Exhibit 10.21  
CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED AS "(CONFIDENTIAL TREATMENT REQUESTED)" IN THE TEXT, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.  
Terms and Conditions for the Manufacture of Products by Ben Venue Laboratories, Inc  
This signed agreement is required to provide services and manufacture your Product at Ben Venue Laboratories, Inc. This agreement covers all Products & services for the development and manufacture of Products for your company at Ben Venue and remains in place until superceded by a formal supply agreement.  
By:  
Ben Venue Laboratories, Inc.  
000 Xxxxxxxxxx Xxxx  
Xxxxxxx, Xxxx 00000  
Hereinafter referred to as BVL, and  
CUSTOMER NAME  
ADDRESS  
CITY, STATE, ZIP  
Hereinafter referred to as Customer,  
agree to the following terms and conditions in reference to the development and manufacture of Customer's Products at BVL.  
1. Facilities  
1.1 BVL will provide manufacturing facilities that conform to current Good Manufacturing Practices established by the FDA and will perform its obligations hereunder and supply Product in accordance with all applicable laws and regulations and in accordance with written documentation provided to Customer.  
1.2 All services will be performed at BVL facilities unless otherwise agreed to in writing by BVL and Customer.  
2. Audits  
2.1 Customer and any third-party consultant appointed by Customer shall have reasonable access to observe and inspect BVL's facilities and procedures with respect to the Products including all analytical and manufacturing documentation directly related to the Products upon scheduling in advance with BVL's compliance manager. Any such Customer appointed third-party consultant must be pre-approved by BVL such approval not to be unreasonably withheld and be bound in writing to the Confidentiality Agreement signed by Customer and BVL. Customer shall have the right to one annual compliance audit each year to (i) observe, inspect and audit the manner in which BVL conducts quality control of Customer Products, (ii) inspect BVL's plant and records relating to BVL's quality and other controls related to its manufacture of the Products. For cause audits will be scheduled as mutually agreed to by the parties.  
2.2 Customer's employees and/or representatives including consultants who inspect BVL facilities shall comply with all BVL policies and procedures. Customer assumes all liability resulting from presence of Customer's employees at BVL facilities, except to the extent that any such liability is a result of BVL's negligence or willful misconduct.  
  
3. Materials & Documentation  
3.1 Customer will provide active drug substance and any other mutually agreed to Customer supplied components at (CONFIDENTIAL TREATMENT REQUESTED) in advance of scheduled manufacturing date in accordance with BVL's procedures.  
3.2 Customer must give BVL permission in writing to do ID only by label verification of the active drug substance, if no identification test is to be performed at BVL.  
3.3 BVL will release all materials provided by BVL.  
3.4 Customer will provide materials and manufacturing information necessary for the development and manufacturing of Products.  
3.5 Customer will specify samples to be sent for testing and provide address for shipment on the purchase order for all sample request not included in the Master Production Record.  
3.6 BVL will provide, at Customer's request, a copy of the BVL Drug Master File (DMF) and authorization for FDA to access the DMF. This may be used by the Customer to prepare a Regulatory filing.  
3.7 BVL shall deliver Product and/or Services to Customer in compliance with quotations provided to Customer which shall be referenced by quotation number on Customer's purchase order, which shall include by reference specifications mutually agreed upon by the Customer and BVL. For manufacturing services said specifications must be incorporated in the master batch record or in a special instruction to a specific batch record.  
3.8 BVL will submit to Customer a Certificate of Compliance, a Certificate of Analysis listing results of testing, and a completed batch record for each lot of Product shipped.  
3.9 Customer will provide written QC testing requirements, methods, specifications and reference standard for the Active Pharmaceutical Ingredient and drug Product. Customer will approve initial testing documents, the Master Production Record and any revisions of the documents thereafter. Revisions of approved documents requested within eight weeks of scheduled manufacturing or other services may cause a delay or postponement of manufacturing and/or other services requested by the Customer.  
3.10 Customer is responsible for notifying BVL with instruction for disposition of tailings and rejects, which will be incorporated into the Master Batch Record and include a shipment address for tailing and rejects if Customer requests return of tailings and rejects.  
3.11 Customer will evaluate BVL Certificate of Analysis and perform at least an identity assay upon all batches of Product manufactured for the Customer.  
3.12 Customer will be financially responsible for all materials purchased by BVL on Customer's behalf based on requirements communicated by Customer to BVL in forecast and/or Purchase Orders, in the event the materials become obsolete for any reason, including but not limited to termination of the project by Customer for any reason.  
4. Purchase Orders  
4.1 Customer will provide Purchase Orders with information defined in Item 4.2 (CONFIDENTIAL TREATMENT REQUESTED) in advance of the requested manufacturing date or (CONFIDENTIAL TREATMENT REQUESTED) in advance of the requested delivery date. Purchase Orders for other services will be issued by the Customer on a mutually agreed upon timeline with BVL. All purchase orders will reference the BVL quotation number(s) provided to Customer.  
  
4.2 The following information must be included on all Purchase Orders  
4.2.1 BVL end item number or description of service outlined in the Quotation provided to Customer  
4.2.2 BVL Product description or service description  
4.2.3 Batch Size in vials from Quotation  
4.2.4 Number of Batches  
4.2.5 Delivery Date (Date for BVL to release the lot and deliver Product & batch record)  
4.2.6 BVL Quotation Number for Product/Service  
4.2.7 Delivery Address  
4.2.8 Shipping requirements & Instructions (temperature, dedicated trucks, preferred carrier, overnight etc.) Contact name for Preferred Carrier, Temperature Monitors, Ship on BVL Release or Hold for Customer Authorization to Ship or Ship in Quarantine.  
4.2.9 Billing Address  
4.2.10 Special Instructions for Specific Batch  
(Examples)  
"Annual Stability Batch"  
"Process Validation Batch"  
"Special Sampling Instructions" mutually agreed to in advance  
4.2.11 Customer Lot# and Expiration Date if Applicable  
5. Forecast & Planning  
5.1 Customer shall submit at least (CONFIDENTIAL TREATMENT REQUESTED) before the start of each calendar quarter an updated estimate for both volumes and delivery dates of its requirement for Product for the following (CONFIDENTIAL TREATMENT REQUESTED). The estimated requirements for the (CONFIDENTIAL TREATMENT REQUESTED) of these (CONFIDENTIAL TREATMENT REQUESTED) shall be considered firm orders for which Customer will issue purchase orders pursuant to Section 4 of this agreement. In addition a (CONFIDENTIAL TREATMENT REQUESTED) forecast will be submitted by the Customer to BVL on an annual basis due by February 28th each year for the following (CONFIDENTIAL TREATMENT REQUESTED). Ben Venue shall provide Customer with a forecast template to be used for all forecasts. All forecasts provided shall be non binding on either party, unless agreed to in writing by both parties and shall be subject to acceptance of a purchase order which will be confirmed in writing by BVL.  
6. Insurance and Liability Limits  
6.1 Customer will retain title to and risk of loss of the bulk active drug substance, in process and in finished Product, except if BVL damages the material while in storage at BVL's facility, due to BVL's negligence or willful misconduct. BVL will maintain general liability insurance in an amount sufficient to cover the replacement cost of Customer supplied raw materials up to (CONFIDENTIAL TREATMENT REQUESTED), and will include Customer as an additional insured under the relevant policies. For Process related losses see BVL 6.2.  
6.2 After such time as all Production and Testing Procedures have been fully developed and validated and a complete and successful technical transfer to BVL's production department has occurred, BVL will reimburse Customer up to $(CONFIDENTIAL TREATMENT REQUESTED) per batch for any loss of customer supplied raw materials and/or components and will issue a credit for the manufacturing fee, if an invoice for the manufacturing fee has been issued for the production, for any batch of Product which does not meet the specifications contained in the master batch record,  
pro-rated over the usable portion of the batch if applicable. The monetary values of all Customer supplied raw materials and components must be disclosed to BVL prior to production in the questionnaire provided by BVL to Customer. The Customer is responsible for notifying BVL in writing of any changes in the value of the raw material or components supplied to BVL. Further, any such claim for a loss must be due to failure of BVL's personnel to follow directions or to gross negligence on their part.  
6.3 Neither party will be liable to the other party for consequential damages, including but not limited too loss of sales, profit, clinical trial costs, regardless of the reason for such consequential damages.  
7. Safety  
7.1 BVL and Customer shall mutually develop safety procedures for the handling and manufacture of Product and treatment and disposal of waste relating thereto that comply with all federal and state environmental and occupational safety and health requirements. Such procedures shall be included in a separate document and shall be followed by BVL and Customer in performing services under this agreement.  
7.2 Customer will provide Material Safety Data Sheets and other handling information required by law, to be provided prior to shipment of any material to BVL. BVL will not receive any material until all required information has been provided.  
7.3 Customer will provide BVL with all information regarding safety of biological and drug Products and will maintain currency of such information.  
8. Payment and Pricing  
8.1 Customer acknowledges that all invoices must be paid to BVL no later than (CONFIDENTIAL TREATMENT REQUESTED) days after the date of invoice, payment terms are (CONFIDENTIAL TREATMENT REQUESTED). For manufacturing services an invoice will be issued after BVL's Documentation Department has issued a Certificate of Compliance or, if applicable, at the time a Quarantine shipment is made, for non production services invoices will be sent in accordance with the terms outlined in Proposals / Quotations provided to Customer as work is performed for those services. Any invoice(s) remaining to be paid after (CONFIDENTIAL TREATMENT REQUESTED) days from the date of the invoice(s), unless such invoice(s) are in dispute, will result in BVL requiring Customer to pay all or part of the fee for services in advance for future orders until such time as Customer has reestablished its credit. In order to avoid penalty, Customer must notify BVL within (CONFIDENTIAL TREATMENT REQUESTED) after receipt of invoice if invoice is to be disputed.  
8.2 Customer acknowledges that all prices of Product shall be on the basis of (CONFIDENTIAL TREATMENT REQUESTED).  
8.3 Customer may be asked to prepay a minimum of (CONFIDENTIAL TREATMENT REQUESTED) of the amount of the Purchase Order with the Purchase Order, until acceptable credit history is established.  
8.4 BVL will consider that the Product has been accepted by Customer, unless BVL is notified in writing within (CONFIDENTIAL TREATMENT REQUESTED) after shipment of the completed batch record that the Product fails to conform to applicable specifications.  
8.5 Pricing will be established in Proposal/Quotations provided to Customer by BVL.  
9. Cancellation or Postponement  
9.1 Customer will pay a cancellation fee of (CONFIDENTIAL TREATMENT REQUESTED) of the price of the quoted batch if cancellation or postponement is within (CONFIDENTIAL TREATMENT REQUESTED) weeks of the scheduled manufacturing date. If cancellation occurs within  
  
(CONFIDENTIAL TREATMENT REQUESTED) weeks of the scheduled fill date, Customer is responsible for paying (CONFIDENTIAL TREATMENT REQUESTED) price of the scheduled production.  
10. Storage  
10.1 (CONFIDENTIAL TREATMENT REQUESTED) is responsible for storage charges for Products stored more than one month beyond BVL's release. A formal quotation for these charges may be obtained from (CONFIDENTIAL TREATMENT REQUESTED) Contract Service Department. These charges are reviewed annually. Short term storage of Product in BVL's warehousing facilities beyond one month must receive prior approval from BVL. Such approval will be granted on a space-available basis.  
11. Stability Program  
11.1 Customer is responsible for stability testing program. Customer may contract with BVL to perform stability testing under separate proposals provided to Customer by BVL based on a mutually agreed to protocol.  
12. Retention Samples  
12.1 Customer is responsible for maintaining retention samples of all finished Product shipped to Customer.  
13. Release for Sale and/or Distribution  
13.1 Customer is responsible for release of the final Product for sale or distribution.  
14. Complaints  
14.1 Customer is responsible for maintaining complaint file and notifying BVL of complaints relating to manufacturing defects.  
15. Regulatory  
15.1 Customer is responsible for securing the necessary regulatory approvals for the Product.  
15.2 Customer is responsible for Drug Listing of Product and providing a copy of Drug Establishment Regulatory Form 2656 to BVL once Product is approved by U.S. FDA for marketing.  
15.3 Customer will certify that the Product to be manufactured by BVL shall not be processed, packed, or distributed in violation of any provision of the Federal Food, Drug and Cosmetic Act.  
15.4 Customer is responsible for all Product specific Agency(s) filings including the Annual Report filing with the FDA.  
15.5 Customer is responsible to insure that all filings with any agency are consistent with the specifications for the Product contained in BVL's Master Batch Record, BVL SOP's or incorporated by reference in these documents.  
16. Confidentiality  
16.1 The terms of this Confidentiality section are mutual between BVL and Customer as either a Disclosing Party or Receiving Party as the case may be.  
  
16.2 The Disclosing party will provide to the Receiving party certain information including but not limited to, data, reports, patents, patent applications, trade secrets, or the like concerning any scientific, technical, financial, trade, or business information applicable to the project, the Confidential Information. The Receiving party agrees to protect and keep confidential all Confidential Information and all notes of information obtained pursuant to this Agreement. The Receiving Party agrees that it shall limit its use of the Confidential Information to performing certain services as mutually agreed to in writing by the Parties. The Receiving Party also agrees that it shall not use any Confidential Information, directly or indirectly, for its own benefit or that of any person, firm or corporation other than the Disclosing Party. All information exchanged regardless of format shall be considered Confidential Information.  
16.3 The Receiving Party agrees and acknowledges that the Confidential Information to be disclosed to it pursuant to this Agreement constitutes unique and valuable commercial and proprietary information of the Disclosing Party. Accordingly, the Receiving Party shall not duplicate, disclose, or discuss any such Confidential Information to or with third parties, without the prior written consent of the Disclosing Party. Except that the Receiving Party may disclose Confidential Information received by it under this Agreement only to those of its directors, officers, employees, agents, and consultants who have a need to know such Confidential Information in the course of the performance of their duties with respect to the purposes of this Agreement and who are bound by written agreement to protect the confidentiality of such Confidential Information in accordance with the terms hereof.  
16.4 Notwithstanding anything to the contrary herein, the Receiving Party shall not be obligated to maintain the confidentiality of any information provided to it under this Agreement which:  
a. Is already in the public domain at the time of disclosure to it, or  
b. at any time after disclosure to the Receiving Party becomes public knowledge through no fault of the Receiving Party;  
c. is disclosed to the Receiving Party by any third party who is free to make such disclosure; or  
d. is disclosed by the Receiving Party with the prior written consent of the Disclosing Party, or  
e. is information which the Receiving Party can establish was in it's possession prior to disclosure or was subsequently and independently developed by employees of or on behalf of the Receiving Party without use, direct or indirect, of Confidential Information protected by this Agreement.  
f. is required to be disclosed pursuant to a requirement of law, subject to provisions outlined in Item 16.8 of Section 16 of this agreement.  
16.5 The confidential undertakings and agreements of the Receiving Party shall survive termination of this Agreement. Promptly upon termination of this Agreement and request of the Disclosing Party, the Receiving Party shall return to the Disclosing Party all notes of information obtained pursuant hereto and summaries thereof and any copies of documents of the Disclosing Party, personnel interviews, or other Confidential Information in its possession. This agreement shall not be construed as a grant of any right or license to the Receiving Party with respect to Confidential Information or the Disclosing Party's Product or as a requirement to either party to enter into any further arrangement with respect to Confidential Information or the Disclosing Party's Product.  
16.6 The confidentiality obligations of this agreement shall be maintained for a period of five years beyond the expiration or termination of this Agreement.  
16.7 Provided all obligations of this agreement are maintained, the parties understand and acknowledge that the other may now market or have under development products which are competitive with products now offered or which may be offered by the other, and the parties' communications hereunder will not serve to impair the right of other to develop, make, use, procure, or market products or services now or in the future which may be competitive to those offered by the other party nor for the parties to disclose any planning or other information to the other.  
  
16.8 Notwithstanding any provision herein to the contrary, in the event that any Receiving Party hereafter becomes obligated by mandatory applicable law, regulatory rule or judicial or administrative order to disclose Confidential Information or any portion thereof, to any third party, governmental authority or court, the Receiving Party shall immediately notify the Disclosing Party thereof of each such requirement and identify the Confidential Information so required thereby, so that the Disclosing Party may seek an appropriate protective order or other remedy with respect to narrowing the scope of such requirement and/or waive Receiving Party's compliance with the provisions of this Agreement.  
16.9 Both parties agree that should this Agreement be breached, money damages would be inadequate to remedy such a breach. As a result, the non-breaching party shall be entitled to seek, and a court of competent jurisdiction may grant, specific performance and injunctive or other equitable relief as a remedy for any such breach of this Agreement. Such remedy shall be in addition to all other remedies, including money damages, available to a non-breaching party at law or in equity.  
16.10 Upon request, each party shall return all copies of the Confidential Information to the other party, except for a single copy to be kept by it's legal counsel in its confidential file for the purpose of determining compliance with its obligations of this agreement.  
16.11 Neither party will issue any press release or other public announcement relating to any activities involving the other party without the prior written consent of the other party, except where such announcements are required by law or regulation. The parties will use all reasonable efforts to consult with the other and cooperate with respect to wording of any such announcement.  
17. Batch Rejections  
17.1 BVL will reserve the right to sample and retest Product if, prior to Customer's release, Customer claims that Product fails to meet applicable specifications.  
17.2 Customer will provide an approved rework procedure (if Product can be reworked).  
17.3 In the event of a rejection of a batch of Product, BVL will cease further production of Product until such time as the results of the investigation have been communicated to Customer and Customer has confirmed the corrective action. Should Customer desire to have Product manufactured while the investigation is in process, (CONFIDENTIAL TREATMENT REQUESTED) will be responsible for the fees for service performed by BVL whether the batch is accepted or rejected by Customer or BVL. (CONFIDENTIAL TREATMENT REQUESTED) will provide a written statement of financial responsibility (CONFIDENTIAL TREATMENT REQUESTED) (CONFIDENTIAL TREATMENT REQUESTED) while investigations and corrective actions are being determined by BVL and Customer.  
17.4 Customer may reject any commercial, developmental or clinical Products manufactured for Customer if such Products fail to comply with Manufacturing Instructions and Specifications, incorporated in the master batch record, previously agreed upon by Customer and Ben Venue. However, until such time as all manufacturing processes and/or analytical procedures are validated, (CONFIDENTIAL TREATMENT REQUESTED) will be financially responsible for all BVL fees for services for each batch of Product provided by BVL, at prices confirmed by quotation(s) and purchase orders, unless such batch is rejected due to the gross negligence of BVL. Customer acknowledges that until all processes and methods are validated that additional cost may be incurred for unanticipated developmental issues.  
18. Term and Termination  
18.1 This agreement remains in effect until superceded by a future agreement or upon termination by either party.  
  
18.2 This agreement may be terminated by (CONFIDENTIAL TREATMENT REQUESTED) by giving (CONFIDENTIAL TREATMENT REQUESTED) written notice to (CONFIDENTIAL TREATMENT REQUESTED).  
19. Notices  
19.1 All notices required or permitted hereunder shall be given in writing and sent by mailed postage prepaid, certified or registered mail, return receipt requested, or sent by a nationally recognized express courier service, or hand-delivered at the following addresses:  
If to Ben Venue: Ben Venue Laboratories, Inc.  
A Boehringer-Ingelheim Company  
Attn: General Manager  
Contract Manufacturing Services  
000 Xxxxxxxxxx Xxxx  
Xxxxxxx, Xxxx 00000  
Fax: 000-000-0000  
  
If to COMPANY:  
   
MedImmune, Inc.  
Attn: Senior Director, Supply Chain Management  
000 Xxxxxxxx Xxxxx  
Xxxxxxxxx, XX 00000  
  
Cc.  
   
MedImmune, Inc.  
Attn: Legal Affairs  
00 Xxxx Xxxxxxx Xxxx Xxxx  
Xxxxxxxxxxxx, XX 00000  
 Notices shall be effective upon receipt. A party may change its address listed above by written notice to the other party.  
20. Amendments and Waiver of Provision  
20.1 This Agreement may only be amended by a written instrument duly executed by both parties.  
20.2 No waiver of any provision of this Agreement shall be effective unless the party whose rights are being waived duly executes it. No waiver with respect to any one occurrence, action, or inaction shall be effective with respect to any subsequent or other occurrence, action or inaction, similar or otherwise.  
21. Assignment  
21.1 This Agreement may not be assigned by either party hereto EXCEPT to an affiliate or a purchaser of all or substantially all of the stock or assets of either one of the parties without the prior written consent of the other and shall be binding upon and inure to the benefit of the successors and permitted assigns of each party.  
22. Governing Law  
22.1 This Agreement and the rights, duties and obligations of the parties hereunder shall be governed by and construed in accordance with the laws of the State of Delaware, USA.  
23. Miscellaneous  
23.1 Customer will provide the name and phone numbers of a contact person(s) who may be called at any hour during the times when BVL is manufacturing the Product.  
  
23.2 Nothing contained in this Agreement shall be construed, by implication or otherwise, as an obligation to enter into any further agreement relating to any of the Confidential Information or as the grant of a license to either party to use the other's Confidential Information other than for the purpose herein.  
 These terms and conditions supersede any conflicting Terms and Conditions contained with the Customer's Purchase Orders or on BVL's Purchase Order acknowledgment. Customer acknowledges that these terms and conditions are incorporated by reference on every purchase order.  
THIS DOCUMENT SUPERSEDES ALL OTHER DOCUMENTS AND AGREEMENTS.  
For BEN VENUE LABORATORIES, INC. (BVL)   
  
BY  
   
/s/ Xxxxx Xxxxxxxx, R. Ph.  
 Xxxxx Xxxxxxxx, R. Ph.  
 General Manager, Contract Manufacturing Services  
   
DATE: 10/17/2003  
  
For: Customer  
   
   
BY  
   
/s/ Xxxxxx Xxxxx  
 Xxxxxx Xxxxx  
 Vice President and General Manager, Manufacturing  
   
DATE: 10/16/2003