EXHIBIT 10.40  
 AMENDED AND RESTATED  
MANUFACTURING AND PACKAGING AGREEMENT  
 This Manufacturing and Packaging Agreement (“Agreement”) is made this day of March, 2007 by and between Cardinal Health PTS, LLC, having a place of business at 0000 Xxxxxxx Xxxxx, Xx Xxxxxxxxxx, Xxxxxxx 00000 (“Cardinal Health”) and Reliant Pharmaceuticals, Inc. (“Reliant”), having its principal place of business at 000 Xxxxx Xxxx, Xxxxxxx Xxxxxx, Xxx Xxxxxx 00000. (Cardinal Health and Reliant are each a “Party” and shall collectively be referred to herein as the “Parties.”)  
 BACKGROUND  
 A. Cardinal Health provides contract pharmaceutical development, manufacturing, packaging, analytical, and sales and marketing services to the pharmaceutical industry.  
 B. Reliant has rights to market certain pharmaceutical products and wants Cardinal Health to assist in the formulation, filling, packaging and testing of such products as provided in this Agreement and the attachments hereto.  
 C. In April 2005, Cardinal Health and Reliant entered into that certain Manufacturing and Packaging Agreement under which Reliant engaged Cardinal Health to provide certain services to Reliant in connection with the processing of the Product (defined below) (the “Initial Agreement”) on a non-exclusive basis.  
 D. The Parties wish to amend and restate the Initial Agreement as set forth below.  
 E. THEREFORE, in consideration of the mutual conditions and covenants set forth herein, the Parties hereby agree as follows:  
 ARTICLE 1  
DEFINITIONS  
 The following terms have the following meanings in this Agreement:  
 1.1 “Affiliate(s)” means any corporation, firm, partnership or other entity that controls, is controlled by or is under common control with a Party. For purposes of this definition, “control” shall mean the ownership of at least fifty percent (50%) of the voting share capital of such entity or any other comparable equity or ownership interest.  
 1.2 “API” means the active pharmaceutical ingredient described in the Manufacturing Specifications, which have been released by Reliant and provided to Cardinal Health as raw material, along with a certificate of analysis, as provided in this Agreement.  
 1.3 “API Cap” shall have the meaning set forth in Section 15.1.  
   
 1.4 “Applicable Laws” means all laws, ordinances, rules and regulations within the Territory applicable to the Manufacturing and Packaging of the Product or any aspect thereof and the obligations of Cardinal Health or Reliant, as the context requires under this Agreement, including, without limitation, (A) all applicable federal, state and local laws and regulations of each Territory; (B) the U.S. Federal Food, Drug and Cosmetic Act, and (C) the current Good Manufacturing Practices promulgated by the Regulatory Authorities, as amended from time to time (“cGMPs”).  
 1.5 “Batch” means defined quantity of finished drug product that has been or is being Manufactured and Packaged in accordance with the Specifications.  
 1.6 “Calendar Quarter” means a period of three (3) consecutive months commencing on January 1, April 1, July 1 or October 1 of any calendar year.  
 1.7 “Cardinal Health Technology” shall have the meaning set forth in Article 12.  
 1.8 “Change Order” shall have the meaning set forth in Section 4.5(A).  
 1.9 “Confidential Information” shall have the meaning set forth in Section 11.2.  
 1.10 “Contract Year” means each consecutive twelve (12) month period beginning on January 1, 2007.  
 1.11 “Defective Product” shall have the meaning set forth in Section 5.2.  
 1.12 “Delivery Date” shall mean the date on which Cardinal Health tenders the relevant Batch(es) to the carrier in accordance with Section 6.1. Each Delivery Date shall be specified by Reliant on the relevant Purchase Order and confirmed by Cardinal Health as set forth in Section 4.4.  
 1.13 “Dispute” shall have the meaning set forth in Section 19.9.  
 1.14 “Effective Date” means January 1, 2007.  
 1.15 “Facility or Facilities” means Cardinal Health’s facilities located in St. Petersburg, Florida or such other facility as agreed by the Parties.  
 1.16 “FDA” means the United States Food and Drug Administration and any successor agency thereto.  
 1.17 “Firm Commitment” shall have the meaning set forth in Section 4.3.  
 1.18 “Manufacture” or “Manufacturing” means the compounding, filling, encapsulation, producing and/or inspection of the API and Raw Materials into Product in accordance with the Specifications and the terms and conditions set forth in this Agreement.  
   
 1.19 “Manufacturing Date” means the day on which the Product is to be compounded by Cardinal Health, which shall not be more than forty-five (45) days prior to the Delivery Date.  
 1.20 “Manufacturing Related Reference Documents” means (a) all completed production/Batch records; (b) all quality control test/request forms (result worksheets) and associated data; (c) dynamic monitoring performed during processing; (d) any alert/action notifications generated during processing; (e) any planned or unplanned deviations associated with the Product; (f) any out of Specification result investigations associated with the Product; (g) the Certificate of Analysis for the Batch comparing testing to Specifications; (h) the appropriate disposition notification for the Batch, and (i) a Yield statement.  
 1.21 “Manufacturing Sample” shall have the meaning set forth in Section 5.1.  
 1.22 “Minimum Requirement” shall have the meaning set forth in Section 4.1.  
 1.23 “Package” or “Packaging” means the labeling and the packaging of the Product onto the bulk product packaging in accordance with the Specifications and the terms and conditions of this Agreement.  
 1.24 “Product” means Omacor® as fully compounded API Manufactured and Packaged in accordance with the Specifications, including both Sample Product and Trade Product.  
 1.25 “Product Maintenance Fee” shall have the meaning set forth in Section 7.2.  
 1.26 “Product Maintenance Services” shall have the meaning set forth in Section 2.3.  
 1.27 “Purchase Order” shall have the meaning set forth in Section 4.4.  
 1.28 “Raw Materials” means all raw materials, supplies, components and packaging, not including API, necessary to Manufacture, Package and ship the Product in accordance with the Specifications.  
 1.29 “Regulatory Authority” means any governmental regulatory authority within a Territory involved in regulating any aspect of the development, manufacture, market approval, sale, distribution, packaging or use of the Product.  
 1.30 “Reliant Technology” shall have the meaning set forth in Article 12.  
 1.31 “Review Period” shall have the meaning set forth in Section 5.1.  
 1.32 “Rolling Forecast” shall have the meaning set forth in Section 4.3.  
 1.33 “Sample Product” shall mean Product supplied to physicians and other permitted recipients without charge in accordance with all Applicable Laws.  
 1.34 “Softgel Technology” means Cardinal Health’s proprietary technology for the manufacture of softgels for the oral administration of pharmaceutical active ingredients having  
   
 certain solubility characteristics and includes proprietary know-how including without limitation know-how relating to (i) the development of fill and shell formulations; (ii) the design and use of the encapsulation process to enhance stability, solubility, bioavailability, and manufacturability of active ingredient chemical entities in softgels; (iii) the selection and preparation of solvents, vehicles, excipients, surfactants, stabilizers, gelatin, plasticizers and other components of the liquid fill and the gelatin shell; (iv) certain encapsulation, drying and related manufacturing techniques and machinery for making commercial quantities of softgels, and (v) Cardinal Health’s proprietary [\*\*\*] technique.  
 1.35 “Specifications” means the procedures, requirements, standards, quality control testing and other data and the scope of services as set forth in Exhibit A, which are hereby incorporated by reference into this Agreement, along with any valid amendments or modifications thereto, subject to the terms and conditions of Article 9.  
 1.36 “Term” shall have the meaning set forth in Section 15.1.  
 1.37 “Territory” means the United States of America, its territories and possessions.  
 1.38 “Trade Product” means any Product which has been designated and packaged for commercial sale in the Territory.  
 1.39 “Unit” means each individual unit of Product, as described more fully in the Specifications.  
 1.40 “Unit Pricing” shall have the meaning set forth in Section 7.1.  
 1.41 “Yield” shall have the meaning set forth in Section 3.4.  
 ARTICLE 2  
VALIDATION, MANUFACTURING, PACKAGING & RELATED SERVICES  
 2.1 Validation Services. During the Term, Cardinal Health shall perform the qualification and validation services described in Exhibit D of this Agreement for the prices specified therein.  
 2.2 Supply and Purchase of Product. During the Term, Cardinal Health shall Manufacture and Package the Products in accordance with the Specifications, Applicable Laws and the terms and conditions of this Agreement. Reliant shall purchase Product from Cardinal Health in accordance with the terms and conditions of this Agreement, including but not limited to the obligations set forth in Section 4.1 and Section 4.2 hereof.  
 2.3 Product Maintenance Services. During the Term and subject to Reliant’s payment of the Product Maintenance Fee as set forth in Section 7.2, if applicable, Reliant shall be entitled to the Product maintenance services set forth below (collectively, the “Product Maintenance Services”). For the avoidance of doubt, in the event that, in accordance with the terms of Section 7.2, Reliant  
 [\*\*\*]: Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.  
   
 is not required to pay the Product Maintenance Fee, Reliant shall nonetheless be entitled to the Product Maintenance Services:  
 • Administration of Foreign Trade Zone;  
• One annual audit;  
• Annual Product review;  
• Access to document library over and above the Quality Agreement, including additional copies of batch paperwork or other batch documentation;  
• Annual Drug Master File update;  
• Preparation of Product licenses or permits under United States local, state or Federal regulations (in each case as more fully set forth in Article 10);  
• Product Document and Manufacturing Sample Storage relating to cGMP requirements;  
• Vendor re-qualification;  
• Maintenance and storage of Audit Reports; and  
• Bulk stability (6 months, warehouse conditions).  
 ARTICLE 3  
MATERIALS  
 3.1 API.  
 A. Reliant shall supply to Cardinal Health for Manufacturing and Packaging, at Reliant’s sole cost, the API and applicable reference standards in quantities sufficient to meet Reliant’s requirements for each Product as further set forth in Article 4. Prior to delivery of any of the API or reference standard to Cardinal Health for Manufacturing and Packaging, Reliant shall provide to Cardinal Health a copy of the API Material Safety Data Sheet (“MSDS”), as amended, and any subsequent revisions thereto. Reliant shall supply the API, reference standards, and Certificate of Analysis FOB the Facility no later than thirty (30) days before the scheduled Manufacture Date upon which such API will be used by Cardinal Health. Upon receipt of the API, Cardinal Health shall conduct identification testing of the API. Cardinal Health shall use the API solely and exclusively for Manufacturing and Packaging under this Agreement. The maximum volume of API that Reliant supplies to Cardinal Health shall not exceed the amount reflected in the Firm Commitment and the next six (6) months of the Rolling Forecast.  
 B. All API provided by Reliant shall meet applicable Specifications that apply thereto, and shall be produced in accordance with all applicable federal, state and local laws and regulations, including, without limitation, cGMPs.  
 C. Cardinal Health shall inspect API as received to verify its identity and shall give Reliant oral and written notice of any nonconformity with Specifications within thirty (30) calendar days of receipt of API by Cardinal Health. Reliant shall provide a Certificate of Analysis with each delivery of API and such certificate shall be the basis for drug potency.  
 D. Reliant shall retain title to API at all times and shall bear the risk of loss thereof; provided, however, subject to Section 15.1, from the time API is received at Cardinal Health’s Facility to the time API is returned (or Product is delivered) to Reliant’s designated carrier at  
   
 Cardinal Health’s loading dock, Cardinal Health shall bear the risk of loss of API arising from Cardinal Health’s negligence or failure to comply with cGMPs or failure to comply with all Specifications.  
 3.2 Raw Materials. Cardinal Health shall be responsible for procuring, inspecting and releasing adequate Raw Materials as necessary to meet the Firm Commitment, unless otherwise agreed to by the Parties in writing. All Raw Material supplier changes must be agreed by the Parties by amending the Specifications in writing.  
 3.3 Reimbursement for Materials. In the event of (A) a Specification change requested by Reliant or Cardinal Health for Reliant’s benefit and agreed by the Parties, or to comply with any new requirement of a Regulatory Authority, (B) termination of this Agreement by Reliant without cause or expiration of this Agreement; or (C) unforeseeable obsolescence of any Raw Material, Reliant shall bear the cost of any unused Raw Materials that cannot be used by Cardinal Health or returned for credit, provided that Cardinal Health purchased such Raw Materials in quantities consistent with Reliant’s most recent Firm Commitment and the supplier’s minimum purchase obligations.  
 3.4 Yield and Inventory Reconciliation. Cardinal Health will achieve a minimum Yield in Manufacturing the Product. “Yield” means the relation between the API content of the Product Manufactured over a certain time period and the actual quantity of API used to Manufacture such quantity of Product. The minimum Yield was determined after the Manufacture of the greater of twenty (20) batches or the number of batches Manufactured during the first three (3) months of production and is set forth in Exhibit C. In the event the minimum yield falls below [\*\*\*]% at any time during the Term, the Parties agree to discuss remedies to elevate the minimum yield in good faith and amend the Agreement as the Parties deem appropriate, provided, however, the foregoing discussions shall not relieve Cardinal Health of its obligations to pay for quantities of API consumed in excess of the minimum Yield under this Section 3.4. In the event the Parties have not agreed on remedies to elevate the Yield to [\*\*\*]% within three (3) months of determining the minimum Yield as set forth above, the Parties expressly agree that for purposes of this Section 3.4 and the obligations set forth herein, the minimum Yield shall be no less than [\*\*\*]%, unless the Parties discuss and agree that it is commercially impracticable under the circumstances. After the Parties have established the minimum Yield, Cardinal Health shall, after Manufacture of each Batch, compare actual Yield for such batch with the minimum Yield. Cardinal Health shall prepare a quarterly report that sets forth all Yields by lot numbers that exceed the minimum Yield. Cardinal Health will reimburse or credit Reliant an amount that is equal to the current price that Reliant actually paid for API per kilo in the Contract Year (currently [\*\*\*] dollars ($[\*\*\*])[\*\*\*]) consumed in excess of the minimum Yield, as evidenced by written documentation submitted to Cardinal by Reliant. The Parties agree that for specific written orders Reliant may provide Cardinal Health with instructions for Manufacturing that result in Yields lower than the minimum Yield. Reliant will not be entitled to reimbursement or credit for API to the extent that API loss is attributable solely to Reliant’s specific instructions. Within three (3) business days of the end of each quarter Cardinal Health shall notify Reliant of the quantities of API (both raw material and in-process) in inventory. Upon reasonable advance notice to Cardinal Health and at mutually agreeable times but not more than twice in any twelve  
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 (12) month period, Reliant shall be permitted to inspect API inventory at Cardinal Health’s Facility.  
 ARTICLE 4  
COMMITMENT OF THE PARTIES, PURCHASE ORDERS & FORECASTS  
 4.1 Minimum Requirement. During each Contract Year, Reliant shall purchase the minimum dollar volume of Product (the “Minimum Requirement”) set forth on Exhibit B. If Reliant does not purchase such Minimum Requirement during any Contract Year, within thirty (30) days after the end of such Contract Year and upon receipt of an invoice from Cardinal Health, Reliant shall pay Cardinal Health the difference between (A) the Minimum Requirement and (B) the sum of all purchases from Cardinal Health for the Product during the just concluded Contract Year.  
 4.2 Commitment of the Parties.  
 (a) INTENTIONALLY OMITTED  
 (b) Reliant commits to purchase a minimum of [\*\*\*]% of its Manufacturing requirements for [\*\*\*] in the Territory per Contract Year from Cardinal Health during the Term of this Agreement, subject to Section 4.2 (c) and (d) below. For the avoidance of doubt, Reliant may, in its sole discretion, purchase any or all of its [\*\*\*] from any third party. Further, for the avoidance of doubt, the pricing for all Product will be at the level assuming that Reliant purchases [\*\*\*]% of its requirements for [\*\*\*] from Cardinal Health, and, in the event Reliant purchases less than [\*\*\*]% of its requirements from Cardinal Health the Parties will conduct a reconciliation of pricing at the conclusion of that Contract Year.  
 Within sixty (60) days following the end of each Contract Year during the Term of this Agreement, and within sixty (60) days following the termination or expiration of this Agreement for any reason, Reliant shall submit to Cardinal Health a written report (each, an “Annual Report”), certified by an officer of Reliant, setting forth, with respect to the immediately preceding Contract Year: (i) Reliant’s Manufacturing requirements for Trade Product in the Territory, (ii) the aggregate Units of Trade Product purchased from Cardinal Health; (iii) the calculation of the percentage of its Manufacturing requirements for Trade Product purchased from Cardinal Health, and (iv) the amount, if any, to be paid to Cardinal Health in accordance with the terms and conditions set forth in Exhibit B based on the actual percentage of Reliant’s Manufacturing requirements purchased from Cardinal Health. In the event that such Annual Report indicates that Cardinal Health is owed an additional amount for Trade Product purchased in the immediately preceding Contract Year, Cardinal Health shall invoice Reliant for such amount, and Reliant shall pay such invoice within thirty (30) days of the date of receipt of such invoice.  
 (c) In the event Cardinal Health (i) determines it cannot meet any of Reliant’s Rolling Forecasts delivered in accordance with Section 4.3 below, or (ii) fails to deliver any Product within ten (10) days of a respective Delivery Date for three (3) consecutive months during the Term, such that at the end of any three month period Cardinal Health has failed to deliver the total number of lots for which Reliant has issued Purchase Orders, Reliant’s obligations under  
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 4.2(b) shall be reduced in direct proportion to the percentage such unfulfilled Purchase Orders represent as measured against Reliant’s obligations in Section 4.2(b), provided, however, Reliant shall use commercially reasonable efforts to return to the purchase requirement level set forth in Section 4.2(b) following resolution of any technical issues.  
 (d) Any quantity of Product which is not delivered to Reliant by Cardinal Health within ten (10) days of any Delivery Date, for any reason whatsoever, during the Term shall give Reliant the option to purchase such quantity of Trade Product, but only such quantity, from a qualified third-party supplier.  
 (e) In the event Cardinal Health’s Facility undergoes expansion and subsequent FDA approval of such expansion, Reliant shall have the option, but not the obligation, to have its Product Manufactured and Packaged in such new wing, provided, however, that Reliant shall bear the cost of relocating to such new wing, up to a cap of $[\*\*\*].  
 4.3 Forecast. On the Effective Date and on or before the first (1st) day of each calendar month following the Effective Date, Reliant shall furnish to Cardinal Health in writing, an eighteen (18) month rolling forecast of the quantities of Product that Reliant intends to order from Cardinal Health during such period (“Rolling Forecast”). The first three (3) months of such Rolling Forecast shall constitute a binding order for the quantities of Product specified therein (“Firm Commitment”) and the following fifteen (15) months of the Rolling Forecast shall be non-binding, good faith estimates.  
 4.4 Purchase Orders. On or before the first (1st) day of each calendar month, Reliant shall submit a purchase order for the Firm Commitment, which specifies the actual number of Batches to be Manufactured and Packaged, the approximate number of Units in each Batch, and the requested Delivery Dates for each Batch (“Purchase Order”). Reliant shall submit each Purchase Order to Cardinal Health at least ninety (90) days in advance of the earliest Delivery Date requested in the Purchase Order. Cardinal Health shall confirm Delivery Dates to Reliant. In the event of a conflict between the terms of any Purchase Order and this Agreement, this Agreement shall control. Notwithstanding the foregoing, Cardinal Health shall supply Reliant with quantities of Product that exceed by not more than [\*\*\*] percent ([\*\*\*]%) the quantities specified in the Firm Commitment (“Excess Quantities”), and shall use best commercial efforts to supply additional quantities of Product requested by Reliant (“Additional Quantities”). Cardinal Health’s supply of Excess Quantities and Additional Quantities are both subject to (i) receipt of a Purchase Order for such Additional Quantities and Excess Quantities at least ninety (90) days in advance of the requested Delivery Date for such Additional Quantities and Excess Quantities, and (ii) Cardinal Health’s possession of sufficient quantities of API to Manufacture Excess Quantities and Additional Quantities. Cardinal Health’s failure to supply Reliant with Additional Quantities shall not constitute a failure to supply under Section 2.2 and 4.2. Should Cardinal Health fail to supply Reliant with its requirements for the Product, specifically excluding Additional Quantities, for any particular month hereunder, Cardinal Health shall be required to make up the difference in the immediately subsequent month.  
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 4.5 Cardinal Health’s Cancellation of Purchase Orders. Notwithstanding the terms and conditions set forth in Section 4.6 below, Cardinal Health reserves the right to cancel all, or any part of, a Purchase Order upon written notice to Reliant (and Cardinal Health shall have no further obligations or liability with respect to such Purchase Order) if Reliant refuses or fails to make scheduled deliveries of the API.  
 4.6 Reliant’s Modification or Cancellation.  
 A. Reliant may modify the delivery date, Specifications or quantity of Product in such Purchase Order only by submitting a written change order (“Change Order”) to Cardinal Health at least thirty (30) business days in advance of the earliest scheduled Manufacturing Date for the Manufacturing and Packaging covered by the change order. Such change order shall be effective and binding upon Cardinal Health only upon the written acceptance by Cardinal Health and, notwithstanding the foregoing, Reliant shall remain responsible for the Firm Commitment portion of the Rolling Forecast.  
 B. Notwithstanding any amounts due to Cardinal Health under Section 4.1 or Section 4.4, if Reliant fails to place Purchase Orders sufficient to satisfy the Firm Commitment, Reliant shall, within thirty (30) days of receipt of invoice, pay to Cardinal Health the difference between the (i) Unit Price for all Units that would have been Manufactured and Packaged if Reliant had placed Purchase Orders sufficient to satisfy the Firm Commitment, and (ii) Cardinal Health’s cost of any Raw Materials that would have been used in such Units, provided, however, that Cardinal Health is not in default of any of its supply obligations hereunder. In the event Cardinal Health has an opportunity to mitigate its damages hereunder, the Parties shall meet in good faith to discuss an appropriate reduction.  
 4.7 Unplanned Delay or Elimination of Manufacturing and Packaging. Cardinal Health shall timely fill each Purchase Order, subject to the terms and conditions of this Agreement applicable to both Parties. Cardinal Health shall notify Reliant as soon as possible after the receipt of a Firm Commitment or Purchase Order if Cardinal Health determines that any Manufacturing or Packaging related to the Firm Commitment or Purchase Order will be delayed or eliminated for any reason.  
 4.8 Inspection of Manufacturing and Packaging. Reliant may base up to two (2) representatives at the Facilities to observe the Manufacturing and Packaging provided that Reliant provide Cardinal Health at least ten (10) days’ advance written notice of the attendance of such Reliant representatives. Reliant shall indemnify and hold harmless Cardinal Health for any action or activity of such representatives while on Cardinal Health’s premises.  
 ARTICLE 5  
TESTING; MANUFACTURING SAMPLES; RELEASE  
 5.1 Manufacturing Samples; Testing. Within seven (7) days after Cardinal Health’s completion of Manufacturing and Packaging of each Batch, Cardinal Health shall deliver to Reliant, or its designee, a sample of the Product (“Manufacturing Sample”) and the Manufacturing Related Reference Documents for such Batch. No later than thirty (30) days after receipt of the Manufacturing Sample and a complete set of the Manufacturing Related Reference  
   
 Documents (“Review Period”), Reliant or its designee shall review the Manufacturing Related Reference Documents and notify Cardinal Health whether the Manufacturing Sample conforms to the warranty set forth in Section 13.1 of this Agreement. Upon receipt of notice from Reliant that a Batch meets the warranty in Section 13.1, or upon failure of Reliant to respond by the end of the Review Period, Cardinal Health will invoice Reliant for such Batch in accordance with Section 7.5 below.  
 5.2 Non-Conforming Product. If Reliant notifies Cardinal Health during the Review Period that the Manufacturing Sample does not conform to the warranty set forth in Section 13.1 and Cardinal Health agrees with Client’s determination, Client shall not be responsible to pay for such batch (the “Defective Product”), and Cardinal Health shall, at Reliant’s option, either (A) replace any Batch of non-conforming Product, or (B) credit any payments made by Reliant for such Batch. If Cardinal Health does not agree with Reliant’s determination that such Product fails to meet the warranty set forth in Section 13.1, then after reasonable efforts to resolve the disagreement, the Parties shall cause a mutually acceptable independent third party to review records, test data and to perform comparative tests and/or analyses on the Manufacturing Sample. The results of the independent review shall be final and binding. Unless otherwise agreed to by the Parties in writing, the costs associated with such testing and review shall be borne by the non-prevailing Party.  
 THE OBLIGATION OF CARDINAL HEALTH TO (A) REPLACE DEFECTIVE PRODUCT IN ACCORDANCE WITH THE SPECIFICATIONS OR CREDIT PAYMENTS MADE BY RELIANT FOR DEFECTIVE PRODUCT AND (B) REIMBURSE RELIANT FOR API LOST IN THE DEFECTIVE BATCH, SUBJECT TO THE LIMITATIONS IN ARTICLE 15.1, SHALL BE RELIANT’S SOLE AND EXCLUSIVE REMEDY (WITHOUT PREJUDICE TO ANY INDEMNIFICATION OBLIGATIONS UNDER SECTION 14.1 OR THE OBLIGATIONS OF SECTION 10.6 (RECALL)) UNDER THIS ARTICLE FOR DEFECTIVE PRODUCT AND IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED.  
 5.3 Supply of Material for Defective Product. In the event Cardinal Health is required to replace Product pursuant to Section 5.2, above, in no instance shall Cardinal Health be liable for damage in excess of fees paid for Defective Product and API, subject to the limitation of liability in Section 15.1 and the indemnification obligations under Section 14.1.  
 ARTICLE 6  
DELIVERY  
 6.1 Delivery. Cardinal Health shall segregate and store all Product until such Product has been Manufactured and Packaged to the Product Specifications. Upon such acceptance, Cardinal Health shall tender the Product for delivery, F.O.B. the Facility. Reliant shall be responsible for all costs and risk of loss associated with shipment of the Product. Reliant shall qualify at least one (1) carrier to ship the Product, and if Reliant qualifies more than one carrier Reliant shall designate the priority of such qualified carriers to Cardinal Health.  
 6.2 Failure to Take Delivery. If Reliant fails to take delivery within seven (7) days of any scheduled delivery date solely with respect to Product that has been deemed acceptable by  
   
 Reliant, Reliant shall be invoiced for such Product pursuant to Section 7.5 On the first day of each subsequent month Reliant shall be invoiced for the stored Product at a rate of [\*\*\*] of Batch price per month for administration and storage costs. For each such batch of accepted but undelivered Product, Reliant agrees that: (A) Reliant has made a fixed commitment to purchase such Product, (B) title and risk of loss for such Product passes to Reliant, (C) such Product shall be on a xxxx and hold basis for legitimate business purposes, (D) if no delivery date is determined at the time of billing, Cardinal Health shall have the right to ship the Product to Reliant or Reliant’s designee within four months after billing, and (E) Reliant will be responsible for any decrease in market value of such Product that relates to factors and circumstances outside of Cardinal Health’s control. Within five (5) days following a written request from Cardinal Health, Reliant shall provide Cardinal Health with a letter confirming items (A) through (E) of this Section for each Batch of undelivered Product.  
 ARTICLE 7  
PRICING AND PAYMENT  
 7.1 Unit Pricing. Reliant shall pay to Cardinal Health the unit pricing set forth on Exhibit B (“Unit Pricing”) for all Product. When a Purchase Order is placed, Reliant shall specify in such Purchase Order whether each lot is designated for Sample Product or Trade Product. For lots designated for Sample Product, Reliant shall pay the Unit Pricing for Sample Products as set forth on Exhibit B. For lots designated for Trade Product, Reliant shall pay the tiered Unit Price based on the number of Units set forth in its Rolling Forecast for the then-current Contract Year. By way of example, as of the date a Purchase Order is submitted, if Reliant’s Rolling Forecast for then current Contract Year estimates a unit volume in excess of One Hundred Million Units, Reliant shall pay the Unit Pricing for such volume indicated on Exhibit B. The Parties shall reconcile all accounts annually, no later than thirty (30) days after the beginning of each Contract Year hereunder, including verification by Reliant of its sampling program. In the event Reliant shall desire to make a Sample Product lot out of a lot otherwise forecast and purchased as Trade Product, the Parties shall reconcile such transfer and Cardinal Health shall credit the difference to Reliant within thirty (30) days of such notification. Unit Pricing for Sample Product to be used by Reliant for physician sampling shall be extended for two (2) years from the Effective Date. In the event Reliant shall receive FDA approval for a new indication for the Product, the Parties agree to discuss in good faith an extension of the Sample Product pricing program at the original sample price. In the event Reliant requests services other than Manufacturing and Packaging Product, Cardinal Health shall provide a written quote of the fee for such additional services and Reliant shall advise Cardinal Health whether it wishes to have such additional services performed by Cardinal Health.  
 7.2 Product Maintenance Fee. In partial consideration of the Product Maintenance Services set forth in Section 2.3, Reliant shall pay Cardinal Health an annual Product Maintenance Fee of [\*\*\*] dollars ($[\*\*\*]) for any Contract Year wherein Reliant purchases less than [\*\*\*] Units of Product from Cardinal Health. For any year in which the Product Maintenance Fee is applicable, it shall be payable by December 31 of such Contract Year. For the avoidance of doubt, no Maintenance Fees are due and owing as of the Effective Date.  
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 7.3 Price Increase. The Unit Pricing may be adjusted on an annual basis, effective on the first day of each Contract Year beginning January 1, 2008, upon ninety (90) days’ written notice from Cardinal Health to Reliant. Such adjustment shall be based on actual increases or decreases in Raw Material or Manufacturing and Packaging costs, subject to the following limitations: The Unit Pricing for Product shall include only: (a) the cost of Raw Materials and (b) Cardinal Health’s Manufacturing and Packaging costs, including without limitation Cardinal Health’s labor, utilities and overhead. Any price adjustment shall limit the increase in component (b) to [\*\*\*] ([\*\*\*]%); provided, however, Cardinal Health shall use its best commercial efforts to limit any increases hereunder as much as possible and Cardinal Health agrees to provide backup documentation for all annual increases, if any, and such costs and related documentation shall be auditable upon reasonable notice by an independent third party reasonably acceptable to Cardinal Health and Reliant. Reliant shall bear all costs associated for such audit, unless such audit reveals that Cardinal Health exceeded the permitted increase, in which case Cardinal Health shall bear the costs of the audit and shall credit such overpayment to Reliant.  
 7.4 Taxes; Duty. All taxes, duties and other amounts assessed on the Raw Materials, API or the Product prior to or upon sale to Reliant are the responsibility of Reliant, and Reliant shall reimburse Cardinal Health for any such taxes, duties or other expenses paid by Cardinal Health, upon receipt of reasonable documentation.  
 7.5 Payment Terms. Cardinal Health shall invoice Reliant for all Product as provided in Section 7.1, and for any amounts due pursuant to Section 4.1 or Section 4.2 and payment for such undisputed invoices shall be due within thirty (30) days after the date of such invoice. In the event payment is not received by Cardinal Health, for any amounts due under this Agreement, on or before the thirtieth (30th) day after the date of the invoice, or in the case of the Product Maintenance Fee, upon the date set forth in Sections 7.2, then such unpaid amounts shall accrue interest at the rate of percent (1.0%) per month until paid in full.  
 ARTICLE 8  
INTENTIONALLY OMITTED  
 ARTICLE 9  
CHANGES TO SPECIFICATIONS  
 All Specifications and any changes thereto agreed to by the Parties from time to time shall be in writing, dated and signed by the Parties. No change in the Specifications shall be implemented by Cardinal Health, whether requested by Reliant or requested or required by any Regulatory Authority, until the Parties have agreed in writing to such change, the implementation date of such change, and any increase or decrease in costs, expenses or fees associated with such change. Cardinal Health shall respond promptly to any request made by Reliant for a change in the Specifications, and both Parties shall use commercially reasonable, good faith efforts to agree to the terms of such change in a timely manner. If after initial Product qualification, Reliant requests a change in the Specifications for its own benefit or to comply with the requirements of a Regulatory Authority, the Specifications shall be amended as soon as  
 [\*\*\*]: Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.  
   
 possible after a request is made for any change in Specifications, and Cardinal Health shall notify Reliant of the costs associated with such change and shall provide such supporting documentation as Reliant may reasonably require. Reliant shall pay all costs associated with such Reliant-requested changes or changes required by a Regulatory Authority as may be agreed upon by the Parties. Changes, agreed to between the Parties, for the benefit of Cardinal Health, shall be at the expense of Cardinal Health. If there is a conflict between the terms of this Agreement and the terms of the Specifications, this Agreement shall control.  
 ARTICLE 10  
RECORDS; REGULATORY MATTERS  
 10.1 Batch Records and Data. Within thirty (30) days following the completion of Manufacturing and Packaging of each batch, Cardinal Health shall provide Reliant with properly completed copies of Manufacturing Related Reference Documents prepared in accordance with the Specifications; provided, however, that if testing reveals an out-of-Specification result, Cardinal Health shall provide such Batch records within ten (10) days following resolution of the out-of Specification result.  
 10.2 Recordkeeping. Cardinal Health shall maintain true and accurate books, records, test and laboratory data, reports and all other information relating to Manufacturing and Packaging under this Agreement, including all information required to be maintained by all Applicable Laws. Such information shall be maintained in forms, notebooks and records for a period of at least two (2) years from the relevant finished Product expiration date or longer if required under Applicable Laws.  
 10.3 Regulatory Compliance. Cardinal Health, with the assistance of Reliant, shall obtain all permits and licenses required by any United States federal, state or local regulatory agency with respect to the Product and the Manufacturing and Packaging under this Agreement, including any product licenses, applications and amendments in connection therewith. Cardinal Health will be responsible to maintain all permits and licenses required by any Regulatory Authority with respect to the Facility. During the Term, Cardinal Health will assist Reliant with all regulatory matters relating to Manufacturing and Packaging under this Agreement, at Reliant’s request and at Reliant’s expense. Each Party intends and commits to cooperate to satisfy all Applicable Laws relating to Manufacturing and Packaging under this Agreement. Cardinal Health shall provide a Certificate of Compliance to Reliant annually during the Term.  
 10.4 Governmental Inspections and Requests. Cardinal Health shall immediately advise Reliant if an authorized agent of any Regulatory Authority visits the Facility concerning the Manufacturing or Packaging of the Product. Cardinal Health shall furnish to Reliant a copy of the report by such Regulatory Authority, if any, within ten (10) days of Cardinal Health’s receipt of such report. Further, upon receipt of a Regulatory Authority request to inspect the Facilities or audit Cardinal Health’s books and records with respect to Manufacturing or Packaging under this Agreement, Cardinal Health shall immediately notify Reliant, and shall provide Reliant with a copy of any written document received from such Regulatory Authority. Cardinal Health shall permit Reliant to have a representative present for any such Product-specific Facility inspection unless such presence would be unreasonable under the circumstances. To the extent specifically related to the Manufacturing or Packaging hereunder, Cardinal Health shall provide Reliant with  
   
 a copy of any proposed written response prior to submission and a reasonable opportunity for Reliant to review and approve, provided such approval is not unreasonably withheld, conditioned or delayed.  
 10.5 Reliant Inspections and Audits.  
 A. Except for circumstances as set forth in Section 10.4, during the term of this Agreement, duly-authorized employees, agents and representatives of Reliant shall be granted access upon at least twenty-four (24) hours prior notice, unless more time is reasonably requested by Cardinal Health, and at reasonable times during regular business hours to only the portion of the Facilities where Cardinal Health Manufactures or Packages API for the purpose of inspecting and verifying that Cardinal Health is Manufacturing and Packaging API in accordance with cGMPs, the Specifications and the Product Master Batch Record. For purposes of this Section 10.5, duly-authorized agents and representatives shall be required to sign Cardinal Health’s standard Confidential Disclosure Agreement prior to being allowed access to Cardinal Health’s Facilities.  
 B. With due regard to information and operations which constitute Proprietary Information of Cardinal Health, duly-authorized employees, agents and representatives of Reliant shall have the right to inspect Cardinal Health Batch Records relating to Product and those portions of Cardinal Health’s Facilities used for Manufacturing and Packaging Product. Reliant’s Quality Assurance Manager will arrange audit visits with Cardinal Health Quality Management.  
 10.6 Recall. In the event Cardinal Health believes a recall, field alert, Product withdrawal or field correction may be necessary with respect to any Product provided under this Agreement, Cardinal Health shall immediately notify Reliant in writing. Cardinal Health will not act to initiate a recall, field alert, Product withdrawal or field correction without the express prior written approval of Reliant, unless otherwise required by Applicable Laws. In the event Reliant believes a recall, field alert, Product withdrawal or field correction may be necessary with respect to any Product provided under this Agreement, Reliant shall immediately notify Cardinal Health in writing and Cardinal Health shall provide all necessary cooperation and assistance to Reliant. Reliant shall solely control the implementation of such recall, filed alert, Product withdrawal or field correction. The cost of any recall, field alert, Product withdrawal or field correction shall be borne by Reliant unless such recall, field alert, Product withdrawal or field correction is caused solely by Cardinal Health’s breach of its representations, warranties and obligations under this Agreement or Applicable Laws or its negligence or willful misconduct, then such cost shall be borne by Cardinal Health. For purposes hereof, such cost shall be limited to reasonable, actual and documented administrative costs incurred by Reliant for such recall, withdrawal or correction, and replacement of the Defective Product to be recalled, in accordance with Article 5.  
 10.7 Quality Agreement. Within thirty (30) days following the execution of this Agreement, the Parties shall execute a Quality Agreement in substantially the form attached to this Agreement as Exhibit E. The Quality Agreement shall in no way determine liability or financial responsibility of the Parties for the responsibilities set forth therein. In the event of a conflict between the terms of this Agreement and the Quality Agreement, this Agreement shall control.  
   
 10.8 Qualification of Additional Facilities. In the event Reliant requests that Cardinal qualify additional Facilities to Manufacture and Package the Product, Reliant shall be solely responsible for any costs associated therewith which shall be limited to technology transfer and technology transfer service costs. In the event that Cardinal Health desires to qualify additional Facilities to Manufacture and Package the Product, Cardinal Health shall be solely responsible for any costs associated therewith.  
 ARTICLE 11  
CONFIDENTIAL INFORMATION  
 11.1 Confidentiality Agreement. The use and disclosure of confidential information exchanged between the Parties shall be governed by the Confidentiality Agreement by and between Cardinal Health, Reliant and Pronova Biocare, a.s., dated July 29, 2004 (the “Confidentiality Agreement”).  
 11.2 No Implied License. Except as otherwise set forth herein, the Party receiving Confidential Information (as such is defined in the Confidentiality Agreement) will obtain no right of any kind or license under any patent application or patent by reason of this Agreement. All Confidential Information will remain the sole property of the Party disclosing such information or data.  
 11.3 Return of Confidential Information. Upon termination or expiration of this Agreement, the Party to which Confidential Information has been disclosed will, upon request, promptly return within thirty (30) days, all such Confidential Information, including any copies thereof, and cease its use or, at the option of the receiving Party, promptly destroy the same and certify such destruction to the disclosing Party, except for a single copy thereof which may be retained for the sole purpose of determining the scope of the obligations incurred under this Agreement.  
 11.4 Disclosure of Confidential Information. Notwithstanding the terms set forth this Article 11 or the Confidentiality Agreement, each of the Parties shall have the right to disclose the existence and terms of this Supply Agreement to those of its directors, managers, officers, employees, accountants, attorneys, advisers, agents, investment bankers, lenders and potential lenders, financing sources, acquirers or business combination candidates who need to know such terms for the purpose of evaluating or entering into a potential business arrangement (“Third Parties”); provided, that such Third Parties are required to maintain the confidentiality of this Supply Agreement to the same extent as if they were Parties hereto Notwithstanding the foregoing, each of the Parties shall have the right to disclose the existence and terms of this Supply Agreement as may be required by applicable laws or rules of any stock exchange to which a Party or any Affiliate of a Party is subject, in which case the disclosing Party shall provide the non-disclosing Party with prompt advance notice of such disclosure so that the non-disclosing Party shall have the opportunity if it so desires to seek a protective order or other appropriate remedy and, in connection with any disclosure required by the Securities and Exchange Commission or the rules of any stock exchange to which a Party or any Affiliate of a Party is subject, the disclosing Party shall use reasonable efforts to obtain confidential treatment for such disclosure.  
   
 11.5 Survival. The obligations of this Article 11 shall terminate five (5) years from the expiration or termination of this Agreement.  
 ARTICLE 12  
INTELLECTUAL PROPERTY  
 All Cardinal Health Technology, including, without limitation, all improvements, developments, derivatives or modifications to the Cardinal Health Technology, shall be owned exclusively by Cardinal Health and, except as set forth herein no right or license in Cardinal Health Technology is transferred or granted to Reliant. All Reliant Technology, including, without limitation, all improvements, developments, derivatives or modifications to the Reliant Technology shall be owned exclusively by Reliant. Reliant hereby grants to Cardinal Health a non-exclusive, royalty-free license for the term of this Agreement to use Reliant Technology, but solely for the purpose of carrying out Cardinal Health’s obligations under this Agreement. For purposes hereof, “Cardinal Health Technology” means all Softgel Technology, Cardinal Health Confidential Information, intellectual property, and developments (including, all patents, patent applications, know-how, inventions, designs, concepts, improvements, technical information, manuals, instructions or specifications), owned, licensed or used by Cardinal Health in developing, formulating, manufacturing, filling, processing or packaging of pharmaceuticals and the packaging equipment, processes or methods of packaging, or any improvements to any of the foregoing, including any container, pouch, vial, ampoule, blister pack or other form of container developed by Cardinal Health. For purposes hereof, “Reliant Technology” means all proprietary information, intellectual property and developments owned, developed, licensed or used by Reliant relating to the API, including, without limitation, patents, patent applications, know-how, inventions, designs, concepts, improvements, technical information, trademarks or trade names.  
 ARTICLE 13  
REPRESENTATIONS AND WARRANTIES  
 13.1 Cardinal Health. Cardinal Health represents and warrants to Reliant that:  
 A. At the time of delivery of the Product as provided in Section 6.1, such Product will conform to and will have been Manufactured and Packaged in conformance with the Product Specifications and Applicable Laws;  
 B. Cardinal Health will be solely responsible for and will obtain all governmental approvals, permits and licenses necessary or desirable in connection with the Manufacturing and Packaging of the API in the Territory.  
 C. It has, and shall have, good, complete and valid rights to utilize the Cardinal Health Technology utilized in connection with the Product and as contemplated by this Agreement. There are no patents owned by others related to the Cardinal Health Technology used with the Product which would be infringed or misused by Cardinal Health’s performance of the Agreement and, to its knowledge, no trade secrets or other proprietary rights of others related to the Cardinal Health Technology used with the Product which would be infringed or misused by Cardinal Health’s performance of this Agreement.  
   
 F. THE LIMITED WARRANTY SET FORTH IN THIS SECTION 13.1 IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY AND ANY WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE. EXCEPT FOR THE WARRANTY EXPRESSED IN THIS SECTION 13.1, CARDINAL HEALTH MAKES NO OTHER WARRANTY, EITHER EXPRESS OR IMPLIED, WITH RESPECT TO THE MANUFACTURING AND PACKAGING OR THE PRODUCT.  
 13.2 Reliant. Reliant represents, warrants and covenants to Cardinal Health that:  
 A. The API and any other materials supplied by Reliant to Cardinal Health (“Reliant-supplied Materials”) will comply with all applicable Specifications, will have been produced in compliance with the Applicable Laws, and will be provided in accordance with the terms and conditions of this Agreement;  
 B. It has all necessary authority and all right, title and interest in and to any Reliant Technology related to the API or any other Reliant supplied materials;  
 C. No specific safe handling instructions are applicable to the Product, the API or any other Reliant supplied materials, except as disclosed to Cardinal Health in writing by the Reliant in sufficient time for review and training by Cardinal Health prior to delivery;  
 D. All Product delivered to Reliant by Cardinal Health will be held, used and/or disposed of by the Reliant in accordance with all applicable laws, rules and regulations;  
 E. Reliant will comply with all laws, rules, regulations and guidelines applicable to Reliant’s performance under this Agreement and its use of Product provided by Cardinal Health under this Agreement;  
 F. If release testing is conducted by Reliant, Reliant will not release any Batch of Product if the required Certificates of Analysis indicate that the Product does not comply with the Specifications;  
 G. The content of all artwork provided to Cardinal Health complies with all Applicable Laws;  
 H. Reliant has all necessary authority and right, title and interest in and to any copyrights, trademarks, trade secrets, patents, inventions and developments related to the API, the manufacture thereof, and any Product artwork;  
 I. To the knowledge of Reliant, the work to be performed by Cardinal Health under this Agreement will not violate or infringe upon any trademark, tradename, copyright, patent or other rights held by any person or entity; and  
   
 J. Reliant will be solely responsible for and will obtain all governmental approvals, permits and licenses necessary or desirable in connection with the testing, marketing, sale, advertising or distribution of the Product in the Territory.  
 13.2 Mutual. Each Party hereby represents and warrants to the other Party that:  
 A. Such Party (1) is duly organized, validly existing and in good standing under the laws of the state in which it is organized, (2) has the power and authority and the legal right to own and operate its property and assets, and to carry on its business as it is now being conducted, and (3) is in compliance with all requirements of applicable law, except to the extent that any noncompliance would not materially adversely affect such Party’s ability to perform its obligations under the Agreement;  
 B. Such Party (1) has the power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder and thereunder and (2) has taken all necessary action on its part to authorize the execution and delivery of the Agreement and the performance of its obligations hereunder;  
 C. This Agreement is validly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against such Party in accordance with its terms;  
 D. All necessary consents, approvals and authorizations of all agencies and other persons required to be obtained by such Party in connection with the Agreement have been obtained; and  
 E. The execution and delivery of this Agreement and the performance of such Party’s obligations hereunder (1) do not conflict with or violate any requirement of applicable laws or regulations or any material contractual obligation of such Party and (2) do not materially conflict with, or constitute a material default or require any consent under, any material contractual obligation of such Party.  
 ARTICLE 14  
INDEMNIFICATION  
 14.1 Indemnification by Cardinal Health. Cardinal Health shall indemnify and hold harmless Reliant, its Affiliates, directors, officers, employees and agents from and against any and all suits, claims, losses, demands, liabilities, damages, costs and expenses (including reasonable attorney’s fees) in connection with any suit, demand or action by any third party (“Losses”) arising out of or resulting from (A) any breach of its representations, warranties or obligations under this Agreement; (B) any negligence or willful misconduct by Cardinal Health, except to the extent that any of the foregoing arises out of or results from the negligence, willful misconduct or breach of this Agreement by of Reliant; or (C) any actual or alleged infringement or violation of any patent, trade secret, copyright, trademark or other proprietary rights used by Cardinal Health in Manufacturing and Packaging the Product, except to the extent such was provided by Reliant.  
   
 14.2 Indemnification by Reliant. Reliant shall indemnify and hold harmless Cardinal Health, its Affiliates, directors, officers, employees and agents from and against all Losses arising out of or resulting from (A) any breach of its representations, warranties or obligations under this Agreement; (B) any manufacture, sale, promotion, distribution, use (other than by Cardinal Health) of or exposure to the Product, the API or any Reliant-supplied materials, including, without limitation, product liability or strict liability; (C) Reliant’s exercise of control over the Manufacturing and Packaging under this Agreement, to the extent that Reliant’s written instructions or directions violate applicable law or regulation; (D) any actual or alleged infringement or violation of any patent, trade secret, copyright, trademark or other proprietary rights provided by Reliant and used by Cardinal Health in Manufacturing and Packaging the Product; or (E) any negligence or willful misconduct by Reliant, except to the extent that any of the foregoing arises out of or results from the negligence, willful misconduct or breach of this Agreement by Cardinal Health.  
 14.3 Indemnification Procedures. All indemnification obligations in this Agreement are conditioned upon the Party seeking indemnification (the “Indemnified Party”): (A) promptly notifying the indemnifying Party (the “Indemnifying Party”) of any claim or liability of which the Party seeking indemnification becomes aware (including a copy of any related complaint, summons, notice or other instrument), provided, however, that failure to provide such notice within a reasonable period of time shall not relieve the Indemnifying Party of any of its obligations hereunder except to the extent the Indemnifying Party is materially prejudiced by such failure; (B) cooperating with the Indemnifying Party in the defense of any such claim or liability (at the Indemnifying Party’s expense), and (C) not compromising or settling any claim or liability without prior written consent of the Indemnifying Party. The liability of an Indemnifying Party under this Article XIV with respect to Losses arising from claims of any Third Party which are subject to the indemnification provided for in this Article XIV (“Third Party Claims”) shall be governed by and contingent upon the following additional terms and conditions. If an Indemnified Party shall receive notice of any Third Party Claim, the Indemnified Party shall give the Indemnifying Party notice of such Third Party Claim within thirty (30) days of the receipt by the Indemnified Party of such notice; provided, however, that the failure to provide such notice shall not release the Indemnifying Party from any of its obligations under this Article XIV except to the extent the Indemnifying Party is materially prejudiced by such failure. The Indemnifying Party shall be entitled to assume and control the defense of such Third Party Claim at its expense and through counsel of its choice if it gives notice of its intention to do so to the Indemnified Party within thirty (30) days of the receipt of such notice from the Indemnified Party; provided, however, that if there exists a material conflict of interest that would make it inappropriate for the same counsel to represent both the Indemnified Party and the Indemnifying Party, then the Indemnified Party shall be entitled to retain its own counsel, at the expense of the Indemnifying Party, provided that the Indemnifying Party shall not be obligated to pay the reasonable fees and expenses of more than one separate counsel for all Indemnified Parties, taken together. In the event the Indemnifying Party exercises the right to undertake any such defense against any such Third Party Claim as provided above, the Indemnified Party shall cooperate with the Indemnifying Party in such defense and make available to the Indemnifying Party, all witnesses, pertinent records, materials and information in the Indemnified Party’s possession or under the Indemnified Party’s control relating thereto as is reasonably required by the Indemnifying Party. Similarly, in the event the Indemnified Party is, directly or indirectly, conducting the defense against any such Third Party Claim, the  
   
 Indemnifying Party shall cooperate with the Indemnified Party in such defense and make available to the Indemnified Party, all such witnesses, records, materials and information in the Indemnifying Party’s possession or under the Indemnifying Party’s control relating thereto as is reasonably required by the Indemnified Party. The Indemnifying Party shall not, without the written consent of the Indemnified Party (which shall not be unreasonably withheld or delayed), (a) settle or compromise any Third Party Claim or consent to the entry of any judgment which does not include as an unconditional term thereof the delivery by the claimant or plaintiff to the Indemnified Party of a written release from all liability in respect of such Third Party Claim or (b) settle or compromise any Third Party Claim if the settlement imposes equitable remedies or material obligations on the Indemnified Party other than financial obligations for which such Indemnified Party will be indemnified hereunder and which contains no admission of fault or wrongdoing. No Third Party Claim shall be settled or compromised by the Indemnified Party without the written consent of the Indemnifying Party (which shall not be unreasonably withheld or delayed) if such settlement or compromise would result in an obligation of the Indemnifying Party to indemnify such Indemnified Party, or would otherwise result in liability of, or have an adverse impact upon, such Indemnifying Party.  
 ARTICLE 15  
LIMITATION OF LIABILITY  
 15.1 CARDINAL HEALTH’S LIABILITY UNDER THIS AGREEMENT FOR ANY AND ALL CLAIMS FOR LOST, DAMAGED OR DESTROYED API OR OTHER RELIANT-SUPPLIED MATERIALS WHETHER OR NOT SUCH API OR RELIANT-SUPPLIED MATERIALS ARE INCORPORATED INTO PRODUCT IS SET FORTH IN EXHIBIT B. THE LIMITATION OF LIABILITY, WITH RESPECT TO ANY GIVEN CONTRACT YEAR, SHALL NOT EXCEED THE APPLICABLE AMOUNTS SET FORTH IN EXHIBIT B (THE “API CAP”). IN THE EVENT THAT CARDINAL HEALTH LIABILITY FOR LOST API SHALL EXCEED THE API CAP FOR ANY CONTRACT YEAR DURING THE TERM, THE PARTIES SHALL MEET WITHIN THIRTY (30) DAYS FROM THE DATE CARDINAL HEALTH’S LIABILITY FOR LOST API EXCEEDS THE API CAP AND NEGOTIATE IN GOOD FAITH WHETHER (A) CARDINAL HEALTH INCREASES THE API CAP FOR SUCH CONTRACT YEAR, OR (B) WHETHER RELIANT’S OBLIGATIONS UNDER SECTION 4.2(B) SHALL BECOME NULL AND VOID. IN THE EVENT THAT THE PARTIES CANNOT REACH AN AGREEMENT WITH REGARD TO THE FOREGOING SENTENCE WITHIN SUCH THIRTY (30) DAY PERIOD, RELIANT SHALL HAVE THE SOLE OPTION TO (X) CONTINUE WITH THE AGREEMENT WITH CARDINAL HEALTH HAVING NO LIABILITY IN EXCESS OF THE API CAP FOR LOST, DAMAGED OR DESTROYED API FOR THE THEN CURRENT CONTRACT YEAR, OR (Y) HAVE PRODUCT MANUFACTURED AND PACKAGED BY A QUALIFIED THIRD-PARTY SUPPLIER WITHOUT REGARD TO ITS OBLIGATIONS UNDER SECTION 4.2(B). ANY AMOUNTS OWING BY CARDINAL HEALTH HEREUNDER SHALL NOT COUNT AGAINST THE LIABILITY CAP SET FORTH IN SECTION 15.2 BELOW.  
 15.2 NOTWITHSTANDING, AND SPECIFICALLY EXCLUDING, ANY AMOUNTS OWED BY CARDINAL HEALTH TO RELIANT UNDER SECTION 15.1 ABOVE, AND SPECIFICALLY EXCLUDING LOSSES RESULTING FROM CARDINAL HEALTH’S GROSS NEGLIGENCE, FRAUD OR WILLFUL MISCONDUCT, CARDINAL HEALTH’S  
   
 TOTAL LIABILITY UNDER THIS AGREEMENT OTHER THAN FOR LOST, DAMAGED OR DESTROYED API, SHALL IN NO EVENT EXCEED FIVE MILLION DOLLARS ($5,000,000).  
 15.3 NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR INDIRECT, INCIDENTAL, SPECIAL OR CONSEQUENTIAL DAMAGES (EXCEPT FOR THOSE INDEMNITY OBLIGATIONS UNDER ARTICLE 14 THAT ARE DEEMED CONSEQUENTIAL DAMAGES) ARISING OUT OF PERFORMANCE UNDER THIS AGREEMENT, INCLUDING WITHOUT LIMITATION, LOSS OF REVENUES, PROFITS OR DATA, WHETHER IN CONTRACT OR TORT, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.  
 15.4 Limitation of Liability for Operation of Foreign Trade Subzone. Cardinal Health has been granted a special purpose subzone (the “FTZ”) that includes the main plant of Cardinal Health’s US Facility. Reliant may recognize a number of economic benefits resulting from Cardinal Health’s operation of the FTZ. However, notwithstanding anything to the contrary contained herein, including but not limited to the provisions of Section 14.1, Cardinal Health’s liability to the Reliant, if any, as a result of any and all liabilities, losses, claims, demands, damages, costs, expenses, settlements made or reasonably approved by Cardinal Health, and money judgments (including attorneys’ fees and other costs of litigation), related to Cardinal Health’s operation of the FTZ, including, but not limited to: (A) Cardinal Health acting as Reliant’s agent for duty drawback purposes pursuant to 19 CFR §191.9 with respect to the Product; and (B) the suspension or closing of the FTZ (whether voluntary or not)), incurred by or rendered against the Reliant for personal injury, sickness, disease or death and other damages shall in no event exceed Fifty Thousand United States Dollars ($50,000).  
 ARTICLE 16  
INSURANCE  
 16.1 Cardinal Health. Cardinal Health shall, at its own cost and expense, obtain and maintain in full force and effect the following insurance during the term of this Agreement: (A) Commercial General Liability insurance with per-occurrence and general aggregate limits of not less than $1,000,000; (B) Products and Completed Operations Liability Insurance with per-occurrence and general aggregate limits of not less than $5,000,000; (C) Workers’ Compensation and Employer’s Liability Insurance with statutory limits for Workers’ Compensation and Employer’s Liability insurance limits of not less than $1,000,000; and (D) Professional Services Errors & Omissions Liability Insurance with per claim and aggregate limits of not less than $1,000,000 covering sums that Cardinal Health becomes legally obligated to pay as damages resulting from claims made by Reliant for errors or omissions committed in the conduct of the services outlined in the Agreements. In lieu of insurance, Cardinal Health may self-insure any or a portion of the above required insurance. In the event that any of the required policies of insurance are written on a claims made basis, then such policies shall be maintained during the entire Term and for a period of not less than three (3) years following the termination or expiration of this Agreement. Cardinal Health shall obtain a waiver from any insurance carrier with whom Cardinal Health carries Workers’ Compensation insurance releasing its subrogation rights against Reliant. Reliant shall be named as an additional insured under the Commercial  
   
 General Liability and Products and Completed Operations Liability insurance policies as respects the manufacturing services outlined in this Agreement. Cardinal Health shall furnish certificates of insurance for all of the above noted policies and required additional insured status to Reliant as soon as practicable after the Effective Date of the Agreement and upon renewal of any such policies. Each insurance policy that is required under this Section shall be obtained from an insurance carrier with an A.M. Best rating of at least A- VII.  
 16.2 Reliant Insurance. Reliant shall, at its own cost and expense, obtain and maintain in full force and effect the following insurance during the term of this Agreement: (A) Products and Completed Operations Liability Insurance with per-occurrence and general aggregate limits of not less than $10,000,000; (B) Workers’ Compensation and Employer’s Liability Insurance with statutory limits for Workers’ Compensation and Employer’s Liability insurance limits of not less than $1,000,000; (C) All Risk Property Insurance in an amount equal to full replacement value covering Reliant’s property while it is at Cardinal Health’s facility; and (D) transit coverage in an amount not less than $1,000,000 while Reliant’s property is in transit to or from Cardinal Health’s facility. In the event that any of the required policies of insurance are written on a claims made basis, then such policies shall be maintained during the entire Term and for a period of not less than three (3) years following the termination or expiration of this Agreement. Reliant shall obtain a waiver from any insurance carrier with whom Reliant carries Workers’ Compensation insurance releasing its subrogation rights against Cardinal Health. Reliant shall obtain a waiver from any insurance carrier with whom Reliant carries Property Insurance releasing its subrogation rights against Cardinal Health. Reliant shall not seek reimbursement for any property claim, or portion thereof, which is not fully recovered from Reliant’s Property Insurance policy. Cardinal Health and its Subsidiaries and Parent Corporation shall be named as additional insureds under the Products and Completed Operations Liability insurance policies as respects the products and completed operations outlined in this Agreement. Reliant shall furnish certificates of insurance for all of the above noted policies and required additional insured status to Cardinal Health as soon as practicable after the Effective Date of the Agreement and upon renewal of any such policies. Each insurance policy that is required under this Section shall be obtained from an insurance carrier with an A.M. Best rating of at least A- VII.  
 ARTICLE 17  
TERM AND TERMINATION  
 17.1 Term. This Agreement shall commence on the Effective Date and shall continue for a period of five (5) Contract Years (January 1, 2007 through December 31, 2011), unless earlier terminated under Section 17.2 (the “Initial Term”). After the Initial Term, this Agreement may be automatically extended for further periods of one (1) year each (the “Renewal Term”), unless terminated by either Party upon written notice given to the other Party at least twelve (12) months prior to the end of the Initial Term. The Initial Term and any Renewal Term shall constitute the Term.  
 17.2 Termination by Either Party.  
 A. Material Breach. Either Party may terminate this Agreement effective upon sixty (60) days prior written notice to the other Party, if the other Party commits a material breach of this Agreement and fails to cure such breach by the end of such sixty (60) day period; provided,  
   
 however, that failure to pay amounts due under this Agreement within thirty (30) days after such payments are due (as set forth in Section 7.5) more than two (2) times in any Contract Year shall constitute cause for immediate termination of this Agreement, provided, however, that Reliant’s Chief Operating Officer, or his designee, and Cardinal’s Facility General Manager from each Party shall discuss such nonpayment in advance of termination.  
 B. Bankruptcy. Either Party may terminate this Agreement effective upon written notice to the other Party, if the other Party becomes insolvent or admits in writing its inability to pay its debts as they become due, files a petition for bankruptcy, makes an assignment for the benefit of its creditors or has a receiver, trustee or other court officer appointed for its properties or assets.  
 17.3 Without Cause. Either Party may terminate this Agreement without cause upon thirty-six (36) months’ written notice to the other Party, following the date which is twenty-four (24) months from the Effective Date.  
 17.4 Effect of Termination.  
 A. Expiration or termination of this Agreement shall be without prejudice to any rights or obligations that accrued to the benefit of either Party prior to such expiration or termination.  
 B. In the event of any termination, Cardinal Health shall promptly return (1) any remaining inventory of materials received from Reliant, (2) all remaining inventories of API and Product, and (3) any other Product, or API being stored for Reliant, to Reliant at Reliant’s expense. Cardinal Health shall have no obligation to return the foregoing until all outstanding undisputed invoices sent by Cardinal Health to Reliant have been paid in full. For termination initiated by Reliant, Reliant shall also be required to pay for (Y) completed but not yet shipped Product and (Z) Product in process and Product shipped but not yet invoiced in the event that this Agreement is terminated for reasons other than Cardinal Health’s default. In the event Reliant breaches or terminates this Agreement (other than as a result of a breach of this Agreement by Cardinal Health) or if Cardinal Health terminates this Agreement under Section 17.2 hereof, Reliant will also be required to pay Cardinal Health for its direct cost of all materials purchased by Cardinal Health for Processing. Reliant shall specify the location in the continental United States to which delivery, at Reliant’s expense, of the foregoing is to be made.  
 ARTICLE 18  
NOTICE  
 All notices and other communications hereunder shall be in writing and shall be deemed given: (A) when delivered personally; (B) when delivered by facsimile transmission (receipt verified); (C) when received or refused, if mailed by registered or certified mail (return receipt requested), postage prepaid; or (D) when delivered if sent by express courier service, to the Parties at the following addresses (or at such other address for a Party as shall be specified by like notice; provided, that notices of a change of address shall be effective only upon receipt thereof):  
   
 To Reliant:  
Reliant Pharmaceuticals, Inc.  
 000 Xxxxx Xxxx  
 Xxxxxxx Xxxxxx, XX 00000  
 Attention: Xxxxxx Xxxxxxx, Ph.D., Vice President,  
 Commercial Operations  
 Facsimile: 908.542.9405  
 With a copy to:  
Reliant Pharmaceuticals, Inc.  
 000 Xxxxx Xxxx  
 Xxxxxxx Xxxxxx, XX 00000  
 Attention: Legal Department  
 Facsimile: 908.542.9405  
 To Cardinal Health:  
Cardinal Health PTS, LLC  
 0000 Xxxxxxx Xxxxx  
 Xx. Xxxxxxxxxx, Xxxxxxx 00000  
 Attention: General Manager, Encapsulation,  
 North America  
 Facsimile: (000) 000-0000  
 With a copy to:  
Cardinal Health, Inc.  
 00 Xxxxxxxxxxx Xxxx  
 Xxxxxxxx, Xxx Xxxxxx 00000  
 Attn: General Counsel  
 Facsimile: (000) 000-0000  
 ARTICLE 19  
MISCELLANEOUS  
 19.1 Entire Agreement; Amendments. This Agreement including the attachments, as well as the Confidentiality Agreement dated July 29, 2004, constitute the entire understanding between the Parties and supersedes any contracts, agreements or understanding (oral or written) of the Parties with respect to the subject matter hereof; provided, however, that this Agreement does not supersede the Initial Agreement with respect to events that happened prior to January 1, 2007. For the avoidance of doubt, as of January 1, 2007, other than payments due and owing of which both parties are aware, there are no payments of any kind due and owing to either party. No term of this Agreement may be amended except upon written agreement of both Parties, unless otherwise provided in this Agreement.  
 19.2 Captions. The captions in this Agreement are for convenience only and are not to be interpreted or construed as a substantive part of this Agreement.  
 19.3 Further Assurances. The Parties agree to execute, acknowledge and deliver such further instruments and to take all such other incidental acts as may be reasonably necessary or appropriate to carry out the purpose and intent of this Agreement.  
   
 19.4 No Waiver. Failure by either Party to insist upon strict compliance with any term of this Agreement in any one or more instances will not be deemed to be a waiver of its rights to insist upon such strict compliance with respect to any subsequent failure.  
 19.5 Severability. If any term of this Agreement is declared invalid or unenforceable by a court or other body of competent jurisdiction, the remaining terms of this Agreement will continue in full force and effect.  
 19.6 Independent Contractors. The relationship of the Parties is that of independent contractors, and neither Party will incur any debts or make any commitments for the other Party except to the extent expressly provided in this Agreement. Nothing in this Agreement is intended to create or will be construed as creating between the Parties the relationship of joint ventures, co-partners, employer/employee or principal and agent.  
 19.7 Successors and Assigns. This Agreement will be binding upon and inure to the benefit of the Parties, their successors and permitted assigns. Neither Party may assign this Agreement, in whole or in part, without the prior written consent of the other Party (which consent shall not be unreasonably withheld, conditioned or delayed), except that either Party may, without the other Party’s consent, assign this Agreement to an Affiliate or to a successor to substantially all of the business or assets of the assigning company (or the assigning company’s business unit responsible for the performance of this Agreement), or, in the case of Reliant, to a successor to all of the assets relating to the Product.  
 19.8 Governing Law. This Agreement shall be governed by and construed under the laws of the State of New York, excluding its conflicts of law provisions.  
 19.9 Alternative Dispute Resolution. If a dispute, controversy or disagreement (“Dispute”) arises between the Parties in connection with this Agreement, then the Dispute shall be presented to the respective presidents or senior executives of Cardinal Health and Reliant for their consideration and resolution. If such Parties cannot reach a resolution of the Dispute, then such Dispute shall be resolved by binding alternative dispute resolution in accordance with the then existing commercial arbitration rules of The CPR Institute for Dispute Resolution (“CPR”), 000 Xxxxxxx Xxxxxx, Xxx Xxxx, XX 00000. Arbitration shall be conducted in New York, New York.  
 19.10 Counterparts. This Agreement may be executed in one or more counterparts, each of which will be deemed an original but all of which together will constitute one and the same instrument.  
 19.11 Publicity. Neither Party will make any press release or other public disclosure regarding this Agreement or the transactions contemplated hereby without the other Party’s express prior written consent (which shall not be unreasonably withheld, conditioned or delayed), except as required under applicable law or by any governmental agency, in which case the Party required to make the press release or public disclosure shall use commercially reasonable efforts to obtain the approval of the other Party (which shall not be unreasonably withheld, conditioned or delayed) as to the form, nature and extent of the press release or public disclosure prior to issuing the press release or making the public disclosure.  
   
 19.12 Survival. The rights and obligations of the Parties shall continue under Articles 5 (Testing; Manufacturing Samples; Release), 7 (Payment Terms), , 10 (Records; Regulatory Matters), 11 (Confidential Information), 12 (Intellectual Property), 14 (Indemnification), 15 (Limitations of Liability), 16 (Insurance) to the extent expressly stated therein, 18 (Notice), 19 (Miscellaneous), and Sections 4.2, 6.2 and 17.4 (Effect of Termination), notwithstanding expiration or termination of this Agreement.  
 19.13 Force Majeure. Except as to payments required under this Agreement, neither Party shall be liable in damages for, nor shall this Agreement be terminable or cancelable by reason of, any delay or default in such Party’s performance hereunder if such default or delay is caused by events beyond such Party’s reasonable control including, but not limited to, acts of God, regulation or law or other action or failure to act of any government or agency thereof, war or insurrection, civil commotion, destruction of production facilities or materials by earthquake, fire, flood or storm, labor disturbances, epidemic, or failure of suppliers, public utilities or common carriers; provided however, that the Party seeking relief hereunder shall immediately notify the other Party of such cause(s) beyond such Party’s reasonable control. The Party that may invoke this section shall use all reasonable endeavors to reinstate its ongoing obligations to the other. If the cause(s) shall continue unabated for sixty (60) days, then both Parties shall meet to discuss and negotiate in good faith what modifications to this Agreement should result from this force majeure.  
 The Parties are executing this Agreement on the date stated in the introductory clause.  
 CARDINAL HEALTH PTS, LLC  
RELIANT PHARMACEUTICALS, INC.  
 By:  
 By:  
 Name: Xxxxx X. Xxxxxx  
Name: Xxxxxx X. Xxxxxxxxxx  
Its: President, Encapsulation North America  
Its: Chief Operating Officer  
   
 EXHIBIT A  
SPECIFICATIONS  
 Finished Product Release Specification  
  
  
Omacor Capsules  
OMA-RSP  
  
  
Version: 03  
 Test  
 Acceptance Criteria  
 Method  
 [\*\*\*]  
 [\*\*\*]  
 [\*\*\*]  
 [\*\*\*]  
 [\*\*\*]  
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 \*  
 \*Microbial limit tests are performed by qualified laboratories, typically bulk capsule manufacturers.  
History:  
• Version 01: Approved on 6/14/05.  
• Version 02: Removed unit for anisidine value (typographical error), modified microbial limit test method numbers and other minor typographical errors. Approved on 8/31/05.  
• Version 03: Changed capsule logo to “REL900” and other editorial changes.  
 Prepared by:  
 Date:  
8/11/06  
 Prepared by:  
 Date:  
8/11/06  
 Xxxxx Xx  
Manager  
QA/QC  
 Xxxx Xxxxx  
Director  
QA/QC  
 [\*\*\*]: Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.  
   
 EXHIBIT B  
UNIT PRICING, LIMITS OF LIABILITY, AND MINIMUM REQUIREMENT  
 UNIT PRICING FOR TRADE PRODUCT– [\*\*\*]% Requirements Level  
 Units (millions)  
 Price per thousand Units  
[\*\*\*]  
 [\*\*\*]  
[\*\*\*]  
 [\*\*\*]  
[\*\*\*]  
 [\*\*\*]  
[\*\*\*]  
 [\*\*\*]  
 UNIT PRICING FOR TRADE PRODUCT– [\*\*\*]% Requirements Level  
 Units (millions)  
 Price per thousand Units  
[\*\*\*]  
 [\*\*\*]  
[\*\*\*]  
 [\*\*\*]  
[\*\*\*]  
 [\*\*\*]  
[\*\*\*]  
 [\*\*\*]  
 In the event Reliant purchases less than [\*\*\*] percent ([\*\*\*]%) but more than [\*\*\*] ([\*\*\*]%) of its [\*\*\*] from Cardinal in any given Contract Year, an additional [\*\*\*] dollars ($[\*\*\*]) shall be added to the amounts set forth in the “Price per thousand Units” column, in accordance with the first chart above i.e., if Reliant purchases up to [\*\*\*] units in a Contract Year, and such [\*\*\*] Units amount represents less than [\*\*\*]% of Reliant’s commercial requirement for that given Contract Year, the price shall be $[\*\*\*] per [\*\*\*] Units ([\*\*\*]).  
 This is a “tiered” pricing system. Therefore, for example, if Reliant purchases [\*\*\*] Units from Cardinal Health in a given Contract Year, and this represents [\*\*\*] percent ([\*\*\*]%) of Reliant’s Manufacturing requirement levels for [\*\*\*] for that Contract Year, the price for the first [\*\*\*] Units shall be $[\*\*\*] per [\*\*\*] Units, the price for [\*\*\*] Units through [\*\*\*] Units shall be $[\*\*\*] per [\*\*\*] Units, the price for [\*\*\*]Units through [\*\*\*] Units shall be $[\*\*\*] per [\*\*\*] Units, and the price for [\*\*\*] Units through [\*\*\*] Units shall be $[\*\*\*]. In the event the [\*\*\*] Units purchased from Cardinal Health does not represent [\*\*\*] percent ([\*\*\*]%) of Reliant’s Manufacturing requirement levels for [\*\*\*] for that Contract Year, the Unit Pricing shall be modified in accordance with the paragraph and applicable chart above.  
 The price for [\*\*\*] shall be $[\*\*\*] per [\*\*\*] Units for any Contract Year wherein Reliant purchases less than [\*\*\*] percent ([\*\*\*]%) of its Manufacturing requirement levels for [\*\*\*] from Cardinal Health. For any Contract Year wherein Reliant purchases [\*\*\*] percent ([\*\*\*]%) of its Manufacturing requirement levels for [\*\*\*] from Cardinal Health, the price of the [\*\*\*] shall be the same as the price for the [\*\*\*] for that Contract Year as reflected in the applicable above chart.  
 [\*\*\*]: Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.  
   
 For the avoidance of doubt, the price for all Product purchased by Reliant from Cardinal Health from July 1, 2006 through and including December 31, 2006 shall be [\*\*\*]dollars ($[\*\*\*]) per [\*\*\*] Units.  
 LIMITATIONS OF LIABILITY  
 Units  
 Liability Limit per Each Contract Year  
Up to and including 200 million  
 $ 1 million  
201 million up to and including 500 million  
 $ 2 million  
501 million up to and including 750 million  
 $ 3 million  
751 million up to and including 1 billion  
 $ 4 million  
1 billion up to and including 1.25 billion  
 $ 5 million  
1.251 billion up to and including 1.50 billion  
 $6 million  
1.51 billion up to and including 1.750 billion  
 $7 million  
1.751 billion and above  
 $8 million  
 MINIMUM REQUIREMENT  
 Contract Year  
 Product / Dosage Form  
 Minimum Requirement  
[\*\*\*]  
 [\*\*\*]  
 [\*\*\*]  
[\*\*\*]  
 [\*\*\*]  
 [\*\*\*]  
 [\*\*\*]: Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.  
   
 EXHIBIT C  
 MINIMUM YIELD SCHEDULE  
 [Reliant Pharmaceuticals Letterhead]  
 May 23, 2006   
VIA FACSIMILE (000) 000-0000  
Cardinal Health PTS, LLC  
0000 Xxxxxxx Xxxxx  
Xx. Xxxxxxxxxx, Xxxxxxx 00000  
Attention: President, Encapsulation,  
North America Oral Technologies  
Re: Minimum Yield  
Dear Xx. Xxxxxx:  
 Reference is made hereby to the Manufacturing and Packaging Agreement dated as of April 14, 2005 (the “Agreement”) between Reliant Pharmaceuticals, Inc. (“Reliant”) and Cardinal Health PTS, LLC (“Cardinal Health”). All capitalized terms in this letter that are not otherwise defined herein shall have the meaning set forth in the Agreement.  
By this letter Reliant and Cardinal Health hereby acknowledge and agree that for purposes of Section 3.4, the parties have established the Minimum Yield to be [\*\*\*] Percent ([\*\*\*]%). This letter shall serve as Exhibit C to the Agreement. In all other respects the Agreement shall remain in full force and effect.  
To confirm your agreement with the foregoing, please execute a copy of this letter in the place indicated below.  
 Reliant Pharmaceuticals, Inc.  
 By:  
 Xxxxxx Xxxxxxx  
 Vice President, Manufacturing  
 Agreed and acknowledged this 23 day  
of May, 2006  
 By:  
 Xxxxx Xxxxxx  
 President, Encapsulation — North America  
 cc:  
Cardinal Health, Inc. Associate General Counsel, Pharmaceutical Technologies and Services (via facsimile — (000) 000-0000)  
 [\*\*\*]: Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.  
   
 EXHIBIT D  
 QUALIFICATION, VALIDATION AND STABILITY SERVICES  
 Quotation  
Process Validation of 1000 mg Omacor  
Softgels at the St. Petersburg, FL  
Facility  
 QTE-RLD-0025.00  
 Confidential for Reliant Pharmaceuticals  
 Prepared for Xxxxx Xxxxx, Ph.D  
000 Xxxxx Xxxx  
Xxxxxxx Xxxxxx, XX 00000  
000-000-0000  
Cardinal Health Contact: Xxxx Xxxxxx  
Phone: 000-000-0000  
February 15, 2005  
   
 CardinalHealth  
BioPharmaceutical Product Development  
Pharmaceutical Product Development  
Clinical Packaging Services  
Analytical Chemistry Services  
Scientific and Regulatory Consulting  
Pulmonary and Nasal Product Development  
Clinical and Small Scale Commercial Manufacturing  
   
 QTE-RLD-0025.00  
 CONFIDENTIAL  
 Executive Summary  
 Reliant Pharmaceuticals (Reliant) has requested Cardinal Health, Pharmaceutical Development (Cardinal Health) to perform process validation for the Omacor 1000 mg softgels at Cardinal Health’s facility in St. Petersburg, FL. The estimated cost for this project is $[\*\*\*] plus cost of softgels, over a period of approximately [\*\*\*].  
 Section 1. Scope of Work  
 Cardinal Health, Somerset has developed and scaled up Omacor 1000 mg softgels to commercial scale in Cardinal Health, St. Petersburg. Cardinal Health will manufacture three (3) process validation batches and generate validation report prior final commercial launch. All clinical batch manufacture activities will be conducted according to cGMP guidelines.  
 Section 2. Activities/Specifications  
 2.1 Project Activities  
 2.1.1 Cardinal Health’s Responsibilities  
 2.1.1.1 Preliminary Activities  
 Cardinal Health will conduct preliminary activities to include the following:  
 • Provide project management and timelines.  
• Identify project team members and outline expectations.  
• Finalize initial protocols.  
• Identify and receive necessary Reference Standards, API lots, and excipients for development.  
Estimated Cost  
Estimated Duration (Weeks)  
 Estimated Cost ($)  
1  
 No Charge  
 2.1.1.2 Omacor Development Report  
 Cardinal Health will carry out project-related activities to include the following:  
 • Compile listing of all batches made in St. Petersburg, FL.  
• Gather all information related to any research and development conduct in the St. Petersburg, FL facility.  
• Issue a development report summarizing all work completed in the St. Petersburg, FL facility.  
00 Xxxxxxxxxxx Xxxx • Xxxxxxxx, XX 00000  
Direct: (000) 000-0000 • Facsimile: (000) 000-0000 • xxx.xxxxxxxx.xxx/xxx  
 [\*\*\*]: Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.  
 2  
  
Estimated Cost  
Estimated Duration (Weeks)  
 Estimated Cost ($)  
[\*\*\*]  
 [\*\*\*]  
 2.1.1.3 Omacor 1000 mg Softgel Process Validation  
 Cardinal Health will perform the following activities in order to validate Omacor 1000 mg softgel manufacturing process at commercial scale:  
 • Generate a process validation protocol and obtain approval from Reliant.  
• Obtain drug substance from Reliant and complete ID test for release (included in analytical support section).  
• Order raw materials and sample for release.  
• Generate product masters.  
• Perform as customer liaison and supervise batches.  
• Complete peroxide test on drug prior to encapsulation (included in analytical support section).  
• Manufacture and validate manufacturing process of three full-scale in-line printed batches at production site.  
• Monitor batches and collect fill and softgel samples for in-process testing as required in the validation protocol.  
• Monitor hardness of softgels during drying.  
• Wash and bulk package softgels for shipping to Reliant.  
• Perform in-process seal thickness, fill and shell weight measurement.  
• Clean equipment as per validated method.  
• Release finished product.  
• Perform QA review of all documentation.  
Estimated Cost  
Estimated Duration (Weeks)  
 Estimated Cost ($)  
[\*\*\*]  
 [\*\*\*]  
 2.1.1.4 DMF Update  
 Cardinal Health will update the DMF to reflect all changes made from the original DMF filing.  
Estimated Cost  
Estimated Duration (Weeks)  
 Estimated Cost ($)  
[\*\*\*]  
 [\*\*\*]  
 [\*\*\*]: Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.  
 3  
  
 2.1.1.5 In-Process and Release Testing of Softgels for Process Validation  
 Cardinal Health will carry out project-related activities for three process validation batches as follows:  
 • Perform appropriate in-process fill weight and content uniformity testing and release testing for three batches of active: appearance, identification (HPLC), assay/related substances, fill weight, disintegration, content uniformity, moisture, and microbial limits testing (MLT).  
• Perform peroxide test and AQL on three batches.  
• Issue CoA.  
Estimated Cost  
Activity and Estimated Duration (Weeks)  
 Estimated Cost ($)  
[\*\*\*]  
 [\*\*\*]  
[\*\*\*]  
 [\*\*\*]  
[\*\*\*]  
 [\*\*\*]  
[\*\*\*]  
 [\*\*\*]  
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[\*\*\*]  
 [\*\*\*]  
[\*\*\*]  
 [\*\*\*]  
\* Additional cost may be incurred for more then three samples ($[\*\*\*] per sample requiring assay). Content uniformity will be charged at $[\*\*\*] per set of samples.  
2.1.2 Reliant Responsibilities  
 Reliant will sign the protocol and provide a technical contact who will be available for technical discussions and make decisions that are needed in reference to this project. Reliant will not use any samples/materials shipped from Cardinal Health for this project in a manner that is inconsistent with the scope of this project.  
 2.2 Specifications  
 2.2.1 Cardinal Health’s Responsibilities  
 Cardinal Health will propose and document the specifications, as applicable, in the Protocol(s).  
 [\*\*\*]: Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.  
 4  
  
 2.2.2 Reliant’s Responsibilities  
 Reliant will provide all specifications necessary to perform this project.  
 Section 3. Cost Proposal  
 3.1 Project Costs  
Total Estimated Project Cost  
Section  
Reference  
 Activity  
 Estimated Duration  
(Weeks)  
 Estimated Cost  
($)  
 2.1.1.1.  
 Preliminary Activities  
 [\*\*\*]  
 [\*\*\*]  
 2.1.1.2.  
 Omacor Development Report  
 [\*\*\*]  
 [\*\*\*]  
 2.1.1.3.  
 Omacor 1000 mg Softgel Process Validation  
 [\*\*\*]  
 [\*\*\*]  
 2.1.1.4.  
 DMF Update  
 [\*\*\*]  
 [\*\*\*]  
 2.1.1.5.  
 In-Process and Release Testing of Softgels for Process Validation  
 [\*\*\*]  
 [\*\*\*]  
 Total Estimated Project Cost  
 [\*\*\*]  
 3.2 Additional Fees  
 If copies of raw data are requested in the course of an active project, Reliant will be invoiced at $[\*\*\*] for time required to generate and compile the data packet. If copies of raw data are requested after a final report has been issued, Reliant will be invoiced at the current laboratory rate for the hours required to generate and compile the data packet.  
 3.3 Revisions to Pricing  
 Cardinal Health reserves the right to revise quoted costs for any project as a result of initial scope change, revisions in Protocols, modifications of test methods, final review of test methods, undocumented requirements, retesting or resynthesis, or any unforeseen difficulty in executing the project. The additional work will be performed based on written agreement from Reliant and will be documented on a Cardinal Health Quotation Amendment Record (QAR).  
 All required investigational work (such as OOS investigations, trouble shooting chromatographic methods, etc.) may be conducted without prior approval from Reliant, for up to 16 scientist hours per occurrence. If the additional work requires going beyond [\*\*\*] hours, Reliant will be contacted prior to continuation. All investigational retesting performed that is not directly due to a Cardinal Health error will be invoiced to Reliant.  
 [\*\*\*]: Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.  
 5  
  
Section 4. Invoicing and Payment Terms  
 4.1 Invoicing  
 Upon request from Reliant, Cardinal Health will purchase all samples/materials necessary to perform the project and will invoice Reliant monthly at cost plus reasonable and customary acquisition and handling costs.  
 Non-standard or special instrumentation or equipment required solely for this project will be invoiced to Reliant following Reliant approval.  
 4.2 Additional Invoicing Terms  
 Cardinal Health will issue invoices based on milestones identified in Section 2.1.1. If a draft report is issued, Reliant will have 10 business days to return comments to Cardinal Health. If no comments are received, Cardinal Health will finalize the report and issue the invoice. If comments are received after issuance of the final report, Reliant will be billed at the current standard hourly rate for the time required to complete changes and reissue the report.  
 4.3 Payment Terms  
 Payments toward all invoices are due within 30 days of receipt of invoice and are non-refundable. Any applicable wire transfer fees must be included in the payment issued to Cardinal Health. All shipments are FOB Somerset, New Jersey. Remit all payments to:  
 Cardinal Health, Pharmaceutical Development, Somerset  
X.X. Xxx 000000  
Xxxxxxxxxxxx, XX 00000-0000  
 Section 5. Scheduling/Deliverables  
 5.1 Scheduling  
 Cardinal Health must receive a signed Quotation with a Purchase Order number (if applicable), a signed Protocol, and all raw materials/intermediates/final product samples in order for this project to be scheduled. Once scheduled, Reliant will be notified by Cardinal Health of the anticipated start and completion date of the project activities.  
 5.2 Deliverables  
 5.2.1 Reports and Certificates of Analysis  
 A report and/or Certificate of Analysis will be issued upon completion of each project phase.  
 6  
  
5.2.2 Communication  
 In order to establish a collaborative relationship between Reliant and Cardinal Health, both parties will appoint a Project Manager to serve as a point of contact to oversee progress on this project. Upon initiation of the project, Cardinal Health and Reliant will establish a communication plan, if requested, that may include conference calls, visits, and timelines.  
 Section 6. Additional Project Terms  
 6.1 Safety  
 6.1.1 Cardinal Health’s Responsibilities  
 Cardinal Health will assess all vendor and Reliant MSDS and all handling data for the samples/materials associated with this project. If categorized as a CDS and/or Category 3 or above, the samples/materials will require special handling precautions and will be subject to a Hazardous Material Fee for all handling and testing directly associated with the samples/materials. If applicable, this Hazardous Materials Handling Surcharge will be included in the project costs.  
 6.1.2 Reliant’s Responsibilities  
 Reliant will provide MSDS and all sample/material handling data for the samples/materials associated with this project. If any sample/material has any special handling considerations, Reliant will notify Cardinal Health prior to the initiation of the project.  
 6.2 Methods/Documentation  
 6.2.1 Cardinal Health’s Responsibilities  
 Cardinal Health will review all project-related documentation and methods received from Reliant associated with this project.  
 6.2.2 Reliant’s Responsibilities  
 Reliant will provide all available project-related documentation and methods to be used for this project.  
 7  
  
6.3 Samples/Materials  
 6.3.1 Cardinal Health’s Responsibilities  
 Cardinal Health will, as necessary, log in all samples/materials according to current Standard Operating Procedures. The sample/material lot numbers will be recorded in the laboratory notebooks at the time of use.  
Upon issuance of the final report or Certificate of Analysis, samples/materials will be stored in quarantine at Cardinal Health for a period of 30 days. After the 30-day quarantine period, samples/materials will be disposed of at Cardinal Health unless requested otherwise by Reliant. If additional storage is requested, Cardinal Health will issue a QAR for the additional cost.  
 6.3.2 Reliant’s Responsibilities  
 If available, Reliant will provide all samples/materials necessary to perform this project. The samples/materials should arrive at Cardinal Health with all proper documentation. If samples/materials are not available, Reliant will request that Cardinal Health purchase all necessary samples/materials needed to perform this project. If return shipment is requested, Reliant will notify Cardinal Health prior to the disposition of samples/materials.  
 6.4 Cancellation  
 If this project is cancelled by Reliant for purposes within their control, Cardinal Health will invoice Reliant the cost of any sample/materials, work performed before cancellation, reference materials, equipment, and supplies purchased by Cardinal Health specifically for this project. In addition, Cardinal Health reserves the right to invoice project cancellation fees according to the following schedule: acceptance of quotation but no approved protocol, $[\*\*\*]; acceptance of protocol but no laboratory work, $[\*\*\*]; and after laboratory work has begun, [\*\*\*]%.  
 For pilot plant manufacture, Cardinal Health reserves the right to invoice project cancellation fees according to the following calendar day schedule: [\*\*\*].  
 6.5 Project Notes  
 Reliant communication is encouraged. To xxxxxx project planning, reviews/updates, and coordination meetings, Cardinal Health will provide four person-hours a month of communication free of charge. Additional communication hours beyond this amount will be invoiced at the standard hourly rate.  
 [\*\*\*]: Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.  
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Reliant shall pay for all product batches, including batches that do not conform to applicable specifications, unless all methods and processes associated with the manufacture, testing, and storage of that product have been fully validated in accordance with generally accepted standards of the pharmaceutical industry.  
 The costs associated with optional testing have not been included in the total estimated project cost.  
 The summary of costs detailed above does not include any extra reformulation activities, any post submission activities, and/or any activities required for commercial batch manufacture. Additionally, it does not include any post approval tasks such as annual stability testing or storage. If requested by Reliant, these costs will be quoted separately.  
 Section 7. Version History  
 Revisions  
 Version  
 Revisions  
00  
 New Issue  
 Section 8. Terms and Conditions  
All work performed under this quotation is subject to the Supply Agreement to be executed between Cardinal Health and Reliant Pharmaceuticals. Upon receipt of an executed Term Sheet and Purchase Order from Reliant, Cardinal Health shall commence the validation process activities and manufacture the validation lots, while the parties negotiate the supply agreement. In the event that the supply agreement has not been executed as of the date of the completion of the manufacture of the validation lots, Cardinal Health shall release the validation lots to Reliant upon payment of the amounts due Cardinal Health as set forth in the Purchase Order and agreement by the parties as to responsibility for any liabilities (i.e. recall, product liability etc) associated with the manufacture or sale of the validation lots.  
 9  
  
Section 9. Project Approval and Authorization  
 By signing below, Reliant agrees to the project details as set forth in this Quotation.  
 Reliant Pharmaceuticals.  
  
 Cardinal Health PTS, LLC  
  
 /s/  
Signature  
 Signature  
 Xxxx Xxxxx, Ph.D.  
Printed Name  
  
 Printed Name  
  
 Vice President, Research and Development  
Title  
  
 Title  
  
 16 Feb 2005  
Date  
  
 Date  
 PO Number  
 Please sign and return a copy of the Quotation Approval Page via fax to  
Xxxxxx XxXxxx at (000) 000-0000 or email to xxxxxx.xxxxxx@xxxxxxxx.xxx.  
   
EXHIBIT E  
 FORM OF QUALITY AGREEMENT  
 COMMERCIAL  
QUALITY AGREEMENT  
Between  
And  
For the manufacture of:  
  
OmaCor Capsules  
   
Commercial Quality Agreement  
 OmaCor Capsules  
Between Reliant Pharmaceuticals, Inc. and Cardinal Health  
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 This Quality Agreement does not supercede or amend any provisions in the Supply Agreement between Reliant Pharmaceutical (Reliant) and Cardinal Health (Cardinal) dated April 14, 2005 (as may be amended from time to time, the “Agreement”). In the event of a conflict between the terms of the Agreement and this Quality Agreement, the Agreement shall be controlling.  
I QUALITY AGREEMENT AND TERM  
 1. It is deemed necessary by Reliant and Cardinal to allocate the responsibilities of current good manufacturing practice (cGMP), as defined in 21 CFR part 210-211, by which OmaCor Capsules shall be manufactured and provided to Reliant.  
2. This Quality Agreement, in conjunction with the Agreement, shall define the responsibilities of the parties involved, and the levels of interaction necessary for the delivery of a compliant drug product.  
3. This Quality Agreement shall expire with the termination of the Agreement. This Quality Agreement can be modified with the written approval of Reliant and Cardinal Quality Departments. A revision history shall be maintained as part of the Quality Agreement.  
II PRODUCTS  
 Cardinal has agreed to manufacture OmaCor Capsules in accordance with all cGMP’s, Product Specifications and all applicable federal, state, and local laws and regulations.  
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 III CONTACT INFORMATION  
 Communication pertaining to the manufacture of the Drug Product shall flow between the established channels detailed below.  
 DEPARTMENT  
 RELIANT CONTACT  
 CARDINAL CONTACT  
QUALITY ASSURANCE  
 Name:  
Phone:  
Fax:  
e-mail:  
Xxxxx Xxxxx  
(000) 000-0000  
(000) 000-0000  
xxxxxx@xxxxxxxxx.xxx  
 Name:  
Phone:  
Fax:  
e-mail:  
Xxxxxxx Xxxxxxxxxx  
(000) 000-0000  
(000) 000-0000  
xxxxxxx.xxxxxxxxxx@xxxxxxxx.xxx  
MANUFACTURING OPERATION  
 Name:  
Phone:  
Fax:  
e-mail:  
Xxxxxxxxxxx Xxxxxxxx  
(000) 000-0000  
(000) 000-0000  
xxxxxxxxx@xxxxxxxxx.xxx  
 Name:  
Phone:  
Fax:  
e-mail:  
Xxxxxxx Xxxxxx  
(000) 000-0000  
(000) 000-0000  
xxxxxxx.xxxxxx@xxxxxxxx.xxx  
REGULATORY  
 Name:  
Phone:  
Fax:  
e-mail:  
Xxxx Xxxx  
(000) 000-0000  
(000) 000-0000  
xxxxx@xxxxxxxxxx.xxx  
 Name:  
Phone:  
Fax:  
e-mail:  
Xxxxxx Kulcheski  
(000) 000-0000  
(000) 000-0000  
xxxxxx.xxxxxxxxx@xxxxxxxx.xxx  
PRODUCTION PLANNING  
 Name:  
Phone:  
Fax:  
e-mail:  
Xxxxx Xxxxx  
(000) 000-0000  
(000) 000-0000  
xxxxxx@xxxxxxxxx.xxx  
 Name:  
Phone:  
Fax:  
e-mail:  
Xxx Xxxxx  
000-000-0000  
000-000-0000  
xxx.xxxxx@xxxxxxxx.xxx  
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 IV MANUFACTURING COMPLIANCE  
OmaCor will be manufactured by Cardinal according to the Agreement at their facility located at 0000 Xxxxxxx Xxxxx, Xx. Xxxxxxxxxx, XX 00000 as detailed in the NDA and Agreement. The FDA facility number for this location is 1811396.  
1. Premises  
1.1 The manufacturing facility shall comply with all aspects of 21 CFR Part 210 and 211 Subpart C, as well as all additional requirements detailed in the Agreement,  
2. Equipment  
2.1 Equipment used to manufacture the Product shall comply with 21 CFR part 211 Subpart D, as well as all additional requirements detailed in the original DMF and subsequent updates.  
2.2 Cardinal shall maintain written records for equipment usage, cleaning, maintenance and calibration of all equipment used in the processing of the Drug Product to ensure that cleaning and maintenance records are readily identifiable with equipment usage in the event of a drug product problem that may be investigated. Cardinal shall maintain approved written procedures including, but not limited to, specifications for cleaning, assignment of responsibility for cleaning and maintaining equipment.  
2.3 Installation qualification (IQ)/ operational qualification (OQ)/ performance qualification (PQ) shall be performed on all equipment used in the manufacture and analysis of the product, and the same equipment shall be placed on a calibration and/or preventive maintenance schedule, as appropriate.  
2.4 Cardinal shall only use the major equipment detailed in the Master Batch Records thereto for the processing and manufacture of the product. Use of equipment other than that stipulated in the mutually agreed to Master Batch production records shall not be permitted without prior written consent from Reliant Quality and Regulatory, irrespective of FDA guidance’s detailing equipment class and subclass equivalencies.  
3. Personnel  
3.1 Cardinal shall maintain quality control and quality assurance units to be responsible for the duties relating to quality control and quality assurance. The responsibilities of these units shall be defined in written procedures.  
3.2 Personnel used to process the drug product shall be appropriately trained in cGMP’s, as well as the processes they perform. Training shall be  
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 documented and available for review. Training shall be conducted on a continuing basis by qualified individuals.  
3.3 There shall be an adequate number of qualified personnel to perform and supervise the processing and manufacture of the drug product.  
4. Materials  
4.1 Cardinal shall use only those excipients, Active Pharmaceutical Ingredients (“API”), components, and bulk capsule packaging materials as detailed in the DMF.  
4.2 Cardinal shall sample all materials according to approved procedures, and shall test and release those materials according to approved analytical methodology and specifications as filled in the DMF.  
4.3 Cardinal shall store all packaging materials, excipients, API, and finished product in a suitable environment so as not to impact the materials’ quality. A suitable retest program shall be used to demonstrate the quality of the stored material versus approved specifications. Certificates of Analysis or analytical test sheets, as defined by Cardinal, shall be generated and reviewed by quality control to release all materials used to process and manufacture the Product.  
5. Documentation  
5.1 Cardinal shall provide written documentation in the form of a master batch record for all processes used in the manufacture of the Product.  
5.2 Cardinal shall maintain and follow Standard Operating Procedures (SOP) required to manufacture, package, analyze, release, and store in-process materials as well as the Product as detailed in the DMF, and required by cGMP.  
5.3 Cardinal shall follow a suitable change control procedure for all documentation. All changes to controlled documents such as, batch records, manufacturing specifications, test methods, and raw materials supplied by Reliant and product specifications must be submitted to Reliant QA for review and approval prior to final approval and implementation. Any documentation necessary to support the change request shall be provided as necessary.  
5.4 Labeling of bulk finished product will be executed per Cardinal’s in-house labeling program. Bulk shipper labels shall contain a minimum of the following information: product name, strength, container number, storage statement, package by date, Cardinal shall follow written procedures for  
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 label control for the receipt, release, dispensing, and reconciliation of all labels, as appropriate.  
6. Lot Numbers and Expiration  
6.1 Cardinal shall assign unique lot numbers to bulk finished product to ensure complete product traceability.  
7. Bulk Product Storage and Shipment  
7.1 Cardinal shall store all finished product in suitable containers, labeled with lot specific information, and in a controlled environment to remove possibility of tampering, theft, adulteration, or contamination.  
7.2 Product shall be labeled with all D.O.T. and O.S.H.A. information, as required, and suitably packaged to minimize damage during transit.  
7.3 Bulk product container shall be sealed with tamper evident closures or seals to remove the possibility of tampering, theft, adulteration, or contamination.  
7.4 Bulk finished product may be shipped by Cardinal to a Reliant specified address once all site specific testing requirements are approved all deviations and investigations are closed, and the batch record is approved.. Materials may be shipped under Quarantine only with the prior written consent from the Quality Department from Reliant and Cardinal.  
7.5 Product should be segregated by lot number prior to shipment.  
8. Processing of Intermediates (Bulk Hold)  
8.1 Each process intermediate for each step of the manufacturing process may be held for a period of up to 30 days. Holding a process intermediate for a period of longer than 30 days must be supported by stability data, generated per an approved protocol that supports a longer storage interval.  
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 V QUALITY CONTROL  
Cardinal shall maintain a cGMP quality control laboratory suitable to test and release all materials; API, components, in-process test samples, and finished product according to the analytical methods and specifications detailed in the DMF and subsequent updates or NDA or approved Supplement. This laboratory is the only qualified laboratory to perform analytical testing in support of the materials, API, components, and drug products, unless otherwise specified in the DMF. Use of any other laboratory for release testing is not permitted.  
1. Premises  
1.1 The quality control laboratory shall comply with all aspects of 21 CFR Part 210 and 211.  
2. Equipment  
2.1 Installation qualification/ operational qualification/ performance qualification shall be performed on all equipment used in analysis of excipients, components, and the product and the same equipment shall be placed on a calibration schedule, as appropriate.  
2.2 Cardinal shall maintain written records for equipment usage, maintenance and calibration.  
3. Vendor Approval  
3.1 Cardinal shall suitably qualify all vendors from which materials are sourced for use in the finished drag product. This includes, but is not limited to excipients, container closure systems, printed commodities, etc.  
4. Personnel  
4.1 Personnel used to test and release the Product shall be appropriately trained in cGMP’s, as well as the methods and techniques they utilize. Training shall be documented and available for review. Training shall be conducted on a continuing basis by qualified individuals.  
5. Out-of-Specification (OOS) Investigations  
5.1 Cardinal is responsible for following its SOP to investigate any test results that fail to meet specifications. A confirmed OOS failure should be conveyed to Reliant Quality within 2 business days. These OOS investigations are open to review by Reliant during an audit.  
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 6. Reference Standards  
6.1 All testing shall use primary reference standards, or appropriately qualified secondary reference standards. Qualification of secondary reference standards must comply with current ICH guidelines.  
7. Product Release  
7.1 Reliant is responsible for assessing final product disposition and release. Cardinal shall provide a COA/COC and product yield page for each lot manufactured.  
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 VI QUALITY ASSURANCE  
Cardinal’s Quality Department shall assure that the drug product was manufactured, tested, released, and stored in accordance with cGMP’s, and all requirements as detailed in the in the approved master batch record/specifications.  
1. Documentation  
1.1 Cardinal will provide both a Certificate of Analysis indicating all Cardinal test results and their specifications, and a Certificate of Compliance indicating the Drug Product has been manufactured, packaged, tested, released and stored according to cGMP’s and all requirements as detailed in the master batch record/specifications.  
1.2 Cardinal shall provide written certification for cGMP Compliance and Debarment annually upon request.  
1.3 Cardinal shall retain all Batch Production Records for the Drug Product for a period of not less than one year past the finished product expiration date.  
1.4 Deviations to the manufacturing process or analytical test methods must be documented, reviewed versus the respective validation, and approved by both Reliant and Cardinal Quality Assurance department s prior to release of the Drug Product.  
1.5 Cardinal is responsible for maintaining all documentation supporting all manufacturing processes, analytical testing, and storage of the Drug Product for a period of not less than one year past the expiration date of any finished product lot containing it.  
1.6 Cardinal shall follow a suitable Change Control Procedure for all documentation. All changes to batch records, manufacturing specifications, or test methods must be submitted to Reliant Quality Assurance for review and approval prior to implementation.  
1.7 Validation records shall be maintained by Cardinal until the NDA is retired.  
2. Samples  
2.1 Cardinal’s Quality Control Unit shall assure that all test samples are taken in accordance with approved SOP’s.  
2.2 Cardinal shall maintain bulk product reserved samples for a period of not less than one year past the expiration date of finished products. At least twice as much material shall be retained as is needed to conduct testing if necessary.  
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 2.3 Cardinal shall retain API reserve samples for one year after the expiration date on the last finished product lot containing it. At least twice as much material shall be retained as is needed to conduct all specification release testing.  
2.4 Manufacturer shall perform annual inspection of the bulk product retained samples as per 21 CFR 211.170, and will perform an investigation of deterioration, if necessary, as per 21 CFR 211.170.  
3. Investigations/Deviations  
3.1 Cardinal shall notify Reliant Quality in writing within two business day after confirmation of any situation that impacts product that has already been released. Cardinal shall also provide Reliant with verbal communication of any such investigation prior to the confirmation so that appropriate action can be implemented to restrict continued distribution of product until the investigation can be finalized.  
3.2 All major and minor manufacturing deviations shall be investigated and approved by both Cardinal and Reliant QA departments. Copies of the final approves investigations shall be conveyed to Reliant Quality with the issuance of the bulk product certificate of analysis. In addition, Cardinal shall inform Reliant QA of any confirmed Out of Specification result.  
A Major Deviation is defined as: A departure from normal operating conditions that is determined to have a significant or unknown impact on the identity, strength, quality, and purity of the drug product. Examples include, but are not limited to: failure of a batch or lot to meet any analytical specification that is not determined to be a laboratory error; or, compounding errors such as dispensing incorrect quantities of material; or processing errors such as using equipment that is outside of approved calibration dating or processing a batch outside the tolerances set forth in the batch record; or observation of foreign materials in a batch; or packaging or labeling errors.  
A Minor Deviation is defined as: A departure from normal operating conditions that is determined to have no impact on the identity, strength, quality, and purity of the drug product. Examples include, but are not limited to: low gross yields; or calculation or rounding errors that have no impact on the batch.  
3.3 Rework/Reinspections: Cardinal shall obtain approval from Reliant QA before performing any rework or reinspection of intermediates or finished product.  
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 4. Product Complaints or Adverse Events  
4.1 All individuals reporting a product related complaint shall be immediately directed to contact Reliant Pharmaceuticals’ Customer Complaints Group at telephone number: 000.000.0000.  
4.2 All individuals reporting an Adverse Event shall be immediately directed to contact Reliant Pharmaceuticals’ Medical Affairs Department at telephone number: 000.000.0000.  
4.3 Reliant Pharmaceutical’s Quality Department shall evaluate all complaints and determine if product retain analysis is required. A written request shall be forwarded to Cardinal detailing any product retain investigation that is required. Cardinal shall provide a written report of the investigation within 20 business days.  
4.4 Cardinal shall maintain a system for logging, tracking, and responding to complaints.  
4.5 Reliant shall be the only authorized group to provide product related responses to the public.  
4.6 Should Reliant discover a product related problem, Reliant Quality Department shall provide a written complaint notification to Manufacturer within 2 business days of the occurrence.  
4.7 Should Cardinal, through routine product review, discover a product related issues that causes an investigation, Cardinal shall provide written notification to Reliant’s Quality Department within 3 business days.  
5. Annual Product Review  
5.1 Cardinal shall perform an annual product review for the Product detailing all product lots manufactured, product investigations, lots released or rejected, specification changes (to excipient, in-process controls, or finished product), and process or method revisions (including validation reports) for all Product lots manufactured in the previous calendar year. All critical release data shall be trended to evaluate the process.  
5.2 The written annual product review report for a given year shall be sent to Reliant Quality Department. The reporting period shall commence with the first day of the month in which the validation campaign started, and shall close 365 days later (i.e. April 1, 2005 through March 31, 2006). This period will be the established reporting period for the product.  
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 5.3 The written annual product review report for a given year shall be sent to Reliant Quality Department within 90 days of the close of the reporting period.  
6. Product Recalls  
6.1 It shall be the sole responsibility of Reliant to issue a FDA Field Alert Notification pertaining to a product quality issue discovered by Cardinal or Reliant. An alert shall only be issued with substantive evidence of a quality issue, for which Cardinal shall have 5 business days from obtaining knowledge of the substantial evidence of a quality issue to provide a full investigation report to Reliant Pharmaceuticals.  
6.2 It shall be the sole responsibility of Reliant to issue a product recall, and discuss with FDA the extent or type of action that should occur. Decisions to initiate a product recall shall be based on product medical reviews and the investigation report used to support the FDA Field Alert.  
7. Audits by Reliant Pharmaceuticals  
7.1 Routine Audits may be performed by Reliant or its agent upon prior notification, and not more than once a year. CGMP compliance audits of Cardinal’s facilities may be conducted during regular business hours, and may cover any system or area, plus associated documentation, used to support receiving, sampling, testing, releasing and holding of raw materials, or manufacturing, sampling, testing, releasing, labeling, holding, and distribution of the drug product.  
7.2 Reliant Quality shall provide 180 days notification for a routine audit, and 7 days notification for a ‘for cause’ audit pertaining to a specific product quality and safety issue. A ‘for cause’ audit does not constitute a routine audit.  
7.3 An exit meeting shall be held to provide significant audit observations. A written report of observations shall be issued.  
7.4 Cardinal shall provide a written response to the audit observations within 30 business days of receipt of written observations from Reliant. The response shall include details of the corrective actions to the observations, and the expected completion date of the action. Reliant Quality shall follow-up on the progress of the corrective actions based on the expected completion dates provided.  
7.5 Reliant shall have the right to be present during the manufacture of any product validation lots, or during the manufacture of a lot in which a CAPA issue is being implemented. These visits shall not go against Reliant’s right to an annual audit.  
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 VII REGULATORY  
All final, Regulatory assessments pertaining to the manufacture, release, and distribution of the Product shall be the responsibility of Reliant’s Regulatory Affairs group. Cardinal shall provide a cGMP compliant facility in order to supply the Product to Reliant Pharmaceuticals.  
1. Inspections by Regulatory Agencies  
1.1 Cardinal shall inform Reliant Pharmaceuticals of any Regulatory Agency performing an inspection relating to the Product, or a facilities inspection affecting the Product within the same business day of notification. Reliant Quality Department may be present at any Product specific inspections and exit meetings with prior approval from Cardinal’s Quality Department.  
1.2 All Product specific regulatory correspondence, or facilities correspondence affecting the manufacturing of the Product shall be conveyed to Reliant Quality Department within 2 business days of receipt. Cardinal shall provide written responses to all Product related observations for Reliant review prior to commitment to any regulatory authority.  
1.3 Cardinal shall provide copies of all regulatory agency inspection documentation (i.e. 483’s, EIR’s, etc.) or any other regulatory correspondence pertaining to the Product to Reliant Quality Department within seven business days of receipt. A redacted copy will be provided to protect other customer’s products.  
2. Annual Reports  
2.1 It shall be the sole responsibility of Reliant Pharmaceuticals to maintain all regulatory communication and updates (Supplements, CBE, Annual Reports, etc.) pertaining to the Product as outlined in ICH and FDA regulatory guidance documents. All necessary CMC documentation updates will be conveyed to Cardinal, who shall provide the necessary documentation to Reliant Regulatory not less than 45 days prior to filing date.  
3. Drug Listing  
3.1 It shall be the responsibility of Reliant Regulatory to submit FDA Form #2657 every June and December updating the Drug Product Listing. When no changes have occurred since the previously submitted list, no report is required.  
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 VIII VALIDATION  
Cardinal shall assure that all systems used to manufacture, test, release, and distribute the Product shall have been appropriately transferred, qualified, and/or validated prior to using that system to process the Product for commercial product.  
1. Process  
1.1 Cardinal shall be responsible for performing and documenting process validation to comply with cGMP’s and to ensure consistency of quality Product. A process validation protocol shall be forwarded to Reliant for review and approval prior to carrying out the validation. A final report will be issued and a copy will be provided to Reliant Quality.  
2. Equipment Cleaning Validation  
2.1 Cardinal is responsible for reviewing toxicity and safety information for all products they manufacture to set appropriate cleaning limits to ensure there are no cross contamination issues between products. Cardinal shall demonstrate, through approved protocol and final report, that cleaning validation has been performed.  
3. Computer  
3.1 Cardinal is responsible for compliance as it pertains to systems validation, electronic records, electronic records retention, and electronic signatures for those systems used in the control of the manufacturing processes, analytical testing, receipt, release and distribution of materials, API, components, and the Product as prescribed by 21 CFR part 11, and any other current, approved FDA Guidance requirements..  
4. Analytical Test Methods  
4.1 Cardinal shall be responsible for demonstrating the suitability (methods transfer or validation, as appropriate) of all methodology used to release raw materials, components, and the finished product, as appropriate.  
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REVISION HISTORY  
Revision  
Date  
 Revision Description  
June 2005  
 New Document  
 APPROVALS  
 Reliant Pharmaceuticals, Inc.  
 Cardinal Health  
 June 1, 0000  
 00-00-00  
Signature  
Date  
 Signature  
Date  
 Xxxxxxx Xxxxx  
 Xxxx Xxxxxxxx  
Director, QA/QC  
 Quality and Regulatory Affairs Director