Exhibit 10.3  
Manufacturing and Supply Agreement  
Between  
CORCEPT THERAPEUTICS INCORPORATED  
000 Xxxxxxxxxxxx Xxxxx  
Xxxxx Xxxx, XX 00000  
XXX  
 •   
Here in after referred to as “CORCEPT”  
and  
Produits Chimiques Auxiliaires et de Synthése SA  
00 xxx Xxxxxxx  
00000 Xxxxxxxxxx Xxxxx  
Xxxxxx  
 •   
Here in after referred to as “PCAS”  
 •   
Here in after collectively referred to as “PARTY/PARTIES”  
Whereas  
 I. CORCEPT has certain patents and know-how with respect to the Product Mifepristone.  
 II. PCAS has the right to produce Mifepristone and has the right to manufacture the Product for CORCEPT for development and commercial use in neuropsychiatric indications.  
 III. PCAS has know-how and currently manufactures the product Mifepristone and wishes to manufacture the Product for CORCEPT and CORCEPT wishes PCAS to continue to produce and manufacture the Product and wishes to purchase the Product from PCAS subject to the terms and conditions set forth in this Agreement and in accordance with the Quality Agreement entered into between the PARTIES. It is the intention of the PARTIES that this Agreement is read in conjunction with the Quality Agreement.  
 Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [\*\*\*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.  
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 NOW THEREFORE IT IS HEREBY AGREED AS FOLLOWS:  
 1. Definitions  
 Finished Products IV. shall mean the finished form of pharmaceutical preparations containing the Product for human use in neuropsychiatric indications.  
Know-How shall mean all technical information known to or developed by PARTY/PARTIES  
Product shall mean the GMP material of Mifepristone, designated. by the chemical formula 11 ß-[p (dimethylamino)phenyl] 17ß- hydroxy-17a-(1-propynyl)estra-4,9-dien-3-one being produced in the form of a powder in bulk destined for Finished Products.  
Specifications shall mean the Specifications of the Product set by CORCEPT and defined in APPENDIX I hereto.  
Affiliates shall mean a corporation or other entity or person that directly or indirectly controls, is controlled by, or is under common control of a PARTY. For purpose of this definition, control shall mean direct or indirect possession of more than 50% of the capital shares of such corporation and effective control of more than 50% of the voting stock thereof.  
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 2. Subject  
 2.1 PCAS agrees to file a Drug Master File (“DMF”) type II with the US FDA as required to support CORCEPT’s NDA filing and will authorize the US FDA to reference the DMF in connection with CORCEPT’s NDA.  
 2.2 PCAS agrees to manufacture at FDA registered facilities and to deliver to CORCEPT the Product as specified in APPENDIX I and according to cGMP as specified in the current US guidelines and regulations (eg, US CFR 21 and ICH Q7A) and the Guide to GMP for Medicinal Products promulgated under European Directive 91/356/EEC, all as in effect from time to time hereafter. PCAS will supply Product for CORCEPT Finished Product from the facility(ies) for which Corcept has received regulatory approval.  
 2.3 CORCEPT agrees to take delivery of the Product on the terms and conditions set forth in this Agreement.  
 3. Supply, Forecast, Orders  
3.1 CORCEPT will, before the [ \*\*\* ] and every [ \*\*\* ] thereafter, advise PCAS of its estimated requirements for the ensuing [ \*\*\* ] on a [ \*\*\* ].  
3.2. CORCEPT will place firm and irrevocable orders, from time to time, at least  
[ \*\*\* ] before the required delivery.  
3.3 PCAS shall supply CORCEPT, at the required delivery dates, with the amounts of Product firmly ordered, up to [ \*\*\* ] of the estimated requirements of Product forecasted by CORCEPT pursuant to Section 3.1 above. To the extent CORCEPT’s firm orders exceed [ \*\*\* ] of the estimated requirements forecasted by CORCEP pursuant to Section 3.1 above, PCAS shall use its best endeavors and make all reasonable effort to fulfil such excess requirements.  
 3.4 PCAS shall confirm the firm orders within ten (10) days after receipt.  
 3.5 In case of reduction of quantity to deliver and/or delay of delivery date due to a Force Majeure as specified in Section 11, PCAS shall state the reasons which led to the reduction of quantity or delay of supply past the given delivery date. The Parties will reasonably cooperate to find a solution, which conforms to the requirements of CORCEPT and the capability of PCAS to ensure the supply of Product to CORCEPT.  
 [\*\*\*] Certain information on this page has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
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Manufacturing and Supply Agreement  
 4. Price/Quantities  
4.1 The price payable by CORCEPT to PCAS for the Product supplied hereunder shall be the price listed in APPENDIX II.  
4.2. In case changes to the Specifications and quality requirements requested by CORCEPT have an impact on manufacturing costs, a price adjustment will be agreed mutually.  
4.3 The price for Product will be adjusted annually starting in 2008 based on the US Government reported Producer Price Index - “Pharmaceutical preparation mfg - pcu325412325412”, with the base year being 2007 and the price adjustment will take effect for deliveries from July 1 to June 30th  
4.4 Corcept agrees to purchase 100% of their requirements from PAS through 6 months after NDA approval, 75% of their requirements from 6 months through 18 months after NDA approval and [ \*\*\* ] of their requirements beyond [ \*\*\* ] after NDA approval for the initial 5 year term of this Agreement and as long as PCAS has the capacity to supply the required amounts during such time. The foregoing obligation of CORCEPT excludes purchases of mifepristone by CORCEPT from an alternate supplier for purposes of development, analytical testing, manufacturing and regulatory activities required for CORCEPT to gain regulatory approval of that alternate supplier.  
 5. Terms of Payment  
5.1 Payments for Product in accordance with the terms of this Agreement will be made in U.S. dollars.  
5.2. Payment is due thirty (30) days after receipt of delivery and invoice.  
 6. Terms of Delivery  
Title of all Product shall pass to CORCEPT at PCAS manufacturing plant. PCAS shall deliver according to incoterms 2000 CIP to the USA via Airfreight. CORCEPT shall indicate the place of destination in the purchase order.  
 7. Specification, Quality Control, Warranty  
7.1 Upon receipt of Product, CORCEPT will have a period of sixty (60) days in which to notify PAS of its rejection of a delivered Product due to failure in whole or in part to conform to the Specifications; provided that in the case of latent defects written notice must be given to PCAS within sixty (60) days after discovery  
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 thereof. In the event CORCEPT has not lodged a notice of rejection of the Product within such sixty (60) day period, as applicable, then CORCEPT shall be deemed to have accepted that quantity of the Product as conforming to the Specifications. Subject to CORCEPT’s right to reject Product due to latent defects, it will not further process Product until it has been accepted.  
7.2 In the event a shipment of Product is rejected by CORCEPT, in whole or in part, PCAS shall promptly conduct appropriate tests as set forth in the Specifications to confirm CORCEPT’s test results PCAS shall not be responsible for any failure of the Product to satisfy the Specifications shown by the test results arising from inappropriate storage conditions of the Product at CORCEPT’s facilities or the facilities of any third party to whom CORCEPT has directed PCAS to deliver the Product or unduly prolonged customs clearance by CORCEPT, or any other cause excused under Article 11 of this Agreement.  
7.3 If PCAS testing does not confirm that CORCEPT’s rejection is justified, it shall immediately notify CORCEPT in writing, and technical representatives of CORCEPT and PCAS, respectively, shall meet to attempt to resolve the issues of disagreement. If the PARTIES cannot resolve the issue, they hereby agree to submit a sample each - one sealed by CORCEPT, one sealed by PCAS for this purpose, before shipping such samples of the Product under dispute to an independent laboratory to be mutually agreed upon. Such independent laboratory shall perform an analysis using the Specifications. The analytical result of the independent laboratory will be final and binding on the Parties. Costs connected with such test by the independent laboratory will be borne by the PARTY whose opinion was found to be in error.  
 8. Indemnification  
8.1 PCAS agrees to indemnify, hold harmless CORCEPT, its agents, directors, officers and employees, from, and defend against, any direct damages from third party claims (a) arising from material breach or gross negligence of PCAS in the performance of this Agreement or (b) from any material failure of the Product to meet the Specifications, in the case of (a) or (b) whether such claims concern personal injury, sickness, disease or death or otherwise. In the event of any such claim against CORCEPT or any agent, director, officer or employee by any third party, CORCEPT shall promptly notify PCAS in writing of the claim so that PCAS may at its option and expense, be represented in any such action or proceeding. PCAS shall bear all costs and expenses (including legal fees) arising in connection with any matter for which CORCEPT or its agents, directors, officers or employees, may be entitled to indemnification under this Section 8.1 and shall pay such costs and expenses on a current basis.  
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 8.2 CORCEPT undertakes to indemnify and hold PCAS its agents, directors, officers and employees harmless from, and defend against, any and all direct damages from third party claims (a) arising from material omissions or gross negligence of CORCEPT in the performance of this Agreement or (b) based upon or related to the manufacture, packaging, use, sale and distribution of the Finished Products containing the Product by CORCEPT, ifs Affiliates or distributors, in the case of either (a) or (b) whether such claims concern personal injury, sickness, disease or death or otherwise. PCAS shall promptly notify CORCEPT in writing of the claim so that CORCEPT may at its option be represented in any such action or proceeding. CORCEPT shall bear all costs and expenses (including legal fees) arising in connection therewith with any matter for which PCAS or its agents directors, officers or employees, may be entitled to indemnification under this Section 8.2 and shall pay such costs and expenses on a current basis.  
8.3 EXCEPT AS MAY BE SPECIFICALLY PROVIDED ELSEWHERE IN THIS AGREEMENT TO THE CONTRARY, IN NO EVENT SHALL EITHER PARTY BE LIABLE FOR INDIRECT, SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, OR FOR LOST PROFITS, BUSINESS OR REVENUES OF ANY PERSON, HOWEVER CAUSED OR BASED ON ANY THEORY OF LIABILITY ARISING OUT OF THE INDEMNITY PROVIDED IN SECTION 8.1 OR 8.2 REGARDLESS OF THE NOTICE OF THE POSSIBILITY OR THE FORESEEABILITY OF SUCH DAMAGES. EXCEPT AS SPECIFICALLY PROVIDED TO THE CONTRARY, EACH PARTY SHALL HAVE ALL REMEDIES TO WHICH THEY MAY BE ENTITLED UNDER THIS AGREEMENT, AT LAW OR IN EQUITY.  
8.4 Each PARTY agrees, at its sole expense, to defend or settle any actions brought against the other PARTY by any person alleging that the manufacture of the Product infringes one or more patent or other rights or constitutes an unauthorized use or misappropriation of its technology to the extent that such infringement or misappropriation would constitute a breach of that PARTY’s representations made in Section 19. In such event, each PARTY agrees to pay all damages and costs awarded by a court of competent jurisdiction against the other and all cost and expenses (including legal fees) arising in connection with any such action and shall pay such costs and expenses on a current basis.  
 9. Term  
9.1 This Agreement shall become effective on Nov 3, 2006 for an initial period of five (5) years. It shall be automatically extended for a one (1) year period unless one PARTY gives twelve (12) months’ prior written notice that it does not want such an extension.  
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 10. Termination for Cause  
10.1 In the event that either PARTY should commit a breach of any of its obligations under this Agreement, and shall have not cured such breach within sixty (60) days after receipt of written notice of breach from the other PARTY, then such other PARTY shall have the right to terminate this Agreement forthwith by written notice.  
10.2 In the event that either PARTY should become insolvent or makes an assignment for the benefit of creditors or proceedings in voluntary or involuntary bankruptcy should be instituted against it or a receiver or trustee of its property should be appointed, then the other PARTY shall have the right to terminate this Agreement forthwith by written notice.  
10.3 In the event that PCAS is not able to manufacture the Product according to the Specifications stated in APPENDIX I or for any reason should be unable (including but not limited to cases of Force Majeure) to supply the Product for a consecutive three (3) months period (whether in the quantities ordered or at all), CORCEPT may require that PCAS promptly transfer to CORCEPT, or its designee, the manufacturing process for Product and Finished Product including, but not limited to, all synthetic protocols, standard operating procedures, assays, standards, contact information for raw material suppliers and other vendors, and the like, together with the right to use and practice the same. In the event that PCAS would not able to manufacture the Product according to the Specifications stated in APPENDIX I or for any reason (including but not limited to cases of Force Majeure) to supply the Product for a total and consecutive six (6) months period (whether in the quantities ordered or at all), CORCEPT shall have the right to terminate this Agreement forthwith by written notice. The right to terminate is in addition to any other remedy available at law or in equity.  
 11. Force Majeure  
11.1 Neither PARTY shall be responsible for a failure or delay in its performance of its obligations hereunder due to causes beyond its control such as wars, insurrection, inability to obtain supplies, strikes, lockouts, acts of God, governmental actions or controls (whether or not contemplated on the date of signature of this Agreement) or other cause beyond the control of such PARTY. A PARTY whose performance has been delayed by causes beyond its control shall use its best efforts to overcome the effect thereof as soon as possible.  
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 12. Hardship  
12.1 If, at any time during the term of this Agreement, there is a substantial change in the economic, technological or market situation which will make the performance of this Agreement unrealistic or exceedingly unfair by either PARTY, aggrieved PARTY can request a meeting with the other PARTY to discuss the situation, but there is no obligation to adjust the terms of this Agreement.  
 13. Confidentiality  
13. 1. During the term of this Agreement and thereafter, each PARTY shall hold in confidence all Know-How provided in writing by the other PARTY, except for and to the extent that  
13.1.1 Know-How required to be disclosed to government agencies for the purpose of registering Products or Finished Products;  
13.1.2. Know-How that is or becomes part of the public domain through no fault of the receiving PARTY;  
13.1.3 Know-How that is disclosed with the prior written approval of the disclosing PARTY;  
13.1.4 Know-How that must be disclosed to those persons who have a need to know in order to effectuate the development of Products or Finished Products, provided that each such person has the obligation to hold the Know-How in confidence to the same extent as the receiving PARTY is obligated hereunder;  
13.1.5. Know-How that becomes known to PARTY from a source other than the disclosing PARTY without breach of this Agreement by the receiving PARTY; provided that such other source has the right to disclose such Know-How;  
13.1.6 Know-How that is disclosed pursuant to an order or requirement of a court, administrative agency or other government body.  
13.2 This obligation of confidentiality shall survive expiration or termination of this Agreement for a period of 10 years.  
13.3. The PARTIES agree to give one another at least two business days’ notice of any public disclosure of their relationship or the terms of this Agreement; provided that nothing shall prevent a PARTY from timely fulfilling its obligations under law or stock exchange regulations. Without limitation, PCAS agrees that CORCEPT may file a copy of this Agreement with the Securities and Exchange Commission without further notice to PCAS if CORCEPT determines that it is legally obligated to do so.  
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 14. Non-Assignability  
14.1 This Agreement and the rights and obligations hereunder shall not be transferable by either PARTY without the prior written consent of the other PARTY, which consent shall not be unreasonably withheld No consent shall be required in the case of a transfer in a merger, sale of shares, sale of assets or similar transaction that results in a change of control.  
14.2  
 15. Severability  
15.1 Should one of the provisions of this Agreement become or prove to be null and void, such event shall be without effect on the validity of this Agreement as a whole. Both Parties will, however, endeavor to replace the void provision with a valid one, which in its economic effect comes as close as possible to effectuating the intention of the void provision.  
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 16. Waiver  
16.1 If either PARTY should at any time refrain from enforcing its rights arising from a breach or default by the other PARTY of any of the provisions of this Agreement, such waiver shall not be construed as a continuing waiver regarding that breach or default or other breaches or defaults of the same or other provisions of this Agreement.  
 17. Entire Agreement and Notification  
17.1 The terms and conditions herein contained constitute the entire Agreement between the Parties with respect to the subject matter hereof.  
17.2. No modification or amendment of this Agreement shall be binding upon either PARTY hereto unless in writing and signed by duly authorized officers of the PARTIES. APPENDIX I and APPENDIX II of this Agreement form an integral part of this Agreement.  
 18. Governing Law; Dispute Resolution  
18.1 This Agreement shall be governed by and construed in accordance with the laws of the State of California without giving effect to the conflict of laws principles thereof. Any controversy, claim or dispute arising out of this Agreement shall be settled if possible through good faith negotiations between the PARTIES. If such negotiations are unsuccessful, such controversy, claim or dispute shall be finally resolved by binding arbitration before three arbitrators in a proceeding conducted in the English language under the commercial arbitration rules of the American Arbitration Association and held in New York, NY. Each PARTY shall select one arbitrator, and the two arbitrators so selected shall select a third, who shall preside. The award shall be made in accordance with California law, and shall be reasoned. The award may be entered by any court of competent jurisdiction. If one PARTY shall substantially prevail, as determined by the arbitrators, it shall be entitled to reimbursement from the other PARTY for its expenses, including reasonable attorneys’ fees.  
 19. Insurance  
19.1 For so, long as this Agreement is in effect, each PARTY shall procure and maintain, at its own expense, insurance policies, including product liability insurance, adequate to cover its obligations hereunder and which are consistent with normal business practices of prudent companies similarly situation. Such policies shall provide protection against claims, demands and causes of action arising out of any defects, alleged or otherwise, of Product and Finished Product.  
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Manufacturing and Supply Agreement  
 19.2 All of the foregoing policies shall be primary and noncontributory and shall include as an additional named insured the other PARTY. Each policy will be endorsed to provide that the insurers will give the other PARTY, or its designee, not less than 30 days prior written notice of any cancellation or material change in coverage. The policies shall be written by insurance companies with an A.M. Best rating of A-VIII or higher.  
19.3 If a PARTY fails to place or maintain insurance as required under this Agreement, the other PARTY of its designee may place and maintain such policy and all premium and other costs incurred by the other PARTY or its designee will be due to the first PARTY, which shall be entitled to offer such amounts against any other amounts due the second PARTY under this Agreement.  
 20. Representations  
20.1 PCAS represents and warrants that it has all right, power and authority to enter into and perform this Agreement, that is has been granted all rights and licenses necessary to manufacture the Product and that nothing contained in any other agreement or legal right prohibits or restricts PCAS from entering into and performing any part of this Agreement. PCAS represents and warrants that its manufacture of the Product will not infringe any patent rights or infringe or misappropriate any other intellectual property rights held by third parties. PCAS represents and warrants that PCAS has the rights that fully allow PCAS to manufacture the Product for CORCEPT in perpetuity and cannot be rescinded or cancelled.  
20.2 PCAS represents and warrants as of the date of this Agreement and continuously during its term that it has never been and none of its employees, affiliates and agents has ever been (i) debarred, (n) convicted or a crime for which a person can be debarred, (vi) threatened to be debarred, or (iv) indicted for a crime or otherwise engaged in conduct for which a person can be debarred under Section 335(a) of 335(b) of the US Federal Food, Drug, and Cosmetic Act or any similar statute of any other jurisdiction. PCAS agrees that it will promptly notify CORCEPT in the event of any facts inconsistent with this representation.  
20.3 The Parties acknowledge that Mifepristone is not covered by any composition of matter patent. CORCEPT represents and warrants that it holds exclusive rights to a U.S. patent covering the use of Mifepristone for the treatment of psychotic major depression.  
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 21. Notices  
Any notices, reports, consents or requests required or permitted under this Agreement shall be in writing and deemed to have been given (i) when actually received; (ii) when delivered personally, (iii) when sent by confirmed facsimile, (iv) ten (10) business days after having been sent by registered or certified mail, return receipt requested, postage prepaid; or (v) five (5) business days after deposit with an internationally recognized commercial overnight courier specifying next day delivery (if available, or two (2) day delivery otherwise) with written verification of receipt. All communications shall be sent to the addresses set forth below:  
If to PCAS:  
Produits Chimiques Auxiliarires et Synthese SA  
00 xxx Xxxxxxx  
00000 Xxxxxxxxxx Xxxxx  
Xxxxxx  
Attention: Xxxxxxx Xxxxxxxxx  
Telephone: 00-0-0000-0000  
Fax: 00-0-0000-0000  
If to Corcept:  
Corcept Therapeutics Incorporated  
000 Xxxxxxxxxxxx Xxxxx  
Xxxxx Xxxx, XX 00000  
XXX  
Attention: Xxxxxx. Xxx  
Telephone: 0-(000) 000-0000  
Fax: 0-(000) 000-0000  
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Manufacturing and Supply Agreement  
 Duly authorized for and Duly authorized for and  
on behalf of Corcept on behalf of PCAS  
08 November 2006  
 3rd November 2006  
Date Date  
/s/ Xxxxxx X. Xxx  
 /s/ Xxxxxxx Xxxxxxxxx  
Signature Signature  
Xxxxxx X. Xxx  
 Xxxxxxx Xxxxxxxxx  
Name Name  
President  
 Managing Director  
Position Position  
 APPENDIX I: Quality Specification  
APPENDIX II: Prices/Quantities  
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Manufacturing and Supply Agreement  
 CORCEPT MANUFACTURING SPECIFICATION  
 Specification No:  
 MAP003.01  
 Page:   
1 of 2  
Effective Date:  
 07 Nov 06 Supercedes: New  
Name:  
 C-1073, mifepristone, (11ß – [p-(dimethylamino)phenyl]-17ß – hydroxy-17a –(1-propynyl)estra-4,9-dien-3-one (IUPAC)  
SPECIFICATIONS  
 Test  
 Acceptance Criteria  
 Method  
Description  
 [ \*\*\* ] [ \*\*\* ]  
Identification  
 IR or  
HPCL  
 [ \*\*\* ]   
[ \*\*\* ]  
 [ \*\*\* ]  
Assay  
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Impurities  
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Water Content  
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Residue on Ignition  
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Melting Range  
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[ \*\*\* ]  
Recommended Packaging: [ \*\*\* ]  
Recommended Storage: [ \*\*\* ]  
Sampling Requirements: [ \*\*\* ]  
 [\*\*\*] Certain information on this page has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
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 CORCEPT MANUFACTURING SPECIFICATION  
 Specification No:  
 MAP003.01  
 Page:   
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Effective Date:  
 07 Nov 06 Supercedes: New  
Name:  
 C-1073, mifepristone, (11ß – [p-(dimethylamino)phenyl] 17ß – hydroxy-17a –(1-propynyl)estra-4, 9-dien-3-one (IUPAC)  
Specifications/Approval  
 Signature  
 Date  
Author  
 /s/ Xxxxxxx X. Xxxxxxx 07 Nov 00  
Xxxxxxx XX/XX Approval  
 /s/ Xxxxxxx X. Xxxxxxx 07 Nov 06  
Corcept Regulatory Approval  
 /s/ Xxxxxx X. Xxx 07 Nov 06  
Document Change History  
 Version  
 Change  
.01 [ \*\*\* ]  
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 APPENDIX II  
Prices  
 Yearly/Quantity  
$/€ Exchange  
Rate  
 [ \*\*\* ]kg  
 $/kg  
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