EX-10.33 63 dex1033.htm MANUFACTURING AND PACKAGING AGREEMENT / CARDINAL HEALTH PTS, LLC  
Exhibit 10.33  
 MANUFACTURING AND PACKAGING AGREEMENT  
 This Manufacturing and Packaging Agreement (“Agreement”) is made this 14th day of April, 2005, 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.  
 BACKGROUND  
 Cardinal Health provides contract pharmaceutical development, manufacturing, packaging, analytical, and sales and marketing services to the pharmaceutical industry.  
 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.  
 Reliant desires to engage Cardinal Health to provide certain services to Reliant in connection with the processing of Reliant’s Product (defined below) and Cardinal Health desires to provide such services pursuant to the terms and conditions set forth in this Agreement.  
 The parties therefore 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 “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”).  
 1.4 “Batch” means defined quantity of finished drug product that has been or is being Manufactured and Packaged in accordance with the Specifications.  
 1.5 “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.  
 1.6 “Cardinal Health Technology” shall have the meaning set forth in Article 12.  
 1.7 “Change Order” shall have the meaning set forth in Section 4.5(A).  
 1.8 “Confidential Information” shall have the meaning set forth in Section 11.2.  
 1.9 “Contract Year” means each consecutive twelve (12) month period beginning on July 1, 2005.  
 1.10 “Defective Product” shall have the meaning set forth in Section 5.2.  
 1.11 “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.  
 1.12 “Dispute” shall have the meaning set forth in Section 19.9.  
 1.13 “Effective Date” means the date this Agreement was fully executed.  
 1.14 “Facility or Facilities” means Cardinal Health’s facilities located in St. Petersburg, Florida or such other facility as agreed by the parties.  
 1.15 “FDA” means the United States Food and Drug Administration and any successor agency thereto.  
 1.16 “Firm Commitment” shall have the meaning set forth in Section 4.3.  
 1.17 “Minimum Requirement” shall have the meaning set forth in Section 4.1.  
 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 “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.  
 1.22 “Product” means Omacor® as fully compounded API Manufactured and Packaged in accordance with the Specifications.  
 1.23 “Product Maintenance Fee” shall have the meaning set forth in Section 7.2.  
 1.24 “Purchase Order” shall have the meaning set forth in Section 4.4.  
 1.25 “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.  
 1.26 “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.  
 1.27 “Reliant Technology” shall have the meaning set forth in Article 12.  
 1.28 “Review Period” shall have the meaning set forth in Section 5.1.  
 1.29 “Rolling Forecast” shall have the meaning set forth in Section 4.3.  
 1.30 “Sample” shall have the meaning set forth in Section 5.1.  
 1.31 “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 [\*\*\*].  
 1.32 “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  
 [\*\*\*]: 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.  
 by reference into this Agreement, along with any valid amendments or modifications thereto, subject to the terms and conditions of Article 9.  
 1.33 “Term” shall have the meaning set forth in Section 15.1.  
 1.34 “Territory” means the United States of America, its territories and possessions.  
 1.35 “Unit” means each individual unit of Product, as described more fully in the Specifications.  
 1.36 “Unit Pricing” shall have the meaning set forth in Section 7.1.  
 1.37 “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, Reliant shall be entitled to the following 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 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 will be determined after the Manufacture of [\*\*\*] or the number of batches Manufactured during [\*\*\*] of production and shall be 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 equals [\*\*\*] for API consumed in excess of the minimum Yield. 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 (12) month period, Reliant shall be permitted to inspect API inventory at Cardinal Health’s Facility.  
 ARTICLE 4  
MINIMUM COMMITMENT, PURCHASE ORDERS & FORECASTS  
 4.1 Minimum Requirement. During each Contract Year, Reliant shall purchase the minimum dollar volume of Product (“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) Cardinal Health commits to using best commercial efforts to Manufacture and Package [\*\*\*], [\*\*\*] to the finished product packaging contractor designated by Reliant. 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.  
 commits to use its best commercial efforts to perform its obligations with regard to validation and the timelines to be met in connection therewith.  
 (b) [\*\*\*].  
 (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 [\*\*\*] of a respective Delivery Date for [\*\*\*] 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, [\*\*\*], provided, however, Reliant shall use commercially reasonable efforts to [\*\*\*] following resolution of any technical issues.  
 (d) Any quantity of Product which is not delivered to Reliant by Cardinal Health within [\*\*\*] of any Delivery Date, for any reason whatsoever, during the Term shall give Reliant the option to [\*\*\*].  
 (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, [\*\*\*].  
 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 [\*\*\*] 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  
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 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.  
 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 4.4 or Section 4.1, 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.  
 4.6 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. Unless agreed to by Reliant in writing, such notice will not relieve Cardinal Health of any of its obligations in this Agreement, including, but in no way limited to, the provisions of Section 4.2.  
 4.7 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; SAMPLES; RELEASE  
 5.1 Samples; Testing. Within [\*\*\*] 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 (“Sample”) and the Manufacturing Related Reference Documents for such Batch. No later than [\*\*\*] after receipt of the 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 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 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 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 INDEMINIFICATION 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  
 [\*\*\*]: 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.  
 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 [\*\*\*] 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 or trade product. For lots designated for samples, [\*\*\*]. 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 [\*\*\*], the parties shall reconcile such transfer and Cardinal Health shall credit the difference to Reliant within thirty (30) days of such notification. [\*\*\*]. [\*\*\*]. 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 [\*\*\*]. The initial Product Maintenance fee is payable on [\*\*\*], and thereafter upon each anniversary of such date during the Term.  
 7.3 Price Increase. The Unit Pricing may be adjusted on an annual basis, effective on each anniversary date of the Effective Date, 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,  
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 utilities and overhead. Any price adjustment shall limit the increase in component (b) [\*\*\*]; 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 Sections 4.1, 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 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 [\*\*\*] per month until paid in full.  
 ARTICLE 8  
[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 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.  
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 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 Agreements. 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 C. 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  
LIMITATIONS 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 SHALL NOT EXCEED [\*\*\*] PER BATCH, UP TO [\*\*\*]. IN THE EVENT THAT CARDINAL HEALTH LIABILITY FOR LOST API SHALL EXCEED [\*\*\*] 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 [\*\*\*], OR (B) [\*\*\*]. 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) [\*\*\*] (Y) [\*\*\*]. FOR AVOIDANCE OF DOUBT, 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  
 [\*\*\*]: 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.  
 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 [\*\*\*].  
 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 [\*\*\*].  
 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  
 [\*\*\*]: 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.  
 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, 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: Director Manufacturing and Distribution  
 Facsimile: 908.542.9405  
With a copy to:  
 Reliant Pharmaceuticals, Inc.  
 000 Xxxxx Xxxx  
 Xxxxxxx Xxxxxx, XX 00000  
 Attention: Vice President, Legal Affairs  
 Facsimile: 908.542.9406  
To Cardinal Health:  
 Cardinal Health PTS, LLC  
 0000 Xxxxxxx Xxxxx  
 Xx. Xxxxxxxxxx, Xxxxxxx 00000  
 Attention: President, Encapsulation,  
 North America Oral Technologies  
 Facsimile: (000) 000-0000  
With a copy to:  
 Cardinal Health, Inc.  
 0000 Xxxxxxxx Xxxxx  
 Xxxxxx, Xxxx 00000  
 Attn: Associate General Counsel,  
 Pharmaceutical Technologies and Services  
 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. 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; 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), Section 17.4 (Effect of Termination), and Sections 6.2 and 17.4, \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  
 EXHIBIT B  
UNIT PRICING, FEES AND MINIMUM REQUIREMENT  
 UNIT PRICING – [\*\*\*]  
Units (millions)  
 Price per thousand Units  
[\*\*\*]  
 [\*\*\*]  
[\*\*\*]  
 [\*\*\*]  
[\*\*\*]  
 [\*\*\*]  
[\*\*\*]  
 [\*\*\*]  
[\*\*\*]  
 [\*\*\*]  
 UNIT PRICING – [\*\*\*]  
Units (millions)  
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 [\*\*\*]: 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  
 [FORTHCOMING]  
 EXHIBIT D  
 QUALIFICATION, VALIDATION AND STABILITY SERVICES  
 EXHIBIT E  
 FORM OF QUALITY AGREEMENT  
 [FORTHCOMING]