MANUFACTURING AND SUPPLY AGREEMENT  
  
This MANUFACTURING AND SUPPLY AGREEMENT (this "Agreement") is made as of June 1, 2011, (the "Effective Date") by and between Mikah Pharma, LLC, organized and existing under the laws of the State of Delaware, having offices at 00 Xxxxxx Xxxxx, Xxxxxxxxxxxx, Xxx Xxxxxx 00000, (referred to herein as "Mikah") and Elite Pharmaceuticals, Inc., a company organized under the laws of Delaware having offices at 000 Xxxxxx Xxxxxx, Xxxxxxxxx, XX 00000 (referred to herein as “Elite” or “Manufacturer”). Mikah and Elite are each a "Party" and together constitute the "Parties" to this agreement.  
  
A. WHEREAS Mikah desires that Elite performs certain services relating to the Product(s) (as defined below), including (a) developing and preparing the documentation required for the transfer of the manufacturing process to Elite’s facility and the filing of a CBE30 for the ANDA, and (b) manufacturing finished dosage forms appropriate for commercial sale, marketing and distribution in the Territory (as defined below) in accordance with the requirements of this Agreement; and  
  
B. WHEREAS Elite desires to perform such technology transfer, manufacturing and supply services to enable Mikah or its designees to commercially market, sell and distribute the Product(s) upon the terms and conditions of this Agreement entered into between the Parties and incorporated herein by reference.  
  
NOW, THEREFORE in consideration of the mutual covenants and agreements contained herein, the sufficiency and satisfaction of which are hereby acknowledged, Mikah and Elite hereby agree as follows:  
  
ARTICLE 1  
DEFINITIONS  
  
The following capitalized terms have the meanings set forth in this Agreement:  
  
"Affiliate(s)" shall mean any person or entity which, directly or indirectly, controls, is controlled by, or is under common control with, a party or its assignee. Control shall be determined based upon either their legal right to control or de facto control of the entity.  
 "ANDA" means Abbreviated New Drug Application and all amendments thereto, that have to date been filed with the FDA seeking authorization and approval to manufacture, package, ship and sell, as more fully defined in 21 C.F.R. Part 314, the Products, as well as the Abbreviated New Drug Application for any other Product hereafter added to the terms of this Agreement.  
  
"API" means the active pharmaceutical ingredient required for the Products.  
  
"Applicable Laws" means all laws, ordinances, codes, rules and regulations within the Territory applicable to the Manufacturing of the Product or in any territory applicable to any aspect thereof and the obligations of Elite or Mikah, as the context requires under this Agreement, including, without limitation: (a) all applicable federal, state and local laws and regulations of the Territory (including Environmental Laws) relating to the Manufacture of the Products; (b) the United States Federal Food, Drug and Cosmetic Act, and (c) the regulations promulgated under the FD&C Act including without limitation those regarding the Good Manufacturing Practices ("cGMP"), each as amended from time to time.  
  
"Confidential Information" is as defined in Section 10.2.  
  
"Data" shall refer to all data, materials, plans, reports, test results and other information developed solely by or for Mikah in connection with the Technology Transfer and/or the Manufacturing of the Products.  
 {\*\*\*} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended  
   
"Defective Product" means any Product that fails to conform to the Specifications or Applicable Laws.  
  
“Exhibit Batch” means a full commercial size GMP batch manufactured and tested by Elite to accommodate the CBE-30 filing.  
  
"Effective Date" means the date this Agreement was fully executed.  
  
“Equipment” means the equipment loaned by Mikah to Elite as defined in Exhibit E. The Equipment shall be returned to Mikah upon request.  
  
"Facility" means Elite's manufacturing facility located at 000 Xxxxxx Xxxxxx, Xxxxxxxxx, XX 00000.  
  
"FDA" means the United States of America Food and Drug Administration.  
  
"Intellectual Property" means without limitation, patents, patent applications, knowhow, trade secrets, copyrights, trademarks, designs, concepts, technical information, manuals, standard operating procedures, instructions or specifications.  
  
"Latent Defect" means a defect: (a) which could not reasonably have been discovered upon receipt and careful inspection of the Product and (b) for which the assignable cause has been attributed to the actions or omissions of Elite prior to delivery of the Product.  
  
"Manufacture(d)" or "Manufacturing" means the compounding, filling, producing, testing and/or packaging of the API and Raw Materials into a finished dosage form in accordance with the Specifications and the terms and conditions set forth in this Agreement.  
  
"Mikah Technology" means any and all data, Specifications, formulations, analytical methods, reports, studies, or other information in whatever form, relating to the Products, that are owned or controlled by Mikah as of the Effective Date and/or during the Term of this agreement.  
  
"Patent Defect" shall mean any instance where a Product, fails to conform to the Specifications or fails to conform to the indemnifications given by Elite herein, and such failure is discoverable upon reasonable physical inspection or standard testing procedures upon receipt by Mikah or its affiliates in accordance with applicable standard operating procedures.  
  
"Product" means each of the pharmaceutical products now or hereafter listed on Exhibit A, as it may be amended by the Parties from time to time.  
  
"Purchase Order" shall have the meaning set forth in Section 3.4.  
  
"Raw Materials" means all raw materials (including APIs), supplies, components and packaging necessary to manufacture and ship the Product in accordance with the Specifications.  
  
"Regulatory Authority" means any governmental regulatory authority within a Territory involved in regulating any aspect of the development, manufacture, testing, market approval, sale, distribution, packaging or use of the Product.  
  
"Rolling Forecast" shall have the meaning set forth in Section 3.2.  
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"Specifications" means with respect to each Product, the procedures, requirements, standards, quality control testing and other data and the scope of services as set forth or referenced in the ANDA, the relevant portions of which shall be supplied to Elite, and are hereby incorporated by reference into this Agreement, along with any amendments or modifications thereto, subject to the terms and conditions set forth in Article 7.  
  
"Technology Transfer" shall mean transfer of the ANDA’s manufacturing process and analytical methods developed or owned by Mikah to Elite, including but not limited to: the transfer of the formulation; range finding; the manufacture of a confirmation batch and an exhibit batch at the Facility; methods transfers and improvements; updating USP and regulatory requirements as they relate to the methods; selection of suitable API, excipients and specifications; the manufacturing of pivotal submission batches at the Facility and the preparation of all documentation required for Mikah’s filing and approval of a CBE30 with FDA.  
  
"Term" shall have the meaning set forth in Article 14.1.  
  
“Territory” means the United States of America, its territories, possessions, commonwealths and any other country, which the Parties agree in writing to add to this definition of Territory in an amendment to this Agreement.  
  
ARTICLE 2  
TECHNOGY TRANSFER, VALIDATION & RELATED SERVICES  
  
2.1 Services. Elite shall perform, at its sole cost and expense, all Technology Transfer, validation and qualification services (including: equipment, methods and facility qualification), validation and stability services required by Applicable Laws to commence manufacturing the Product for commercial sale by Mikah or its designees in accordance with the terms of this Agreement.  
  
2.2 Supply of API, Excipients and Packaging Material. Elite shall provide the API, excipients, capsules, bottles, labels and chemicals needed for the manufacture of the Product pursuant to this Agreement. Elite will be responsible for the testing and conforming release of the API, excipients and packaging materials and maintaining the required storage conditions directed by the Specifications.  
  
2.3 Labeling. Mikah shall provide Elite with all artwork copy or other material templates developed or produced by Mikah or its Affiliates for the Product labels, printed packaging materials and Product inserts. Elite shall purchase the labels and printed materials. Elite shall not make any changes to the artwork, copy or other materials submitted by Mikah without the prior written approval of Mikah or its Affiliates. Elite will submit to Mikah, for Mikah’s approval, a proof of all Product labels, printed packaging materials and Product inserts prior to printing.  
  
ARTICLE 3  
MANUFACTURE AND SUPPLY  
  
3.1 Supply and Purchase of Product. During the Term of this Agreement and subject to the provisions herein, Mikah shall purchase from Elite and Elite agrees to manufacture and supply solely and exclusively to Mikah, such Product as Mikah may order from time to time pursuant to this Agreement. Mikah hereby grants to Elite a nonexclusive, royalty-free license, under which Elite has no right to grant sublicenses, and to use Mikah Technology and the Work Product to Manufacture and supply Product solely for and to Mikah. Elite shall manufacture the Product at its Facility in accordance with the ANDA, the Specifications, Applicable Laws, and the terms and conditions of this Agreement. During the Term of this Agreement and subject to Mikah receiving final approval of the Product ANDAs from FDA, Mikah shall purchase the Product, in finished packaged form, from Elite in accordance with the terms and conditions of this Agreement. Elite shall not manufacture the Product or any derivative thereof, whether for itself or for any other company, broker, or distributor whatsoever subject to Section 9.1.13.  
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3.2 Forecasts. Commencing three months before the anticipated commercial launch of each Product, Mikah or Actavis, Mikah’s designee, shall provide Elite with non-binding rolling twelve (12) month forecasts of its Product requirements by delivery date. These forecasts will become binding only upon issuance of a Purchase Order by Mikah. The forecasts will be updated monthly during the first business week of each calendar month (“Rolling Forecasts”). The Parties agree to discuss the forecasts and the status of the business for the Product quarterly. The Parties further agree that all such forecasts are for planning purposes only and Mikah shall have no obligation to purchase Product consistent with such forecasts hereunder except as may be set forth in a Purchase Order (defined below). Elite agrees to keep at least that amount of inventory of Raw Materials on hand or with Elite to meet Mikah's forecasted Product requirements. It is understood between the Parties that all forecast information must be kept completely confidential.  
 3.3 Reliance on Forecasts. Elite shall use the forecasts to order and maintain the Raw Materials necessary to fulfil the forecasted Product requirements, taking into account the Raw Material vendor’s lead times, minimum order quantities, and Elite’s lead time. In no case will Elite maintain more than a three (3) month supply of Raw Materials without Mikah’s prior written consent.  
  
3.4 Purchase Orders. Mikah or Actavis, Mikah’s designee, shall submit Purchase Orders for Product (“Purchase Orders”) specifying: (a) the number of units of Product to be purchased, (b) the Price, (c) the expected delivery date, and (d) such other special terms and conditions that may be applicable to such order. For every delivery, per Product, a firm binding order must be made at least two (2) months in advance of delivery date or such lesser period of time that the Parties may agree to, in writing. Elite shall confirm the order and projected date of shipment within seven (7) calendar days after having received a Purchase Order. All Purchase Orders received and not rejected by Elite within 7 days of Elite’s receipt shall be deemed to have been confirmed by Elite in accordance with its reflected terms. Elite shall accept all Mikah Purchase Orders (whether submitted by Mikah or Actavis), as described herein. Though Elite shall not be obligated to fulfill any order received less than two (2) months prior to a requested shipment date for any Product, Elite shall use commercially reasonable efforts to accommodate any requested shipment date.  
 3.5 Capacity. Elite shall, at all times during the term hereof, maintain the Manufacturing capacity to supply at least 125% of the quantities forecasted by Mikah.  
 3.6 Terms of Sale. Mikah’ orders for Product shall be made pursuant to its (or Actavis’) standard form of Purchase Order. To the extent such Purchase Order contains terms or conditions that are in conflict with the terms and conditions of this Agreement, the conflicting terms or conditions of the Purchase Order will have no effect, unless Elite agrees, in writing, to such terms or conditions or that such terms and conditions will supersede the terms of this Agreement.  
 3.7 Order Cancellation or Changes. Mikah may cancel a Purchase Order or modify the date of shipment or the quantity of Product specified in a Purchase Order, by submitting a written change order to Elite at least thirty (30) days in advance of the previously requested date of shipment. All such change orders shall be binding and effective upon receipt by Elite. If Mikah requests a cancellation or modification of a Purchase Order less than 30 days in advance of the previously requested delivery date, such change order shall be binding and effective only upon the written approval by Elite. Elite shall use commercially reasonable efforts to approve the cancellation or modification requested by Mikah, or such other modifications that might be mutually acceptable, and shall advise Mikah of its determination within 3 business days of the submission of Mikah’s proposed change order. In the case of partial acceptance, Elite shall specify the quantities and date of shipment of the portion of the Order it can accept, and Mikah shall be entitled to fill any additional amounts not Manufactured by Elite from a Second Source.  
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3.8 Timeliness of Delivery. It is of essence to this Agreement that Elite delivers the Product at the date of shipment stated in the order confirmation. If for any reason Elite believes that delivery of any Purchase Order will be delayed, Elite shall promptly advise Mikah as well as the new anticipated delivery date. If Elite fails to deliver the full quantity of Product on or before the delivery date specified in the applicable confirmed Purchase Order, for any reason other than Force Majeure, Elite shall compensate Mikah for any losses or fines imposed by its direct or indirect customer, and Mikah shall have the right to find or use a second source for the supply of the Product.  
  
3.9 Shipment. All Products shall be delivered EXW, Elite’s loading dock. Upon Elite’s delivery of the Product EXW, Mikah will bear all risk of loss, delay, or damage in transit as well as all costs of further shipment and appropriate insurance. All Product delivered hereunder shall be suitably packed for shipment by Elite in accordance with good commercial practice, and instructions provided to Elite by Mikah, with respect to protection of such Product during transportation and marked for shipment to Mikah. Such shipment shall also include a Certificate of Analysis (“C of A”) and a Certificate of Compliance (“C of C”) in accordance with the terms of the Quality Agreement.  
 3.10 Residual Materials. If Mikah (i) cancels or modifies its Purchase Orders pursuant to Section 3.7, or (ii) requests that Elite purchase any Raw Materials prior to the placement of the related Purchase Order, which creates residual inventory of the API or other Raw Materials that Elite has purchased in accordance with the terms of this Agreement, Mikah shall purchase any API and other Raw Materials that Elite purchased in accordance with Section 3.3 of this Agreement which Elite cannot return or use elsewhere, as reasonably determined by Elite. Mikah shall purchase such API or other Raw Materials from Elite for an amount equal to Elite’s actual cost therefore, within sixty (60) days of Elite’s written request and delivery of such Raw Materials, provided Elite certifies to Mikah that the API and other Raw Materials purchased by Mikah have been stored and otherwise maintained by Elite under cGMP conditions.  
  
3.11 First Priority. Elite hereby agrees that it shall not Manufacture or process goods for itself or for a third party where to do so will, as a consequence, delay delivery of Mikah's firm Purchase Order requirements of Product under this Agreement or cause Elite to refuse or fail to accept a Purchase Order in the manner set forth herein. With respect to Phedimetazine tartrate 37 mg finished product; in addition to other obligations and remedies under this Agreement, whenever shipment of Product orders is delayed beyond the date specified in this Agreement, Elite shall use commercially reasonable efforts to expedite shipment of the Product to MIKAH, and shall exert at least equivalent effort in resolving a Product shortage as compared to ELITE’s production requirements for its other customers’ production requirements.  
 3.12 Second Source. During the term of this Agreement, Mikah may, upon six (6) months written notice to Elite, seek to establish a second source for the Manufacture of any or all of the Products. Upon notice of such intention, and in compliance with all applicable confidentiality obligations set forth herein or elsewhere, Elite shall cooperate in any way reasonably necessary to permit such second source to be validated as a Manufacturing site of the Product under the ANDA.  
  
3.13 Facility Transfer. In the event that Elite breaches any of its obligations or requirements under this Agreement and fails to cure any such breach within 60 days of notice thereof by Mikah (or if earlier, on the date such breach results in the inability of Mikah to sell and market the Products or any of them under the provisions of the FD&C Act or applicable laws), Mikah shall have the right to take all actions necessary to accomplish a Technology Transfer to a different manufacturing facility for the Product so effected (a “Facility Transfer”). The Facility Transfer shall be at the cost and expense of Elite. Upon and after a Facility Transfer made pursuant to this Section, Mikah shall not be obligated to make any payments to Elite with respect to Product that is not manufactured at Elite's Facility. Any Facility Transfer shall be effective until the Product Termination Date for each individual Product. The rights of Mikah under this Section shall be in addition to its other rights under this Agreement.  
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ARTICLE 4  
PRICE AND PAYMENT  
  
4.1 Supply Price and Other Payments. Attached hereto as Exhibit B is the pricing for the Product and certain additional payments that shall be made by Mikah to Elite in connection with this Agreement.  
  
4.2 Audit Right. Mikah reserves the right, upon advance written notice to audit Elite's documentation related to any charges submitted to Mikah. In the event that such an audit results in a calculation, which differs, from the audited party's calculations, the Parties agree to negotiate in good faith to reach agreement as to the amount of the Price adjustment. In the event that the Parties cannot reach agreement, the Parties agree to hire an independent third party auditor, and share the costs of such audit, whose determination shall be binding on both Parties.  
  
4.3 Payment Terms. All amounts payable under this Section shall be expressed in United States Dollars and shall be due and payable by Mikah to Elite within 60 of delivery of the finished packaged lots. All payments shall be made by wire transfer in accordance with written instructions given by Elite from time to time.  
  
ARTICLE 5  
PRODUCT CONFORMITY TO SPECIFICATIONS  
  
5.1 Notification of Defective Product. Mikah shall notify Elite within sixty (60) days after receiving the Product if Mikah has determined that such shipment contains a quantitative defect such that Elite has delivered a quantity of Product that is less than the quantity stated in any invoice or xxxx of landing. Elite shall, at its own cost and expense, supply Mikah with any missing quantities of Product as soon as practical after receipt of such Notice (as defined herein). Notice of Patent Defect shall be provided by Mikah to Elite within sixty (60) days of inspection of Product in such shipment. Mikah shall provide Elite a sample of such Defective Product. Notice of a Latent Defect shall be provided within thirty (30) days after Mikah notices the Latent Defect.  
  
5.2 Resolution of Defective Product. Notwithstanding the foregoing, Mikah shall have the right to reject any batch of Product having Latent Defects prior to the expiry of such batch of Product. If Elite agrees that the batch is Defective Product, Elite shall, at its option, replace the Defective Product or repay the full amount of any payments, including shipping and recall costs and cost of API, made by Mikah for such Product. If Elite does not agree with Mikah's determination that such Product is Defective Product, then after reasonable efforts to resolve the disagreement, either Party may submit a sample of such Product to a mutually agreed upon independent third party who is an expert or is familiar with the industry to determine whether the Product meets the Specifications. The independent party's results shall be final and binding and if such results indicate that the Product was a Defective Product, Elite shall, at its option, replace the Defective Product or repay the full amount of any payments, including shipping costs and cost of API, made by Mikah for such Product. Unless otherwise agreed to by the Parties in writing, the costs associated with such testing and review shall be borne by the non-prevailing Party.  
  
ARTICLE 6  
DELIVERY  
  
6.1 Delivery. Elite shall segregate and store all Product until its shipment on the dates reasonably meeting the delivery dates specified by Elite’s commitments issued in connection with Mikah's Purchase Orders. Elite shall tender the Product for delivery to the destination specified by Mikah. Mikah shall be responsible for all costs associated with the Product after delivery by Elite to the specified destination in accordance with the terms of this Agreement.  
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 6.2 Shelf Life. All Product shipped to Mikah shall have at least twenty-one (21) months of saleable shelf life remaining upon receipt of Product at destination in accordance with Section 6.1 except for the exhibit and validation lots.  
  
ARTICLE 7  
CHANGES TO SPECIFICATIONS  
  
All Specifications and any changes thereto agreed to by the Parties from time to time shall be in writing, dated and signed by the Parties. No change in the Specifications shall be implemented by Elite without the prior written approval of Mikah. Elite shall respond promptly to any request made by FDA or Mikah for a change in the Specifications or the Facility, and both Parties shall use commercially reasonable, good faith efforts to agree to the terms of any requested change in the Specifications or the Facility that affects the Manufacture of the Product in a timely manner.  
  
ARTICLE 8  
RECORDS AND REGULATORY MATTERS  
  
8.1 Batch Records and Data. Within a reasonable period of time following the completion of Manufacturing of the first batch of each Product, and on the anniversary of the signing of this Agreement thereafter, Elite shall provide Mikah with properly completed copies of batch records prepared in accordance with the Specifications; provided, however, that if testing reveals an out-of-Specification result, Elite shall provide such batch records within 14 days following resolution of the out-of- Specification result. In addition, for all shipments of Product, Elite shall provide Mikah with an accurate COA and Mikah shall accept such COA given in good faith, regardless of whether or not Mikah shall accept the Product.  
  
8.2 Recordkeeping. Elite shall maintain true and accurate books, records, test and laboratory data, reports and all other information relating to Manufacturing under this Agreement, including all information required to be maintained by all Applicable Laws. Such information shall be maintained in original forms, notebooks and records for a period of at least three (3) years from the relevant finished Product expiration date or longer if required under Applicable Laws.  
  
8.3 Regulatory Compliance. Elite shall act as Mikah’s regulatory agent and shall be responsible for the correspondence with the Regulatory Authority with respect to the Product and the Specifications, including any product licenses, applications and amendments in connection therewith. Elite will be responsible to maintain all permits and licenses required by any Regulatory Authority with respect to the Facility and its equipment and the manufacture and distribution of the Product. Each Party intends and commits to cooperate to satisfy all Applicable Laws within the scope of its respective responsibilities under this Agreement.  
  
8.4 Regulatory Correspondence. Mikah shall be the sole owner of the ANDA. Elite shall notify Mikah immediately of any correspondence, any inspections, and the result of any inspection(s) with the FDA or any Regulatory Authority. Elite shall immediately send a draft to Mikah of all correspondence Elite intends to send to any Regulatory Authority, related to the Product. For all correspondence with a Regulatory Authority, related to the Product that is not in response to a regulatory deficiency or problem, Mikah shall have fourteen (14) business days to approve the draft correspondence, and if Mikah is silent after fourteen (14) business days, it is understood Mikah gives its constructive consent to the correspondence. For all correspondence with a Regulatory Authority, related to the Product that is in response to a regulatory deficiency or problem, Mikah shall have the absolute right to approve the draft correspondence before such correspondence is sent to the Regulatory Authorities. In such a case, Mikah will make every effort to act expediently in approving the draft correspondence.  
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8.5 Governmental Inspections and Requests. Elite shall immediately advise Mikah if an authorized agent of any Regulatory Authority visits the Facility or any portion thereof, which may affect the Manufacturing of the Product. Elite shall furnish to Mikah a copy of the report by such Regulatory Authority, if any, within ten (10) days of Elite's receipt of such report. Further, upon receipt of a Regulatory Authority request to inspect the Facility or audit Elite's books and records and such inspection would affect the Manufacturing under this Agreement, Elite shall immediately notify Mikah, and shall provide Mikah with a copy of any written document received from such Regulatory Authority.  
  
8.6 Recall. In the event Elite believes a recall, field alert, Product withdrawal or field correction may be necessary with respect to any Product provided under this Agreement, Elite shall immediately notify Mikah in writing. (For the sake of clarification "immediately" as used in this section shall mean no more than two (2) days.). Elite will not act to initiate a recall, field alert, Product withdrawal or field correction without the express prior written approval of Mikah, unless otherwise required by Applicable Laws. In the event Mikah believes a recall, field alert, Product withdrawal or field correction may be necessary with respect to any Product provided under this Agreement, Mikah shall immediately notify Elite in writing and Elite shall provide all necessary cooperation and assistance to Mikah. The cost of any recall, field alert, Product withdrawal or field correction shall be borne by Mikah except that Elite shall be obligated to reimburse Mikah for recall, field alert, Product withdrawal or field correction costs incurred by Mikah to the extent such recall, field alert, Product withdrawal or field correction is caused by Elite's breach of its representations, warranties, or obligations under this Agreement, Applicable Laws or its negligence or willful misconduct. For purposes hereof, recall costs shall be limited to reasonable, actual and documented administrative costs incurred by Mikah or third party customers directly in connection with such recall, withdrawal or correction, replacement and disposal of the Defective Product to be recalled, in accordance with Article 5.  
  
8.7 Inspections and Audits by Mikah. Representatives of Mikah shall have access to the Facility for the purpose of: (a) conducting inspections of such facility and Elite's maintenance and usage of the equipment utilized in the development and manufacture of Product, (b) performing quality control audits or (c) witnessing the development, manufacturing, storage or transportation of the Product or the materials related to or used in the manufacture of Product including API. Mikah shall have access to the results of any tests performed by Elite relating to Product and the API or the processes or materials used in the development and manufacture. Elite shall use its best efforts to ensure that Mikah has similar access to the facilities, data and records of Elite's or Elite’s agents. Such inspections do not relieve Elite of any of its obligations under this Agreement or create new obligations on the part of Mikah. Such visits by Mikah's representatives shall be conducted during normal business hours.  
  
ARTICLE 9  
REPRESENTATIONS AND WARRANTIES  
  
9.1 Elite. Elite hereby represents, warrants and covenants to Mikah that:  
  
9.1.1 At the time of each delivery of the Product as provided under this Agreement, such Product and its corresponding Raw Materials will conform to and will have been manufactured, stored and transported in full conformance with the Specifications, cGMPs and all Applicable Laws;  
  
9.1.2 The Product shall not, at the time of delivery to Mikah, contain any material or be manufactured, handled or stored in any way that would cause the Product to be adulterated in any way within the meaning of Section 501 or misbranded within the meaning of Section 502 of the Food, Drug and Cosmetic Act, as amended;  
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 9.1.3 As of the Effective Date and at all times during the Term, Elite and the Facility and all equipment utilized in the manufacture of the Product is and will be in compliance with all Applicable Laws, including all applicable workplace safety regulations under OSHA (or the equivalent local governmental entity), all tax regulations and Environmental Laws;  
  
9.1.4 At all times during the Term, Elite shall obtain Mikah's written approval for the use of any third party contract laboratory intended for the testing and release of API, excipients and/or finished Product if such laboratory is not filed in said ANDA.  
  
9.1.5 At all times during the Term, Elite shall continue to hold all licenses, approvals, permits and similar authorizations of Regulatory Authorities necessary or required to operate the Facility and its equipment;  
  
9.1.6 Neither Elite nor any of its employees has ever been: (a) debarred, or (b) convicted of a crime for which a person can be disbarred under Section 306 (a) or (b) of the Generic Drug Enforcement Act of 1992, as amended from time to time, or (c) been convicted of any crime in the country where the Product is manufactured. Elite agrees to immediately notify Mikah should any Regulatory Authority threaten any action that could possibly result in a breach of this Section;  
  
9.1.7 The Manufacture, storage, packaging and labeling of the Product shall be in complete accordance with all Applicable Laws, the ANDA and the Specifications and will be made, stored, packaged, labeled and controlled by Elite in accordance with any other applicable manufacturing information, or regulatory requirements;  
  
9.1.8 Unless otherwise agreed by the Parties in writing, Elite has: (a) reviewed and approved all Specifications, (b) if applicable, reviewed and approved all in-process and finished Product test results to ensure conformity of such results with the Specifications, regardless of which Party is responsible for finished Product release;  
  
9.1.9 The COA which will accompany each shipment of Product shall be accurate, truthful and made in good faith such that Mikah shall be able to legally rely on each COA;  
  
9.1.10 During the Term of this Agreement, and subject to the provisions herein, including but not limited to Section 3.2, Elite shall not develop, manufacture, market or sell any product competitive with the Product, nor shall it offer any assistance, or permit any of its employees to offer any assistance to any third party (including for this purpose any Affiliate of Elite in the world) to take any action which Elite would be prohibited from engaging in pursuant to this Article subject to Section 9.1.13;  
  
9.1.11 Neither Elite nor any of its Affiliates is manufacturing the Product or any derivative thereof for any other person, entity or company whatsoever. Following the execution of this Agreement, neither Elite nor any of its Affiliates shall develop or manufacture the Products with or for any third party.  
  
9.1.12 Neither Elite nor any of its Affiliates shall manufacture, market or distribute any of the Products, whether for their own benefit or for the benefit of a third party, for a period of five years following the termination of this Agreement.  
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9.1.13 As far as Phendimetrazine tartrate 35 mg is concerned, Mikah acknowledges that Elite has developed its own generic phendimetrazine tartrate 35 mg product. Notwithstanding anything to the contrary contained in this Agreement, Mikah acknowledges that Elite may develop a generic product containing phendimetrazine of any strength including the filing of an abbreviated new drug application relating to such product and nothing herein shall be construed to limit or otherwise restrict Elite from developing, commercializing, manufacturing and distributing any pharmaceutical product similar to, or which may compete with, the Product or the ANDA. Elite shall not use, incorporate or utilize Mikah’s know-how, methodology or technology in Elite products or process.  
 9.2 Mikah. Mikah hereby represents, warrants and covenants to Elite that:  
  
9.2.1 All artwork templates and the content thereof provided to Elite shall comply with all Applicable Laws;  
  
9.2.2 All Product delivered to Mikah by Elite will be held, used and/or disposed of by Mikah in accordance with all Applicable Laws; and  
  
9.2.3 Mikah will comply with all Applicable Laws applicable to Mikah's performance under this Agreement and its use of any materials or Product provided by Elite under this Agreement; and  
  
  
9.3 Mutual. Each Party hereby represents, warrants and covenants to the other Party that:  
  
9.3.1 Existence and Power. Such Party: (a) is duly organized, validly existing and in good standing under the laws of the state in which it is organized, (b) has the power and authority and the legal right to own and operate its property and assets, and to carry on its business as it is now being conducted, and (c) is in compliance with all requirements of Applicable Laws.  
  
9.3.2 Authorization and Enforcement of Obligations. Each Party: (a) has the power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder and (b) has taken all necessary action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder;  
  
9.3.3 Execution and Delivery. This Agreement has been duly executed and delivered on behalf of each Party, and constitutes a legal, valid, binding obligation, enforceable against such Party in accordance with its terms;  
  
9.3.4 No Consents. All necessary consents, approvals and authorizations of all Regulatory Authorities and other persons required to be obtained by such Party in connection with the Agreement have been obtained; and  
  
9.3.5 No Conflict. The execution and delivery of this Agreement and the performance of such Party's obligations hereunder: (a) do not conflict with or violate any requirement of Applicable Laws; and (b) do not materially conflict with, or constitute a material default or require any consent under, any current contractual obligation of such Party.  
  
9.4 Survival. The obligations of this Article 9 will terminate five (5) years from the expiration or termination of this Agreement.  
  
9.5 Limitations. THE REPRESENTATIONS AND WARRANTIES SET FORTH IN THIS ARTICLE ARE THE SOLE AND EXCLUSIVE REPRESENTATIONS AND WARRANTIES MADE BY EACH PARTY TO THE OTHER AND NEITHER PARTY MAKES ANY OTHER REPRESENTATIONS, WARRANTIES OR GUARANTEES OF ANY KIND WHATSOEVER, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTIES OF MERCHANTABILITY, NON-INFRINGEMENT OR FITNESS FOR A PARTICULAR PURPOSE.  
 {\*\*\*} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended  
 ARTICLE 10  
CONFIDENTIAL INFORMATION  
  
10.1 Mutual Obligation. Elite and Mikah agree that they will not disclose the other Party's Confidential Information (defined below) to any third party without the prior written consent of the other Party except as required by law, regulation or court or administrative order; provided, however, that prior to making any such legally required disclosure, the Party making such disclosure shall give the other Party as much prior notice of the requirement for and contents of such disclosure as is practicable under the circumstances. Notwithstanding the foregoing, each Party may disclose the other Party's Confidential Information to any of its Affiliates that: (a) need to know such Confidential Information for the purpose of performing under this Agreement, (b) are advised of the contents of this Article, and (c) agree to be bound by the terms of this Article.  
  
10.2 Definition. As used in this Agreement, the term "Confidential Information" includes all such information related to the Product furnished by Elite or Mikah, or any of their respective representatives or Affiliates, to the other or its representatives or Affiliates, whether furnished before, on, or after the date of this Agreement and furnished in any form, including but not limited to written, verbal, visual, electronic or in any other media or manner. Confidential Information includes all proprietary technologies, Intellectual Property, analyses, compilations, business or technical information and other materials prepared by either Party, or any of their respective representatives, containing or based in whole or in part on any such information furnished by the other Party or its representatives. Confidential Information also includes the existence of this Agreement and its terms as well as the Confidentiality Agreement signed as of May 18, 2010, which is hereby made a part of this Agreement and is attached hereto as Exhibit D.  
  
10.3 Exclusions. Notwithstanding Section 10.2, Confidential Information does not include information that: (a) is or becomes generally available to the public or within the industry to which such information relates other than as a result of a breach of this Agreement, or (b) is already known by the receiving Party at the time of disclosure as evidenced by the receiving Party's written records, or (c) becomes available to the receiving Party on a non-confidential basis from a source that is entitled to disclose it on a non-confidential basis, or (d) was or is independently developed or discovered by or for the receiving Party without reference to the Confidential Information, as evidenced by the receiving Party's written records.  
  
10.4 Return of Confidential Information. Upon termination of this Agreement, the receiving Party shall, upon request, promptly return within thirty (30) days all such Confidential Information, including any copies thereof, and cease its use or, at the request of the disclosing Party, shall promptly destroy the same and certify such destruction to the disclosing Party; except for a single copy thereof, which may be retained for the sole purpose of complying with the scope of the obligations incurred under this Agreement.  
  
10.5 Survival. The obligations of this Article 10 will terminate five (5) years from the expiration of this Agreement.  
 ARTICLE 11  
INTELLECTUAL PROPERTY  
  
11.1 Notice of Infringement Claim. In the event that a third party at any time provides written notice of a claim to, or brings an action, suit or proceeding against, any Party, any of their respective Affiliates, in each case claiming infringement of third party patent rights based upon an assertion or claim arising out of the filing of an ANDA for the Product, or development, manufacture, marketing, distribution, sale, import or use of the Products in the Territory by Mikah ("Infringement Claim"), such Party shall promptly notify the other Party of the claim or the commencement of such action, suit or proceeding, enclosing a copy of the claim and all papers served.  
 {\*\*\*} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended  
 11.2 Exclusive Right to Defend. Mikah shall have the sole and exclusive right, but not the obligation, to defend and/or settle any such Infringement Claim. If an Infringement Claim is brought against Elite ("Elite Infringement Claim"), then Elite shall so notify Mikah in writing within fifteen (15) days of receipt. Upon proper notification of the Elite Infringement Claim,  
  
 (i)  
Mikah shall have the sole and exclusive right to select counsel for such claim and final decision-making authority regarding all aspects of the defense and settlement of such claim,  
 (ii)  
Elite shall be entitled to participate in the defense of an Elite Infringement Claim and to employ counsel at its expense to assist therein, and  
 (iii)  
Elite shall provide Mikah with such information and assistance as Mikah may reasonably request.  
  
11.3 Elite Assistance. Upon written request from Mikah, Elite shall promptly provide Mikah and/or its counsel with such access to information about, and personnel knowledgeable of, the Products and their formulation, use and process of manufacture to enable Mikah to:  
  
 (i)  
ascertain whether the manufacture, marketing, distribution, sale, import or use of the Products in and for the Territory will infringe any existing patent of a third party;  
 (ii)  
determine its conduct in relation to any proceedings alleging infringement of a third party's patent in the Territory;  
 (iii)  
provide witnesses or documentation from Elite in any proceedings alleging infringement of a third party's patent in the Territory; and  
 (iv)  
if deemed advisable, the Parties shall enter into a joint defense agreement containing customary terms and conditions for the purpose of, inter alia, preserving confidentiality and any applicable privilege attaching to information and data exchanged by the parties under and pursuant to this Agreement.  
  
ARTICLE 12  
INDEMNIFICATION  
  
12.1 Indemnification by Elite. Elite shall defend, indemnify and hold harmless Mikah, and its directors, officers, employees and agents ("Mikah Indemnitees") from and against any and all suits, claims, losses, demands, liabilities, damages, costs and expenses (including reasonable attorneys' fees) in connection with any suit, demand or action by any third party ("Losses") arising out of or resulting from: (a) any breach of its representations, warranties or obligations set forth in this Agreement or resulting from the breach of its obligations to deliver Product in full conformity to the Specifications, or for Product to remain in full conformity through its expiration date and in conformity with all Applicable Laws or (b) any negligence or willful misconduct by Elite, except to the extent that any of the foregoing arises out of or results from any Mikah Indemnitee's obligations set forth in Section 12.2 below.  
  
12.2 Indemnification by Mikah. Mikah shall defend, indemnify and hold harmless Elite, its Affiliates, and their respective directors, officers, employees and agents ("Elite Indemnitees'') from and against all Losses arising out of or resulting from: (a) any breach of its representations, warranties or obligations set forth in this Agreement; or (b) any negligence or willful misconduct by Mikah, except to the extent that any of the foregoing arises out of or results from any Elite Indemnitee's obligations set forth in Section 12.1 above.  
 {\*\*\*} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended  
   
12.3 Indemnification Procedures. All indemnification obligations in this Agreement are conditioned upon the Party seeking indemnification: (a) promptly notifying the indemnifying Party of any claim or liability of which the Party seeking indemnification becomes aware (including a copy of any related complaint, summons, notice or other instrument); provided, however, that failure to provide such notice within a reasonable period of time shall not relieve the indemnifying Party of any of its obligations hereunder except to the extent the indemnifying Party is prejudiced by such failure; (b) cooperating with the indemnifying Party in the defense of any such claim or liability; and (c) not compromising or settling any claim or liability without prior written consent of the indemnifying Party.  
  
ARTICLE 13  
INSURANCE  
  
13.1 Elite Insurance. Elite shall, at its own cost and expense, obtain and maintain in full force and effect the following insurance during the term of this Agreement: (i) Commercial General Liability insurance with per-occurrence and general aggregate limits of not less than $1,000,000; (ii) Products and Completed Operations Liability Insurance with per-occurrence and general aggregate limits of not less than $5,000,000; (iii) Statutory Workers’ Compensation and Employer’s Liability Insurance with an amount not less than $500,000 including excess liability coverage. In the event that any of the required policies of insurance are written on a claims made basis, then such policies shall be maintained during the entire term of this Agreement and for a period of not less than three (3) years following the termination or expiration of this Agreement. Elite shall waive subrogation rights against Mikah for workers’ compensation benefits and shall obtain a waiver from any insurance carriers with which Elite carries workers’ compensation insurance releasing their subrogation rights against Mikah. Mikah shall be named as an additional insured under the Commercial General Liability and Products and Completed Operations Liability insurance policies as respects the manufacturing services outlined in this Agreement. Elite shall furnish certificates of insurance for all of the above noted policies and required additional insured status to Mikah within 10 days after the Effective Date of the Agreement and upon renewal of any such policies.  
  
13.2 Mikah Insurance. Mikah or its affiliate shall, at its own cost and expense, obtain and maintain in full force and effect the following insurance during the term of this Agreement: (i) Products and Completed Operations Liability Insurance with per-occurrence and general aggregate limits of not less than $5,000,000; (ii) Statutory Workers’ Compensation and Employer’s Liability Insurance with an amount not less than $500,000 including excess liability coverage. In the event that any of the required policies of insurance are written on claims made basis, then such policies shall be maintained during the entire term of this Agreement and for a period of not less than three (3) years following the termination or expiration of this Agreement. Mikah shall waive subrogation rights against Elite for workers’ compensation benefits and shall obtain a waiver from any insurance carriers with which Mikah carries workers’ compensation insurance releasing their subrogation rights against Elite. Elite shall be named as an additional insured under the Products and Completed Operations Liability insurance policies as respects the Product and completed operations outlined in this Agreement. Mikah shall furnish certificates of insurance for all of the above noted policies and required additional insured status to Elite within 10 days after the Effective Date of the Agreement and upon renewal of any such policies.  
  
ARTICLE 14  
TERM AND TERMINATION  
  
14.1 Term. This Agreement shall commence on the Effective Date and shall continue for a period of five (5) years after commercial launch of Product, on a Product-by-Product basis, unless earlier terminated under this section (the “Term"). The Term shall automatically renew for additional periods of one (1) year each ("Renewal Term") unless Mikah provides written notice of termination to Elite at least six (6) months prior to the expiration of the Term or any Renewal Term. Elite agrees to continue to supply Product to Mikah under the terms of this Agreement until Mikah has satisfactorily qualified a Second Source of Product.  
  
14.2  
Termination by Either Party.  
 {\*\*\*} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended  
   
 14.2.1 Material Breach. Either Party may terminate this Agreement effective upon sixty (60) days prior written notice to the other Party, if the other Party commits a material breach of this Agreement and fails to cure such breach by the end of such sixty (60) day period;  
  
14.2.2 Bankruptcy. Either Party may terminate this Agreement effective upon written notice to the other Party, if the other Party becomes insolvent or admits in writing its inability to pay its debts as they become due, files a petition for bankruptcy, makes an assignment for the benefit of its creditors or has a receiver, trustee or other court officer appointed for its properties or assets, and shall comply with Section 2 herein.  
  
14.3 Termination by Mikah.  
  
14.3.1 Mikah shall have the right, on six (6) months written notice, to terminate this Agreement, or a single Product under this Agreement for any reason and without penalty.  
  
14.3.2 In the event of a termination pursuant to Section 14.3.1 above, other than for intellectual property or safety reasons, the Parties shall coordinate to sell off all in process inventory (and/or Safety Stock) that may remain in Elite's Facility upon receipt of the Notice. In order that Elite get the benefit of absorption and Mikah have the ability to retain its customer base until such post-notification inventory is processed and Safety Stock sold, the post notification inventory shall be manufactured into finished dosage Product by Elite as well as the Safety Stock sold to Mikah at cost or the Parties can split the costs of the components which were purchased by Elite to fill a Purchase Order at the time of termination or to manufacture the Safety Stock.  
  
14.3.3 Elite shall provide Mikah all reasonable assistance in transferring the Product(s) to a manufacturing facility of Mikah's choice, while maintaining shipment of product orders placed by Mikah or her affiliates.  
  
14.4 Termination by Elite.  
  
14.4.1 Elite shall have the right, on six (6) months written notice, to terminate this Agreement, or a single Product under this Agreement for any reason and without penalty, if and only if Mikah was able to secure FDA approval for an alternate manufacturing site during the defined period. Mikah shall do whatever is commercially reasonable to qualify a second CMO. Elite shall continue supplying Mikah with Finished Product until such time where the said products are transferred to a CMO and the transfer is approved by the FDA.  
  
14.4 Force Majeure. Except as to payments required under this Agreement, if any default or delay occurs which prevents or materially impairs a Party's performance and is due to a cause beyond the Party's reasonable control, and provided that the default or delay is not caused by or the fault of such Party, including but not limited to an act of God, flood, fire, explosion, earthquake, casualty, accident, terrorism, war, revolution, civil commotion, blockade, terrorism or embargo, injunction, law, proclamation, order, regulation or governmental demand, the affected Party shall promptly notify the other Party in writing of such cause and shall exercise diligent efforts to resume performance under this Agreement as soon as possible. Neither Party will be liable to the other Party for any loss or damage due to such cause; nor will the Term be extended thereby. Neither Party may terminate this Agreement because of such default or delay except upon thirty (30) days' prior written notice to the other Party if the default or delay has existed for five (5) months and is continuing at the end of the thirty (30) day notice period.  
 {\*\*\*} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended  
   
14.5 Effect of Termination. Expiration or termination of this Agreement shall be without prejudice to any rights or obligations that accrued to the benefit of either Party prior to such expiration or termination. In the event that this Agreement is terminated by either Party, Elite shall assist Mikah in effecting a smooth transition to an alternate contractor of the Product at Mikah's sole cost and expense. The rights and obligations of the Parties shall continue under Articles 4, 6, 8, 9, 10, 11, 12, 13, 14, 15, and 16 notwithstanding expiration or termination of this Agreement.  
  
ARTICLE 15  
LIMITATIONS OF LIABILITY  
  
NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR INDIRECT, INCIDENTAL, SPECIAL OR CONSEQUENTIAL (EXCEPT FOR THOSE INDEMNITY OBLIGATIONS UNDER ARTICLE 12 THAT ARE DEFINED AS CONSEQUENTIAL DAMAGES) DAMAGES ARISING OUT OF PERFORMANCE UNDER THIS AGREEMENT, INCLUDING WITHOUT LIMITATION, LOSS OF REVENUES, PROFITS OR DATA, WHETHER IN CONTRACT OR TORT, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.  
  
ARTICLE 16  
NOTICE  
  
All notices and other communications hereunder ("Notice(s)") shall be in writing and shall be deemed given: (a) when delivered personally; (b) when delivered by facsimile transmission (receipt verified); (c) when received or refused, if mailed by registered or certified mail (return receipt requested), postage prepaid; or (d) when delivered if sent by reliable express courier service with a confirmation, to the Parties at the following addresses (or at such other address for a Party as shall be specified by like notice; provided, that notices of a change of address shall be effective only upon receipt thereof):  
  
To Mikah:  
 Mikah Pharma LLC  
 00 Xxxxxx Xxxxx  
 Xxxxxxxxxxxx, Xxx Xxxxxx 00000  
 Attn: Xxxxxx Xxxxx, President  
 Email: xxxxxxxxxxx@xxxxxxxxxxx.xxx  
 To Elite:  
 Elite Pharmaceuticals, Inc.  
 000 Xxxxxx Xxxxxx  
 Xxxxxxxxx, XX 00000  
 Attn: Xxxxx Xxxx, Chief Operating Officer & President  
 Email: xxxxx@xxxxx.xxx  
  
ARTICLE 17  
MISCELLANEOUS  
  
17.1 Entire Agreement; Amendments. This Agreement, the exhibits, attachments, and any amendments hereto or thereto, including the Quality Agreement and the Confidentiality Agreement, constitute the entire understanding between the Parties with respect to the specific subject matter hereof. No term of this Agreement may be amended except upon written agreement of both Parties, unless otherwise provided in this Agreement.  
  
17.2 Recitals. The recitals are hereby incorporated by reference and made part of this Agreement.  
 {\*\*\*} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended  
   
17.3 Captions. The captions in this Agreement are for convenience only and are not to be interpreted or construed as a substantive part of this Agreement. The terms "Article" and "Section" shall be used interchangeably.  
  
17.4 Further Assurances. The Parties agree to execute, acknowledge and deliver such further instruments and to take all such other incidental acts as may be reasonably necessary or appropriate to carry out the purpose and intent of this Agreement.  
  
17.5 No Waiver. Failure by either Party to insist upon strict compliance with any term of this Agreement in any one or more instances will not be deemed a waiver of its rights to insist upon such strict compliance with respect to any subsequent failure.  
  
17.6 Severability. If any term of this Agreement is declared invalid or unenforceable by a court or other body of competent jurisdiction, the remaining terms of this Agreement will continue in full force and effect.  
  
17.7 Independent Contractors. The relationship of the Parties is that of independent contractors, and neither Party will incur any debts or make any commitments for the other Party except to the extent expressly provided in this Agreement. Nothing in this Agreement is intended to create or will be construed as creating between the Parties the relationship of joint ventures, co-partners, employer/employee or principal and agent.  
  
17.8 Successors and Assigns. This Agreement will be binding upon and inure to the benefit of the Parties, their successors and permitted assigns. Neither Party may assign this Agreement, in whole or in part, without the prior written consent of the other Party, except that either Party may, without the other Party's consent, assign this Agreement to an Affiliate or to a successor to substantially all of the business or assets of the assigning company.  
  
17.9 Governing Law. This Agreement shall be governed by and construed under the laws of the State of Delaware, United States of America, excluding its conflicts of law provisions.  
  
17.10 Alternative Dispute Resolution. If any dispute arises between the Parties ("Dispute"), such Dispute shall be presented to the respective presidents or senior executives of the Parties for their consideration and resolution. Each Party shall endeavor to amicably resolve the dispute in good faith as a first step, prior to taking any other action.  
  
17.11 Prevailing Party. In any dispute resolution proceeding between the Parties in connection with this Agreement, the prevailing Party will be entitled to its reasonable attorney's fees and costs in such proceeding.  
  
17.12 Counterparts. This Agreement may be executed in one or more counterparts, each of which will be deemed an original but all of which together will constitute one and the same instrument. Any photocopy, facsimile or electronic reproduction of the executed Agreement shall constitute an original.  
  
17.13 Publicity. Neither Party will make any press release or other public disclosure regarding this Agreement or the transactions contemplated hereby without the other Party's express prior written consent, except as required under applicable law or by any governmental agency, in which case the Party required to make the press release or public disclosure shall use commercially reasonable efforts to obtain the approval of the other Party as to the form, nature and extent of the press release or public disclosure prior to issuing the press release or making the public disclosure.  
  
17.14 Conflicting Terms. To the extent this Agreement and the ANDA Development Agreement have directly conflicting terms, this Agreement shall govern.  
 {\*\*\*} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended  
   
17.15 Currency. Wherever a currency is indicated throughout this Agreement, that currency shall be United States Dollars, unless otherwise clearly indicated.  
  
17.16 Days. Wherever reference is made to days, working days or any measurement of time in days, calendar days shall be used regardless of weekends and holidays.  
  
17.17 Sophisticated Parties. Each Party to this Agreement is a sophisticated business party negotiating in good faith with the advice of legal counsel. Each Party is hereby advised to seek the advice of legal counsel prior to executing this Agreement.  
  
17.18 English Language. This Agreement has been negotiated and is written in the English language, and while some of the Parties may not speak English as their first language, they have sought the use of translators, if necessary and understand the meaning of this entire Agreement.  
 IN WITNESS WHEREOF, the Parties have caused their duly authorized representative to execute this Agreement effective as of the Effective Date.  
  
MIKAH PHARMA LLC  
ELITE PHARMACEUTICALS, INC.  
 Name: Xxxxxx Xxxxx  
Name: Xxxxx Xxxx  
Title: President & CEO  
Title: COO & President  
 {\*\*\*} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended  
   
EXHIBIT A  
PRODUCTS  
  
ANDA(s) and all amendments thereto:  
  
 Bottle of  
30’s  
 Bottle of  
90’s  
 Bottle of  
500’s  
00-000  
Xxxxxxxxxx Casules USP, 2.5 mg and 5 mg  
 X  
 X  
 X  
40-762  
Phendimetrazine Tartrate Tablets USP, 35 mg  
 X  
 X  
  
Specifications  
As set forth by each product’s ANDA, United States Pharmacopeia, applicable GMP and FDA.  
 {\*\*\*} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended  
   
EXHIBIT B  
SUPPLY PRICE AND OTHER PAYMENTS  
  
1.  
Pricing for Isradipine: Elite will test, manufacture and package the Finished Product, as outlined in this agreement, for an amount equal to its actual cost for the API (if Elite purchased the API) plus {\*\*\*} (whether capsules or tablets), packaged in the requested configuration. In addition, Elite will receive a {\*\*\*} royalty on Isradipine’s finished product sales “net profit”. The payment is to be calculated and paid quarterly. Mikah shall be responsible for the cost and procurement of the API.  
  
2.  
Pricing for Phendimetrazine: Elite will test, manufacture and package the finished product, as outlined in this agreement, for an amount equal to its actual cost for the API (if Elite purchased the API) plus {\*\*\*} (whether capsules or tablets), packaged in the requested configuration.  
  
3.  
Mikah will pay Elite a one time payment of {\*\*\*} for each ANDA (Isradipine and Phendimetrazine), for the extra work associated with the Technology transfer, the validation lots and stabilities. The payment shall be made upon the successful manufacturing and testing of the exhibit batch.  
  
4.  
Two years from the launch date of the finished product identified in Exhiblit A, price adjustments may occur, upon mutual agreement of the Parties, in the event (i) modifications to the Specifications requested by Mikah increases or decreases the cost of Manufacturing or Raw Materials as a result of such changes in Spcifications, or (ii) there are special increases or decreases in the cost of Raw Materials that impact the total costs of goods for that SKU by more than 10%.  
 {\*\*\*} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended  
   
EXHIBIT C  
FORM OF QUALITY AGREEMENT  
  
 [To be finalized by the Parties within 60 days of executing this Agreement.]  
 {\*\*\*} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended  
   
EXHIBIT D  
CONFIDENTIALITY AGREEMENT  
  
Previously Executed  
Attached.  
 {\*\*\*} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended  
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 EXHIBIT D  
 Equipment List  
 Description: {\*\*\*}  
Serial number: {\*\*\*}  
Model: {\*\*\*}  
ID number: {\*\*\*}  
  
Description: {\*\*\*}  
Capacity: {\*\*\*}  
ID number: {\*\*\*}  
 {\*\*\*} Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended