consent of the Client. Client may assign this Agreement or any of its rights or obligations hereunder without approval from Patheon provided that the proposed assignee is credit-worthy in the opinion of Patheon acting reasonably, Client shall give prior written notice of any assignment to Patheon and any assignee shall covenant in writing with Patheon (and Patheon shall be reasonable in connection therewith) to be bound by the terms of this Agreement. Notwithstanding the foregoing provisions of this Section 10.9, either party may assign this Agreement to any of its Affiliates or to a successor to all or substantially all of its business and, in the case of Client, all or substantially all of the business related to the Products covered by this Agreement, provided that the proposed assignee is credit-worthy in the opinion of the non-assigning party  
 \* Redacted text has been omitted and filed separtely pursuant to a request for confidential treatment.  
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 acting reasonably and that such assignee executes an agreement with the non-assigning party hereto whereby it agrees to be bound hereunder  
 10.10 Force Majeure. Neither party shall be liable for the failure to perform its obligations under this Agreement if such failure is occasioned by a contingency beyond such party’s reasonable control, including, but not limited to, strikes or other labour disturbances, lockouts, riots, wars, fires, floods or storms. A party claiming a right to excused performance under this Section 10.10 shall immediately notify the other party in writing of the extent of its inability to perform, which notice shall specify the occurrence beyond its reasonable control that prevents such performance. Such other party shall have the right to receive alternative arrangements during the period of the force majeure and, after 3 months, shall have the right to terminate this Agreement.  
 10.11 New Products. The parties covenant and agree that additional products may be added to this Agreement and such additional products shall be governed by the general conditions hereof with any special terms (including, without limitation, price) governed by an addendum hereto.  
 10.12 Debarment. Patheon represents and warrants that it and its employees, Affiliates and agents have never been (i) debarred or (ii) convicted of a crime for which a person can be debarred, under Section 306(a) of the Generic Drug Enforcement Act of 1992 (Section 306 (a) or (b)). Patheon represents and warrants that it has never been and, to the best of its knowledge after due inquiry, none of its employees, affiliates or agents has ever been (1) threatened to be debarred or (2) indicted for a crime or otherwise engaged in conduct for which a person can be debarred, under Section 306(a) or (b). Patheon agrees that it will promptly notify Client upon learning of any such debarment, conviction, threat or indictment.  
 10.13 Notices. Any notice, approval, instruction or other written communication required or permitted hereunder shall be sufficient if made or given to the other party by personal delivery, by telecopier communication or by sending the same by first class mail, postage prepaid to the mailing address, or telecopier number set forth below:  
 If to Client:  
 First Horizon Pharmaceutical Corporation  
0000 Xxxxxx Xxxx  
Xxxxxxxxxx, Xxxxxxx  
XXX 00000  
 Attention: Vice President of Operations  
 Telecopier No.: 000-000-0000  
 \* Redacted text has been omitted and filed separtely pursuant to a request for confidential treatment.  
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 With a copy to:  
 First Horizon Pharmaceutical Corporation  
0000 Xxxxxx Xxxx  
Xxxxxxxxxx, Xxxxxxx  
XXX 00000  
 Attention: General Counsel  
 If to Patheon:  
 Patheon Inc.  
0000 Xxxxxxxxxxx Xxxx, Xxxxx 000  
Xxxxxxxxxxx, Xxxxxxx  
Xxxxxx X0X 0X0  
 Attention: President  
 Telecopier No.: (000) 000-0000  
 or to such other addresses or telecopier number provided to the other party in accordance with the terms of this Section 10.13. Notices or written communications made or given by personal delivery or by telecopier shall be deemed to have been sufficiently made or given when sent (receipt acknowledged), or if mailed, five (5) days after being deposited in the United States or Canadian mail, postage prepaid or upon receipt, whichever is sooner.  
 10.14 Entire Agreement. The Confidentiality Agreement and this Agreement constitute the full, complete, final and integrated agreement between the parties hereto relating to the subject matter hereof and supersedes all previous written or oral negotiations, commitments, agreements, transactions or understandings with respect to the subject matter hereof, including, without limitation, the Original Agreement. Any modification, amendment or supplement to this Agreement must be in writing and signed by authorized representatives of both parties.  
 10.15 Headings. The titles and headings herein are for convenience only and shall not be used to interpret or construe the terms and conditions of this Agreement.  
 10.16 Singular Terms. Except as otherwise expressly provided herein or unless the context otherwise requires, all references to the singular shall include the plural as well.  
 10.17 Execution in Counterparts. This Agreement may be executed in two (2) counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.  
 \* Redacted text has been omitted and filed separtely pursuant to a request for confidential treatment.  
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 10.18 Governing Law. This Agreement shall be construed and enforced in accordance with the laws of New York.  
 IN WITNESS WHEREOF, the duly authorized representatives of the parties have executed this Agreement as of the date first written above.  
 Patheon Inc.  
 By:  
 /s/ Xxxxx X. Xxxxxxx  
 Title  
President Patheon North America  
 First Horizon Pharmaceutical Corporation  
 By:  
 /s/ Xxxxxx X. Zacks  
 Title  
VP, Legal & Administration  
 \* Redacted text has been omitted and filed separtely pursuant to a request for confidential treatment.  
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 EXHIBIT A  
 PRODUCTS  
 PRODUCT  
 ACTIVE MATERIAL  
 Prenate EliteTM (Metafolin formulation) Tablets in Bulk  
 Metafolin  
 OptinateTM (Prenate Elite formulation and DHA 250 mg L-V capsule packaged together as one pharmaceutical drug product)  
 Metafolin  
 \* Redacted text has been omitted and filed separtely pursuant to a request for confidential treatment.  
   
 EXHIBIT B  
 FACILITIES  
 The Products may be manufactured at the following Patheon facilities:  
 Patheon Niagara Region Operations:  
000 Xxxxxx Xxxxxx  
Xxxx Xxxx, Xxxxxxx  
X0X 0X0  
Xxxxxx  
 Patheon York Xxxxx Operations:  
000 Xxxx Xxxxx Xxxx  
Xxxxxxx, Xxxxxxx  
X0X 0X0  
Xxxxxx  
 \* Redacted text has been omitted and filed separtely pursuant to a request for confidential treatment.  
   
 EXHIBIT C  
 PRICE LIST  
 TOTAL VOLUME OF PRODUCTS  
DURING A CALENDAR YEAR  
 PRICE  
65 million tablets or less  
 ###### per 1000 tablets  
65 million to 130 million tablets  
 ###### per 1000 tablets in excess of 65 million  
All volumes over 130 million tablets  
 ###### per 1000 tablets in excess of 130 million  
 Minumum order quanity: 6 batches representing an aggregate of 7,182,000 tablets  
 \* Redacted text has been omitted and filed separtely pursuant to a request for confidential treatment.  
   
 EXHIBIT D  
 QUALITY AGREEMENT  
 \* Redacted text has been omitted and filed separtely pursuant to a request for confidential treatment.  
   
 EXHIBIT E  
 LOT NUMBERING AND EXPIRATION DATES  
 Patheon Niagara Region Operations:  
 Products manufactured at Patheon will bear lot numbers and will have expiry dates as described in Patheon SOP NROQ009.  
 Patheon York Xxxxx Operations:  
 Products manufactured at Patheon will bear lot numbers as described in Patheon SOP #MMG011 and will have expiry dates as described in Patheon SOP #MCT 154.  
 \* Redacted text has been omitted and filed separtely pursuant to a request for confidential treatment.