Exhibit 10.42  
MANUFACTURING AND SUPPLY AGREEMENT  
By and Between  
GUILFORD PHARMACEUTICALS INC.  
and  
XXXXXX HEALTHCARE CORPORATION  
\*The asterisk denotes that confidential portions of this exhibit have been  
omitted and submitted separately to the Securities and Exchange Commission.  
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 MANUFACTURING AND SUPPLY AGREEMENT  
This Manufacturing and Supply Agreement (the “Agreement”), is effective as of July 1, 2004 (the “Effective Date”), between Xxxxxx Healthcare Corporation, a Delaware corporation, having its principal office at Xxx Xxxxxx Xxxxxxx, Xxxxxxxxx, Xxxxxxxx 00000 X.X.X. (“Baxter”) and Guilford Pharmaceuticals Inc., a Delaware corporation, having its principal office at 0000 Xxxxxxxxx Xxxxxx, Xxxxxxxxx, Xxxxxxxx 00000 X.X.X. (“Guilford”).  
WITNESSETH:  
WHEREAS, Guilford has acquired from Merck & Co, Inc. (“Merck”) the commercial and intellectual property rights to the Product (as defined herein) in the United States and its territories; and  
WHEREAS, Guilford desires to engage the facilities and services of Baxter to Manufacture (as defined herein) the Product for Guilford, and Baxter has appropriate facilities and the ability to Manufacture Product for Guilford and is willing to undertake the Manufacturing of Product for Guilford in accordance with the terms and conditions set forth herein; and  
WHEREAS, Guilford will supply Bulk Active (as defined herein) to Xxxxxx and Xxxxxx will Manufacture the Product for Guilford at the Facility (as defined herein) on the terms specified herein; and  
WHEREAS, Baxter and Guilford will enter into a separate CTM Supply Agreement (as defined herein) whereby Baxter will Manufacture clinical trial material for Guilford at the Facility on the terms and conditions specified in the CTM Supply Agreement and, for terms and conditions not specified in the CTM Supply Agreement, in accordance with the terms and conditions herein;  
NOW, THEREFORE, in consideration of the mutual premises and covenants contained herein the parties agree as follows:  
1. DEFINITIONS  
 Unless specifically set forth to the contrary herein, the following capitalized terms, whether used in the singular or plural, shall have the respective meanings set forth below:  
1.1 The term “Baxter” as used hereinafter shall mean Baxter and its Affiliates.  
 1.2 The term “Affiliate” of Guilford or Baxter shall mean any corporation or business entity which controls, is controlled by or is under common control with Guilford or Baxter, as the case may be. A corporation or business entity shall be deemed to control another corporation or business entity if it owns, directly or indirectly, fifty percent (50%) or more of the securities or other ownership interests representing the equity, the voting stock or general partnership interest of such corporation or business entity.  
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omitted and submitted separately to the Securities and Exchange Commission.  
 1.3 The term “Act” shall mean the U.S. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., as amended, and the regulations promulgated thereunder, as amended from time to time.  
 1.4 The term “Applicable Law” shall mean any United States (including federal, territorial, state, municipal and local) statute, law, ordinance, rule, regulation, administrative interpretation, order, writ, injunction, judicial decision, decree or other requirement of any Governmental Authority.  
 1.5 The term “Bulk Active” shall mean the pharmacologically active ingredient N-(Butylsulfonyl)-O-[4-(4-piperindinyl)butyl]-L-tyrosine monohydrochloride monohydrate, also known as “tirofiban hydrochloride”, and meeting the specifications specified in Schedule A.  
 1.6 The term “Bulk Active Specifications” shall mean the specifications and test methods for Bulk Active, specified in Schedule A, as they may be modified from time to time by Guilford.  
 1.7 The term “Bulk Production Lot” shall mean the total quantity of solution which has been mixed in one tank during the process of Manufacturing Product.  
 1.8 The term “Bulk Production Lot Number” shall mean the unique number assigned by Baxter to each Bulk Production Lot.  
 1.9 The term “Calendar Month” shall mean each month of the Calendar Year beginning with the first date of that month and ending with the last date of that same month.  
 1.10 The term “Calendar Quarter” shall mean each period of three (3) consecutive Calendar Months ending March 31, June 30, September 30 and December 31, as the case may be.  
 1.11 The term “Calendar Year” shall mean the period of January 1 to December 31.  
 1.12 The term “cGMPs” shall mean the current Good Manufacturing Practices as specified in the United States Code of Federal Regulations or in applicable regulations promulgated or issued by the FDA.  
 1.13 The term “Container” and “Flexible Container” shall mean Xxxxxx’x container, the description and specifications of which are set forth in the Quality Agreement and in Xxxxxx’x FDA filings, which is either a 250-mL or a 100-mL flexible non-PVC container having a single administration port containing PVC and wrapped in an overpouch.  
 1.14 The term “Container Drug Master File” or “CDMF” shall mean a separate filing with the FDA consisting of confidential detailed information about the facilities,  
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 processes and/or materials used in the manufacturing, processing, testing and/or storing of the Container. Information contained in a CDMF shall be used to support filings made to the FDA to obtain and maintain registration of the Product.  
 1.15 \*  
 1.16 The term “CTM Supply Agreement” shall mean the Clinical Trial Material Supply Agreement dated as of the date hereof between Baxter and Guilford for the Manufacture and supply by Baxter to Guilford of batches of clinical trial material.  
 1.17 The term “Deliver”, “Delivered”, “Delivering” or “Delivery” by Baxter shall mean the act of Baxter in making complete shipment(s) of Product available to Guilford at Xxxxxx’x Facility for immediate shipment and transportation by Guilford in accordance with Section 5.2, which Product shall be completely Manufactured, packaged and ready for administration.  
 1.18 The term “Distributors” shall mean those persons and/or entities engaged by Guilford and/or Guilford’s Affiliates to distribute Product in the Territory on behalf of Guilford and its Affiliates, but shall not include Licensees.  
 1.19 The term “Facility” shall mean that portion of Xxxxxx’x facilities located at Xxxxxxx 000 Xxxxx Xxxxxx, Xxxxx Xxxxxxxx, used in the Manufacturing of the Product.  
 1.20 The term “FDA” shall mean the United States Food and Drug Administration and its successors.  
 1.21 The term “FIFO” shall mean first-in, first-out.  
 1.22 The term “Filling Production Lot” shall mean a quantity of solution taken from a Bulk Production Lot and filled into Containers.  
 1.23 The term “Filling Production Lot Number” shall mean (i) with respect to the first Filling Production Lot filled from a Bulk Production Lot, the Bulk Lot Production Number for such Bulk Product Lot, and (ii) with respect to each Filling Production Lot filled from the same Bulk Production Lot thereafter, a unique number assigned by Baxter to such Filling Production Lot.  
 1.24 The term “Firm Order” shall mean a binding commitment in writing and evidenced by a Purchase Order made by Guilford to purchase Product from Baxter pursuant to Section 3.1.2.  
 1.25 The term “Governmental Authority” shall mean any United States (including federal, territorial, state, municipal and local) governmental authority, quasi-  
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 governmental authority, instrumentality, court, government or self-regulatory organization (including any national or international securities exchange and The NASDAQ Stock Market), commission, tribunal or organization or any regulatory, administrative or other agency (including the FDA), or any political or other subdivision, department or branch of any of the foregoing.  
 1.26 The term “Licensees” shall mean those persons and/or entities to which Guilford and/or Guilford’s Affiliates shall, subject to Section 12, license its rights to market and sell the Product in the Territory.  
 1.27 The term “Lot Numbers” shall mean, collectively, the Bulk Production Lot Numbers and the Filling Production Lot Numbers.  
 1.28 The terms “Manufacture”, “Manufacturing” and “Manufactured” shall mean all operations of Baxter and its successors, permitted assigns and permitted subcontractors in the acquisition of Materials and the formulation of Product from Bulk Active, and in filling, labeling, packaging, warehousing and quality control testing of Product.  
 1.29 The term “Manufacturing Fee” shall mean the fee per unit paid by Guilford to Baxter for Product Manufactured in accordance with the terms of this Agreement.  
 1.30 The term “Materials” shall mean all raw materials, excipients, components, packaging materials (including the Container), and other items necessary for the Manufacture of Product as supplied by Baxter other than the Bulk Active, package inserts and any other items which are supplied by Guilford to Baxter.  
 1.31 The term “Merck/Baxter Agreement” means the Manufacturing and Supply Agreement dated as of April 15, 1995, as amended, by and between Merck and Baxter.  
 1.32 The term “NDA” shall mean the New Drug Application relating to Product filed in accordance with FDA regulations.  
 1.33 The term “Parametric Release” shall mean a review and comparison of sterilization records to validated parameters to effect release of a Filling Production Lot of Product in lieu of routine end product sterility testing.  
 1.34 The term “Product” shall mean AGGRASTAT® Pre-Mixed Injection in either (i) a 0.05 mg/mL bulk active in 0.9% normal saline and packaged as a terminally steam sterilized pre-mixed intravenous (I.V.) solution in Container, in package size and meeting the Product Specifications specified in Schedule A, which comprise a 12.5 mg dosage, 250 mL diluent volume pharmaceutical form (the “250 mL Product”), or (ii) a 0.05 mg/mL bulk active in 0.9% normal saline and packaged as a terminally steam sterilized pre-mixed intravenous (I.V.) solution in Container, in package size and meeting the Product Specifications specified in  
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 Schedule A, which comprise a 5.0 mg dosage, 100 mL diluent volume pharmaceutical form (the “100 mL Product”).  
 1.35 The term “Product Specifications” shall mean the specifications and test methods for Product as specified in Schedule A, as they may be modified from time to time in accordance with the Quality Agreement.  
 1.36 The term “Quality Agreement” shall mean the Quality Agreement dated as of the date hereof by and between Baxter and Guilford, together with the exhibits thereto, that provides the details on the responsibilities of the technical and quality activities required to Manufacture the Product.  
 1.37 The term “Related Agreements” shall mean, collectively, the Quality Agreement and the CTM Supply Agreement.  
 1.38 The term “Securities Laws” shall mean the United States Securities Act of 1933, as amended, the United States Securities Exchange Act of 1934, as amended, and any other similar law or regulation of a United States Governmental Authority, or any successor to any such laws or regulations, together with any rules, regulations or listing standards or agreements of any national or international securities exchange or The NASDAQ Stock Market, as generally applicable.  
 1.39 The term “Territory” shall mean the United States of America and its territories and possessions, including without limitation the Commonwealth of Puerto Rico, Guam and the U.S. Virgin Islands.  
 1.40 The term “Trademarks” shall mean, collectively, Xxxxxx’x United States registered trademarks for the Container and Guilford’s United States registered trademark for Product.  
2. ENGAGEMENT  
2.1 Engagement of Baxter. Guilford hereby engages Baxter to Manufacture the Product at the Facility, subject to the conditions and terms set forth in this Agreement and the Related Agreements. Baxter accepts such engagement to Manufacture the Product and to perform such other acts as are provided in this Agreement and the Related Agreements.  
 2.2 Permits, Licenses and Authorizations. Except as otherwise agreed by the parties in writing, Baxter shall be responsible for obtaining, at its cost, all the necessary permissions, licenses and approvals for the Manufacture of Product in the Facility for distribution in the Territory.  
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 3. SUPPLY, FORECASTS AND ORDERS  
3.1 Forecasts and Orders. During the term of this Agreement the forecasting and ordering provisions set forth in this Section shall apply.  
3.1.1 Forecasts. In order to assist Baxter in its production planning, at least \* before the beginning of each Calendar Quarter, Guilford shall provide to Baxter a statement of its estimated purchase requirements (“Estimated Requirements”) and expected Delivery dates for Product for the \* next succeeding such Calendar Quarter. It is understood that such Estimated Requirements shall not constitute commitments to purchase Product or Firm Orders.  
 3.1.2 Firm Orders. At least \* prior to the beginning of each Calendar Quarter, Guilford shall place a Firm Order for its requirements and requested Delivery dates of Product for such Calendar Quarter. Firm Orders shall be placed in amounts equal to the Filling Production Lot sizes, multiplied by whole number increments of the applicable minimum order quantities as set forth on Schedule C. Firm Orders for Product in such Calendar Quarter shall not be for less than \* nor more than \* of Guilford’s Estimated Requirements of Product for such Calendar Quarter as most recently updated. Notwithstanding the foregoing, Baxter shall use reasonable efforts to comply with any subsequent changes in such Firm Orders, but shall not be held liable for its inability to do so. Guilford shall limit the number of requested Delivery dates to no more than two (2) per Calendar Month.  
 3.1.3 Initial Forecast and Firm Order. Attached hereto as Schedule G is Guilford’s initial Firm Order for its requirements of Product and requested Delivery dates for the period beginning on the Effective Date and ending on \*, as well as Guilford’s Estimated Requirements and estimated Delivery dates for the next succeeding \* beginning \*. Guilford shall deliver Estimated Requirements and estimated Delivery dates for the \* beginning \* on or before \*.  
3.2 Satisfaction of Firm Orders. Baxter shall confirm the receipt of each Firm Order within \* of its receipt thereof. Subject to Section 23.1, Baxter shall meet Guilford’s requested Delivery dates. Baxter shall satisfy each Firm Order by Delivering not less than \* and not more than \* of the quantity of Product ordered by Guilford in each Firm Order to Guilford. Deliveries of Product shall be made on the date specified in the Firm Order, but in no event more than \* in advance of the date specified in the Firm Order without Guilford’s prior written approval. Baxter shall notify Guilford at least \* prior to actual Delivery of Product if Baxter is not Delivering Product to Guilford on the requested Delivery date.  
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 3.3 Terms. Firm Orders will be made on the form of purchase order attached hereto as Schedule H or in such other form as Baxter and Guilford shall agree in writing from time to time (a “Purchase Order”), provided that the terms and conditions of this Agreement shall be controlling over any terms and conditions included in any such Purchase Order used in ordering Product.  
 3.4 Short Supply of Materials and/or Resources. In the event that the Materials and/or resources required to Manufacture Product are in short supply, Baxter shall notify Guilford of such shortage as soon as possible and shall allocate to Guilford a proportionate share of the available amount of such Materials and/or resources (as existing as of the time of such shortage and going forward) required for Manufacture of Product hereunder based upon Guilford’s projected requirements for Product hereunder, as compared to the projected requirements of other customers of Baxter who require use of such Materials or resources, for the ensuing \* period.  
 3.5 Exclusive Manufacture and Supply. Except as otherwise contemplated in this Agreement, during the term and subject to the provisions of this Agreement and the Related Agreements, Baxter shall Product exclusively to Guilford in the Territory, and Guilford shall purchase exclusively from Baxter quantities of Product equal to Guildford’s needs for the Territory.  
 3.6 Cancellation of Firm Orders and Rescheduling. Guilford may cancel a Firm Order or reschedule requested Delivery dates to a later date by giving Baxter prior written notice to such effect. Baxter will use reasonable efforts to comply with Guilford’s requests and to avoid or minimize any costs incurred by Baxter as a result of such cancellation or change. If, however, either (i) a cancellation by Guilford of a Firm Order or (ii) a rescheduling of Delivery dates for a Firm Order that causes a rescheduling by Baxter of the Product manufacturing date, occurs less than \* but more than \* prior to Xxxxxx’x scheduled production date for the Firm Order, Guilford will pay Baxter a cancellation fee or rescheduling fee equal to \* of the Manufacturing Fee for such Firm Order, and if any such cancellation or rescheduling occurs \* or less prior to Xxxxxx’x scheduled production date for the Firm Order, Guilford will pay Baxter a cancellation fee or rescheduling fee equal to \* of the Manufacturing Fee for such Firm Order. Notwithstanding the foregoing, if any such cancellation or rescheduling occurs \* or more prior to Xxxxxx’x scheduled production date for the Firm Order, Guilford shall not have any obligation to pay any cancellation fee, rescheduling fee or other penalty to Baxter.  
4. MANUFACTURING FEES & PAYMENTS  
4.1 Manufacturing Fees. The Manufacturing Fees charged by Baxter to Guilford for Product Manufactured hereunder shall be determined and paid as set forth in this Section 4 and in Schedule X. Xxxxxxxx will purchase a minimum of one hundred thousand (100,000) units of Product during each Calendar Year of this Agreement, except the first Calendar Year (the “First Calendar Year”). During the First Calendar Year, the minimum requirement shall be 75,000 units and shall be reduced by the number of units that Guilford purchased from Merck during 2004. The 100,000 units may be any combination of 100 mL Product and 250 mL Product units, \* If Guilford desires to have a different packaging configuration than shown on Schedule D, then the parties shall negotiate in good faith applicable Manufacturing Fees for such configuration.  
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 4.2 Application of Prices for each Tier. The Manufacturing Fees shown in Schedule C \*. Firm Orders shall be placed by Guilford in whole number increments of the Order Quantities set forth in the tables provided in Schedule X. Xxxxxx shall invoice Guilford at the Manufacturing Fee corresponding to applicable pricing tier reflected on Schedule C for each such unit.  
 4.3 Underlying Assumptions. The Manufacturing Fees set forth herein are based upon the following key assumptions:  
(i) The Manufacturing Fees include all labor and Material costs incurred by Baxter (it being understood that Baxter shall incur no costs in connection with the Bulk Active or any other materials, such as package inserts, provided by Guilford) and excludes all applicable sales and value added taxes.  
 (ii) In the event either Guilford or Baxter shall desire to make any change in any label for the Product (including without limitation the bag label, the intermediate carton label and the case label) during the term of this Agreement, the parties shall meet to negotiate the additional costs to be incurred by Baxter, which costs shall be allocated between Guilford and Baxter as set forth in this Section 4.3(ii). With respect to label changes by Guilford, including both discretionary changes and changes required by the FDA or Applicable Law, Guilford may request, and Baxter shall implement \*. If Guilford shall request (or shall be required by the FDA or Applicable Law to implement) \*, the parties shall meet to negotiate in good faith the additional costs to be incurred by Baxter in connection with such changes, which costs shall be invoiced separately by Baxter to Guilford, and Guilford will pay such amount to Baxter within \* of invoicing by Baxter. With respect to label changes by Baxter, including both discretionary changes and changes required by the FDA or Applicable Law, Baxter shall bear the cost of such changes.  
 (iii) \* testing is utilized throughout the Territory. \* testing, if required, shall be separately paid for by Guilford as set forth in the Quality Agreement.  
4.4 Fee to Re-Package Product. In the event that Guilford requests Baxter to re-package Product (for example, due to a change in the package insert), Baxter shall perform such re-packaging and will invoice Guilford on delivery of the re-packaged Product. \*  
 4.5 User Fees. Baxter will pay all user and/or filing fees charged by Governmental Authorities in the Territory which relate to separate Container submissions. Guilford will pay all user and/or filing fees charged by Governmental Authorities in the Territory which relate to the NDA and ongoing marketing of the Product, including, but not limited to, the application fee (other than in connection with the  
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 Container), the drug product fee, and that portion of the drug establishment fee (DEF) assessed to Guilford by the FDA.  
 4.6 Amount and Timing of Manufacturing Fee Increases. Baxter may increase the Manufacturing Fees, \*, which shall be further limited to a maximum increase of \* for each Calendar Year. Baxter shall use its commercially reasonable efforts to minimize increases in its Material costs to Manufacture Product.  
 4.7 Notification, Effective Date and Application of Manufacturing Fee Increases. Baxter will provide to Guilford written notification, \*, of any proposed Manufacturing Fee increase pursuant to Section 4.6, which increase will become effective the following January 1. Such Manufacturing Fee increase shall not apply to Product already invoiced to Guilford, but shall apply to Product which has been released, Delivered and invoiced by Baxter to Guilford after the January 1 effective date.  
 4.8 Payment for Product. Baxter shall invoice Guilford upon release of Product to Guilford that has been quality control tested by Baxter in accordance with the Quality Agreement. Invoicing requirements are specified in Schedule X. Xxxxxxxx shall make payment \* of receipt of said invoice of Product in accordance with this Section 4.8 or of Delivery of Product by Baxter, whichever is later. Payment shall be remitted by wire transfer in U.S. dollars to a bank account designated in writing by Baxter. \*  
 4.9 Payment Penalties Charged to Guilford. In addition to any other remedies available to Baxter under this Agreement, Baxter may charge Guilford a penalty for amounts not paid within the required \* period set forth in Section 4.8. Such penalty shall be assessed based on the amount not paid when due at the rate of \*. Such penalty shall not be assessed if the reason for the late payment is due to (i) discrepancies between Xxxxxx’x invoice and the shipping records, (ii) incomplete documentation accompanying the Product Delivered by Baxter hereunder, or (iii) due to a claim asserted by Guilford pursuant to Section 8.2 or 8.3. Guilford shall notify Baxter as soon as practicable after it is aware that any of these circumstances exist, and the parties will in good faith attempt to resolve the discrepancy, incompleteness, error and/or dispute in a timely manner. In the event that such circumstances exist, then Guilford will have \* after resolution of the matter to pay the amount so due before Baxter may assess the aforementioned penalty.  
 4.10 Payment Penalties Charged to Baxter. In addition to any other remedies available to Guilford under this Agreement, in the event that Baxter fails to Deliver on time (i.e., no later than Guilford’s requested Delivery date as set forth in Section 3.1.2) the Product subject to a Firm Order, Guilford may (i) reduce the invoice price relating to such Firm Order, or (ii) cancel such Firm Order if Baxter fails to Deliver to Guilford within \* after Guilford’s requested Delivery date.  
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 The amount of any such reduction in (i) above shall be equal to:  
 \*  
 Notwithstanding the foregoing, if Baxter does not Deliver Product to Guilford in accordance with the requested Delivery date as provided for in Section 3 because of Guilford’s breach or negligence or a force majeure event affecting Xxxxxx as set forth in Section 23.1, then the number of days by which Delivery by Baxter is considered late for purposes of enabling Guilford to reduce the invoice price shall commence upon \*.  
5. PRODUCT DELIVERY, TITLE AND RISK OF LOSS  
5.1 Delivery of Product. Xxxxxx shall notify Guilford no less than \* prior to each Delivery of Product by Xxxxxx hereunder.  
 5.2 Shipment of Product. Guilford shall arrange for transportation of the Product Manufactured hereunder from Xxxxxx’x Facility. Guilford shall assume the freight and insurance costs and risk of loss for the Product after Xxxxxx physically transfers the Product to Guilford’s designated carrier at Xxxxxx’x Facility. Delivery shall be F.O.B. Xxxxxx’x Facility. Guilford shall be subject to a penalty if Guilford or Guilford’s designated carrier does not pick up the Product from Xxxxxx’x Facility within \* after Delivery of such Product by Xxxxxx to Guilford hereunder. The amount of such penalty will be equal to \* of the invoice price. Notwithstanding the foregoing, if Guilford does not pick up the Product due to Xxxxxx’x breach or negligence or a force majeure event affecting Guilford as set forth in Section 23.1, then the number of days Guilford is considered late for purposes of enabling Xxxxxx to charge the penalty set forth in this Section 5.2 shall commence upon \* after the date on which such situation shall be rectified.  
 5.3 Title and Risk of Loss. Title and risk of loss to Product sold hereunder shall pass to Guilford upon delivery at the F.O.B. point specified in Section 5.2.  
6. BULK ACTIVE and MATERIALS  
6.1 Bulk Active Title, Risk of Loss and Use. Guilford shall, at no cost to Xxxxxx, at least \* prior to the date of requested Delivery of Product pursuant to a Firm Order, supply to Xxxxxx sufficient quantities of Bulk Active, and Bulk Active reference standard material for use in conducting assays, which will allow Xxxxxx to meet its obligations to Manufacture Product in accordance with the terms of this Agreement. Xxxxxx shall not be responsible for delays in Delivering Product to Guilford caused by delays in receipt of Bulk Active provided by Guilford. Title to Bulk Active shall remain at all times with Guilford; however, risk of loss shall pass to Xxxxxx at the time Bulk Active arrives at the Facility and is accepted by Xxxxxx from Guilford’s carrier. Xxxxxx shall not use Bulk Active supplied by  
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omitted and submitted separately to the Securities and Exchange Commission.  
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 Guilford for any purpose other than the Manufacture of Product exclusively for Guilford hereunder or as otherwise agreed by the parties in writing.  
 6.2 Certificate of Analysis. Guilford shall provide Xxxxxx with a certificate of analysis for each lot of Bulk Active delivered by Guilford to Xxxxxx using the format set forth in the Quality Agreement. Guilford shall also provide Xxxxxx with a certificate of analysis for each lot of Bulk Active reference standard material delivered to Xxxxxx in the format set forth in the Quality Agreement.  
 6.3 Inventory Counts. Physical inventory counts of all Bulk Active shall be taken by Xxxxxx at the end of each Calendar Month, reconciled to Xxxxxx’x books and perpetual records, and promptly reported to Guilford in a form and level of detail specified in the Quality Agreement. Data trail/accountability information will be kept by Xxxxxx for all receipts and disbursements of Bulk Active in accordance with the Quality Agreement. All inventories of Bulk Active will be subject to audit by Guilford in accordance with the Quality Agreement.  
 6.4 Bulk Active Freight Claims. Xxxxxx shall maintain paperwork on all freight claims arising from Bulk Active that Xxxxxx claims was delivered to its Facility in a damaged state. Xxxxxx will assist Guilford in obtaining recovery for such freight claims, and Guilford shall reimburse Xxxxxx for all reasonable direct expenses including, but not necessarily limited to, salaries and wages of personnel and out-of-pocket costs, which are incurred and documented by Xxxxxx in connection with such assistance.  
 6.5 Materials – Container. Xxxxxx shall manufacture the Container itself and shall be responsible for approving all vendors of raw materials therefor. The Container shall meet the requirements of the Container specifications set forth in the Quality Agreement and shall be manufactured in accordance with cGMPs and all Applicable Laws, FDA requirements, CDMFs and approved FDA filings. Changes to the Container specifications shall be made only in accordance with the Quality Agreement.  
 6.6 Materials – Other than Container. All Materials (other than the Container) required for Manufacture of Product supplied by Xxxxxx shall be purchased by Xxxxxx from vendors approved by Xxxxxx in accordance with Xxxxxx’x vendor qualification and approval procedures, copies of which have been provided to Guilford. Xxxxxx shall provide Guilford with copies of any amendments or revisions to such procedures during the term of this Agreement. Notwithstanding the foregoing, excipient vendors shall be approved in writing by Guilford in advance of use by Xxxxxx for Manufacture of Product. Excipient vendors currently approved by Guilford are set forth on Schedule B; additional vendors may be added to Schedule B from time to time upon prior written agreement of the parties. Such Materials shall meet the requirements of the Product Specifications. All Materials supplied to Xxxxxx by Guilford shall be purchased,  
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omitted and submitted separately to the Securities and Exchange Commission.  
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 inspected and released by Guilford per Guilford’s Standard Operating Procedures. Materials supplied by Guilford will be purchased from Guilford approved vendors.  
7. GUILFORD WARRANTY AND LIMITATIONS  
7.1 Guilford Warranties. Guilford represents and warrants that all Bulk Active shall, at the time of delivery to Xxxxxx’x Facility (i) meet the Bulk Active Specifications; (ii) be manufactured in accordance with cGMPs; (iii) be manufactured in accordance with Applicable Laws and FDA requirements in effect on the day of delivery; and (iv) be fit for the Manufacture of the Product. Without limiting the warranty in Section 7.1(iii), Guilford represents and warrants that no Bulk Active shall, at the time of delivery, be (a) adulterated or misbranded within the meaning of the Act, or any similar law of any other jurisdiction in the Territory; or (b) an article which may not, under the provisions of the Act, or any similar law of any other jurisdiction in the Territory, be introduced into interstate commerce. Guilford also represents and warrants that the Bulk Active reference standard material shall, at the time of delivery to Xxxxxx’x Facility, meet the assigned purity as set forth in the related certificate of analysis for such reference standard material. Guilford also represents and warrants (x) that it has acquired all commercial and intellectual property rights to the Product for the Territory which are necessary for Xxxxxx to realize its rights and fulfill its obligations under this Agreement and the CTM Supply Agreement and to xxxxx Xxxxxx the licenses set forth in Article 11 below, and (y) that it has the right to enter into this Agreement and require Xxxxxx to Manufacture Product in accordance with the terms and conditions set forth herein and in the Quality Agreement. Guilford also represents and warrants that it has the right to enter into this Agreement in accordance with the terms and conditions set forth herein and in the Related Agreements, and that this Agreement and the Related Agreements will not conflict with, contravene or constitute a default under any other agreement, contract or other arrangement by which Guilford is bound, including without limitation the Merck/Guilford Agreement. NO OTHER EXPRESS OR IMPLIED WARRANTY EXISTS, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, AND GUILFORD EXPRESSLY DISCLAIMS ANY SUCH WARRANTIES.  
 7.2 Claims for Failure to Meet Bulk Active Specifications. Claims by Xxxxxx on account of quality or concerning any failure of Bulk Active to meet the warranty specified in Section 7.1(i) shall be made promptly by Xxxxxx, in writing, but no later than \* following Xxxxxx’x receipt of Bulk Active at the Facility. Claims by Xxxxxx on account of shortage, loss or damage shall be made promptly by Xxxxxx, in writing, but no later than \* following Xxxxxx’x receipt of Bulk Active at the Facility. In connection with such claim(s), Xxxxxx shall, at Guilford’s request, investigate and re-test such Bulk Active and shall permit one or more  
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omitted and submitted separately to the Securities and Exchange Commission.  
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 representatives from Guilford to be present and participate in the investigation and re-testing by Xxxxxx, which investigation and re-testing will be done at Xxxxxx’x own cost. If Guilford and Xxxxxx agree that the Bulk Active did not meet the warranties set forth in Section 7.1(i) upon delivery to Xxxxxx, then Xxxxxx shall destroy or return the Bulk Active to Guilford in accordance with Guilford’s instructions in accordance with the provisions of Section 7.4. If the Bulk Active is determined upon agreement by the parties to meet such warranty, then Xxxxxx shall utilize the Bulk Active to Manufacture Product. If the parties are unable to agree as to whether such Bulk Active met such warranties, Xxxxxx shall return the Bulk Active to Guilford and the parties shall cooperate to have the Bulk Active in dispute analyzed by an independent testing laboratory of recognized repute agreeable to both parties. The results of such laboratory testing shall be final and binding on the parties on the issue of compliance of the Bulk Active with such warranty. \*  
 7.3 Other Claims. If Xxxxxx claims that any shipment of Bulk Active did not, at the time of delivery, meet the warranties specified in Section 7.1(ii) or (iii), Xxxxxx shall promptly (and in any event within \*) notify Guilford and either destroy or return such Bulk Active to Guilford in accordance with Guilford’s instructions, and if Guilford and Xxxxxx are unable to agree as to whether or not such Bulk Active met such warranties, the dispute shall be settled in accordance with the dispute resolution provisions set forth in Section 23.6. If the Bulk Active is determined to have met such warranties, then Xxxxxx shall bear the cost of such dispute resolution proceedings, including Guilford’s reasonable attorneys’ fees. If the Bulk Active is determined not to have met any such warranty, then Guilford shall bear the cost of such proceedings, including Xxxxxx’x reasonable attorneys’ fees, and shall pay Xxxxxx for any Product Manufactured which incorporates such Bulk Active at the Manufacturing Fees specified in Section 4.  
 7.4 Bulk Active not Meeting Warranties. Any Bulk Active which fails to meet the warranties under Section 7.1 and which is in Xxxxxx’x possession or control shall, at Guilford’s option, either be destroyed by Xxxxxx or returned to Guilford pursuant to Guilford’s written instructions. Unless otherwise provided in Sections 7.2 and 7.3, Guilford shall assume the cost of destruction of such Bulk Active, or the freight and insurance costs and risk of loss for return of such Bulk Active after Xxxxxx physically transfers the Bulk Active to Guilford’s designated carrier at Xxxxxx’x Facility.  
8. XXXXXX WARRANTY AND LIMITATIONS  
8.1 Xxxxxx Warranties. Xxxxxx represents and warrants that all Product shall, at the time of Delivery to Guilford (i) meet the Product Specifications; (ii) be Manufactured in accordance with cGMPs; and (iii) be Manufactured in accordance with the validated processes and test methods specified in NDA and other filings with the FDA maintained in the Territory with respect to Product,  
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 and with all Applicable Laws and regulations and FDA requirements in effect on the day of Delivery. Without limiting the warranty in Section 8.1(iii), Xxxxxx guarantees that no Product shall, at the time of Delivery, be (a) adulterated or misbranded within the meaning of the Act, or any similar law of any other jurisdiction in the Territory, or (b) an article which may not, under the provisions of the Act, or any similar law of any other jurisdiction in the Territory, be introduced into interstate commerce. Xxxxxx also represents and warrants that it has the right to enter into this Agreement and to Manufacture and supply Product to Guilford in accordance with the terms and conditions set forth herein and in the Related Agreements, and that this Agreement and the Related Agreements will not conflict with, contravene or constitute a default under any other agreement, contract or other arrangement by which Baxter is bound, including without limitation the Merck/Baxter Agreement. NO OTHER EXPRESS OR IMPLIED WARRANTY EXISTS, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, AND XXXXXX EXPRESSLY DISCLAIMS ANY SUCH WARRANTIES.  
 8.2 Claims for Failure to Meet Product Specifications. If Guilford claims that any shipment of Product did not, at the time of Delivery to Guilford, meet the warranty specified in Section 8.1(i), Guilford shall notify Xxxxxx within \* from Guilford’s receipt of Product at the designated location; provided that in the case of latent defects that are not discoverable upon exercise of reasonable diligence within such \* period, Guilford shall notify Xxxxxx as soon as practicable upon discovery of such defect, however, in no event after the Product has expired according to its expiry date. If Guilford and Xxxxxx are unable to agree as to whether such Product met such warranty, then the parties shall cooperate to have the Product in dispute analyzed by an independent testing laboratory of recognized repute selected by Guilford and approved by Xxxxxx, which approval shall not be unreasonably withheld. The results of such laboratory testing shall be final and binding on the parties on the issue of compliance of the Product with such warranty. If the Product is determined to have met such warranty, then Guilford shall bear the cost of such laboratory testing. If the Product is determined not to have met such warranty for reasons unrelated to a breach of Guilford’s warranty under Section 7.1, then Xxxxxx shall:  
(i) bear the cost of such laboratory testing;  
 (ii) pay Guilford, \*, which price may be adjusted by Guilford no more than once per Calendar Year by a percentage up to the percentage increase in the \* for the most recently ended Calendar Year over the prior Calendar Year which shall be further limited to a maximum of \* for that Calendar Year;  
 (iii) at Guilford’s written election, within \* after receipt of such determination, either (a) replace the rejected Product within \* of the date of such  
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omitted and submitted separately to the Securities and Exchange Commission.  
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 determination; or (b) at Xxxxxx’x option either credit Guilford’s account or refund to Guilford an amount equal to the Manufacturing Fees paid for such Product, plus any applicable delivery charge paid by Guilford. In the event that Guilford does not make such written election within \*, then the election shall be made at Xxxxxx’x option after written notification to Guilford;  
 (iv) pay to Guilford interest at the rate of \* on the amount of payment(s) made by Guilford for such Product, if any, from the date that such payment was made until, as applicable, (a) \* after delivery of the replacement Product and associated invoice to Guilford, or (b) deduction of the credit from an amount due by Guilford to Xxxxxx on the date when due (i.e., the credit must actually be used by Guilford and not simply be posted by Xxxxxx to Guilford’s account) or refund to Guilford, as applicable, pursuant to Section 8.2(iii)(b); and  
 (v) cancel any late fees assessed by Xxxxxx to Guilford for non-payment or late payment of the invoice(s) relating to such Product which did not meet such warranty.  
8.3 Other Claims. If Guilford claims that any shipment of Product did not, at the time of Delivery to Guilford, meet the warranties specified in Section 8.1(ii) or (iii), Guilford shall notify Xxxxxx, and if Guilford and Xxxxxx are unable to agree as to whether or not such Product met such warranties, the dispute shall be settled in accordance with the dispute resolution provisions set forth in Section 23.6. If the Product is determined to have met such warranties, then Guilford shall bear the cost of such dispute resolution proceedings, including Xxxxxx’x reasonable attorneys’ fees. If the Product is determined not to have met any such warranty for reasons unrelated to a breach of Guilford’s warranty under Section 7.1, then Xxxxxx shall:  
(i) bear the cost of such dispute resolution proceedings, including Guilford’s reasonable attorneys’ fees;  
 (ii) pay Guilford, at the price established in Section 8.2(ii), for the Bulk Active consumed in the Manufacture of such Product;  
 (iii) at Guilford’s written election, within \* after receipt of such determination, either (a) replace the rejected Product within \* of the date of such determination; or (b) at Xxxxxx’x option either credit Guilford’s account or refund to Guilford an amount equal to the Manufacturing Fees paid for such Product, plus any applicable delivery charge paid by Guilford. In the event that Guilford does not make such written election within \*, then the election shall be made at Xxxxxx’x option after written notification to Guilford;  
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 (iv) pay to Guilford interest at the rate of \* on the amount of payment(s) made by Guilford for such Product, if any, from the date that such payment was made until, as applicable, (a) \* after delivery of the replacement Product and associated invoice to Guilford, or (b) deduction of the credit from an amount due by Guilford to Xxxxxx on the date when due (i.e., the credit must actually be used by Guilford and not simply be posted by Xxxxxx to Guilford’s account) or refund to Guilford, as applicable, pursuant to Section 8.3(iii)(b); and  
 (v) cancel any late fees assessed by Xxxxxx to Guilford for non-payment or late payment of the invoice(s) relating to such Product which did not meet such warranty.  
8.4 Product Not Meeting Warranties. Any Product which fails to meet the warranties under Section 8.1 and which is in Guilford’s possession or control shall, at Guilford’s option, either be returned to Xxxxxx for destruction in accordance with Xxxxxx’x written shipping instructions, or destroyed by Guilford, in either case at Xxxxxx’x expense. If returned to Xxxxxx, then risk of loss for such Product shall pass to Xxxxxx upon shipment from Guilford’s facility.  
9. INDEMNIFICATION  
9.1 Xxxxxx Indemnification. Xxxxxx shall defend, indemnify and hold harmless Guilford and its Affiliates, and their respective directors, officers, shareholders, employees and agents, and each of their successors and permitted assigns (collectively, the “Guilford Indemnitees”), from and against any and all claims, actions, causes of action, liabilities, losses, damages, costs or expenses, and resulting settlements, awards or judgments, including reasonable attorneys’ fees (collectively, “Damages”), which arise out of or relate to (i) the failure of Product provided by Xxxxxx hereunder to meet the warranties set forth in Section 8.1; (ii) a breach by Xxxxxx of any of its other representations, warranties, covenants, agreements or obligations under this Agreement or the Related Agreements; (iii) the negligence or willful misconduct of Xxxxxx in Manufacturing Product or in the performance or nonperformance of any obligations under this Agreement or the Related Agreements; or (iv) any patent, trade name, trademark, service xxxx or copyright infringement or misuse, or any claim or judgment of such infringement or misuse thereof, relating to the Container or the Manufacture of the Product by Xxxxxx (except to the extent covered by Guilford’s indemnification obligations pursuant to Section 9.2), or the use of the Xxxxxx Trademarks, trade names or copyrightable materials in connection with any labeling or promotional materials for the Product authorized by this Agreement; provided, that Xxxxxx shall have no obligation to indemnify Guilford under this Section 9.1 to the extent such Damages arise out of or relate to any matter for which Guilford is obligated to indemnify Xxxxxx under this Agreement or the Related Agreements.  
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omitted and submitted separately to the Securities and Exchange Commission.  
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 9.2 Guilford Indemnification. Guilford, on its own behalf, and on behalf of its Affiliates and Licensees, shall defend, indemnify and hold harmless Xxxxxx and its Affiliates and their respective directors, officers, shareholders, employees and agents, and each of their successors and permitted assigns (collectively, the “Xxxxxx Indemnitees”), from and against any and all Damages which arise out of or relate to (i) the failure of Bulk Active provided by Guilford hereunder to meet the warranties set forth in Section 7.1; (ii) a breach of any of Guilford’s other representations, warranties, covenants, agreements or obligations under this Agreement or the Related Agreements; (iii) negligence or willful misconduct in the performance or nonperformance of Guilford’s obligations under this Agreement or the Related Agreements; (iv) personal injury or property damage caused by the Product (except to the extent covered by Xxxxxx’x indemnification obligations hereunder, including those set forth in Sections 9.1, 14 and 17, and the Related Agreements); or (v) any patent, trade name, trademark, service xxxx or copyright infringement or misuse, or any claim or judgment of such infringement or misuse thereof, relating to the Bulk Active supplied by Guilford or to the Product (except to the extent covered by Xxxxxx’x indemnification obligations hereunder, including those set forth in Section 9.1) or the use or printing of any trademarks, trade names or copyrightable materials of Guilford or its Affiliates, Licensees and Distributors as authorized by this Agreement; provided, that Guilford shall have no obligation to indemnify Xxxxxx under this Section 9.2 to the extent such Damages arise out of or relate to any matter for which Xxxxxx is obligated to indemnify Guilford under this Agreement or the Related Agreements.  
 9.3 No Claim for Losses. In no event shall either party or their respective Affiliates be liable for any special, indirect, incidental or consequential damages arising out of this Agreement, except to the extent any such special, indirect, incidental or consequential damages shall be payable to a third party.  
 9.4 Prompt Notice. Each party agrees to give the other prompt written notice of any claims made for which the other might be liable under the foregoing indemnifications. The party from whom indemnification is sought hereunder shall have the right to assume responsibility for any such claim for indemnification, including the defense thereof, by providing notice to the indemnified party within \* of receipt of such notice and by selecting counsel reasonably acceptable to the indemnified party within such \* period. The indemnified party will cooperate fully with the indemnifying party in defending or otherwise resolving any claim subject to indemnification hereunder, and the indemnifying party will have full control of the defense of any such litigation; however, the indemnified party, at its expense, shall be entitled to be represented by its own counsel in any such litigation. The indemnifying party agrees to bear all other costs and expenses of litigation, including its own attorneys’ fees, in connection with such litigation. In the event the indemnifying party refuses or fails to assume defense of any such claim in accordance with the foregoing, or  
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omitted and submitted separately to the Securities and Exchange Commission.  
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 refuses or fails to appoint counsel reasonably acceptable to the indemnified party within the \* time period set forth above, the indemnified party may retain reasonable counsel to defend the claim and the indemnifying party agrees to bear all reasonable costs and expenses of such litigation, including the indemnified party’s reasonable attorneys’ fees, in connection with such litigation.  
 9.5 Refund Due to Injunction. In the event that the sale of Product is enjoined due to an alleged or actual infringement of third party intellectual property rights by either party, then, in addition to all other rights and obligations of the parties hereunder (i) if Guilford is obligated under Section 9.2(v) to indemnify Xxxxxx and Xxxxxx’x Affiliates, Guilford shall pay Xxxxxx for any affected Product remaining in Xxxxxx’x possession at the Manufacturing Fees set forth in Section 4.1; and (ii) if Xxxxxx is obligated under Section 9.1(iv) to indemnify Guilford and Guilford’s Affiliates, Xxxxxx shall (a) return to Guilford any affected Bulk Active remaining in Xxxxxx’x possession; and (b) refund to Guilford the Manufacturing Fees paid by Guilford, calculated on a FIFO basis, for all affected Product remaining in Guilford’s and its Affiliates’, Licensees’ and Distributors’ inventory as of the applicable date of injunction and subsequently returned to Guilford by its customers pursuant to the injunction after the injunction date.  
 9.6 Not Binding. Neither party nor its respective Affiliates shall be responsible or bound by any settlement made by the other party without its prior written consent.  
 9.7 Additional Remedies. The indemnification obligations of the parties established in this Section 9 shall be in addition to, and shall be available to the parties irrespective of the availability of, any other remedies expressly contemplated in this Agreement, including without limitation those contemplated in Sections 7, 8, 14, 17 and 22; provided, that no party shall be entitled to recover multiple damages for the same claim under multiple sections of this Agreement.  
10. MARKETING  
10.1 Catalog Listings. Each party may list Product in its catalogs as a regularly available item in the Territory. Xxxxxx shall also be permitted to provide customers with its “sell sheets” listing the availability of Product. Xxxxxx listings in catalogs and “sell sheets” will show no prices and Xxxxxx will provide Guilford with a copy of such listings for prior written approval.  
 10.2 Xxxxxx Promotion. Xxxxxx shall not promote Product or its therapeutic qualities. Xxxxxx will use reasonable efforts to promote acceptance and use of Container in the Territory. Any such promotion of the Container that is to include reference to the Product shall be approved in writing in advance by Guilford.  
 10.3 Product Sales. Nothing in Section 10.1 or 10.2 shall be construed to xxxxx Xxxxxx a license to sell Product. Guilford and its Affiliates, Licensees and Distributors  
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omitted and submitted separately to the Securities and Exchange Commission.  
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 shall be the exclusive marketers, sellers and distributors of Product in the Territory.  
 10.4 Guilford Promotional Materials. Guilford is responsible for, and is not required or expected to forward to Xxxxxx for written approval, any promotional materials for Product, except as to the use of Xxxxxx’x Trademarks as provided in Section 11 and except as to any statements and/or claims made regarding the Container. Xxxxxx hereby agrees to the use of its Trademarks and the statements and/or claims regarding the Container made in the promotional materials that have been approved in writing by Xxxxxx (the “Approved Materials”). Guilford need not submit individual promotional materials to Xxxxxx for approval provided that any statements and/or claims made in such promotional materials using Xxxxxx’x Trademarks or related to the Container are identical to the statements and/or claims made in the Approved Materials. If Guilford desires to make statements and/or claims related to the Container, or desires to use Xxxxxx’x Trademarks, in either case in a manner not identical to the Approved Materials, then Guilford shall submit such statements and/or claims to Xxxxxx in writing, and if Xxxxxx does not object to such statements and/or claims within \* of receipt from Guilford, then Guilford shall have been authorized to use such Trademarks, statements and/or claims and the Approved Materials shall be deemed to be amended to include such new items.  
 10.5 Labeling. Prescribing information and all labeling copy, including all changes therein, to accompany the Product in the Territory on the Product label and in the Product insert shall be the responsibility of Guilford. Notwithstanding the foregoing, Guilford will collaborate with Xxxxxx in determining the appropriate information and statements to be made regarding the description, characteristics and/or use of the Container and will utilize, to the greatest extent possible and appropriate for the Product, statements which are consistent with language used by Xxxxxx for other products packaged in Xxxxxx’x Container.  
11. INTELLECTUAL PROPERTY  
11.1 Registration of Trademarks. Each party or its Affiliates, as the case may be, will seek to maintain in force during the term of this Agreement, its Trademark(s), at its own cost, in the Territory.  
 11.2 Ownership of Trademarks. Each party warrants that it or its Affiliate, as the case may be, has full right, title and interest in and to its Trademark(s) and registrations obtained in the Territory. Each party retains all right, title and interest in or to its Trademark(s) and shall not assert any claim to any goodwill, reputation or ownership of the other party’s Trademark(s). All uses of Guilford’s Trademark by Xxxxxx shall inure to the benefit of Guilford, and all uses of Xxxxxx’x Trademarks by Guilford shall inure to the benefit of Xxxxxx. However, neither  
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 party shall be obligated to compensate the other for benefits which may inure as the results of the use of such other party’s Trademark(s).  
11.3 License to Use Trademarks. During the term of this Agreement, on a non-exclusive and royalty-free basis, solely for the Territory and solely in connection with the rights and responsibilities of the parties as provided in this Agreement and the Related Agreements, (a) Guilford hereby grants Xxxxxx a license to use its Trademark in connection with the Manufacturing of Product hereunder and in connection with activities permitted pursuant to Sections 10.1 and 10.2; and (b) Xxxxxx hereby grants Guilford a license to use its Trademarks in connection with the registration, promotion, sale and distribution of the Product. Neither party may sublicense this license to the other party’s Trademark(s), except that Guilford may sublicense this license to Guilford’s Affiliates, Licensees and Distributors of Product, without obtaining the prior written consent of Xxxxxx. Any such sublicense granted shall incorporate the terms of this Agreement by reference and shall bind the sublicensee to the provisions of Section 11.  
11.4 Trademark Marking. Each party shall approve in writing the proper manner in which its Trademark(s) must be displayed by the other party when used in connection with the terms of this Agreement prior to any use of such Trademark(s), including appropriate indication of each party’s ownership and registration status of its Trademark(s).  
 11.5 Quality Control. Each party shall use the other party’s Trademark(s) only as specified in Section 11 and in strict accordance with the approved use under Section 11.4. The quality control provisions of the Quality Agreement apply to the use of Trademarks.  
 11.6 Goodwill of Trademarks. Neither party shall use the other party’s Trademark(s) in any way which will adversely affect the goodwill of the other party’s Trademark(s) and shall exercise the necessary controls to maintain the good reputation and good will of such Trademark(s). A requesting party may periodically inspect, sample and review the other party’s actual use of the Trademark(s) of the requesting party to determine whether the other party is maintaining the goodwill of such Trademark(s). Such inspections, sampling and review shall be undertaken by the other party at the requesting party’s expense and request, but no more than once per year, to which the other party shall promptly respond and cooperate.  
 11.7 Protection of Trademarks. Each party will in good faith protect its Trademark rights against any infringement or claim that the Trademarks are invalid or infringe the rights of others. Each party will give prompt written notice to the other party of any infringement or possible infringement of the other party’s Trademark(s) during the term of this Agreement. The commencement, strategies, termination and settlement of any action relating to the validity or infringement of each party’s Trademark(s) shall be decided by the party owning such Trademark(s).  
 11.8 License to Patents and Unpatented Technology. During the term of this Agreement, on a non-exclusive and royalty free basis solely for the Territory and solely to the extent necessary for Xxxxxx to realize its rights and fulfill its obligations under this Agreement, Guilford hereby grants to Xxxxxx a license under all patents, unpatented technology, and other intellectual property rights owned or controlled by Guilford relating to the Product; provided that (i) Xxxxxx shall only have the right to such license, and to use such patents, unpatented technology, and intellectual property rights, if and to the extent necessary for Xxxxxx to realize its rights and fulfill its obligations under this Agreement and that Xxxxxx shall have no right to use any such patents, unpatented technology or intellectual property rights in any other manner or for any other purpose, and (ii) Xxxxxx shall not sublicense the license granted pursuant to this Section 11.8 without Guilford’s prior written consent except in connection with the assignment of this Agreement to an Affiliate in accordance with Section 23.2.  
12. GUILFORD LICENSEES AND DISTRIBUTORS  
12.1 Notification. If Guilford and/or its Affiliates desire to license Guilford’s rights to market and sell Product in the Territory, Guilford shall first notify Xxxxxx in writing of the identity of the proposed Licensee and the nature of the rights to be licensed.  
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omitted and submitted separately to the Securities and Exchange Commission.  
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 12.2 Xxxxxx Disapproval Due to Confidentiality Concerns. With respect to those proposed Licensees which will need access to Xxxxxx’x Confidential Information, Xxxxxx shall have the right, within \* after written notice given by Guilford pursuant to Section 12.1, to disapprove any such proposed Licensee; provided that in order to exercise such right, Xxxxxx must demonstrate to Guilford’s reasonable satisfaction that such proposed Licensee is engaged in, or is preparing to engage in, the development or manufacture of Flexible Containers.  
 12.3 Other Xxxxxx Disapproval. \* In the event that Xxxxxx shall for any reason become subject to any provision or restriction in any contract or other arrangement which would interfere with Guilford’s utilization of third parties as Licensees in the Territory after the date of this Agreement, this Section 12.3 shall not apply with respect to such contract or arrangement. Without limiting the generality of the foregoing, in no event shall Xxxxxx be entitled to enter into any contract which would interfere with Guilford’s utilization in the Territory of a previously approved Licensee.  
 12.4 No Unreasonable Disapproval. Xxxxxx will not unreasonably disapprove any proposed Licensee pursuant to Section 12.2 or 12.3.  
 12.5 Guilford License with Licensees. Guilford shall not license any responsibilities under this Agreement to any proposed Licensee disapproved by Xxxxxx pursuant to Section 12.2 or 12.3.  
 12.6 \*  
 12.7 Distributors. Notwithstanding anything to the contrary in this Section 12, there shall be no restriction upon, and Xxxxxx shall not have the right to approve or disapprove, Guilford’s or its Affiliates’ use of any Distributors; provided that Guilford shall not license its rights to market and sell Product to such Distributors except in accordance with this Section 12 and Guilford shall not disclose Xxxxxx’x Confidential Information to any Distributor without Xxxxxx’x prior written consent, which consent shall not be unreasonably withheld or delayed.  
 12.8 Guilford Continuing Obligations. No license or contract with a Licensee or Distributor shall relieve Guilford of its obligations under this Agreement or any other written agreement entered into by the parties. Furthermore, Guilford shall be responsible for the performance of any Licensee concerning the Product in the Territory and shall indemnify Xxxxxx and its Affiliates with respect thereto as provided in Section 9.2.  
13. BULK ACTIVE LOSSES  
 Xxxxxx shall reimburse Guilford for Bulk Active Losses in connection with the Manufacture of Product pursuant to the provisions of Schedule E.  
\*The asterisk denotes that confidential portions of this exhibit have been  
omitted and submitted separately to the Securities and Exchange Commission.  
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 14. ENVIRONMENT  
14.1 Compliance with Laws. Xxxxxx represents and warrants that its operations and activities connected with or relating to the preparation and Manufacture of the Product will comply with all Applicable Laws relating to protection of human health and the environment.  
 14.2 Indemnification. Xxxxxx agrees to indemnify, defend and hold harmless the Guilford Indemnitees from and against any and all Damages arising out of or relating to a breach of the covenant in Section 14.1, including without limitation (i) any condition in, on, under or near the Facility, and (ii) any condition caused by Xxxxxx, its employees or agents arising out of or in any way connected to any act or omission whatsoever of Xxxxxx and/or its Affiliates, employees or agents. Such duty of indemnification shall include, but not be limited to, claims for injury to person(s) or damage to property, including natural resources, and further including claims for environmental investigation and/or remediation of property at or around the Facility or any off-site location where material from the Facility may have been transported or otherwise came to be located. Xxxxxx has the option of selecting the attorneys for the defense of claims under this provision and shall be responsible for all costs and expenses of such attorneys. Guilford may elect to have its own attorneys as additional counsel, in which case Guilford shall be responsible for its own attorneys’ fees.  
15. CONFIDENTIALITY  
15.1 Confidentiality. With respect to the terms of this Agreement and all information furnished by one party to the other party pursuant to or under this Agreement or the Confidentiality Agreement entered into on October 15, 2003, whether or not identified herein as specifically subject to Section 15, (collectively, “Confidential Information”), the party receiving such Confidential Information shall maintain the confidential and proprietary status of such Confidential Information, keep such Confidential Information and each part thereof within its possession or under its control, use all reasonable efforts to prevent the disclosure of any Confidential Information to any other person or entity, and use all reasonable efforts to ensure that such Confidential Information is used only for those purposes specifically authorized by this Agreement. These mutual obligations shall not apply to any information to the extent that such information is:  
(i) developed by a receiving party independently of the Confidential Information and not in violation of this Agreement;  
 (ii) in the public domain at the time of its receipt from the disclosing party or thereafter becomes part of the public domain through no fault of the recipient;  
\*The asterisk denotes that confidential portions of this exhibit have been  
omitted and submitted separately to the Securities and Exchange Commission.  
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 (iii) received without obligation of confidentiality from a third party having the right to disclose such information;  
 (iv) released from the restrictions of this Section 15.1 by the express written consent of the disclosing party; or  
 (v) known by the receiving party prior to its receipt from the disclosing party as evidenced by the receiving party’s business records.  
15.2 Exceptions. Notwithstanding the provisions of Section 15.1, the parties shall have the right to disclose Confidential Information hereunder to the extent:  
(i) required by Applicable Laws to be disclosed (the disclosing party shall, however, give the other party reasonable prior notice thereof and a copy of the disclosure proposed to be made, and will also reasonably cooperate with the other party to prevent or to limit such disclosure and permit the other party to participate in seeking an appropriate protective order);  
 (ii) required by Securities Laws to be disclosed (the disclosing party shall, however, consult with the other party on the provisions of this Agreement to be redacted in any filings made by the parties with the United States Securities and Exchange Commission or as otherwise required by Applicable Law);  
 (iii) disclosed to the FDA and/or other governmental agencies by a party in fulfillment of its obligations under this Agreement in order to obtain or maintain FDA approval of the Product, or to obtain or maintain patents (but such disclosure shall only be made pursuant to the provisions of this Agreement, as appropriate);  
 (iv) necessary to be disclosed to Affiliates, Licensees, Distributors, agents, consultants, and/or other third parties, for the research and development, manufacturing and/or marketing of the Product in the Territory, but only on the condition that the prior written approval of Xxxxxx has been obtained for disclosure to Distributors in accordance with Section 12.7 and such recipients of the Confidential Information shall, prior to such disclosure, agree in writing to be bound by the confidentiality and non-use obligations contained in this Agreement; or  
 (v) necessary to effect the licenses granted under this Agreement, the Related Agreements or any other written agreement entered into by the parties, but only on the condition that such recipients of the Confidential Information shall, prior to such disclosure, agree in writing to be bound by the confidentiality and non-use obligations contained in this Agreement and any other written agreement entered into by the parties.  
\*The asterisk denotes that confidential portions of this exhibit have been  
omitted and submitted separately to the Securities and Exchange Commission.  
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 15.3 Further Exception. Nothing in this Section 15 shall prohibit a party from disclosing its own Confidential Information to third parties unless such information also constitutes Confidential Information of the other party hereunder or otherwise is contemplated to be kept as confidential in this Agreement or the Related Agreements.  
 15.4 Export. A recipient of Confidential Information shall adhere to the U.S. Export Administration laws and regulations and shall not export or re-export, to the extent covered by such laws and regulations, any technical data or information received from the disclosing party or the direct product of such technical data or information to any proscribed country listed in the U.S. Export Administration regulations unless properly authorized by the U.S. Government.  
 15.5 Enforcement. Each party specifically recognizes that any breach by it of this Section 15 may cause irreparable injury to the other party and that actual damages may be difficult to ascertain and in any event, may be inadequate. Accordingly (and without limiting the availability of legal or equitable, including injunctive, remedies under any other provision of this Agreement) each party agrees that in the event of any such breach, notwithstanding the provisions of Section 9 or 23.6 hereof, the other party shall be entitled to seek, by way of private litigation in the first instance, injunctive relief and such other legal and equitable remedies as may be available.  
 15.6 Prior Arrangements. The parties acknowledge that they have executed earlier agreements regarding confidential information exchanged pursuant to the Confidentiality Agreement entered into on October 15, 2003. The parties agree that Section 15 of this Agreement shall supersede all provisions in such earlier agreements relating to confidentiality and non-use obligations of the parties with regard to confidential information disclosed under such earlier agreements, except that where such agreements contain confidentiality and non-use obligations which are more restrictive than those set forth in Section 15 of this Agreement then those more restrictive provisions shall continue to apply after execution of this Agreement to confidential information disclosed under such more restrictive provisions.  
 15.7 Return of Confidential Information. All Confidential Information, including copies thereof, shall remain the property of the disclosing party and, to the extent readily identifiable or clearly identified, and upon request of the disclosing party, shall be returned to it upon expiration or termination of this Agreement, except to the extent retention is necessary to effect the licenses granted under this Agreement or to comply with Applicable Laws.  
 15.8 Survival. The obligations of confidentiality and non-use referred to in Section 15.1 shall survive until five (5) years after termination or expiration of this Agreement.  
\*The asterisk denotes that confidential portions of this exhibit have been  
omitted and submitted separately to the Securities and Exchange Commission.  
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 16. TERM AND TERMINATION  
16.1 \*  
16.2 Term. The initial term of this Agreement shall be effective as of the Effective Date, and shall continue in effect for five (5) years. Thereafter, this Agreement shall be renewed automatically for consecutive two (2) year periods unless and until either party shall give written notice of termination at least \* before the end of the initial term or any renewal thereof.  
16.3 Termination for Default or Bankruptcy. This Agreement may be terminated upon written notice by either party to the other party at any time during the term of this Agreement:  
(i) if the other party, by act or omission, breaches or defaults on a material term or condition of this Agreement and such party fails to cure such breach within \* after written notice by the other party, or if by its nature such breach cannot be cured within such period and such party does not take all reasonable steps which can be taken within such \* period to correct or remedy such breach and thereafter diligently pursues such corrective measures, which shall be completed not later than \* from the date of such notice, unless the parties shall agree otherwise in writing; or  
(ii) upon the filing or institution with respect to the other party of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of its assets for the benefit of creditors by the other party; provided, however, in the case of any involuntary proceeding such right to terminate shall only become effective if the other party consents to the involuntary proceeding or such proceeding is not dismissed within \* after the filing thereof.  
16.4 Termination by Either Party Due to Change in Ownership. Each party shall provide written notice to the other party prior to, or upon first becoming aware of (or, if prior notice is not practicable or is otherwise prohibited, as soon as practicable or after such notice is no longer prohibited), a change of fifty percent (50%) or more of the direct or indirect ownership of, or a change in control of, the notifying party (a “Change in Control”). If the party entitled to notice reasonably believes that such Change in Control will result in material harm to its business as a result of competition between Guilford (and its Affiliates) and Xxxxxx (and its Affiliates) as a result of such Change in Control, then such party shall have the option, within \* of such notice, to terminate this Agreement effective immediately after notifying the other party in writing.  
 16.5 Termination by Guilford if Product Is Withdrawn from the U.S. Market. This Agreement may be terminated or suspended immediately by Guilford if Product  
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omitted and submitted separately to the Securities and Exchange Commission.  
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 shall be withdrawn from the market in the U.S. by Guilford due to (a) serious problems relating to safety or efficacy; or (b) failure to obtain or maintain FDA approval or any other license, permit or authorization required for the Manufacture and sale of the Product in the United States. In case of any termination or suspension of this Agreement under this Section 16.5, Guilford’s sole liability shall be to pay Xxxxxx for Product as provided in Section 16.8. This Agreement may be reinstated by Guilford for the balance of the existing contract term if Guilford shall reintroduce Product within \* following suspension of this Agreement under this Section 16.5; thereafter, this Agreement may be reinstated by Guilford upon agreement by Xxxxxx, which shall not be unreasonably withheld.  
 16.6 Termination by Guilford in the Event of Relocation of Facility. Guilford shall have the right to terminate this Agreement if the Facility used to Manufacture Product is relocated in accordance with the procedures set forth in this Section 16.6, provided, however, that Guilford’s approval of any such relocation of Facility shall not be unreasonably withheld. \* Guilford must provide Xxxxxx with written notice of its intent to terminate as set forth herein no later than \* after receipt of Xxxxxx’x notice of its intent to relocate Manufacture of Product to a new facility, which termination shall be effective as of the end of the \* notice period provided by Xxxxxx. In the event that Xxxxxx intends to relocate Manufacturing of Product to another facility, then, in addition to its other obligations set forth herein, Xxxxxx shall, at its own cost, be obligated to meet pre-approval inspection and readiness requirements of the FDA, revalidate equipment and Manufacturing processes, Manufacture new stability batches, conduct required stability studies, reimburse Guilford for any associated reasonable documented direct costs of amending its filings with the FDA, including, but not necessarily limited to, salaries and wages of personnel and out-of-pocket costs, and pay for any other reasonable direct costs associated with the relocation. Xxxxxx will continue to supply Product from the Facility until the new facility is approved by the FDA.  
 16.7 \*  
 16.8 Dispositions of Inventory Upon Termination or Expiration.  
16.8.1 Certain Terminations by Guilford. In the event of any termination of this Agreement by Guilford pursuant to Section 16.3, 16.4, 16.6 or 16.7, then (i) Xxxxxx shall promptly return any remaining inventory of Bulk Active, and package inserts and materials relating to the packaging of the Product which contain Guilford’s or its Affiliates’, Licensees’ or Distributors’ trademarks or trade names, in accordance with Guilford’s written instructions, and Xxxxxx shall pay the freight and insurance costs and shall assume the risk of loss for return of such items until Xxxxxx physically transfers the items to Guilford at Guilford’s designated location; (ii) Guilford shall have the option to cancel any outstanding Firm Orders for Product, without penalty to Guilford, or to compel Xxxxxx to Manufacture  
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omitted and submitted separately to the Securities and Exchange Commission.  
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 and Deliver Product relating to any outstanding Firm Orders in accordance with the terms of this Agreement; and (iii) Guilford shall have the option to purchase from Xxxxxx all Product which meets the warranties and other requirements of this Agreement, in accordance with the terms of this Agreement.  
 16.8.2 Certain Terminations by Xxxxxx. In the event of any termination of this Agreement by Xxxxxx pursuant to Section 16.3 or 16.4, then (i) Xxxxxx shall promptly return any remaining inventory of Bulk Active, and package inserts and materials relating to the packaging of the Product which contain Guilford’s or its Affiliates’, Licensees’, or Distributors’ trademarks or trade names, in accordance with Guilford’s written instructions, and Guilford shall pay the freight and insurance costs and assume the risk of loss for return of such items after Xxxxxx physically transfers the items to Guilford’s designated carrier at Xxxxxx’x Facility; (ii) Xxxxxx shall have the option to cancel any outstanding Firm Orders for Product, without penalty to Xxxxxx, or to Manufacture and Deliver Product relating to any outstanding Firm Orders in accordance with the terms of this Agreement; and (iii) Guilford shall purchase from Xxxxxx all Product Manufactured pursuant to Firm Orders which meets the warranties and other requirements of this Agreement, in accordance with the terms of this Agreement.  
 16.8.3 Termination for Any Other Reason or Expiration. In the event of termination of this Agreement for any reason other than those contemplated in Sections 16.8.1 and 16.8.2, or in the event of expiration of this Agreement, then (i) Xxxxxx shall promptly return any remaining inventory of Bulk Active, and package inserts and materials relating to the packaging of the Product which contain Guilford’s or its Affiliates’, Licensees’, or Distributors’ trademarks or trade names, in accordance with Guilford’s written instructions, and the parties shall share equally the freight and insurance costs and the risk of loss for return of such items after Xxxxxx physically transfers the items to Guilford’s designated carrier at Xxxxxx’x Facility; and (ii) the parties shall cooperate in good faith to either cancel any outstanding Firm Orders for Product, without penalty to either party, or to Manufacture and Deliver Product relating to any outstanding Firm Orders for purchase by Guilford in accordance with the terms of this Agreement.  
 16.8.4 Destruction and Bulk Active Loss Calculations. Any Product which is not purchased by Guilford under the provisions of Section 16.8.1(iii) shall be destroyed by Xxxxxx in accordance with Section 17, and such Product shall be included in Line F of the Bulk Active Usage Variance form(s) prepared for the relevant Bulk Production Lot pursuant to Schedule E.  
\*The asterisk denotes that confidential portions of this exhibit have been  
omitted and submitted separately to the Securities and Exchange Commission.  
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 16.9 Remaining Obligations. Expiration or termination of this Agreement shall not relieve the parties of any of their respective obligations accruing prior to such expiration or termination. The covenants and agreements of the parties that require by their terms performance or compliance after expiration or termination of this Agreement shall survive the termination of this Agreement.  
 16.10 Use of Trademarks. Except as may be required to dispose of Product in existence at the time of expiration or termination of this Agreement, any and all rights of either party to use the Trademark(s) and trade names of the other party for the Product shall end upon termination or expiration of this Agreement.  
 16.11 Alternative Suppliers. At the expiration of the term of this Agreement, or in the event of early termination of this Agreement by Guilford pursuant to any of Sections 16.3, 16.4, 16.6, 16.7 or 23.1, at Guilford’s written request, \*. The reasonable costs for such technology transfer shall be reimbursed by Guilford if the transfer results from expiration of the Agreement and the costs of the transfer shall be born by Xxxxxx if the transfer results from a material breach by Xxxxxx. Upon the earlier of (i) Guilford’s delivery of notice of termination pursuant to any of Sections 16.3, 16.4, 16.6 or 16.7, (ii) the existence and continuation of a circumstance contemplated by 23.1 for a period of at least \*, and (iii) \* prior to the expiration of this Agreement by its terms, Guilford shall be entitled to qualify an alternative supplier (other than Xxxxxx or its Affiliates) of Product, and Guilford’s reasonable activities in connection with such qualification shall not constitute a violation of Section 3.5; provided that Guilford shall not be otherwise relieved of its obligations hereunder, including its obligation under Section 15.  
17. WASTE/DISPOSAL  
17.1 Xxxxxx Warranty. To the extent of its responsibilities therefor pursuant to this Agreement, Xxxxxx warrants that in connection with handling and/or disposing of (i) any and all Bulk Active, Materials and/or Product, and (ii) those waste streams derived from or associated with Bulk Active, Materials and/or Product, or derived from or associated with the preparation and Manufacturing of the Product, it will comply with all Applicable Laws governing the transportation, unloading, discharge, generation, storage, treatment, disposal, and handling of Bulk Active, Materials and/or Product Manufactured under this Agreement, including, but not limited to:  
(i) the Toxic Substance Control Act (P.L. 94-469);  
 (ii) the Federal Food, Drug and Cosmetic Act, as amended, 21 U.S. Code, Section 301, et. seq.  
 (iii) the Clean Air Act, 42, U.S.C. Section 7401, et. seq.;  
\*The asterisk denotes that confidential portions of this exhibit have been  
omitted and submitted separately to the Securities and Exchange Commission.  
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 (iv) the Federal Water Pollution Control Act, 33 U.S.C. Section 1251, et. seq.; and  
 (v) the Resource Conservation and Recovery Act, 42 U.S.C. Section 6901, et. seq.  
17.2 Xxxxxx Indemnification. Xxxxxx agrees to defend, indemnify and hold Guilford and its Affiliates harmless from any and all third party claims, losses, damages, costs and expenses, including reasonable attorneys’ fees, arising from the transportation, unloading, discharge, generation, storage, treatment, disposal and handling of waste Bulk Active, Materials and Product and of waste streams derived from or associated with the preparation and Manufacturing of Product hereunder.  
 17.3 Limitation. The warranty and indemnity set forth in Sections 17.1 and 17.2 shall not apply with respect to handling or disposal of Bulk Active, Product, package inserts and other materials used in Manufacturing of Product to the extent that Guilford is responsible therefor pursuant to this Agreement or otherwise, including Xxxxxx returns of Bulk Active to Guilford for destruction in accordance with the terms of this Agreement.  
 17.4 Guilford Indemnification. Guilford agrees to defend, indemnify and hold Xxxxxx and its Affiliates harmless from any and all third party claims, losses, damages, costs and expenses, including reasonable attorneys’ fees, arising from the transportation, unloading, discharge, generation, storage, treatment, disposal and handling of Bulk Active, Product, package inserts and other materials used in the Manufacture of Product to the extent that Guilford is responsible therefor pursuant to this Agreement or otherwise, including handling and disposal by Guilford of any and all customer return of Product in accordance with the terms of this Agreement, except to the extent such claims, losses, damages, costs and expenses are covered by Xxxxxx’x indemnification obligations hereunder, including pursuant to Section 17.2.  
18. INSURANCE  
18.1 Insurance Coverage. Xxxxxx shall, at its sole cost and expense, procure and maintain throughout the life of this Agreement and any extension thereof the following insurance with carriers satisfactory to Guilford:  
(i) Statutory Workers Compensation insurance as required by Applicable Law and Employers Liability insurance in an amount not less than \* for each accident.  
 (ii) Commercial General Liability insurance for bodily injury or death of persons and/or loss of or damage to property as follows:  
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omitted and submitted separately to the Securities and Exchange Commission.  
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 (a) General Aggregate \*  
 (b) Premises/Operations \*  
 (c) Blanket Contractual Liability \*  
 (d) Completed Products Operations \*  
 (e) Personal & Advertising Injury \*  
(iii) Excess Liability insurance with limits of \* per occurrence and in the aggregate.  
18.2 Evidence of Insurance. Xxxxxx shall provide Guilford with written evidence of such insurance naming Guilford as an additional insured and shall notify Guilford at least \* prior to any cancellation, non-renewal or material change in such insurance. Xxxxxx may elect to self-insure all or part of the limits described above (including deductibles or retentions); however, such decision to self-insure shall not in any way limit Xxxxxx’x liability with respect to its indemnification obligations under this Agreement and the Related Agreements.  
19. REGULATORY MATTERS  
19.1 Maintenance of NDA. Guilford shall be responsible for maintaining the NDA and all regulatory filings and submissions associated with the Product in the Territory. Xxxxxx shall provide Manufacturing-related Product information to Guilford as may be reasonably necessary or helpful for Guilford to meet its regulatory obligations to maintain the NDA and file the required reports thereunder in the Territory, including providing such information relating to any changes to the Product Specifications, the Manufacturing process or otherwise pursuant to the Quality Agreement. Each party shall cooperate with the other in making and maintaining all regulatory filings that may be necessary in connection with the performance of this Agreement and the Related Agreements.  
 19.2 Communications with the FDA. Guilford shall have the responsibility for communications with the FDA relating to the Product. Xxxxxx shall provide Guilford, in a timely manner, all information reasonably in its (or its Affiliates’) control concerning the Product within or outside the Territory reasonably necessary or helpful to meet Guilford’s regulatory obligations.  
20. QUALITY AGREEMENT  
 Simultaneously with the execution of this Agreement, the parties are entering into the Quality Agreement. Quality control testing and other quality related matters shall be governed by, and performed by the parties in accordance with, the terms and conditions of the Quality Agreement. The Quality Agreement is intended to supplement this  
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omitted and submitted separately to the Securities and Exchange Commission.  
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 Agreement, and is hereby incorporated in this Agreement in its entirety, except that in the event of a conflict between any term, condition or provision of this Agreement and any term, condition or provision of the Quality Agreement, the applicable term, condition or provision of this Agreement shall control unless otherwise agreed in writing by the parties.  
 21. CTM SUPPLY AGREEMENT  
 Simultaneously with the execution of this Agreement, the parties are entering into the CTM Supply Agreement. Manufacture and supply of clinical trial material and related matters shall be governed by, and performed by the parties in accordance with, the terms and conditions of the CTM Supply Agreement. The CTM Supply Agreement is intended to supplement this Agreement, and is hereby incorporated in this Agreement in its entirety, except that in the event of a conflict between any term, condition or provision of this Agreement and any term, condition or provision of the CTM Supply Agreement, the applicable term, condition or provision of this Agreement shall control unless otherwise agreed in writing by the parties.  
 22. SAFETY MATTERS, PRODUCT RETURN AND PRODUCT RECALL  
22.1 Safety. Xxxxxx shall comply at all times with all applicable health and safety regulations, policies and procedures relating to the Manufacture of the Product, including the transmission by Xxxxxx to its employees of health and safety information relating to the Product and its manufacture, storage, disposal and transportation  
 22.2 Adverse Experience Reporting. The parties shall be responsible for reporting adverse experiences and complaints with respect to the Product (including the Bulk Active and the Materials), and for responding to any such reports and complaints, in accordance with the terms and conditions of the Quality Agreement.  
 22.3 Product Returns. In the event that Xxxxxx (or any of its Affiliates) shall receive any returned goods of Product from a third party, Xxxxxx shall notify Guilford of such returned goods and, at Guilford’s option, either destroy such returned goods or deliver such return goods to Guilford, in each case at Guilford’s expense. Guilford shall not have the right to return any Product received by Guilford as returned goods from third parties to Xxxxxx, other than in accordance with Section 8.2. The parties shall notify each other of, and shall respond to, any customer complaints associated with returned Product in accordance with the terms and conditions of the Quality Agreement.  
 22.4 Product Recall. Product recalls shall be conducted in accordance with the terms of the Quality Agreement. Each party shall make a permanent, complete and accurate record of all costs incurred by it in connection with any Product recall, a  
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omitted and submitted separately to the Securities and Exchange Commission.  
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 copy of which shall be delivered to the other as soon after the completion of such recall or seizure as practically may be done. If the cause of or reason for said recall or seizure arises from or is attributable to Xxxxxx’x negligence or breach of this Agreement, Baxter shall, in addition to its other obligations hereunder, reimburse Guilford for (i) all Bulk Active incorporated into the recalled or withdrawn Product at the price per kilo set forth in Section 8.2(ii), (ii) the Manufacturing Fees paid by Guilford for the recalled or withdrawn Product calculated on a FIFO basis, and (iii) all reasonable direct expenses including, but not necessarily limited to, salaries and wages of personnel and out-of-pocket costs which are incurred by Guilford and its Affiliates in connection with such recall and documented and invoiced by Guilford to Xxxxxx. If the cause of or reason for said recall or seizure is directly attributable to Guilford’s negligence or breach of this Agreement, Guilford shall, in addition to its other obligations hereunder, reimburse Xxxxxx for all reasonable direct expenses including, but not necessarily limited to, salaries and wages of personnel and out-of-pocket costs which are incurred and documented by Xxxxxx in connection with such recall and invoiced by Xxxxxx to Guilford. If Xxxxxx and Guilford cannot agree which party is at fault, then an independent technical expert, acceptable to both, will be designated to make the determination. The so designated technical expert shall not be an employee, consultant, officer, director or shareholder of or otherwise associated with either party or an Affiliate of either party. The technical expert’s determination shall be, in the absence of fraud or manifest error, binding and conclusive upon the parties.  
23. MISCELLANEOUS  
23.1 Force Majeure. Except as otherwise contemplated in Section 3.4, Section 16.11 and this Section 23.1, neither party shall be liable to the other for the failure or delay in performing any obligation under this Agreement if and to the extent such failure or delay is due to causes beyond the reasonable control of the affected party, including (i) acts of God; (ii) weather, fire or explosion; (iii) war, invasion, riot or other civil unrest; (iv) governmental laws, orders, restrictions, actions, embargos or blockades; (v) national or regional emergency; (vi) injunctions, strikes, lockouts, labor trouble or other industrial disturbances; (vii) shortage of adequate fuel, power, Materials, Bulk Active or transportation facilities; or (viii) any other event which is beyond the reasonable control of the affected party; provided that the party affected shall promptly notify the other party, in writing, of the force majeure condition and shall exert reasonable efforts to eliminate, cure or overcome any such causes, at its own cost, and to resume performance of its obligations as soon as possible. After notice has been given by the affected party to the other party of the force majeure event, the parties will discuss and attempt to resolve the issues related to the force majeure event on terms and conditions agreeable to both parties. Notwithstanding the foregoing, if as the result of a force majeure event Xxxxxx cannot supply Product to Guilford for a period  
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 exceeding \*, then Guilford shall be entitled to terminate this Agreement upon written notice to Xxxxxx and such termination shall be effective immediately.  
 23.2 Assignment. Neither this Agreement nor the rights and obligations of the parties hereunder may be assigned, delegated or otherwise transferred by either party without the prior written consent of the other party, which shall not be unreasonably withheld or delayed, except (i) as contemplated in Section 12.6, and (ii) that either party shall have the right to assign this Agreement, or delegate its rights and obligations hereunder, in whole or in part, to any Affiliate of such party; provided, that such assigning party shall remain primarily responsible for its obligations hereunder. In addition to the foregoing, and notwithstanding anything to the contrary therein, Guilford shall have the right to grant a security interest in, or to collaterally assign, this Agreement to the extent, but only to the extent, required in connection with the financing arrangements described in Schedule I hereto, and such grant or assignment shall include the right of the grantee or assignee to foreclose upon such security interest or collateral upon default by Guilford and, in such event, to sell, assign, license or otherwise dispose of such security interest or collateral to a third party; provided, however, that any such sale, assignment, license or other disposal shall be subject to the provisions of Section 16.4 to the extent applicable. Any attempted assignment of this Agreement in violation of this Section 23.2 shall be void. Notwithstanding the foregoing, the prohibition on assignment set forth in this Section 23.2 shall not apply to any assignment that constitutes a Change in Control, which shall be governed by the provisions of Section 16.4.  
 23.3 Severability. In the event any one or more of the provisions contained in this Agreement should be held invalid, illegal or unenforceable in any respect in any jurisdiction, such provisions shall be ineffective to the extent (and only to the extent) of such invalidity or unenforceability in such jurisdiction and the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the parties. The parties agree to replace any invalid, illegal or unenforceable provision(s) or parts thereof by new provision(s) which closely approximate the result intended by the parties.  
 23.4 Notices. All notices or other communications which are required or permitted hereunder shall be in English and in writing and shall be sufficient and deemed given on the same business day if delivered personally, on the same business day if sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail, or overnight courier), on the business day after dispatch is sent by nationally recognized overnight courier which provides a delivery receipt, or on the third business day following the date of mailing if sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:  
\*The asterisk denotes that confidential portions of this exhibit have been  
omitted and submitted separately to the Securities and Exchange Commission.  
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 if to Guilford: Guilford Pharmaceuticals Inc.  
 0000 Xxxxxxxxx Xxxxxx  
 Xxxxxxxxx, Xxxxxxxx 00000  
 Attention: Senior Vice President -  
 Technical Operations  
 Fax Number: (000) 000-0000  
 with a copy to: Guilford Pharmaceuticals Inc.  
 0000 Xxxxxxxxx Xxxxxx  
 Xxxxxxxxx, Xxxxxxxx 00000  
 Attention: General Counsel  
 Fax Number: (000) 000-0000  
 if to Baxter: Xxxxxx Healthcare Corporation  
 Xxxxx 000 & Xxxxxx Xx.  
 Xxxxx Xxxx, XX 00000  
 Attention: General Manager  
 Global Drug Delivery  
 Fax Number: 000-000-0000  
 with a copy to: Xxxxxx Healthcare Corporation  
 Xxxxxxx 000 Xxxxx  
 Xxxxxx, Xxxxx Xxxxxxxx 00000  
 Attention: Plant Manager  
 Fax Number: 000-000-0000  
 or to such other address as the party to whom notice is to be given may have furnished to the other party in accordance herewith.  
 23.5 Applicable Law. This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware without reference to any rules of conflict of laws or renvoi.  
 23.6 Alternative Dispute Resolution. The parties will attempt to settle any claim or controversy arising out of this Agreement through good faith negotiations and in the spirit of mutual cooperation. If those attempts fail, except as otherwise contemplated in this Agreement or the Related Agreements (including without limitation Sections 7.2, 8.2 and 15.5 of this Agreement) and subject to the provisions of this Section 23.6, such dispute between the parties will be mediated by a mutually acceptable mediator to be chosen by the parties within \* after written notice by the party demanding mediation. The disputes referred to in Sections 7.2, 8.2 and 15.5 of this Agreement, or elsewhere in this Agreement or  
\*The asterisk denotes that confidential portions of this exhibit have been  
omitted and submitted separately to the Securities and Exchange Commission.  
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 the Related Agreements, shall be settled as specified therein. Neither party may unreasonably withhold consent of the selection of the mediator and the parties will share the costs of the mediation equally. The parties may agree to replace mediation with some other form of Alternative Dispute Resolution (“ADR”), such as neutral fact-finding, mini-trial or arbitration. Any dispute which cannot be resolved by the parties through mediation or another form of ADR within \* of the date of the initial written demand for mediation may then be submitted to the Federal or state courts, as appropriate, for resolution. The use of any ADR procedures with respect to unresolved disputes will not be construed under the doctrine of latches, waiver or estoppel to affect adversely either party’s right to assert any claim or defense. Notwithstanding the foregoing, nothing in this Section 23.6 will prevent either party from resorting to judicial process at any time if (i) good faith efforts to resolve the dispute under these procedures have been unsuccessful and such party reasonably believes that good faith efforts to continue to attempt to resolve the dispute under these procedures would be unsuccessful (irrespective of whether the \* period contemplated herein has expired), or (ii) injunctive relief from a court is necessary to prevent serious and irreparable injury to one party or to others.  
 23.7 Entire Agreement. This Agreement, together with the Related Agreements, contains the entire understanding of the parties with respect to the subject matter hereof and cancels all previous agreements, negotiations, commitments and writing in respect to the subject matter hereof except for the confidentiality agreements between the parties to the extent referred to in Section 15.3.  
 23.8 Amendment. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by both parties hereto.  
 23.9 Subcontracting. Xxxxxx shall not contract with a third party to undertake any portion of the Manufacture of Product without Guilford’s prior written consent.  
 23.10 Headings. The captions to the Sections hereof are not a part of this Agreement, but are merely guides or labels to assist in locating and reading the Sections hereof.  
 23.11 Independent Contractors. It is expressly agreed that Xxxxxx and Guilford shall be independent contractors and that the relationship between the two parties shall not constitute a partnership, joint venture, agency or similar relationship. Neither Xxxxxx nor Guilford shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other, without the prior written consent of the other party to do so.  
 23.12 Waiver. The waiver by either party hereto of (i) any right hereunder; (ii) the failure to perform by the other party; or (iii) a breach by the other party shall not be effective unless set forth in a writing signed by the party against who such  
\*The asterisk denotes that confidential portions of this exhibit have been  
omitted and submitted separately to the Securities and Exchange Commission.  
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 waiver is to be enforced, and shall not be deemed a waiver of any other right hereunder or of any other breach or failure by said other party, whether of a similar nature of otherwise.  
 23.13 Counterparts. This Agreement may be executed in two counterparts, each of which shall be deemed an original, but which together shall constitute one and the same instrument. Each party may execute this Agreement on a facsimile of the Agreement and facsimile signatures of authorized signatories of either party shall constitute due execution and delivery of this Agreement.  
 23.14 Successors and Assigns. The terms and conditions of this Agreement shall be binding upon and shall inure to the benefit of the parties hereto and their respective successors and permitted assigns.  
 23.15 Execution. Each party agrees to execute such further papers, agreements, documents, instruments and the like as may be necessary or desirable to effect the purpose of this Agreement and to carry out its provisions.  
 23.16 Remedies. Except as may be otherwise expressly provided herein, no remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.  
 23.17 Review with Counsel. Each of the parties agrees that it has had the opportunity to review this Agreement with its legal counsel. Accordingly, the rule of construction that any ambiguity in this Agreement is to be construed against the drafting party shall not apply.  
 23.18 Benefit. Except as otherwise provided in Section 23.19, nothing in this Agreement or the Related Agreements, express or implied, is intended to or shall confer on any person other than the parties hereto, and their respective successors and permitted assigns, any rights, remedies, obligations or liabilities under or by reason of this Agreement or the Related Agreements.  
 23.19 \*  
\*The asterisk denotes that confidential portions of this exhibit have been  
omitted and submitted separately to the Securities and Exchange Commission.  
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 IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives as of the date first set forth above.  
 Guilford Pharmaceuticals Inc. Xxxxxx Healthcare Corporation  
 By:  
 /s/ Xxxx X. Xxxxxxx By: /s/ Xxxxx X. Xxxxxx  
 Name:  
 Xxxx X. Xxxxxxx Name: Xxxxx X. Xxxxxx  
 Title:  
 Senior Vice President,  
Technical Operations Title: Senior Vice President,  
Medication Delivery  
 Date:  
 July 1, 2004 Date: July 1, 2004  
 \*The asterisk denotes that confidential portions of this exhibit have been  
omitted and submitted separately to the Securities and Exchange Commission.  
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 SCHEDULE A  
SPECIFICATIONS FOR PRODUCT and BULK ACTIVE  
 \*  
\*The asterisk denotes that confidential portions of this exhibit have been  
omitted and submitted separately to the Securities and Exchange Commission.  
 SCHEDULE B  
APPROVED VENDORS FOR EXCIPIENTS  
 \*  
\*The asterisk denotes that confidential portions of this exhibit have been  
omitted and submitted separately to the Securities and Exchange Commission.  
 SCHEDULE C  
MANUFACTURING FEES  
 \*  
\*The asterisk denotes that confidential portions of this exhibit have been  
omitted and submitted separately to the Securities and Exchange Commission.  
 SCHEDULE D  
PRODUCT DEFINITIONS  
 \*  
\*The asterisk denotes that confidential portions of this exhibit have been  
omitted and submitted separately to the Securities and Exchange Commission.  
 SCHEDULE E  
BULK ACTIVE LOSSES  
 \*  
\*The asterisk denotes that confidential portions of this exhibit have been  
omitted and submitted separately to the Securities and Exchange Commission.  
 SCHEDULE F  
INVOICING REQUIREMENTS  
 \*  
\*The asterisk denotes that confidential portions of this exhibit have been  
omitted and submitted separately to the Securities and Exchange Commission.  
 SCHEDULE G  
INITIAL FIRM ORDER AND FORECAST  
 \*  
\*The asterisk denotes that confidential portions of this exhibit have been  
omitted and submitted separately to the Securities and Exchange Commission.  
 SCHEDULE H  
FORM OF PURCHASE ORDER  
 \*  
\*The asterisk denotes that confidential portions of this exhibit have been  
omitted and submitted separately to the Securities and Exchange Commission.  
 SCHEDULE I  
FINANCING ARRANGEMENTS  
 In order to finance its acquisition of the rights to the Product in the Territory from Merck, Guilford entered into a revenue interest financing arrangement with Xxxx Royalty Fund, L.P. and Xxxx Royalty Fund II, L.P. (collectively, “PRF”) pursuant to a revenue interest assignment agreement. Under Guilford’s arrangement with PRF, and subject to the terms and conditions thereof, PRF is entitled to receive a certain percentage of Guilford’s annual net sales of the Product. In order to secure its obligations to PRF, Guilford granted PRF a security interest in the assets related to the Product.