ELITE PHARMACEUTICALS INC /DE/
Form 8-K/A
July 20, 2005

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K/A

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(D)
OF THE SECURITIES EXCHANGE ACT OF 1934

March 30, 2005
Date of Report (Date of earliest event reported)

ELITE PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	333-45241	22-3542636
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

165 Ludlow Avenue, Northvale, New Jersey 07647
(Address of principal executive offices)

(201) 750-2646
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

[ ] Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

[ ] Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

[ ] Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

[ ] Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

This Amendment No. 3 to the Form 8K amends the Form 8K, dated March 30, 2005 and

filed with the Securities and Exchange Commission (the "Commission") on April 5, 2005 (the "Original Filing"), as amended by Amendment No. 1 to the Form 8K, dated March 30, 2005 and filed with the Commission on May 10, 2005, as amended by Amendment No. 2 to the Form 8K, dated March 30, 2005 and filed with the Commission on June 13, 2005 for the purpose of further amending Exhibit 10.1. Except as indicated below and filed herewith, the exhibits listed below were filed as exhibits to the Original Filing.

ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS

c) Exhibits

10.1 Product Development, Manufacturing and Distribution Agreement, dated as of March 30, 2004*

99.1. Copy of Press Release, dated April 5, 2005

* The Registrant has requested confidential treatment with respect to the referenced exhibit. In the event that the Commission should deny such request in whole or in part, such exhibit or the relevant portions thereof shall be filed by amendment to this Current Report on Form 8-K.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: July 19, 2005

ELITE PHARMACEUTICALS, INC.

By: /s/ Bernard Berk

Name: Bernard Berk
Title: Chief Executive Officer

CONFIDENTIAL TREATMENT REQUEST
[*] INDICATES REDACTED PORTION

EXECUTION COPY

PRODUCT DEVELOPMENT, MANUFACTURING, AND DISTRIBUTION AGREEMENT

[*] COATED PELLETS ORAL CAPSULE [*]

This PRODUCT DEVELOPMENT, MANUFACTURING AND DISTRIBUTION AGREEMENT ("Agreement") entered into as of this 30th day of March 2005, among Harris Pharmaceutical, Inc. ("Harris") located at 12500 World Plaza Lane, Suite 3 Fort Myers, Florida 33907, a corporation of the State of Florida, Tish Technologies LLC ("Tishtec"),

located at 27 Yale Court, Livingston, NJ], a corporation of the State of New Jersey, and Elite Laboratories, Inc., ("Elite") a wholly owned subsidiary of Elite Pharmaceuticals, Inc., located at 165 Ludlow Ave, Northvale, NJ 07647, a corporation of the State of New Jersey.

RECITALS

Whereas, Harris, Tishtec and Elite (each, a "Party" and collectively, the "Parties") represent and warrant to each other that the recitals, as pertains to such Party herein are true and correct;

Whereas, Elite is in the business of research and development, and manufacturing pharmaceutical drug products in a manner conforming with applicable regulations found at 21 CFR Parts 210 and 211 ("cGMPs");

Whereas, Tishtec is in the business of pharmaceutical product formulation development and pharmaceutical product analytical test method development and ANDA filing in a manner conforming with applicable regulations found at 21 CFR Parts 210 and 211 ("cGMPs');

Whereas, Harris is in the business of marketing pharmaceutical drug products;

Whereas, the Parties desire that Harris shall be the sponsor, and the owner of the ANDA asset; and

Whereas, the Parties desire to collaborate to develop, obtain regulatory approval for, manufacture, and sell [*] Coated Pellets Oral Capsule [*] (the "Product") in accordance with the terms and conditions specified herein and in the Exhibits hereto.

Now, therefore, for the consideration and covenants set forth herein, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

ARTICLE I: DEFINITIONS

The following terms as used in this Agreement have the following respective meanings:

1.1. FDA: The term "FDA" means the United States Food and Drug Administration.

1.2. MILESTONES: The term "Milestones" means the project activities and performance descriptions set forth on Exhibit "A."

* Portions of this exhibit have been omitted and filed separately pursuant to an application for confidential treatment filed with the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

1.3. ANDA: The term "ANDA" means Abbreviated New Drug Application for the Product prepared and submitted to FDA under this Agreement.

1.4. DEVELOPMENT COSTS: The term "Development Costs" means the fully absorbed direct and indirect cost of performing the Product development activities provided for in Article II of this Agreement and as estimated in Exhibit "A" hereto.

1.5. PROFIT SHARE: The term "Profit Share" means a Party's share of Profits as determined in accordance with Exhibit "C" to this Agreement.

1.6 BIOEQUIVALENCE STUDY OR STUDIES: The term "Bioequivalence Study" or "Bioequivalence Studies" means a study conducted to ensure the Product's compliance with the FDA Bioequivalence requirement in accordance with 21 CFR 320.1.

1.7 FDCA: The term "FDCA" means the Federal Food, Drug and Cosmetic Act set forth in 21 U.S.C ss.301 et. seq.

1.8. TRANSFER PRICE: is defined in Section 4.4.

1.9 PROPRIETARY RIGHTS: The term "Proprietary Rights" means, with respect to the Product, all know-how, technical and clinical data generated during the Term related to the development of the Product (including, without limitation, inventions, whether or not patentable and whether or not tested or reduced to practice, any and all data, techniques, discoveries, developments, designs, trade secrets, confidential business information, know-how and tangible expressions, tests, reports, processes, formulae, specifications, improvements, results, experiments, samples, statistics and test analyses relating to the Product), except to the extent any of the foregoing is based on or incorporates Confidential Information of any Party to this Agreement or of any third party.

1.10 TERRITORY: The term "Territory" means the United States of America, Canada, Mexico, and Puerto Rico.

1.11 REFERENCED LISTED DRUG: The term "Reference Listed Drug" means [*].

ARTICLE II: DEVELOPMENT OF PRODUCT; PROPRIETARY RIGHTS

2.1. PRODUCT DEVELOPMENT.

A. Elite shall be responsible for, and shall exert commercially reasonable best efforts in, developing the Product according to the activity descriptions and the timelines set forth in Exhibit "A". Without limiting the foregoing, Tishtec shall be responsible for, and shall exert commercially reasonable best efforts in providing to Elite the initial Product formulation composition and process, and conducting, through an acceptable third party, pilot and pivotal Bioequivalence Studies for the Product to evidence bioequivalence to the Reference Listed Drug in accordance with study plan protocols agreed upon by the Parties to this Agreement, and compiling an approvable ANDA for submission to the FDA. Elite shall be responsible for overseeing packaging related activities for the Product, including, but not limited to subcontracting such packaging services to a qualified cGMP facility.

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B. Elite shall be responsible for [*] percent ([*]%) of the Development Costs, including, but not limited to, packaging costs, and preparation, submission and prosecution of the ANDA for the Product to the FDA, as set forth in Sections 4.1 and 5.1 below.

C. Harris shall be responsible for [*] percent ([*]%) of the Development Costs, including but not limited to packaging, and

preparation, submission and prosecution of the ANDA for the Product to the FDA, as set forth in Sections 4.1 and 5.1 below.

2.2. INTELLECTUAL PROPERTY

All rights, title and interest in and to all intellectual property rights relating to the Product, including without limitation, inventions, discoveries, creations, information, data, reports, results, and/or improvements to any confidential information, know-how, study inventions, regulatory filings, patent rights, processes, techniques, and any improvements, modifications, alterations thereto and patents issuing thereon made during the term of this Agreement (collectively, "Intellectual Property") are and shall, in all events, be the sole and exclusive property of the Party who develops such Intellectual Property. The other Parties may not grant any sublicense to such Party's Intellectual Property Rights without such Party's prior written consent, which consent may be granted or withheld in such Party's sole discretion. Such Intellectual Property may be used by the developing Party on other unrelated products, however the developing Party or Parties hereby grant Harris the exclusive right and license to use such Intellectual Property in a commercial manner for the production of the Product. Notwithstanding the above, in no event shall any of the Parties hereto use the Intellectual Property in connection with the development of any product containing the [*] molecule.

2.3. STATUS MEETINGS AND MONTHLY REPORTS

The Parties shall conduct meetings to review and discuss the Product development progress. These meetings will be held monthly or quarterly depending upon the needs of Harris, Tishtec, and Elite. The meetings shall be attended by at least one (1) member or designee of each Party and may be held by telephone conference call at the request of any Party. Five (5) days prior to the meeting, both Tishtec and Elite shall provide the other Parties with a report summarizing its Product development activities for the preceding period. At the meetings, the Parties shall discuss and review the development of the Product, the budgeted Development Costs, the scheduling of Product development, and such other information and topics relating to the Product as each Party may reasonably request. The discussions and all information discussed at these meetings shall be briefly summarized in the form of minutes. Tishtec and Elite will prepare those portions of the minutes relating to their responsibilities. Harris shall prepare the balance of the minutes, incorporating Tishtec's and Elite's portions and distributing the complete minutes to all Parties. Such minutes shall not be considered final until they have been received, reviewed and acknowledged as accepted by an attending representative of each Party. The time and location of such monthly meetings shall be mutually agreed upon by the Parties.

2.4 FDA/HARRIS INSPECTION

A. Tishtec hereby agrees, and any third party conducting the Bioequivalence Study shall agree, to permit representatives of Harris and/or of the FDA to examine at any reasonable time during normal business hours, and where applicable, make copies of relevant information and facilities necessary to confirm that the clinical trials (or

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studies) being conducted pursuant to this Agreement (each, a "Study") are being conducted in compliance with the protocol, this Agreement and applicable law.

B. Tishtec and any such third party conducting the Bioequivalence Study shall immediately notify Harris and Elite if FDA schedules, or, without scheduling, begins an inspection of a study site, or Tishtec. In addition, Tishtec will immediately provide Harris and Elite copies of any correspondence form or to the FDA or other regulatory authorities related to the clinical trials, including but not limited to any FD-483s or warning letters, as well as any other correspondence with a governmental agency that is reasonably likely to affect the suitability of Tishtec or such third party to continue conducting the Bioequivalence Study.

2.5. MARKETING OUTSIDE OF THE TERRITORY

This Agreement sets forth the obligations, rights and responsibilities of the Parties for developing, securing regulatory approval, manufacturing, marketing, distributing and selling the Product in the Territory. The Parties will negotiate separate agreements governing their respective obligations, rights and responsibilities for countries outside of the Territory.

ARTICLE III: CONFIDENTIALITY

3.1. CONFIDENTIALITY OBLIGATION

Harris, Tishtec and Elite shall keep in strictest confidence all materials and information provided by the other, in whatever form provided, that are confidential or proprietary in nature, relating to the other Party's business, operations and technology ("Confidential Information"). Such Confidential Information includes, but is not limited to, information and technology relating to each Party's marketing plans, research and development activities, marketing trends, products, designs, technical specifications and data for the Product, Proprietary Rights, flowcharts, logic diagrams' notes, memoranda, know-how, trade secrets and products, as well as any materials and information that, from the circumstances in which they are made available to the other Party, in good faith ought to be treated as confidential or proprietary. Except as necessary in carrying out its obligations under this Agreement, no Party shall use or disclose, nor permit its employees, suppliers, customers or agents to use or disclose, any such Confidential Information without the prior written consent of the disclosing Party. The confidentiality obligation contained in this Section 3.1 shall remain binding on all Parties for five (5) years after any termination of this Agreement, regardless of the cause of such termination.

3.2. EXCEPTION TO CONFIDENTIALITY OBLIGATION

The obligations of each Party under this Article III shall not apply to information which is: (a) presently available to the public domain (except as disclosed by any Party in violation of this Agreement); (b) lawfully received by any Party from a third party who is not or was not bound in a confidential relationship to either Harris, Tishtec or Elite; or (c) required to be disclosed as a matter of law in legal proceedings, and regulation or government authority, in which event the Party so required to disclose the information shall forthwith give notice to the

originating Party and duly allow it to appeal or litigate the required disclosure.

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3.3. RETURN OF CONFIDENTIAL INFORMATION

Each Party shall, at the termination of this Agreement, return to the originating Party all of its Confidential Information and copies thereof and any information related to the development and manufacture of the Product, except to the extent the Party is entitled to retain such Confidential Information under another provision of this Agreement.

ARTICLE IV: OBLIGATIONS OF THE PARTIES

4.1. PRODUCT DEVELOPMENT, BIOEQUIVALENCE STUDIES, AND REGULATORY APPROVAL TO MARKET PRODUCT

A. DEVELOPMENT. Per Section 2.1, each of Tishtec and Elite shall use commercially reasonable efforts to develop the Product according to the activity descriptions set forth in Exhibit "A," and Harris will pay [*] percent ([*]%) of the Development Costs in accordance with Section 5.1.

B. BIOEQUIVALENCE STUDY. Harris shall have the final decision as to the clinical research organization used for the pilot and the pivotal Bioequivalence Studies. Harris and Elite shall be responsible for funding the pilot and the pivotal Bioequivalence Studies in their proportionate allocated share of [*] percent ([*]%) Harris and [*] percent ([*]%) Elite as set forth in Exhibit "A". It is expressly understood and agreed that Harris shall have all rights, title and interest in the Product.

C. ANDA. Harris shall be the sponsor and owner of the ANDA for the Product Elite will provide copies of all correspondence with the FDA and required supporting filing (i.e. copies of annual reports etc.) to Harris within ten (10) days of filing such documents with the FDA. Harris, Elite and Tishtec shall be responsible for prosecuting and filing the ANDA. Harris shall be responsible for maintaining the ANDA after approval of the ANDA.

4.2. ASSIGNMENTS, TRANSFER, SALE OR LICENSE OF PRODUCT

A. At any time prior to filing the ANDA with the FDA, if Harris wishes to terminate for any reason, it shall comply with the provisions of Sec. 9.1 of this Agreement.

B. Following approval of the ANDA by the FDA, should Harris desire to assign, transfer, sell or license the Product or any of its Proprietary Rights:

a. Harris shall notify Tishtec and Elite in writing within ninety (90) days of the decision.

b. Tishtec shall have the right of first negotiation to acquire such Product or Proprietary Rights as Harris may

transfer.

c. If Tishtec declines the opportunity to enter into such negotiations, or if the Parties are not able to conclude such negotiations and reach an agreement within sixty (60) days after beginning negotiations (subject to the negotiations commencing within ten (10) days of the end of the ninety (90) day notice period, Harris then shall enter into negotiations with Elite.

d. If Elite thereafter, declines the opportunity to enter into such negotiations, or if the Parties are not able to conclude such negotiations and reach an agreement within sixty (60) days after beginning negotiations (subject to negotiations

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commencing), Harris is free to assign, transfer, sell or license the Product and its Proprietary Rights within thirty (30) days on terms no less favorable to Harris than those offered to Tishtec and Elite.

e. If Harris fails to consummate such assignment, transfer, sale or license of the Product and the Proprietary Rights to a third party within such 30-day period, then the license rights shall once again be subject to Tishtec's and Elite's right of first negotiation as set forth above.

f. Harris shall pay for all Product ordered by Harris through the date of assignment, transfer, and sale or licensing. Harris may not transfer any of its rights to the Product, whether to Tishtec, Elite, or a third party, unless the transferee agrees in writing to be bound by Harris' obligations under this Agreement, including without limitation Harris' obligations to market the Product and pay Tishtec and Elite their Profit Shares.

C. If Elite desires to sell its manufacturing facility:

a. Elite shall inform Harris of its intent to sell within ninety (90) days of the decision.

b. Harris would prefer the right to continue to have the product manufactured at the Elite facility under the same terms and conditions granted under this Agreement. If the successor to Elite's facility elects not to continue manufacturing and supplying the Product under this Agreement, Elite must give nine (9) months notice to Harris prior to terminating Elite's obligations under this Agreement. Elite and Tishtec shall in good faith and with due diligence, use its best efforts to assist in the transfer of the manufacturing process (including the transfer of any and all documentation related to the Product and/or the ANDA) to another facility.

c. If Harris elects to transfer the Product manufacture to another facility, Elite shall provide all information, including but not limited to the documentation and technical support necessary to transfer the Product manufacture to a manufacturing facility designated by Harris within sixty (60) days of such election.

D. Upon the sale of all or substantially all of Harris' assets to a third party entity, Harris shall inform Elite of their intended change of control within ninety (90) days of the decision. Elite shall have the option of continuing to manufacture the Product under the same terms and conditions granted under this Agreement (and the acquiring entity of Harris then shall assume all of Harris' obligations under this Agreement), or of terminating this Agreement. If the successor to Harris does not wish manufacturing of this Product to be continued at the Elite facility, Harris must give nine (9) months notice to Elite.

4.3. MANUFACTURING, PACKAGING & DELIVERY

Following ANDA approval, Elite shall manufacture the Product in accordance with the terms and conditions of this Agreement. In connection with its manufacturing obligations under this Agreement, Elite shall be responsible for overseeing the packaging of the Product at a cGMP facility in its retail package, preparing the Master Label, including final printed labeling, text and printing the required labels and inserts for the Product under a designated Harris label or Harris designated private label, all in accordance with the ANDA review process and the ANDA and all applicable laws and regulations, including,

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but not limited to the laws and regulations enforced by the FDA. Tishtec, Elite and Harris shall review and approve the form of the label and insert before final printing. Notwithstanding any such review and approval by them, Elite shall be responsible for manufacturing, storing and overseeing the labeling, packaging and shipping of the Product in a manner that complies with all applicable legal requirements, including, but not limited to the laws and regulations enforced by the FDA. It is expressly understood and agreed by the Parties that Elite shall not assign or transfer its responsibility to manufacture the Product under this Agreement without the prior written consent of Harris, which consent may be withheld by Harris for any reason in its sole discretion.

4.4. PURCHASE AND DISTRIBUTION

A. Harris shall purchase finished (ready to market) Product from Elite at the Transfer Price established in Exhibit "B" (the "Transfer Price"), subject to Elite's (including any third party supplier's) compliance with the terms and conditions of this Agreement.

B. Harris shall distribute Product in a commercially prudent manner and in a manner consistent with its status as a generic drug and in compliance with all applicable laws and regulations. Harris shall diligently market and promote the Product in the Territory

using commercially reasonable efforts to maximize Product sales and Profit Share. Harris shall devote such marketing efforts to the Product as its competitors customarily would exert for generic products with comparable market size and profit potential under comparable competitive conditions. Following approval of the ANDA by the FDA, Harris shall, at least once per calendar quarter, provide to Elite and Tishtec, in writing, an outline of Harris' commercial plans, planned marketing activities, and sales expectations for the Product for the upcoming three (3) calendar quarters.

C. Harris shall file all labeling, marketing, advertising and promotional materials to the regulatory agency. Harris shall store, transport, sell, market and distribute the Product in compliance with all applicable laws and regulations. If requested by Harris, Tishtec shall make any additional regulatory filings as Harris' agent under the ANDA filing for advertising as well as any additional scientific questions.

4.5. EXCLUSIVITY

During the term of this Agreement, except as otherwise provided in this Agreement, each of Tishtec and Elite agrees that, unless directed by Harris, it will not develop or manufacture the Product for itself or any other party other than Harris and Harris agrees not to have the Product developed or manufactured for sale by any party other than Tishtec and Elite, subject to and in accordance with the terms and conditions of this Agreement. It is the intent of this Agreement that, except as otherwise provided in this Agreement, Harris shall be the exclusive distributor of the Product, Elite will be the exclusive manufacturer of the Product, Elite will supply Harris with all of Harris' requirements of the Product for distribution and sale by Harris, in the Territory and Harris will purchase all of its requirements of the Product in the Territory from Elite, subject to and in accordance with the terms and conditions of this Agreement and in all events following regulatory authorization to market the Product in that country. Notwithstanding the above, if FDA regulatory action limits or precludes Elite's ability to produce the Product, Tishtec and Harris shall have the option to have the Product manufactured at an alternate manufacturing site and by an alternate manufacturer, subject to Harris' ongoing obligation to pay Elite's Profit Share for all such Product (regardless of

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the site of manufacture), and subject to the alternate manufacturer's entering into confidentiality obligations running to Elite safeguarding Elite's Confidential Information.

ARTICLE V: DEVELOPMENT COSTS, MANUFACTURING COSTS AND SALES

5.1. DEVELOPMENT COSTS.

A. The Parties have developed an agreed upon budget setting forth the projected Development Costs, by Activity, which is attached hereto as Exhibit "A." Harris will be responsible for payment of [*]% of the Development Costs. Elite, shall be responsible for [*]%

of the Development Costs. No Party shall be responsible for Development Costs in excess of [*] percent ([*]%) of the estimated costs of the development as per Exhibit "A" hereto incurred without such Party's prior written consent. It is the belief of the Parties that only one (1) pivotal Bioequivalence Study will be required to obtain the approval of both Product strengths because they will be dose-proportional.

B. Tishtec or Elite, as the designated Party responsible for the Activity, shall issue invoices for the actual Development Costs of the Product, including costs of the validation batches on an Activity basis, and on a monthly basis. With each invoice, they shall provide an accounting detail supporting the actual time and costs associated with each Activity (including but not all-inclusive of experiments and lab records). Harris shall pay its respective share of such Development Costs within thirty (30) days after receipt of such invoice. Harris has the right to terminate this Agreement in its entirety if a pilot Bioequivalence Study has not been successfully completed within nine (9) months of the date of this Agreement as per Exhibit A.

5.2. MANUFACTURING COSTS AND SALES; PROFIT SHARE.

A. All parties shall agree as to the timing to make the validation batches, giving Elite ninety (90) days advance notice.

B. Upon FDA approval of the ANDA for the Product under this Agreement, if any validation batch of Product is not saleable due to short dating, Elite shall be entitled to payment from Harris, for the costs of such validation batches, including but not limited to all raw materials costs, as part of its Development Costs.

C. Upon FDA approval of the ANDA for the Product under this Agreement, if any validation batch of Product is not saleable due to failure of such batch to meet Product specifications of the ANDA (other than relating to expiry dating), then Elite shall be responsible for the costs of such validation batches, including but not limited to all raw materials costs.

D. Harris shall pay Elite [*] percent ([*]%) of the Transfer Price for a given shipment of Product within thirty (30) days of the date of the invoice.

E. During the term of this Agreement, on a quarterly basis within thirty days of the calendar quarter then ended, Harris shall pay each of Elite and Tishtec its respective Profit Share for such calendar quarter, along with a detailed statement setting forth the calculation of Profit Share.

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5.3. AUDIT; INSPECTION

Within one hundred eighty (180) days following the close of each calendar year during the term of this Agreement and for a period of twelve (12)

months following expiration or earlier termination of this Agreement, upon the request of a Party ("Requesting Party") the other Party shall provide the Requesting Party's accountants, at Requesting Party's sole cost and expense, with access, during regular business hours and upon reasonable prior written notice, and subject to the confidentiality obligations set forth herein, to the other Party's books and records relating to the Product in the Territory solely for purposes of verifying costs and expenses and Profit Share in connection with this Agreement, and for verifying the accuracy of the calculations hereunder for the calendar year then ended and for the two (2) calendar years prior thereto. If any such verification shows any underpayment or overpayment, a correcting payment or a refund shall be made within thirty (30) days of completion of such verification and submission of the results thereof, with details of the calculations included therein.

ARTICLE VI: PRODUCT DEVELOPMENT FEES AND INTELLECTUAL PROPERTY

6.1. It is agreed between Harris and Tishtec, that upon the execution of this Agreement, Harris shall pay Tishtec a fee of $[*] for the identification and development of the Product opportunity and the oversight of the formulation development work to be completed at Elite and/or Tishtec. Tishtec agrees that documentation of this process shall be provided to Harris on a monthly basis.

6.2. It is agreed between Harris, Tishtec, and Elite that if, during any process of Product development (including but not all inclusive to packaging and marketing), if any Parties develop patentable manufacturing not currently available in the market place:

A. The developing Party shall be the sole owner of the intellectual property and may seek to protect this process as either a "trade secret" or patent the process.

B. If Elite and/or Tishtec develops such intellectual property, they shall be required to license the use of such "trade secret" or patentable technology to Harris or Elite (as applicable), on an exclusive basis for the manufacture of the Product, for a fee of $[*] per year of each year in which there are a full twelve (12) months sales of the Product, for use by Elite in the manufacture and Harris in the sales of the Product under this Agreement.

C. Such "trade secret" or patentable technology may be used by the developing Party on other unrelated products, however Harris shall have the right of first refusal to use such process in a commercial manner for the production of the Product.

ARTICLE VII: DELIVERY, GUARANTEE, INSURANCE, INDEMNITY AND RELATIONSHIP OF THE PARTIES

7.1. ORDERING AND DELIVERY

A. Elite will deliver to Harris or shall cause the finished Product to be delivered to Harris in bottles packed in cases and stacked on pallets as specified by Harris under Section 7.1(c) below. Harris shall order Product in multiples of Elite's batch size for the Product.

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B. Harris will provide to Elite on a monthly basis a forecast of its expected supply needs for the Product for the then following six (6) months, along with requested shipment dates for the Product. Each monthly forecast shall be deemed to be a firm purchase order as to the Product, binding upon Harris and subject to Elite's acceptance or rejection, in whole or in part, scheduled for the first three (3) months of the forecast, and non-binding as to the last three (3) months of the forecast. If a monthly forecast increases the monthly quantity of Product by more than 25% over the quantity scheduled in the immediately preceding month forecast, Elite shall not be required to manufacture and ship the quantity of Product that exceeds a 25% increase. At the time of each quarterly forecast, the Parties will agree on shipment dates for the Product scheduled for the first three (3) months of the forecast, to the extent they have not already agreed, and Elite will make shipments, or cause all shipments to occur, in accordance with the agreed dates. If a monthly forecast increases the quantity of any Product over the quantity scheduled in the immediately preceding monthly forecast, the Parties will agree on an equitable adjustment in the shipment dates.

C. In addition to monthly forecasts, at least thirty (30) days before the shipment date agreed upon for any Product, Harris shall provide Elite with specific written instructions concerning the packaging, labeling (unless under a private label other than Harris, which will require 60 days prior notice to Elite and Harris shall ensure that Elite has sufficient inventory of such private labels at least thirty days before the desired shipment date of Product), and shipping of such Product.

D. Elite will ship, or shall ensure that any third party labeler/packager ships, the Product in accordance with Harris shipping and delivery instructions. Elite shall pay the cost to ship the bulk packaged Product to a third party labeler/packager and Harris shall pay the shipping cost of the finished Product shipped from a pre-approved cGMP facility under Section 4.3, to Harris' desired location. Each shipment shall be made to arrive within five (5) days of the shipping date. Upon shipment, Elite shall invoice Harris in writing for the Transfer Price. Harris shall pay Elite the Transfer Price within thirty (30) days of the date of the invoice as in accordance with Section 5.2(c). Elite shall be deemed to have delivered the Product to Harris when the Product has been tendered to the shipper, and title and risk of loss of the Product shall be deemed to pass to Harris upon such tender.

7.2. GUARANTEE

Elite guarantees that the Product delivered to Harris will not be, on the date of delivery, adulterated or misbranded within the meaning of the FDCA or an article which may not, under the provisions of Sections 404, 505 or 512 of the FDCA, be introduced into interstate commerce. Elite further guarantees that the Product will be manufactured in all respects in accordance with the ANDA and will conform in all respects with cGMPs. Elite agrees to comply with and be bound by all reasonable Harris quality standards that may be agreed to by the Parties in writing and appended to this Agreement. If any Product is found to fail to conform to the specifications of the ANDA or is not manufactured in accordance with current good manufacturing practices, and such failure is due to acts or

omissions of Elite, then Harris shall have the right to reject such nonconforming shipment of Product or the nonconforming portion thereof, as the case may be. Harris shall give written notice to Elite of its rejection within fifteen (15) days of Harris' receipt of the Product, specifying the grounds for such rejection. The nonconforming Product shall be held for Elite's disposition, or shall be returned to Elite, as directed by Elite in writing. Nonconforming packaged

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Product shall be returned to Elite within ten (10) business days of Elite's so directing. Elite will replace the Product at no cost to Harris. Elite will bear the cost of any Recall (as defined below) of any Product due to acts or omissions of Elite. Harris will bear the cost of any Recall of any Product due to acts or omissions of Harris. In all other events, the costs of any Product Recall shall be allocated [*] percent ([*]%) to Harris, [*] percent ([*]%) to Elite.

7.3. OTHER REPRESENTATIONS AND WARRANTIES

A. Elite represents and warrants that it will use commercially reasonable efforts to ensure that any third party supplier of the Active Pharmaceutical Ingredient ("API") for the Product shall have an active Drug Master File with the FDA, shall have been qualified by FDA to supply the API under the ANDA, and is in compliance with the obligations imposed by the FDCA.

B. Elite represents and warrants that it will use commercially reasonable efforts to ensure that any third party packager/labeler it subcontracts with pursuant to Section 4.4 shall perform its packaging, storing, labeling and shipping services in a manner which comports with all obligations hereunder, and is in compliance with the obligations imposed by the FDCA.

C. Each of Tishtec and Elite represents that performance of its obligations set forth in this Agreement (whether performed directly by Elite or through a supplier, such as provision of API from a third party supplier) shall not infringe on the intellectual property rights, including but not limited to any patent rights, of any third party. Tishtec further represents and warrants that none of Tishtec or any of its officers, directors, employees or shareholders is bound by any restrictions or obligations (of confidentiality, nondisclosure or otherwise) owing to any third party with respect to the formulations, technology, know-how or information to be provided by Tishtec under this Agreement.

D. Harris represents and warrants that its sale and distribution of the Product will not violate any agreement or order to which it is a party or by which it is bound. The Parties will immediately notify each other of, and assist each other in answering customer or regulatory inquiries and complaints concerning the Product.

E. DISCLAIMER OF WARRANTIES: EXCEPT AS SPECIFICALLY PROVIDED HEREIN, ELITE EXPRESSLY DISCLAIMS ANY AND ALL OTHER WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION THE

WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

F. Elite and Harris each agrees to notify the other within twenty-four (24) hours of any serious and unexpected adverse reactions reported to either of them resulting from the use of the Product (whether inside or outside of the Territory). Elite and Harris shall each notify the other promptly of any other complaints or adverse reactions from third parties reported to either of them resulting from use of the Product sold under Harris' label.

G. In the event either party believes it may be necessary to conduct a recall, field correction, market withdrawal, stock recovery, or other similar action with respect to any Product sold by Elite to Harris under this Agreement (a "Recall"), Elite and Harris

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shall consult with each other as to how best to proceed, it being understood and agreed that the final decision as to any Recall of any Product shall be made by Elite; provided, however, that Harris shall not be prohibited hereunder from taking any action that it is required to take by applicable law.

7.4. COMPLIANCE WITH LAW

The Parties herein represent and warrant that they will perform their respective obligations hereunder in accordance with all applicable law.

7.5 LIMITATION OF LIABILITY

EXCEPT WITH RESPECT TO (x) CONSEQUENTIAL DAMAGES AWARDED TO THIRD PARTIES FOR PRODUCT LIABILITY CLAIMS COVERED BY THE INDEMNIFICATION OBLIGATIONS SET FORTH IN SECTION 7.7(A) OF THIS AGREEMENT, ELITE INFRINGEMENT CLAIMS AND Tishtec INFRINGEMENT CLAIMS COVERED BY SECTIONS 7.7(B) and 7.7(C) OF THIS AGREEMENT, AND (y) ANY BREACH OF THE CONFIDENTIALITY OBLIGATIONS SET FORTH IN ARTICLE III OF THIS AGREEMENT, NO PARTY TO THIS AGREEMENT SHALL BE LIABLE FOR ANY OTHER PARTY'S CONSEQUENTIAL, INCIDENTAL, SPECIAL OR PUNITIVE DAMAGES, OR LOSS OF PROFITS.

7.6. INSURANCE

A. Elite represents and warrants that it has product liability insurance in the amount of at least $1,000,000 per claim and $5,000,000 in the aggregate covering the Product developed, manufactured, packaged and labeled hereunder and shall ensure that any third party supplier hired by Elite in connection with its obligations hereunder shall carry product liability insurance in the same amounts. Elite will provide evidence of his coverage to Harris on an annual basis or whenever any change is made by Elite or any third-party supplier in such policy of insurance.

B. Harris represents and warrants that it has product liability insurance in the amount of at least $1,000,000 per claim and

$5,000,000 in the aggregate including products covering Product distributed from its facility. Harris will provide evidence of this coverage to Elite on an annual basis or whenever any change is made by Harris in such policy of insurance.

7.7. INDEMNIFICATION

A. Elite and Tishtec agree to indemnify and hold harmless Harris, its directors, officers, employees and agents(collectively, "Harris Indemnified Parties"), from any liability or expense, including reasonable fees and costs of defense, they incur arising out of or in connection with third party claims relating to: (i) Elite's, or any third party supplier engaged by Elite's, negligence with respect to the manufacturing, storage, packaging, labeling or shipment of the Product; (ii) personal injury or death resulting from use of Product that was manufactured, stored, or shipped by Elite, or any third party supplier engaged by Elite, in a manner that does not comply with the terms and conditions of this Agreement (a "Product Liability Claim"); or (iii) any breach of Elite's or Tishtec's representations or warranties set forth in this Agreement, including but not limited to those set forth in Sections 7.2, 7.3 (but specifically excluding Section 7.3(C)), and 7.4; all provided that the liability or expense which is the subject of the third party claim is

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not related in any way to Harris', or any third party supplier engaged by Harris', negligence, fault, or other act or omission. Harris agrees to indemnify, defend and hold harmless Elite, Tishtec, and their respective directors, officers, employees and agents (individually, "Elite Indemnified Parties" and "Tishtec Indemnified Parties"), from any liability or expense, including reasonable fees and costs of defense, they incur arising out of or in connection with third party claims relating to: (i) a breach of Harris' representations or warranties set forth in this Agreement; (ii) Harris', or any third party supplier engaged by Harris', negligence with respect to the transporting, storing, sale, marketing, promotion or distribution of Product hereunder; or (iii) any third party supplier engaged by Harris' packaging, labeling or shipment of Product in accordance with the terms and conditions of this Agreement; all provided that the liability or expense which is the subject of the claim is not related in any way to Elite's or Tishtec's (or any third party supplier engaged by Elite or Tishtec's) negligence, fault, or other act or omission.

B. Elite shall indemnify, defend and hold harmless Harris Indemnified Parties and Tishtec Indemnified Parties from the costs and expenses of settling, paying or defending any and all claims, actions or proceedings resulting from an assertion against Tishtec Indemnified Parties or Harris Indemnified Parties that Elite's Intellectual Property infringes upon a third party's intellectual property rights ("Elite Infringement Claims"); provided however that Elite shall not be responsible for any Infringement Claim relating to Intellectual Property provided by Tishtec, Harris, or

any third party.

C. Tishtec shall indemnify, defend and hold harmless Harris Indemnified Parties and Elite Indemnified Parties and pay all costs and expenses of settling, paying or defending any and all claims, actions or proceedings resulting from an assertion against Elite Indemnified Parties or Harris Indemnified Parties that Tishtec's Intellectual Property infringes upon a third party's intellectual property rights ("Tishtec Infringement Claims"); provided however that Tishtec shall not be responsible for any Infringement Claim relating to Intellectual Property provided by Elite, Harris, or any third party.

D. Except with respect to Product Liability Claims, breaches of confidentiality obligations, and Elite Infringement Claims and Tishtec Infringement Claims, in no event shall a Party's liability to indemnify under this Section 7.7 or otherwise exceed the aggregate Profit Share payments received by such Party as of the date of the claim for indemnity hereunder.

7.8 RELATIONSHIP OF THE PARTIES

It is expressly understood and agreed that Tishtec, Elite and Harris are independent contractors and that the relationship between them by virtue of this Agreement shall not constitute a partnership or agency of any kind. No Party to this Agreement shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party without the prior written authorization of that other Party. It is further understood that Harris is not a tenant of Elite or its Lessee or Lessor, and shall not be responsible for any rent or lease expense incurred by Elite.

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ARTICLE VIII; DISPUTE RESOLUTION/ARBITRATION

8.1. In the event that a dispute arising out of or relating to this Agreement cannot be resolved through negotiation between the Parties, the Parties hereto agree to submit the dispute to mediation and will jointly appoint a mutually acceptable mediator, seeking assistance in such regard from the CPR Institute of Dispute Resolution (366 Madison Avenue, New York, NY 10017, telephone number 212-949-6490) if they are unable to promptly agree upon such appointment. Mediation must commence within fifteen (15) days after either Party hereto serves a written notice of mediation upon the other and the Parties hereto shall bear equally the cost of the mediation. The Parties agree to participate in good faith in the mediation and related negotiations for a period of five [5] days. If the Parties are not successful in resolving the dispute through mediation, the parties may then arbitrate. This Agreement shall be governed by and construed in accordance with the laws of the State of Florida without regard to conflicts of laws provisions.

8.2. ARBITRATION: In the event a dispute cannot be resolved in accordance with Section 8.1, all controversies or claims arising out of or relating to this Agreement, or of a breach of it, shall be submitted to binding arbitration pursuant to Section 682.01 et seq, of the Florida Statutes

(Florida Arbitration Code) as amended from time to time and not under the rules of the American Arbitration Association.

A. The arbitration shall be before one (1) arbitrator. If the Parties fail to agree on the sole arbitrator within fifteen (15) days of written notice from either Party of a dispute to be submitted to arbitration, either Party may apply to have the arbitrator appointed by a court of competent jurisdiction pursuant to Section 682.04, Florida Statutes. All arbitration proceedings shall be held in Lee County, Florida.

B. The arbitration hearing shall be held within forty-five (45) days from the date of the arbitrator's acceptance of his or her duties, unless otherwise agreed by all Parties, or extended by the arbitrator on good cause shown.

C. The fees and costs of the arbitration shall be equally divided so that each Party shall pay one third. If a Party fails to pay the fees of the arbitrator as requested from time to time, the other Party may advance any such fees, which shall be due with interest at the maximum legal rate permitted by law from the date of advancement, and shall be part of the award in arbitration.

D. The Parties agree that the Arbitrator shall be granted the power to award reasonable attorneys' to the prevailing Party.

E. Any award rendered in the arbitration shall be binding and conclusive upon the Parties and shall not be subject to retrying or appeal before any court. The arbitrator shall have the right to decree specific performance. Judgment upon the award rendered in the arbitration may be entered in any court having jurisdiction.

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ARTICLE IX: TERM AND TERMINATION OF AGREEMENT

This Agreement shall continue in effect as of the Effective Date for a period of ten (10) years from the first shipment of commercial production quantities of the Product under this Agreement (the "Initial Term"). After the Initial Term, this Agreement shall continue for successive terms of five (5) years each (the "Additional Terms"), unless either Harris or Elite provides written notice to the other Party at least forty-five (45) days before the end of the then-current Term that such Party desires to terminate this Agreement (the Additional Terms and Initial Terms being referred to herein collectively as the "Term"). Notwithstanding the foregoing, this Agreement may be terminated in accordance with the following provisions:

9.1. TERMINATION WITHOUT CAUSE DURING DEVELOPMENT

Before the FDA approves the ANDA with respect to the Product, if Harris wishes to terminate for any reason:

A. Harris shall give thirty (30) days notice in writing to Tishtec and Elite.

B. All of Harris' rights to the Product and the ANDA shall revert

back to Tishtec upon repayment to Harris by Tishtec of the one time Product development fee of $[*]. If Tishtec does not pay the $[*] to Harris within thirty (30) days of Harris' notice, Elite shall have the right to all of Harris' rights upon payment of $[*] to Harris.

C. Harris shall pay Tishtec and Elite its prorated share of Development Costs through the date of notice and as set forth on Exhibit "A".

9.2. TERMINATION WITHOUT CAUSE AFTER DEVELOPMENT.

After eighteen (18) months of launch of the Product into the market, either Harris or Elite may terminate this Agreement on six (6) months' written notice to the other if the Profit Share to the terminating party for the twelve (12) month period preceding the date of notice of termination is less than [*] dollars ($[*]). If the Agreement is terminated under this section by Harris, Harris agrees to pay for all Product ordered by it.

If the Agreement is terminated under this section by Harris, Harris shall have the option to transfer and sell the ANDA and its rights to the Product to Tishtec and Harris shall take such actions, and execute and deliver such documents, as Tishtec may from time to time reasonably request to effectuate the transfer of the ANDA to Tishtec hereunder. If Tishtec does not accept rights and does not request transfer of the ANDA in writing within thirty (30) days of the notice, Elite may elect to accept the transfer of the ANDA its rights to the Product and Harris shall take such actions, and execute and deliver such documents, as Elite may from time to time reasonably request to effectuate the transfer of the ANDA to Elite hereunder. The accepting party shall have all of Harris' rights and obligations for the Product.

If the Agreement is terminated under this section by Elite, Elite agrees, at the request of Harris, to transfer the Product manufacturing to another facility and shall provide all information necessary to transfer the Product manufacturing to a manufacturing facility designated by Harris within sixty (60) days of such termination notice. Any such termination by Elite shall be effective upon FDA approval of the new manufacturing facility, or if earlier, on nine months' from the date of Elite's notice of termination.

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9.3. TERMINATION FOR CAUSE

This Agreement may be terminated by either Elite or Harris in the event of a material breach or default by a Party which is not cured within thirty (30) days after receipt of written notice detailing the breach or default.

9.4. RIGHTS UPON TERMINATION

Subject to Sections 9.1(B) and 9.2, or upon termination of the Agreement due to a material breach by Harris, upon the termination or expiration of

this Agreement, Harris shall continue to have the ownership rights to the ANDA, including the right to license, sell or transfer the ANDA.

9.5 ACTS OF INSOLVENCY

Either Elite or Harris may terminate this Agreement for default by written notice if the other Party becomes insolvent, makes a general assignment for the benefit of creditors, files a voluntary petition of bankruptcy, suffers or permits the appointment of a receiver for its business assets, or becomes subject to any proceeding under any bankruptcy or insolvency law, whether domestic or foreign, or has wound up or liquidated, voluntarily or otherwise. A Party hereto shall immediately notify the other Party upon an occurrence of any such event.

9.6 FORCE MAJEURE

Either Party, Elite or Harris or Tishtec, shall be excused from failure to perform any of its obligations hereunder to the extent such failure is caused by acts of God, fires, floods, war, sabotage, unavailability of raw materials, governmental laws or regulations, labor disputes, strikes or similar occurrences, where such Party is without fault or negligence (a "Force Majeure Event"), provided such Party gives immediate notice of such Force Majeure Event to the other Party, and exercises due diligence to remove the cause as soon as practicable. As applicable due to natural disaster, Elite will make reasonable efforts to assist Harris to find/establish another approved cGMP manufacturing site.

ARTICLE X: MISCELLANEOUS

10.1 ASSIGNMENT

Neither this Agreement nor any interest therein may be assigned, in whole or in part, by either Party, Elite or Harris or Tishtec, without the prior written consent of the other, except that either Party may assign its rights and obligations to an affiliate, division, subsidiary, or parent company, or to a successor approved by (i) Elite, if Harris is the assignor, (ii) Harris, if Elite is the assignor, or (iii) Elite and Harris, if Tishtec is the assignor (such approval not to be unreasonably withheld), in which event such assignee or successor shall assume the respective Party's rights and obligations hereunder. Subject to the foregoing, this Agreement shall be binding upon and inure to the benefit of the Parties hereto, and their respective successors and assigns.

10.2. NO WAIVER

No delay or omission by any Party hereto to exercise any right of power occurring upon any noncompliance or default by the other Party or Parties with respect to any of the terms of this Agreement shall impair any such right or power or be construed to be a waiver thereof.

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A waiver by any of the Parties hereto of any of the covenants, conditions, or agreements to be performed by the other shall not be construed to be a waiver of any succeeding breach thereof of any covenant, condition, or agreement herein contained. Unless stated

otherwise, all remedies provided for in this Agreement shall be cumulative and in addition to and not in lieu of any other remedies available to any Party at law, in equity, or otherwise.

10.3. ENTIRE AGREEMENT; MODIFICATIONS TO THE AGREEMENT

This Agreement, including all Exhibits attached hereto, constitutes the entire agreement between the Parties. All prior contemporaneous agreements, proposals, understandings, whether oral or written, relating to the subject matter hereto are hereby superceded by this Agreement, except of the Confidentiality Agreement dated December 1, 2004, among Harris, Tishtec, and Elite, which shall continue in full force and effect. No modification or waiver of any of the provisions of this Agreement shall be valid unless it is provided in writing and signed by Harris and Elite and, if and to the extent such modification or waiver modifies Tishtec's rights or obligations, by Tishtec, too.

10.4. GOVERNING LAW

This Agreement shall be governed by the laws of the State of Florida, United States of America.

10.5. NOTICES

All communications required or permitted hereunder, shall be in writing, and shall be effective upon delivery to the above provided addresses.

10.6. AUTHORITY

Each person signing on behalf of a Party to this Agreement below herein represents and warrants that it has the legal right and authority to enter into this Agreement, and to fully perform its obligations hereunder, and that none has made nor will make any commitments in conflict with its respective obligations hereunder.

10.7. HEADINGS

The headings and subheadings utilized herein are not a part of this Agreement, but are merely guides or labels to assist in locating and reading the provisions hereof.

10.8. SURVIVAL

The following provisions in this Agreement shall survive termination or expiration of this Agreement for any reason: Article I, Article II Section 2.2, Article III, Sections 7.2, 7.3(A), (B) (C) (D), (E), (F) and (G), 7.5, and 7.7, Article VIII, Article IX, and Article X

10.9 SEVERABILITY

It is not the intention of any Party hereto to violate any public policy statutory or common laws, rules, regulations, treaty, or decisions of any government agency or executive body thereof of any country or community or association of countries. Should one or more provisions of this Agreement be or become invalid or unenforceable by reason of such a violation, then the Parties hereto shall substitute, by mutual consent, valid provisions for

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such invalid provisions, which valid provisions in their economic effect come so close to the invalid provisions that it can be reasonably assumed that the Parties would have contracted this Agreement with those new provisions. In case such provisions cannot be found, the invalidity of one or more provisions of the Agreement shall not affect the validity for the Agreement as a whole, unless the invalid provisions are of such essential importance for this Agreement that it is to be reasonably assumed that the Parties would not have contracted this Agreement without the invalid provisions.

IN WITNESS WHEREOF, each of Harris, Tishtec and Elite have executed this Product Development, Manufacturing, and Distribution Agreement by their duly authorized officers as of the Effective Date.

ELITE LABORATORIES, INC.

Bernard J. Berk, President

TISH TECHNOLOGIES, LLC

Satish Patel, Ph.D., M.B.A., President

HARRIS PHARMACEUTICAL, INC.

Brian A. Harris, M.D., President

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ATTACHMENTS

EXHIBIT A: Product development activity schedule

EXHIBIT B: Transfer price for [*] Capsule Coated Pellets [*]

EXHIBIT C: Profit Sharing Calculation

EXHIBIT D: Example of Profit Sharing Calculation

ELITE LABORATORIES, INC.

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EXHIBIT A: Product Development Activity Schedule [*] BASE STRENGTHS (03-06-05)
FOR THE UNITED STATES MARKET

#	ACTIVITIES	RESPONSIBILITY		TIME LINES	
		ELITE	HARRIS	ELITE	HARRIS
	[*]				
	[*]	[*]			
1	[*]	[*]	[*]	[*]	[*]
	[*]	[*]			
	[*]	[*]			
	[*]				
2	[*]	[*]	[*]	[*]	[*]
	[*]	[*]	[*]	[*]	[*]
	[*]				
3	[*]	[*]	[*]	[*]	[*]
	[*]	[*]	[*]	[*]	[*]
4	[*]	[*]	[*]	[*]	[*]
5	[*]	[*]	[*]	[*]	[*]
6	[*]	[*]	[*]	[*]	[*]
7	[*]	[*]	[*]	[*]	[*]
	TOTALS				

The cost of $[*] includes the cost of the active pharmaceutical ingredient

*ALL DEVELOPMENT COSTS ARE TO SHARED [*]% HARRIS, [*]% ELITE.

**PRODUCT FORMULATION, COMPOSITION AND MANUFACTURING PROCESS SHALL BE PROVIDED BY TISHTEC.

EXHIBIT B

ESTIMATED TRANSFER PRICE (MANUFACTURING COSTS) FOR [*]

100 MG

ACTIVITIES	PER BOTTLE OF 50 CAPSULES, $
Active pharmaceutical ingredient	[*]
Inactive pharmaceutical ingredients, capsules, and any other materials included in the product	[*]
Packaging from a third party: Packaging components, container closure system, labels, insert, and shipping	[*]
Manufacturing labor	[*]
Manufacturing facilities, equipment, utilities	[*]
Analytical labor	[*]

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ACTIVITIES	100 MG PER BOTTLE OF 50 CAPSULES, $
Analytical facilities, equip, utilities, materials	[*]
Indirect costs (regulatory, accounting, etc.)	[*]
COST PER BOTTLE OF [*]CAPSULES, $	[*]

YEARLY OBLIGATION OF STABILITY - ONE BATCH OF EACH STRENGTH (TOTAL OF 2 BATCHES) = $[*]

Assumptions:

1. [*]

2. [*]

3. [*]

4. [*]

[*]

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EXHIBIT C

PROFIT SHARING CALCULATION

Gross Sales	= Aggregate invoice price
Net Sales	= Gross sales - Trade Deductions (capped at [*]% of Gross Sales) (see below)
Gross Margins	= Net Sales- Transfer Price
Net Gross Margins	= Gross Margins less a one time charge, up to $[*], to be agreed upon by all Parties for the advertisement and promotional marketing activities, less Royalties, less the Product Development Fee

---

Royalties	= Amount paid on potential Intellectual Property as provided in Section 6.2(B)._
Product Development Fee	= One time fee of $[*] paid to Tishtec

The Profit Share for each Party shall equal the following percentage of NET GROSS MARGINS:

[*]% Harris
[*]% Elite
[*]% Tishtec

Trade Deductions include:

- Customs and excise duties or other sales taxes (but, for the avoidance of doubt not income or corporation tax), directly related to the sale of the Product

- Costs incurred by Harris in respect of transport, shipping and insurance

costs; and industry standard or mandatory discounts or rebates related to the sale of the Product, including, without limitation, any credit in respect of any Federal or state Medicaid, Medicare or similar program; and

- Amounts repaid or credited by Harris, consistent with its ordinary or customary business practices for similar products, by reason of the rejection or return of goods and allowances, including trade, quantity and cash discounts and any other adjustments, including those granted on account of price or shelf stock adjustments, billing errors, rejected goods, damaged goods, recalls, returns, rebates, charge backs, reimbursements, similar payments granted or given to wholesalers or other distributors, buying groups, health care insurance carriers or other institutions.

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EXHIBIT D

EXAMPLE OF PROFIT SHARING CALCULATION
SAMPLE - [*]

Gross Sales	=	[*]
Net Sales	=	[*]
Gross Margins	=	[*]
Royalties	=	[*]
Product Development Fee	=	[*]
One time charge agreed upon by All parties for the advertisement And Promotional marketing activities	=	[*]
NET GROSS MARGINS	=	[*]

The NET GROSS MARGINS will be shared by the three parties as follows:

[*]% Harris
[*]% Elite
[*]% Tishtec

* Trade deductions
** Transfer price

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Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.