Exhibit 10.48  
 \*\*\*Text Omitted and Filed Separately  
Confidential Treatment Requested  
Under 17 C.F.R. §§ 200.80(b)(4)  
And 240.24b-2  
 C O N F I D E N T I A L  
 EXENATIDE MANUFACTURING AGREEMENT  
 THIS AGREEMENT effective October 1, 2003, the (“Effective Date”) is made by and between Amylin Pharmaceuticals, Inc., a Delaware corporation having a principal place of business at 0000 Xxxxx Xxxxxx Xxxxx, Xxxxx 000, Xxx Xxxxx, Xxxxxxxxxx 00000 (“AMYLIN”) and Mallinckrodt Inc., a Delaware corporation, having a principal place of business at 000 XxXxxxxxx Xxxx., Xx. Xxxxx, Xxxxxxxx 00000 (“MALLINCKRODT”).  
 WHEREAS, AMYLIN requires the manufacture of commercial supplies of Product (as defined below) on a non-exclusive basis;  
 WHEREAS, MALLINCKRODT desires to manufacture for AMYLIN commercial supplies of Product on a non-exclusive basis; and  
 NOW, THEREFORE, in consideration of the premises and the mutual covenants and agreements contained herein, MALLINCKRODT and AMYLIN agree as follows:  
 1. Definitions  
 As used in this Agreement, the following words and phrases shall have the following meanings:  
 1.1 “Adjustment Date” shall have the meaning ascribed to it in Paragraph 2.4 hereof.  
 1.2 “Affiliate” means any party that directly (or indirectly through one or more intermediaries) controls, is controlled by, or is under common control with a party. For purposes of this definition only, the terms “controls,” “controlled,” and “control” means (i) the direct or  
   
 CONFIDENTIAL  
 indirect ability or power to direct or cause the direction of the management and policies of an entity or otherwise direct the affairs of such entity, whether through ownership of equity, voting securities, or beneficial interest, by contract, or otherwise, or (ii) the ownership, directly or indirectly, of at least 50% of the voting securities (or other comparable ownership interest for an entity other than a corporation) of a party.  
 1.3 “Agreement” means this Agreement, together with all exhibits.  
 1.4 “AMYLIN Indemnitees” shall have the meaning ascribed to it in Paragraph 9.2 hereof.  
 1.5 “Annual Adjustment Notice” shall have the meaning ascribed to it in Paragraph 2.4 hereof.  
 1.6 “Applicable Laws” means all United States, European, and any other jurisdiction’s federal, state, local and other laws, statutes, rules, regulations, ordinances, (including any amendments thereto), applicable to the import, export, manufacture and distribution of Product, including, without limitation, the applicable regulations and guidance of the FDA and all applicable cGMPs, but only where MALLINCKRODT has authorized reference of its Drug Master File for Product (it being understood that MALLINCKRODT will authorize reference of its Drug Master File in the United States and the European Union).  
 1.7 “cGMP” means “current Good Manufacturing Practices” as defined and in effect from time to time in regulations and guidelines promulgated by the FDA under the FDCA governing the manufacture and testing of Product, including without limitation, those specified in The Rules Governing Medicinal Products in the European Union, the principles of which are specified in Chapter II of European Commission Directive 91/356/EEC, and any other laws, regulations, and guidelines applicable to the manufacture and testing of Product but only where MALLINCKRODT has authorized reference of its Drug Master File for Product.  
 2  
  
 1.8 “COA” means the certificate of analysis furnished by MALLINCKRODT to AMYLIN in connection with any Lot hereunder indicating the Lot number, specifications, and all results of analytical and other Product testing required under this Agreement.  
 1.9 “Collaboration Partner” means Xxx Xxxxx and Company, with whom AMYLIN has entered into a collaboration arrangement regarding Product.  
 1.10 “Confidential Information” shall have the meaning ascribed to it in Paragraph 10.1 hereof.  
 1.11 “Contaminant” means a substance contained in Product that (i) causes Product to fail to meet any Product Requirements or (ii) causes Product to be adulterated within the meaning of the FDCA.  
 1.12 “Contract Year” means each consecutive calendar year during the term of this Agreement commencing on October 1 and ending on September 30.  
 1.13 “Contract Year Forecast” shall have the meaning ascribed to it in Paragraph 2.6 hereof.  
 1.14 “Damage Claim” shall have the meaning ascribed to it in Paragraph 9.3.  
 1.15 “Damages” shall have the meaning ascribed to it in Paragraph 9.1.  
 1.16 “Defective Product” shall have the meaning ascribed to it in Paragraph 6.1 hereof.  
 1.17 “Drug Master File” means the drug master file (as such term is defined in 21 C.F.R. Part 314.420) relating to Product manufactured hereunder.  
 1.18 “Effective Date” means the date first written above.  
 3  
  
 1.19 “Exenatide Injection Drug” means finished formulated injectable drug product containing Product, for use and administration twice daily (BID).  
 1.20 “Facility” means MALLINCKRODT’s manufacturing, testing, and storage facility located in St. Louis, Missouri.  
 1.21 “FDA” means the United States Food and Drug Administration and any successor entity.  
 1.22 “FDCA” means the Federal Food Drug and Cosmetics Act, as amended from time to time, and all regulations promulgated thereunder (or any successor law and all regulations promulgated thereunder).  
 1.23 “Force Majeure” shall have the meaning ascribed to it in Article 11 hereof.  
 1.24 “Governmental Agency” means any federal, state, foreign or local government agency or authority that has jurisdiction over the manufacture, testing, distribution, sale or use of Product where MALLINCKRODT has authorized reference to its Drug Master File for Product.  
 1.25 “Hidden Defect” means any defect in any Lot that could not reasonably be expected to have been found by diligent and adequate inspection and testing by AMYLIN, such as failure to follow CGMPs.  
 1.26 “Indemnified Party” shall have the meaning ascribed to it in Paragraph 9.3.  
 1.27 “Indemnifying Party” shall have the meaning ascribed to it in Paragraph 9.3.  
 4  
  
 1.28 “Lot” means that quantity of Product produced from a single homogeneous solution in a single cycle of lyophilization.  
 1.29 “MALLINCKRODT Indemnitees” shall have the meaning ascribed to it in Section 9.1 hereof.  
 1.30 “MALLINCKRODT Technology” means all technical information, whether tangible or intangible and whether or not patentable, including patents, patent applications and any method, procedure, process, assay, composition of matter, trade secret, invention, technology, information or other subject matter, including license application materials and all supporting documents, specifications for materials (including purification techniques), data, information (including information contained in registration dossiers, drug master files and other documents filed with regulatory authorities), quality control, validation and equipment necessary or useful for the manufacture, production, scale-up and processing of Product, which is conceived, reduced to practice, developed, owned or licensed by MALLINCKRODT and necessary or useful in the manufacture of Product.  
 1.31 “NDA” means AMYLIN’s New Drug Application for Exenatide Injection Drug filed with the FDA and any other functionally equivalent applications for approval to market Exenatide Injection Drug outside of the United States.  
 1.32 “Nominal Lot” means a Lot containing at least [\*\*\*] grams ([\*\*\*]g) of Product or such other minimum quantity of Product as specified in any applicable Purchase Order.  
 1.33 “OUS Sales” means Exenatide Injection Drug commercially sold outside of the United States.  
 1.34 “Product” means AMYLIN’s exenatide compound with the structure described in Exhibit A manufactured in accordance with this Agreement.  
 \* CONFIDENTIAL TREATMENT REQUEST(ED)  
 5  
  
 1.35 “Product Costs” shall have the meaning ascribed to it in Paragraph 2.4 hereof.  
 1.36 “Product Price” shall have the meaning ascribed to it in Paragraph 2.4 hereof.  
 1.37 “Product Requirements” means all of the requirements set forth, contained, and referenced in Paragraph 8.1(i)(a - d) of this Agreement.  
 1.38 “Product Specifications” means the written specifications for Product set forth in Exhibit B, as amended from time to time pursuant to Paragraph 3.1.  
 1.39 “Product Validation Lots” means those Lots manufactured under this Agreement for the purpose of validating the manufacturing and testing activities under this Agreement to ensure that Product is manufactured in accordance with all Product Requirements and Applicable Laws for use in commercial production of Exenatide Injection Drug.  
 1.40 “Quality Agreement” means the Quality Agreement dated as of the Effective Date between AMYLIN and MALLINCKRODT containing, identifying, and outlining the specifications, and certain of the technical and regulatory terms and conditions, for the manufacture of Product under this Agreement. The Quality Agreement is incorporated into this Agreement and made a part hereof. However, it is understood that in the event of any conflict of inconsistency between the terms of the Quality Agreement and any other terms or conditions of this Agreement, the latter shall prevail.  
 1.41 “Purchase Order” shall have the meaning ascribed to it in Paragraph 2.2 hereof.  
 1.42 “Recall Action” shall have the meaning ascribed to it in Paragraph 4.1 hereof.  
 1.43 “Third Party” means any person or entity other than MALLINCKRODT or AMYLIN, or their respective Affiliates.  
 6  
  
 1.44 “Validation Batch Production Records” means the documented procedures used to produce Product Validation Lots that fully comply with Product Specifications and Validation Requirements.  
 1.45 “Validation Requirements” means all processes, procedures, yield requirements, in-process sampling and analysis, and other actions required to be completed or performed for the manufacture of all Product Validation Lots in accordance with Applicable Laws, including, without limitation, any re-manufacturing and other actions required to bring Product into conformance with Governmental Agency requirements.  
 2. Purchase and Sale of Product  
 2.1 MALLINCKRODT understands and agrees that AMYLIN shall have the right to manufacture Product itself or have Product manufactured by other manufacturers.  
 2.2 MALLINCKRODT agrees to manufacture and supply to AMYLIN the amounts of Product as ordered by AMYLIN pursuant to written purchase orders issued hereunder by AMYLIN using a form of purchase order mutually acceptable to both parties (“Purchase Order”), specifying the quantity, Nominal Lot quantity, and delivery date. AMYLIN shall submit each Purchase Order to MALLINCKRODT at least [\*\*\*] ([\*\*\*]) months in advance of the shipment date specified in the Purchase Order and otherwise in accordance with the requirements hereof. In the event that AMYLIN requests a change to a Purchase Order, MALLINCKRODT shall use commercially reasonable efforts to accommodate such request. All Purchase Orders shall be subject to written acceptance by MALLINCKRODT, which acceptance shall not unreasonably be withheld or delayed. Notwithstanding any other provision hereof, except with respect to Product volumes, delivery dates and shipping instructions, no term or condition of any Purchase Order issued by AMYLIN, any acknowledgement by MALLINCKRODT or any other document of either party that is in any manner additional to, different from or varies the terms and conditions hereof shall be deemed to be of any force or effect.  
 \* CONFIDENTIAL TREATMENT REQUEST(ED)  
 7  
  
 2.3 Notwithstanding the provisions of Paragraph 2.2 above, AMYLIN agrees to purchase from MALLINCKRODT (except to the extent MALLINCKRODT does not accept a Purchase Order pursuant to Paragraph 2.2 above):  
 (i) during the period from the Effective Date through the end of the first Contract Year hereof (i.e., during the period from October 1, 2003 through September 30, 2004) a minimum of [\*\*\*] ([\*\*\*]) [\*\*\*] (or [\*\*\*]) of Product which will consist of the Product Validation Lots,  
 (ii) during the second Contract Year, a minimum of [\*\*\*] ([\*\*\*]) [\*\*\*] (or [\*\*\*]) of Product,  
 (iii) during the third Contract Year hereof, a minimum of [\*\*\*] ([\*\*\*]) [\*\*\*] (or [\*\*\*]) of Product, and  
 (iv) during the fourth Contract Year and every subsequent Contract Year thereafter, at least [\*\*\*] percent ([\*\*\*]%) of the total quantity of Product purchased by AMYLIN during each Contract Year for the manufacture of Exenatide Injection Drug for commercial sale anywhere in the world that MALLINCKRODT has authorized reference of its Drug Master File for Product or [\*\*\*] ([\*\*\*]) [\*\*\*] of Product whichever is greater.  
 Notwithstanding the above, AMYLIN shall not be required to purchase Product under this Agreement unless MALLINCKRODT manufactures and delivers all Product Validation Lots meeting all Product Requirements and Validation Requirements in accordance with this Agreement.  
 2.4 For each gram of Product supplied hereunder by MALLINCKRODT, AMYLIN will pay to MALLINCKRODT a price per gram based on the cumulative volume of Product ordered for supply during any given Contract Year. The per gram price to be billed to AMYLIN for any Lot or other discrete volume of Product shipped to AMYLIN during any Contract Year will be at the applicable price for Product based on the most recent Contract Year Forecast submitted by AMYLIN prior to the shipment by MALLINCKRODT of any such amount of  
 \* CONFIDENTIAL TREATMENT REQUEST(ED)  
 8  
  
 Product. Based on the foregoing, AMYLIN will pay to MALLINCKRODT a per gram price for Product (“Product Price”) in accordance with the following:  
 (i) if in any given Contract Year the amount of Product ordered for delivery is less than or equal to [\*\*\*] ([\*\*\*]) [\*\*\*], the price per gram will be $[\*\*\*],  
 (ii) if in any given Contract Year the amount of Product ordered for delivery is greater than [\*\*\*] ([\*\*\*]) [\*\*\*] but less than or equal to [\*\*\*] ([\*\*\*]) [\*\*\*], the price per gram will be $[\*\*\*],  
 (iii) if in any given Contract Year the amount of Product ordered for delivery is greater than or equal to [\*\*\*] ([\*\*\*]) [\*\*\*] but less than or equal to [\*\*\*] ([\*\*\*]) [\*\*\*], the price per gram will be $[\*\*\*],  
 (iv) if in any given Contract Year the amount of Product ordered for delivery is greater than [\*\*\*] ([\*\*\*]) [\*\*\*] but less than or equal to [\*\*\*] ([\*\*\*]) [\*\*\*], the price per gram will be $[\*\*\*],  
 (v) if in any given Contract Year the amount of Product ordered for delivery is greater than [\*\*\*] ([\*\*\*]) [\*\*\*] but less than or equal to [\*\*\*] ([\*\*\*]) [\*\*\*], the price per gram will be $[\*\*\*], and  
 (vi) if in any given Contract Year the amount of Product ordered for delivery is greater than [\*\*\*] ([\*\*\*]) [\*\*\*], the price per gram will be $[\*\*\*].  
 The Product Prices set forth in the immediately preceding sentence shall be firm through the first Contract Year ending on September 30, 2004, the date of October 1, 2004 being hereinafter referred to as the “Adjustment Date”. From and after the Adjustment Date, the Product Prices shall be adjusted to reflect increases or decreases in the cost to MALLINCKRODT of all raw materials, directly associated regulatory compliance costs and all  
 \* CONFIDENTIAL TREATMENT REQUEST(ED)  
 9  
  
 directly allocated labor (all of which costs are hereinafter referred to as “Product Costs”) [\*\*\*] compared to the immediately preceding Contract Year, in accordance with the following procedures. Within fifteen (15) days after the end of each Contract Year hereunder during the term hereof, MALLINCKRODT will notify AMYLIN in writing of the amount by which its Product Costs hereunder have changed during the immediately preceding Contract Year period and, if applicable, the adjusted Product Price to be charged for the next Contract Year just commenced as a consequence of such changes (“Annual Adjustment Notice”). The amount of any change in the Product Prices as set forth in any Annual Adjustment Notice shall be effective for all Product invoices by MALLINCKRODT to AMYLIN in accordance herewith during the Contract Year for which such Annual Adjustment Notice is issued.  
 2.5 If, with respect to any given Contract Year, it is clear that the annual volume assumptions on which the Product Prices reflected in any one or more invoices for Product shipped to AMYLIN during such Contract Year are based are incorrect, then within thirty (30) days after the end of such Contract Year, MALLINCKRODT will send corrected invoices to AMYLIN indicating the actual per gram price for Product shipped during such Contract Year with respect to such invoices based on the actual volume of Product ordered for delivery during such Contract Year. If, on the basis of all such corrected invoices with respect to a particular Contract Year, when considered in the aggregate, the amount paid or payable by AMYLIN for Product shipped during such Contract Year against invoices previously issued by MALLINCKRODT is in excess of the amount payable by AMYLIN pursuant to all such corrected invoices then MALLINCKRODT shall, contemporaneous with the delivery of such corrected invoices and at AMYLIN’s option, give AMYLIN a full refund of the excess amount or, with respect to any previously issued but as yet unpaid invoice, issue an appropriate credit equal to the excess amount of any such invoice. If, on the basis of all such corrected invoices with respect to a particular Contract Year, when considered in the aggregate, the amount paid or payable by AMYLIN for Product shipped during such Contract Year against invoices previously issued by MALLINCKRODT is less than the amount payable by AMYLIN pursuant to all such corrected invoices, then AMYLIN shall, within thirty (30) days after the receipt of such  
 \* CONFIDENTIAL TREATMENT REQUEST(ED)  
 10  
  
 corrected invoices, pay to MALLINCKRODT the full additional amount due as reflected on such corrected invoices.  
 2.6 Notwithstanding Paragraph 2.5 set forth immediately above, AMYLIN shall have the right (through any independent agents or representatives that are reasonably acceptable to MALLINCKRODT and upon advance written notice to MALLINCKRODT), with respect to any Contract Year ending not more than [\*\*\*] ([\*\*\*]) months prior to the date of notice requesting an audit, to audit the books and records of MALLINCKRODT to determine whether or not the amounts reflected on any original invoices relevant to any such Contract Year or any corrected invoices issued by MALLINCKRODT to AMYLIN in accordance with Paragraph 2.5 set forth immediately above are accurate, and in particular (without limitation) whether or not the Product Costs as reflected in any Annual Adjustment Notice have been reported and invoiced correctly by MALLINCKRODT, as applicable in any given case. In the event that, as a consequence of any such audit or examination, AMYLIN reasonably disagrees with any amounts set forth on original or corrected invoices issued by MALLINCKRODT, AMYLIN shall inform MALLINCKRODT in writing and in reasonable detail of the amounts to be refunded and, unless and to the extent MALLINCKRODT disputes the amounts set forth by AMYLIN in any such notice, MALLINCKRODT will refund to AMYLIN any such undisputed amounts within fifteen (15) days of the receipt of any such notice from AMYLIN. In the event MALLINCKRODT does dispute all or any portion of any refund claimed by AMYLIN, MALLINCKRODT will so notify AMYLIN within such fifteen (15) day period and the parties will attempt thereafter to resolve such dispute amicably and, if they cannot do so, may agree to submit the dispute to binding arbitration or independently pursue any other remedies available to them to resolve such dispute. AMYLIN shall bear the expense of such audit; provided, however, that, if such audit reflects overpayments by AMYLIN, which are undisputed or confirmed as overpayments pursuant to the dispute resolution procedure referred to in the preceding sentence, in excess of [\*\*\*] percent ([\*\*\*]%) of the payments actually due by AMYLIN hereunder for the applicable period, then MALLINCKRODT shall reimburse AMYLIN for the reasonable expenses of such audit.  
 2.7 At the time of shipment by MALLINCKRODT to AMYLIN of any Lot hereunder, MALLINCKRODT shall submit to AMYLIN an invoice setting forth the total  
 \* CONFIDENTIAL TREATMENT REQUEST(ED)  
 11  
  
 amount of Product being shipped to AMYLIN and the amount due to MALLINCKRODT pursuant to the volume assumptions made in accordance with Paragraph 2.4 hereof. Each such invoice shall also contain a certification that the Product for which AMYLIN is being billed has been produced fully in conformance with Product Requirements. Any such invoice shall be payable by AMYLIN within sixty (60) days after AMYLIN’s receipt of such invoice.  
 2.8 Within thirty (30) days after the Effective Date, AMYLIN shall submit to MALLINCKRODT a rolling forecast of Product that AMYLIN in good faith estimates it will order from MALLINCKRODT for the first Contract Year (as updated on a rolling basis, the “Contract Year Forecast”). Thereafter, on and as of the first day of each calendar [\*\*\*], AMYLIN will furnish MALLINCKRODT with an updated Contract Year Forecast indicating AMYLIN’s good faith estimate of the amounts of Product it expects to order during the next [\*\*\*] ([\*\*\*]) month period. The Contract Year Forecast will be non-binding and will be used by MALLINCKRODT for production planning, but in all circumstances AMYLIN shall act in good faith and with reasonable care to submit forecasts for Product which are as accurate as possible under the circumstances.  
 3. Manufacture of Product; Recordkeeping; Regulatory  
 3.1 Each party shall notify the other in advance of any proposed changes in Product Specifications, release testing, stability testing, packaging or processes in manufacturing of Product under this Agreement. No changes in Product Specifications, release testing, stability testing, packaging or the processes used to manufacture Product under this Agreement, except changes required by government or compendial standards, will be made unless AMYLIN and MALLINCKRODT have agreed to such changes in writing prior to adoption of modified release testing, stability testing, packaging, Product Specifications or process changes. Any such changes to the Product Specifications, release testing, stability testing, packaging or processes of manufacturing Product shall be handled in accordance with the procedures established in the Quality Agreement, with costs paid as described below:  
 \* CONFIDENTIAL TREATMENT REQUEST(ED)  
 12  
  
 (i) in the event AMYLIN requests any such changes be made, other than changes requested by any Governmental Agency or required to bring the Facility into compliance with Applicable Laws, MALLINCKRODT shall, to the extent technologically feasible, accommodate AMYLIN’s requested changes, provided that AMYLIN shall promptly reimburse MALLINCKRODT (i.e., upon presentation of an invoice from MALLINCKRODT with appropriate supporting documentation) for any incremental capital and other costs reasonably required in connection with such changes (provided Mallinckrodt has given AMYLIN advance written notice of the nature of such capital and other costs and provided further that AMYLIN shall have the right to withdraw any request for a change before implementation has begun if AMYLIN disagrees with or is unwilling to pay all of such capital and other costs); and provided further that, any ongoing costs incurred by MALLINCKRODT and reasonably required in connection with such changes shall be deemed to be [\*\*\*] for all purposes hereof;  
 (ii) in the event MALLINCKRODT requests any such changes be made, other than changes requested by any Governmental Agency or required to bring the Facility into compliance with Applicable Laws or to meet Validation Requirements, all costs reasonably required in connection with such changes shall be paid as mutually agreed by both parties; and  
 (iii) in the event changes are requested by a Governmental Agency or required to bring the Facility into compliance with Applicable Laws, or additional changes, activities, or manufacturing is required to bring the process into compliance with Applicable Laws, cGMP, Product Specifications, or other Product Requirements, MALLINCKRODT shall, to the extent technologically feasible, accommodate such changes, and all costs reasonably required in connection with such changes, activities, or manufacturing shall be deemed to be [\*\*\*] for all purposes hereof.  
 3.2 MALLINCKRODT shall maintain true and accurate books, records, test and laboratory data, reports and all other information relating to manufacturing under this Agreement, including without limitation all Validation Production Batch Records and all information required to be maintained by Applicable Laws. Such information shall be  
 \* CONFIDENTIAL TREATMENT REQUEST(ED)  
 13  
  
 maintained in accordance with MALLINCKRODT’s standard operating procedures for a period of at least five (5) years after the term of this Agreement, or longer if required under Applicable Laws.  
 3.3 MALLINCKRODT shall be responsible for obtaining and maintaining any establishment licenses or permits required by the FDA, Applicable Laws or Governmental Agencies that pertain to the manufacturing, handling and storage of the Product at the Facility. MALLINCKRODT hereby grants to AMYLIN and its Collaboration Partner the right to reference such establishment files for the purpose of obtaining and maintaining any regulatory approvals.  
 3.4 MALLINCKRODT shall advise AMYLIN within three (3) business days after an agent of any Governmental Agency visits a facility where manufacturing activity with respect to Product takes place. In such circumstance, MALLINCKRODT shall furnish to AMYLIN a copy of sections of any report issued by such Governmental Agency that relate to the Product or MALLINCKRODT’s performance hereunder, if any, within ten (10) days of receipt of such report. MALLINCKRODT shall provide to AMYLIN such notice as is reasonably practical under the circumstances of any action by a Governmental Agency resulting from an inspection of the Facility if such action may reasonably be anticipated to affect adversely either MALLINCKRODT’s ability to perform its obligations under this Agreement or AMYLIN’s rights hereunder.  
 3.5 MALLINCKRODT shall permit personnel and representatives of AMYLIN and its Collaboration Partner, upon reasonable advance notice, at reasonable intervals, and for reasonable duration during regular business hours, to visit the Facility or any other relevant MALLINCKRODT locations to audit compliance with this Agreement, including but not limited to the Product Specifications, cGMPs and Applicable Laws; provided, however, that such audits shall be conducted not more than once in any twelve (12) month period, except that AMYLIN and its Collaboration Partner shall be entitled to conduct “for cause” audits at any reasonable time and upon advance notice (i) following the implementation of measures in response to Form 483’s or similar reports delivered by Governmental Agencies to MALLINCKRODT pertaining to the manufacture of Product or (ii) if circumstances exist that are reasonably likely to adversely  
 14  
  
 affect the manufacture of Product or AMYLIN’s rights hereunder, and AMYLIN first discusses the reasons with MALLINCKRODT. All such audits by AMYLIN and its Collaboration Partner shall be conducted in a manner reasonably calculated not to interfere with MALLINCKRODT’s business activities and in compliance with MALLINCKRODT’s security and safety policies and procedures. All information obtained by AMYLIN or its Collaboration Partner in any such review (including, without limitation, the findings and results related thereto but excluding all Confidential Information of AMYLIN and its Collaboration Partner), shall be deemed MALLINCKRODT’s Confidential Information, provided, however. AMYLIN and its Collaboration Partner shall not be precluded from disclosing such MALLINCKRODT Confidential Information to Governmental Agencies to the extent and only to the extent required by law or for their regulatory filings. MALLINCKRODT will have the responsibility to audit its permitted subcontractors and suppliers at reasonable intervals for compliance with the Product Requirements, CGMPs and Applicable Laws. AMYLIN shall have the right to confirm audits of subcontractors and suppliers of MALLINCKRODT for any Products manufactured under this Agreement during its audits of MALLINCKRODT’s facilities.  
 3.6 MALLINCKRODT agrees to use its commercially reasonable efforts to assist AMYLIN and its Collaboration Partner in obtaining regulatory approvals from all Governmental Agencies with respect to the Product, including FDA approval of the NDA, subject to reimbursement by AMYLIN of all reasonable costs incurred in connection therewith. MALLINCKRODT specifically agrees to cooperate with any inspection by the FDA or other Governmental Agency, including but not limited to any pre-approval inspection in connection with the NDA. MALLINCKRODT shall, on a timely basis, provide AMYLIN and its Collaboration Partner with documentation, data, and such other information relating to Product that is reasonably necessary for and relevant to AMYLIN’s or its Collaboration Partner’s efforts to obtain, maintain, and support regulatory approvals relating to Product. MALLINCKRODT shall also provide, upon request by AMYLIN or its Collaboration Partner, non-proprietary and nonconfidential information concerning its production processes and quality control procedures with respect to Product. Without limiting the generality of the foregoing, MALLINCKRODT agrees to establish and maintain a Drug Master File (including, upon six (6) months advance notice from AMYLIN a foreign equivalent of a Drug Master File in those countries reasonably requested by AMYLIN) for the Product in accordance with the requirements of the FDA and any  
 15  
  
 other applicable Governmental Agency, and to provide AMYLIN and its Collaboration Partner with letters of authorization to, and rights to reference, the Drug Master File and any foreign equivalents thereof. Further, AMYLIN and its Collaboration Partner shall have the right to review the open Drug Master File, and all stability data, release testing results, impurity profiles, facility and equipment data, validation data and all information related to the validation of analytical method with respect to the Product. MALLINCKRODT shall update the Drug Master File and any foreign equivalents thereof in a timely manner to support any NDA filing. All information regarding all aspects of manufacture of Product necessary for and/or related to AMYLIN’s and/or its Collaboration Partner’s regulatory filings shall, at MALLINCKRODT’s option, either be (i) maintained by MALLINCKRODT in a Drug Master File or (ii) provided to AMYLIN or its Collaboration Partner for inclusion in their respective regulatory filings. During the course of a Governmental Agency’s review of the NDA, MALLINCKRODT shall inform AMYLIN and its Collaboration Partner of any comments (including indication of deficiencies) to the Drug Master File or any foreign equivalents thereof from any such Governmental Agencies, and MALLINCKRODT shall consult with AMYLIN and, in the case of Governmental Agencies outside of the United States, its Collaboration Partner, in drafting responses to any such comments.  
 3.7 AMYLIN and MALLINCKRODT shall promptly (and in any event within two (2) business days) advise the other of any safety or toxicity problem of which such party becomes aware regarding Product.  
 3.8 The obligations of MALLINCKRODT and AMYLIN set forth in this Section 3 are intended to comply with the Applicable Laws of each country where the Product is distributed, but only where MALLINCKRODT has authorized reference of its Drug Master File for Product. The requirements of this Section 3 shall therefore be construed and interpreted to comply with all such Applicable Laws, but only where MALLINCKRODT has authorized reference of its Drug Master File for Product.  
 3.9 Any and all release testing methods, Product Specifications, and stability data provided by AMYLIN or generated from information or data provided by AMYLIN shall be the Confidential Information of AMYLIN.  
 16  
  
 4. Recalls and Similar Actions  
 4.1 If there is a recall, withdrawal or field correction with respect to, or any governmental seizure of, Exenatide Injection Drug (“Recall Action”), which Recall Action is due in part to (i) the failure of Product manufactured by MALLINCKRODT to meet any of the Product Requirements, or (ii) the alleged negligent or intentional wrongful act or omission of MALLINCKRODT in connection with the manufacture of Product, then AMYLIN or, in the case of OUS Sales subject to a Recall Action, Collaboration Partner, will notify MALLINCKRODT promptly of the details regarding such Recall Action, including providing copies of all relevant documentation concerning such Recall Action. MALLINCKRODT will assist AMYLIN and its Collaboration Partner in investigating any such Recall Action, if AMYLIN or its Collaboration Partner so requests, and all regulatory contacts that are made and all activities concerning such Recall Action will be initiated and coordinated by AMYLIN or, in the case of OUS Sales subject to a Recall Action, Collaboration Partner with MALLINCKRODT’s involvement and assistance, as reasonably requested by AMYLIN or its Collaboration Partner.  
 4.2 If any Recall Action occurs which is due in part to (i) the failure of Product manufactured by MALLINCKRODT to meet any of the Product Specifications or Product Requirements, (ii) the failure of MALLINCKRODT to comply with cGMP requirements and the requirements of any other Applicable Laws, rules or regulations or (iii) the negligent or intentional wrongful act or omission of MALLINCKRODT in connection with the manufacture of Product, then MALLINCKRODT shall, to the extent and only to the extent of its relative responsibility, bear the cost and expense of any such Recall Action. Therefore, if both MALLINCKRODT and AMYLIN contribute to the cause of such a Recall Action, the cost and expense thereof will be shared in proportion to each party’s contribution to the problem.  
 5. Shipment and Delivery  
 On or before the delivery date of each shipment of Product MALLINCKRODT shall deliver to AMYLIN the COA for each Lot of Product being shipped. Delivery of the COA by  
 17  
  
 MALLINCKRODT to AMYLIN shall mean MALLINCKRODT has tested and analyzed such Lot of Product to ensure compliance with Product Specifications as defined in Exhibit B and other Product Requirements and, if applicable, Validation Requirements. MALLINCKRODT shall be primarily responsible for all such initial testing of Product; provided, however, AMYLIN shall have the right to subsequent inspection and final acceptance or rejection of such Product pursuant to the terms of this Agreement. MALLINCKRODT shall deliver each Lot of Product to the location specified by AMYLIN in its Purchase Order for such Lot. Each Lot of Product will be packed by MALLINCKRODT in accordance with AMYLIN’s specific instructions and standard operating procedure (currently AMYLIN SOP-QUM-146), a copy of which shall be provided to MALLINCKRODT. Product shall be delivered F.C.A. (Incoterms 2000) MALLINCKRODT’s Facility. Freight shall be pre-paid to the destination specified by AMYLIN in its Purchase Order. MALLINCKRODT will be responsible for arrangements regarding the shipping of Product to designated destinations but AMYLIN shall reimburse MALLINCKRODT for all applicable shipping charges.  
 6. Acceptance/Rejection of Product  
 6.1 Not later than [\*\*\*] ([\*\*\*]) days after receipt of each Lot of Product (other than Product Validation Lots), if AMYLIN believes that any such Lot does not comply with all of the Product Requirements (any Product failing to comply with the foregoing a “Defective Product”), AMYLIN shall notify MALLINCKRODT in writing of AMYLIN’s rejection of such Lot and the specific reasons therefor. If MALLINCKRODT does not agree that any such rejected Lot is Defective Product, both MALLINCKRODT and AMYLIN shall submit a sample of such Lot and other relevant information for analysis by an independent expert mutually satisfactory to the parties, and the decision of this independent expert as to whether such Lot of Product is Defective Product shall be final and binding upon the parties. The fees of such expert shall be borne by AMYLIN if such Lot is determined by such expert not to be Defective Product, or by MALLINCKRODT if such Lot is determined to be Defective Product.  
 6.2 If a Lot of Product (other than a Product Validation Lot) is rejected by AMYLIN as Defective Product and either MALLINCKRODT agrees to the rejection or the independent  
 \* CONFIDENTIAL TREATMENT REQUEST(ED)  
 18  
  
 expert determines that such Lot constitutes Defective Product, MALLINCKRODT shall, upon request from AMYLIN and at AMYLIN’s option, (i) promptly replace such Lot of Product at no additional expense to AMYLIN, (ii) promptly remedy the deficiency at MALLINCKRODT’s expense or (iii) immediately refund any amounts paid by AMYLIN for such rejected Lot. It is agreed that the remedies set forth in this Paragraph 6.2 are AMYLIN’s sole remedies in the event of any rejection by AMYLIN of Defective Product (but are subject to AMYLIN’s rights set forth in Paragraph 6.3). If AMYLIN has properly rejected Product and the deficiency causing it to be Defective Product cannot be remedied, AMYLIN will, at MALLINCKRODT’s option, either return such Defective Product to MALLINCKRODT or destroy or dispose of it in the least expensive and most environmentally sound manner and, in any event, MALLINCKRODT shall be responsible for the expense of any such return, destruction or disposal. Failure of AMYLIN to notify MALLINCKRODT in writing of rejection of a Lot as set forth herein within [\*\*\*] ([\*\*\*]) days of receipt of such Lot shall constitute acceptance of such Product Lot and such Lot cannot subsequently be rejected except for a Hidden Defect in accordance with Paragraph 6.3 set forth immediately below.  
 6.3 If, after AMYLIN’s acceptance of a Lot (including without limitation any Product Validation Lot), AMYLIN discovers in such Lot a Hidden Defect such as a Contaminant at any time after acceptance, AMYLIN shall notify MALLINCKRODT within [\*\*\*] ([\*\*\*]) days of such discovery of the Hidden Defect, and AMYLIN has the right to reject the Lot under the procedures regarding rejection set forth immediately above in Paragraph 6.2 and, in the case of a Product Validation Lot, in Paragraph 6.4.  
 6.4 With respect to all Product Validation Lots manufactured under this Agreement, AMYLIN shall have the right to reject any such Product Validation Lot, if such Lot, upon delivery to AMYLIN, does not comply with all Validation Requirements or Product Requirements. AMYLIN will have the right to reject any such Product Validation Lot by providing written notice to MALLINCKRODT not later than the later of either (i) [\*\*\*] ([\*\*\*]) days after receipt of such Lot, or (ii) [\*\*\*] ([\*\*\*]) days after the date when AMYLIN discovers or receives notice that the Lot does not meet all Product Requirements or all Validation Requirements (e.g., Governmental Agency deems that Lot does not satisfy all Validation Requirements and requires the re-manufacture of the Lot). If, after AMYLIN’s acceptance of any Product Validation Lot, AMYLIN rejects any of the other Product Validation Lots, then AMYLIN will have the right to reject any or all Product Validation Lots that were  
 \* CONFIDENTIAL TREATMENT REQUEST(ED)  
 19  
  
 previously accepted as not being in compliance with the requirement in Paragraph 8.1(vi) that all Product Validation Lots meet all Validation Requirements upon delivery to AMYLIN. For all Product Validation Lots rejected by AMYLIN, MALLINCKRODT shall, upon request from AMYLIN and at AMYLIN’s option, (x) promptly replace such Lot at no additional expense to AMYLIN, (y) promptly remedy the deficiency at MALLINCKRODT’s expense, or (z) immediately refund any amounts paid by AMYLIN for such rejected Lot. It is agreed that the remedies set forth in the immediately preceding sentence are AMYLIN’s sole remedies in the event of any rejection by AMYLIN of Product Validation Lot(s). Disposal of rejected Product Validation Lots and all work associated with completing all Validation Requirements to ensure that Product Validation Lots meet all Validation Requirements (including without limitation re-manufacture of Product Validation Lots to bring such Lots into conformance with Governmental Agency requirements) shall be at the sole cost and expense of MALLINCKRODT.  
 7. Term and Termination  
 7.1 This Agreement shall commence on the Effective Date, and unless earlier terminated as stated below, will continue for a period of five (5) Contract Years (“Initial Term), automatically renewing on an annual basis thereafter for additional single Contract Year terms.  
 7.2 This Agreement may be terminated as follows:  
 (i) either party may terminate this Agreement by written notice to the other party effective immediately (a) upon the institution by such other party of voluntary proceedings in bankruptcy or insolvency, or (b) sixty (60) days after the filing of an involuntary petition under any bankruptcy or insolvency law (unless such petition is dismissed or set aside within such 60-day period) against the other party, or (c) sixty (60) days after the appointment of a receiver or trustee for the assets of business of the other  
 20  
  
 party (unless such appointment is dismissed or set aside within such 60-day period);  
 (ii) if either party shall have committed a material breach and such material breach remains uncured and continues for a period of thirty (30) days following receipt of notice thereof by the non-breaching party, the non-breaching party may terminate this Agreement upon additional written notice given on or after the expiration of such thirty (30)-day period; or  
 (iii) AMYLIN may terminate this Agreement at any time by giving MALLINCKRODT at least thirty (30) days written notice in each of the following situations:  
(a) upon notice by the FDA or other applicable Government Agency that MALLINCKRODT has failed successfully to complete its Pre- Approval Inspection or equivalent non-United States inspection by failing adequately to respond to any FDA or other applicable Government Agency findings within thirty (30) days of inspection, and therefore is not an approved commercial supplier of Product,  
(b) upon notification by the FDA or other applicable Government Agency that it will not approve any NDA filed in the United States relative to Product,  
(c) upon withdrawal by AMYLIN of any Investigational New Drug Application containing Product,  
(d) if AMYLIN reasonably determines that discontinuation of all development and commercialization of Product is in the best interests of AMYLIN, and AMYLIN takes reasonable steps in order to discontinue all development and commercialization efforts by AMYLIN, its agents and licensees, or  
(e) in the event of a Force Majeure event preventing or impairing MALLINCKRODT’s performance hereunder which event has existed for at least ninety (90) continuous days;  
 21  
  
 (iv) AMYLIN may terminate this Agreement, in its sole discretion, at any time following the Initial Term, without cause, by providing at least ninety (90) days prior written notice to MALLINCKRODT; or  
 (v) either party may terminate this Agreement, effective as of the end of the Initial Term or any Contract Year renewal term following the Initial Term, by providing written notice to the other party hereunder at least one (1) year prior to the effective date of such termination, which notice may be sent at any time on or after the fourth (4th) Contract Year of this Agreement.  
 The parties acknowledge that the Collaboration Partner shall have the right, but not the obligation, to cure a breach of any material provision of this Agreement by Amylin if Amylin does not do so.  
 7.3 In the event of a termination by AMYLIN pursuant to subclauses (b), (c) and (d) of subparagraph (iii), subparagraph (iv) or subparagraph (v) of Paragraph 7.2 above, AMYLIN shall compensate MALLINCKRODT for (i) all inventory of finished Product then held by MALLINCKRODT at the applicable Product Price, (ii) MALLINCKRODT’s direct manufacturing costs for all then existing work-in-process with respect to Product and (iii) all actual costs of MALLINCKRODT for existing raw materials inventory to be used in any manner in connection with manufacture hereunder, in each case as the foregoing exist on and as of the effective date of such termination, and in each case to the extent related to purchase orders received by MALLINCKRODT through the effective date of termination.  
 7.4 Termination or expiration of this Agreement through any means or for any reason shall not relieve the parties of any obligation accruing prior thereto and shall be without prejudice to the rights and remedies of any party with respect to any antecedent breach of any of the provisions of this Agreement. The representations and warranties of the parties, which by their terms have effect after termination or expiration hereof, and the parties’ confidentiality and indemnification obligations, as well as this Paragraph 7.4, shall survive termination or expiration of this Agreement.  
 22  
8. Warranties  
 8.1 MALLINCKRODT represents, warrants, and covenants that  
 (i) upon delivery to AMYLIN, all Product shall:  
 a) meet all Product Specifications at the time of delivery and shall have been manufactured and packaged at the Facility in accordance with the Product Specifications,  
 b) be manufactured in accordance with all applicable requirements of the FDCA (including but not limited to cGMPs) and all other Applicable Laws, and be free from any Contaminants,  
 c) not be adulterated within the meaning of the FDCA or any Applicable Laws in which the definition of adulteration is substantially the same as in the FDCA (as such Applicable Laws are constituted and effective at the time of delivery), and will not be an article which may not, under the FDCA or any other Applicable Laws, be introduced into interstate commerce,  
 d) be manufactured using starting materials that are certified to be free of any TSE/BSE (transmittable spongiform encephalitis/bovine spongiform encephalitis) and originate from sources that are not of human, bovine, or ruminant animal tissue, and  
 e) be in undamaged containers;  
 (ii) each COA shall accurately and completely reflect the results of the tests conducted on the Lot of Product to which it relates;  
 (iii) the records maintained by MALLINCKRODT will reflect in all material respects the processes and procedures followed by it in manufacturing Product;  
 (iv) the use of the MALLINCKRODT Technology in connection herewith will not infringe any third party patent, copyright, trademark or other known intellectual property rights of any Third Party as such rights currently exist;  
 23  
  
 (v) all Product delivered shall be received by AMYLIN no later than either (a) [\*\*\*] ([\*\*\*]) months after the date of its actual manufacture if the applicable use period of such Product is [\*\*\*] ([\*\*\*]) years, or (b) [\*\*\*] ([\*\*\*]) months after the date of its actual manufacture if the applicable use period of such Product is [\*\*\*] ([\*\*\*]) years; and (vi) in addition to complying with the terms of 8.1 (i)(a) through (e) above, all Product Validation Lots shall meet all Validation Requirements upon delivery to AMYLIN.  
 8.2 EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, MALLINCKRODT MAKES NO OTHER WARRANTIES, EXPRESSED OR IMPLIED, WITH RESPECT TO PRODUCT OR ITS PERFORMANCE HEREUNDER, AND ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING WITHOUT LIMITATION, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE ARE HEREBY DISCLAIMED BY MALLINCKRODT.  
 8.3 EXCEPT FOR ANY DAMAGES AWARDED OR PAID TO A THIRD PARTY FOR WHICH A MALLINCKRODT INDEMNITEE (AS DEFINED BELOW) IS SEEKING INDEMNIFICATION PURSUANT TO THE PROVISIONS OF CLAUSE (iv) of PARAGRAPH 9.1, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO ANY PARTY OR PERSON FOR ANY SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES OF ANY NATURE WHATSOEVER, INCLUDING WITHOUT LIMITATION LOSS OF PROFITS OR BUSINESS INTERRUPTION, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES AND EVEN IF, UNDER ANY PARTICULAR SET OF CIRCUMSTANCES, SUCH DAMAGES ARE REASONABLY FORESEEABLE. THIS PARAGRAPH SHALL NOT BE CONSTRUED TO LIMIT A PARTY’S RIGHT TO SEEK ANY AVAILABLE REMEDIES FOR BREACH OF CONFIDENTIALITY AND NON-USE OBLIGATIONS.  
 9. Indemnification  
 9.1 AMYLIN shall defend, indemnify, and hold MALLINCKRODT and its Affiliates and its and their directors, officers, shareholders, insurers, employees, and agents  
 \* CONFIDENTIAL TREATMENT REQUEST(ED)  
 24  
  
 (“MALLINCKRODT Indemnitees”) harmless against any liability, judgment, demand, action, suit, loss, damage, cost or other expense, including reasonable attorney’s fees (“Damages”), resulting from any Third Party claims made or proceedings brought against a MALLINCKRODT Indemnitee to the extent that such liability arises from (i) AMYLIN’s negligence or willful act or omission regarding Product supplied under this Agreement, (ii) AMYLIN’s breach of any warranty or provision of this Agreement, (iii) AMYLIN’s violation of any Applicable Laws, rules or regulations and (iv) the manufacture (other than the manufacture of Product by MALLINCKRODT under this Agreement), sale, promotion, distribution or use of any product containing Product supplied under this Agreement by or on behalf of AMYLIN, including all product liability claims or proceedings; provided, however, that AMYLIN shall have no liability under this Paragraph 9.1 with respect to any Damages to the extent arising from matters as to which MALLINCKRODT has the obligation to indemnify pursuant to Paragraph 9.2 set forth immediately below.  
 9.2 MALLINCKRODT shall defend, indemnify, and hold AMYLIN and its Collaboration Partner and their respective Affiliates and its and their directors, officers, shareholders, insurers, employees, and agents (“AMYLIN Indemnitees”) harmless against any Damages resulting from any Third Party claims made or proceedings brought against an AMYLIN Indemnitee to the extent that such liability arises from (i) MALLINCKRODT’s negligence or willful act or omission in the manufacture, storage or delivery of Product, (ii) MALLINCKRODT’s breach of any warranty or provision of this Agreement, or (iii) MALLINCKRODT’s violation of any Applicable Laws, rules or regulation.  
 9.3 Procedures.  
 9.3.1 A party (the “Indemnified Party”) that intends to claim indemnification under this Section shall promptly notify the other party (the “Indemnifying Party”) in writing of any claim of a Third Party which may reasonably be expected to result in a claim for Damages (“Damage Claim”) by the Indemnified Party. Notice by the Indemnified Party to the Indemnifying Party shall include a copy of the Third Party claim. An Indemnifying Party shall have the right to direct the defense, compromise or settlement of  
 25  
  
 such claim with counsel selected by it, provided the Indemnifying Party gives written notice to the Indemnified Party of its election to do so within twenty (20) days after receipt of notice in accordance with the preceding sentence. If the Indemnifying Party fails to so notify the Indemnified Party of its election to defend any such Third Party claim, the Indemnified Party will (upon further notice to the Indemnifying Party) have the right to undertake the defense, compromise or settlement of such claim on behalf of and for the account and expense of the Indemnifying Party, subject to the right of the Indemnifying Party to assume the defense of such claim at any time prior to settlement, compromise or final determination thereof if and only if such assumption would not prejudice the defense of such claim or the rights of the Indemnified Party.  
 9.3.2 In the event an Indemnifying Party has assumed the defense of any such claim, the Indemnified Party shall nonetheless have the right to select its own counsel and participate in the defense of such claim at and for its own expense and account. Where the Indemnifying Party has assumed defense of any Damage Claim, the Indemnified Party and its counsel, if retained, shall consult and cooperate with counsel for the Indemnifying Party in defending against any such Third Party claim. Such cooperation shall include, without limitation, providing documents, making employees available for interviews, depositions and testimony and consultation on technical matters.  
 9.3.3 An Indemnifying Party shall not under any circumstances, without the written consent of the Indemnified Party, settle or compromise any claim or consent to the entry of any judgment which might in any material way prejudice or adversely affect the Indemnified Party or its continued business activities and which does not include as an unconditional term thereof the giving by the claimant or the plaintiff to the Indemnified Party a release from all liability in respect of such claim, in form and substance reasonably satisfactory to the Indemnified Party.  
 9.3.4 Notwithstanding anything to the contrary contained herein, with respect to a Third Party claim that can be settled by the payment of money, if a Third Party claim is made which the Third Party is unequivocally willing to settle but an Indemnified Party  
 26  
  
 elects not to settle, then the Indemnifying Party shall not be liable hereunder, with respect to any Damage Claim arising from such Third Party claim, for more than the amount which such Third Party at any time unequivocally agrees in writing to accept in payment or compromise of the claim plus any related costs and expenses incurred by the Indemnified Party as of the date of such offer of settlement.  
 9.3.5 All Damage Claims for indemnification hereunder shall be made in a written notice setting forth, with particularity, the nature of the claim for which indemnification is sought. The parties agree that no Damage Claim for indemnification shall be made hereunder unless the party requesting indemnification shall have a good faith belief that it is entitled to indemnification hereunder.  
 10. Confidential Information  
 10.1 Any and all knowledge, know-how, practices, specifications, methods, release testing methods, stability data, processes or other confidential or proprietary information of MALLINCKRODT, or AMYLIN and its Collaboration Partner (hereinafter referred to as “Confidential Information”) disclosed orally, by means of inspection or submitted in writing or in other tangible form by the disclosing party to the receiving party shall be deemed to be confidential and shall be received and maintained in strict confidence and shall not be disclosed to any Third Party without the prior written consent of the disclosing party, which consent shall not unreasonably be withheld or delayed. The recipient shall not use said Confidential Information for any purpose other than to facilitate the recipient’s performance under this Agreement, and the disclosing party’s Confidential Information shall at all times be and remain the sole and exclusive property of the disclosing party. The recipient may disclose Confidential Information to employees and/or consultants requiring access thereto for the purposes of this Agreement, and in the case of AMYLIN, to its Collaboration Partner; provided, however, that prior to making any such disclosures, Collaboration Partner and each such employee and consultant shall be apprised of the duty and obligation to maintain Confidential Information in confidence and not to use such information for any purpose other than in accordance with the terms and conditions of this Agreement. In any event, the recipient of any Confidential  
 27  
  
 Information shall be fully responsible for the improper disclosure or use of the Confidential Information by anyone to whom such Confidential Information is disclosed by the recipient. Each party shall take all steps reasonably necessary to assure that the Confidential Information received will be maintained in confidence by such party, including taking such steps as it normally takes to prevent the disclosure of its own proprietary and confidential information of like character.  
 10.2 The nondisclosure and non-use obligations of Paragraph 10.1 above shall not apply to Confidential Information which:  
 (i) is publicly known prior to disclosure or, subsequent to disclosure hereunder, has become publicly known and the recipient can demonstrate became publicly known without fault on the part of the receiving party,  
 (ii) the recipient can demonstrate was otherwise known by the receiving party prior to disclosure hereunder or was generated for the receiving party by persons who have not had access to or knowledge of the Confidential Information, or  
 (iii) the recipient party can demonstrate was received by the receiving party at any time from a source other than the disclosing party or its agents, lawfully having possession of such information and under no obligation of confidentiality with respect to such information.  
 Notwithstanding Paragraph 10.1, the recipient party may disclose Confidential Information of the disclosing party, without violating the obligations of this Agreement, to the extent the disclosure is required by a valid order of a court or other governmental body having jurisdiction, by any Governmental Agency or by Applicable Laws; provided that, the recipient party gives reasonable prior written notice to the disclosing party of such required disclosure and makes a reasonable effort to obtain, or to assist the disclosing party in obtaining, a protective order preventing or limiting the disclosure and/or requiring that the Confidential Information so disclosed be used only for the purposes for which the law or regulation requires, or for which the order was issued.  
 28  
  
 10.3 The obligations of this Article 10 shall be in effect during the term of this Agreement and for a period of five (5) years from the expiration or any earlier termination of this Agreement.  
 10.4 The parties hereto acknowledge and agree that any breach by either of them of the obligations set forth in this Article 10 may cause the other party irreparable damage of a type that cannot be adequately compensated by monetary damages and, therefore, in the event of such breach, the non-defaulting party shall have the right to seek an injunction or other appropriate equitable relief (without the requirement of posting a bond or any other financial assurance), in addition to any other remedies at law the non-defaulting party may have.  
 11. Force Majeure  
 If the performance by either party of any obligation under this Agreement is prevented or impaired by an event of “Force Majeure”, such party shall be excused from performance so long as such event continues to prevent or impair performance, provided the party claiming such excuse shall have promptly notified the other party of the existence, nature, expected duration and other significant details of such event and shall at all times use diligent and commercially reasonable efforts to resume performance. If either party anticipates that a Force Majeure event may occur, that party shall notify the other immediately and explain the nature, significant details and expected duration thereof. The party affected by an event of Force Majeure will advise the other from time to time as to its progress in remedying the situation and as to the time when the affected party expects to resume its performance of its obligations. Additionally, the party affected by an event of Force Majeure shall notify the other party of the expiration of any event of Force Majeure as soon as the affected party knows the date thereof. For purposes hereof, an event of “Force Majeure” shall mean an event beyond the reasonable control of a party including, but not limited to, fire, flood, sabotage, shipwreck, embargo, acts of terrorism, explosion, accident, riot, act of governmental authority, acts of God, acts of war, and unusually severe weather; provided that, MALLINCKRODT’s capacity constraints shall not be considered an event of Force Majeure hereunder. Notwithstanding the occurrence of a Force Majeure event,  
 29  
  
 if MALLINCKRODT shall be unable to supply during any Contract Year any Product ordered by AMYLIN that is not in excess of those estimated amounts stated in the applicable Contract Year Forecasts, AMYLIN and MALLINCKRODT will consult with each other to determine what measures may reasonably be taken to solve the supply problem. Notwithstanding the foregoing, if MALLINCKRODT undergoes a Force Majeure event that results in MALLINCKRODT failing to manufacture Product pursuant to any Purchase Order under this Agreement, the volume of any Product purchased by AMYLIN from alternate Third-Party suppliers during the duration of the Force Majeure event shall be applied towards the minimum purchase amounts in Paragraph 2.3 above for the applicable Contract Year. Further notwithstanding the foregoing, a party’s failure to pay to the other party any amounts payable hereunder as and when due shall in no event be excused by the occurrence of an event of Force Majeure.  
 12. Insurance. Upon AMYLIN’s request, MALLINCKRODT shall provide to AMYLIN written evidence reasonably satisfactory to AMYLIN of the sufficiency of MALLINCKRODT’s insurance program.  
 13. Notices  
 All notices, consents, approvals or other notifications required to be sent by one party to the other party hereunder shall be in writing and shall be deemed served upon the other party if delivered by hand or sent by United States registered or certified mail, postage prepaid, with return receipt requested, or by facsimile, air courier or telex, addressed to such other party at the address set out below, or the last address of such party as shall have been communicated to the other party. If a party changes its address, written notice shall be given promptly to the other party of the new address. Notice shall be deemed given on the day it is sent (in the case of delivery by method other than hand delivery) or the date of delivery (in the case of delivery by hand) in accordance with the provisions of this paragraph. The addresses for notices are as follows:  
 30  
  
 If to AMYLIN:  
Amylin Pharmaceuticals, Inc.  
 0000 Xxxxx Xxxxxx Xxxxx, Xxxxx 000  
 Xxx Xxxxx, Xxxxxxxxxx 00000  
 Attn: Xxxx Xxxxx, Senior Director of Manufacturing  
 Fax No.: (000) 000-0000  
 With a copy to:  
Amylin Pharmaceuticals, Inc. 0000  
 Xxxxx Xxxxxx Xxxxx, Xxxxx 000  
 Xxx Xxxxx, Xxxxxxxxxx 00000 Attn:  
 Xxxxx X. Xxxxxxx, Esq., Vice  
 President and General Counsel  
 Fax No.: (000) 000-0000  
 If to MALLINCKRODT:  
Mallinckrodt Inc.  
 X.X. Xxx 0000 000  
 XxXxxxxxx Xxxx. Xx. Xxxxx,  
 Xxxxxxxx 00000 Attn:  
 Xxxxxxx X. Xxxxxxx Fax No.:  
 000-000-0000  
 With a copy to:  
Mallinckrodt Inc.  
 X.X. Xxx 0000 000  
 XxXxxxxxx Xxxx. Xx. Xxxxx,  
 XX 00000  
 Attn: C. Xxxxxxx Xxxxxx  
 Fax No.: 000-000-0000  
 31  
  
 14. Binding Effect  
 This Agreement shall be binding upon and shall inure to the benefit of the parties hereto and their respective permitted assigns and successors in interest. Collaboration Partner is an intended Third Party beneficiary of the provisions and only those provisions of this Agreement specifically referring to Collaboration Partner.  
 15. Independent Contractor  
 In all matters relating to this Agreement, MALLINCKRODT shall be acting as an independent contractor and not as an employee of AMYLIN.  
 16. Assignment  
 Neither party shall assign this Agreement or any part thereof without the prior written consent of the other party; provided, however, that either party, without such consent, may assign or transfer the same: (i) in connection with the transfer or sale of substantially its entire business to which this Agreement pertains or in the event of its merger or consolidation with another company, or (ii) to an Affiliate, provided that such party guarantees the performance of the Affiliate to which the Agreement is assigned. Any permitted assignee shall assume all obligations of its assignor under this Agreement. No assignment shall relieve any party of responsibility for the performance of any accrued obligation which such party then has hereunder. MALLINCKRODT shall not subcontract the manufacture of Product or any other activity under this Agreement without the prior express written consent of AMYLIN, which consent shall not unreasonably be withheld or delayed.  
 32  
  
 17. Entire Agreement  
 This Agreement sets forth the entire agreement between AMYLIN and MALLINCKRODT with respect to its subject matter, and fully supersedes any and all prior and contemporaneous agreements or understandings pertaining to the subject matter hereof.  
 18. Severability  
 A determination that any portion of this Agreement is unenforceable or invalid shall not affect the enforceability or validity of any of the remaining portions hereof or of this Agreement as a whole, unless such unenforceability or invalidity goes to the essence of the agreement between the parties, in which case this Agreement shall be and become null and void as and from the date of such unenforceability or invalidity. In the event that any part of any of the covenants, sections or provisions herein may be determined by a court of law or equity to be overly broad or against applicable precedent or public policy, thereby making such covenants, sections or provisions invalid or unenforceable, and such determination does not go to the essence of this Agreement for either one of the parties hereto, then the parties shall attempt to reach agreement with respect to a valid and enforceable substitute for the deleted provisions, which shall be as close in its intent and effect as possible to the deleted portions.  
 19. Waiver - Modification of Agreement  
 No waiver or modification of any of the terms of this Agreement shall be valid unless in writing and signed by authorized representatives of both parties hereto. No course of dealing or usage of trade shall be applicable unless expressly incorporated in this Agreement. Failure by either party on any occasion to enforce any rights under this Agreement shall not be construed as a waiver of such rights nor shall a waiver by either party in one or more instances be construed as constituting a continuing waiver or as a waiver in other instances.  
 33  
  
 20. Publicity  
 In the absence of specific agreement between the parties, neither party shall originate any publicity, news release or other public announcement, written or oral, whether to the public press, to stockholders or otherwise relating to this Agreement or to performance hereunder.  
 21. Exhibits  
 All Exhibits referenced herein are hereby made a part of this Agreement.  
 22. Governing Law  
 This Agreement shall be construed and enforced in accordance with the laws of the State of New York, without reference to its conflict of laws principles that might apply the law of another jurisdiction.  
 23. Counterparts  
 This Agreement may be executed in any number of separate counterparts, each of which shall be deemed to be an original, but which together shall constitute one and the same instrument.  
 24. Headings  
 The parties agree that the section and article headings are inserted only for ease of reference, shall not be construed as part of this Agreement, and shall have no effect upon the construction or interpretation of any part hereof.  
 34  
  
 IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives.  
 MALLINCKRODT INC.  
AMYLIN PHARMACEUTICALS, INC.  
 By:  
 BY:  
 Name:  
 Name:  
 Title:  
 Title:  
 35  
  
 EXHIBIT A  
 STRUCTURE OF EXENATIDE COMPOUND  
 EXENATIDE Sequence: The sequence of said EXENATIDE shall be:  
[\*\*\*]  
 [\*\*\*]: Said EXENATIDE shall be [\*\*\*] from a [\*\*\*].  
 \* CONFIDENTIAL TREATMENT REQUEST(ED)  
 36  
  
 EXHIBIT B  
 PRODUCT SPECIFICATIONS  
 Purchase Specification AC2993 (Mallinckrodt)  
 [\*\*\*]  
 [\*\*\*]  
 [\*\*\*]  
[\*\*\*]  
 [\*\*\*] to [\*\*\*]  
 [\*\*\*]  
[\*\*\*]  
 [\*\*\*] mole ratio  
 [\*\*\*]  
 [\*\*\*] mole ratio  
 [\*\*\*]  
 [\*\*\*] mole ratio  
 [\*\*\*]  
 [\*\*\*] mole ratio  
 [\*\*\*]  
 [\*\*\*] mole ratio  
 [\*\*\*]  
 [\*\*\*] mole ratio  
 [\*\*\*]  
[\*\*\*]  
 [\*\*\*] mole ratio  
 [\*\*\*]  
 [\*\*\*] mole ratio  
 [\*\*\*]  
 [\*\*\*] mole ratio  
 [\*\*\*]  
 [\*\*\*] mole ratio  
 [\*\*\*]  
 [\*\*\*] mole ratio  
 [\*\*\*]  
 [\*\*\*] mole ratio  
 [\*\*\*]  
 [\*\*\*] mole ratio  
 [\*\*\*]  
 [\*\*\*] mole ratio  
 [\*\*\*]  
 [\*\*\*] mole ratio  
 [\*\*\*]  
 [\*\*\*] mole ratio  
 [\*\*\*] avg. [\*\*\*] by [\*\*\*]  
 [\*\*\*] Daltons  
 [\*\*\*]  
[\*\*\*]  
 Consistent with [\*\*\*]  
 [\*\*\*]  
[\*\*\*]  
 [\*\*\*]%  
 [\*\*\*]  
[\*\*\*] by [\*\*\*]  
 [\*\*\*]%  
 [\*\*\*]  
[\*\*\*]  
 [\*\*\*]%  
 [\*\*\*]  
[\*\*\*]  
 [\*\*\*]%  
 [\*\*\*]  
Total [\*\*\*] by [\*\*\*]  
 [\*\*\*]%  
 [\*\*\*]  
Individual [\*\*\*]  
 [\*\*\*]% [\*\*\*]% or greater  
 [\*\*\*]  
[\*\*\*]  
 [\*\*\*]%  
 [\*\*\*]  
 \* CONFIDENTIAL TREATMENT REQUEST(ED)  
 37  
  
 [\*\*\*]  
 [\*\*\*]  
 [\*\*\*]  
[\*\*\*]  
 Total [\*\*\*] by [\*\*\*]  
 [\*\*\*]%  
 [\*\*\*]  
Individual [\*\*\*] by [\*\*\*]  
 [\*\*\*]%[\*\*\*]% or greater  
 [\*\*\*]  
[\*\*\*] by [\*\*\*]  
 [\*\*\*]%-[\*\*\*]% of [\*\*\*]  
 [\*\*\*]  
 ([\*\*\*]%):  
 [\*\*\*]%-[\*\*\*]%[\*\*\*]  
 Purchase Specification AC2993 (Mallinckrodt) - Continued  
 [\*\*\*]  
 [\*\*\*]  
 [\*\*\*]  
[\*\*\*]  
 £ [\*\*\*]% ([\*\*\*])  
 [\*\*\*]  
 £ [\*\*\*]% ([\*\*\*])  
 [\*\*\*]  
 £ [\*\*\*]% ([\*\*\*])  
 [\*\*\*]  
[\*\*\*]  
 £ [\*\*\*]% ([\*\*\*])  
 [\*\*\*]  
 £ [\*\*\*]% ([\*\*\*])  
 [\*\*\*]  
 £ [\*\*\*]% ([\*\*\*])  
 [\*\*\*]  
 [\*\*\*] ppm  
 Report individual values  
 [\*\*\*]  
[\*\*\*]  
 [\*\*\*] EU/mg  
 [\*\*\*]  
[\*\*\*]  
 [\*\*\*]/g  
 [\*\*\*]  
[\*\*\*]  
 Report Result  
 [\*\*\*]  
[\*\*\*] analysis  
 Report Result  
 [\*\*\*]  
[\*\*\*] of [\*\*\*]  
 [\*\*\*] at [\*\*\*] mg/mL in [\*\*\*]  
 [\*\*\*]  
 [\*\*\*] Method  
 \* CONFIDENTIAL TREATMENT REQUEST(ED)  
 38