EXHIBIT 10.25  
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\* Certain portions of this exhibit have been omitted pursuant to a request for confidential  
treatment which has been filed separately with the SEC.  
MANUFACTURING AGREEMENT  
This Manufacturing Agreement is effective as of February 6, 2008 (“Effective Date”) by and among Bayer HealthCare, LLC, a Delaware limited liability company with an office at 00000 Xxxx Xxxxxxx Xxxxxxx Xxxxxxx, Xxxxxxx, XX 00000 (hereinafter “Bayer”), and Cumberland Pharmaceuticals Inc., a Tennessee corporation, organized under the laws of Tennessee, having its principal place of business at Nashville, TN (hereinafter “Cumberland”) and their products described herein.  
WITNESSETH:  
 WHEREAS, Cumberland is a manufacturer and developer of healthcare products and is the owner of all rights to certain proprietary technical information, patents, and patent applications relating to its products.  
 WHEREAS, Bayer is a manufacturer of healthcare products and possesses the requisite expertise, personnel, and facilities for the manufacture and supply of injectable products and is willing to manufacture for and supply to Cumberland such products as specified in Exhibit 1 and to perform such services described in Exhibit 1 (One Time Costs to Cumberland).  
 WHEREAS, Cumberland wishes to engage Bayer and Bayer desires to accept such engagement to perform at Bayer’s facilities certain manufacturing, packaging, labeling, and/or laboratory services on behalf of and for the benefit of Cumberland with respect to production of its Product (the “ Manufacturing Services”).  
 NOW, THEREFORE, in consideration of the premises, the mutual covenants herein contained, and other good and valuable consideration the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:  
1. DEFINITIONS  
 For the purposes of this Agreement, the following terms shall have the meanings set forth below:  
 1.1 Active Pharmaceutical Ingredient” shall mean the pharmacologically active agent for the manufacture of a Product.  
 1.2 Affiliate — Any person or business entity which directly or indirectly controls, is controlled by, or is under common control with a party to this Agreement. In this Agreement, an Affiliate of Cumberland will include the distributor of Products. A business entity shall be deemed to “control” another business entity, if it owns directly or indirectly, fifty percent (50%) or more of the outstanding voting securities, capital stock, or other comparable equity or ownership interest of such business entity, or exercises equivalent influence over such entity. If the laws of the jurisdiction in which such entity operates prohibit ownership by a party of fifty percent (50%) or more, “control” shall be deemed to exist at the maximum level of ownership allowed by such jurisdiction.  
 1.3 Components — All materials (including, Active Pharmaceutical Ingredient, packaging and shipping materials), whether produced by Bayer or procured from Cumberland or a third party vendor, which are incorporated into the Product by Bayer in the performance of its Manufacturing Services.  
 1.4 Cumberland Components means those “Components” which are furnished by Cumberland or by a third party vendor on behalf of Cumberland.  
 1.5 Drug Master File shall mean the Drug Master File for manufacturing an Active Latent Pharmaceutical Ingredient filed with the United States Food & Drug Administration, and the equivalent filing with the governing health authority of any other country.  
 1.6 Latent Defect — Any instance where all or portion of batch of a Product fails to conform to the  
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applicable Specifications, Legal Requirements or is otherwise defective or fails to conform to the warranties given by Bayer herein, and such failure would not be discoverable upon reasonable physical inspection performed pursuant to Bayer’s standard operating procedures of such Product. Product containing Latent Defects may be rejected in accordance with the procedures set forth in Sections 2.5 and 2.6 hereof.  
1.7 Legal Requirements — Any present and future national, state, or local law (whether under statute, rule, regulation, or otherwise), including, without limitation, US Federal Food, Drug and Cosmetic Act of 1934, and the regulations promulgated there under, as the same may be amended from time to time (the “Act”); requirements under permits, orders, decrees, judgments, or directives; and requirements of a Regulatory Agency and any other applicable government authorities, including without limitation Good Manufacturing Practices as promulgated by the United States Food and Drug Administration and specified in the U.S. Code of Federal Regulations Parts 210 and 211, as amended from time to time. The determinations of Cumberland regarding Legal Requirements shall be dispositive for purposes of this Agreement.  
1.8 Process — The practices and procedures to be followed in the manufacturing, labeling, packaging, storage, and transport of the Product, as agreed to by the parties.  
1.9 Product(s) — The final Product(s) that is (are) delivered by Bayer to Cumberland or Cumberland’s designee after all Manufacturing Services have been completed by Bayer as specified in Exhibit 1. Additional Products may be added to Exhibit 1 by mutual written agreement signed by both parties.  
1.10 Quality Agreement — The certain Quality Agreement executed by the parties hereto in connection with this Agreement.  
1.11 Regulatory Agency — A regulatory authority having jurisdiction over the manufacture or sale of a Product.  
1.12 Specifications — The specifications set forth in the Quality Agreement, as may be amended by Cumberland after written notice to Bayer, from time to time.  
 2. DESCRIPTION OF SERVICES  
 2.1 Bayer will perform all Manufacturing Services described in the attached Exhibit 1 in accordance with the terms and conditions of this Agreement and the Quality Agreement, as well as in accordance with any manufacturing procedure adopted by written agreement of the parties hereto after production of pilot batches (a “Master Batch Record”), as applicable, and with all Legal Requirements. Bayer shall perform the Manufacturing Services on a timely basis so as to meet the volume requirements of Cumberland as set forth pursuant to Article 3 below. Without limiting the generality of the foregoing, Cumberland will, at its sole cost and expense, obtain and maintain all Drug Master Files, licenses, permits, certifications, and approvals from any and all Regulatory Agencies which are or may become necessary for the lawful performance of the Manufacturing Services. Bayer shall not make any change whatsoever in the manufacturing facilities, equipment, processes, testing procedures, validation procedures, Specifications, materials or Components, Cumberland Components, or documentation systems used to perform the Manufacturing Services if such change would cause any variation in the quality or merchantability or affect any Regulatory Agency submission, license, permit, certification, or approval required for the performance of the Manufacturing Services, either foreign or domestic, without the prior written consent of Cumberland.  
 2.2 Bayer shall use commercially reasonable efforts to meet Cumberland’s requested delivery dates, which shall be not more than 90 days after Bayer’s receipt of Cumberland’s purchase orders. Requested delivery dates may be changed only by mutual written agreement. In the event that Bayer has reason to believe that it will be unable to meet the agreed upon delivery dates, Bayer will notify Cumberland promptly and state the reason(s) for the delay.  
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In addition to all other available remedies available, Cumberland may procure products from an alternate source in order to meet delivery dates that are unattainable by Bayer. Bayer shall not be responsible for delays caused by carriers selected by Cumberland.  
2.3 Bayer warrants that all Products delivered to Cumberland or Cumberland’s designee pursuant to this Agreement will conform to the Specifications at the time of delivery and will comply with all Legal Requirements in effect at the time of such delivery and shall not be adulterated or misbranded within the meaning of the Act. Bayer agrees to promptly notify Cumberland in writing of any defects in the Products or of any defects as they relate to the manufacture and/or supply of the Products. Bayer shall notify Cumberland and their designee within three (3) business days of learning of any failure of any batch of Products to meet the standards provided by Cumberland pursuant to this Agreement or as otherwise set forth in the Quality Agreement.  
 EXCEPT AS PROVIDED IN THIS SECTION 2.3, BAYER MAKES NO REPRESENTATION OR WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, WITH RESPECT TO THE SUPPLY OF THE PRODUCTS, ITS MERCHANTABILITY, OR ITS FITNESS FOR A PATICULAR PURPOSE. BAYER SHALL NOT BE LIABLE FOR ANY CONSEQUENTIAL DAMAGES OR LOSS OF ANTICIPATED PROFITS SUSTAINED BY CUMBERLAND.  
2.4 If Bayer notifies Cumberland of the non-conformance of Products and Bayer is unable to provide Products that conform to the Specifications and comply with all applicable Legal Requirements within ninety (90) days of such notice, contingent on supply of components including new materials, Cumberland may, without limiting any remedies available to it, discontinue the purchase of non-conforming Products from Bayer, without any further obligation to Bayer, and purchase replacement products from an alternate manufacturer until such time as Bayer is able to resume production of Products with Cumberland’s approval in accordance with the Specifications and applicable Legal Requirements, subject to depletion of any inventory on hand that was purchased or is to be delivered pursuant to contractual commitments to purchase such Product from the alternate source or sources. In the event Cumberland orders Product from an alternate supplier as provided herein, Bayer shall, at Cumberland’s request, provide all reasonable assistance requested by Cumberland to qualify an alternate supplier and supply such alternate supplier with the necessary Active Pharmaceutical Ingredient at Bayer’s actual manufacturing or acquisition cost. Bayer shall reimburse Cumberland on demand for the difference between the cost of obtaining such substitute Product (plus any commercially reasonable charges, expenses or commissions incurred by Cumberland in connection with effecting cover, and any other reasonable expenses incident to such failure), less the price which would have been due to Bayer for the like quantity of Product if supplied by Bayer hereunder.  
2.5 Bayer shall obtain and maintain all equipment required to fulfill its obligations under this Agreement consistent with applicable Good Manufacturing Practices. All Products are subject to Cumberland’s inspection prior to acceptance. Cumberland shall have fifteen (15) business days following the receipt of Products to inspect the Products for the purposes of rejecting all or a portion of such Products if all or a portion of the Products (i) fails to conform to the Specifications, (ii) shall not have been manufactured in compliance with then applicable Bayer requirements, or (iii) otherwise fails to conform to the warranties set forth in this Agreement; provided, however, that in the event there is a Latent Defect in the Products, Cumberland shall have the right to reject all or a portion of the Products that contain such Latent Defects following discovery thereof, subject to the requirements of Section 2.6 below. Upon detection of any defect, Cumberland shall give notice to Bayer specifying the manner in which all or part of such shipments fails to meet the foregoing requirements and may withhold payment for that shipment or portion thereof which it has rejected.  
2.6 Upon detection of any material defect, including a Latent Defect, Cumberland shall give notice within three (3) business days to Bayer specifying the manner in which all or part of such shipment fails to meet the foregoing requirements and may withhold payment for that shipment or portion thereof which it has rightfully rejected. Bayer shall have fifteen (15) days within which to cure such defect. In the event that Cumberland rightfully rejects any products  
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and payment has already been made for such Products, Cumberland shall be entitled to recoup the payment amount if Bayer is unable to cure such defect within the fifteen (15) day period. In the event of any dispute between the parties as to whether Cumberland has rightfully rejected any products, the parties shall submit such dispute to a mutually agreed to independent laboratory. The determination by such laboratory shall be final and binding and the costs therefor shall be borne by the non-prevailing party.  
2.7 Bayer shall provide all documents and updates with regard to the Product which are required by any Regulatory Agency, and shall submit to all inquiries and inspections by any such Regulatory Agency. All documents provided by Bayer to any Regulatory Agency with regard to the Product shall be provided to Cumberland in advance, if feasible, and in any case within two (2) business days after such documents are provided to any Regulatory Agency. Bayer shall promptly notify Cumberland of all scheduled inspections of Bayer’s facilities or records by a Regulatory Agency concerning the Product, whereupon Cumberland shall have the right to be present for such inspection. Bayer shall provide any and all written and verbal communications from any Regulatory Agency pertaining to or affecting the Active Pharmaceutical Ingredient or the Product no more than two (2) business days after Bayer receives such communications, including any summary or other record of inspectional observations or findings and all related communications by Bayer with such Regulatory Authority. Cumberland shall have the right to audit Bayer’s facilities or records during regular business hours on not less than seven (7) days prior written notice by the Cumberland. Such audit shall be limited to facilities and records pertaining to the Product.  
2.8 Nothing in this Agreement shall prevent Cumberland or its Affiliates from manufacturing Product for amounts in excess of the orders for Product placed with Bayer in accordance with this Agreement. Further, Cumberland or its Affiliates shall not be prevented from qualifying and using sources of supply other than Bayer and securing Manufacturing Services or Product from those other sources, as long as such activities do not interfere with the requirements of this Agreement. In no event, however, shall Bayer disclose to any third party Cumberland Confidential Information (as defined in Article 7 below) belonging to Cumberland, it being understood that any information contained in the Master Batch Record does constitute Confidential Information belonging to Cumberland.  
 3. SUPPLY OF PRODUCT  
3.1 Bayer and Cumberland shall cooperate in estimating and scheduling the performance of the Manufacturing Services and the delivery of Product to Cumberland.  
3.2 Within [\*\*\*] days after execution of this Agreement and thereafter monthly within [\*\*\*] days of that respective month, Cumberland shall provide non-binding forecasts for Product to Bayer by month for the immediately succeeding twelve (12) month period.  
3.3 Cumberland shall issue purchase orders setting forth the quantities and delivery dates at least [\*\*\*] days in advance of the requested delivery date. Bayer shall be obligated to formulate and supply Product in accordance with quantities and delivery dates requested in the firm orders placed by Cumberland, Bayer will procure sufficient bulk quantities to produce product prior to or at the time a purchase order is issued.  
3.4 Bayer agrees to give timely notice to Cumberland of any maintenance, plant modifications, or other event that may affect Bayer’s capacity or otherwise affect its ability to meet forecasted quantities with sufficient advance notice to permit Cumberland to order additional Product to meet its requirements for such periods. Bayer shall use commercially reasonable efforts to assure that adequate capacity is available to fulfill future requirements of Cumberland.  
3.5 Bayer shall use Cumberland designated carriers. In the event that a Cumberland designated carrier is not available, Bayer may use a qualified carrier of its choice, with prior written approval from Cumberland. Products shall be packed and shipped in accordance with Cumberland’s instructions, good commercial practices and in compliance with all Legal Requirements. Each shipment of Product shall be clearly marked as per Cumberland’s  
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requirements. Shipment will be FOB Shawnee, Kansas. Number of shipments are limited to no more than three (3) locations per batch quantity.  
3.6 Neither Bayer nor any Affiliate thereof will sell, give away, or deleiver to any other person, firm, or corporation any form of Product for indications currently approved as of the Effective Date while this Agreement is effective and for two years after the termination of this Agreement.  
 4. FEES  
4.1 In consideration for the services to be performed by Bayer, Cumberland will pay Bayer a fee per unit of Product delivered to and accepted by Cumberland. The quantity and fee per unit to be paid by Cumberland shall be as specified in the attached Exhibit 2. The quantity and one-time costs to be paid by Cumberland shall be as spedified in the attached Exhibit 1. Regarding definition of Cumberland as described on page 1, responsibility of payment solely resides with Cumberland.  
4.2 Except as otherwise provided in Exhibit 2, beginning on the [\*\*\*] anniversary of the Effective Date and on each anniversary thereafter, either Bayer or Cumberland may propose an adjustment to the prices ser forth in Exhibit 2. Either party hereto shall notify the other party hereto in writing of any proposed fee adjustment at least [\*\*\*] days prior to implementation of any price adjustment. Such notice shall include a cost matirx and reasonable and reasonable justification for such fee adjustment. Fee adjustments shall be based solely on significant changes in cost of goods or manufacturing and may not exceed the actual increases in costs incurred by Bayer in the manufacture of the Product. In the event the fees specified by Bayer in a notice to Cumberland pursuant to this Paragraph 4.2 represent an increase of more than [\*\*\*] over the then current fees, the parties agree to negotiate in good faith the new contract fee based upon actual increases in Bayer’s underlying cost of providing the Manufacturing Services. If the parties cannot agree as to the new contract fee, either party, at its election, may terminate this Agreement, subject to the provisions of Paragraph 8.6 below, as of a date specified which is not less than [\*\*\*] months after written notice of any such termination. Notwithstanding the foregoing, the percentage change in the then current fees shall not exceed the appropriately adjusted reflecting the cost of living on [\*\*\*] of the year in which the fee adjustment is to become effective over and above such costs as of [\*\*\*] of the index for urban wage earners and clerical workers published by the Bureau of Labor Statistics of the United States Department of Labor or a successor or substitute index appropriately adjusted.  
4.3 In the event of any change in the Specifications requested by Cumberland, Cumberland shall reimburse Bayer for costs actually incurred by Bayer in connection with such change, including without limitation, one-time development costs specifically related to such change, costs of obsolescence of raw materials, goods-in-process, packaging material components and supplies (bulk containers and labels), and finished goods, which shall be valued at the cost incurred by Bayer, except that finished goods inventory will be valued at the Price pursuant to Exhibit 2 of this Agreement.  
4.4 All fees shall be determined on the basis of Product being delivered F.O.B. Cumberland’s third party packager [plant location] and may be subject to change by mutual agreement of the parties hereto after the third anniversary of the Effective Date.  
4.5 Fees payable by Cumberland to Bayer under this Agreement shall be due and payable [\*\*\*] days after the receipt of Bayer’s invoice and all required accompanying documentation to be supplied by Bayer and acceptance of the delivered Product by Cumberland. If Cumberland does not timely issue a notice of non-conformity of the delivered Product to Bayer pursuant to the Quality Agreement, such delivered Product shall be considered accepted by Cumberland. Bayer will issue its invoice only at such time as Product  
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has been released pursuant to the terms and conditions of the Quality Agreement, and only at such time as the documents specified in the Quality Agreement have been delivered by Bayer to Cumberland. Past due invoices are subject to a late charge at the maximum rate of 18% per annum or a minimum charge of $2.00, whichever is greater. A 15-day grace period will apply.  
5. ADVERSE EVENTS/RECALLS/WITHDRAWALS  
 5.1 Bayer shall inform Cumberland immediately of any important information relating to the activity, side effects, toxicity, and/or safety of the Product that becomes known to Bayer during the term of this Agreement. Furthermore, Bayer shall inform Cumberland immediately of any defects in the manufacturing processes for the Product that becomes known to Bayer during the term of this Agreement. Bayer agrees to carry out its obligations with respect to the reporting of adverse drug reactions as described in the attached Exhibit 3.  
5.2 Cumberland shall inform Bayer immediately of any important information relating to the activity, side effects, toxicity, and/or safety of the Product that becomes known to Cumberland during the term of this Agreement and that is relevant to the performance of the Manufacturing Services by Bayer. Cumberland agrees to carry out its obligation with respect to the reporting of adverse drug reactions as described in the attached Exhibit 3.  
5.3 In the event that a recall or market withdrawal of a Product is required by a governmental agency or authority of competent jurisdiction, or if a recall or market withdrawal of Product is deemed advisable by Cumberland in its sole discretion, such recall shall be implemented and administered in a manner which is appropriate and reasonable under the circumstances and in conformity with any requests or orders of local Regulatory Agencies, as well as accepted trade practices. The costs and expenses associated with the recalling or withdrawing a Product shall be paid by Cumberland, provided, however, that if the recall or withdrawal is related to a failure of Bayer to follow the Specifications or to any act or omission of Bayer in its performance of the Manufacturing Services, the costs of the recall solely related to Bayer’s failure in performance shall be borne by Bayer. In the event that a Product is recalled or that Cumberland is required to disseminate information relating to a Product covered by this Agreement, Cumberland shall so notify Bayer within a reasonable time so as to enable Bayer to provide Cumberland with such assistance in connection with such recall as may reasonably be requested by Cumberland. Bayer will comply with all such reasonable requests from Cumberland. Cumberland shall handle exclusively the organization and implementation of all recalls of the Product.  
 6. INDEMNIFICATION  
 6.1 Bayer shall indemnify, defend and hold Cumberland, its Affiliates, and their respective principals, directors, officers, employees, representatives and agents harmless from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys’ and consultants’ fees and amounts paid in settlement with the consent of Bayer, which consent shall not be unreasonably withheld or delayed) arising from any claim, lawsuit, or other action made, brought, or threatened against Cumberland as a result of (i) a breach or default of this Agreement or the Quality Agreement by Bayer, or (ii) any act or omission by Bayer in the performance of the Manufacturing Services, except to the extent such claim, lawsuit, or other action results from any act or omission by Cumberland relating to its performance of this Agreement. Cumberland shall inform Bayer of any such claim, lawsuit, or other action to which this Paragraph 6.1 applies within a reasonable time after receiving notice thereof. Cumberland shall have the right to retain, at its own expense, its own legal counsel to defend it with respect to such claim, lawsuit, or other action and to participate in the defense thereof, provided, however, that to the extent Bayer is obligated to indemnify Cumberland, Bayer shall have control of the defense of the action.  
6.2 Cumberland shall indemnify, defend and hold Bayer, its Affiliates, and their respective principals, directors, officers, employees, representatives and agents harmless from and against any and all losses, damages, liabilities, costs and expenses (including reasonable  
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attorneys’ and consultants’ fees and amounts paid in settlement with the consent of Cumberland, which consent shall not be unreasonably withheld or delayed) arising from any claim, lawsuit, or other action made, brought, or threatened against Bayer as a result of (i) a breach or default of this Agreement or the Quality Agreement by Cumberland, or (ii) the sale, use, or distribution of the Product by Cumberland, except to the extent such claim, lawsuit, or other action results from any act or omission by Bayer in the performance of the Manufacturing Services specified herein. Bayer shall inform Cumberland of any such claim, lawsuit, or other action to which this Paragraph 6.2 applies within a reasonable time after receiving notice thereof. Bayer shall have the right to retain, at its own expense, its own legal counsel to defend it with respect to such claim, lawsuit, or other action and to participate in defense thereof; provided, however, that to the extent Cumberland is obligated to indemnify Bayer, Cumberland shall have control of the defense of such action.  
6.3 Bayer or Cumberland, as the case may be, will respond to all reasonable requests from the other to assist in the disposition of any claim, lawsuit, or other action to which Paragraphs 6.1 and/or 6.2 apply.  
6.4 Title and risk of loss to the the in-process and released Product shall remain with Bayer while such Product is in the possession of Bayer.  
 7. CONFIDENTIALITY  
7.1 Each party may from time to time provide to the other party information (hereinafter “Confidential Information”). For purposes of this Agreement, Confidential Information shall not include:  
 a. information which was known to the receiving party prior to receipt from the disclosing party, as evidenced by written records;  
 b. information which was in the public domain or generally known to the trade at the time of receipt from the disclosing party;  
 c. information which enters the public domain or becomes generally known to the trade through no fault of the receiving party;  
 d. information which is disclosed to the receiving party by a third party who is not under an obligation of confidentiality to the disclosing party;  
 e. information which is independently developed by the receiving party without use of the disclosing party’s Confidential Information, as evidenced by written records; or  
 f. information which is required to be disclosed by law, regulatory, administrative or judicial order, provide that the receiving party has provided the disclosing party with sufficient advance notice or such disclosure to enable the disclosing party to seek to restrict the public disclosure of such Confidential Information.  
7.2 Each party’s Confidential Information shall be kept confidential by the other party and shall not be disclosed by such other party for a period that is five (5) years from the expiration or termination of this Agreement. Such Confidential Information shall not be disclosed by such other party other than to its officers, employees, and agents who are engaged in its operations relating to the Product and who have the need to know such Confidential Information for purposes of meeting its obligations under this Agreement and the Quality Agreement. The receiving party will only use Confidential Information of the disclosing party in the furtherance of the purposes of this Agreement. Either party may use a discloser’s Confidential Information for the purpose of obtaining and maintaining approvals of a Regulatory Agency or to otherwise meet Legal Requirements with respect to Product. Notwithstanding the foregoing, Confidential Information may be disclosed if it is required to be disclosed in compliance withapplicable laws or regulations, subpoena, court order, or order of such other governmental or regulatory agency having competent jurisdiction; or either party reasonably believes that it is necessary to disclose Confidential Information in connection with any action, suit, or proceeding before any court or any governmental or other  
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regulatory agency or body, or any arbitral panel; or any audit or investigation brought by any governmental or other regulatory agency or body; or the assertion of any claim against any insurer or other third party; provided, however, that reasonable measures shall be taken to assure confidential treatment of such information. Each party recognizes that any violation of this confidentiality provision would cause the other irreparable harm and agrees that the other party shall be entitled, in addition to any other right or remedy it may have, at law or in equity, to an injunction without the posting of any bond or other security, enjoining the disclosing party, its affiliates and their respective officers, directors, employees, and agents from any violation or potential violation of this Article 7.  
7.3 All new techniques, discoveries, inventions, processes, and know-how (each a “New Development”) relating to the Product which are developed by Bayer during the performance of this Agreement and which result from access to Cumberland or its Affiliates Confidential Information shall be the property of Cumberland or its Affiliates. Cumberland or its Affiliates shall grant to Bayer a nontransferable, nonexclusive, royalty-free, worldwide, perpetual license to make, use, sell, and offer to sell such New Development(s). This licensing shall expire upon termination of this agreement. Notwithstanding the grant of such license, Bayer shall not use such New Development(s) of Cumberland or its Affiliates Confidential Information to compete, or assist third parties in competing, directly or indirectly, with Cumberland or its Affiliates in the use or sale of the Product Bayer agrees to cooperate in the filing and prosecution of all New Development(s) patent applications filed by Cumberland or its Affiliates, but Cumberland or its Affiliates shall bear all associated expenses. As to New Development(s) which may be developed by Bayer during the performance of this Agreement which relate to the Product but which do not result from access to Confidential Information of Cumberland or its Affiliates, Bayer grants to Cumberland or its Affiliates a nontransferable, royalty-free, irrevocable, worldwide, nonexclusive license to make, have made, sell, or offer to sell the New Development(s) in connection with the Product.  
7.4 Neither party shall use the other’s name or refer to it directly or indirectly in an advertisement, news release, or release to any professional or trade publication without written approval from such party. The parties expressly consent to such disclosure in filings with the Securities and Exchange Commission and the Food and Drug Administration and analogous agencies in other countries. Cumberland or its Affiliates and Bayer agree that the existence and contents of this Agreement shall be maintained in confidence and not disclosed or used for any purpose without the prior written consent of each party, except as otherwise provided herein or required by law.  
 7.5 The provisions of this Article 7 shall survive termination of this Agreement for any reason.  
 8. TERM  
 8.1 This Agreement shall become effective on the Effective Date and, except as otherwise provided herein, shall be in effect for an initial term of five (5) years. Thereafter, so long as this Agreement is in force, it shall be automatically renewed for additional terms of one (1) year, unless one party elects to terminate this Agreement by notice thereof to the other party in writing at least six (6) months prior to expiration of the then existing term.  
8.2 Either party may terminate this Agreement for a material breach by the other party by giving the breaching party written notice, specifying the breach relied on, and giving the breaching party thirty (30) days to cure such breach. If the breaching party has not cured the default at the end of the thirty (30) day period, then, upon notice thereof to the breaching party by the other, this Agreement shall terminate. Termination for breach will have no effect on obligations that have accrued up to the effective date of such termination or any obligations that, by their terms, survive the termination of this Agreement.  
8.3 Cumberland shall have the right to terminate this Agreement upon thirty (30) days notice in the event of a change of the site of manufacture of any Products to any site that has not been approved by Cumberland. Such approval shall not be unreasonably withheld.  
 8.4 Cumberland may terminate this Agreement in the event of a change in control of Bayer. A  
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change in control shall mean the occurrence of either of the following events: (i) any “person” or “group” (as such terms are defined in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”)), which is a competitor to Cumberland, is or becomes the “beneficial owner” (as such term is used in Rule 13d-3 under the Exchange Act) of more than fifty percent (50%) of the total voting power of Bayer (whether by acquisition of stock, merger, or otherwise) or (ii) Bayer sells all or substantially all of the assets utilized in connection with this Agreement. Any termination pursuant to this Paragraph 8.4 shall be effective on the thirtieth (30th) day following the date on which such written notice is given.  
8.5 In the event of any proceedings, voluntary or involuntary, in bankruptcy or insolvency, by or against Cumberland or Bayer, or the appointment with or without the party’s consent of a receiver for either party, or the other party makes or seeks to make a general assignment for the benefit of its creditors or applies for or consents to the appointment of a trustee or custodian for it or a substantial part of its property, and such situation is not cured within thirty (30) days from its occurrence, the other party shall be entitled to terminate this Agreement upon giving written notice.  
8.6 In the event of termination pursuant to this Section 8, the parties will cooperate in the orderly transition of supply so as not to cause inconvenience to either party. Should termination in accordance with this section 8 be initiated by Bayer, Bayer shall notify Cumberland in writing of its desire to so terminate; provided, however, that termination by Bayer shall not be effective until Cumberland has located and arranged for continuation of any ongoing Manufacturing Services with another product manufacturer, so long as such termination procedure shall not extend beyond eighteen (18) months from Bayer’s written notice of termination to Cumberland. In the event Bayer terminates this Agreement as provided hereunder, Bayer shall, at Cumberland’s request, provide commercially reasonable assistance requested by Cumberland to qualify an alternate supplier. The parties will cooperate during such period to continue the Manufacturing Services on the basis set forth in this Agreement. In the event of notice of such early termination by Cumberland, Bayer shall perform such functions reasonably necessary or required in connection with the orderly wind-down of the Manufacturing Services as required by the terms of this Agreement and/or any Legal Requirements, including any applicable Regulatory Agency regulations, and Cumberland shall pay Bayer for the Manufacturing Services performed, under the terms and conditions of this Agreement.  
8.7 Cumberland shall also have the right to terminate this Agreement upon thirty (30) days written notice to Bayer in the event a Regulatory Agency does not approve the Product for marketing; or a Regulatory Agency withdraws marketing approval; or Cumberland otherwise terminates the commercial sale of Product. If Cumberland terminates pursuant to this provision or a Regulatory Agency does not approve the Product for marketing or withdraws marketing approval, Cumberland shall reimburse Bayer for any purchases of Components used in the performance of the Manufacturing Services which cannot be cancelled, as well as associated documented out-of-pocket costs incurred by Bayer in performances of Manufacturing Services. The reimbursement shall be made within thirty (30) days following receipt by Cumberland of an invoice itemizing the costs of such Components and Manufacturing Services. Bayer agrees to transfer to Cumberland any Components paid for by Cumberland under this provision. Termination under this provision shall have no effect on payment obligations that otherwise may have accrued up to the effective date of termination.  
 9. COMPLIANCE WITH APPLICABLE LAW  
9.1 During the term of this Agreement, Bayer and all its subcontractors, employees, agents, representatives, and invitees shall comply with all applicable laws, governmental regulations, rules, requirements, ordinances, and other requirements of federal, state, and local authorities. Bayer is not authorized to take any action in the name of or otherwise on behalf of Cumberland which would violate any of the foregoing.  
9.2 Bayer represents and warrants that at the time of submission of its proposal for the performance of the Services, it was and remains properly licensed and qualified to do business in all jurisdictions in which the Services are to be performed, and agrees that it will maintain such licenses and qualifications and acquire any additional licenses and  
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qualifications as may be thereafter required by law or otherwise. If any licenses required by law are revoked or altered, Bayer shall immediately notify Cumberland.  
9.3 Bayer represents and warrants that it has not and has never been, nor has any of its employees, agents, or subcontractors who may provide services under this Agreement ever been debarred or, to the best of its knowledge, (i) convicted of a crime for which a person or entity can be debarred, under Section 306(a) or 306(b) of the United States Generic Drug Enforcement Act of 1992 or under 42 USC Section 1320a-7, or (ii) sanctioned by, suspended, excluded, or otherwise ineligible to participate in any federal health care program, including Medicare and Medicaid, or in any federal procurement or non-procurement programs.  
 9.4 Bayer agrees:  
 a. to comply with the equal employment opportunity and affirmative action provision of: (1) Executive Order 11246, as amended and U.S. Dept. of Labor regulations issued pursuant thereto (41 CFR 60); (2) Section 503 of the Rehabilitation Act of 1973 (29 U.S.C. 793), as amended; and U.S. Dept. of Labor regulation issued pursuant thereto (41 CFR 60-741), in contracts for $2500 or more; and (3) Section 402 of the Vietnam Era Veterans Readjustment Assistance Act of 1974 (38 U.S.C. 2012), and U.S. Dept. of Labor regulations pursuant thereto (41 CFR 60-250), in contracts for $10,000 or more; Title VII of Civil Rights of 1964, 78 Stat. 253, as amended, and regulations issued pursuant thereto.  
10. INSURANCE  
 a. Each Party shall obtain and maintain insurance coverage against such liability in limits provided in Exhibit 4. Each Party stipulates that it will use its best efforts such that the insurance will not be cancelled while this Agreement is in effect without thirty (30) days prior written notice to the other Party. Each Party shall maintain such insurance during the Term and thereafter for so long as it customarily maintains insurance for itself for similar products and activities. Each Party shall use its best efforts so that the other Party is named as an additional insured under the Product Liability policy and shall provide the other Party proof of such insurance upon request. Each party shall use its best efforts to provide reasonable notice to the Party listed as additional insured on its Product Liability Policy of any cancellation, termination, or change in such insurance, such prior written notice to be no less than thirty (30) days of any such change. Each Party shall obtain and maintain product liability insurance coverage against such liability in limits provided in Exhibit 4. Each Party stipulates that the insurance will not be cancelled while this Agreement is in effect without thirty (30) days prior written notice to the other Party.  
11. MISCELLANEOUS  
 11.1 Except as provided in Paragraph 7.3, nothing in this Agreement will be deemed or construed as providing either party any right, title, interest, or license in or under any intellectual property right owned or controlled by the other party.  
 11.2 Modifications and amendments to this Agreement and its Exhibits require the written consent of both parties.  
 11.3 No waiver of any requirement of this Agreement, whether by conduct or otherwise, will be effective unless in writing. The waiver in any one or more instances will not be deemed or construed to be a further or continuing waiver of any such requirement or of any other requirement of this Agreement.  
 11.4 The provisions of this Agreement shall be deemed separate. Accordingly, the invalidity, illegality, or unenforceability of any particular provision of this Agreement shall not in any way affect or impair the other provisions, and this Agreement shall be construed in all respects as if such invalid, illegal, or unenforceable provision were omitted, except in cases where such unenforceable provision is a basic requirement of any party or both parties to  
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enter into this Agreement.  
11.5 Any notice required or permitted to be given hereunder will be deemed sufficient if delivered by hand or sent by overnight courier to the parties at the addresses set forth below, or such other addresses as either party may designate. Notice will be deemed given when received.  
If to Bayer, to:  
Xx. Xxxxxx Xxxxxx  
VP of Operations  
00000 Xxxx Xxxxxxx Xxxxxxx Xxxxxxx  
Xxxxxxx, XX 00000  
with a courtesy copy, which shall not constitute notice hereunder, sent to:  
Xxxxxxx Xxxxxx-Xxxxx  
Assistant General Counsel  
00000 Xxxx Xxxxxxx Xxxxxxx Xxxxxxx  
Xxxxxxx, XX 00000  
If to Cumberland, to:  
Cumberland Pharmaceuticals Inc.  
0000 Xxxx Xxx Xxxxxx  
Xxxxx 000  
Xxxxxxxxx, XX 00000  
Attn X.X. Xxxxxx  
with a courtesy copy, which shall not constitute notice hereunder, sent to:  
Xxxxx and Xxxxx LLP  
000 Xxxxxx Xxxxxx  
Xxxxx 0000  
Xxxxxxxxx, XX 00000  
Attn. Xxxxxx X. Xxxxx, Xx.  
11.6 Neither party will assign this Agreement, or subcontract any of its obligations hereunder, to any other person or entity other than to one or more Affiliates, without the prior written consent of the other party, which consent will not be unreasonably withheld; however, in the event of any assignment or subcontract, the party effecting such assignment or subcontract shall guarantee the performance of the assignee or subcontractor in a form satisfactory to the other party. Notwithstanding the foregoing, either party may, without such written consent, assign this Agreement, and its rights and objections hereunder, in connection with the transfer or sale of all or substantially all of its business or part of its business to which this Agreement pertains, or in the event of its merger or consolidation or change in control or similar transaction, provided the permitted assignee shall have assumed all obligations of the assignor under this Agreement.  
11.7 This Agreement will be binding upon and inure to the benefit of the permitted successors or permitted assigns of Bayer and Cumberland.  
 11.8 This Agreement shall be construed, interpreted, and applied in accordance with the laws of the State of New York ,without reference to it conflict of laws provisions.  
11.9 Product labeling (primary, secondary, and insert) and filings with a Regulatory Agency may indicate that the Product has been manufactured for Cumberland by Bayer. Except when Legal Requirements mandate or when necessary to seek the approval of any Regulatory Agency,  
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neither party shall make any other use of the other party’s name without the other party’s prior written approval.  
11.10 If either of Bayer or Cumberland is impeded in fulfilling its undertakings in accordance with this Agreement due to any cause beyond the reasonable control of Bayer or Cumberland, as the case may be, such as, but not limited to fires, flood, earthquakes, lightening strike, acts of God, catastrophic accident, terrorism, war, mobilization or unforeseen military call-up of a large magnitude, requisition, confiscation, commandeering, public decrees, acts, restraints, regulations or directions of governmental authorities, riots, insurrections, general shortage of transport, goods, or energy and faults or delays in deliveries from subcontractor or supplier caused by any circumstances referred to in this Paragraph 11.10, the impediment shall be considered a Force Majeure, and the party shall be exempted from liability for delays due to such reasons, provided always that it notified the other party thereof without undue delay after such a circumstance has occurred. Upon such notification, Bayer and Cumberland shall agree upon a reasonable extension of the delivery time, not to exceed two (2) months. If, after two (2) months following notification of the Force Majeure condition, such condition persists, Cumberland may cancel the purchase orders affected by the Force Majeure condition. Notwithstanding any of the foregoing, if any extension of the delivery time causes hardship to Cumberland in the maintenance of its business, Cumberland may purchase its Products requirements during such extension period from a third party as provided above.  
11.11 Neither party shall have the right to control the activities of the other in the performance of this Agreement, and each shall perform as an independent contractor, and nothing herein shall be construed to be inconsistent with that relationship or status. Under no circumstances shall the employees or agents of one party be considered employees or agents of the other. This Agreement shall not constitute, create, or in any way be interpreted as a joint venture, partnership, or formal business organization of any kind.  
11.12 This Agreement, together with its attached Exhibits and the Quality Agreement and the Services Agreement dated February 6, 2008, constitutes the entire agreement between Bayer and Cumberland with respect to the Manufacturing Services to be performed by Bayer. The requirements of this Agreement supersede all prior understandings and agreements, whether oral or written, all terms and conditions contained within any purchase order, acknowledgement, invoice, or other agreement between Bayer and Cumberland with respect to the Manufacturing Services. Other terms and conditions not inconsistent with the terms and conditions of this Agreement covering Products to be supplied under this Agreement will be provided in purchase orders and releases issued by Cumberland and in order acknowledgements and invoices issued by Bayer. In the event of a conflict between the terms and conditions of any of these documents, including the Quality Agreement, Bayer and Cumberland agree to negotiate in good faith to resolve such differences, unless such terms conflict with the terms of this Agreement, in which case the terms of this Agreement shall control.  
11.13 Bayer and Cumberland covenant and agree that subsequent to the execution and delivery of this Agreement and without any additional consideration, each of Bayer and Cumberland shall execute and deliver any further legal instruments and perform such acts which are or may become necessary to effectuate the purposes of this Agreement.  
11.14 Bayer and Cumberland agree to use their best efforts to resolve any and all disputes arising out of or relating to this Agreement. If after thirty (30) days following receipt of notice by one party from the other of a dispute under this Agreement, the parties are unable to resolve the dispute, then the matter shall be fully and finally resolved in a court of law.  
11.15 The heading of the Articles and Paragraphs used in this Agreement are included for convenience only and are not to be used in construing or interpreting this Agreement.  
11.16 This Agreement may be executed in any number of counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. Bayer and Cumberland may rely upon facsimile signatures as binding execution of this Agreement and the instruments contemplated hereby. Each of Bayer and Cumberland shall promptly send originally executed versions of any documents or instruments bearing facsimile signatures to the other party  
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for record keeping purposes.  
IN WITNESS WHEREOF, the parties have caused this Agreement to be executed in duplicate by their respective duly authorized representatives, as of the date first written above.  
BAYER HEALTHCARE, LLC  
Signature: /s/ Xx. Xxxxxx Xxxxxx  
Name: Xx. Xxxxxx Xxxxxx  
Title: Vice President of Operations  
Cumberland  
Signature: /s/ X.X. Xxxxxx  
Name: X.X. Xxxxxx  
Title: Chief Executive Officer  
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Exhibits  
Exhibit 1 Description of Manufacturing Services and One Time Costs  
Exhibit 2 Quantities and Prices per Unit of Product  
Exhibit 3 Procedures for the Reporting of Adverse Drug Reactions  
Exhibit 4 Minimum Insurance Requirements  
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EXHIBIT 1  
DESCRIPTION OF MANUFACTURING SERVICES AND ONE TIME COSTS  
In the event that improved technology relating to Manufacturing Services production or costs (hereinafter “Improvements”) becomes known and available to Cumberland, then Cumberland may request Bayer to investigate the feasibility of incorporating such Improvements into the Bayer’s production. Improvements are defined as quantifiable advantages in economic, functional, or quality traits, and may include, but are not limited to, measurable improvements in Product integrity or quality, efficiencies in production, consumer satisfaction, or reduced costs. Bayer and Cumberland shall use their best efforts to implement cost, quality, and cycle time improvements. Cumberland shall bear the costs of such investigation and incorporation of improvements in to Bayer’s production.  
Project Scope Document  
Cumberland.  
Annual Quantities: See Exhibit 2  
Bayer and Cumberland are to perform the following services related to product development/product transfer activities:  
 • Bayer to perform necessary scale up/engineering batch, demonstration batching to move product to commercial manufacturing.  
 • Bayer to source all materials required to perform scale up/product transfer and begin to qualify all excipient materials.  
 • Cumberland to provide and Bayer to transfer lab methods required to support scale up and engineering batch production and cleaning validation.  
 • Bayer to produce Cumberland recommended and mutually agreed upon amount and scale of validation batches and prepare specified number of stability samples (if required).  
 • Bayer to develop validation documents and circulate for Cumberland approval and execute protocols.  
 • Bayer to develop stability program protocols (if required), circulate for Cumberland approval and execute protocols.  
 • Bayer to prepare final reports for validation and stability activities and provide to Cumberland for inclusion in the regulatory submission, as appropriate.  
 • Cumberland will advise if any tight container testing is required. Bayer may develop the protocols, for a fee, and perform that testing.  
 • Cumberland will decide and perform any leechable or extractable testing required for in-process or finish product containers.  
Bayer to perform the following services related to commercial batch production:  
 • Based on issuance of a purchase order by Company, manufacture commercial batch quantities of Product.  
 • Develop material specifications for all materials, identify suppliers of materials, procure materials and manage material inventory levels (based on forecasts).  
 • Using transferred laboratory methods for product engineering batch production/scale up activities perform incoming material testing, in-process testing and final release testing. Based on this testing a certificate of analysis will be issued, along with copy of batch records, to Cumberland on a per batch basis.  
 • Per batch, retained samples will be maintained and held by Bayer.  
 • Develop ongoing sampling protocols for stability program and maintain samples (if required)  
 • Maintain waste material and Health and Environmental Saftey (“HES”) reporting for ongoing production requirements.  
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 • Provide Cumberland audit access to manufacturing area and documents related to the production of their product(s).  
 • Ship lot quantities of finished and released vials to Cumberland, single point location. Shipment will be FOB Shawnee, KS using the carrier/method of choice from Cumberland.  
Bayer will not provide the following support activities:  
 • Assistance in the recommendation for the components or facilitate the actual submission of regulatory documents.  
 • Assume the commercial viability of this formulation and/or packaging configuration of this product in the marketplace, except as otherwise set forth in the Manufacturing Agreement.  
 • Performance/assurance of the product regarding scalability. Cumberland is requested to be present, support and approve all follow up Bayer scale up activities and share in accepted performance (and costs) of the product during those scale up activities.  
 • Assure the accuracy/reliability of original laboratory methods.  
 • Support or make claims about the placement of this product in the marketplace.  
One Time Costs:  
See Attachment I for Ibuprofen Inj One-Time Costs  
See Attachment II for Acetadote Inj One-Time Costs  
Both One-Time Costs have been readjusted to account for the reduced Acetylcysteine unit price. Both contain the manufacturing/ filling cost for one engineering feasibility study. A second engineering/ feasibility study for either product would cost:  
Ibuprofen Inj: [\*\*\*]  
Acetadote Inj: [\*\*\*]  
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ATTACHMENT I  
 Cumberland Pharmaceuticals, Inc.  
 One Time Costs — Ibuprofen Inj  
 9/7/2007  
 [\*\*\*]  
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[\*\*\*]  
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ATTACHMENT II  
 Cumberland Pharmaceuticals, Inc.  
 One Time Costs — Acetadote Inj.  
 9/7/2007  
 [\*\*\*]  
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[\*\*\*]  
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EXHIBIT 2  
QUANTITIES AND PRICES PER UNIT OF PRODUCT  
 Ibuprofen Inj.  
 [\*\*\*] Total Cost Per Vial [\*\*\*]  
 [\*\*\*] Total Cost Per Vial [\*\*\*]  
Acetadote Inj.  
 [\*\*\*] Total Cost Per Bottle [\*\*\*]  
 [\*\*\*] Total Cost Per Bottle [\*\*\*]  
Minimum Commercial Volumes:  
The pricing listed above for Acetadote is based on Cumberland’s purchase of a minimum of [\*\*\*] batches of Acetadote on an [\*\*\*] basis. The pricing listed above for Ibuprofen Inj. is based on Cumberland’s purchase of a minimum of [\*\*\*] batches of [\*\*\*] mL vials and [\*\*\*] batches of [\*\*\*] mL vials on an annual basis.  
In the event Cumberland does not meet the minimum annual commercial Volume requirments, Bayer shall provide Cumberland an invoice within [\*\*\*] days of year end that shall include a fee adjustments on the pricing listed above. This fee adjustment shall be based the actual increases in costs incurred by Bayer in the manufacture of the Product. If Cumberland fails to meet the minimum commercial volumes for [\*\*\*] Bayer at its election, may terminate this Agreement subject to the provisions of Paragraph 8.6.  
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EXHIBIT 3  
PROCEDURES FOR REPORTING OF ADVERSE DRUG REACTIONS  
(See Quality Agreement)  
 EXHIBIT 4  
MINIMUM INSURANCE REQUIREMENTS  
1.0 Commercial General Liability Insurance:  
Bayer and Cumberland shall each maintain a policy or policies of commercial general liability insurance with the premiums thereon paid on or before the due dates, issued by and binding upon a solvent insurance company authorized to transact business in the state where the insured party resides. Such insurance shall be written on an occurrence basis and shall afford minimum protection (which may be affected by primary and/or excess coverage) of not less than $2 million per occurrence for bodily injury and property damage.  
2.0 Workers’ Compensation  
Bayer and Cumberland shall maintain Statutory Coverage for Workers’ Compensation.  
3.0 Product Liability  
Bayer and Cumberland shall maintain Product Liability Insurance [\*\*\*] Each Occurrence and in the Aggregate  
 4. Basis of Insurance:  
4.1 All policies, other than for Product Liability, shall be issued on an “occurrence” basis unless such coverage is not available on commercially reasonable terms. Where insurance is on a “Claims Made” basis, each Party shall maintain the coverage until the later of the expiration of three years after the manufacture of the final batch of Product by Bayer or of all applicable statutes of limitations. Each Party shall list the other Party as an additional insured.  
4.2 The Product Liability policy shall be issued on a ”Claims Made” basis. Each Party shall maintain the Product Liability coverage until the later of the expiration of three years after the manufacture of the final batch of Product by Bayer or the applicable statute of limitations.  
4.3 Bayer reserves the right to self-insure for any and all coverages.