18-05037-E

foiapa

From: Mark Edwards <medwards@biosciadvisors.com>
Sent: Friday, June 29, 2018 6:57 PM
To: foiapa
Subject: FOIA Request

I would like to request access to Exhibit 10.1 to the 6/30/10 10-Q, filed by Santarus, Inc. on 8/3/2010. Confidential treatment was sought as to certain portions when initially filed with the Commission.

In the event that confidential treatment has not expired or has been extended, I further request that you send me the expiration date(s) from the relevant CT order(s) so I will know when I should resubmit my request.

I authorize up to $61 in search and retrieval fees. Please send the exhibit(s) by PDF if possible.

Sincerely,

Mark

Mark G Edwards
Managing Director
Bioscience Advisors
2855 Mitchell Dr., Suite 103
Walnut Creek, CA 94598
medwards@biosciadvisors.com
925 954-1397

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
STATION PLACE
100 F STREET, NE
WASHINGTON, DC 20549-2465

Office of FOIA Services

July 26, 2018

Mr. Mark G. Edwards
Bioscience Advisors
2855 Mitchell Dr., Suite 103
Walnut Creek, CA 94598

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552
Request No. 18-05037-E

Dear Mr. Edwards:

This letter is in response to your request, dated June 29, 2018 and received in this office on July 2, 2018, for Exhibit 10.1 to the June 30, 2010 Form 10-Q, filed by Santarus, Inc. on August 3, 2010.

The search for responsive records has resulted in the retrieval of 37 pages of records that may be responsive to your request. They are being provided to you with this letter.

As shown on the enclosed invoice, the processing fee is $30.50 in accordance with our fee schedule. You may use our Online Payment option to pay by debit or credit card. If paying by mail, checks or money orders should be made payable to the SEC and a copy of the invoice should be mailed to our payment address: Enterprise Services Center, HQ Bldg., Room 181, AMZ-341, 6500 South MacArthur Boulevard, Oklahoma City, OK 73169. Please refer to the following link for detailed instructions on how to remit payments. http://www.sec.gov/about/offices/ofm.htm

If you have any questions, please contact me directly at andersonc@sec.gov or (202) 551-8315. You may also contact me at foiapa@sec.gov or (202) 551-7900. You also have the right to seek assistance from Ray J. McInerney as a FOIA Public Liaison or contact the Office of Government Information Services (OGIS) for dispute resolution services. OGIS can be reached at 1-877-684-6448 or Archives.gov or via e-mail at ogis@nara.gov.

Sincerely,

Clarissa Anderson

Clarissa Anderson
FOIA Research Specialist

Enclosures

DISTRIBUTION AND SUPPLY AGREEMENT

by and between

Santarus, Inc.

and

Prasco, LLC

dated April 26, 2010

DISTRIBUTION AND SUPPLY AGREEMENT

This Distribution and Supply Agreement (this "Agreement") is made as of April 26, 2010 (the "Effective Date"), by and among Santarus, Inc., a Delaware corporation (hereinafter referred to as "Manufacturer"), and Prasco, LLC, an Ohio limited liability company (hereinafter referred to as "Distributor").

Recitals

WHEREAS, Manufacturer will supply, and Distributor will purchase, distribute and sell, the Products (as defined herein) in the Territory in accordance with the terms hereof.

NOW THEREFORE, in consideration of the mutual covenants and consideration set forth herein, the Parties hereto agree as follows:

ARTICLE 1

DEFINITIONS

As used in this Agreement, the following defined terms shall have the meanings set out in this Article 1.

1.1 "**Act**" means the United States Federal Food, Drug, and Cosmetic Act, as amended.

1.2 "**Adverse Drug Experience**" means any of the following: an "adverse drug experience," a "life-threatening adverse drug experience," a "serious adverse drug experience," or an "unexpected adverse drug experience," as those terms are defined at 21 C.F.R. § 314.80.

1.3 "**Affiliate**" of a Party means any entity that directly or indirectly controls, is controlled by, or is under common control with, such Party. An entity shall be regarded as in control of another entity if it owns or controls at least fifty percent (50%) of the equity securities of the subject entity entitled to vote in the election of directors (or, in the case of an entity that is not a corporation, for the election of the corresponding managing authority), except that the term "Affiliate" shall not include subsidiaries or other entities in which a Party or its Affiliates owns a majority of the ordinary voting power necessary to elect a majority of the board of directors or other governing board, but is restricted from electing such majority by contract or otherwise, until such time as such restrictions are no longer in effect.

1.4 "**Allowance for Distribution and Marketing**" means two percent (2%) of Net Sales.

1.5 "**Audited Party**" has the meaning given in Section 5.9(d) hereof.

1.6 "**Auditing Party**" has the meaning given in Section 5.9(d) hereof.

1.7 "**Bailment Agreement**" has the meaning given in Section 5.1(b).

1.8 **"Bailment Product"** has the meaning given in Section 5.1(b).

1.9 "**Bankruptcy Event**" means, with respect to a Person, that such Person becomes insolvent, or voluntary or involuntary proceedings by or against such Person are instituted in bankruptcy or under any insolvency law, or a receiver or custodian is appointed for such Person, or proceedings are instituted by or against such Person for corporate reorganization or the dissolution of such Person, which proceedings, if involuntary, shall not have been dismissed within sixty (60) days after the date of filing, or such Person makes an assignment for the benefit of its creditors, or substantially all of the assets of such Person are seized or attached and not released within sixty (60) days thereafter.

1.10 "**Branded Products**" means (a) the brand drug Zegerid® (omeprazole/sodium bicarbonate) Capsules 20mg/1100mg and 40mg/1100mg, manufactured and distributed in accordance with NDA No. 21-849 and marketed under the Trademark; and (b) the brand drug Zegerid® (omeprazole/sodium bicarbonate) Powder for Oral Suspension 20mg/1680mg and 40mg/1680mg, manufactured and distributed in accordance with NDA No. 21-636 and marketed under the Trademark.

1.11 "**Change in Control**" means (i) the liquidation or dissolution of a Party or the sale or other transfer by a Party (excluding transfers to subsidiaries) of all or substantially all of its assets; or (ii) the occurrence of a tender offer, stock purchase, other stock acquisition, merger, consolidation, recapitalization, reverse split, sale or transfer of assets or other transaction, as a result of which any person, entity or group (a) becomes the beneficial owner, directly or indirectly, of securities of a Party representing more than 50% of the ordinary shares of such Party or representing more than 50% of the combined voting power with respect to the election of directors (or members of any other governing body) of such Party's then outstanding securities, or (b) obtains the ability to appoint a majority of the Board of Directors (or other governing body) of a Party, or obtains the ability to direct the operations or management of a Party or any successor to the business of a Party; provided, however, that for purposes of this definition, the term "Party", in the case of Distributor, shall be deemed to mean both Distributor and Scion Companies, LLC, the corporate parent of Distributor.

1.12 "**Commencement Date**" has the meaning given in Section 2.1.

1.13 **"Commercially Reasonable Efforts"** means, with respect to the efforts to be expended by any Party with respect to any objective, those reasonable, diligent, good faith efforts to accomplish such objective as such Party would normally use to accomplish a similar objective under similar circumstances. "Commercially Reasonable Efforts" with respect to a product shall mean those efforts and resources normally used by such Party with respect to a product owned or controlled by such Party, or to which such Party has similar rights, which product is of similar market potential and is at a similar stage in its life as is the Product, taking into account issues of safety, efficacy, product profile, the competitiveness of the marketplace, the proprietary position of the Product, the regulatory structure involved, profitability of the Product and other relevant commercial factors.

1.14 "**Competitive Product**" means a drug product, other than the Products, that contains omeprazole and is marketed as a generic product AB rated to and substitutable for any of the Branded Products.

1.15 "**Confidential Information**" means all proprietary materials, data or other information (whether or not patentable) regarding a Party's know how, products, business information or objectives, that is designated as confidential in writing by the disclosing Party, whether by letter or by the use of an appropriate stamp or legend, prior to or at the time any such material, data or other information is disclosed by the disclosing Party to the other Party. Notwithstanding the foregoing, materials, data or other information that are disclosed by a Party in writing without an appropriate letter, stamp or legend, or that are orally, electronically or visually disclosed by a Party, shall constitute Confidential Information of such Party if (a) such Party, within thirty (30) days after such disclosure, delivers to the receiving Party a written document or documents describing the materials, data or other information, indicating that such materials, data or other information constitute Confidential Information, and referencing the place and date of such oral, visual, electronic or written disclosure and the names of the persons to whom such disclosure was made, or (b) such materials, data or other information are of the type that is customarily considered to be confidential information by persons engaged in activities that are substantially similar to the activities being engaged in by the Parties.

1.16 "**Distributor Discretionary Change**" has the meaning given in Section 4.2(b) hereof.

1.17 "**Event of Default**" has the meaning given in Section 10.4 hereof.

1.18 "**FDA**" means the United States Food and Drug Administration.

1.19 "**First Commercial Sale**" means the date of the first sale of a Product in the Territory by Distributor pursuant to the terms of this Agreement.

1.20 "**Force Majeure Event**" has the meaning given in Section 10.7 hereof.

1.21 "**Initial Term**" has the meaning given in Section 10.1 hereof.

1.22 "**Invoice Supply Price**" has the meaning given in Section 3.2 hereof.

1.23 "**License Fees and Royalties**" means any license fees or royalties payable by Manufacturer to the University of Missouri based on Net Sales by Distributor.

1.24 "**Manufacturer Discretionary Change**" has the meaning given in Section 4.2(a) hereof.

1.25 "**NDA**" means a New Drug Application pursuant to Section 505 of the Act (21 U.S.C. Section 355), or the applicable regulations (21 CFR Part 314), including any supplements, amendments or modifications submitted to or required by the FDA or any successor application or procedure for approval to market a pharmaceutical product.

1.26 "**NDC#**" means a unique 3-segment number that identifies the labeler/vendor, the product and the trade package size.

1.27 "**Net Distributable Profits**" for a calendar month means Distributor's Net Sales of all Products in the Territory for such calendar month minus the sum of (a) the Invoice Supply Price for such Products (as incurred or calculated for the applicable month), (b) the Allowance for Distribution and Marketing for such Net Sales, (c) License Fees and Royalties arising out of the Net Sales for such calendar month, and (d) the out-of-pocket costs reasonably incurred by Distributor associated with the shipment and delivery of Products to Distributor, limited to the cost of in-bound freight, insurance, handling, fees, taxes, export licenses, import licenses and customs formalities, and other similar costs, provided that except as provided in Section 3.4(c), in no event shall Net Distributable Profits be less than zero for any monthly period.

1.28 "**Net Sales**" means the gross amount billed or invoiced to independent Third Party customers (including taxes) for sales of Products on an SKU basis, less deductions for (a) quantity, trade or cash discounts or allowances (including customer rebates) actually allowed and taken, (b) amounts accrued by reason of rejections or returns of goods and government mandated rebates, or because of chargebacks or retroactive price reductions, and (c) taxes charged to the customer and itemized on the invoice and directly related to the sale of Products, all determined in accordance with United States generally accepted accounting principles consistently applied. Products shall be considered sold as of the date title passes to the customer (upon delivery).

1.29 "**Party**" means Manufacturer or Distributor, as the case may be, and "**Parties**" means Manufacturer and Distributor.

1.30 "**Person**" means any individual, corporation, partnership, limited liability company, joint venture, association, trust, unincorporated organization or other entity.

1.31 "**Product Listing**" means filing with the FDA a list of drugs in commercial distribution as required by law.

1.32 "**Products**" means (a) omeprazole/sodium bicarbonate capsules 20mg/1100mg and 40mg/1100mg; and (b) omeprazole/sodium bicarbonate powder for oral suspension 20mg/1680mg and 40mg/1680mg, each in finished final packaged form that are manufactured by or on behalf of Manufacturer for sale to and subsequent resale by Distributor in the Territory. In addition to the foregoing, the term Products shall also include any other dosage formulation of omeprazole that Manufacturer has elected to include in this Agreement pursuant to Section 2.2.

1.33 "**Regulatory Agency**" means the FDA and the regulatory agency or notified body in a country that performs the same or equivalent function as the FDA in the United States. Any reference to a rule or requirement of the FDA herein shall refer, if the circumstances make it applicable, to the equivalent rule or requirement of any other Regulatory Agency.

1.34 "**Remaining Supply Price**" has the meaning given in Section 3.4 hereof.

1.35 "**Renewal Term**" has the meaning given in Section 10.1 hereof.

1.36 "**Required Manufacturing Change**" has the meaning given in Section 4.1 hereof.

1.37 "**Rolling Forecast**" has the meaning given in Section 5.5(a) hereof.

1.38 "**SKU**" means each of the following unit configurations of the Products: (a) omeprazole/sodium bicarbonate capsules 20mg/1100mg (30-count bottle); (b) omeprazole/sodium bicarbonate capsules 40mg/1100mg (30-count bottle); (c) omeprazole/sodium bicarbonate powder for oral suspension 20mg/1680mg (carton of 30 single dose packets); and (d) omeprazole/sodium bicarbonate powder for oral suspension 40mg/1680mg (carton of 30 single dose packets).

1.39 "**Specifications**" means the specifications for each Product contained in the NDA for the Branded Products.

1.40 "**Supply Price**" has the meaning given in Section 3.1 hereof.

1.41 "**Term**" has the meaning given in Section 10.1 hereof.

1.42 "**Territory**" means the United States of America and its territories and possessions.

1.43 "**Third Party(ies)**" means any Person other than the Parties or their respective Affiliates.

1.44 "**Third Party Vendors**" has the meaning given in Section 2.10.

1.45 "**Trademark**" means Zegerid®.

ARTICLE 2

DISTRIBUTION RIGHTS AND OBLIGATIONS

2.1 **Commencement Date; First Commercial Sale**.

(a) The Parties acknowledge that Manufacturer has multiple SKUs of the Products and may elect to launch individual SKUs of the Products at different times.

(b) Manufacturer shall have the sole right and discretion to determine if and when to launch each individual SKU of the Products. If Manufacturer decides to launch an SKU of the Products, Manufacturer shall provide Distributor with written notice specifying a date for Distributor to commence distributing and marketing such SKU. A notice delivered by Manufacturer under this Section 2.1(b) for an SKU of the Products is referred to herein as a "Commencement Notice" with respect to such SKU of the Products, and the date specified in a Commencement Notice is referred to herein as the "Commencement Date" with respect to such SKU of the Products.

(c) Effective as of the Commencement Date with respect to each SKU of the Products, Manufacturer grants to Distributor a nonsublicensable, nontransferable license under the NDA for the applicable Branded Product to distribute and sell such SKU of the Products in the Territory as a generic product AB rated to and substitutable for the applicable Branded Product. Upon delivery of the Commencement Notice for an SKU of the Products, Manufacturer shall supply such SKU of the Products to Distributor (except for pre-launch supply quantities, which Manufacturer may supply prior to the Commencement Notice), and Distributor shall distribute and market such SKU of the Products in the Territory as a generic product commencing as of the Commencement Date, in each case in accordance with this Agreement. Until the Commencement Date with respect to an SKU of the Products, Distributor shall have no right to distribute, advertise, promote or sell such SKU of the Products, except that Distributor may engage in pre-booking activities of the type described in Exhibit 2.1 with respect to such SKU of the Products, subject to the prior written approval of Manufacturer. If Manufacturer fails to send at least one Commencement Notice, Distributor's exclusive remedy shall be to terminate this Agreement in accordance with Section 10.3(a) or 10.3(c) hereof.

(d) Distributor shall use Commercially Reasonable Efforts to launch each SKU of the Products on the applicable Commencement Date; provided, however, and subject to Section 10.7, such launch shall occur not later than one (1) business day after the later of (x) the Commencement Date for such SKU of the Products, and (y) Distributor's receipt of launch quantities of such SKU of the Products in compliance with this Agreement. Within ten (10) business days after the First Commercial Sale of each SKU of the Products, Distributor shall send written notice to Manufacturer specifying the date of the First Commercial Sale of such SKU of the Products. In addition, Distributor shall confirm the date of First Commercial Sale via email (to an email address designated by Manufacturer) within one (1) business day after the date of the First Commercial Sale.

2.2 Additional Product. During the Term, Manufacturer may specify additional dosage forms of omeprazole, either as a single entity or in combination, to be included in the definition of "Product" and to be distributed and sold by Distributor in accordance with this Agreement. If Manufacturer elects to include such other dosage forms, Manufacturer shall provide Distributor prior written notice of such election (the "Added Product Election"), together with the Invoice Supply Price for such added Product. The Invoice Supply Price for such added Product shall be determined in accordance with the same criteria as the Invoice Supply Prices set forth in Exhibit 3.2. Following such Added Product Election, such added Product shall be deemed a "Product" for all purposes hereunder. Distributor shall launch such added Products within one (1) business days after the later of (x) Distributor's receipt of the Added Product Election, and (y) Distributor's receipt of launch quantities of such added Products.

2.3 Supply and Commercial Exploitation. Distributor shall purchase all of its requirements of the Products exclusively from Manufacturer in accordance with this Agreement. Distributor shall use Commercially Reasonable Efforts to distribute, promote and expand the sale of the Products as generic products in the Territory, and in performing such activities, Distributor shall devote the same level of effort to Manufacturer and the Products as it does for its other customers and products. In promoting and distributing the Products, Distributor shall not use the Trademark or any other trademark or trade name, except that Distributor may (a) use the

Trademark on promotional materials to the extent necessary to indicate that the Products are substitutable for the Branded Products and are "authorized generics" of the Branded Products, and (b) identify itself as the distributor of the Product using its "Prasco" trade name and trade dress; provided, however, that all such promotional materials shall be approved by Manufacturer in accordance with Section 6.2.

2.4 Limitation on Distributing Competing Products. Except for Distributor's distribution and sale of the Products in accordance with this Agreement, during the Term, Distributor shall not, and Distributor shall cause its Affiliates to not, manufacture, supply, promote, advertise, merchandise, distribute, sell or offer for sale, directly or indirectly any Competitive Product in the Territory. Except as provided in Section 2.13, during the period that a Product (on an SKU basis) is covered by this Agreement, Manufacturer shall supply such Product SKU exclusively to Distributor for marketing and sale as a generic product.

2.5 Distribution Obligations. Distributor shall: (i) store, handle and distribute its inventory of the Products in clean and sanitary conditions as required to maintain the quality and traceability of the Products, and in accordance with the labeling for the Products; (ii) not alter the Products in any manner; (iii) comply with the Act and all other applicable federal, state and local food, health and other relevant laws and regulations within the Territory in connection with its storage, handling, distribution and sale of the Products; (iv) not promote or market the Products in any manner which is inconsistent with the labeling of the Products or applicable laws and regulations (including without limitation, 21 CFR Section 201), or otherwise make any false or misleading representations to customers or others regarding the Products.

2.6 Solicitation Outside Territory. Distributor shall not, and Distributor shall cause its Affiliates to not (i) solicit or accept orders for sales of any Product or Products to any existing or prospective customer outside the Territory, (ii) deliver or tender (or cause to be delivered or tendered) any Product or Products outside of the Territory, or (iii) sell any Product or Products to, or solicit any sales from, a customer if Distributor knows or has reason to know that such customer intends to resell the Products outside of the Territory.

2.7 Pricing. Distributor shall have sole discretion in establishing the prices at which Distributor sells the Products. In exercising its pricing discretion, if Distributor or its Affiliates sell Products to a customer who also purchases other products or services from Distributor or its Affiliates, then Distributor agrees not to, and shall require its Affiliates not to, allocate the sales price of the jointly-purchased units of the Product and the other products or services, or any discounts offered in connection therewith, in a manner that is reasonably likely to disadvantage Distributor's Net Sales of the Products in order to benefit sales or prices of other products or services offered by Distributor or its Affiliates. Distributor will not sell any Products as part of a bundle of distinct products without the prior written consent of Manufacturer.

2.8 Reservation of Rights. Except as expressly provided in this Agreement, Manufacturer is not granting to Distributor any right, title or interest, whether express or implied, under any intellectual property right or other right that Manufacturer or its Affiliates may own or otherwise control. Nothing in this Agreement shall preclude or prevent Manufacturer or its Affiliates from manufacturing, marketing or selling the Branded Products (either by itself or

through a Third Party) in the Territory. Except as set forth in Section 2.1, nothing contained in this Agreement shall grant (or be construed as granting) to Distributor any right, title or interest in, to or under any NDA held in the name of Manufacturer, or any supplement thereto, or any other intellectual property right owned or controlled by Manufacturer.

2.9 NDC#; Manufacturer. Distributor shall distribute and sell the Products using only an NDC# that reflects Distributor as the distributing and selling party. Distributor shall take all actions necessary to obtain such new NDC# prior to the first Commencement Date. Manufacturer shall be listed as the manufacturer on the label for the Products.

2.10 Contract Manufacture. Distributor acknowledges that Manufacturer may use an Affiliate or one or more Third Parties to supply, contract manufacture or package the Products (collectively, "Third Party Vendors").

2.11 Compliance with Laws. Each of Distributor and Manufacturer shall perform its obligations under this Agreement in all material respects in compliance with applicable laws, rules and regulations.

2.12 Key Performance Indicators. During each calendar quarter during the Term (or less frequently as the Parties may mutually agree), Distributor and Manufacturer shall discuss (a) Distributor's and Manufacturer's performance against the key performance indicators set forth on Exhibit 2.12 (the "KPIs") and (b) any proposed amendments to the KPIs for the forthcoming quarterly period, as may be mutually agreed by the Parties. In the event that either Party fails to meet one or more of the KPIs at any time during the Term, then Distributor and Manufacturer shall work diligently to address such failure, including through discussions between members of each Party's management and implementation of a mutually agreed corrective action plan.

2.13 Settlement of Patent Litigation. Nothing in this Agreement shall be deemed to prohibit Manufacturer from settling any patent litigation relating to the Branded Products or authorizing a Third Party that is a party to such a settlement to sell, market or distribute a Competitive Product (including an authorized generic of the Branded Products) in the Territory.

ARTICLE 3

FINANCIAL PROVISIONS

3.1 Supply Price. Following the first Commencement Date, and during the remaining Term, Distributor shall pay Manufacturer the Supply Price for the Products on an SKU basis, consisting of the Invoice Supply Price, the Remaining Supply Price and any applicable License Fees and Royalties.

3.2 Invoice Supply Price. The initial invoice supply price for each Product is set forth in Exhibit 3.2. Each such price shall be firm until the first anniversary of the First Commercial Sale and shall be subject to adjustment from time to time thereafter as set forth herein. With respect to each Product, the price set forth in Exhibit 3.2 as adjusted from time to

time as set forth herein is referred to as the "Invoice Supply Price". Notwithstanding the foregoing, if the First Commercial Sale of a Product has not occurred by December 31, 2011, then the initial invoice supply price for each such Product shall be adjusted as of December 31, 2011 as contemplated by Section 3.2(a).

(a) The Invoice Supply Price set forth in Exhibit 3.2 for each Product shall be adjusted (i) from time to time after the first anniversary of First Commercial Sale of such Product to pass through any pricing increases or decreases that Manufacturer incurs after the Effective Date for such Product under its Third Party Vendor agreements (including pricing increases of the type covered by Sections 4.1 and 4.2, but excluding one-time costs covered by such Sections, which one-time costs are addressed as applicable in Section 3.2(b) below), and (ii) on each anniversary of the First Commercial Sale of such Product to reflect any increases or decreases in Manufacturer's Indirect Manufacturing Overhead for Products (as defined below) after the Effective Date (in the case of the first adjustment) or during the previous twelve (12) months (in the case of subsequent adjustments). To the extent that any such increase exceeds the percentage increase, if any, in the Producer Price Index (Pharmaceutical Preparations, prescription (325412/325412), published by the U.S. Department of Labor, Bureau of Labor Statistics) for the most recently completed twelve (12) month period ending on the last day of the month immediately preceding the month in which the adjustment occurs, then Manufacturer shall also provide documentation to Distributor verifying such increase (provided that for the initial adjustment the percentage increase in the Producer Price Index, if any, will be based on the change since January 1, 2010). At least two (2) weeks before any such increase or decrease, Manufacturer shall provide to Distributor written notice of any such increase or decrease to the Invoice Supply Price pursuant to this Section 3.2(a). For such purposes, the term "Manufacturer's Indirect Manufacturing Overhead for Products" shall mean Manufacturer's internal personnel costs and travel, supply, facilities and other similar costs directly associated with the manufacturing and inventory process for Products (excluding SG&A costs) and shall be consistent with the cost of goods included in Manufacturer's audited financial statements prepared in accordance with United States generally accepted accounting principles.

(b) In addition, to the extent that Manufacturer incurs one-time costs under its Third Party Vendor agreements in addition to those costs contemplated by Section 3.2(a) (including costs of the type covered by Section 4.1 and excluding costs of the type covered by Section 4.2(a)), Manufacturer and Distributor shall agree in good faith on an equitable sharing of such costs, taking into account the respective volumes of Products and Branded Products being supplied, manufactured or packaged under the applicable Third Party Vendor agreement. Manufacturer shall provide Distributor with documentation reasonably acceptable to Distributor substantiating any such one-time costs.

3.3 Payment of Invoice Supply Price. Manufacturer shall invoice Distributor for the Invoice Supply Price together with, or promptly after, each shipment of Product to Distributor, and as one-time costs are incurred, except that with respect to the Bailment Product, Manufacturer shall invoice Distributor for the Invoice Supply Price of each SKU of Bailment Product on the date of First Commercial Sale of such SKU of Bailment Product, in accordance

with the contingent purchase order for such Bailment Product in a form to be mutually agreed by Manufacturer and Distributor following the Effective Date (the "Contingent P.O."). Distributor shall pay Manufacturer's invoices for each Product: (A) within sixty (60) days after the date of First Commercial Sale of the Product if Manufacturer ships the Product prior to such First Commercial Sale or if Manufacturer ships the Product within thirty (30) days after such First Commercial Sale; and (B) within thirty (30) days from the date of invoice for shipments of such Product thereafter. For all Products added under Section 2.2, Distributor shall pay Manufacturer's invoices for each Product: (I) within sixty (60) days after the date of the First Commercial Sale of the Product if Manufacturer ships the Product prior to such First Commercial Sale or if Manufacturer ships the Product within thirty (30) days after such First Commercial Sale; and (II) within thirty (30) days from the date of invoice for shipments of such Product thereafter. The date of each invoice for Bailment Product shall be the date of First Commercial Sale of such Bailment Product, and the date of each invoice for other Products shall be the date of shipment of such Products to Distributor. Distributor shall make payment without deduction, deferment, set-off, lien or counterclaim of any nature, other than for rejected or returned goods for which Manufacturer has issued a credit acknowledgment.

3.4 Remaining Supply Price/License Fees and Royalties.

(a) Following the first Commencement Date, and during the remaining Term, Distributor shall pay Manufacturer an amount equal to a percentage of Net Distributable Profits per calendar month as specified in Exhibit 3.4(a) (the "Remaining Supply Price"), as well as an amount equal to any applicable License Fees and Royalties payable by Manufacturer based on Net Sales during such calendar month, and shall make such payments in accordance with Section 3.5. For purposes hereof, a "calendar month" is measured as follows with respect to each SKU of the Products that has a different date of First Commercial Sale: (i) for the first calendar month, the stub period beginning on the date of the First Commercial Sale of such Product and ending on the last day of the calendar month in which the First Commercial Sale occurs; (ii) for the next succeeding months, the full calendar month period; and (iii) for the final calendar month, the stub period beginning on the first day of the calendar month and ending on the termination or expiration of this Agreement.

(b) The Parties acknowledge that the deductions from Net Sales set forth in Section 1.28(b) shall be accrued during the applicable calendar month but that the actual deductions of such items for such month may not finally be known until after Distributor makes a payment to Manufacturer under Section 3.5(b) for such calendar month. Accordingly, on an ongoing basis, Distributor shall compare actual deductions for such items against the accruals for such items used to calculate payments under Section 3.5(b) in prior calendar months. By the last day of each calendar quarter, Distributor shall provide to Manufacturer (in accordance with the Accrual Rollforward Report included in Exhibit 3.4(b)) a rollforward of accrual activity for the first two months of such calendar quarter and the last month of the calendar quarter immediately preceding such period. Such rollforward shall show accruals at the beginning of the period, additions to accruals, actual charges against such accruals, any adjustments to accruals deemed necessary by Distributor, and ending accruals held by Distributor at the end of the calendar

quarter. Any adjustments to existing accruals shall be included in the computation of Net Sales in the month following the distribution of the accrual analysis.

(c) Upon the expiration or termination of this Agreement, Distributor shall continue to provide Manufacturer with an Accrual Rollforward Report as provided above until all adjustments to existing accruals are determined, and within thirty (30) days after Distributor delivers each such Accrual Rollforward Report, (i) if Distributor reports a decrease in amounts previously accrued, Distributor shall pay Manufacturer the resulting increase in the Remaining Supply Price, and (ii) if Distributor reports an increase in amounts previously accrued, Manufacturer shall pay Distributor the resulting decrease in the Remaining Supply Price. Nothing contained herein shall require Manufacturer to pay any disputed amounts set forth in such report or notice, or otherwise constitute a waiver of any right of Manufacturer to dispute the amounts set forth in such report or notice.

(d) On or prior to the first Commencement Date, Manufacturer shall notify Distributor of the percentage of Distributor's Net Sales to be used to calculate the License Fees and Royalties payable to Manufacturer, and if there is a change in such percentage, Manufacturer shall notify Distributor within five (5) business days after the end of the calendar month in which the change occurs. In calculating License Fees and Royalties payable to Manufacturer, Distributor shall use the current percentage so specified by Manufacturer.

3.5 Payment of Remaining Supply Price and License Fees and Royalties. During the period commencing after the First Commercial Sale of a Product and continuing thereafter until the end of the calendar quarter following the calendar quarter in which this Agreement terminates or expires:

(a) Within seven (7) days after the end of each calendar month, ending after the Commencement Date for such Product, Distributor shall deliver to Manufacturer a written report, showing with respect to the immediately preceding month (i) inventory of Product in Distributor's distribution facilities as of the first and last days of such month, and units of Product received and shipped during such month (all in accordance with the report included in Exhibit 3.5(a)(i)), and (ii) a written report in the form of Exhibit 3.5(a)(ii), completed with respect to the prior month, including the calculation of the Net Sales, Net Distributable Profits, the Remaining Supply Price payable to Manufacturer for such calendar month and License Fees and Royalties payable to Manufacturer for such calendar month.

(b) Within sixty (60) days after the end of the calendar month in which the First Commercial Sale of a Product occurs (provided that such time period may be extended to ninety (90) days with regard to the amount of Product sold during such calendar month for which Distributor has not received payment as of the sixtieth (60^{th}) day), and within sixty (60) days after the end of each calendar month thereafter, Distributor shall remit the total amount due to Manufacturer for the Remaining Supply Price and License Fees and Royalties for such calendar month by wire transfer in U.S. dollars to the credit of such bank account as shall be designated in advance by Manufacturer. Notwithstanding any provision of this Agreement to the contrary, if the License Fees and Royalties payable for any calendar month exceed the sum

of the Net Distributable Profits for such calendar month plus the License Fees and Royalties payable for such calendar month, Distributor shall not be obligated to pay the excess amount for such calendar month, and such excess amount shall be carried forward and added to the calculation of License Fees and Royalties in the next calendar month.

(c) Within thirty (30) days after the first Commencement Date and within thirty (30) days after the end of each calendar year thereafter, Distributor shall submit to Manufacturer a written forecast of the Remaining Supply Price for the applicable partial or full calendar year. In addition, Distributor shall provide interim updated forecasts of the Remaining Supply Price from time to time upon the reasonable request of Manufacturer.

3.6 Taxes and Withholding. Distributor shall make all payments to Manufacturer under this Agreement without any deduction or withholding for, or on account of, any tax.

3.7 Currency. All amounts hereunder, including, without limitation, Net Sales, expense amounts and the amounts due to Manufacturer hereunder, shall be expressed in U.S. dollars.

3.8 Maintenance of Records; Audit. Distributor shall maintain, and shall require its Affiliates to maintain, complete and accurate books and records in connection with the handling, sale, and distribution of all Products hereunder, as necessary to allow the accurate calculation consistent with generally accepted accounting principles of the amounts due to Manufacturer, the reporting obligations contemplated herein, and compliance with the terms of this Agreement, and Distributor shall maintain such books and records for a period of at least five (5) years after the end of the calendar year in which they were generated, or for such longer period as may be required by law. Once per calendar year during the Term, Manufacturer shall have the right to engage an independent accounting firm reasonably acceptable to Distributor, at Manufacturer's expense, which shall have the right to examine in confidence the relevant books and records as may be reasonably necessary to determine or verify the amount of payments due hereunder and compliance with obligations hereof. Such accounting firm shall conduct such examination, and Distributor shall make such books and records available, during normal business hours at the facility(ies) where such books and records are maintained. Each such examination shall be limited to pertinent books and records for any year ending not more than twenty-four (24) months prior to the date of request; provided that Manufacturer shall not be permitted to audit the same period of time more than once. Before permitting such independent accounting firm to have access to such books and records, Distributor may require such independent accounting firm and its personnel involved in such audit to sign a confidentiality agreement (in form and substance reasonably acceptable to Distributor) as to any Confidential Information which is to be provided to such accounting firm or to which such accounting firm will have access while conducting the audit under this Section. The independent accounting firm will prepare and provide to each Party a written report stating whether the reports submitted and amounts paid are correct or incorrect and the amounts of any discrepancies. If there was an underpayment by Distributor hereunder, Distributor shall promptly (but in no event later than thirty (30) days after its receipt of the independent auditor's report so concluding) make payment to Manufacturer of any shortfall by wire transfer in U.S. dollars, including interest calculated in accordance with Section 3.9. If there was an overpayment by Distributor hereunder, Manufacturer shall promptly

(but in no event later than thirty (30) days after Manufacturer's receipt of the independent auditor's report so concluding) refund to Distributor the excess amount by wire transfer in U.S. dollars. In the event of any underpayment by Distributor resulting in a cumulative discrepancy during any calendar year in excess of the greater of (i) 5% or (ii) one hundred thousand dollars ($100,000.00), all costs of the audit, including the expenses of the independent accounting firm, shall be borne and promptly paid by Distributor.

3.9 Interest on Late Payments. If any payment under this Agreement is late, interest shall accrue on the past due amount at a rate equal to the lesser of (a) eighteen percent per annum, and (b) the maximum rate permitted by law. Time for any payments hereunder shall be of the essence.

ARTICLE 4

MARKET REQUIREMENTS AND SPECIFICATIONS

4.1 Mandatory Changes to Specifications. Manufacturer shall use Commercially Reasonable Efforts to make changes to the Specifications that are required by applicable law (a "Required Manufacturing Change"). To the extent reasonably practicable and in any event prior to shipment, Manufacturer shall notify Distributor of such proposed changes prior to implementing such changes. Manufacturer shall bear the cost of all internal and external costs incurred by Manufacturer as a result of a Required Manufacturing Change; provided, however, that such costs (including any costs associated with inventory or component write-off) may be passed through to Distributor as part of the Invoice Supply Price in accordance with Sections 3.2(a) and 3.2(b).

4.2 Discretionary Changes to Specifications.

(a) Manufacturer shall be permitted to make changes to the Specifications or manufacturing processes that are not Required Manufacturing Changes (a "Manufacturer Discretionary Change"); provided, however, that Manufacturer shall provide Distributor at least ninety (90) days prior notice of any such Manufacturer Discretionary Change that requires pre-approval from the FDA and at least thirty (30) days prior notice of any other such Manufacturer Discretionary Changes; and provided further that Manufacturer shall comply with all applicable legal requirements concerning any Manufacturer Discretionary Change. Manufacturer shall pay all one-time costs associated with a Manufacturer Discretionary Change pursuant to this Section 4.2(a) (including any costs associated with inventory or component write-off) (provided that increases or decreases to the ongoing pricing under Third Party Vendor agreements shall be passed through to Distributor in accordance with Section 3.2(a)). At any time during the Term, Manufacturer may in its sole discretion, without the consent of Distributor but with the applicable prior notice to Distributor described above, change the manufacturer used in the manufacturing or labeling of Products and change any suppliers of raw materials or components used in making such Products. Distributor shall cooperate with Manufacturer in a reasonable manner to effect such change or transfer. Manufacturer shall be responsible for

making any required regulatory filings with respect to such change in supplier or manufacturing facility and shall be responsible for obtaining all approvals in connection therewith.

(b) Subject to Section 6.1, Distributor shall be permitted to make changes to the labeling that are not Required Manufacturing Changes (a "Distributor Discretionary Change"), subject to Manufacturer's prior written consent; provided, however, that Distributor shall provide Manufacturer at least ninety (90) days prior notice of any such Distributor Discretionary Change, Manufacturer shall then work diligently with Distributor and any Third Party Vendors to implement such change, and Distributor shall comply, and take all actions necessary for Manufacturer to comply with all applicable legal requirements concerning any Distributor Discretionary Change. Distributor shall pay all one-time costs associated with a Distributor Discretionary Change pursuant to this Section 4.2(b) (including any costs associated with inventory or component write-off) (provided that increases to the ongoing pricing under Third Party Vendor agreements shall be passed through to Distributor in accordance with Section 3.2(a)).

4.3 Regulatory Filings; Communication with Regulatory Agency. Manufacturer will have control over, and authority and responsibility for, monitoring and coordinating all maintenance of, regulatory actions with respect to, and communications and filings with and submissions to, any Regulatory Agency with respect to the NDA for the Products and the distribution and sale of the Products under this Agreement, including making all filings with the FDA required for Product Listing, any Required Manufacturing Change or Manufacturer Discretionary Change, as well as reporting of Adverse Drug Experiences. Manufacturer shall use Commercially Reasonable Efforts to make such filings with applicable Regulatory Agencies as necessary for Manufacturer to carry out its obligations under this Agreement. In the case of the Product Listing, Distributor shall assist Manufacturer in preparing the required form for filing by Manufacturer. Notwithstanding the foregoing, Distributor shall be solely responsible for communications and filings with and submissions to any Regulatory Agency or other federal, state or local governmental authority concerning Product sales, prices, discounts, rebates, fees, charge-backs, and other payments associated with Distributor's distribution and sale of Products under this Agreement, including without limitation, all reporting, and disclosure obligations under the Medicaid Drug Rebate Program (Monthly and Quarterly Average Manufacturer Price, Baseline Average Manufacturer Price, and Rebate Per Unit), Medicare Part B (Quarterly Average Sales Price), the Veteran's HealthCare Act 602 (Public Health Service 340B Quarterly Ceiling Price), the Veteran's HealthCare Act 603 (Quarterly and Annual Non-Federal Average Manufacturer Price and Federal Ceiling Price), and Federal Supply Schedule Contract Prices. Distributor shall also cooperate fully with Manufacturer and shall timely supply all data and information requested by Manufacturer to enable Manufacturer to comply with any applicable federal, state or local reporting and disclosure requirements concerning Manufacturer's supply of Products to Distributor under this Agreement.

4.4 Distributor Communication with Regulatory Agency. If Distributor reasonably concludes, after consultation with its regulatory counsel, that it is necessary or advisable for Distributor to communicate with a Regulatory Agency regarding Distributor's activities under this Agreement, then Distributor shall so advise Manufacturer reasonably in advance and shall provide Manufacturer with copies of all correspondence between Distributor

and the applicable Regulatory Agency. Distributor shall provide Manufacturer with copies of all correspondence, documents and materials received from a Regulatory Agency concerning any Product or any activities under this Agreement. Distributor shall provide Manufacturer with copies of any proposed correspondence or communications of any kind to a Regulatory Agency that relates to any Product or any activities under this Agreement at least seven (7) days before the submission of such correspondence. Distributor shall adopt all reasonable suggestions and recommendations of Manufacturer concerning any meeting or written or oral communication with such Regulatory Agency.

4.5 Regulatory Cooperation. Each Party shall provide the other with all reasonable assistance and take all actions reasonably needed to enable such other Party to comply with any law applicable to such other Party's activities under this Agreement. Except as otherwise provided in Article 7, such assistance and actions shall include, without limitation, informing the other Party within forty-eight (48) hours of receiving any information that:

(a) Raises any material concerns regarding the safety or efficacy of any Product;

(b) Indicates or suggests a potential material liability for either Party to Third Parties arising in connection with any Product;

(c) Is reasonably likely to lead to a recall or market withdrawal of any Product in the Territory; or

(d) Concerns any material investigation, inspection, detention, seizure or injunction involving any Product by any Regulatory Agency in the Territory.

Manufacturer and Distributor shall, in each such case, jointly determine whether subsequent notification to a Regulatory Agency is required, and if necessary, which Party shall provide such notification. Except as otherwise provided in Article 7, if the parties disagree on whether to notify a Regulatory Agency, the position of Manufacturer shall control.

4.6 Payment of Rebates on the Products. Distributor shall be solely responsible for all federal, state and local government and private purchasing, pricing or reimbursement programs with respect to the Products sold by Distributor, including taking all necessary and proper steps to execute agreements and file other appropriate reports and other documents with governmental and private entities. Distributor shall be solely responsible for payment and processing of all rebates, whether required by contract or local, state or federal law, for the Products sold by Distributor.

4.7 Product Returns. Except as otherwise set forth in Article 5 (and subject to Section 1.28), Distributor shall be solely responsible for handling any Product returns, including responsibility for destruction and any associated costs.

ARTICLE 5

ORDERS AND TERMS

5.1 Delivery Terms; Title Passage

(a) Except with respect to Bailment Product, (i) Manufacturer shall deliver all quantities of Product to Distributor FCA (Incoterms 2000) Manufacturer's manufacturing facility, warehouse or such other facility mutually agreed to by the Parties, (ii) risk of loss and title shall pass to Distributor once the Products are placed on the loading dock of Manufacturer's facility, and (iii) Distributor shall be responsible for all freight, insurance, handling, fees, taxes and other costs associated with the shipment of Products, as well as all export licenses, import licenses and customs formalities for the import and export of goods.

(b) From time to time prior to the Commencement Date for each SKU of the Products, Manufacturer may ship Distributor quantities of such SKU of the Products under bailment (the "Bailment Product") on the terms of the Bailment Agreement between the parties to be entered into following the Effective Date (the "Bailment Agreement") and in accordance with the quantities set forth in the Contingent P.O. The Bailment Agreement shall govern the terms of shipment, freight and insurance costs, and risk of loss of Products shipped to Distributor's warehouse pursuant to the Bailment Agreement. Title to the inventory of each SKU of the Bailment Product held by Distributor shall be deemed to transfer to Distributor (and all units held by Distributor of such SKU of Bailment Product shall be deemed to have been delivered to Distributor) simultaneously with Distributor's shipment of a unit of such SKU of the Bailment Product to a customer on or after the Commencement Date. Notwithstanding the foregoing, any such invoice for Bailment Product will include the costs Manufacturer incurred in connection with shipping such Bailment Product to Distributor pursuant to the Bailment Agreement, including, without limitation, freight, insurance, handling, fees, taxes and other costs associated with the shipment of such Bailment Products.

5.2 Shipping Documentation. All shipments of Products shall be accompanied by a packing slip that describes the Products and states the purchase order number. Manufacturer shall supply with each shipment a Certificate of Analysis for each lot of the Products included in the shipment. Each Certificate of Analysis shall include, at a minimum, the Product name, batch number, date of manufacture, analytical test results, product specifications, microbiological test results (if applicable), and certification by Manufacturer's Quality Assurance that all Specifications have been met as of the time of shipment and that the Product was produced and tested in accordance with cGMP requirements.

5.3 Governing Terms. To the extent there is any conflict or inconsistency between this Agreement and any purchase order, purchase order release, confirmation, acceptance or any similar document, the terms of this Agreement shall govern.

5.4 Other Costs. Except as expressly set forth in this Agreement, Distributor shall be solely responsible for all costs and expenses related to the marketing, sale and distribution of Products in the Territory.

5.5 Forecasts and Purchase Orders.

(a) Forecasts. Commencing on the Effective Date (or such later date as the parties may mutually agree) with respect to quantities required for launch of the Products (including quantities included in the Contingent Purchase Order), and on the first business day of each calendar month following the first Commencement Date, Distributor shall provide to Manufacturer a non-binding, good faith written estimate (the "Rolling Forecast") by month of Distributor's quantity requirements for Products by SKU for next twelve-months. For example, Distributor's Rolling Forecast provided on January 1 of any year shall cover the period from January 1 through December 31 of that year.

(b) Ongoing Firm Orders. Accompanying each Rolling Forecast, Distributor shall place monthly binding purchase orders for Products for the fourth month contained in such Rolling Forecast by written or electronic purchase order to Manufacturer (or by any other means agreed to by the Parties), except that the binding purchase orders accompanying the first Rolling Forecast shall cover the first four (4) months contained in such Rolling Forecast. Distributor shall be required to purchase at a minimum one hundred percent (100%) of the amount of Products forecasted for the months of each Rolling Forecast subject to binding purchase orders, except that if (i) Manufacturer fails to meet the order quantity or delivery requirements under Section 5.5(d) and (ii) Distributor has exhausted its inventory of Products (including Distributor's safety stock maintained in accordance with Section 5.10), the failure has caused Distributor to be unable to fulfill customer orders and such failure has reduced the demand of Distributor's customers for the Products, then Distributor may by written notice to Manufacturer, within thirty (30) days after the failure to supply Distributor's customers, reduce Distributor's binding commitments under the Rolling Forecast then in effect to the extent necessary to reflect such actual reduction in demand, and Distributor may also reduce future Rolling Forecasts to the extent necessary to reflect such actual reduction in demand. Manufacturer shall use Commercially Reasonable Efforts to accept firm orders for Products that are up to one hundred twenty percent (120%) of the units of Products contained in the immediately preceding Rolling Forecast. Each purchase order shall specify the quantity and type of each Product by SKU and delivery schedule. Orders shall be placed in accordance with the batch sizes and minimum order quantities set forth on Exhibit 5.5(b) hereto, which may be amended by written notice from Manufacturer from time to time. Manufacturer shall use its Commercially Reasonable Efforts to fulfill purchase orders submitted to Manufacturer which meet the volume requirements set forth in this Section. Manufacturer may, in its sole discretion, satisfy its delivery obligations by authorizing Distributor to take title to all or any portion of any Bailment Product.

(c) Dating. All Products supplied by Manufacturer shall, upon receipt by Distributor or its designee, have dating no less than twenty four (24) months prior to expiration (in the case of omeprazole/sodium bicarbonate capsules 40mg/1100mg and omeprazole/sodium bicarbonate powder for oral suspension 40mg/1680mg) and no less than twenty (20) months prior to expiration (in the case of omeprazole/sodium bicarbonate capsules 20mg/1100mg and omeprazole/sodium bicarbonate powder for oral suspension 20mg/1680mg).

Supply of any Products having shorter dating shall be subject to the written consent of Distributor, which shall not be unreasonably withheld.

(d) Delivery. Any shipment delivered that is within plus or minus 10% of the quantity ordered will be considered as meeting such order quantity, and any shipment delivered on a date within plus or minus seven days (+/-7 days) of the delivery date specified on the purchase order will be considered as delivered on time. In addition, in no event shall Manufacturer be deemed in breach or default under this Agreement if Distributor has sufficient inventory to cover any shortfalls under purchase orders.

5.6 Acceptance and Rejection and Product Defects.

(a) Delivery of any Products by Manufacturer to Distributor shall constitute a certification by Manufacturer that such Products conform to the warranties in Section 5.7(a). Distributor shall have thirty (30) days after receipt of each shipment of Products to determine if such Products conform to such warranties and to accept or reject any of such Products that fail to conform to such warranties. Distributor shall submit any claims for failure to so conform ("Claims") in writing to Manufacturer within such thirty (30) day period describing in detail the nonconforming characteristics of the Products. Distributor shall be deemed to have accepted any Products if it fails to submit a Claim during such thirty (30) day period.

(b) If Distributor submits a Claim and Manufacturer does not agree with the Claim, the Parties shall submit the Products in question to a mutually agreed independent party that has the capability of testing the Products to determine whether they comply with the warranties in Section 5.7(a). The determination of such independent party shall be binding on the Parties. The losing Party shall bear all costs and expenses related to such testing. Manufacturer shall be deemed to have agreed with a Claim if it fails to give Distributor objection in writing to the Claim within fifteen (15) days after it receives the Claim.

(c) If Manufacturer agrees with the Claim, or if Manufacturer disagrees with the Claim but an independent party determines under Section 5.6(b) that the Products do not comply with the warranties in Section 5.7(a), then Manufacturer shall (a) credit Distributor the Invoice Supply Price for the Products in question as promptly as reasonably possible (but in any event within fifteen (15) days), (b) instruct Distributor whether to return or destroy the Products in question, and (c) provide Distributor with replacement Products as promptly as reasonably possible (invoiced in accordance with Section 3.3 for payment by Distributor). Manufacturer shall pay for all costs of returning or destroying non-conforming Products and shall bear the risk of loss for such Products from the time they leave Distributor's premises for return delivery or destruction. In addition, Manufacturer shall pay for all freight and insurance costs of sending the replacement Products.

5.7 Product Warranty.

(a) Manufacturer warrants that (i) upon delivery to Distributor's warehouse under the Bailment Agreement of all Bailment Product supplied to Distributor pursuant to the Bailment Agreement, and (ii) upon delivery at the shipping point of all other

Product supplied to Distributor in accordance with Section 5.1(a), such Product (i) shall comply with the Specifications, (ii) shall have been manufactured in material compliance with all applicable laws, rules and regulations, including current good manufacturing practices, (iii) shall not be adulterated or misbranded within the meaning of the Act, and (iv) may be introduced into interstate commerce pursuant to the Act.

(b) If any Product accepted by Distributor does not conform to the above warranties, including, without limitation, in the context of any recall of, or other corrective actions with respect to, the Products, Manufacturer shall be obligated, at its option, to promptly (but in any event within thirty (30) days after Distributor notifies Manufacturer of the non-conformity) replace such Product at its own expense and ship such replacement Product back to either Distributor or the applicable customer at its own expense, or to credit to Distributor the Invoice Supply Price for the Product. If customers return defective Products to Distributor that are covered by the foregoing warranties, at Manufacturer's option, Distributor shall either (i) destroy such Products, or (ii) ship them to Manufacturer at Manufacturer's expense for such replacement. If the Parties disagree on whether any Product fails to comply with the warranties in Section 5.7(a), the Parties shall resolve the disagreement as provided in Section 5.6(b).

(c) Warranty claims shall not apply to damaged Products to the extent such damage is caused in whole or in part by Distributor's negligence or breach of this Agreement or use, handling, or storage by any party other than Manufacturer (other than the carrier utilized by Manufacturer to deliver the Bailment Product to Distributor) that is not in accordance with Manufacturer's instructions (consistent with current good manufacturing practices) or the Product labeling or that constitutes improper treatment.

5.8 **Sole Remedy**. Except as provided in Section 9.1(a) and Section 7.2, the provisions of Section 5.6 and Section 5.7 above shall be the sole and exclusive remedy available to Distributor with respect to any Product that fails to meet the warranties in Section 5.7(a)

5.9 **Inspection and Audit**.

(a) From and after the first Commencement Date, Distributor shall have the right, upon reasonable advance notice and during regular business hours, to have a Third Party reasonably acceptable to Manufacturer inspect and audit the facilities being used by Manufacturer for production of Products (including those of any Third Party Vendor used by Manufacturer) to assure compliance by Manufacturer and/or the Third Party Vendor with prevailing FDA or other Regulatory Agency good manufacturing practices. Manufacturer shall be entitled to accompany Distributor on any such audit.

(b) From and after the first Commencement Date, Manufacturer shall have the right, upon reasonable advance notice and during regular business hours, to inspect and audit the facilities being used by or for the benefit of Distributor for the handling, storage and distribution of Products (including those of any subcontractor or agent used by Distributor) to assure compliance by Distributor with applicable laws, rules and regulations.

(c) A Party shall not carry out the audits provided for under this Section 5.9 more than once per year unless there is reasonable cause for an additional audit

(including, but not limited to, following up any prior deficiencies noted in the course of prior audits or notification of an issue in any of the foregoing areas). Each Party performing an inspection or audit shall conduct it in a manner that minimizes disruption of the business operations of the Party being audited.

(d) If an inspection or audit reveals that the facilities do not satisfy the requirements above in all material respects, then the Party conducting the audit (the "Auditing Party") shall promptly provide to the other Party (the "Audited Party") written notice of such fact, which notice shall contain in reasonable detail the deficiencies found in the facilities and, if practicable, those steps the Auditing Party believes should be undertaken in order to remedy such deficiencies. The Parties shall discuss in good faith the proposed deficiencies and, to the extent there is agreement on the proposed deficiencies, the Audited Party shall use Commercially Reasonable Efforts to remedy such deficiencies, or implement a plan to remedy such deficiencies, as soon as reasonably practical following receipt of the notification thereof; (provided, however, that in the case of an audit by Distributor of a Third Party Vendor's facilities, Manufacturer shall discuss any such noted deficiencies with the applicable Third Party Vendor and shall request that the Third Party Vendor implement reasonably appropriate corrective measures).

(e) Distributor's rights under this Section 5.9 are subject to the rights and obligations of Manufacturer under its Third Party Vendor agreements. Distributor shall be responsible for any costs charged by a Third Party Vendor for an audit requested by Distributor.

5.10 **Safety Stock**. From and after each Commencement Date, and subject to Manufacturer's ability to supply, Distributor shall use Commercially Reasonable Efforts to maintain a minimum of two (2) months' safety stock of inventory for each Product SKU (based on the most recent Rolling Forecast). Distributor shall be entitled to use the safety stock if Manufacturer fails to deliver Product on time or Distributor receives an unexpected large order, but Distributor shall use Commercially Reasonable Efforts to rebuild such safety stock promptly after such use.

5.11 **Quality Agreement**. Manufacturer and Distributor shall negotiate in good faith to enter into a quality agreement (the "Quality Agreement") with additional customary terms and conditions, consistent with the terms of this Agreement, within thirty (30) days following the Effective Date.

ARTICLE 6

PACKAGING AND REMINDER MATERIALS

6.1 **Packaging**. All Products supplied to Distributor hereunder shall be in finished packaged form. Manufacturer shall provide Distributor with sufficient information concerning packaging and labeling components for Distributor to develop appropriate artwork, and Distributor shall design such artwork and supply it to Manufacturer. Manufacturer shall produce all package and labeling materials to be used for the Products (including print-ready artwork with Distributor's NDC#). Any changes to the packaging and labeling specifications requested by

Distributor after the First Commercial Sale of a Product shall require the prior written consent of Manufacturer. If Manufacturer consents to such changes, such changes will be at Distributor's cost and expense (including any costs associated with inventory or component write-off), in accordance with Section 4.2(b). Distributor shall clearly identify Manufacturer as the manufacturer of the Product on all packaging materials unless otherwise requested by Manufacturer.

6.2 Promotional Materials. Unless otherwise agreed by Manufacturer, Distributor shall have the right to use only the following promotional materials in connection with the marketing of the Products: professional purchasing information consisting of a trade fact sheet (containing a product profile using standard drug listing information) and a related flyer (containing information from the trade fact sheet and a statement that the Products are an authorized generic version of the Branded Products); trade show graphics; and a page on Distributor's publicly available web site comparing the Products to the Branded Products. All promotional materials prepared by Distributor in connection with the Products shall comply with all applicable laws, rules and regulations, including without limitation, Section 502(n) of the Act and 21 CFR Part 200.200 and Part 202. Distributor shall be solely liable for all statements and representations in Distributor's promotional materials that are inconsistent with the labeling for the Branded Products, or which otherwise violate any applicable laws or regulations. Manufacturer shall have final approval authority for all promotional materials. Distributor shall submit to Manufacturer for its approval all such materials for the Products prior to their use by Distributor, and Manufacturer shall respond to any requests for approval within ten (10) business days of receipt; provided, however, that Manufacturer shall not have any approval rights over any portion of Distributor's promotional materials to the extent they relate solely to the resale pricing of the Products or any potential competition between Distributor and Manufacturer, and Distributor shall redact any such information from its submissions to Manufacturer. Manufacturer shall be responsible for submitting promotional materials to FDA/DDMAC as required by law under the NDA for the Branded Products. For purposes of this Agreement, "promotional materials" includes all labeling and reminder materials (consisting of trade show graphics) as defined in 21 CFR Section 200.200 and Section 202.1(e)(2), as well as any other applicable provisions of the Act or applicable regulations.

6.3 Sampling. Distributor shall not provide or cause to be provided any samples of Products to any Third Party for use by consumers.

ARTICLE 7

REGULATORY; RECALLS

7.1 Adverse Drug Experiences; FDA Audits; etc.

(a) Notification.

(i) Adverse Drug Experiences. Distributor shall notify Manufacturer of any Adverse Drug Experience with respect to a Product within one (1) business day of the time such Adverse Drug Experience becomes known to Distributor or its employees

or any of their Affiliates and such reports shall be made in accordance with and in the manner set forth on the form attached hereto as Exhibit 7.1.

(ii) Complaints. Each Party shall refer any complaints, including medical complaints and drug product complaints, that it receives concerning any Product in the Territory to the other Party within ninety-six (96) hours of receiving such complaint; provided that all complaints concerning suspected or actual product tampering, contamination or any Product that is out-of-specification shall be delivered within twenty-four (24) hours of receiving such complaint, and any complaint that includes a possible Adverse Drug Experience shall be reported to Manufacturer in accordance with Section 7(a)(i).

(b) Disclosure. Except as required by applicable laws, Distributor shall not disclose any information concerning any Adverse Drug Experience or any complaint concerning any Product to any Third Party without the prior written consent of Manufacturer.

(c) Training. Distributor shall provide its employees and agents with adequate training in order to ensure compliance with the reporting requirements under Section 7.1(a). For purposes of training its personnel as to what an Adverse Drug Experience is, a Distributor shall use the following definition:

> An Adverse Drug Experience is any adverse event, including any untoward, unwanted or "bad" thing that happens to an individual during or after any use of the Product, even if a particular event is not thought to be related to Product use (e.g., getting hit by a car), and even if an event is mentioned in the Product labeling (e.g., what is sometimes called a "side effect"). Reports of exposure during pregnancy, drug overdose, drug or product abuse, unanticipated beneficial effects, inadvertent or accidental exposure, drug exposure through breast feeding, medication error, adverse drug experience occurring from withdrawal of the drug or product and failure of pharmacological action (e.g., it doesn't work) should also be considered Adverse Drug Experiences for internal reporting purposes. An Adverse Drug Experience is also sometimes referred to as an adverse drug reaction, adverse event or side effect.

(d) Reporting. Manufacturer shall be solely responsible for Adverse Drug Experience reporting for the Products. Manufacturer shall comply with applicable FDA requirements concerning Adverse Drug Experience Reporting reporting for the Products, including 21 C.F.R. Section 314.80.

(e) Pharmacovigilance. As part of the Quality Agreement, Manufacturer and Distributor shall negotiate in good faith additional customary terms and conditions relating to pharmacovigilance, consistent with the terms of this Agreement.

7.2 Recalls.

(a) If a recall of any Product sold by or on behalf of Distributor is required or recommended by the FDA, or if a recall, suspension or other withdrawal of any Product sold by or on behalf of Distributor is deemed advisable by Distributor and Manufacturer,

such recall, suspension or other withdrawal shall be implemented and administered by the Parties in a manner that is appropriate and reasonable under the circumstances and in conformity with accepted trade practices and any requests, recommendations, or orders of the FDA. Each Party shall cooperate with the other Party to effectuate such recall, suspension or other withdrawal.

(b) In the absence of an order or recommendation of the FDA, if the Parties are unable to agree upon a Product recall, suspension or other withdrawal, Manufacturer shall make the final decision on all matters related to the recall, suspension or other withdrawal (including matters relating to the method of implementation), except that Distributor may implement and administer a recall or suspension of Product distributed by it if it reasonably believes, based on the advice of outside regulatory counsel and after good faith discussion with Manufacturer, that a failure to administer a recall or suspension would pose health risks to the public.

(c) Manufacturer shall pay all Recall Costs and Expenses in connection with a recall under this Section 7.2, except that Distributor shall bear such Recall Costs and Expenses to the extent such recall is implemented as a result of Distributor's negligence or breach of its obligations under this Agreement. As used in this Section 7.2, the term "Recall Costs and Expenses" means only (i) actual expenses or obligations to Third Parties for such recall (but not including payments for lost profits or economic loss), (ii) the costs and expenses of notifying customers, (iii) the costs and expenses associated with shipment of the recalled units of Product, and (iv) the costs and expenses of destroying and replacing such recalled units (or, in the case of Manufacturer, reimbursing Distributor for the Invoice Supply Price paid with respect to the recalled units if such units cannot be replaced).

(d) Distributor undertakes to use Commercially Reasonable Efforts to establish a tracing and recall system which will enable Distributor, to the extent reasonably possible, to identify, as quickly as possible, customers within the Territory who have been supplied with Product of any particular batch, and to recall such Product from such customers. Distributor also agrees to reasonably coordinate with Manufacturer and its third party reverse logistics vendor from time to time during the Term to prepare for any potential recall, suspension or other withdrawal.

7.3 Information. Within fifteen (15) days after Manufacturer's request from time to time, Distributor shall provide Manufacturer all information in Distributor's possession or control necessary for Manufacturer to comply with FDA reporting requirements.

ARTICLE 8

REPRESENTATIONS AND WARRANTIES

8.1 Manufacturer Representations and Warranties. Manufacturer represents and warrants to Distributor that, as of the Effective Date:

(a) all necessary corporate and other authorizations, consents and approvals which are necessary or required for it to enter into of this Agreement have been duly obtained;

(b) the entering into of this Agreement by Manufacturer shall not (i) violate any provision of law, statute, rule or regulation or any ruling, writ, injunction, order, judgment or decree of any court, administrative agency or other governmental body to which Manufacturer is subject, or (ii) conflict with or result in any breach of any of the terms, conditions or provisions of, any agreement to which Manufacturer or any of its Affiliates is a party or by which it or its Affiliates or any of its or their properties or assets is bound or affected;

(c) the Products will be sold to Distributor free and clear of all liens, claims and encumbrances of any nature;

(d) to the best of its knowledge, the manufacture, use and sale of the Products does not infringe the patents of any Third Party in the Territory; and

(e) it has not granted any license, right or interest in or to the Products, or any method of manufacture thereof, to any Third Party that would conflict with the rights being granted to Distributor under this Agreement.

(f) Manufacturer has supplied Distributor with a correct and complete copy of the agreements between Manufacturer and the University of Missouri that govern the calculation of License Fees and Royalties payable by Manufacturer to the University of Missouri, and there are no other agreements that govern such calculation.

8.2 Distributor Representations and Warranties. Distributor represents and warrants to Manufacturer as of the Effective Date that:

(a) all necessary corporate and other authorizations, consents and approvals which are necessary or required for it to enter into this Agreement have been duly obtained; and

(b) the entering into of this Agreement by Distributor shall not (i) violate any provision of law, statute, rule or regulation or any ruling, writ, injunction, order, judgment or decree of any court, administrative agency or other governmental body, or (ii) conflict with or result in any breach of any of the terms, conditions or provisions of, any agreement to which Distributor, or any of its Affiliates is a party or by which it or its Affiliates or any of their properties or assets is bound or affected.

8.3 Disclaimer of Warranties.

(a) EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY OTHER REPRESENTATION OR WARRANTY TO THE OTHER PARTY OF ANY KIND INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

(b) NEITHER PARTY MAKES ANY WARRANTIES, EXPRESS OR IMPLIED, CONCERNING THE SUCCESS OF THE COMMERCIAL EXPLOITATION OF THE PRODUCTS.

8.4 Limitations of Liabilities.

(a) Limitation on Certain Damages. EXCEPT FOR AND ONLY TO THE EXTENT OF ANY AMOUNTS PAID TO A THIRD PARTY RESULTING IN AN INDEMNIFIABLE CLAIM HEREUNDER AND IN THE CASE OF BREACH OF ARTICLE 11, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY SPECIAL, INDIRECT, PUNITIVE, OR CONSEQUENTIAL DAMAGES OF ANY KIND (INCLUDING, WITHOUT LIMITATION, LOST PROFITS, BUSINESS, OR GOODWILL) IN CONNECTION WITH ANY PRODUCTS SUPPLIED OR TO BE SUPPLIED HEREUNDER, OR ANY OTHER MATTER COVERED BY THIS AGREEMENT, REGARDLESS OF WHETHER SUCH LIABILITY IS BASED ON BREACH OF CONTRACT, TORT, STRICT LIABILITY, BREACH OF WARRANTY, OR ANY OTHER THEORY, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

(b) Maximum Aggregate Liability. EXCEPT FOR AND ONLY TO THE EXTENT OF ANY AMOUNTS PAID TO A THIRD PARTY RESULTING IN AN INDEMNIFIABLE CLAIM HEREUNDER, OBLIGATIONS UNDER SECTIONS 5.6 OR 5.7 (WHICH ARE SUBJECT TO SECTION 5.8) OR SECTION 7.2, AND ACCRUED AND UNPAID AMOUNTS DUE UNDER ARTICLE 3, IN NO EVENT SHALL EITHER PARTY'S MAXIMUM AGGREGATE LIABILITY TO THE OTHER PARTY OR ANY OTHER PERSON WITH RESPECT TO ANY AND ALL CLAIMS CONCERNING THE PRODUCTS OR ANY OTHER MATTER COVERED BY THIS AGREEMENT, REGARDLESS OF THE FORM OF ACTION, EXCEED $5 MILLION.

(c) Allocation of Risks. The limitation of liability set forth in this Article 8 reflects a deliberate and bargained for allocation of risks between Distributor and Manufacturer and is intended to be independent of any exclusive remedies available under this Agreement, including any failure of such remedies to achieve their essential purpose.

(d) Essential Part of the Bargain. The Parties acknowledge that the limitations of liability set forth in this Article 8 are an essential element of this Agreement between the Parties and that the Parties would not have entered into this Agreement without such limitations of liability.

ARTICLE 9

INDEMNIFICATION

9.1 Indemnification. In order to distribute among the Parties the responsibility for claims arising out of this Agreement, and except as otherwise specifically provided for herein, the Parties agree as follows:

(a) Manufacturer agrees to defend and indemnify and hold Distributor harmless against any and all Third Party claims, demands, suits or proceedings, and all associated expenses, recoveries and damages, including court costs and reasonable attorneys fees and expenses, arising out of, based on, or caused by (i) the breach by Manufacturer of any representation, covenant or warranty contained in this Agreement, (ii) any personal injury (including death) caused by the use of Products, (iii) any claim that the sale of the Products (including, without limitation, the patents used in connection with making, using or selling the Products) infringes the intellectual property rights of a Third Party, (iv) any certification filed with the FDA by a Third Party with respect to a Competitive Product under and pursuant to 21 U.S.C. Section 355(j)(2)(A)(vii)(IV) of the Act, or (v) any governmental investigation or proceeding (administrative or otherwise) or Third Party claim relating to a potential or actual settlement agreement between Manufacturer and a Third Party that plans to market or is marketing a Competitive Product, except in the case of each of subsections (i), (ii) or (iii) hereof, to the extent that such claims, suits, proceedings, expenses, recoveries or damages arise from or are aggravated by acts of or failure to act by Distributor, including without limitation, any breach by Distributor of this Agreement.

(b) Distributor agrees to defend and indemnify and hold Manufacturer harmless against any and all Third Party claims, demands, suits, proceedings, and all associated expenses, recoveries, and damages including court costs and reasonable attorneys fees and expenses, arising out of, based on, or caused by (i) Distributor's performance under this Agreement, including the storage, sale, shipment, promotion or distribution of the Products by or on behalf of Distributor, or (ii) the breach by Distributor of any representation, covenant or warranty contained in this Agreement, except in each case to the extent that such claims, suits, proceedings, expenses, recoveries or damages arise from or are aggravated by acts of or failure to act by Manufacturer, including without limitation, any breach by Manufacturer of this Agreement.

9.2 Procedures. In connection with any claim for indemnification under Section 9.1(a) or (b), (i) the Party seeking indemnification shall provide the other Party with reasonably prompt written notice of any claim or action for which it seeks indemnification, (ii) the indemnifying Party shall have the right to control the defense and settlement of any such claim or action (but only to the extent no injunctive relief is being sought), and (iii) the indemnified Party shall reasonably cooperate and provide reasonable assistance in connection with the defense and settlement of any such claim or action.

ARTICLE 10

TERM AND TERMINATION

10.1 Term. This Agreement shall commence as of the Effective Date and shall continue for a period of five (5) years after the first Commencement Date to occur, unless terminated earlier as provided below (the "Initial Term"). This Agreement will automatically renew for additional one (1) year terms (each, a "Renewal Term") unless either Party elects not to renew this Agreement by written notice to the other Party, which notice must be provided at least six (6) months prior to the expiration of the Initial Term or the applicable Renewal Term, as

the case may be. The Initial Term and any applicable Renewal Term are collectively referred to herein as the "Term."

10.2 Termination by Manufacturer.

(a) Delay in First Commercial Sale. If there has not been a First Commercial Sale of at least one SKU of the Products before December 31, 2012, Manufacturer may terminate this Agreement with respect to one or more SKUs of the Products at any time prior to the occurrence of a First Commercial Sale upon written notice to Distributor.

(b) Convenience. Manufacturer may terminate this Agreement (i) with respect to a Product SKU, at any time prior to the First Commercial Sale of that Product SKU for any reason upon written notice to Distributor, provided Manufacturer gives the notice before it gives any written approval under Section 2.1(c) for Distributor to engage in pre-booking activities, (ii) with respect to a Product SKU, at any time following the First Commercial Sale of that Product SKU upon thirty (30) days written notice to Distributor in the event that a Competitive Product (with respect to that Product SKU) that was previously launched is no longer available, and (iii) in whole or on a Product SKU basis, at any time following the First Commercial Sale of a particular Product SKU for any reason upon nine (9) months' written notice to Distributor.

(c) Distributor Change of Control. If Distributor agrees to become or otherwise becomes subject to any Change of Control, Distributor shall so notify Manufacturer, in writing, within ten (10) days. Manufacturer may terminate this Agreement upon sixty (60) days written notice to Distributor after a Change in Control of Distributor, which notice must be given no later than thirty (30) days after Distributor gives Manufacturer written notice of the Change of Control, or if no notice is provided by Distributor, at any time following such Change of Control.

(d) Non-availability of Competitive Product after Launch. If one or more Competitive Products are launched and all Competitive Products are no longer available, Manufacturer may, in addition to the other rights set forth in this Article 10, suspend (but not terminate) this Agreement immediately upon written notice to Distributor. Such suspension will continue until a Competitive Product is again available and Manufacturer notifies Distributor to commence distributing and marketing the Product or Products.

10.3 Termination by Distributor.

(a) Delayed Commencement Notice or Failure to Deliver Launch Quantities. Distributor may terminate this Agreement with regard to a particular SKU of the Products upon prior written notice to Manufacturer if (i) Manufacturer fails to deliver a Commencement Notice with respect to that SKU within sixty (60) days after the launch by a Third Party in the Territory of a Competitive Product (with respect to that Product SKU), or (ii) Manufacturer delivers a Commencement Notice within such sixty (60) day period, but Manufacturer fails to deliver to Distributor launch quantities of the applicable SKU of the Products in compliance with this Agreement and such failure prevents Distributor from making the First Commercial Sale of the applicable SKU of the Products within such sixty (60) day period.

(b) Significant Selling Price Decrease. If Distributor's net selling price of an SKU of the Products decreases to less than 125% of the Invoice Supply Price for that SKU of the Products sold during any sixty (60) day period, then Distributor may provide written notice (the "Supply Notice") to Manufacturer of such occurrence and a calculation of the Invoice Supply Price for such SKU that would have been necessary to avoid such occurrence. If Distributor and Manufacturer fail to negotiate a new Invoice Supply Price for the applicable SKU acceptable to both Parties within thirty (30) days after delivery of the Supply Notice, either Party shall have the right to terminate this Agreement with regard to the applicable SKU immediately upon written notice delivered within fifteen (15) days after such initial thirty (30) day period; provided however, that Distributor shall not have a termination right under this Section 10.3(b) if prior to the expiration of such thirty (30) day period Manufacturer notifies Distributor that it is reducing the Invoice Supply Price for future deliveries of the applicable SKU of the Products to the amount specified for such SKU in Distributor's Supply Notice to Manufacturer under this Section 10.3(b). For purposes of this Section 10.3(b), the Invoice Supply Price of the Products sold by Distributor and Distributor's selling price of those Products shall be determined on a SKU by SKU basis and any new Invoice Supply Price mutually agreed pursuant to this Section 10.3(b) shall be applied on a going-forward basis and also retroactively to an amount of inventory of each impacted Product SKU actually held by Distributor not to exceed the amount of such Product SKU sold by the Distributor during the two (2) full calendar months immediately preceding the date of the Supply Notice.

(c) Continuing Suspension. If Manufacturer suspends this Agreement under Section 10.2(d) and the suspension lasts for more than two (2) years, Distributor may terminate this Agreement upon written notice to Manufacturer.

10.4 Termination by Non-Defaulting Party upon Event of Default. Upon the occurrence of an Event of Default, in addition to all rights and remedies provided by applicable law, the non-defaulting Party in its sole discretion may terminate this Agreement upon thirty (30) days' prior notice to the defaulting Party. For purposes of this Section 10.4, the occurrence of any one or more of the following acts, events or occurrences shall constitute an "Event of Default" under this Agreement: (a) either Party becomes the subject of a Bankruptcy Event; or (b) either Party fails to cure any material breach of its obligations under this Agreement within sixty (60) days after written notice of the breach from the other Party. In the case of Manufacturer's supply obligations under Section 5.5, an "Event of Default" shall be deemed to have occurred if Manufacturer has failed to supply (i) at least fifty percent (50%) of firm purchase order quantities for four (4) consecutive months; or (ii) at least seventy percent (70%) of firm purchase order quantities for a total six (6) month period; provided, however, that in such event, an "Event of Default" shall not be deemed to have occurred to the extent that (A) the failure to supply is a result of Product failing to meet the applicable Specifications or product warranties (wherein Section 5.8 shall be the sole and exclusive remedy); or (B) Distributor has sufficient inventory to cover any shortfalls under purchase orders.

10.5 Termination by Mutual Agreement. In the event that the Parties mutually determine that the arrangements contemplated by this Agreement are no longer in the best interests of the Parties or the Parties are not otherwise compatible, the Parties may at any time,

by mutual written agreement, terminate this Agreement in its entirety or with regard to one or more Product SKUs.

10.6 Termination for Withdrawal of NDA or Branded Products. Either Party shall have the right to terminate this Agreement with regard to one or more Product SKUs upon thirty (30) days written notice to the other Party in the event of: (i) withdrawal of the NDA for the applicable Branded Products; (ii) withdrawal of the applicable Branded Products from the market for medical or scientific concerns as to toxicity, safety or efficacy; or (iii) withdrawal of the applicable Branded Products upon the written request of any Regulatory Agency.

10.7 Force Majeure Events. If either Party is prevented from performing any of its obligations hereunder due to any cause which is beyond the non-performing Party's reasonable control, including fire, explosion, flood, or other acts of God; acts, regulations, or laws of any government; war or civil commotion; strike, lock-out or labor disturbances; or failure of public utilities or common carriers (a "Force Majeure Event"), such non-performing Party shall not be liable for breach of this Agreement with respect to such non-performance to the extent any such non-performance is due to a Force Majeure Event. Such non-performance will be excused for as long as such event shall be continuing, provided that the non-performing Party gives prompt written notice to the other Party of the Force Majeure Event. Such non-performing Party shall exercise all Commercially Reasonable Efforts to eliminate the Force Majeure Event and to resume performance of its affected obligations as soon as practicable. Should the event of Force Majeure continue unabated for a period of sixty (60) days or more, the Parties shall enter into good faith discussions with a view to alleviating its affects or to agreeing upon such alternative arrangements as may be fair and reasonable having regard to the circumstances prevailing at that time, up to and including termination of the Agreement in whole or on a Product SKU basis.

10.8 Statutory Rights. Distributor acknowledges that it is cognizant of certain state statutes that impose on a wholesaler, distributor or importer specific duties and obligations with regard to the termination of a distribution agreement. Notwithstanding the rights conferred under those statutes to a distributor, Distributor hereby waives its rights thereunder with respect to a valid termination pursuant to a right under this Agreement and in consideration of its appointment hereunder covenants not to sue Manufacturer, or submit a complaint to any Regulatory Agency or governmental authority, in the event of the termination of this Agreement except for the purpose of enforcing Distributor's rights under this Agreement. This Section in no way affects the enforcement rights of Distributor to recover amounts earned pursuant to this Agreement.

10.9 Obligations Following Termination.

(a) Cessation of Distribution Efforts. Upon expiration or termination of this Agreement for any reason, as of the date of such expiration or termination (i) Distributor shall immediately stop all distribution, marketing and sales of the applicable SKU of the Products, and (ii) Distributor's binding purchase commitments under Section 5.5(b) for the applicable SKU of the Products shall be canceled automatically, except that in the case of termination by Distributor under Section 10.4 for Manufacturer's Event of Default, Distributor may elect to complete the purchase of Products under its binding purchase commitments and sell off its remaining inventory.

(b) Repurchase of Inventory. Upon termination of this Agreement by Manufacturer under Section 10.2(b)(ii) or (iii) (Manufacturer's convenience after First Commercial Sale) or 10.2(c) (Manufacturer's choice upon Distributor's Change of Control), by Distributor under Section 10.3(c) (Continuing Suspension) or 10.4 (Manufacturer's Event of Default), or by either Party under Section 10.3(b) (Significant Selling Price Decrease) or 10.6 (termination of NDA or withdrawal of Branded Products), Manufacturer shall purchase from Distributor, at the Invoice Supply Price paid for such Products, all inventory of Products then held by Distributor that has no less than twelve (12) months of remaining shelf life as of the date of termination (except that in no event shall the Products to be purchased back from Distributor exceed twelve (12) weeks of inventory based on the average sales by Distributor for the twelve (12) weeks prior to the date of notice of termination) and except that the shelf life requirement shall not apply in the case of termination under Section 10.3(c)), provided that Distributor has used its Commercially Reasonable Efforts to reduce the amount of inventory held at termination. In addition to the foregoing, upon termination of this Agreement by Manufacturer under Section 10.2(b)(ii) or (iii) (Manufacturer's Convenience after First Commercial Sale), by Distributor under Section 10.3(c) (Continuing Suspension) or 10.4 (Manufacturer's Event of Default), or by either Party under Section 10.6 (termination of NDA or withdrawal of Branded Products) , Manufacturer shall reimburse Distributor for all out-of-pocket shipping costs previously paid by Distributor under Section 5.1 for all inventory of Products purchased by Manufacturer under this Section 10.9(b) and all out-of-pocket shipping costs associated with returning such inventory to Manufacturer.

(c) Return of Launch Quantities. Upon termination of this Agreement under Section 10.2(a) (Delay in First Commercial Sale), 10.2(b)(i) (Manufacturer's Convenience prior to First Commercial Sale), 10.3(a) (Delayed Commencement Notice or Failure to Deliver Launch Quantities), or 10.3(c) (Continuing Suspension), Distributor shall promptly return all Products supplied by Manufacturer to Distributor, at Manufacturer's expense (including Distributor's out-of-pocket shipping costs), and any outstanding invoices from Manufacturer for such Products shall be canceled automatically.

(d) Application to Individual SKUs of Product. To the extent the applicable termination event applies to less than all of the Products, then the provisions contained in this Section 10.9 shall apply only to the Product so affected.

10.10 Effects of Termination. Upon termination of this Agreement, (a) this Agreement shall thereafter have no effect, except as provided in Section 12.2, (b) payment obligations that have accrued and have been invoiced prior to the date of termination shall remain due and payable in accordance with the terms of this Agreement, and payment obligations that have accrued but have not been invoiced as of the date of termination shall be invoiced and paid in full within thirty (30) days of receipt of such invoice, (c) all rights and licenses granted by Manufacturer to Distributor shall immediately cease, and (d) except as otherwise set forth herein, neither Party shall be relieved from liability for any breach of any representation, warranty or agreement hereunder occurring prior to such termination.

ARTICLE 11

CONFIDENTIALITY, PUBLIC ANNOUNCEMENTS AND DISCLOSURE

11.1 Confidentiality. Except to the extent expressly authorized by this Agreement or otherwise agreed by the Parties in writing, until the later of (i) the termination of this Agreement or (ii) ten (10) years after the date of disclosure, each of Distributor and its Affiliates, on the one hand, and Manufacturer and its Affiliates on the other (the "Recipient"), receiving or learning of any Confidential Information of the other Party (the "Disclosing Party") in connection with this Agreement or the Bailment Agreement, shall keep such information confidential and shall not publish or otherwise disclose or use it for any purpose other than as provided for in this Agreement, except to the extent that it can be established by the Recipient that the Confidential Information:

(a) Was already known to the Recipient (other than under an obligation of confidentiality) at the time of receipt by the Recipient, and the Recipient can so demonstrate by documentary evidence to that effect;

(b) Was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Recipient;

(c) Became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission in breach of a confidentiality obligation of the Recipient;

(d) Was disclosed to the Recipient (other than under an obligation of confidentiality) by a Third Party who had no obligation to the Disclosing Party not to disclose such information to others; or

(e) Was independently discovered or developed by the Recipient without the use of the Confidential Information of the Disclosing Party, and the Recipient can so demonstrate by documentary evidence to that effect.

11.2 Authorized Disclosure. Notwithstanding the foregoing, a Recipient may disclose Confidential Information of the Disclosing Party to a Third Party to the extent such disclosure is reasonably necessary to:

(a) Prosecute or defend litigation;

(b) Effectively exercise rights granted to the Recipient hereunder; or

(c) Comply with applicable governmental laws and regulations, orders, rulings, guidance documents, pronouncements, filing requirements and the like.

In the event a Recipient shall deem it necessary to disclose, pursuant to this Section 11.2, Confidential Information of the Disclosing Party, the Recipient shall, to the extent possible, give reasonable advance notice of such disclosure to the Disclosing Party, shall use reasonable efforts to minimize the scope of such disclosure, and shall cooperate with the Disclosing Party to take

reasonable measures to ensure confidential treatment of such information, including, but not limited to, by requiring the Third Party to whom the Confidential Information is disclosed to agree in writing to maintain such information in confidence and to use it only for the purposes for which it is disclosed.

11.3 SEC Filings. Either Party may disclose the terms of this Agreement to the extent required, in the reasonable opinion of such Party's legal counsel, to comply with applicable laws, including, without limitation, the rules and regulations promulgated by the United States Securities and Exchange Commission. Notwithstanding the foregoing, before disclosing this Agreement or any of the terms hereof pursuant to this Section 11.3, the Parties will reasonably consult with one another on the terms of this Agreement to be redacted in making any such disclosure. If a Party discloses this Agreement or any of the terms hereof in accordance with this Section 11.3, such Party agrees, at its own expense, to seek confidential treatment of portions of this Agreement or such terms, as may be reasonably requested by the other Party.

11.4 Public Announcements. Neither Manufacturer nor Distributor shall issue any press release or make any other public announcement or otherwise disclose or announce this Agreement, the existence thereof, or the terms, conditions or subject matter hereof, without the prior written approval of the other Party, including without limitation, approval of the specific text of such release, announcement or statement; provided, that to the extent Manufacturer or Distributor, as the case may be, shall have received written advice of counsel that it is required to make an announcement or furnish a statement pursuant to the laws of its jurisdiction of incorporation or any jurisdiction in which any of its securities are publicly traded or the rules of any stock exchange upon which its securities are listed or any registered securities quotation system on which such securities are traded, it shall be permitted, after providing the other Party with a copy of such announcement or statement at least five (5) business days (or such shorter time as may be set forth in such written advice of counsel, but in no event less than one (1) business day) prior to its proposed issuance or submission, and after discussing such announcement or statement with the other Party and considering in good faith the modifications to such announcement or statement proposed by the other Party, to do so even if it has not obtained the approval of the other Party. Any determination that disclosure by a Party pursuant to this Section 11.4 is required shall be consistent with such Party's past practices with respect to such disclosure.

11.5 Injunctive Relief. Anything herein to the contrary notwithstanding, the Parties acknowledge that any breach of the provisions of this Article 11 could cause irreparable harm and significant injury, which may be difficult to ascertain, and are not susceptible to monetary damages. Accordingly, the Parties agree that the Disclosing Party shall have the right to seek the issuance of an ex parte restraining order or injunction to prevent any breach or continuing violation of the Recipient's obligations hereunder, in addition to (and not in substitution of) any other remedies that may be available to the Disclosing Party at law or in equity.

ARTICLE 12

MISCELLANEOUS

12.1 Insurance. Each Party agrees to procure and maintain in full force and effect during the term of this Agreement and for as long as the Products sold by or on behalf of Distributor are in the marketplace valid and collectible insurance policies in connection with this Agreement, which policies shall provide for the type of insurance and amount of coverage described in Exhibit 12.1 to this Agreement. Upon written request, a Party shall provide the other a certificate of coverage or other written evidence reasonably satisfactory of such insurance coverage.

12.2 Survival. The provisions of Articles 7, 9, 10, 11 and 12 and those provisions of this Agreement dealing with rights and obligations after termination of this Agreement shall survive termination of this Agreement to the extent necessary to give effect to such provisions.

12.3 Independent Contractor Status; No Joint Venture or Partnership. Neither Party shall have any authority to obligate the other in any respect or to hold itself out as having any such authority. All personnel of Manufacturer shall be solely employees of Manufacturer and shall not represent themselves as employees of Distributor, and all personnel of Distributor shall be solely employees of Distributor and shall not represent themselves as employees of Manufacturer. Nothing herein shall be deemed to create a partnership or joint venture between the Parties.

12.4 Binding Effect; Benefits; Assignment.

(a) This Agreement shall inure to the benefit of and be binding upon the Parties hereto and their respective permitted successors and assigns. Nothing contained herein shall give to any other person any benefit or any legal or equitable right, remedy or claim.

(b) This Agreement shall not be assignable by Distributor without the prior written consent of Manufacturer, except that, subject to Section 10.2(c), Distributor shall be permitted to assign this Agreement without the prior written consent of Manufacturer to a Person acquiring all or substantially all of Distributor's assets or voting stock. Such assignment shall be subject to the assignee agreeing in writing to assume the benefits and obligations of this Agreement. Distributor shall provide Manufacturer prompt notice of any such sale, or other Change of Control, of Distributor promptly following consummation thereof.

(c) This Agreement shall not be assignable by Manufacturer without the prior written consent of Distributor, except that Manufacturer shall be permitted to assign this Agreement without the prior written consent of Distributor to a Person acquiring all or substantially all of Manufacturer's assets or voting stock or to a Person purchasing the NDA with respect to a Branded Product. Such assignment shall be subject to the assignee agreeing in writing to assume the benefits and obligations of this Agreement. Manufacturer shall provide Distributor prompt notice of any such sale, or other Change of Control, of Manufacturer promptly following consummation thereof.

12.5 Entire Agreement; Amendments. This Agreement, including all Exhibits, and the Bailment Agreement and the Quality Agreement constitute the entire agreement between the Parties with respect to the subject matter of this Agreement and all prior agreements, understandings, promises and representations, whether written or oral, with respect thereto are

superseded hereby. Each of the Parties acknowledges that in deciding to enter into this Agreement and to consummate the transaction contemplated hereby none of them has relied upon any statements or representations, written or oral, other than those explicitly set forth herein or therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties hereto unless reduced to writing and signed by the respective authorized officers of the Parties.

12.6 Severability. In the event that any provision of this Agreement would be held in any jurisdiction to be invalid, prohibited or unenforceable for any reason, such provision, as to such jurisdiction, shall be ineffective, without invalidating the remaining provisions of this Agreement or affecting the validity or enforceability of such provision in any other jurisdiction. Notwithstanding the foregoing, if such provision could be more narrowly drawn while maintaining the intent of the Parties, so as not to be invalid, prohibited or unenforceable in such jurisdiction, it shall, as to such jurisdiction, be so narrowly drawn, without invalidating the remaining provisions of this Agreement or affecting the validity or enforceability of such provision in any other jurisdiction.

12.7 Remedies. Unless otherwise expressly provided, all remedies hereunder are cumulative, and in addition to any other remedies provided for by law and may, to the extent permitted by law, be exercised concurrently or separately, and the exercise of any one remedy shall not be deemed to be an election of such remedy or to preclude the exercise of any other remedy.

12.8 Notices. Any notice, request, consent or communication (collectively, a "Notice") under this Agreement shall be effective if it is in writing and (i) personally delivered, (ii) sent by certified or registered mail, postage prepaid, return receipt requested, (iii) sent by an internationally recognized overnight delivery service, with delivery confirmed, or (iv) sent by facsimile, with receipt confirmed and hard copy delivered by regular mail; addressed as set forth in this Section 12.8 or to such other address as shall be furnished by either Party hereto to the other Party hereto. A Notice shall be deemed to have been given as of (i) the date when personally delivered, (ii) seven (7) business days after being deposited with the United States Postal Service, certified or registered mail, properly addressed, return receipt requested, postage prepaid, (iii) two business days after being delivered to said overnight delivery service properly addressed, or (iv) immediately upon receiving confirmation of receipt of the facsimile, as the case may be. All Notices shall specifically state: (i) the provision (or provisions) of this Agreement with respect to which such Notice is given, and (ii) the relevant time period, if any, in which the Party receiving the Notice must respond.

If to **Manufacturer:**

Santarus, Inc.
3721 Valley Centre Drive, Suite 400
San Diego, CA 92130
Attn: Gerald T. Proehl, President and CEO
Fax: (858) 314-5701

With a copy to:

Santarus, Inc.
3721 Valley Centre Drive, Suite 400
San Diego, CA 92130
Attn: Legal Affairs Department
Fax: (858) 314-5702

If to **Distributor**: Prasco, LLC
6125 Commerce Court
Mason, OH 45040
Attn: E. Thomas Arington, Chairman and CEO
Fax: (513) 204-1120

With a copy to:

Glenn S. Vraniak
Senior Vice President, CFO
Prasco, LLC
6125 Commerce Court
Mason, Ohio 45040
Fax: (513) 204-1120

12.9 Waivers. The failure of either Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other Party. The observance of any provision of this Agreement may be waived (either generally or in any particular instance) only with the written consent of the waiving Party.

12.10 Counterparts. This Agreement may be executed in any number of counterparts, and execution by each of the Parties of any one of such counterparts will constitute due execution of this Agreement. Each such counterpart hereof shall be deemed to be an original instrument, and all such counterparts together shall constitute but one agreement.

12.11 Headings. The article and section headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement.

12.12 Construction. The Parties expressly agree that any rule of construction to the effect that ambiguities are to be resolved against the drafting Party shall not be applied in the construction or interpretation of this Agreement.

12.13 Governing Law. This Agreement shall be governed by, and construed and enforced in accordance with, the laws of the State of New York.

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IN WITNESS WHEREOF, Distributor and Manufacturer intending legally to be bound hereby have caused this Agreement to be duly executed as of the date first above written.

SANTARUS, INC.

By: /s/ Gerald T. Proehl
Name: Gerald T. Proehl
Title: President and CEO

PRASCO, LLC

By: /s/ E. Thomas Arington
Name: E. Thomas Arington
Title: Chairman and CEO