



IN THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

PART F
STATE OF OKLAHOMA } S.S.
CLEVELAND COUNTY }

FILED

MAY 23 2019

In the office of the
Court Clerk MARILYN WILLIAMS

STATE OF OKLAHOMA, ex rel.,
MIKE HUNTER,
ATTORNEY GENERAL OF OKLAHOMA,

Plaintiff,

vs.

- (1) PURDUE PHARMA L.P.;
- (2) PURDUE PHARMA, INC.;
- (3) THE PURDUE FREDERICK COMPANY,
- (4) TEVA PHARMACEUTICALS USA, INC.;
- (5) CEPHALON, INC.;
- (6) JOHNSON & JOHNSON;
- (7) JANSSEN PHARMACEUTICALS, INC.,
- (8) ORTHO-MCNEIL-JANSSEN
PHARMACEUTICALS, INC., n/k/a
JANSSEN PHARMACEUTICALS;
- (9) JANSSEN PHARMACEUTICA, INC.,
n/k/a JANSSEN PHARMACEUTICALS, INC.;
- (10) ALLERGAN, PLC, f/k/a ACTAVIS PLC,
f/k/a ACTAVIS, INC., f/k/a WATSON
PHARMACEUTICALS, INC.;
- (11) WATSON LABORATORIES, INC.;
- (12) ACTAVIS LLC; and
- (13) ACTAVIS PHARMA, INC.,
f/k/a WATSON PHARMA, INC.,

Defendants.

Case No. CJ-2017-816
Honorable Thad Balkman

William C. Hetherington
Special Discovery Master

CONFIDENTIAL
FILED UNDER SEAL PURSUANT
TO PROTECTIVE ORDER DATED
APRIL 16, 2018

DEFENDANTS TEVA PHARMACEUTICALS USA, INC., CEPHALON, INC., WATSON
LABORATORIES, INC., ACTAVIS LLC, AND ACTAVIS PHARMA, INC., f/k/a
WATSON PHARMA, INC.'S MOTION FOR PROTECTIVE ORDER AND TO
MAINTAIN CONFIDENTIALITY OF CERTAIN DOCUMENTS AT TRIAL

DOCUMENTS SEALED PER COURT ORDER
DATED APRIL 16, 2018

CONFIDENTIAL—TO BE FILED UNDER SEAL

EXHIBIT 15

611638

API SUPPLY AGREEMENT

This API Supply Agreement (this "Agreement") is made as of this 27th day of September 2006, (the "Effective Date") by and between Anesta Corp., 4745 Wiley Post Way, Salt Lake City, Utah 84116 ("Anesta") and Johnson Matthey Inc., 2003 Nolte Drive, West Deptford, NJ 08066-1742 ("Johnson Matthey"). Anesta and Johnson Matthey are hereinafter collectively referred to as the "Parties." This Agreement may be referenced in orders and other correspondence related hereto as Agreement No. 509.

WHEREAS, Anesta holds certain rights to manufacture, market and sell worldwide the pharmaceutical product containing the API (as defined below);

WHEREAS, Anesta wishes to purchase from Johnson Matthey bulk API for subsequent formulation, tableting, packaging, and commercial sale by Anesta worldwide and for certain clinical and other purposes; and

WHEREAS, Johnson Matthey is in the business of, among other things, developing, manufacturing and marketing raw materials and active pharmaceutical ingredients, including API, used to produce the Product (as defined below) and has suitable facilities and equipment and sufficient qualified personnel to manufacture API in bulk form, and is willing to provide such supply on the terms and conditions set forth below.

NOW, THEREFORE, the parties hereto, intending to be legally bound, agree as follows:

I. DEFINITIONS

As used in this Agreement:

- 1.1 "Active Pharmaceutical Ingredient" or "API" means the Milled Fentanyl Citrate used in the Product.
- 1.2 "Adverse Experience" or "AE" shall mean any unfavorable and unintended change in the structure, function, or chemistry of the body temporally associated with any use of a product or of a derivative thereof containing API, whether or not the adverse experience is considered to be related to the use of such product, including but not limited to any of the following: an unexpected side effect, injury, toxicity or sensitivity reaction, which may include an experience of unexpected incidence and severity; an adverse experience occurring in the course of the use of a drug product in professional practice; an adverse experience occurring in clinical studies; an adverse experience occurring from drug overdose, whether accidental or intentional; an adverse experience occurring from drug abuse; an adverse experience occurring from drug withdrawal; and any significant failure of expected pharmacological action.

- 1.3 "Affiliate" means any corporation or other business entity which, directly or indirectly, is controlled by, controls, or is under common control with Anesta or Johnson Matthey. For this purpose, "control" shall be deemed to mean ownership of fifty percent (50%) or more of the stock or other equity of such entity.
- 1.4 "Calendar Quarter" shall mean any of the three-month periods beginning January 1, April 1, July 1 and October 1 of any Contract Year during the term of this Agreement.
- 1.5 "cGMP" means those current practices, as amended from time to time, applicable to the manufacture of active pharmaceutical ingredients laid down in and as a guidance document "regulations such as the United States Code of Federal Regulations (Title 21, Parts 210-211)", and the guidance document ICH Q7A for API Manufacture Guide to Inspection of Bulk Pharmaceutical Chemicals (U.S. Department of Health and Human Services, Revised September 1991)..
- 1.6 "Confidential Information" means all information, data, know-how and all other business, technical and financial data disclosed hereunder by one party or any of its Affiliates to the other party or any of its Affiliates, except any portion thereof which:
- (a) at the time of disclosure, is public knowledge;
 - (b) after disclosure, becomes public knowledge by publication or otherwise, except by breach of this Agreement by the recipient;
 - (c) the recipient can demonstrate by its written records was in the recipient's possession at the time of such disclosure, and which was not acquired, directly or indirectly, from the disclosing party;
 - (d) is lawfully disclosed to the recipient on a non-confidential basis by a third party who is not obligated to the disclosing party or any other third party to retain such Confidential Information in confidence;
 - (e) results from research and development by the recipient independent of such disclosure as shown by competent evidence; or
 - (f) is required to be disclosed by legal process; provided, in each case the party so disclosing information timely informs the other party and maintains confidentiality to the extent possible and, if possible, permits, and cooperates with, the other party to attempt by appropriate legal means to limit such disclosure.

All information exchanged pursuant to this Agreement shall be considered Confidential Information until the earlier of i) the time it falls within one of the above exceptions; or ii) ten (10) years from the expiration or termination of Term

of this Agreement. Confidential Information disclosed orally, visually and/or in another intangible form shall be identified by the disclosing party to the receiving party as confidential at the time of such disclosure and confirmed in writing to the receiving party within thirty (30) days after such disclosure.

- 1.7 "Contract Year" means each consecutive twelve (12) month period during the term of this Agreement, beginning with the first contract year commencing on Effective Date and ending on December 31, 2006. The Contract Year for the last year of this Agreement shall be from January 1 through the date of termination or expiration of the Term.
- 1.8 "DEA" means the United States Drug Enforcement Agency.
- 1.9 "FDA" means the United States Food and Drug Administration.
- 1.10 "Initial Term" has the meaning provided in Section 2.4.
- 1.11 "NDA" means Anesta's new drug application for formulated Product.
- 1.12 "Order" has the meaning provided in section 5.1.
- 1.13 "Quality Agreement" or "QTA" means the form of quality assurance/quality control agreement to be entered into by Anesta and Johnson Matthey as set forth in Schedule B dated July 19, 2004, as amended from time to time by written agreement of the Parties.
- 1.14 "Product" means Actiq and Fentora developed and/or manufactured by or for Anesta using the API in accordance with FDA regulations.
- 1.15 "Purchase Price" shall have the meaning set forth in Section 6.3 hereof.
- 1.16 "Specifications" means those specifications and qualified assays for the API described in Schedule A, as may be amended from time to time by written amendment signed by both Parties.
- 1.17 "Term" has the meaning provided in Section 2.4.

II. PURCHASE AND SALE; TERM; RIGHT OF FIRST REFUSAL

2.1 Purchase and Sale.

2.1.1 Minimum Purchase Requirements. Anesta shall use commercially reasonable efforts to qualify Johnson Matthey as manufacturer of API for all Product wherever sold. Once Johnson Matthey has become an FDA approved supplier, during the Initial Term of this Agreement and any extensions thereof, Anesta hereby agrees to purchase from Johnson Matthey at least sixty percent (60%) of its annual worldwide requirements for API for all Products (except and only to the extent otherwise provided in Section 2.1.2 below) during every Contract Year of this Agreement.

2.1.2 Limited Exception to Minimum Purchase Requirements. Notwithstanding the foregoing, for the twelve month period beginning from the date the FDA approves Johnson Matthey as API supplier for the Product marketed by Anesta as Actiq, (the "Actiq Transition Period"), Anesta shall be obligated to purchase at least twenty (20%) percent of Anesta's API requirements for the Actiq Product. Unless Johnson Matthey is in breach of the limited warranties set forth in Section 9.1(a) (the "Limited Warranties") with respect to the API for Actiq Product which breach has not been timely cured during the Actiq Transition Period, this exception to the minimum purchase requirement shall terminate at the expiration of the Actiq Transition Period and the minimum purchase requirements of Section 2.1.1 shall apply to Anesta's API requirements for the Actiq Product. In the event Johnson Matthey has failed to timely cure such breach of the Limited Warranties for the Actiq Product, this limited exception to the Minimum Purchase Requirements shall continue until Johnson Matthey complies with its Limited Warranties for a continuous twelve month period at which point such exception shall terminate.

If Johnson Matthey is unable to ship the quantity of API ordered by Anesta within the lead-time provided in Section 5, then Anesta will be permitted to purchase such quantity from another supplier without prejudice to its obligation to purchase sixty percent (60%) of its requirements for the API hereunder.

Johnson Matthey agrees to sell to Anesta API pursuant to purchase orders placed by Anesta from time to time for Product, subject to forecasting requirements of Section 5 and the terms of Schedule C. Johnson Matthey shall supply the API in bulk containers.

2.2 Cooperation. Anesta and Johnson Matthey will cooperate with each other as may be necessary and customary in consideration of industry practice, and will disclose all material information necessary to enable each other to perform under this Agreement in a timely fashion, including providing necessary DEA-222 forms, Procurement forms, Quota Letter, and Forecasts. Anesta will provide Johnson

Matthey with DEA-222 and Certificate of Available Quota Forms in accordance with forecasts provided by Anesta pursuant to Article V not less than ten (10) days prior to any requested delivery date.

- 2.3 Specific Duties. In addition to its general obligations relating to the supply of API, Johnson Matthey shall be responsible for performing the following services at Johnson Matthey's cost:
- (i) quality control and testing of all API in order to monitor compliance with all applicable standards and specifications required by this Agreement, including any Schedules hereto;
 - (ii) conducting stability testing of API in accordance with the procedures as set forth in the Quality Agreement;
 - (iii) summarizing implemented changes and supplying latest versions of approved critical documentation, and providing other information necessary for Anesta to prepare, submit, obtain and maintain all regulatory filings relating to the manufacture of the API under the terms of this Agreement;
 - (iv) performing such other services as agreed upon in writing by the parties; and
 - (v) maintaining a safety stock of API of approximately 6-8 Kilograms from which supply will be withdrawn on a first in, first out basis. Each Contract Year, the parties may agree in writing to increase or decrease the amount kept as safety stock based on increases or decreases in Johnson Matthey's average annual supply of API for the prior Contract Year.
- 2.4 Term. Unless terminated in accordance with the provisions of Article XVI, this Agreement will become effective as of the Effective Date and remain in effect for a period of five (5) years from the earlier of: i) the last date Johnson Matthey is approved by the FDA as a supplier of the API for any Product (the "Initial Term"), or ii) August 30, 2007. Unless either party gives written notice of non-renewal at least twelve (12) months prior to the end of the Initial Term or any renewal term, this Agreement shall be renewed for consecutive terms of two (2) years (collectively, the Initial Term and all renewals shall be referred to as the "Term").

III. API QUANTITY, QUALITY AND MANUFACTURING PROCESSES

- 3.1 Quantity. Subject to the terms and conditions of this Agreement, Johnson Matthey will manufacture and supply to Anesta quantities of API ordered by Anesta for subsequent formulation, tableting, packaging and commercial sale by Anesta or for clinical or other purposes anywhere in the world.
- 3.2 Quality. All API manufactured and sold by Johnson Matthey to Anesta under this Agreement will meet the Specifications, as well as the quality assurance standards established in the Quality Agreement. Such Specifications, as well as the terms and conditions of the Quality Agreement, are subject to modification from time to time by mutual written agreement of the Parties. Prior to implementation of any Specification changes, the Parties agree to negotiate in good faith in an attempt to reach agreement on (a) the new price for any API manufactured and supplied hereunder by Johnson Matthey which embodies such changes, based solely on the effect of such changes on Johnson Matthey's manufacturing costs, including without limitation material and labor, for manufacturing and delivering the API and (b) any other amendments to this Agreement which may be necessitated by such changes (i.e., an adjustment to the lead time for purchase orders).
- 3.3 Quality Agreement. Within sixty (60) days after the date of this Agreement, representatives of the parties' Quality Assurance departments shall meet to develop, agree and approve a Quality Agreement outlining responsibilities and key contacts for quality and compliance related issues. Johnson Matthey will provide Anesta with certain production and control information for review prior to release as specified in the Quality Agreement. The Quality Agreement will also address, without limitation, annual product reviews, returned goods, regulatory audits, compliance with cGMP, and such other quality related concerns deemed appropriate. The final agreed Quality Agreement will be attached to this Agreement as Schedule B and will be deemed a part of this Agreement when completed.

IV. CONFIDENTIAL INFORMATION

- 4.1 The parties acknowledge that they have provided Confidential Information to each other in connection with the manufacture and supply of the API, and further acknowledge that all such Confidential Information (as well as any additional Confidential Information provided by one party to the other hereunder) shall be subject to the provisions of this Article IV. Any and all information, knowledge, technology, and trade secrets relating to the API and provided by Johnson Matthey shall be deemed Confidential Information. Any and all information, knowledge, technology, and trade secrets relating to the Product and provided by Anesta shall be deemed Confidential Information.

- 4.2 Upon request by Anesta, Johnson Matthey will disclose to Anesta all Confidential Information of Johnson Matthey concerning the API reasonably necessary for, and Anesta may use such Confidential Information for the limited purpose of, Anesta's compliance with FDA regulatory requirements or to secure intellectual property rights pursuant to Section 13.1 below, subject at all times to the obligations of confidentiality herein. Anesta shall take all necessary measures to ensure that the security and confidentiality of such Confidential Information is maintained and shall promptly notify Johnson Matthey of all third-parties receiving such Confidential Information for such regulatory purposes. .
- 4.3 All Confidential Information shall be held in confidence by the receiving party, shall not be used by the receiving party for any purpose except as provided hereunder and shall not be disclosed to third parties except for disclosure to its Affiliates or governmental authorities who need to know such Confidential Information for purposes of this Agreement, or except as otherwise necessary to carry out the receiving party's obligations under this Agreement. If a receiving party finds it necessary to disclose such Confidential Information to a third party, the receiving party will not do so without first obtaining the written consent of the disclosing party (which shall not be unreasonably withheld) and entering into an agreement with the third party which binds the third party to the same obligations of restricted use and disclosure as are undertaken by the parties in this Agreement.
- 4.4 Neither party shall distribute any Confidential Information of the other except to its employees or agents who have a need to know in connection with the performance of their duties in satisfying the obligations of such party hereunder. Any employee or agent who receives Confidential Information shall be advised as to the confidential nature thereof and the prohibitions contained herein. All copies of any portions of any Confidential Information distributed as provided in this section will be identified as confidential. Upon termination of this Agreement, and upon the request of the disclosing party, the receiving party shall return or destroy all such Confidential Information and any copies thereof in its possession, except that each party may retain one copy of Confidential Information solely for archival purposes.
- 4.5 Termination of this Agreement shall not operate to extinguish either party's obligation to treat Confidential Information as provided herein, and the same shall continue in effect in accordance with this Article.
- 4.6 Nothing contained herein shall be deemed to grant to either party, either expressed or implied, a license or other right or interest in the Confidential Information of the other or in any patent, trademark or other similar property of the other.

- 4.7 Neither party shall use the name of the other, nor disclose the existence of this Agreement for any purpose, without the prior written consent of the other, which shall not be unreasonably withheld or delayed.

V. FORECASTS AND ORDERS

- 5.1 Orders and Forecasts. At least three (3) months prior to the anticipated date of FDA approval of a Product, Anesta agrees to supply Johnson Matthey, on a quarterly basis, with a rolling twelve (12) month forecast of its requirements for the API. The forecast for the first Calendar Year (broken out in Calendar Quarters) shall be provided within thirty days of the Effective Date of this Agreement. The forecast for the first two (2) Calendar Quarters of each rolling forecast shall be firm and binding orders without the need of a purchase order (the "Order"). At least thirty (30) days prior to the start of a Calendar Quarter, Anesta shall provide Johnson Matthey with i) a purchase order for such Calendar Quarter (for record purposes only), and ii) an updated twelve month forecast of its requirements for the next three Calendar Quarters.

For illustrative purposes only, on November 30, 2006, Anesta shall provide a purchase order for the January 1 Order and an updated rolling forecast for the next three Calendar Quarters beginning April 1 (which shall be a binding Order), July 1 and Oct. 1, 2007. On February 28, 2007, Anesta shall provide a purchase order for the April 1, 2007 Order, and an updated forecast for the next three Calendar quarters beginning July 1 (which is a binding Order), Oct. 1, and Jan. 1, 2008, and so on.

The forecast for the last two (2) Calendar Quarters of each rolling forecast is non-binding and will be used by Johnson Matthey for production planning.

- 5.2 Forecasts Changes and Forecast Updates. Anesta may update its forecast to increase its API order at any time and Johnson Matthey will use reasonable commercial efforts to accommodate such changes, provided however, in no event shall Johnson Matthey be obligated to provide amounts in excess of the forecasted requirements unless it has been given 90 days advance written notice of such increase.

VI. PRICE, SHIPMENT AND PAYMENT

- 6.1 Johnson Matthey Responsibilities. Johnson Matthey will properly manufacture and ship the API to Anesta, ensuring that the preparation of the shipment conforms to all current DOT, Federal, state and local regulations. Johnson Matthey will prepare and execute all reasonably necessary shipping documents, consisting of Packing List, Dangerous Goods Declaration, and MSDS. Reference the QTA for conformance to the current specifications for packaging

configuration as agreed upon by both parties. If there is an inconsistency between the Quality Agreement and the current shipping laws and regulations, the current shipping laws and regulations will govern.

- 6.2 Terms of Shipment. All shipments are made ExWorks, Johnson Matthey facility in West Deptford, New Jersey.
- 6.3 Price and Taxes. Johnson Matthey shall invoice Anesta the Purchase Price for all API shipped as set forth in Schedule C attached hereto. Johnson Matthey shall send its invoice no earlier than the time of shipment. Risk of loss shall pass to Anesta upon delivery of API to carrier. Title of API shall pass to Anesta upon receipt of payment for such API. Anesta shall be responsible for any duty, sales, use, excise, value added, custom, inspection or any other tax applicable (except income taxes) to the sales of API by Johnson Matthey to Anesta. In the event Johnson Matthey is required to pay any such tax or charge, Anesta shall reimburse Johnson Matthey therefore; or in lieu of such payment, Anesta shall provide Johnson Matthey at the time the Order is submitted an exemption certificate or other document acceptable to the authority imposing the tax or charge.
- 6.4 Terms of Payment. Anesta will pay Johnson Matthey the Purchase Price together with any taxes due within thirty (30) days after the date of receipt of shipment. Johnson Matthey shall provide copies of all documentation required for API release as provided in the Quality Agreement and this Agreement. If Anesta delays or prevents delivery on the date specified by the Order, payment of the Purchase Price, taxes due and any storage fees described in Section 6.5 shall be within thirty (30) days after the date Johnson Matthey notifies Anesta that the API is available for shipment. Late payments shall bear interest at the rate of 1% per month, or, if less, the highest rate permitted under applicable law.
- 6.5 Storage. In the event Anesta delays or prevents delivery on the date specified by an Order, Johnson Matthey shall have the right to impose a storage fee of USD \$1,000 per month of storage. Safety stock provision provided in Section 2.3 (v) shall be exempt from any storage fees.

VII. INSPECTION AND ANALYSIS

- 7.1 Inspection by Johnson Matthey. Johnson Matthey will analyze each API lot for compliance with the Specifications set forth in Schedule A. Johnson Matthey will send to Anesta a certificate of analysis (together with any other documentation required under the Quality Agreement) together with each shipment of API. In this regard, Johnson Matthey agrees to retain all records and documents necessary to fulfill the requirements established by all applicable regulatory agencies.

- 7.2 Inspection by Anesta. Anesta or its authorized representative will inspect all shipments upon their receipt and will report any reasonably discernible defects in the API to Johnson Matthey within ninety (90) days of its receipt of the API and related records. Unless Anesta promptly notifies Johnson Matthey in writing within such ninety (90) day period that the API does not meet the Specifications or is subject to any claim of damage, defect or shortage, such API will be deemed accepted by Anesta ninety (90) days after receipt of the API. Any defects not reasonably discernible by proper testing within such ninety (90) day period, will be reported to Johnson Matthey by Anesta within ten (10) days of Anesta's discovery of the same.
- 7.3 Non-Conforming API. In the event the API does not meet Specifications, or is subject to any claim of damage, defect or shortage, the rejected API shall not be used by Anesta and shall promptly be returned by Anesta to Johnson Matthey at Johnson Matthey's expense, or such other mutually agreed upon response shall be undertaken. Johnson Matthey shall have the right, but not the obligation, to re-test the rejected API in accordance with Schedule A. If (i) the API is determined by Johnson Matthey, or an independent testing laboratory pursuant to 7.4, not to meet the Specifications or the warranties set forth in Section 9 or (ii) Johnson Matthey fails to retest the rejected API within thirty (30) days from the date of Anesta's original notification pursuant to 7.2, then, upon return of any rejected API pursuant to this 7.3, Johnson Matthey will replace the API at Johnson Matthey's cost and send such replacement API to Anesta within sixty (60) days of receipt of additional raw materials or, at Johnson Matthey's option, will refund the purchase price paid therefor. Johnson Matthey shall reimburse Anesta for the costs incurred by Anesta in properly disposing of such non-conforming API in accordance with Johnson Matthey's reasonable instructions. Any notice given hereunder shall specify the manner in which the API fails to conform to the order therefore or fails to meet such warranty or the Specifications.
- 7.4 Independent Testing. If Anesta notifies Johnson Matthey that any API does not meet the warranties in Section 9, and Johnson Matthey does not agree with Anesta's position, the parties will attempt to reach a mutually acceptable resolution of the dispute. If they are unable to do so after a reasonable period of time (such period not to exceed thirty (30) days from the date of original notification), the matter will be submitted to an independent testing laboratory acceptable to both parties for testing in accordance with the Specifications and associated analytical methods in effect at the time of the occurrence. Both parties will accept the judgment of the independent laboratory. The cost of such testing will be borne by the party whose position is determined to have been in error. If the API is determined by said independent laboratory to have been conforming, then the provisions of Section 7.3 hereof shall not apply, and Anesta shall not be relieved of its obligations to pay Johnson Matthey for such API and any replacement API provided by Johnson Matthey.

VIII. REGULATORY MATTERS; REGULATORY FILINGS AND APPROVALS

- 8.1 General. Johnson Matthey shall be responsible for obtaining and maintaining all site licenses for the manufacture of the API and shall comply with other applicable regulations promulgated by, but not limited to, the Food and Drug Administration ("FDA") and the Drug Enforcement Administration ("DEA") in connection with Johnson Matthey manufacture of the API.
- 8.2 Johnson Matthey will maintain throughout the pendency of this Agreement, the expertise, with respect to personnel and equipment, to fulfill the obligations established hereunder, and has obtained all requisite material licenses, authorizations and approvals required by federal, state or local government authorities including, but not limited to, the FDA, DEA, Environmental Protection Agency ("EPA"), Occupational Safety and Health Administration ("OSHA"), etc. to manufacture the API in accordance with this Agreement
- 8.3 There are no pending or uncorrected citations or adverse conditions noted in any inspection of the production facility to be employed which would cause the API to be misbranded or adulterated within the meaning of the federal Food, Drug and Cosmetic Act, as amended, or other applicable laws.
- 8.4 The execution, delivery and performance of this Agreement by Johnson Matthey does not conflict with, or constitute a breach of any order, judgment, agreement, or instrument to which Johnson Matthey is a party; and the execution, delivery and performance of this Agreement by Johnson Matthey does not require the consent of any person or the authorization of (by notice or otherwise) any governmental or regulatory authority (other than those relating to the granting of approval to commercialize and manufacture the product containing the API).

IX. REPRESENTATIONS AND WARRANTIES

9.1 Limited Warranty.

(a) Johnson Matthey represents and warrants to Anesta that (i) the API delivered to Anesta will conform to the Specifications, the Quality Agreement and current Good Manufacturing Practices ("cGMP") at the time each such batch of API is produced and, in accordance with §306(k) of the Food, Drug, and Cosmetic Act (21 USC 335a(k)) as amended, Johnson Matthey has not been debarred by the United States Food and Drug Administration (or by any analogous agency or under any analogous law or regulation), and neither the firm, any director, nor any employee of the firm has been convicted of any crime resulting in debarment under § 306(k)(1), and it did not and will not use in any capacity the services of any person convicted of any crime resulting in debarment under § 306(k)(1) of the Food, Drug, and Cosmetic Act. Johnson Matthey further warrants that it will not

directly cause the API delivered to Anesta to be adulterated, or misbranded within the meaning of any federal, state or local law or regulation.

(b) EXCLUDING INDEMNIFICATION/RECALL, ANESTA'S EXCLUSIVE REMEDY FOR BREACH OF WARRANTY SHALL BE DIRECT DAMAGES AND JOHNSON MATTHEY'S LIABILITY FOR ANY AND ALL LOSSES OR DAMAGE FROM ANY CAUSE WHATSOEVER, INCLUDING ALLEGED NEGLIGENCE, SHALL IN NO EVENT EXCEED THIS OBLIGATION TO REPLACE THE MATERIAL AND RESUBMIT IT TO ANESTA WITHIN THE TIME PERIOD STATED OR REFUND THE PRICE PAID. Johnson Matthey shall not be liable for, and Anesta assumes responsibility for, all personal injury and property damage resulting from the handling, possession, or use of the API following Anesta's receipt of the API. Johnson Matthey will be responsible for all shipping charges to and from the destination of the original shipment for such API found to be nonconforming.

(c) Anesta represents and warrants to Johnson Matthey that (i) the execution, delivery and performance of this Agreement by Anesta does not conflict with, or constitute a breach of any order, judgment, agreement, or instrument to which Anesta is a party; and (ii) the execution, delivery and performance of this Agreement by Anesta does not require the consent of any person or the authorization of (by notice or otherwise) any governmental or regulatory authority (other than those relating to the granting of approval to commercialize the product containing the API); and (iii) Anesta is in compliance with all applicable laws and regulations applicable to its use or sale of the API and Product.

9.2 Warranty Disclaimer. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, EACH PARTY EXPRESSLY DISCLAIMS ANY WARRANTIES, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER MATTER WITH RESPECT TO THE API WHETHER USED ALONE OR IN COMBINATION WITH OTHER SUBSTANCES.

X. QUALITY CONTROL, RECORDS AND INSPECTIONS

- 10.1 API Drug Substance. Johnson Matthey will maintain a sample of API as required by applicable regulatory standards or as otherwise mutually agreed by Anesta and Johnson Matthey. Johnson Matthey will be responsible for maintaining retention samples of the API as may be required by applicable regulatory standards.
- 10.2 Validation. Johnson Matthey will validate all process, methods, equipment, utilities, facilities and computers used in the formulation, storage, testing and release of API in conformance with all applicable laws and regulations. Anesta will have the right to review the results of said validation upon request.

- 10.3 Quality Compliance. Johnson Matthey will provide Anesta with timely notification of all significant deviations, notes to file, and other deficiencies that may reasonably be expected to impact the quality of the API, as well as all FDA or other applicable regulatory authority reports regarding testing, manufacture, bulk packaging or labeling of the API.
- 10.4 Manufacturing Records. Johnson Matthey will maintain complete and accurate records relating to the API and the manufacture, bulk packaging, labeling and testing thereof for the period required by applicable regulatory standards, and Johnson Matthey shall provide copies thereof to Anesta upon Anesta's request, provided however, such records and all copies thereof shall not be removed from Johnson Matthey's facility unless in support of governmental and/or regulatory filings (including, without limitation, any filings to secure intellectual property rights pursuant to Section 13.1). Any copies of manufacturing records, and information contained therein, sent or disclosed to Anesta by Johnson Matthey shall be deemed Confidential Information of Johnson Matthey, and Anesta shall use such copies only for internal purposes or governmental and regulatory filings subject to the obligations of Article IV. The records shall be subject to audit and inspection under this Article X.
- 10.5 Batch Records. Records which include the information relating to the manufacturing, bulk packaging and quality operation for each lot of API will be prepared by Johnson Matthey at the time such operations occur. Johnson Matthey will prepare such records in accordance with cGMP's, the Specifications and the Quality agreement.
- 10.6 Records Retention. Johnson Matthey will retain records and documents for periods meeting all applicable regulations of the FDA, or other applicable regulatory authority.
- 10.7 Regulatory Inspections. Johnson Matthey will promptly inform Anesta of any contact, inspection or audit by any governmental agency (other than EPA and OSHA inspections), related to or affecting the API (other than contacts, inspections or audits affecting products generally). Johnson Matthey will promptly provide Anesta with copies of any government-issued inspection observation reports (including without limitation FDA Form 483s and equivalent forms from other regulatory bodies) and agency correspondence that may reasonably be expected to adversely affect the API. Johnson Matthey and Anesta will cooperate in resolving any concerns with any governmental agency, provided however, all actions taken with respect to the governmental agency shall be at Johnson Matthey's sole discretion. Johnson Matthey will also inform Anesta of any action taken by any governmental agency against Johnson Matthey or any of its officers and employees which may reasonably be expected to adversely affect

the API or Johnson Matthey ability to supply API hereunder within three (3) business days after the action is taken.

- 10.8 Anesta Inspections. Anesta employees or Anesta authorized representatives will have the right during normal business hours, at reasonable intervals and on reasonable prior notice, to conduct inspections at Anesta's sole expense, of Johnson Matthey facilities used in the manufacturing, bulk packaging, storage, testing, shipping or receiving of API. All such employees and representatives shall be bound by the same confidentiality obligations as contained herein and shall abide at all times with Johnson Matthey rules and regulations, including without limitation safety rules and regulations. Such inspections may include GMP inspections and system audits. Persons conducting such inspections will have access only to documents, records, reports, data, procedures, facilities, regulatory submissions, and all other information required to be maintained by applicable government regulations relating to the API. Johnson Matthey shall take appropriate actions, in its sole discretion, to adopt reasonable suggestions of Anesta to correct any deficiencies identified by such inspection or audit. In addition, Anesta shall have the right to observe from time to time the manufacture, bulk packaging and quality control testing of API by Johnson Matthey at mutually agreeable times and subject to Johnson Matthey's policies and procedures, to be provided or advised of, to the extent applicable, at the time of the initial access to Johnson Matthey's facility. No testing of the API by Anesta and no inspection or audit by Anesta of the Johnson Matthey production facility under this Agreement shall operate as a waiver of or otherwise diminish Johnson Matthey responsibility with respect to API quality under this Agreement. The duration of an inspection or audit will be limited to no more than 3 days (inspections or audits that last over 3 days will be charged at Johnson Matthey specified FTE rates), and inspections and audits may not interfere with Johnson Matthey normal operations.

XI. COMPLAINTS, ADVERSE EXPERIENCES AND RECALLS

- 11.1 API Complaints and AE's. Anesta shall maintain complaint files with respect to the product containing API in accordance with cGMPs. Johnson Matthey will promptly notify Anesta by facsimile transmission of all API and AEs received by Johnson Matthey within two (2) days of its receipt thereof. All such notices shall be sent to the attention of the Director, Medical Affairs at Anesta, see schedule D. Anesta shall promptly provide Johnson Matthey with copies of any complaints received by Anesta relating to the manufacture or bulk packaging of the API. Anesta shall have responsibility for responding to all complaints, and for promptly providing Johnson Matthey with a copy of any responses to complaints relating to the manufacture or bulk packaging of the API. Anesta or its affiliates shall have responsibility for reporting all complaints relating to the product containing API to the FDA and any other regulatory authorities, including, but not limited to,

complaints relating to the manufacture or bulk packaging of the API as well as adverse experience (AE) reports. Anesta will correspond with complainants as to any complaints associated with product containing API, whether received during or after the term hereof. Johnson Matthey will assist Anesta in investigating API complaints relating to the manufacture or bulk packaging of the API by analyzing API and manufacturing processes to determine the nature and cause of an alleged API manufacturing defect or alleged API failure. Johnson Matthey will also assist Anesta in the investigation of any Adverse Experience (AE) reported to either party when such AEs are reasonably believed to be attributable to the manufacture or bulk packaging of the API. If Anesta determines that any reasonable physical, chemical, biological or other evaluation should be conducted in relation to an AE or API complaint relating to the manufacture or bulk packaging of the API, Johnson Matthey will conduct the evaluation and provide Anesta with a written report of such evaluation within thirty (30) days from receipt of Anesta's written request for same, together with samples of the API from the relevant lot. Unless the alleged defect or failure is determined to be solely caused by the negligence or breach of warranty by Johnson Matthey, Anesta shall reimburse Johnson Matthey for its costs and expenses of its cooperation and assistance at standard rates in the industry for similar services or as otherwise mutually agreed upon at the commencement of such assistance.

- 11.2 Recall Action. If Anesta should elect or be required to initiate a recall of product containing API, a withdrawal or field correction of such product solely because of (i) supply by Johnson Matthey of API that does not conform to the Specifications and warranties established by this Agreement, Anesta will notify Johnson Matthey within two business days of such determination and provide Johnson Matthey a copy of its recall letter prior to initiation of the recall. Johnson Matthey will assist Anesta (and its designated Affiliate) in an investigation to determine the cause and extent of the problem. All regulatory authority contacts and coordination of any recall activities will be initiated by, and will be the sole responsibility of, Anesta.
- 11.3 Recall Expenses. If any product containing API is recalled solely as a result of supply by Johnson Matthey of API that does not conform to the Specification and warranties contained in Sections 9.1(a) or 9.2, then Johnson Matthey will bear all costs and expenses of such recall up to, and not to exceed, USD\$1,000,000 in the aggregate. Recalls for any other reason will be at Anesta's sole expense. Unless the recall is determined to be solely caused by Johnson Matthey, Anesta shall reimburse Johnson Matthey for its costs and expenses of its cooperation and assistance at Johnson Matthey's then current rates.
- 11.4 Recall Records. Johnson Matthey will maintain complete and accurate records for such periods as may be required by applicable law or regulation.

XII. INSURANCE

- 12.1 Johnson Matthey Insurance. During the term hereof, Johnson Matthey shall maintain in full force and effect valid and effective insurance policies in connection with its obligations and liabilities as contemplated herein. In particular, Johnson Matthey's coverage shall be not less than United States Dollars two million (USD \$2,000,000) (or the equivalent amount in another currency) per loss occurrence and four million (USD\$4,000,000) (or the equivalent amount in other currency) per aggregated loss occurrences per year. Johnson Matthey will provide to Anesta, upon Anesta's written request, a certificate of insurance evidencing such liability insurance coverages and the amounts thereof. Such coverage shall cover a worldwide coverage territory and shall be with a financially sound insurance company maintaining an A.M. Best Rating of A X or better.
- 12.2 Anesta Insurance. During the term hereof, Anesta agrees to maintain in full force and effect valid and effective insurance policies in connection with its obligations, liabilities, representations and warranties as contemplated herein. In particular, Anesta's coverage shall be not less than United States Dollars ten million (USD \$10,000,000) per loss occurrence and per aggregated loss occurrences per year. Anesta will provide to Johnson Matthey, upon Johnson Matthey's written request, evidence of adequate liability insurance coverages and the amounts thereof. Such coverage shall cover a worldwide coverage territory, shall be with a financially sound insurance company maintaining an A.M. Best Rating of A X or better and shall have to be maintained for not less than ten (10) years following expiration or termination of this Agreement for any reason.

XIII. INVENTIONS

- 13.1 Except as otherwise provided, any information, inventions, improvements or the like derived or coming from Anesta's Confidential Information or from any other information directly related to the drug product formulation for the API, provided to Johnson Matthey by Anesta, will be automatically considered as Confidential Information under the terms of the Section IV. To the extent Johnson Matthey has testing results or related analytical information necessary or appropriate to assist in Anesta's protection of such API formulation, Johnson Matthey shall, upon request, communicate such information to Anesta which Anesta may use for the limited purposes of obtaining such intellectual property protection.
- 13.2 It is expressly agreed that Section 13.1 above is not applicable to any inventions, information, developments and improvements (and relevant intellectual property rights) related to procedures, processes and manufacturing of Johnson Matthey. In this case, therefore, all such information, and the relevant intellectual property rights, shall belong to exclusively to Johnson Matthey.

XIV. INDEMNIFICATION

- 14.1 By Johnson Matthey. Johnson Matthey will indemnify and hold Anesta, its Affiliates, directors, officers, employees, agents, successors, and assigns harmless from any and all liability, damage, loss, cost, or expense (including reasonable attorneys' fees, hereinafter "Loss") arising out of third-party claims, which arise solely from i) Johnson Matthey breach of Sections 8.2, 8.3 and 8.4 and any of the warranties and representations contained in Section 9.1(a) or 9.2 hereof, or ii) Johnson Matthey negligence or other willful misconduct except to the extent such claim arises from or relates to Anesta's indemnification obligations in Section 14.2 and 14.3, provided however, in no event shall Johnson Matthey's aggregate liability under this Agreement, including without limitation under this Section 14.1, 14.3 and 11.3 shall not exceed the amount paid by Anesta for API during the twelve month period ending on the earlier of the date such claim or recall arises, as the case may be, or the date of termination of this Agreement.
- 14.2 By Anesta. Anesta will indemnify and hold Johnson Matthey, its Affiliates, directors, officers, employees, agents, successors, and assigns harmless from any and all Loss arising out of third party claims relating to this Agreement, except to the extent such claim arises from or relates to Johnson Matthey's indemnification obligations in Section 14.1 and 14.3.
- 14.3 By Each Party. In the event that negligence or willful misconduct of, or breaches of this Agreement by, both Johnson Matthey and Anesta contribute to any such loss, damage, claim, injury, cost or expense, Johnson Matthey and Anesta will each indemnify and hold harmless the other with respect to that portion of the loss, damage, claim, injury, cost or expense attributable to its negligence or willful misconduct or breach.
- 14.4 Procedures. In the event that one party receives notice of a claim, lawsuit, or liability for which it is entitled to indemnification by the other party, the party receiving notice shall give prompt notification to the indemnifying party. The party being indemnified shall cooperate fully with the indemnifying party throughout the pendency of the claim, lawsuit or liability, and the indemnifying party shall have complete control over the conduct and disposition of the claim, lawsuit, or liability including the retention of legal counsel engaged to handle such matter. The indemnifying party hereunder will not be liable for any costs associated with the settlement of any claim or action brought against it or the other party unless it has received prior notice of the settlement negotiations and has agreed to the settlement.

XV. LIMITATION OF LIABILITY

IN NO EVENT SHALL JOHNSON MATTHEY OR ANESTA BE LIABLE TO THE OTHER FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR INDIRECT DAMAGES ARISING IN ANY WAY OUT OF THE MANUFACTURE AND SUPPLY OF THE API TO THE OTHER HOWEVER CAUSED AND BASED ON ANY THEORY OF LIABILITY; PROVIDED HOWEVER, THIS LIMITATION SHALL NOT APPLY TO THIRD PARTY CLAIMS COVERED IN ARTICLE XIV FOR WHICH THE OTHER PARTY IS INDEMNIFIED HEREUNDER.

XVI. TERMINATION

- 16.1 Breach. If either party hereto commits a material breach of any of its obligations hereunder, the non-breaching party may, at its option, terminate this Agreement by giving the other party at least ninety (90) days prior written notice of its intent to terminate this Agreement, which notice shall specify the breach and the termination date, unless the breaching party cures said breach prior to the specified termination date (or prior to the expiration of a longer period as may be reasonably necessary to cure a breach, provided that the breaching party is making diligent efforts to cure such breach, and provided further that such longer period shall not in any event exceed one hundred twenty (120) days from the date of notice).
- 16.2 Insolvency. Either party may terminate this Agreement immediately in its entirety if the other Party files a petition of bankruptcy, is adjudged bankrupt, takes advantage of any insolvency act, or executes a bill of sale, deed of trust, or assignment for the benefit of creditors.
- 16.3 Survival. The rights and obligations contained in sections covering representations and warranties, indemnification and confidentiality will survive termination of this Agreement, as will any rights to payment or other rights or obligations that have accrued under this Agreement prior to termination. Termination will not affect the liability of either party by reason of any act, default, or occurrence prior to said termination.

XVII. ALTERNATIVE DISPUTE RESOLUTION

Except as set forth in Section 7.4, any dispute concerning or arising out of this Agreement or concerning the existence or validity hereof, shall be determined by the following procedure.

- 17.1 Both parties understand and appreciate that their long term mutual interest will be best served by effecting a rapid and fair resolution of any claims or disputes which may arise out of services performed under this contract or from any dispute concerning contract terms. Therefore, both parties agree to use their best efforts to resolve all such disputes as rapidly as possible on a fair and equitable basis. Toward this end both parties agree to develop and follow a process for presenting, rapidly assessing, and settling claims on a fair and equitable basis.
- 17.2 If any dispute or claim arising under this contract cannot be readily resolved by the parties pursuant to the process described in Section 17.1, the parties agree to refer the matter to a panel consisting of one (1) senior executive employed by each party who is not directly involved in the claim or dispute for review and resolution. A copy of the contract terms, agreed upon facts (and areas of disagreement), and concise summary of the basis for each side's contentions will be provided to both such senior executives who shall review the same, confer, and attempt to reach a mutual resolution of the issue.
- 17.3 If the matter has not been resolved utilizing the process set forth in this Article XVII, and the parties are unwilling to accept the non-binding decision of the panel, either or both parties may elect to pursue resolution through litigation, or other legal remedies available to the parties.

XVIII. GROSS INEQUITIES

It is the intent of the parties hereto that they shall mutually benefit from the terms, conditions and provisions of this Agreement, and in the event that either party shall suffer a gross inequity resulting from such terms, conditions or provisions, or from a substantial change in circumstances or conditions, the parties shall negotiate in good faith to resolve or remove such inequity. It is mutually understood and agreed, however, that nothing herein shall be construed to relieve either party of any of its obligations under this Agreement, unless and until such resolution or removal has been agreed to in writing by both parties.

XIX. MISCELLANEOUS

- 19.1 Headings. The headings and captions used herein are for the convenience of the parties only and are not to be construed to define, limit or affect the construction or interpretation hereof.
- 19.2 Severability. In the event that any provision of this Agreement is found to be invalid or unenforceable, then the offending provision shall not render any other provision of this Agreement invalid or unenforceable, and all other provisions shall remain in full force and effect and shall be enforceable, unless

the provisions which have been found to be invalid or unenforceable shall substantially affect the remaining rights or obligations granted or undertaken by either party.

- 19.3 Entire Agreement. This Agreement, including all those Schedules appended hereto, contains the entire agreement of the Parties regarding the subject matter hereof and supersedes all prior agreements, understandings or conditions (whether oral or written) regarding the same. Further, this Agreement may not be changed, modified, amended or supplemented except by a written instrument signed by both parties.
- 19.4 Assignability. This Agreement and the rights hereunder may not be assigned or transferred by either party without the prior written consent of the other party, provided however, that either party may assign this Agreement to an Affiliate, and provided further that in the event of a merger, acquisition or sale of substantially all of the assets of Anesta, the rights and obligations of Anesta under this Agreement may be assigned to the survivor or Anesta in that transaction. In the event that this Agreement is assigned, it shall be binding upon and inure to the benefit of the parties and their respective successors and assigns.
- 19.5 Further Assurances. Each party hereto agrees to execute, acknowledge and deliver such further instruments, and to take such other actions, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.
- 19.6 Waiver. The waiver by either party of a breach of any provisions contained herein shall be effective only if made in writing and shall in no way be construed as a waiver of any succeeding breach of such provision or the waiver of the provision itself.
- 19.7 Force Majeure. A party shall not be liable for nonperformance or delay in performance (other than of obligations regarding any payments or of confidentiality) caused by any event reasonably beyond the control of such party including, without limitation, wars, hostilities, revolutions, riots, civil disturbances, national emergencies, strikes, lockouts, other labor trouble, unavailability or failure in whole or in part of supplies, equipment or machinery, interruption of or delay in transportation, epidemics, fires, floods, earthquakes, other forces of nature, explosions, embargoes, or any other Acts of God or public enemy, or any laws, proclamations, regulations, ordinances, or other acts or orders of any court, government or governmental agency. Any occurrence of Force Majeure shall be reported promptly to the other party. A party whose performance has been excused will perform such obligation as soon as is reasonably practicable after the termination or cessation of such event or circumstance.

- 19.8 Remedies. Each party agrees and acknowledges that its disclosure of Confidential Information in breach of this Agreement may cause irreparable harm to other party, and therefore that any such breach or threatened breach may entitle such party to injunctive relief, in addition to any other legal remedies available in a court of competent jurisdiction.
- 19.9 Governing Law. This Agreement shall in all respects be construed and enforced in accordance with the law of the State of Delaware, USA.
- 19.10 Independent Contractors. The parties are independent contractors under this Agreement. Nothing contained in this Agreement is to be construed so as to constitute Anesta and Johnson Matthey as partners, agents or employees of the other, including with respect to this Agreement. Neither party hereto shall have any express or implied right or authority to assume or create any obligations on behalf of, or in the name of, the other party or to bind the other party to any contract, agreement or undertaking with any third party unless expressly so authorized in writing by the other party.
- 19.11 Counterparts. This Agreement may be executed in multiple counterparts, each of which shall be considered and shall have the force and effect of an original.
- 19.12 Notices. Except as set forth in Section 11.1 above, or as otherwise stated herein, all notices, consents or approvals required by this Agreement shall be in writing and sent by overnight courier service, certified or registered air mail, postage prepaid, or by facsimile or cable (confirmed by such certified or registered mail) to the parties at the following addresses or such other addresses as may be designated in writing by the respective parties. Notices shall be deemed effective on the date of mailing.

If to Anesta:

Purchasing Dept.
Anesta Corp.
4745 Wiley Post Way
Salt Lake City, Utah 84116
Facsimile: (801)-595-1406

All Johnson Matthey invoices and/or charges in billing should be directed to the Accounting Department at:

Anesta
4745 Wiley Post Way
Salt Lake City, Utah 84116
Attention: Accounts Payable

If to Johnson Matthey:

Johnson Matthey
2003 Nolte Drive _____
West Deptford, NJ 08066-1742
Attention: General Manager

Facsimile:

All Anesta purchase orders shall be sent to:
Sr. Customer Service Rep

[Johnson Matthey]

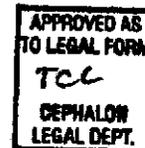
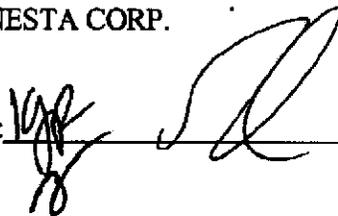
Any legal notices required to be provided pursuant to Article 14 or 16 shall also be sent to:

Johnson Matthey
North American Corporate
Suite 600
435 Devon Park Drive
Wayne, PA 19087-1998
Tel: (610) 971-3000
Facsimile: (610) 971-3022
ATTN: General Counsel

IN WITNESS WHEREOF, the undersigned parties have caused this Agreement to be executed as of the date first above written.

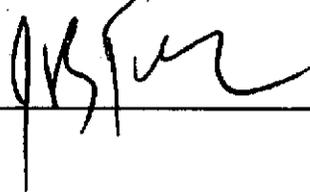
ANESTA CORP.

By: _____



JOHNSON MATTHEY INC.

By: _____



Schedule A

API Specifications

The parties have agreed upon all those applicable specifications for the API as set forth in the following documents. The parties shall agree upon any modifications to any such specifications in writing.

Milled Fentanyl Citrate USP/JP/EP

SPECIFICATIONS

<u>#</u>	<u>Test</u>	<u>Specification</u>
1.0	Appearance	White powder, free from visible evidence of contamination
2.0	Identification (USP) A. IR	Exhibits maxima only at the same wavelengths as that of a similar preparation of the corresponding Standard.
3.0	B. UV	Exhibits maxima and minima at the same wavelengths as the Standard
4.0	Loss on Drying (USP)	NMT 0.5 %
5.0	Residue on Ignition (USP)	NMT 0.5 %
6.0	Heavy Metals (USP)	NMT 0.002 %
7.0	Ordinary Impurities (USP)	NMT 2.0 %
8.0	Assay (USP)	98.0 % - 102.0 % (dried basis)
9.0	Purity (HPLC)	98.0 % - 102.0 %, (dried basis)
10.0	Impurities HPLC	NMT 0.50 % Total Impurities NMT 0.15 % Acetyl (<i>Ph. Eur.</i> Impurity C) NMT 0.15 % FC-1001 (<i>Ph. Eur.</i> Impurity B) NMT 0.10 % Individual Unspecified Impurities
11.0	Residual Solvents (GC)	NMT 0.5 % IPA
12.0	Bromide	NMT 40 ppm
13.0	Melting Range	Between 147° - 153 °C
14.0	Particle Size	D10 NLT 1.1 and NMT 2.5 D50 NLT 3.1 and NMT 7.1 D90 NLT 6.5 to NMT 18 SPAN NLT 1 to NMT 3
15.0	Identification (JP) A. UV	Exhibits similar intensities of absorption at the same wavelengths as the Standard
16.0	B. IR (same as USP)	Exhibits similar intensities of absorption at the same wave numbers as the Standard
17.0	C. Citrate	A red-brown solution develops
18.0	pH (JP)	Between 3.0 and 5.0
19.0	Melting Point (JP)	150° - 154 °C
20.0	Loss on Drying (JP)	NMT 0.5 %
21.0	Residue on Ignition (JP)	NMT 0.2 %
22.0	Assay (Titration) (JP)	98.0 % to 101.0 % (dried basis)
23.0	Limit Test for Phenethyl Bromide (HPLC)	NMT 0.01% w/w

Milled Fentanyl Citrate USP/JP/EP

<u>#</u>	<u>Test</u>	<u>Specification</u>
24.0	Purity (JP) A. Heavy metals	NMT 20 ppm
25.0	B. Related Substances (TLC)	The spots other than the principal spot from the sample solutions are not more intense than the spot from the standard solution.
26.0	Identification (EP) A. IR (same as USP)	Exhibits similar intensities of absorption at the same wave numbers as the Standard.
27.0	B. Melting Point	At about 152°C with decomposition
28.0	Appearance of Solution (EP)	The solution is clear and colorless.
29.0	Related Substances (HPLC) (EP)	<i>Ph. Eur.</i> Specified Impurities NMT 0.25 % Each Unspecified Impurity NMT 0.10 % Total Unspecified peaks NMT 0.50 %
30.0	Loss on Drying (EP) (same as USP)	NMT 0.5 %
31.0	Assay (EP) (Titration)	99.0 – 101.0 % (dried basis)
32.0	Metal Impurities (ICP)	NMT 0.005 % Palladium
33.0	Low Level Arylamines	NMT 0.01 % Impurity B (<i>Ph. Eur. Impurity D</i>) NMT 0.01 % Impurity A (<i>not mentioned in Ph. Eur.</i>) NMT 0.01 % FC-1003 (<i>not mentioned in Ph. Eur.</i>)

NOTE: Check RMT-163 Fentanyl Citrate monograph when FP-0030 monograph is updated to determine if it needs updating.

CAUTION: Great care should be taken to prevent particle inhalation and skin exposure

Schedule B

Form of Quality Agreement



Cephalon Incorporated
Vendor Quality Technical Agreement
(Version: 2004)

THIS VENDOR QUALITY TECHNICAL AGREEMENT is made this 19th day of July, 2004 by and between Cephalon Incorporated, a Delaware corporation, having a principle place of business at 145 Brandywine Parkway, Westchester, Pennsylvania, 19380, USA (hereinafter referred to as "Cephalon");

And

Johnson Matthey Inc., a Pennsylvania
Corporation having its principle place of business at 2003 White Drive, West Deptford, NJ 08066, USA
(Hereinafter referred to as "Vendor"),

WHEREAS

- Cephalon is engaged in the business of developing, manufacturing and distribution of Pharmaceutical products.
- Raw materials, process consumables, parts, manufacturing and packaging components are required to meet certain standards in order to be used by Cephalon in its primary business.

AND WHEREAS

- Vendor wishes to supply raw materials, process consumables, parts, manufacturing and packaging components to Cephalon meeting such standards.

NOW THEREFORE, in consideration of the mutual promises hereinafter set forth, and intending to be legally bound hereby, Cephalon and the Vendor hereby agree to abide by this Quality Agreement.

DEFINITIONS

Animal Derived – required traceable records identifying all the countries where the animals used to produce the material lived and traceable records for where animal-derived products were manufactured.

Certificate of Analysis – A document indicating the quality of the material through the results of laboratory analysis.

Certificate of Conformance/Compliance – A document indicating that the material is manufactured under appropriate regulatory standards and/or that the materials have been processed according to an agreed upon process.

Certificate of Testing – A document provided by the manufacturer/Vendor indicating that the material has been tested to meet applicable quality standards.

Lot – A batch or a specific identified portion of a batch, having uniform character and quality within specified limits; or, in the case of a drug product produced by continuous process, it is a specific identified amount produced in a unit of time or quantity in a manner that assures its having uniform character and quality within specified limits.

Process Controls – The regulation of variables influencing the conduct of a process in such a way as to obtain a product of desired quality and quantity in an efficient manner.

Quality Records – Batch records, laboratory notebooks and quality control data, or any data related to the manufacture or testing of the raw material or product.

Raw Materials – Any ingredient intended for use in the manufacture of a drug product, including those that may not appear in the final drug product.

Vendor Review Committee – A committee of Cephalon employees whose charter is to authorize addition of prospective Vendors to the approved vendors list, and monitor the performance of approved Vendors.

Product – The Active Pharmaceutical Ingredient (API) supplied by Vendor

ABBREVIATIONS

BSE – Bovine Spongiform Encephalopathy
CFR – Code of Federal Regulations
COA – Certificate of Analysis
COC – Certificate of Conformance
GMP – Good Manufacturing Practices
VRC – Vendor Review Committee
QTA – Quality Technical Agreement
SOP – Standard Operating Procedure
QA – Quality Assurance
NA – Not Applicable

1. **Change Control of the Quality Agreement**

All changes in terms of this Quality Agreement must be documented as a new version of the original document that will be reviewed and approved by representatives of QA from Cephalon and the Vendor.

2. **Vendor Approval**

Cephalon procures materials intended for use in the manufacture of pharmaceutical products from approved Vendors. Vendor approval is based upon a successful vendor quality assessment, qualification of new raw materials and packaging components intended for production use, and documented acceptance of the Vendor Quality Requirements Agreement referenced herein.

3. **Process Controls**

Process controls must be implemented during each phase of the Vendor's operation to ensure consistent quality of products or services.

4. Qualifications and Training

All employees of vendor will have adequate education, training, and experience to perform their assigned functions. All employees must be trained on the task that they are performing. Vendor will have written SOPs that address job requirements, job descriptions, training records, training procedures and periodic review of the training program.

5. Product Specification Conformance

Products shipped to Cephalon must conform to Cephalon's product specifications. The Vendor must at no time ship products that are defective.

Documentation supporting Animal-derived raw materials shall be provided, listing the country (ies) of origin and demonstrating absence of Bovine Spongiform Encephalopathy (BSE), in accordance with Title 9, Code of Federal Regulation (CFR), Part 94.18. For all such materials, Cephalon requires that the Vendor:

- Provide a general signed statement that the material(s) and related production processes are either not Animal-derived or if Animal-derived, not from a BSE implicated country.
- Notify Cephalon of any material or process related changes that involve Animal-derived materials (see section 7).
- Provide lot specific and other related documentation upon request, if available.

6. Deviations and Out-of-Specification (OOS) Investigation

Any deviation from the process during manufacture must be investigated and documented by the Vendor's Production Manager or designees and approved by the Vendor's Quality Manager or designees.

Vendor is responsible for investigating any testing performed that yields an out-of-specification result. Each investigation must be reviewed and approved by the vendor's designated Quality person, and must follow the procedures established in the relevant vendor's Standard Operating Procedure.

7. Change Control

Vendors shall notify Cephalon's Quality Assurance department in writing of significant specification and process changes 30 days prior to implementation. Cephalon requests timely notification regarding changes to:

- Manufacturing processes
- Raw materials
- Product formulation or composition
- Manufacturing sites/sources
- COA/COC
- Final product acceptance criteria
- Company name/acquisitions
- Packaging components
- Change of country of origin of Animal-derived materials
- Reworked/reprocessed lots

8. Quality System

The Vendor must have a documented and effective quality system that ensures the consistent manufacture of products. Quality systems should be designed with a focus on error prevention not error detection. Vendor quality systems may be assessed periodically by Cephalon to ensure compliance with applicable regulatory standards and to ensure acknowledgment and enforcement of Cephalon's Vendor Quality Agreement.

9. Quality Records

The Vendor is responsible for maintaining quality records for each Lot of product produced. Records shall be retained for a period equal to the products expiration date plus one year. Quality records shall be readily available for review during a Cephalon quality assessment. Electronic records should be validated in accordance with 21 CFR Part 11.

10. Certificates of Analysis/Certificates of Conformance/Certificates of Test

COA/COC containing information detailed below shall be provided with each lot of product procured by Cephalon as applicable. The COA/COC (recorded on Vendor letterhead or bearing the Vendor's name) shall include but is not limited to:

- Product description
- Product lot number
- Date of manufacture
- Expiration date, if applicable
- Quality signature

11. Corrective/Preventive Action – Rejected Lots

In the event that any lot of product, material or component is considered suspect and is subsequently rejected by Cephalon, it may be returned to the Vendor within 30 days of the receipt of the material. If the problem is determined to be Vendor related, Cephalon will file a formal complaint. The Vendor is required to investigate the nonconformance, identify the root cause of the problem and implement appropriate action to prevent recurrence. Written documentation supporting product discrepancies and assigned corrective/preventive action (s), if applicable, will be reviewed by Cephalon's Quality Assurance department. Written documentation will be retained in the appropriate vendor files.

12. Dispute Resolution

In the event that a dispute arises between a vendor and Cephalon in the nonconformity of a lot of product, the appropriate Quality Management from both companies will in good faith promptly attempt to reach an agreement. However, Cephalon's Quality Unit retains the right to determine the use of such a lot of the API product in Cephalon's formulation

13. Quality Audits/Quality Surveys

Cephalon reserves the right to perform Vendor quality system assessments at least once annually. Vendor audits are conducted to ensure compliance with governing regulations and Cephalon Vendor Quality Requirements. Vendor audits may include but are not limited to: facility qualification audits, problem-instigated audits and periodic routine audits. Manufacturing operations and quality records supporting the

manufacture of products procured by Cephalon should be accessible during on-site audits. A quality survey may be used to assess a Vendor's quality system initially.

14. Confidentiality

The Vendor will not, either during or after the term of this Quality Agreement, disclose to any third person or use the results of the services or any confidential or proprietary information of Cephalon or its affiliates for any purpose other than the performance of the services, without prior written authorization of Cephalon.

15. Vendor Disqualification

Disqualification of a Vendor can occur as a result of the Vendor's:

- Failure to provide materials/services that consistently meet Cephalon's specifications/quality requirements
- Failure to consistently provide timely deliveries of materials
- Refusal to permit Cephalon on-site quality assessments
- Refusal to respond to audit findings identified during a Cephalon quality assessment
- Refusal to adhere to Cephalon's Vendor Quality Agreement
- Refusal to investigate and respond to suspected vendor related product nonconformances

16. FDA Debarment

Vendor certifies that none of its employees are debarred under subsection 306 (a) or (b) of the Federal Food, Drug and Cosmetic Act and that it has not and will not use in any capacity the services of any person debarred under such law with respect to materials to be provided under this agreement.

17. Responsibility

Cephalon views Vendors of goods and services as an extension of our manufacturing operations. Cephalon will hold Vendors fully responsible for the quality of the products they produce as well as the quality of goods and services provided by their subcontractors.

The concepts disclosed reflect Cephalon's commitment to achieving the goal of exceeding customer expectations by consistently providing quality products. Cephalon recognizes the alliance established with our Vendors and encourages a team effort in achieving quality goals.

Contacts for Change Notifications/Inquiries regarding this Agreement

Cephalon

Primary contact for change notifications:

Name: Vanessa Marino
Title: Senior Manager, Compliance/Training
Address: Cephalon Inc, 4745 Wiley Post Way, Salt Lake City, UT 84116
Telephone: 801-401-7448
Fax: 801-595-1406
Email address: Vmarino@cephalon.com

Secondary contact for change notifications:

Name: Troy Wagner
Title: Associate Director, Quality Assurance
Address: Cephalon Inc, 4745 Wiley Post Way, Salt Lake City, UT 84116
Telephone: 801-401-7571
Fax: 801-595-1406
Email address: Twagner@cephalon.com

Vendor

Primary contact for change notifications:

Name: Danielle Morelli-Blevins
Title: Technical Service Coordinator
Address: Johnson Matthey Pharmaceutical Materials – USA, 2003 Nolte Drive, West Deptford, NJ 08066
Telephone: 856-384-7146
Fax: 856-384-7276
Email Address: moreldl@jmus.com

Secondary contact for change notifications:

Name: Ramesh Sonecha
Title: Director, QA & cGMP Compliance
Address: Johnson Matthey Pharmaceutical Material – USA, 2003 Nolte Drive, West Deptford, NJ 08066
Telephone: 856-384-7044
Fax: 856-384-7276
Email Address: sonecr@jmus.com

VENDOR AGREEMENT

Company Johnson Matthey Inc.
Address 2003 Nolte Drive
City/State/Zip Code West Deptford, NJ 08066

I, Ramesh Sonecha, have read and understood Cephalon's Vendor Quality
(Officer of the company)

Agreement. By signing this agreement, Johnson Matthey Inc acknowledges
(Company name)

understanding and adherence to this Quality Agreement.

Print Name Ramesh Sonecha
Title Director, QAR cGMP Compliance
Signature Ramesh Sonecha

date 7/23/04

Cephalon Quality Assurance:

Print Name: Etukudo Akpaifa

Title: Senior Director, Quality Assurance

Signature Etukudo Akpaifa

date 07/19/2004

Schedule C

Purchase Price

The parties anticipate Anesta's total requirements for the Product for Contract Year 2007 will be greater than 50 Kilograms. Johnson Matthey agrees to supply the API Milled Fentanyl Citrate required by Anesta at the prices listed below:

<u>ANNUAL VOLUME*</u>	<u>PRICE</u>
For the first 20,000 gm	USD \$55 per gm
For greater than the first 20,000 gm up to 30,000 grams	USD \$38 per gm
For greater than the first 30,000 grams	USD \$36 per gm

* Annual volume purchased from JMI is calculated on the date the Order is delivered by Johnson Matthey.

The price for the API shall be held firm for the first two years from the date of first shipment by Johnson Matthey.

The price for the API shall be subject to an automatic price escalation or de-escalation on the first day of each calendar year beginning with January 1, 2010, by a percentage equal to the percentage change in the producer price index ("PPI") not to exceed four (4%) percent per year. The PPI referenced herein shall be determined from Table VI of the Producer Prices and Price Index, commodity code 063 for drugs and pharmaceuticals, Bureau of Labor Statistics (or if discontinued such equivalent index as is mutually agreed to by the parties). The percentage change in the PPI shall be determined by dividing the final annual average PPI for the immediately preceding calendar year by the final annual average PPI for the next preceding calendar year. For example, the price increase effective January 1, in year X would be determined under the above formula by dividing the final annual average from calendar year X-1 by the final annual average PPI from calendar year X-2.

Schedule D

Contacts

Director, Medical Affairs at Anesta, facsimile number (610) 738-6313.

EXHIBIT 16

**OXYCODONE, BUPRENORPHINE AND NALOXONE
MATERIAL SUPPLY AGREEMENT**

This Agreement is made and entered into and effective as of May 8, 2009 (the "Effective Date"), by and between Johnson Matthey Inc., a Pennsylvania corporation, on behalf of itself and its Affiliate companies ("JMI") and Teva Pharmaceuticals USA, Inc. of North Wales, Pennsylvania, a Delaware corporation, on behalf of itself and its Affiliate companies including without limitation Barr Laboratories, Inc. (collectively "Teva"). This Agreement may be referenced in orders and other correspondence related hereto as Agreement No. 628.

WITNESSETH:

WHEREAS, Teva is in the business of developing, manufacturing and marketing pharmaceutical products and Teva wishes to develop and file, or has developed and filed, as the case may be, with the FDA (as defined below) abbreviated new drug applications for the Products (as defined below) and that, upon final approval by the FDA of a Product, Teva will manufacture and market such Product in the United States of America and all its lawful districts, possessions, territories and commonwealths, including, without limitation, the Commonwealth of Puerto Rico (the "Territory"); and

WHEREAS, JMI is in the business of, among other things, developing, manufacturing and marketing raw materials, including active raw material consisting of the active pharmaceutical ingredients listed in **Schedule A**, used to produce the respective Products (the "Active Drug Substances") and JMI wishes to supply Teva the Active Drug Substances for the Products; and

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained herein, the parties agree as follows:

ARTICLE 1. Definitions

- a) "Act" means the Federal Food, Drug and Cosmetic Act of 1938, including any amendments thereto and all regulations promulgated thereunder.
- b) "Affiliate" means with respect to a party hereto, any person or entity directly or indirectly controlling, controlled by or under common control with, such party, with "control" meaning the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies, whether through the ownership of voting securities, by contract or otherwise.
- c) "ANDA" means abbreviated new drug application for the Product filed by Teva with the FDA.
- d) "Calendar Quarter" means a three (3) consecutive month period ending on March 31, June 30, September 30 or December 31.

- e) "Calendar Year" means a twelve (12) consecutive month period commencing January 1 and ending December 31.
- f) "DEA" has the meaning given such term in Section 3(c).
- g) "DMF" means a drug master file or any supplement thereto for Active Drug Substance filed by JMI with the FDA pursuant to the Act.
- h) "FDA" means the United States Food and Drug Administration and any successor agency thereto.
- i) "First Commercial Sale" means the first sale of Product by Teva or its Affiliates or licensees to an independent third party after FDA approval of the ANDA for such Product.
- j) "Products" means the pharmaceutical drug products described for each Active Drug Substance listed in Schedule A hereto, which products may be expanded by mutual written signed agreement.
- k) "Specifications" has the meaning given such term in Section 3(e) hereof.

ARTICLE 2. Product Qualification.

- a) Except to the limited extent (i) JMI fails to satisfy the Standard Operating Procedures Requirements set forth on Schedule C attached hereto or JMI otherwise acts or fails to act in a manner that has a material adverse effect on Teva's ability to qualify JMI, or (ii) any other event which is not within the control of Teva has occurred or is then occurring that, despite Teva using commercially reasonable efforts to overcome such event, prevents Teva from qualifying JMI, Teva shall qualify JMI, and JMI will support Teva's qualification efforts, as its supplier of Active Drug Substance for the Products for sale in the Territory in accordance with Teva's minimum aggregate annual purchase requirements in the Territory (based upon actual orders by Teva for Active Drug Substance for Products for the Territory on a Calendar Year basis) provided in Schedule A and in conformity in all material respects with all applicable federal, state and local laws, regulations, orders and ordinances pertinent thereto.
- b) JMI shall supply Teva with such Active Drug Substance prior to the First Commercial Sale of the relevant Product in the quantities reasonably required by Teva for the development of such Product at the price agreed for such Active Drug Substance in Schedule A.
- c) Teva shall provide to JMI notice of the First Commercial Sale of each Product in the Territory as soon as practicable after such sale.
- d) JMI acknowledges and understands that although Teva shall commence the process of qualifying JMI as its supplier of Active Drug Substance in accordance herewith, Teva will not submit a supplemental ANDA that includes JMI's Active Drug Substance Buprenorphine for Teva's generic Suboxone ODT Product until Teva has received final approval

from the FDA for such Product.

e) Nothing contained in this Agreement shall in any way limit Teva's right to purchase all of its requirements of any Active Drug Substance from a third party source or from a Teva Affiliate (i) until JMI is so qualified, or in the event that JMI cannot be qualified pursuant to Section 2(a), as a supplier to Teva of any such Active Drug Substance or (ii) in the event of any interruption in supply by JMI to Teva of any Active Drug Substance. Further, in such event, Teva shall not be obligated to issue a Firm Order for a period of six (6) months after the date JMI is able to supply the Active Drug Substance and Teva's minimum aggregate annual purchase requirements in the Territory for such Active Drug Substance(s) during the Calendar Year in question will be prorated using the mechanism set forth in Article 5 to account for such inability or interruption, as the case may be, in supply.

ARTICLE 3. Purchase and Sale of Active Drug Substance; Forecasts

a) Subject to the exceptions contained in Sections 2(a), (d) and (e), this Section 3(a), Section 4(c) and Article 5, Teva agrees to purchase the Active Drug Substances for the respective Products for sale in the Territory from JMI in the minimum aggregate annual purchase requirements for the Territory provided in **Schedule A** for such Active Drug Substances during the Initial Term and each Extension Term (if applicable) (each as defined in Section 6(a)) and JMI shall satisfy such requirements by selling directly to Teva the Active Drug Substances in accordance herewith. In the event the parties are unable to agree upon a price adjustment for an Active Drug Substance in accordance with Section 4(c), Teva shall not be subject to minimum aggregate annual purchase requirements for the Territory for such Active Drug Substance.

b) **Forecasts and Orders.** Within sixty (60) days after the last signature date below, Teva shall provide JMI with a forecast of its anticipated requirements for each Active Drug Substance (each such forecast of anticipated requirements a "Requirement Forecast") for the period commencing on the first day of the first full Calendar Quarter immediately following delivery of such Requirement Forecast and continuing through the first eighteen (18) months thereafter broken out into Calendar Quarter delivery dates. Teva shall update its then-current Requirement Forecast on a rolling twelve (12) month basis not later than thirty (30) days prior to the commencement of each subsequent Calendar Quarter. Teva shall issue purchase orders no less than six (6) months prior to the anticipated delivery date for each applicable Active Drug Substance which purchase order shall not exceed, nor be less than, the third Calendar Quarter of the most recent Requirement Forecast by more than twenty percent (20%) ("Firm Order"); provided that JMI shall use commercially reasonable efforts to fill any Firm Order to the extent of quantities exceeding one hundred and twenty percent (120%) of the amount last forecasted for the applicable Calendar Quarter. Except to the extent set forth in the immediately preceding sentence, neither party will be bound by a Requirement Forecast, unless receipt of a Firm Order is confirmed by JMI in writing to Teva. For the avoidance of doubt, JMI shall confirm receipt of a Firm Order within one (1) week of Teva's dispatch of such Firm Order.

c) Active Drug Substance shall be shipped FOB origin (JMI's West Deptford plant), in such containers as may be agreed upon by the parties, packed in accordance with Drug Enforcement Administration ("DEA") and Department of Transportation requirements for interstate shipment. JMI shall ship the quantity of Active Drug Substance ordered by Teva in accordance with the written delivery instructions provided by Teva to JMI with respect to each Firm Order confirmed by JMI pursuant to Section 3(b). For the avoidance of doubt, Teva shall

have absolute and sole discretion to determine the carrier and mode of transportation.

d) Except as otherwise expressly provided in this Article 3, any terms and conditions contained in any purchase order, acknowledgment or invoice issued by either party in connection with this Agreement shall be void and of no effect unless expressly agreed upon in writing signed by both parties if contrary to the terms and conditions of this Agreement.

e) JMI shall produce the Active Drug Substance in conformance with the specifications set forth at **Schedule B** (the "Specifications"). If the FDA modifies the Specifications as a condition for obtaining ANDA approval and Teva so notifies JMI, JMI shall use commercially reasonable efforts to perform its obligations under this Agreement at no additional cost to Teva; provided that in the event that the Specifications are changed in a manner that results in an adjustment to the costs to JMI, the parties shall negotiate in good faith a price adjustment.

ARTICLE 4. Price and Payment for Active Drug Substance

a) Except for the price adjustments set forth in this Agreement, the price for Active Drug Substance shall be in accordance with the schedule provided in **Schedule A** and shall be fixed for a period of thirty-six (36) months from the First Commercial Sale of any Product containing such Active Drug Substance. Thereafter, such Active Drug Substance price shall be subject to a price adjustment, not more than once per Calendar Year, based on then existing sourcing and processing costs, provided, however, that JMI will provide Teva with sixty (60) days advance written notice of any price adjustment and the parties agree to negotiate in good faith the terms of any such price adjustment.

b) Teva shall pay all invoices from JMI or submitted on behalf of JMI for the Active Drug Substance in full within forty-five (45) days after the date of the invoice by wire or in the form of a check or money order (or other method of payment approved by JMI in writing). JMI shall be entitled to charge a late fee of 1.5% per month on any payment which is not made when due. JMI shall have the right, in addition to any other available remedies, to cease work and stop deliveries until payment of all outstanding overdue amounts.

c) On a Product-by-Product basis, Teva's minimum aggregate annual purchase requirements for the Territory set out on **Schedule A** shall be non-terminable for the first thirty-six (36) months after the First Commercial Sale of such Product, except as otherwise provided in Sections 2(a),(d) and (e), Article 5 and Sections 6(b) through (f). Teva shall have the right to solicit competitive offers at any time during the term of this Agreement for supply of an Active Drug Substance from third party manufacturers, having service and quality assurance capabilities reasonably comparable to those of JMI, including without limitation a FDA approved facility for such Active Drug Substance, to supply like quantities of Active Drug Substance of similar quality under like terms and conditions for a lower price. At any time after such thirty-six (36) month period, in the event bona fide evidence of such offer (including, without limitation, a quotation or similar documentation of such third-party supply offer which may be redacted to remove any confidential information) is provided by notice to JMI, the parties shall endeavor to

negotiate in good faith a mutually agreeable price for the Active Drug Substance. In the event the parties cannot agree on a price within thirty (30) days after JMI's receipt of such notice, then Teva shall have the right to purchase such Active Drug Substance from such third-party at a price no less favorable to Teva than the best price offered by JMI and/or terminate this Agreement as to the applicable Active Drug Substance. In the event that Teva identifies that equivalent Active Drug Substance is being sold in the marketplace at materially lower prices than the Active Drug Substance being provided by JMI, which causes Teva's market share to decline for such Product, Teva and JMI shall discuss in good faith such circumstances and any change to pricing terms that might be mutually agreeable. Notwithstanding the foregoing, in the event that at any time during a Term, Teva acquires, merges with or into, or otherwise combines with any other entity (such that the entity in question becomes an Affiliate of Teva) that owns, manufactures, produces, distributes and/or sells one or more of the Active Drug Substances, Teva shall be permitted to present, after the foregoing thirty-six (36) month period, the pricing of such Active Drug Substance(s) to JMI as a competitive alternative to JMI's price for its corresponding Active Drug Substance as if such Active Drug Substance(s) were, for purposes of this Section 4(c), a third party's Active Drug Substance(s).

d) Notwithstanding anything contained in this Agreement to the contrary, Teva shall be permitted to qualify during the term of this Agreement alternate sources of supply for any or all of the Active Drug Substances.

ARTICLE 5. DEA Supply Conditions

Both Active Drug Substances, Oxycodone HCl and Buprenorphine, and their related Products, are scheduled under the Federal Controlled Substances Act. JMI and Teva are required to obtain a quota from the DEA before producing such Products or the related Active Drug Substances. Such quotas are limited, therefore, the parties agree to use reasonable commercial efforts to obtain the necessary DEA quotas. The parties shall cooperate and supply all supporting documentation necessary to obtain applicable DEA permits, the DEA quotas, and to fulfill all other DEA related requirements necessary for performance under this Agreement. Teva's purchase obligations hereunder, and JMI's supply obligations hereunder, are each expressly subject to both parties obtaining US import permits and DEA quotas from the DEA. In the event of any DEA permitting or quota restrictions or interruptions outside of the reasonable control of Teva and/or JMI, as the case may be, Teva's purchase obligations hereunder, and JMI's delivery obligations hereunder, of such Active Drug Substance(s) shall be suspended during the period of such restriction or interruption. In the event of any such restriction or interruption in Teva's purchase obligations, such restriction or interruption and resulting failure to purchase JMI Active Drug Substance shall not be deemed a breach hereunder by Teva, provided, however, JMI shall have the right to sell to a third party any and all Active Drug Substance that has been manufactured for Teva but which Teva is unable to purchase due to such restriction or interruption, as applicable. In the event of any such restriction or interruption of JMI's supply obligations, such restriction or interruption and resulting failure to supply Active Drug Substance to Teva shall not be deemed a breach hereunder by JMI; provided, however, Teva shall be permitted to purchase all of its requirements of the applicable Active Drug Substance(s) (or that amount of Active Drug Substance JMI is unable to supply in the event of a restriction) from a third party supplier or multiple third party suppliers (or from a Teva Affiliate) for so long as such

restriction or interruption, as the case may be, continues. In addition, such purchases shall not be deemed a breach by Teva hereunder and Teva's minimum aggregate annual purchase requirements for the Territory for such Active Drug Substance(s) during the Calendar Year in question will be prorated, as determined by multiplying (a) the quotient obtained by (i) dividing the number of days during the Calendar Year in question that JMI is able to supply (with the cut off date being the last day of the Calendar Quarter during which JMI delivers its final supply of the Active Drug Substance in question, which Calendar Quarter will be prorated accordingly if JMI supplies less than Teva's order of the applicable Active Drug Substance for such Calendar Quarter) to Teva the applicable Active Drug Substance in connection with such restriction or interruption in supply by (ii) 365 and (b) what would have been Teva's minimum aggregate annual purchase requirements for the Territory for the applicable Active Drug Substance for the given Calendar Year, but for such restriction or interruption. In the event JMI is able to resume supplying such Active Drug Substance(s) to Teva, JMI shall provide Teva with written notice of the date JMI will be able to resume such supply. Promptly after JMI's notice to Teva, Teva shall issue a Requirement Forecast to JMI; provided however, that notwithstanding anything contained in Section 3(b) to the contrary, Teva shall not be obligated to, but shall have the right at its option to, issue a Firm Order for a period of six (6) months after the date JMI is able to supply the applicable Active Drug Substance(s). Notwithstanding the foregoing, but subject to the next sentence, Teva shall remain bound by its prorated minimum aggregate annual purchase requirements for the Territory for such Active Drug Substance(s) during the Calendar Year in question. In the event that due to Teva's purchase obligations to a third party supplier as a result of a restriction or interruption in supply Teva is unable to satisfy its minimum aggregate annual purchase requirements for the Territory to JMI in a given Calendar Year, such failure shall not be deemed a breach by Teva hereunder, but instead any such shortfall shall be added to Teva's minimum aggregate annual purchase requirement for the Territory for the immediately following Calendar Year, except with respect to the Active Drug Substance Naloxone, for which any such shortfall shall not be added to Teva's minimum aggregate annual purchase requirement for the Territory for the immediately following Calendar Year.

ARTICLE 6. Term

a) With respect to each Active Drug Substance, this Agreement shall become effective on the Effective Date and shall continue in force on a Product-by-Product basis through the period ending five (5) years from the First Commercial Sale for such Product unless earlier terminated in accordance with the terms herein ("Initial Term"). On a Product-by-Product basis, this Agreement shall continue in force thereafter solely upon the mutual written agreement of the parties for such period of time agreed to by the parties, provided that if either party desires to continue the term of this Agreement, it shall provide written notice thereof to the other party not less than twelve (12) months in advance of the expiration of the Initial Term or any subsequent extension term (each, an "Extension Term" and together with the Initial Term, each, a "Term").

b) Notwithstanding the foregoing, the term of this Agreement shall terminate upon the unanimous written consent of the parties.

c) In the event of a material breach of this Agreement by a party, the other party shall have the right to deliver a written notice of breach to the defaulting party. If such breach is

not cured within ninety (90) days after delivery of such notice, the non-defaulting party, at its sole option, may terminate the term of this Agreement at any time by delivery of written notice of termination to the defaulting party.

d) In the event that a party shall (i) voluntarily commence any proceeding or file an petition seeking relief under any Federal, state or local bankruptcy, insolvency, liquidation, receivership or similar law (a "Bankruptcy Law"), (ii) consent to the institution of, or fail to contravene in a timely and appropriate manner, any such proceeding or the filing of any such petition, (iii) apply for or consent to the appointment of a receiver, trustee, custodian, sequestrator or similar official for such party or for a substantial part of its property or assets, (iv) file an answer admitting the material allegations of a petition filed against it in any such proceeding or (v) make a general assignment for the benefit of creditors, the other party, at its sole option, may terminate the term of this Agreement at any time by delivery of written notice of termination to the party subject to such event.

e) In the event that a party shall be subject to the commencement of any involuntary proceeding or the filing of any involuntary petition in a court of competent jurisdiction seeking (i) relief in respect of such party or of a substantial part of its property or assets under any Bankruptcy Law, (ii) the appointment of a receiver, trustee, custodian, sequestrator, or similar official for such party or for a substantial part of its property or assets or (iii) the winding-up or liquidation of such party, and such proceeding or petition shall continue undismissed for one hundred and twenty (120) days or an order or decree approving or ordering any of the foregoing shall continue unstayed and in effect for sixty (60) days, the other party, at its sole option, may terminate the term of this Agreement at any time by delivery of written notice of termination to the party subject to such event.

f) Teva shall have the right to terminate this Agreement with respect to an Active Drug Substance pursuant to Section 9(d) below.

g) Termination for default or breach hereunder or for any other reason shall have no effect on performance obligations or amounts to be paid which have accrued up to the effective date of such termination. Articles 8, 9, 10, 11 and 15 and this Section 6(g) shall survive the expiration or other termination of this Agreement indefinitely or, if shorter, in accordance with its terms.

ARTICLE 7. Assignment or Transfer of Interest

Neither party shall directly or indirectly sell, assign or transfer any part or all of its interest in this Agreement without the prior written consent of the other party, which consent shall not be unreasonably withheld; provided, however, that a change in control of a party shall not be deemed to constitute a transfer of such party's interest. JMI may transfer its interest to an Affiliate of JMI which is a qualified manufacturer, subject to prior written notice to Teva and Teva's approval, which will not be unreasonably withheld. Notwithstanding the foregoing, Teva may transfer its interest to an Affiliate without the prior approval of JMI.

ARTICLE 8. Confidentiality

(a) Each party agrees to maintain the confidentiality and secrecy of this Agreement and its terms and conditions, and any proprietary information provided to it by or on behalf of the other party under this Agreement, including any proprietary, financial, trade secret, technical, know-how, business, marketing, data or other confidential information such as information relating to the Product, pricing, facilities, methods, formulae, processes, strategies, corporate initiatives, production efforts or requirements, operations, income, projections, contractual and business arrangements, personnel data, whether in verbal, written or other tangible form (collectively, "**Confidential Information**") using no less than a reasonable degree of care. Neither party shall use the other party's Confidential Information for any purpose other than to fulfill its duties and obligations under this Agreement. Each party will also keep in confidence and not disclose to any third parties the terms and conditions of this Agreement. Each party may, however, disclose the other party's Confidential Information to its Affiliates, officers, directors, employees and agents who have a need to know or who have access to that Confidential Information in order to fulfill its duties and obligations under this Agreement, subject to the terms and conditions of this Article 8. Each party shall be responsible for any breach of this Article 8 by its Affiliates, officers, directors, employees and agents to whom the other party's Confidential Information is disclosed. The obligations of confidentiality do not apply to information that:

(i) is or becomes known to the public through no fault or omission on the part of the receiving party;

(ii) as evidenced by the receiving party's written records, was independently developed by or for the receiving party without any reference to, or reliance upon, the disclosing party's Confidential Information;

(iii) is made available to the receiving party from another source rightfully in possession of the disclosing party's Confidential Information and not under an obligation of confidentiality with respect thereto;

(iv) is disclosed with the prior written approval of the disclosing party; or

(v) is required to be disclosed by the receiving party in order to comply with applicable laws, so long as the receiving party gives notice of that disclosure to the disclosing party so that the disclosing party may seek a protective order. Where such disclosure is required, the receiving party shall, to the fullest extent permitted by the applicable law, redact the Confidential Information prior to said disclosure.

(b) The confidentiality and non-use obligations hereunder shall survive expiration or termination of this Agreement and remain valid for a period of five (5) years thereafter.

ARTICLE 9 Warranties, Covenants and Limitations

EXECUTION COPY

a) JMI warrants that the Active Drug Substance supplied to Teva hereunder will conform to the Specifications, as the Specifications may from time-to-time be amended by mutual written agreement or as required by the FDA, other governmental body in the United States or the then current edition of the U.S. Pharmacopoeia.

b) JMI warrants to Teva that, as of the date of each shipment hereunder of any articles subject to the provision of the Act, such article is not, when shipped from JMI's West Deptford, New Jersey plant, adulterated by or misbranded by JMI within the meaning of the Act or of any applicable state law in which the definitions of adulteration and misbranding are substantially the same as those contained in the Act, or an article that may not, under the provision of Sections 404, 505, or 512 of the Act, be introduced into interstate commerce.

c) JMI covenants to Teva that it shall not make any material amendments, changes or supplement to any of the following, without Teva's approval, which approval shall not be unreasonably withheld or delayed, except as may be required to comply with applicable law: (i) test methods used to manufacture the Active Drug Substance and (ii) the process for manufacturing the Active Drug Substance. As used herein, material amendments, changes or supplements are those (i) requiring FDA approval as determined by the FDA guidelines and regulations or otherwise require notification to a regulatory authority, including, without limitation, the FDA, or (ii) in the reasonable judgment of JMI, could cause the applicable Active Drug Substance(s) to lose the benefit of any freedom to operate opinion obtained by JMI with respect to such Active Drug Substance. To the extent such changes are required by applicable law, JMI shall provide Teva with prompt written notice of such changes in applicable law that would require any of the foregoing amendments, changes or supplements.

d) JMI warrants that, to the best of its knowledge, the Active Drug Substance supplied by JMI, and the process used by JMI to manufacture the Active Drug Substance, does not infringe the patent rights or misappropriate the trade secrets of any third party. The foregoing warranty shall not apply to (i) any claim of infringement resulting from JMI's compliance with Teva's instructions to modify the Specifications or the manufacturing process of the Active Drug Substance; (ii) any claim of infringement resulting from the use of or change in Active Drug Substance made subsequent to JMI's delivery or performance; or (iii) any claimed infringement that is settled without the consent of JMI. In the event Teva identifies a potential infringement issue with respect to the Active Drug Substance, Teva and JMI shall mutually work together in good faith to resolve or overcome any potential issue. The parties shall ensure that all communication shall be conducted to avoid loss of attorney client privilege. In the event the parties are unable to overcome or resolve the potential infringement issue, Teva may, at any time during the term of this Agreement, terminate qualification or supply of such Active Drug Substance from JMI.

e) Each of JMI and Teva warrants that it will fully comply with the testing requirements for the Active Drug Substance as detailed in the applicable Specifications. Teva further warrants that its testing procedures for Active Drug Substance will meet prevailing industry standards applicable to pharmaceutical manufacturers.

f) Except as expressly stated in paragraphs a), b), c), d) and e) of this Article 9, JMI

MAKES NO OTHER REPRESENTATION OR WARRANTY OF ANY KIND, EXPRESSED OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY AS TO MERCHANTABILITY, FITNESS FOR PARTICULAR PURPOSE, OR ANY OTHER MATTER WITH RESPECT TO THE ACTIVE DRUG SUBSTANCE WHETHER USED ALONE OR IN COMBINATION WITH OTHER SUBSTANCES.

g) JMI will provide Teva together with each shipment or invoice the results of all assays required to be run under the Specifications. If such shipment of Active Drug Substance, in any of the following cases, as a result of any deficiencies that are or should have been reasonably discoverable by Teva under its receipt testing procedures in light of the Specifications and provided that such testing procedures meet prevailing industry standards applicable to pharmaceutical manufacturers (i) does not comply with the Specifications, (ii) has been damaged prior to being provided to the carrier for shipment, or (iii) if there is a shortage in the quantity prior to being provided to the carrier for shipment (each of the foregoing a "Discoverable Defect"), Teva shall promptly notify JMI in writing, not later than sixty (60) days after receipt. Any shipment of Active Drug Substance having a Discoverable Defect will be deemed accepted by Teva in the absence of providing such notice. Teva or its designee shall promptly return such Active Drug Substance to JMI at JMI's expense, or Teva shall undertake such other response as is mutually agreed upon in writing by the parties. In addition, if Teva or its designee, despite the application of testing procedures meeting prevailing industry standards applicable to pharmaceutical manufacturers, subsequently discovers a deficiency or shortage set forth in this paragraph g)(i)-(iii) above that is not a Discoverable Defect, it shall have the right to return such Active Drug Substance provided that it notifies JMI in writing within thirty (30) days of the discovery of such latent defect. JMI shall have the right, but not the obligation, to re-test the rejected Active Drug Substance. In the event that JMI disputes Teva's determination that Active Drug Substance does not meet the Specifications or has been damaged or is subject to a shortage in quantity, the parties shall meet to resolve, in good faith, such dispute. In the event the parties are not able to reach a mutually agreeable resolution, the matter shall be referred to an independent third party laboratory mutually acceptable to the parties for final determination. In such instance, the replacement Active Drug Substance and the cost of the laboratory will be at JMI's cost if the laboratory finds that the lot in question is non-conforming to the Specifications or otherwise defective and the costs of the independent laboratory will be paid by Teva if the lot in question is found by the laboratory to be conforming and compliant. For the avoidance of doubt, JMI shall dispose of all non-conforming Active Drug Substance at its sole cost and expense.

h) Upon return of any rejected Active Drug Substance, and JMI's agreement, or a final determination in accordance with this Agreement, that such Active Drug Substance fails to comply with JMI's limited warranty or has been damaged, JMI will replace the Active Drug Substance at JMI's cost. EXCEPT FOR REMEDIES FOR THIRD-PARTY CLAIMS AS PROVIDED IN SECTION 9(i), AND ARTICLES 10 AND 11, TEVA'S EXCLUSIVE REMEDY FOR BREACH OF WARRANTIES IN SECTIONS a) AND b) AND e) OF THIS ARTICLE 9 SHALL BE DIRECT DAMAGES AND JMI'S LIABILITY TO TEVA FOR ANY AND ALL LOSSES OR DAMAGE FROM ANY CAUSE WHATSOEVER, INCLUDING, WITHOUT LIMITATION, ALLEGED NEGLIGENCE, SHALL IN NO EVENT EXCEED THIS OBLIGATION TO REPAIR OR REPLACE THE ACTIVE DRUG SUBSTANCE AND

RESUBMIT IT TO TEVA. In the event that JMI is unable to repair or replace such non-conforming Active Drug Substance, JMI shall refund the price paid for such non-conforming Active Drug Substance and reimburse Teva for related shipping and shipping insurance costs incurred by Teva in connection therewith.

i) EXCEPT AS OTHERWISE PROVIDED IN ARTICLES 10 AND 11, TEVA'S EXCLUSIVE REMEDY FOR BREACH OF COVENANTS AND WARRANTY OF SECTIONS c) and d) OF THIS ARTICLE 9 SHALL BE DIRECT DAMAGES AND JMI'S LIABILITY TO TEVA FOR ANY AND ALL LOSSES OR DAMAGE, SHALL IN NO EVENT EXCEED THIS OBLIGATION TO, AT ITS EXPENSE AND OPTION, EITHER PROCURE THE NECESSARY LICENSE TO AVOID INFRINGEMENT, MODIFY THE INFRINGED MATERIAL OR PROCESS TO BE NON-INFRINGEMENT, OR REQUIRE THE RETURN OF SUCH PRODUCT OR PROCESS TO JMI FOR A REFUND.

j) Each party shall notify the other as soon as reasonably possible of any information of which it is aware concerning any Active Drug Substance supplied to Teva which may affect the safety or efficacy claims or the continued marketing of any Product containing Active Drug Substance. Any such notification will include all related information in detail. Upon receipt of any such information, JMI shall consult with Teva in an effort to arrive at a mutually acceptable procedure for taking appropriate action; provided, however, that nothing contained herein shall be construed as restricting the right of either party to make a timely report of such matter to any agency or take other action that it deems to be appropriate or required by applicable law or regulation. Each party will notify the other as soon as reasonably possible of any health hazards with respect to any Active Drug Substance or any Product which may impact employees involved in the manufacture of any Active Drug Substance or formulation of any Active Drug Substance into any Product.

ARTICLE 10. Limitation on Liability

NEITHER PARTY WILL BE LIABLE TO THE OTHER PARTY FOR LOST PROFITS, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES SUSTAINED DIRECTLY BY THAT PARTY, WHETHER SUCH PARTY'S CLAIM IS IN CONTRACT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, OTHER THAN IN CONNECTION WITH SUCH PARTY'S OBLIGATION TO INDEMNIFY THE OTHER PARTY WITH RESPECT TO THIRD PARTY CLAIMS PURSUANT TO ARTICLE 11.

ARTICLE 11. Indemnification; Insurance

a) Teva Indemnification. Teva agrees to indemnify and hold harmless JMI and its Affiliates and their respective officers, directors, agents and representatives thereof from any and all losses, liability, damages, and/or expenses (including reasonable attorneys fees and expenses) which may be sustained or claimed by third parties against JMI arising out of the handling and possession of the Active Drug Substance following Teva's or its designee's receipt thereof, or use of the Active Drug Substance, following Teva's or its designee's acceptance thereof, except to the extent of JMI's liability under Section 11(b). The foregoing indemnity is subject to JMI promptly notifying Teva in writing of all claims and threatened claims against JMI for which

JMI may be entitled to indemnity hereunder. Teva shall have the right to defend and/or settle any such claim and JMI shall give Teva such defense, provided that JMI shall have the right to choose its counsel and consent to any settlement (which consent not to be unreasonably withheld). JMI shall have the right to participate in such defense at its cost.

b) JMI Indemnification.

1. JMI agrees to indemnify and save harmless Teva and its Affiliates and their respective officers, directors, agents and representatives thereof from any and all losses, liability, damages and/or expenses (including reasonable attorneys fees and expenses) which may be sustained or claimed by third-parties against Teva based on i) JMI's material breach of its representations or warranties or JMI's negligence, gross negligence or willful misconduct in the manufacture, handling or storage of the Active Drug Substance, which causes the Active Drug Substance to fail to meet Specifications, become adulterated prior to delivery to Teva or its designee, or otherwise fail to comply with current Good Manufacturing Practices in accordance with FDA regulations, guidelines and other administrative interpretations and rulings in connection therewith, or ii) JMI's failure to perform its covenants contained in Section 9(c), to the extent such failure results in the Active Drug Substance supplied by JMI, or the process used by JMI to manufacture the Active Drug Substance, to infringe the patent or intellectual property rights of any third party, except in all cases to the extent of Teva's liability under Section 11(a). The foregoing indemnification obligation of JMI shall be subject to the limitations provided in paragraph 2 of this Section 11(b) below.

2. (i) Notwithstanding any other provision of this Agreement, JMI's maximum liability for damages under this Agreement shall not exceed, in the aggregate -
(I) in the case of oxycodone and buprenorphine, \$30 million, and
(II) in the case of naloxone, \$15 million; provided however

(ii) unless in the case and to the extent such damages are directly attributable to and proximately caused by JMI's gross negligence, in which case JMI's maximum aggregate liability limits stated in Section 11.b.2(i) above shall be increased for only such damages so caused to and not exceed -

(I) in the case of oxycodone and buprenorphine, an additional \$45 million for a total aggregate liability limit of \$75 million, and

(II) in the case of naloxone, an additional \$15 million for a total aggregate liability limit of \$30 million; provided further

(iii) unless in the case and to the extent such damages are directly attributable to and proximately caused by JMI's willful misconduct, in which case JMI's liability for only such damages so caused shall not be limited, and provided further

(iv) in the event punitive damages are imposed by a court of competent jurisdiction to the extent directly attributable to, proximately caused by and resulting from JMI's gross negligence (as defined below) and the amount of damages with such

punitive award would exceed the limitations set forth in Section 11(b)(2)(ii) above for gross negligence (as defined below), the Section 11(b)(2)(ii) sub-paragraphs (I) and (II) limits will be increased for only such damages so caused by an additional amount for the punitive damages only in excess of the applicable limit as follows:

(I) in the case of oxycodone and buprenorphine, an additional \$40 million for a total aggregate liability limit amount of \$115 million, and

(II) in the case of naloxone, an additional \$20 million for a total aggregate liability limit amount of \$50 million.

3. Notwithstanding the determination of a finder of fact to the contrary, the parties hereby agree that, for purposes of this Section 11(b), "gross negligence" means conduct which is greater in degree than ordinary negligence, but less in degree than willful and wanton misconduct (as defined herein) and refers to a person's conduct where an act or a failure to act creates an unreasonable risk of harm to another because of the person's failure to exercise slight care or diligence. "Willful and wanton misconduct" means conduct which is done with the deliberate intent to cause harm or with reckless disregard for the safety of another's person or property.

4. The foregoing indemnity of JMI under this Section 11(b) is further subject to Teva promptly notifying JMI in writing of all claims and threatened claims against Teva for which Teva may be entitled to indemnity hereunder. JMI shall have the right to defend and/or settle any such claim and Teva shall give JMI such defense assistance provided that Teva shall have the right to choose its counsel and consent to any settlement (which consent not to be unreasonably withheld). Teva shall have the right to participate in such defense at its cost.

c) Insurance. Each Party shall carry comprehensive general liability insurance, including product liability insurance against claims for bodily injury or property damage in an amount of not less than \$2,000,000 per occurrence and \$30,000,000 in the aggregate. Such policy shall be endorsed to include an agreement by the insurer to provide thirty (30) days' prior written notice to the other party of cancellation or material change in the coverage before such cancellation or change takes effect.

ARTICLE 12. Gross Inequities

It is the intent of the parties hereto that they shall mutually benefit from the terms, conditions and provisions of this Agreement, and in the event that either party shall suffer a gross inequity resulting from such terms, conditions or provisions, or from a substantial change in circumstances or conditions, the parties shall negotiate in good faith to resolve or remove such inequity. It is mutually understood and agreed, however, that nothing herein shall be construed to relieve either party of any of its obligations under this Agreement, unless and until such resolution or removal has been agreed to in writing by both parties.

ARTICLE 13. Force Majeure

Failure of JMI or Teva to perform its obligations under this Agreement, other than the payment of amounts invoiced, shall not subject JMI or Teva to any liability if such failure is caused or occasioned by an event of force majeure, including but not limited to, an act of God, or the public enemy, fire, explosion, flood, drought, war, riot, sabotage, embargo, strikes, or other labor trouble, failure in whole or in part, of suppliers to deliver on schedule materials, equipment or machinery, to interruption of or delay in transportation, compliance with any order, regulation or request of any government of competent jurisdiction or any officer, department, agency or committee thereof, including requisition or allocation or establishment of priority, or by compliance with a request authorized by such governmental authority of any manufacturer for material to be used by it, or by any other event or circumstance of like or different character to the foregoing beyond the reasonable control of the non-performing party. If either party suffers an event of force majeure, it shall immediately notify the other party and shall use all commercially reasonable efforts to minimize the loss or inconvenience suffered by both parties. Both parties shall cooperate in good faith in order to minimize such loss and inconvenience and to reach an agreement as to how to proceed.

ARTICLE 14. Authorization

Each party represents and warrants to the other that all corporate action on the part of such party necessary for the authorization, execution and delivery of this Agreement and the performance of all obligations hereunder has been taken and persons executing this Agreement have due power and authority to do so.

ARTICLE 15. Other Provisions

a) In connection with the storage, distribution, development, sale or marketing of the Products or the Active Drug Substances pursuant to this Agreement, JMI and Teva agree to use commercially reasonable efforts to perform their respective obligations under this Agreement and such activities in compliance with all applicable federal, state, and local laws, regulations and ordinances, including, but not limited to, the Act, as amended from time to time, and all rules and regulations promulgated thereunder.

b) Nothing contained in this Agreement and no action taken by any party to this Agreement shall be deemed to constitute such party or any such party's employees, agents, or representatives to be an employee, agent, or representative of the other party or shall be deemed to create any partnership, joint venture, association, or syndicate among the parties, or shall be deemed to confer on any party any express or implied right, power, or authority to enter into any agreement or commitment, expressed or implied, or to incur any obligation or liability, on behalf of the other party.

c) The parties shall execute any other instruments or perform any other acts that are or may be reasonably necessary to effectuate and carry on the obligations created by this Agreement.

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d) This Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the parties.

e) As to its subject matter, this Agreement constitutes the entire agreement of the parties and supersedes all prior agreements between the parties, including, without limitation that certain Binding Term Sheet, dated May 8, 2009, between the parties. This Agreement may not be modified or amended except by an instrument in writing executed by the parties.

f) Failure of either party to exercise any right under this Agreement shall not be deemed to be a waiver thereof.

g) This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, and all of which shall constitute one and the same instrument.

h) This Agreement shall be governed by and construed under the laws of the State of New Jersey, excluding its conflict of law principles.

i) Any notice or other communication that a party desires to give to another party shall be in writing, and shall be deemed effectively given upon personal delivery, delivery by overnight courier, or upon transmission by telegram, telex, or, with receipt confirmed, telecopy, addressed to the other party at the address show below or at such other address as a party may designate by written notice in accordance with this subparagraph (i).

If to JMI: Johnson Matthey Inc.
2003 Nolte Drive
West Deptford, NJ 08066-1742
Attention: Vice President & General Manager
Fax: (856) 384-7276

with a copy to: Johnson Matthey Inc.
435 Devon Park Drive, Suite 600
Wayne, PA 19087
Attention: Vice President & General Counsel
Fax: (610) 971-3022

If to TEVA: Teva Pharmaceuticals USA, Inc.
1090 Horsham Road
North Wales, PA 19454
Attention: Sr. Director, Supply Chain
Fax: (215)591-8815

with a copy to: Teva North America Legal Affairs
425 Privet Road
Horsham, PA 19044

Attention: General Counsel
Fax: (215) 293-6499

j) In the event that any term or provision of this Agreement is invalid or is declared null and void, then both parties shall agree on a substitute for such invalid and void terms with the intent of achieving the economic intent of the parties. The invalidity or voidness of any term or condition shall not affect the validity of any other term or condition contained herein nor the Agreement as a whole unless the provisions are the essence of, or inseparable from the remainder of the Agreement.

k) JMI's quality assurance records, which shall include, but not be limited to, quality systems, policies and procedures, test results, reports, and any other documentation relating to JMI's manufacture and handling of the of Active Drug Substance, shall be open to inspection and subject to a quality assurance audit at mutually agreeable times, during normal working hours, by an independent third party designated by Teva and reasonably acceptable to JMI. JMI shall preserve such records for a period of five (5) years after the end of the Initial Term and any Extension Term or for such longer period as may be required by law. For the purpose of such audits, inspections, examinations and evaluations, the independent auditor shall have access to such records beginning on the Effective Date and continuing until five (5) years after the satisfaction of JMI's obligations under this Agreement. In addition, JMI shall provide adequate and appropriate workspace for Teva or its authorized representatives to conduct such audit. The independent auditor shall give JMI reasonable advanced notice of an intent to audit.

l) The headings and titles of Articles, Sections, Schedules and the like in this Agreement are inserted for convenience of reference only, form no part of this Agreement and shall not be considered for purposes of interpreting or construing the text hereof.

m) Any and all press releases, publicity or other form of public written disclosures relating to this Agreement shall be mutually agreed to by the parties (the consent of a party not to be unreasonable withheld or unduly delayed and in any event a party shall respond within two (2) business days of receiving a request, failing which it shall be deemed to have consented) including, if applicable, the time of release of such public written disclosures as well as the content of such public written disclosures. For releases or announcements required by applicable law, the party making the release or announcement shall, before making any such release or announcement, afford the other party a reasonable opportunity to review and comment. Any copy of this Agreement to be filed with the Securities and Exchange Commission or any other governmental entity shall be redacted to the fullest extent permitted by applicable law and to the reasonable satisfaction of the parties; provided, however, in the event that the Securities and Exchange Commission or other governmental entity, as applicable, objects to the redaction of any portion of this Agreement after the initial submission, the filing party shall inform the other party of the objections and shall in good faith respond to the objections in an effort to limit the disclosure required by the Securities and Exchange Commission or governmental entity, as applicable.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first above written.

Johnson Matthey Inc.

By: JBF

Print Name: John B. Fowler IV

Title: President

Date: 9/11/09

Teva Pharmaceuticals USA, Inc.

By: T.C. Crew

Print Name: Timothy C. Crew

Title: Sr. VP, Commercial Operations Officer

Date: 9-3-09

By: [Signature]

Print Name: Darren C. Atkins

Title: Vice President, Business Development and Alliance Management

Date: 9-3-09

LEGAL AFFAIRS
[Signature]

Schedule A

ACTIVE DRUG SUBSTANCE	PRODUCT	MINIMUM AGGREGATE ANNUAL PURCHASE REQUIREMENT FOR THE TERRITORY	PRICE
Oxycodone HCl	generic oxycodone ER tablet product, AB Rated to Oxycontin ER tablet	50% of Teva's [as of 1/1/10] aggregate annual purchase requirements*	\$2.50/gram
Buprenorphine	generic buprenorphine/ naloxone ODT tablet product, AB Rated to Suboxone 8mg/2mg and 2mg/0.5mg ODT tablets	50% of Teva's aggregate annual purchase requirements*	\$40.00/gram
Buprenorphine	generic buprenorphine ODT tablet product, AB Rated Subutex 2mg and 8mg ODT tablets	50% of Teva's aggregate annual purchase requirements*	\$40.00/gram
Naloxone	generic buprenorphine/ naloxone ODT tablet product, AB Rated to Suboxone 8mg/2mg and 2mg/0.5mg ODT tablets	100% of Teva's aggregate annual purchase requirements*	First 60Kg: \$10.00/gram >60 Kg.: \$8.50/gram

* Teva's minimum aggregate annual purchase requirements for the Territory will be based upon actual orders by Teva for Active Drug Substance for the Products for the Territory on a Calendar Year basis. Teva's aggregate annual purchase requirements for the Territory will be determined by Teva in its sole and absolute discretion.

Schedule B

Active Drug Substance Specifications

3.2.S.4.1 SPECIFICATIONS [OXYCODONE HYDROCHLORIDE, USP]

Material: Oxycodone Hydrochloride, USP	
Material Number: R18368	Method Number: 18368RM

TESTS & SPECIFICATIONS

<Test Source: TEVA USA, USP>

Test	Acceptance Criteria	Analytical Procedure	Alternate Analytical Procedure
Identification A	The precipitate melts between 218°C and 223°C, and the range between beginning and end of melting does not exceed 2°C.	<741> Melting Range or Temperature USP Method	Alternate Identification
Identification B	The infrared absorption spectrum of a potassium bromide pellet of a dried portion of the precipitate obtained for <i>Identification A</i> exhibits maxima only at the same wavelengths as that of a dried Oxycodone BS preparation run concomitantly.	<197K> USP Method	Alternate Identification
Alternative Identification	Near infrared identification can be substituted as an alternate identification test for <i>Identification tests A and B</i> . A conforming identification result must be obtained for each measurement.	TEVA USA Method	N/A
Assay	Oxycodone Hydrochloride contains not less than 97.0% and not more than 103.0% of $C_{18}H_{21}NO_4 \cdot HCl$, calculated on the anhydrous, solvent-free basis.	HPLC TEVA USA, USP Method	N/A

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3.2.S.4.1 SPECIFICATIONS [OXYCODONE HYDROCHLORIDE, USP]

Material: Oxycodone Hydrochloride, USP	
Material Number: R18368	Method Number: 18368RM

TESTS & SPECIFICATIONS (CONTINUED)

<Test Source: TEVA USA, USP >

Test	Acceptance Criteria	Analytical Procedure	Alternate Analytical Procedure
Chromatographic Purity	1. Individual Unknown Impurity: NMT 0.1% 2. 7, 8 Dihydro-14-hydroxycodone: NMT 0.5%. 3. (8 β) 7, 8 Dihydro-8, 14-dihydroxycodone: NMT 0.5%. 4. 14-Hydroxycodone: NMT 0.5%. 5. Oxycodone Ethylenolate: NMT 0.25%. 6. 1-Hydroxyoxycodone: NMT 0.25%. 7. Total Impurities: NMT 2.0%.	HPLC TEVA USA, USP Method	N/A
Residue On Ignition	NMT 0.05%, the use of sulfuric acid being omitted.	<281> USP Method	N/A
Specific Rotation	Between -137° and -149° calculated on the anhydrous, solvent-free basis.	<781S> USP Method	N/A
Water	NMT 7.0%.	<921> Method I USP Method	N/A
Limit of Alcohol	NMT 1.0% (w/w)	GC USP Method	N/A
Chloride Content	The content of Cl is between 9.8% and 10.4%, calculated on the anhydrous, solvent-free basis.	Potentiometric Titration USP Method	N/A

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Teva Pharmaceuticals USA
 Effective Date: 01-Feb-2008

QDS0003141
 Valid For 7 Days from 09-Sep-2008

Version 1.0 Effective
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3.2.S.4.1 SPECIFICATIONS [OXYCODONE HYDROCHLORIDE, USP]

Material: Oxycodone Hydrochloride, USP	
Material Number: R18368	Method Number: 18368RM

TESTS & SPECIFICATIONS (CONTINUED)

<Test Source: TEVA USA, USP >

Test	Acceptance Criteria	Analytical Procedure	Alternate Analytical Procedure
Particle Size Distribution	D[v, 0.5] = NMT 36.05 μm (calculated on a volume basis) D[v, 0.9] = NMT 253.64 μm (calculated on a volume basis)	Malvern Light Scattering Analysis TEVAUSA Method	N/A

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Teva Pharmaceuticals USA
Effective Date: 01-Feb-2008

QDS0003141
Valid For 7 Days from 09-Sep-2008

Version 1.0 Effective
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Teva Pharmaceuticals USA
Oxycodone Hydrochloride USP

APPROVALS

John Kovaleski	Analytical Research & Development Approval	10-Jan-2008 11:02:18 PM
Bob Tucker	Quality Control Approval	11-Jan-2008 09:14:42 PM
Kevin Fanning	Quality Control Approval	14-Jan-2008 11:51:32 PM
Rachel Disc	Quality Control Approval	15-Jan-2008 10:06:50 PM
Dan Cocco	Quality Control Approval	18-Jan-2008 12:34:22 PM
Angela Walker	Regulatory Assessment and Approval	30-Jan-2008 03:23:59 PM

3.2.S.4.1 SPECIFICATIONS [BUPRENORPHINE HYDROCHLORIDE, IVAX PHARMACEUTICALS]

Material: Buprenorphine Hydrochloride, USP	
Material Number: 333-40-022046	Method Number: 22046RM, QDS0002719

TESTS & SPECIFICATIONS

Test Source: USP monograph and IVAX Pharmaceuticals s.r.o. Czech Republic

Tests	Acceptance Criteria	Analytical Procedure
Description:	A white or almost white crystalline powder	Visual
Identification A:	The infrared absorption spectrum of the sample exhibits maxima only at the same wavelengths as the reference standard spectrum.	IR, USP <197K>
Identification B:	A blue color appears immediately	Color test
Identification C:	Meets the requirements of the tests for Chloride	USP <191>
Specific Rotation:	Between -92° and -98°	USP <781S>
pH:	Between 4.0 and 6.0 in a solution containing 10 mg per mL	USP <791>
Water:	NMT 1.0%	USP <921>, Method I
Residue on Ignition:	NMT 0.1%	USP <281>
Related Substances:	3-butenyl-DH-nornorthevinol: NMT 0.25% Dihydrocyanothevinol: NMT 0.10% Dihydronornorthevinol: NMT 0.10% 3-methylbuprenorphine: NMT 0.10% 6-demethylbuprenorphine: NMT 0.10% Didehydrobuprenorphine: NMT 0.15% 7-(S)-buprenorphine: NMT 0.15% Largest Unknown Impurity: NMT 0.10% Total Impurities: NMT 0.65%	HPLC

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3.2.S.4.1 SPECIFICATIONS [BUPRENORPHINE HYDROCHLORIDE, IVAX PHARMACEUTICALS]

Material: Buprenorphine Hydrochloride, USP	
Material Number: 333-40-022046	Method Number: 22046RM, QDS0002719

Tests	Acceptance Criteria	Analytical Procedure
Assay:	Buprenorphine Hydrochloride contains not less than 98.5% and not more than 101.0%, of C ₂₉ H ₄₁ NO ₄ HCl, calculated on an anhydrous basis.	Titration
Residual Solvents:	Diethyl ether: NMT 1000 ppm Methanol: NMT 2000 ppm Toluene: NMT 80 ppm	GC
Residual Solvents Limit Test B:	Acetone: NMT 100 ppm	GC
Particle Size Distribution: (For Information Only)	D(0.1) = NMT 110µm D(0.5) = NMT 250 µm D(0.9) = NMT 400 µm	Malvern Mastersizer

THIS IS A REPRESENTATION OF AN ELECTRONIC RECORD THAT WAS SIGNED ELECTRONICALLY AND THIS PAGE IS THE MANIFESTATION OF THE ELECTRONIC SIGNATURE

Teva Pharmaceuticals USA

Buprenorphine HCl Raw Material Specifications

APPROVALS

Signed by	Meaning of Signature	Server Date
Remi Nnodimele	Analytical Research & Development Approval	19-Nov-2008 11:01:00 PM
Bela Kraut	Analytical Research & Development Approval	20-Nov-2008 12:04:35 AM

4. CONTROL OF DRUG SUBSTANCE

4.1 Specification

The following specification complies with the current USP monograph for naloxone hydrochloride:

Appearance	: White to off white powder
Identification (Ph Eur) *	: IR spectrum conforms
Specific optical rotation (USP)	: -170° to -181° (dry basis)
Loss on drying (USP)	: Not more than 11.0%
Chloride content (USP)	: 9.54% to 9.94%
Assay (USP)	: 98.0% to 100.5%

Related substances (HPLC) (Ph Eur) **

Noroxymorphone (A)	: Not more than 0.2%
3-O-Allylnaloxone (B)	: Not more than 0.2%
10 α -Hydroxynaloxone (C)	: Not more than 0.2%
2,2'-Bisnaloxone (E)	: Not more than 0.2%
10 β -Hydroxynaloxone (F)	: Not more than 0.2%
Individual unknowns	: Not more than 0.10%
Total impurities	: Not more than 0.8%
7,8-Didehydronaloxone (D) (HPLC) (in-house)	: Not more than 0.01%

Residual solvents (GC) (in-house)

Ethanol	: Not more than 5000ppm
1-Propanol	: Not more than 5000ppm
Methanol	: Not more than 3000ppm
Chloroform	: Not more than 60ppm

* Suitable for compliance to USP

** Replaces USP TLC test for noroxymorphone and others

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Schedule B

Active Drug Substance Specifications

BARR QC RAW MATERIAL SPECIFICATIONS & TEST RECORD			Code No: 01-0747			
Material: Buprenorphine Hydrochloride, USP/EP C3 (Milled) (Subutex)			Specification No.: 01-0747 Rev. 4 (12/12/08)			
Comm. Designation: _____ Mfr. PIN No.: _____			Supersedes: 01-0747 Rev. 3 (05/14/08)			
Manufacturer: _____ Mfr. Lot No.: _____			QA Approval: <i>[Signature]</i>			
Comments: _____			QC Approval: <i>[Signature]</i>			
Barr Lot #: _____ Date Assigned: _____			RA Approval: <i>[Signature]</i>			
Expiration Date: _____			Status: Effective			
Initial Testing <input type="checkbox"/> Scheduled Re-Eval. <input type="checkbox"/> Other: _____			Effective Date: JAN 06 2009			
TESTS	METHOD	LIMITS	RESULTS	NB. REF.	ANALYST/TEST DATE	AUDITOR/DATE
Description:*	MTH-854 ()**	White to off-white powder or matches a current reference sample				
Identification: * (A) IR		Spl IR matches Std. (maxima)				
(B) Color		A blue color appears immediately.				
(C) Chloride		1. Yields a white, curdy precipitate with Silver Nitrate TS 2. Precipitate formed is soluble in a slight excess of 6 N Ammonium Hydroxide				
Appearance of Solution:						
- Clarity of Solution		Spl. solution is clear				
- Color of Solution		Spl. solution is NMT B ₉				
Acidity/Alkalinity:		NMT 0.2 mL of 0.02 M Sodium Hydroxide or 0.02 M Hydrochloric Acid is required to change the color of the indicator				
Water:*		NMT 1.0 %				
Loss On Drying:*		NMT 1.0 %				
Specific Rotation:						
- Anhydrous Basis		-92° to -98°				
pH:		4.0 - 6.0				
Residue on Ignition:		NMT 0.1%				
Assay: *						
Anhydrous Basis:		98.5 - 101.0%				
Dried basis:		98.5 - 101.0%				
As-is basis (where applicable):		Report Results				

continued on page 2

BARR QC RAW MATERIAL SPECIFICATIONS & TEST RECORD				Code No: 01-0747		
Material: Buprenorphine Hydrochloride, USP/EP C3 (Milled)				Specification No.: 01-0747 Rev. 4 (12/12/08)		
Comm. Designation: _____		Mfr. PIN No.: _____		Supersedes: 01-0747 Rev. 3 (05/14/08)		
Manufacturer: _____		Mfr. Lot No.: _____		QA Approval: <i>[Signature]</i>		
Comments: _____				QC Approval: <i>[Signature]</i>		
Barr Lot #: _____		Date Assigned: _____		RA Approval: <i>[Signature]</i>		
Expiration Date: _____				Status: Effective		
Initial Testing <input type="checkbox"/> Scheduled Re-Eval. <input type="checkbox"/> Other: _____				Effective Date: JAN 06 2009		
TESTS	METHOD	LIMITS	RESULTS	NB. REF.	ANALYST/ TEST DATE	AUDITOR/ DATE
Chromatographic Purity: - Impurity A	MTH-854 ()**	NMT 0.25%				
- Impurity B		NMT 0.25%				
- Impurity C		NMT 0.25%				
- Individual Unspecified		NMT 0.10%				
- Total Impurities (Specified and Unspecified):		NMT 0.65%				
Residual Solvents: - Methylene Chloride		NMT 300 ppm				
- Methanol		NMT 1000 ppm				
- Ethanol		NMT 7500 ppm				
Particle Size: - D(10%):		NMT 10 µm				
- D(50%):		10 µm - 30 µm				
- D(90%):	LT 60 µm					
Shelf-Life	Not less than 18 months from the date of shipment					
REMARKS:						
1. *Re-evaluate every year						
2. ()**Analyst to fill in applicable version at time of testing and to initial and date in the method column.						
3. Manufacturer's certificate of analysis is also required.						
Lab. Review: Required Tests Completed? (Y/N)		Limits Met? (Y/N)		Results Valid? (Y/N)		
Lab Disposition: Acceptable (Y/N)		By:		Date:		
QA Disposition:		By:		Date		Re-Evaluation Date:

HISTORY (Code No. 01-0747)

Specification 01-0747 was created on 04/27/07.

Rev. 0 (04/27/07) was updated to Rev. 1 on 05/18/07 and authorized by CC-12927 as follows:

1. Under the specification limits for the *Chloride Identification* test, changed the criteria of part 2 to read, "Precipitate formed is soluble in a slight excess of 6 N *Ammonium Hydroxide*" from "Precipitate formed is readily soluble in *Ammonia TS*" to agree with the verbiage outlined under USP General Chapter <191> for Chloride Test.
2. Format and textual changes were made to improve the clarity and readability of the document.

Rev. 1 (05/18/07) was updated to Rev. 2 on 01/14/08 and authorized by CC-15037 for (1-3) and CC-15193 for (4 and 5) as follows:

1. Under *pH*, the limit was revised from "4.0 and 6.0" to "4.0 – 6.0".
2. Under *Chromatographic Purity*, the limit for the Individual Unspecified was revised from "NMT 0.1%" to "NMT 0.10%".
3. Under *Particle Size*, the limits were revised as follows: "D(10%) – Report Results to NMT 10 μm "; "D(50%) – Report results to 10 μm – 30 μm "; "D(90%) – Report Results to NLT 60 μm " and VMD was removed.
4. Under *Residual Solvents*, the limit for Ethanol was changed from "NMT 5000 ppm" to "NMT 7500".
5. Format and textual changes were made to improve the clarity and readability of the document.

Rev. 2 (01/14/08) was updated to Rev. 3 on 05/14/08 as authorized by CC-15835 as follows:

1. Changed the acceptance limits for the "D(90%)" *Particle Size* test from "NLT 60 μm " to "LT 60 μm ".
2. Format and textual changes were made to improve the clarity and readability of the document.

Rev. 3 (05/14/08) was updated to Rev. 4 on 12/12/08 as authorized by PR-28304 (#1) and CC-16101(#2-3) as follows:

1. As per FDA comment letter dated 8/21/08, under the *Residual Solvents* test updated the *Methylene Chloride* limits from NMT 600 ppm to NMT 300 ppm and the *Methanol* limits from NMT 3000 ppm to NMT 1000 ppm.
2. Added "Milled" as text to the material name in parenthesis to read "Buprenorphine Hydrochloride, USP/EP C3, Milled".
3. Format and textual changes were made to improve the clarity and readability of the document.

3.2.S.4.1 SPECIFICATIONS [BUPRENORPHINE HYDROCHLORIDE, IVAX PHARMACEUTICALS]

Material: Buprenorphine Hydrochloride, USP (Suboxone)	
Material Number: 333-40-022046	Method Number: 22046RM, QDS0002719

TESTS & SPECIFICATIONS

Test Source: USP monograph and IVAX Pharmaceuticals s.r.o. Czech Republic

Tests	Acceptance Criteria	Analytical Procedure
Description:	A white or almost white crystalline powder	Visual
Identification A:	The infrared absorption spectrum of the sample exhibits maxima only at the same wavelengths as the reference standard spectrum.	IR, USP <197K>
Identification B:	A blue color appears immediately	Color test
Identification C:	Meets the requirements of the tests for Chloride	USP <191>
Specific Rotation:	Between -92° and -98°	USP <781S>
pH:	Between 4.0 and 6.0 in a solution containing 10 mg per mL	USP <791>
Water:	NMT 1.0%	USP <921>, Method I
Residue on Ignition:	NMT 0.1%	USP <281>
Related Substances:	3-butenyl-DH-nornorthevinol: NMT 0.25% Dihydrocyanothevinol: NMT 0.10% Dihydronorthevinol: NMT 0.10% 3-methylbuprenorphine: NMT 0.10% 6-demethylbuprenorphine: NMT 0.10% Didehydrobuprenorphine: NMT 0.15% 7-(S)-buprenorphine: NMT 0.15% Largest Unknown Impurity: NMT 0.10% Total Impurities: NMT 0.65%	HPLC

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3.2.S.4.1 SPECIFICATIONS [BUPRENORPHINE HYDROCHLORIDE, IVAX PHARMACEUTICALS]

Material: Buprenorphine Hydrochloride, USP	
Material Number: 333-40-022046	Method Number: 22046RM, QDS0002719

Tests	Acceptance Criteria	Analytical Procedure
Assay:	Buprenorphine Hydrochloride contains not less than 98.5% and not more than 101.0%, of $C_{28}H_{41}NO_4HCl$, calculated on an anhydrous basis.	Titration
Residual Solvents:	Diethyl ether: NMT 1000 ppm Methanol: NMT 2000 ppm Toluene: NMT 80 ppm	GC
Residual Solvents Limit Test B:	Acetone: NMT 100 ppm	GC
Particle Size Distribution: (For Information Only)	D(0.1) = NMT 110 μm D(0.5) = NMT 250 μm D(0.9) = NMT 400 μm	Malvern Mastersizer

Shelf-Life Not less than 18 months from the date of shipment

THIS IS A REPRESENTATION OF AN ELECTRONIC RECORD THAT WAS SIGNED ELECTRONICALLY AND THIS PAGE IS THE MANIFESTATION OF THE ELECTRONIC SIGNATURE

Teva Pharmaceuticals USA

Buprenorphine HCl Raw Material Specifications

APPROVALS

Signed by	Meaning of Signature	Server Date
Remi Nnodimele	Analytical Research & Development Approval	19-Nov-2008 11:01:00 PM
Bela Kraut	Analytical Research & Development Approval	20-Nov-2008 12:04:35 AM

3.2.5.4.1 SPECIFICATIONS [OXYCODONE HYDROCHLORIDE, USP]

Material: Oxycodone Hydrochloride, USP

Material Number: R18368

Method Number: 18368RM

TESTS & SPECIFICATIONS

<Test Source: TEVA USA, USP>

Test	Acceptance Criteria	Analytical Procedure	Alternate Analytical Procedure
Identification A	The precipitate melts between 218°C and 223°C, and the range between beginning and end of melting does not exceed 2°C.	<741> Melting Range or Temperature USP Method	Alternate Identification
Identification B	The infrared absorption spectrum of a potassium bromide pellet of a dried portion of the precipitate obtained for <i>Identification A</i> exhibits maxima only at the same wavelengths as that of a dried Oxycodone RS preparation run concomitantly.	<197K> USP Method	Alternate Identification
Alternative Identification	Near infrared identification can be substituted as an alternate identification test for <i>Identification tests A and B</i> . A confirming identification result must be obtained for each measurement.	TEVA USA Method	N/A
Assay	Oxycodone Hydrochloride contains not less than 97.0% and not more than 103.0% of $C_{19}H_{21}NO_4 \cdot HCl$, calculated on the anhydrous, solvent-free basis.	HPLC TEVA USA, USP Method	N/A

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3.2.S.4.1 SPECIFICATIONS [OXYCODONE HYDROCHLORIDE, USP]

Material: Oxycodone Hydrochloride, USP

Material Number: R18368

Method Number: 18368RM

TESTS & SPECIFICATIONS (CONTINUED)

<Test Source: TEVA USA, USP >

Test	Acceptance Criteria	Analytical Procedure	Alternate Analytical Procedure
Chromatographic Purity	1. Individual Unknown Impurity: NMT 0.1% 2. 7, 8 Dihydro-14-hydroxycodone: NMT 0.5%. 3. (8 β) 7, 8 Dihydro-8, 14-dihydroxycodone: NMT 0.5%. 4. 14-Hydroxycodone: NMT 0.5%. 5. Oxycodone Ethyleneolate: NMT 0.25%. 6. 1-Hydroxycodone: NMT 0.25%. 7. Total Impurities: NMT 2.0%.	HPLC TEVA USA, USP Method	N/A
Residue On Ignition	NMT 0.05%, the use of sulfuric acid being omitted.	<281> USP Method	N/A
Specific Rotation	Between -137° and -149° calculated on the anhydrous, solvent-free basis.	<781S> USP Method	N/A
Water	NMT 7.0%.	<921> Method I USP Method	N/A
Limit of Alcohol	NMT 1.0% (w/w)	GC USP Method	N/A
Chloride Content	The content of Cl is between 9.8% and 10.4%, calculated on the anhydrous, solvent-free basis.	Potentiometric Titration USP Method	N/A

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Teva Pharmaceuticals USA
 Effective Date: 01-Feb-2008

QDS0003141
 Valid For 7 Days from 09-Sep-2008

Version 1.0 Effective
 Page 2 of 4

3.2.S.4.1 SPECIFICATIONS [OXYCODONE HYDROCHLORIDE, USP]

Material: Oxycodone Hydrochloride, USP	
Material Number: R18368	Method Number: 18368RM

TESTS & SPECIFICATIONS (CONTINUED)

<Test Source: TEVA USA, USP >

Test	Acceptance Criteria	Analytical Procedure	Alternate Analytical Procedure
Particle Size Distribution	D[v, 0.5] = NMT 36.05 µm (calculated on a volume basis) D[v, 0.9] = NMT 253.64 µm (calculated on a volume basis)	Malvern Light Scattering Analysis TEVAUSA Method	N/A

Shelf-Life Not less than 18 months from the date of shipment

Teva Pharmaceuticals USA
Oxycodone Hydrochloride USP

APPROVALS

John Kovalski	Analytical Research & Development Approval	10-Jan-2008 11:02:18 PM
Bob Tucker	Quality Control Approval	11-Jan-2008 09:14:42 PM
Kevin Fanning	Quality Control Approval	14-Jan-2008 11:51:32 PM
Rachel Dise	Quality Control Approval	15-Jan-2008 10:06:50 PM
Dan Cocco	Quality Control Approval	18-Jan-2008 12:34:22 PM
Angela Walker	Regulatory Assessment and Approval	30-Jan-2008 03:23:59 PM

Teva Pharmaceuticals USA
Effective Date: 07-Oct-2008

QDS0003478

Version 2.0
Effective

3.2.S.4.1 SPECIFICATIONS [NALOXONE HYDROCHLORIDE DIHYDRATE, JOHNSON MATTHEY PHARMACEUTICAL MATERIALS]

Material: Naloxone Hydrochloride Dihydrate (Suboxone)	
Material Number: 333-40-020497	Method Number: 20497RM

TESTS & SPECIFICATIONS

<Test Source: TEVA Pharmaceuticals, USP, Ph Eur and Johnson Matthey Pharmaceutical>

Tests	Acceptance criteria	Analytical procedure
Appearance	White to off-white powder	Visual
Identification A	Exhibits maxima only at the same wavelengths as that of a similar preparation of the USP Naloxone RS.	IR USP <197K>
Identification B	The Rf value of the principal spot of the sample preparation is comparable to that of USP Naloxone RS.	TLC
Specific rotation	Between -170° and -181°	USP <781S>
Loss on drying	NMT 11.0%	USP <731>
Noroxymorphone HCl and other impurities	Other than the principal spot corresponding in Rf value to that of USP Naloxone RS and the spot at the origin, no other spot is more intense than the spot corresponding to the USP Noroxymorphone Hydrochloride RS (1.0%)	TLC
Chloride content	NLT 9.54% and NMT 9.94% on a dried basis	Titration
Assay	Naloxone Hydrochloride contains not less than 98.0% and not more than 100.5% of C ₁₉ H ₂₁ NO ₄ ·HCl calculated on the dried basis	Titration
Residual Solvents	Ethanol NMT 5000 ppm 1-Propanol NMT 5000 ppm Methanol NMT 3000 ppm Chloroform NMT 60 ppm	GC

Teva Pharmaceuticals USA
Effective Date: 07-Oct-2008

QDS0003478

Version 2.0
Effective

**3.2.S.4.1 SPECIFICATIONS [NALOXONE HYDROCHLORIDE
DIHYDRATE, JOHNSON MATTHEY PHARMACEUTICAL
MATERIALS]**

Material: Naloxone Hydrochloride Dihydrate	
Material Number: 333-40-020497	Method Number: 20497RM

Tests	Acceptance criteria	Analytical procedure
Related Substances	Noroxymorphone: NMT 0.2% 3-O-Allylnaloxone: NMT 0.2% 10 α -hydroxynaloxone: NMT 0.2% 2,2'-Bisnaloxone: NMT 0.2% 10 β -Hydroxynaloxone: NMT 0.2% Individual unknowns: NMT 0.10% Total impurities: NMT 0.8%	HPLC
7,8-didehydronaloxone Assay	7,8-didehydronaloxone: NMT 0.01%	HPLC

Shelf-Life Not less than 18 months from the date of shipment

Teva Pharmaceuticals USA
Effective Date: 07-Oct-2008

QDS0003478

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Version 2.0
Effective

Naloxone HCl Dihydrate Raw Material Specifications

APPROVALS

Signed by	Meaning of Signature	Server Date
Bela Kraut	Analytical Research & Development Approval	07-Oct-2008 06:44:05 PM
Remi Nnodimele	Analytical Research & Development Approval	07-Oct-2008 06:46:32 PM

Date of Print: 22-Sep-2008

Valid for 7 days from date of print

Page 3 of 3

Schedule C

Standard Operating Procedures Requirements

General Considerations:

Facilities must be open to periodic audits, (no Major Findings identified) Major Finding is defined as: (i) an audit observation(s) that could significantly impact the quality of the product or a combination of minor deficiencies which indicate a major quality system failure, and would prevent supply of the product to Teva/Barr, or (ii) a major deviation identified by a regulatory agency (US FDA);

FDA Inspections results must be forwarded (i.e., 483)

Facility must remain in GMP compliance. GMP compliance defined as: complies with all statutes, ordinances, rules, and regulations of the United States that are applicable to APIs, including current Good Manufacturing Practices for APIs, as defined by the US FDA in guidance and regulation, and applicable guidances for APIs promulgated by the International Conference on Harmonization

Specific to APIs:

Technical package including:

- Characterization studies using NMR, MS, DSC, TGA, XRD, Elemental analysis, etc.
- Potency assay and the corresponding method and method validation report
- Impurity profile and the corresponding method and method validation report.
- Classification of the type of impurity, such as process related or potential degradation product.
- Residual solvent list (including a separate list of all solvents used in the last two manufacturing steps) and the corresponding method and method validation report
- Reference Standard and its use as primary standard in the case of non-compendial API – Full characterization of the material along with full testing as per Certificate of Analysis and the specification.
- Stability data

Samples from one (1) lot will be required for Qualification, and samples from three (3) separate fully validated, GMP manufacturing lots will be required for commercial launch. A certificate of Analysis, with full testing, must accompany each lot of material.

For primary source APIs, a mutually agreeable specification is to be developed that is in accord with any official US compendial monograph should one be available. Revisions thereto are also

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to be mutually agreeable and in accord with any official US compendial monograph should one be available.

For alternate source APIs, Barr/Teva's current API specifications must be met, except for impurity and residual solvent specifications, which must meet ICH guidelines. Mutually agreeable specification changes may be made as required and are to be in accord with any official US compendial monograph should one be available.

Material Status:

Unqualified:

- New material and manufacturer combination that is in the process of being evaluated for use by Barr/Teva.

Qualified:

- Successful audit of the site where the API is manufactured.
- Executed cGMP statement from the manufacturer.
- Material must be manufactured from qualified batch/lot size.
- One (1) lot of material must be fully tested and successfully meet all required analytical specifications.
- The material be successfully used in the manufacture of one (1) batch of finished drug product and meet all analytical specifications and perform as intended.

Approved/Qualified:

- Meet all requirements for Qualified
- Regulatory Agency Approval for the finished drug has been received
- A total of three (3) lots of API must be fully tested and successfully meet all required analytical specifications.

Certified:

- Meet all requirements for Approved/Qualified
- A total of ten (10) lots of API must be fully tested and successfully meet all required analytical specifications.

EXHIBIT 17

**OXYMORPHONE HCL FOR GENERIC OPANA IR
MATERIAL SUPPLY AGREEMENT**

This Agreement is made and entered into and effective as of December 19, 2012 (the "Effective Date"), by and between Johnson Matthey Inc., a Pennsylvania corporation, on behalf of itself and its Affiliate companies (collectively, "JMI") and Teva Pharmaceuticals USA, Inc. of North Wales, Pennsylvania, a Delaware corporation, on behalf of itself and its Affiliate companies including without limitation Barr Laboratories, Inc. (collectively "Teva"). This Agreement may be referenced in orders and other correspondence related hereto as Agreement No. 705.

WITNESSETH:

WHEREAS, Teva is in the business of developing, manufacturing and marketing pharmaceutical products and Teva wishes to develop and file, or has developed and filed, as the case may be, with the FDA (as defined below) an abbreviated new drug application for the Product (as defined below) and that, upon final approval by the FDA of the Product, Teva will manufacture and market the Product in the United States of America and all its lawful districts, possessions, territories and commonwealths, including, without limitation, the Commonwealth of Puerto Rico (the "Territory"); and

WHEREAS, JMI is in the business of, among other things, developing, manufacturing and marketing raw materials, including active raw material consisting of the active pharmaceutical ingredient listed in **Schedule A**, used to produce the Product (the "Active Drug Substance") and JMI wishes to supply Teva the Active Drug Substance for the Product; and

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained herein, the parties agree as follows:

ARTICLE 1. Definitions

a) "Act" means the Federal Food, Drug and Cosmetic Act of 1938, including any amendments thereto and all regulations promulgated thereunder.

b) "Affiliate" means with respect to a party hereto, any person or entity directly or indirectly controlling, controlled by or under common control with, such party, with "control" meaning the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies, whether through the ownership of voting securities, by contract or otherwise.

c) "ANDA" means abbreviated new drug application for the Product filed by Teva with the FDA.

d) "Calendar Quarter" means a three (3) consecutive month period ending on March 31, June 30, September 30 or December 31.

e) "Calendar Year" means a twelve (12) consecutive month period commencing January 1 and ending December 31.

f) "DEA" has the meaning given such term in Section 3(c).

g) "DMF" means a drug master file or any supplement thereto for Active Drug Substance filed by JMI with the FDA pursuant to the Act.

h) "FDA" means the United States Food and Drug Administration and any successor agency thereto.

i) "First Commercial Sale" means the first sale of the Product, in any dosage strength, by Teva or its Affiliates or licensees to an independent third party after FDA approval of the ANDA for the Product.

j) "Product" means Teva's generic Opana® immediate-release (IR) drug product.

k) "Specifications" has the meaning given such term in Section 3(e) hereof.

ARTICLE 2. Product Qualification.

a) Except to the limited extent (i) JMI fails to satisfy the Standard Operating Procedures Requirements set forth on **Schedule C** attached hereto or JMI otherwise acts or fails to act in a manner that has a material adverse effect on Teva's ability to qualify JMI, or (ii) any other event which is not within the control of Teva has occurred or is then occurring that, despite Teva using commercially reasonable efforts to overcome such event, prevents Teva from qualifying JMI, Teva shall qualify JMI, and JMI will support Teva's qualification efforts, as its supplier of Active Drug Substance for the Product for sale in the Territory in accordance with Teva's minimum aggregate annual purchase requirements in the Territory (based upon actual orders by Teva for Active Drug Substance for the Product for the Territory on a Calendar Year basis) provided in **Schedule A** and in conformity in all material respects with all applicable federal, state and local laws, regulations, orders and ordinances pertinent thereto.

b) JMI shall supply Teva with the Active Drug Substance prior to the First Commercial Sale of the Product in the quantities reasonably required by Teva for the development of the Product at the price agreed for the Active Drug Substance in **Schedule A**.

c) Teva shall provide to JMI notice of the First Commercial Sale of the Product in the Territory as soon as practicable after such sale.

ARTICLE 3.

Purchase and Sale of Active Drug Substance; Forecasts

a) Subject to the exceptions contained in Section 2(a), this Section 3(a), Section 4(c) and Article 5, Teva agrees to purchase the Active Drug Substance for the Product for sale in the Territory from JMI in the minimum aggregate annual purchase requirements for the Territory provided in **Schedule A** for the Active Drug Substance during the Initial Term and each Extension Term (if applicable) (each as defined in Section 6(a)) and JMI shall satisfy such requirements by selling directly to Teva the Active Drug Substance in accordance herewith. In the event the parties are unable to agree upon a price adjustment for the Active Drug Substance in accordance with Section 4(c), Teva shall not be subject to minimum aggregate annual purchase requirements for the Territory for the Active Drug Substance. For the avoidance of doubt, the parties hereby acknowledge and agree that the Active Drug Substance supplied by JMI to Teva under this Agreement shall only be for use in connection with the Product and not in connection with any generic Opana® extended-release (ER) or tamper-resistant (TR) product.

b) Forecasts and Orders.

(i) Except as otherwise mutually agreed in writing, at least six (6) months in advance of Teva's first order for the Active Drug Substance hereunder, Teva shall provide JMI with a twelve-month rolling forecast, by Calendar Quarter, of its requirements of such Active Drug Substance, which shall be updated each Calendar Quarter ("Forecast"). The first Calendar Quarter of each such updated Forecast shall be a binding order except as otherwise mutually agreed (the "Firm Order"). For record purposes only, Teva shall provide JMI with a purchase order. At the beginning of each Calendar Quarter, Teva shall update its estimates for the four (4) Calendar Quarters succeeding the Firm Order and JMI shall be entitled to rely on the Forecast for the first two (2) Calendar Quarters after the Firm Order in such rolling forecast for purposes of purchasing raw materials. For example, if Teva desires that commercial supply of an Active Drug Substance begin on July 1, 2013, Teva shall provide to JMI no later than January 1, 2013, a forecast of the quantities required for the Calendar Quarters beginning on July 1, 2013, October 1, 2013, January 1, 2014, and April 1, 2014. On or about April 1, 2013, the forecast for the Calendar Quarter beginning on July 1, 2013 (the Firm Order in this example), will become a binding order, and Teva will provide JMI with a forecast of the quantities required for the Calendar Quarters beginning on October 1, 2013 and January 1, 2014 (upon which JMI may rely for the purpose of obtaining raw materials), April 1, 2014, and July 1, 2014.

(ii) JMI will supply 100% of Teva's Firm Orders; provided, however, such Firm Order does not exceed the previous Calendar Quarter Forecast by more than 20%. Notwithstanding the foregoing, upon request by Teva, JMI will use Commercially Reasonable Efforts to supply Teva with Active Drug Substance in excess of 120% of the Forecast provided that failure to meet such excess shall not be deemed to be a breach of this Agreement.

(iii) For the initial order of Active Drug Substance following execution of this Agreement, the parties will agree on Forecasts, including shipment schedules, at the earliest practicable time and JMI will use Commercially Reasonable Efforts to supply such Active Drug Substance as specified in those orders.

c) Active Drug Substance shall be shipped FCA origin (JMI's West Deptford plant), in such containers as may be agreed upon by the parties, packed in accordance with Drug Enforcement Administration ("DEA") and Department of Transportation requirements for interstate shipment. JMI shall ship the quantity of Active Drug Substance ordered by Teva in accordance with the written delivery instructions provided by Teva to JMI with respect to each Firm Order confirmed by JMI pursuant to Section 3(b). For the avoidance of doubt, Teva shall have absolute and sole discretion to determine the carrier and mode of transportation.

d) Except as otherwise expressly provided in this Article 3, any terms and conditions contained in any purchase order, acknowledgment or invoice issued by either party in connection with this Agreement shall be void and of no effect unless expressly agreed upon in writing signed by both parties if contrary to the terms and conditions of this Agreement.

e) JMI shall produce the Active Drug Substance in conformance with the specifications set forth at **Schedule B** (the "Specifications"). If the FDA modifies the Specifications as a condition for obtaining ANDA approval and Teva so notifies JMI, JMI shall use commercially reasonable efforts to perform its obligations under this Agreement at no additional cost to Teva; provided that in the event that the Specifications are changed in a manner that results in an adjustment to the costs to JMI, the parties shall negotiate in good faith a price adjustment.

ARTICLE 4. Price and Payment for Active Drug Substance

a) Except for the price adjustments set forth in this Agreement, the price for Active Drug Substance shall be in accordance with the schedule provided in **Schedule A** and shall be fixed for a period of thirty-six (36) months from the First Commercial Sale of the Product. Thereafter, the Active Drug Substance price shall be subject to a price adjustment, not more than once per Calendar Year, based on then existing sourcing and processing costs, provided, however, that JMI will provide Teva with sixty (60) days advance written notice of any price adjustment and the parties agree to negotiate in good faith the terms of any such price adjustment.

b) Teva shall pay all invoices from JMI or submitted on behalf of JMI for the Active Drug Substance in full within forty-five (45) days after the date of the invoice by wire or in the form of a check or money order (or other method of payment approved by JMI in writing). JMI shall be entitled to charge a late fee of 1.5% per month on any payment which is not made when due. JMI shall have the right, in addition to any other available remedies, to cease work and stop deliveries until payment of all outstanding overdue amounts.

c) Teva's minimum aggregate annual purchase requirements for the Product for the Territory set out on **Schedule A** shall be non-terminable for the first thirty-six (36) months after the First Commercial Sale of the Product, except as otherwise provided in Section 2(a), Article 5 and Sections 6(b) through (f). Teva shall have the right to solicit competitive offers at any time during the term of this Agreement for supply of the Active Drug Substance from third party manufacturers, having service and quality assurance capabilities reasonably comparable to those of JMI, including without limitation a FDA approved facility for the Active Drug Substance, to supply like quantities of Active Drug Substance of similar quality under like terms and conditions for a lower price. At any time after such thirty-six (36) month period, in the event bona fide evidence of such offer (including, without limitation, a quotation or similar documentation of such third-party supply offer which may be redacted to remove any confidential information) is provided by notice to JMI, the parties shall endeavor to negotiate in good faith a mutually agreeable price for the Active Drug Substance. In the event the parties cannot agree on a price within thirty (30) days after JMI's receipt of such notice, then Teva shall have the right to purchase the Active Drug Substance from such third-party at a price no less favorable to Teva than the best price offered by JMI and/or terminate this Agreement. In the event that Teva identifies that equivalent Active Drug Substance is being sold in the marketplace at materially lower prices than the Active Drug Substance being provided by JMI, which causes Teva's market share to decline for the Product, Teva and JMI shall discuss in good faith such circumstances and any change to pricing terms that might be mutually agreeable. Notwithstanding the foregoing, in the event that at any time during a Term, Teva acquires, merges with or into, or otherwise combines with any other entity (such that the entity in question becomes an Affiliate of Teva) that owns, manufactures, produces, distributes and/or sells the Active Drug Substance, Teva shall be permitted to present, after the foregoing thirty-six (36) month period, the pricing of the Active Drug Substance to JMI as a competitive alternative to JMI's price for its corresponding Active Drug Substance as if such Active Drug Substance were, for purposes of this Section 4(c), a third party's Active Drug Substance.

d) Notwithstanding anything contained in this Agreement to the contrary, Teva shall be permitted to qualify during the term of this Agreement alternate sources of supply for the Active Drug Substance.

ARTICLE 5. DEA Supply Conditions

The Active Drug Substance and the Product, are scheduled under the Federal Controlled Substances Act. JMI and Teva are required to obtain a quota from the DEA before producing the Product or the Active Drug Substance. Such quotas are limited, therefore, the parties agree to use reasonable commercial efforts to obtain the necessary DEA quotas. The parties shall cooperate and supply all supporting documentation necessary to obtain applicable DEA permits, the DEA quotas, and to fulfill all other DEA related requirements necessary for performance under this Agreement. Teva's purchase obligations hereunder, and JMI's supply obligations hereunder, are each expressly subject to both parties obtaining US import permits and DEA quotas from the DEA. In the event of any DEA permitting or quota restrictions or interruptions outside of the reasonable control of Teva and/or JMI, as the case may be, Teva's purchase obligations hereunder, and JMI's delivery obligations hereunder, of the Active Drug Substance shall be

suspended during the period of such restriction or interruption. In the event of any such restriction or interruption in Teva's purchase obligations, such restriction or interruption and resulting failure to purchase JMI Active Drug Substance shall not be deemed a breach hereunder by Teva, provided, however, JMI shall have the right to sell to a third party any and all Active Drug Substance that has been manufactured for Teva but which Teva is unable to purchase due to such restriction or interruption, as applicable. In the event of any such restriction or interruption of JMI's supply obligations, such restriction or interruption and resulting failure to supply Active Drug Substance to Teva shall not be deemed a breach hereunder by JMI; provided, however, Teva shall be permitted to purchase all of its requirements of the Active Drug Substance (or that amount of Active Drug Substance JMI is unable to supply in the event of a restriction) from a third party supplier or multiple third party suppliers (or from a Teva Affiliate) for so long as such restriction or interruption, as the case may be, continues. In addition, such purchases shall not be deemed a breach by Teva hereunder and Teva's minimum aggregate annual purchase requirements for the Territory for the Active Drug Substance during the Calendar Year in question will be prorated, as determined by multiplying (a) the quotient obtained by (i) dividing the number of days during the Calendar Year in question that JMI is able to supply (with the cut off date being the last day of the Calendar Quarter during which JMI delivers its final supply of the Active Drug Substance, which Calendar Quarter will be prorated accordingly if JMI supplies less than Teva's order of the Active Drug Substance for such Calendar Quarter) to Teva the Active Drug Substance in supply by (ii) 365 and (b) what would have been Teva's minimum aggregate annual purchase requirements for the Territory for the Active Drug Substance for the given Calendar Year, but for such restriction or interruption. In the event JMI is able to resume supplying the Active Drug Substance to Teva, JMI shall provide Teva with written notice of the date JMI will be able to resume such supply. Promptly after JMI's notice to Teva, Teva shall issue a Requirement Forecast to JMI; provided, however, that notwithstanding anything contained in Section 3(b) to the contrary, Teva shall not be obligated to, but shall have the right at its option to, issue a Firm Order for a period of six (6) months after the date JMI is able to supply the Active Drug Substance. Notwithstanding the foregoing, but subject to the next sentence, Teva shall remain bound by its prorated minimum aggregate annual purchase requirements for the Territory for the Active Drug Substance during the Calendar Year in question. In the event that due to Teva's purchase obligations to a third party supplier as a result of a restriction or interruption in supply Teva is unable to satisfy its minimum aggregate annual purchase requirements for the Territory to JMI in a given Calendar Year, such failure shall not be deemed a breach by Teva hereunder, but instead any such shortfall shall be added to Teva's minimum aggregate annual purchase requirement for the Territory for the immediately following Calendar Year.

ARTICLE 6. Term

a) This Agreement shall become effective on the Effective Date and shall continue in force through the period ending five (5) years from the First Commercial Sale for the Product unless earlier terminated in accordance with the terms herein ("Initial Term"). This Agreement shall continue in force thereafter solely upon the mutual written agreement of the parties for such period of time agreed to by the parties, provided that if either party desires to continue the term of this Agreement, it shall provide written notice thereof to the other party not less than twelve

(12) months in advance of the expiration of the Initial Term or any subsequent extension term (each, an "Extension Term" and together with the Initial Term, each, a "Term").

b) Notwithstanding the foregoing, the term of this Agreement shall terminate upon the unanimous written consent of the parties.

c) In the event of a material breach of this Agreement by a party, the other party shall have the right to deliver a written notice of breach to the defaulting party. If such breach is not cured within ninety (90) days after delivery of such notice, the non-defaulting party, at its sole option, may terminate the term of this Agreement at any time by delivery of written notice of termination to the defaulting party.

d) In the event that a party shall (i) voluntarily commence any proceeding or file an petition seeking relief under any Federal, state or local bankruptcy, insolvency, liquidation, receivership or similar law (a "Bankruptcy Law"), (ii) consent to the institution of, or fail to contravene in a timely and appropriate manner, any such proceeding or the filing of any such petition, (iii) apply for or consent to the appointment of a receiver, trustee, custodian, sequestrator or similar official for such party or for a substantial part of its property or assets, (iv) file an answer admitting the material allegations of a petition filed against it in any such proceeding or (v) make a general assignment for the benefit of creditors, the other party, at its sole option, may terminate the term of this Agreement at any time by delivery of written notice of termination to the party subject to such event.

e) In the event that a party shall be subject to the commencement of any involuntary proceeding or the filing of any involuntary petition in a court of competent jurisdiction seeking (i) relief in respect of such party or of a substantial part of its property or assets under any Bankruptcy Law, (ii) the appointment of a receiver, trustee, custodian, sequestrator, or similar official for such party or for a substantial part of its property or assets or (iii) the winding-up or liquidation of such party, and such proceeding or petition shall continue undismissed for one hundred and twenty (120) days or an order or decree approving or ordering any of the foregoing shall continue unstayed and in effect for sixty (60) days, the other party, at its sole option, may terminate the term of this Agreement at any time by delivery of written notice of termination to the party subject to such event.

f) Teva shall have the right to terminate this Agreement pursuant to Section 9(d) below.

g) Termination for default or breach hereunder or for any other reason shall have no effect on performance obligations or amounts to be paid which have accrued up to the effective date of such termination. Articles 8, 9, 10, 11 and 15 and this Section 6(g) shall survive the expiration or other termination of this Agreement indefinitely or, if shorter, in accordance with its terms.

ARTICLE 7. Assignment or Transfer of Interest

Neither party shall directly or indirectly sell, assign or transfer any part or all of its interest in this Agreement without the prior written consent of the other party, which consent shall not be unreasonably withheld; provided, however, that a change in control of a party shall not be deemed to constitute a transfer of such party's interest. JMI may transfer its interest to an Affiliate of JMI which is a qualified manufacturer, subject to prior written notice to Teva and Teva's approval, which will not be unreasonably withheld. Notwithstanding the foregoing, Teva may transfer its interest to an Affiliate without the prior approval of JMI.

ARTICLE 8. Confidentiality

(a) Each party agrees to maintain the confidentiality and secrecy of this Agreement and its terms and conditions, and any proprietary information provided to it by or on behalf of the other party under this Agreement, including any proprietary, financial, trade secret, technical, know-how, business, marketing, data or other confidential information such as information relating to the Product, pricing, facilities, methods, formulae, processes, strategies, corporate initiatives, production efforts or requirements, operations, income, projections, contractual and business arrangements, personnel data, whether in verbal, written or other tangible form (collectively, "**Confidential Information**") using no less than a reasonable degree of care. Neither party shall use the other party's Confidential Information for any purpose other than to fulfill its duties and obligations under this Agreement. Each party will also keep in confidence and not disclose to any third parties the terms and conditions of this Agreement. Each party may, however, disclose the other party's Confidential Information to its Affiliates, officers, directors, employees and agents who have a need to know or who have access to that Confidential Information in order to fulfill its duties and obligations under this Agreement, subject to the terms and conditions of this Article 8. Each party shall be responsible for any breach of this Article 8 by its Affiliates, officers, directors, employees and agents to whom the other party's Confidential Information is disclosed. The obligations of confidentiality do not apply to information that:

- (i) is or becomes known to the public through no fault or omission on the part of the receiving party;
- (ii) as evidenced by the receiving party's written records, was independently developed by or for the receiving party without any reference to, or reliance upon, the disclosing party's Confidential Information;
- (iii) is made available to the receiving party from another source rightfully in possession of the disclosing party's Confidential Information and not under an obligation of confidentiality with respect thereto;
- (iv) is disclosed with the prior written approval of the disclosing party; or
- (v) is required to be disclosed by the receiving party in order to comply with

applicable laws, so long as the receiving party gives notice of that disclosure to the disclosing party so that the disclosing party may seek a protective order. Where such disclosure is required, the receiving party shall, to the fullest extent permitted by the applicable law, redact the Confidential Information prior to said disclosure.

(b) The confidentiality and non-use obligations hereunder shall survive expiration or termination of this Agreement and remain valid for a period of five (5) years thereafter.

ARTICLE 9 Representations, Warranties, Covenants and Limitations

a) JMI warrants that the Active Drug Substance supplied to Teva hereunder will conform to the Specifications, as the Specifications may from time-to-time be amended by mutual written agreement or as required by the FDA, other governmental body in the United States or the then current edition of the U.S. Pharmacopoeia.

b) JMI warrants to Teva that, as of the date of each shipment hereunder of any articles subject to the provision of the Act, such article is not, when shipped from JMI's West Deptford, New Jersey plant, adulterated by or misbranded by JMI within the meaning of the Act or of any applicable state law in which the definitions of adulteration and misbranding are substantially the same as those contained in the Act, or an article that may not, under the provision of Sections 404, 505, or 512 of the Act, be introduced into interstate commerce.

c) JMI covenants to Teva that it shall not make any material amendments, changes or supplement with respect to the Active Drug Substance, without Teva's prior written approval, which approval shall not be unreasonably withheld or delayed, except as may be required to comply with applicable law, which would (i) require FDA approval as determined by the FDA guidelines and regulations or otherwise require notification to a regulatory authority, including, without limitation, the FDA, or (ii) in the reasonable judgment of JMI, would cause the Active Drug Substance to lose the benefit of any freedom to operate opinion obtained by JMI with respect to the Active Drug Substance (in either case, a "Material Change"). To the extent such changes are required by applicable law, JMI shall provide Teva with prompt written notice of such changes in applicable law that would require any of the foregoing amendments, changes or supplements.

d) JMI represents that, to its knowledge as of the Effective Date, neither the process used by JMI to manufacture nor the composition of the Active Drug Substance infringes any claim of a third-party U.S. patent which JMI believes to be valid and enforceable or to which JMI does not have an affirmative defense to infringement. The foregoing representation shall not apply to (i) any claim of infringement resulting from JMI's compliance with Teva's instructions to modify the Specifications or the manufacturing process of the Active Drug Substance; (ii) any claim of infringement resulting from the use of or change in Active Drug Substance made subsequent to JMI's delivery or performance; or (iii) any claimed infringement that is settled by Teva without the consent of JMI, such consent not to be unreasonably withheld or delayed. In the event Teva identifies a potential infringement issue with respect to the Active Drug Substance, Teva and JMI shall mutually work together in good faith to resolve or overcome any

potential issue. The parties shall ensure that all communication shall be conducted to avoid loss of attorney client privilege. In the event the parties are unable to overcome or resolve the potential infringement issue, Teva may, at any time during the term of this Agreement, terminate qualification or supply of the Active Drug Substance from JMI without any penalty, termination fee or other damages solely as a result of such termination. Notwithstanding the foregoing, Teva shall remain liable for any and all of its obligations under this Agreement already accrued as of the termination date plus the cost of any quantities of Active Drug Substance manufactured for Teva as of such termination date in connection with JMI's performance of its obligations under this Agreement; provided, however, that Teva shall not be liable for such costs and expenses to the extent that the potential infringement issue giving rise to termination under this Section 9(d) was caused by JMI's making a Material Change (or a material amendment, change or supplement with respect to the Active Drug Substance which JMI determined not to be a Material Change) without Teva's prior written approval pursuant to Section 9(c).

e) Each of JMI and Teva warrants that it will fully comply with the testing requirements for the Active Drug Substance as detailed in the applicable Specifications. Teva further warrants that its testing procedures for Active Drug Substance will meet prevailing industry standards applicable to pharmaceutical manufacturers.

f) Except as expressly stated in paragraphs a), b), c), d) and e) of this Article 9, JMI MAKES NO OTHER REPRESENTATION OR WARRANTY OF ANY KIND, EXPRESSED OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY AS TO MERCHANTABILITY, FITNESS FOR PARTICULAR PURPOSE, OR ANY OTHER MATTER WITH RESPECT TO THE ACTIVE DRUG SUBSTANCE WHETHER USED ALONE OR IN COMBINATION WITH OTHER SUBSTANCES.

g) JMI will provide Teva together with each shipment or invoice the results of all assays required to be run under the Specifications. If such shipment of Active Drug Substance, in any of the following cases, as a result of any deficiencies that are or should have been reasonably discoverable by Teva under its receipt testing procedures in light of the Specifications and provided that such testing procedures meet prevailing industry standards applicable to pharmaceutical manufacturers (i) does not comply with the Specifications, (ii) has been damaged prior to being provided to the carrier for shipment, or (iii) if there is a shortage in the quantity prior to being provided to the carrier for shipment (each of the foregoing a "Discoverable Defect"), Teva shall promptly notify JMI in writing, not later than sixty (60) days after receipt. Any shipment of Active Drug Substance having a Discoverable Defect will be deemed accepted by Teva in the absence of providing such notice. Teva or its designee shall promptly return such Active Drug Substance to JMI at JMI's expense, or Teva shall undertake such other response as is mutually agreed upon in writing by the parties. In addition, if Teva or its designee, despite the application of testing procedures meeting prevailing industry standards applicable to pharmaceutical manufacturers, subsequently discovers a deficiency or shortage set forth in clauses (i)-(iii) above of this Section 9(g) that is not a Discoverable Defect, it shall have the right to return such Active Drug Substance provided that it notifies JMI in writing within thirty (30) days of the discovery of such latent defect. JMI shall have the right, but not the obligation, to re-test the rejected Active Drug Substance. In the event that JMI disputes Teva's determination that such Active Drug Substance does not meet the Specifications or has been damaged or is subject

to a shortage in quantity, the parties shall meet to resolve, in good faith, such dispute. In the event the parties are not able to reach a mutually agreeable resolution, the matter shall be referred to an independent third party laboratory mutually acceptable to the parties for final determination. In such instance, the replacement Active Drug Substance and the cost of the laboratory will be at JMI's cost if the laboratory finds that the lot in question is non-conforming to the Specifications or otherwise defective and the costs of the independent laboratory will be paid by Teva if the lot in question is found by the laboratory to be conforming and compliant. For the avoidance of doubt, JMI shall dispose of all non-conforming Active Drug Substance at its sole cost and expense.

h) Upon return of any rejected Active Drug Substance, and JMI's agreement, or a final determination in accordance with this Agreement, that such Active Drug Substance fails to comply with JMI's limited warranty or has been damaged, JMI will replace the Active Drug Substance at JMI's cost. EXCEPT FOR REMEDIES FOR THIRD-PARTY CLAIMS AS PROVIDED IN ARTICLE 11, TEVA'S EXCLUSIVE REMEDY FOR BREACH OF WARRANTIES IN SECTIONS a) AND b) AND e) OF THIS ARTICLE 9 SHALL BE DIRECT DAMAGES AND JMI's LIABILITY TO TEVA FOR SUCH DIRECT DAMAGES FROM ANY CAUSE WHATSOEVER, INCLUDING, WITHOUT LIMITATION, ALLEGED NEGLIGENCE, SHALL IN NO EVENT EXCEED THE OBLIGATION TO REPAIR OR REPLACE THE ACTIVE DRUG SUBSTANCE AND RESUBMIT IT TO TEVA. In the event that JMI is unable to repair or replace such non-conforming Active Drug Substance, at Teva's option, JMI shall refund the price paid for such non-conforming Active Drug Substance and reimburse Teva for related shipping and shipping insurance costs incurred by Teva in connection therewith.

i) EXCEPT AS OTHERWISE PROVIDED IN ARTICLE 11, TEVA'S EXCLUSIVE REMEDY FOR BREACH OF COVENANTS AND WARRANTY OF SECTIONS c) and d) OF THIS ARTICLE 9 SHALL BE DIRECT DAMAGES AND JMI's LIABILITY TO TEVA FOR ANY AND ALL LOSSES OR DAMAGE, SHALL IN NO EVENT EXCEED THIS OBLIGATION TO, AT ITS EXPENSE AND OPTION, EITHER PROCURE THE NECESSARY LICENSE TO AVOID INFRINGEMENT, MODIFY THE INFRINGED MATERIAL OR PROCESS TO BE NON-INFRINGEMENT, OR REQUIRE THE RETURN OF SUCH PRODUCT OR PROCESS TO JMI FOR A REFUND.

j) Each party shall notify the other as soon as reasonably possible of any information of which it is aware concerning the Active Drug Substance supplied to Teva which may affect the safety or efficacy claims or the continued marketing of the Product. Any such notification will include all related information in detail. Upon receipt of any such information, JMI shall consult with Teva in an effort to arrive at a mutually acceptable procedure for taking appropriate action; provided, however, that nothing contained herein shall be construed as restricting the right of either party to make a timely report of such matter to any agency or take other action that it deems to be appropriate or required by applicable law or regulation. Each party will notify the other as soon as reasonably possible of any health hazards with respect to the Active Drug Substance or the Product which may impact employees involved in the manufacture of the Active Drug Substance or formulation of the Active Drug Substance into the Product.

k) Notwithstanding Section 9(d) above, JMI represents that JMI's manufacture and supply of the Active Drug Substance to Teva under this Agreement, and Teva's sale of the Product containing the Active Drug Substance in the Territory, shall not give rise to any claim of infringement of U.S. Patent No. 7,851,482 so long as Teva is not in breach of the restrictions on use of the Active Drug Substance set forth in Section 3(a) of this Agreement.

ARTICLE 10. Limitation on Liability

NEITHER PARTY WILL BE LIABLE TO THE OTHER PARTY FOR LOST PROFITS, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES SUSTAINED DIRECTLY BY THAT PARTY, WHETHER SUCH PARTY'S CLAIM IS IN CONTRACT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, OTHER THAN IN CONNECTION WITH SUCH PARTY'S OBLIGATION TO INDEMNIFY THE OTHER PARTY WITH RESPECT TO THIRD PARTY CLAIMS PURSUANT TO ARTICLE 11.

ARTICLE 11. Indemnification; Insurance

a) Teva Indemnification. Teva agrees to indemnify and hold harmless JMI and its Affiliates and their respective officers, directors, agents and representatives thereof from any and all losses, liability, damages, and/or expenses (including reasonable attorneys fees and expenses) which may be sustained or claimed by third parties against JMI arising from or out of (i) any patent infringement claim related to the Product or the Active Drug Substance, except to the extent a patent infringement claim related to the Active Drug Substance is explicitly based on an allegation that (A) the process used by JMI in the manufacture and the composition of the Active Drug Substance or (B) a Material Change, or an amendment, a change or a supplement made by JMI with respect to the Active Drug Substance for which Teva did not provide its prior written consent, infringes a U.S. patent; (ii) the handling and possession of the Active Drug Substance following Teva's or its designee's receipt thereof; or (iii) the use of the Active Drug Substance, following Teva's or its designee's acceptance thereof, except to the extent of JMI's liability under Section 11(b). The foregoing indemnity is subject to JMI promptly notifying Teva in writing of all claims and threatened claims against JMI for which JMI may be entitled to indemnity hereunder. Teva shall have the right to defend and/or settle any such claim and JMI shall give Teva such defense, provided that JMI shall have the right to choose its counsel and consent to any settlement (which consent not to be unreasonably withheld). JMI shall have the right to participate in such defense at its cost.

b) JMI Indemnification.

1. JMI agrees to indemnify and save harmless Teva and its Affiliates and their respective officers, directors, agents and representatives thereof from any and all losses, liability, damages and/or expenses (including reasonable attorneys fees and expenses) which may be sustained or claimed by third-parties against Teva arising from or out of (i) JMI's material breach of its representations or warranties; (ii) JMI's

negligence, gross negligence or willful misconduct in the manufacture, handling or storage of the Active Drug Substance, which causes the Active Drug Substance to fail to meet Specifications, become adulterated prior to delivery to Teva or its designee, or otherwise fail to comply with current Good Manufacturing Practices in accordance with FDA regulations, guidelines and other administrative interpretations and rulings in connection therewith; or (iii) any alleged claim of infringement of a U.S. patent resulting from JMI's making a Material Change, or an amendment, a change or a supplement with respect to the Active Drug Substance for which Teva did not provide its prior written consent; or (iv) any actual or alleged claim of infringement of U.S. Patent No. 7,851,482, except in all cases to the extent of Teva's liability under Section 11(a). The foregoing indemnification obligation of JMI shall be subject to the limitations provided in paragraph 2 of this Section 11(b) below.

2. (i) Notwithstanding any other provision of this Agreement, JMI's maximum liability for damages under this Agreement shall not exceed, in the aggregate, \$15 million; provided however

(ii) unless in the case and to the extent such damages are directly attributable to and proximately caused by JMI's gross negligence, in which case JMI's maximum aggregate liability limits stated in Section 11(b)(2)(i) above shall be increased for only such damages so caused to and not exceed an additional \$15 million for a total aggregate liability limit of \$30 million; provided further

(iii) unless in the case and to the extent such damages are directly attributable to and proximately caused by JMI's willful misconduct, in which case JMI's liability for only such damages so caused shall not be limited, and provided further

(iv) in the event punitive damages are imposed by a court of competent jurisdiction to the extent directly attributable to, proximately caused by and resulting from JMI's gross negligence (as defined below) and the amount of damages with such punitive award would exceed the limitations set forth in Section 11(b)(2)(ii) above for gross negligence (as defined below), the Section 11(b)(2)(ii) limits will be increased for only such damages so caused by an additional amount for the punitive damages only in excess of an additional \$20 million for a total aggregate liability limit amount of \$50 million.

3. Notwithstanding the determination of a finder of fact to the contrary, the parties hereby agree that, for purposes of this Section 11(b), "gross negligence" means conduct which is greater in degree than ordinary negligence, but less in degree than willful and wanton misconduct (as defined herein) and refers to a person's conduct where an act or a failure to act creates an unreasonable risk of harm to another because of the person's failure to exercise slight care or diligence. "Willful and wanton misconduct" means conduct which is done with the deliberate intent to cause harm or with reckless disregard for the safety of another's person or property.

4 The foregoing indemnity by JMI under this Section 11(b) is further subject to Teva promptly notifying JMI in writing of all claims and threatened claims against Teva for which Teva may be entitled to indemnity hereunder. JMI shall have the right to defend and/or settle any such claim and Teva shall give JMI such defense assistance provided that Teva shall have the right to choose its counsel and consent to any settlement (which consent not to be unreasonably withheld). Teva shall have the right to participate in such defense at its cost.

c) Insurance. Each Party shall carry comprehensive general liability insurance, including product liability insurance against claims for bodily injury or property damage in an amount of not less than \$2,000,000 per occurrence and \$30,000,000 in the aggregate. Such policy shall be endorsed to include an agreement by the insurer to provide thirty (30) days' prior written notice to the other party of cancellation or material change in the coverage before such cancellation or change takes effect.

ARTICLE 12. Gross Inequities

It is the intent of the parties hereto that they shall mutually benefit from the terms, conditions and provisions of this Agreement, and in the event that either party shall suffer a gross inequity resulting from such terms, conditions or provisions, or from a substantial change in circumstances or conditions, the parties shall negotiate in good faith to resolve or remove such inequity. It is mutually understood and agreed, however, that nothing herein shall be construed to relieve either party of any of its obligations under this Agreement, unless and until such resolution or removal has been agreed to in writing by both parties.

ARTICLE 13. Force Majeure

Failure of JMI or Teva to perform its obligations under this Agreement, other than the payment of amounts invoiced, shall not subject JMI or Teva to any liability if such failure is caused or occasioned by an event of force majeure, including but not limited to, an act of God, or the public enemy, fire, explosion, flood, drought, war, riot, sabotage, embargo, strikes, or other labor trouble, failure in whole or in part, of suppliers to deliver on schedule materials, equipment or machinery, to interruption of or delay in transportation, compliance with any order, regulation or request of any government of competent jurisdiction or any officer, department, agency or committee thereof, including requisition or allocation or establishment of priority, or by compliance with a request authorized by such governmental authority of any manufacturer for material to be used by it, or by any other event or circumstance of like or different character to the foregoing beyond the reasonable control of the non-performing party. If either party suffers an event of force majeure, it shall immediately notify the other party and shall use all commercially reasonable efforts to minimize the loss or inconvenience suffered by both parties. Both parties shall cooperate in good faith in order to minimize such loss and inconvenience and to reach an agreement as to how to proceed.

ARTICLE 14. Authorization

Each party represents and warrants to the other that all corporate action on the part of such party necessary for the authorization, execution and delivery of this Agreement and the performance of all obligations hereunder has been taken and persons executing this Agreement have due power and authority to do so.

ARTICLE 15. Other Provisions

a) In connection with the storage, distribution, development, sale or marketing of the Product or the Active Drug Substance pursuant to this Agreement, JMI and Teva agree to use commercially reasonable efforts to perform their respective obligations under this Agreement and such activities in compliance with all applicable federal, state, and local laws, regulations and ordinances, including, but not limited to, the Act, as amended from time to time, and all rules and regulations promulgated thereunder.

b) Nothing contained in this Agreement and no action taken by any party to this Agreement shall be deemed to constitute such party or any such party's employees, agents, or representatives to be an employee, agent, or representative of the other party or shall be deemed to create any partnership, joint venture, association, or syndicate among the parties, or shall be deemed to confer on any party any express or implied right, power, or authority to enter into any agreement or commitment, expressed or implied, or to incur any obligation or liability, on behalf of the other party.

c) The parties shall execute any other instruments or perform any other acts that are or may be reasonably necessary to effectuate and carry on the obligations created by this Agreement.

d) This Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the parties.

e) As to its subject matter, this Agreement constitutes the entire agreement of the parties and supersedes all prior agreements between the parties. This Agreement may not be modified or amended except by an instrument in writing executed by the parties.

f) Failure of either party to exercise any right under this Agreement shall not be deemed to be a waiver thereof.

g) This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, and all of which shall constitute one and the same instrument.

h) This Agreement shall be governed by and construed under the laws of the State of New Jersey, excluding its conflict of law principles.

i) Any notice or other communication that a party desires to give to another party shall be in writing, and shall be deemed effectively given upon personal delivery, delivery by overnight courier, or upon transmission by telegram, telex, or, with receipt confirmed, telecopy, addressed to the other party at the address show below or at such other address as a party may designate by written notice in accordance with this subparagraph (i).

If to JMI: Johnson Matthey Inc.
2003 Nolte Drive
West Deptford, NJ 08066-1742
Attention: Vice President & General Manager
Fax: (856) 384-7276

with a copy to: Johnson Matthey Inc.
435 Devon Park Drive, Suite 600
Wayne, PA 19087
Attention: President & General Counsel
Fax: (610) 971-3022

If to TEVA: Teva Pharmaceuticals USA, Inc.
1090 Horsham Road
North Wales, PA 19454
Attention: Sr. Director, Supply Chain
Fax: (215)591-8815

with a copy to: Teva North America Legal Affairs
425 Privet Road
Horsham, PA 19044
Attention: General Counsel
Fax: (215) 293-6499

j) In the event that any term or provision of this Agreement is invalid or is declared null and void, then both parties shall agree on a substitute for such invalid and void terms with the intent of achieving the economic intent of the parties. The invalidity or voidness of any term or condition shall not affect the validity of any other term or condition contained herein nor the Agreement as a whole unless the provisions are the essence of, or inseparable from the remainder of the Agreement.

k) JMI's quality assurance records, which shall include, but not be limited to, quality systems, policies and procedures, test results, reports, and any other documentation relating to JMI's manufacture and handling of the of Active Drug Substance, shall be open to inspection and subject to a quality assurance audit at mutually agreeable times, during normal working hours, by an independent third party designated by Teva and reasonably acceptable to JMI. JMI shall preserve such records for a period of five (5) years after the end of the Initial Term and any Extension Term or for such longer period as may be required by law. For the purpose of such

audits, inspections, examinations and evaluations, the independent auditor shall have access to such records beginning on the Effective Date and continuing until five (5) years after the satisfaction of JMI's obligations under this Agreement. In addition, JMI shall provide adequate and appropriate workspace for Teva or its authorized representatives to conduct such audit. The independent auditor shall give JMI reasonable advanced notice of an intent to audit.

l) The headings and titles of Articles, Sections, Schedules and the like in this Agreement are inserted for convenience of reference only, form no part of this Agreement and shall not be considered for purposes of interpreting or construing the text hereof.

m) Any and all press releases, publicity or other form of public written disclosures relating to this Agreement shall be mutually agreed to by the parties (the consent of a party not to be unreasonable withheld or unduly delayed and in any event a party shall respond within two (2) business days of receiving a request, failing which it shall be deemed to have consented) including, if applicable, the time of release of such public written disclosures as well as the content of such public written disclosures. For releases or announcements required by applicable law, the party making the release or announcement shall, before making any such release or announcement, afford the other party a reasonable opportunity to review and comment. Any copy of this Agreement to be filed with the Securities and Exchange Commission or any other governmental entity shall be redacted to the fullest extent permitted by applicable law and to the reasonable satisfaction of the parties; provided, however, in the event that the Securities and Exchange Commission or other governmental entity, as applicable, objects to the redaction of any portion of this Agreement after the initial submission, the filing party shall inform the other party of the objections and shall in good faith respond to the objections in an effort to limit the disclosure required by the Securities and Exchange Commission or governmental entity, as applicable.

[SIGNATURE PAGE FOLLOWS]

EXECUTION COPY

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first above written.

Johnson Matthey Inc.

By: _____

Print Name: _____

Title: _____

Date: _____

Teva Pharmaceuticals USA, Inc.

By: Alisa Capreri

Print Name: Alisa Capreri

Title: Director, Purchasing

Date: 12/21/2012

By: Michael J. Bagdy

Print Name: Michael J. Bagdy

Title: EVP Americas Tech ops

Date: 12/21/2012



IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first above written.

Johnson Matthey Inc.

By: Ted Dolan

Print Name: TED DOLAN

Title: General Manager

Date: 12/17/12

Teva Pharmaceuticals USA, Inc.

By: _____

Print Name: _____

Title: _____

Date: _____

By: _____

Print Name: _____

Title: _____

Date: _____

Schedule A

**ACTIVE DRUG
SUBSTANCE**

PRODUCT

PRICE

**MIN. AGG. ANNUAL
REQUIREMENT**

Oxymorphone HCl

generic Opana® IR

\$8,500/kg

Schedule B
Active Drug Substance Specifications

Schedule C

Standard Operating Procedures Requirements