IN THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

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 8

Amendment to Development and Supply Agreement

This Amendment to Development and Supply Agreement (the "Amendment"), dated January 7th, 2010, is made by and between Noramco, Inc., a Georgia corporation, with its principal office at 500 Swedes Landing Road, Wilmington, Delaware and its Affiliates ("NORAMCO"), and Teva Pharmaceuticals USA, Inc., a Delaware corporation, with its principal location at 1090 Horsham Road, North Wales, Pennsylvania, 19454 and its Affiliates ("TEVA").

WHEREAS, the parties hereto entered into a Development and Supply Agreement, dated June 7, 2004 ("Agreement"); and

WHEREAS, the Parties desire to modify said Agreement as set forth herein.

NOW, THEREFORE, in consideration of the mutual promises, covenants and agreements hereinafter set forth and those contained in the underlying Agreement and incorporated herein by reference, the Parties hereby agree as follows:

A. The Agreement is hereby amended by adding the following definition as Section 1.6 thereof:

1.6 "**Commercial Requirements**" – means the amount of API required to manufacture all Teva Product.

For the avoidance of doubt, commencing with the definition "Confidential Information" and each definition thereafter shall be renumbered accordingly.

B. Section 2.1 of the Agreement is hereby amended by deleting it in its entirety and replacing it with the following:

> "2.1 In accordance with the terms and conditions of this Agreement, Noramco shall supply to Teva and its Affiliates and Teva and its Affiliates shall purchase from Noramco, for use in connection with the manufacture in the Territory of Product by Teva and/or its Affiliates, the following amounts of API: Eighty percent (80%) of their respective annual Commercial Requirements for Oxycodone Hydrochloride for the following ANDAs: (a) Oxycodone and Acetaminophen Capsules 5 mg/500 mg; and Oxycodone and Ibuprofen Tablets, 5mg/400mg; and (b) Eighty percent (80%) of their annual Commercial Requirements for Hydrocodone Bitartrate, and Codeine Phosphate."

C. Section 13.1 of the Agreement is hereby amended by deleting it in its entirety and replacing it with the following:

13.1 The term of this Agreement commences as of the Effective Date and expires December 31, 2011, unless sooner terminated as otherwise expressly provided for in this Agreement. Thereafter, the Agreement automatically renews for additional terms of one

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(1) year each, unless written notice of termination is given by any Party to the other at least six (6) months before the term or start of each renewal year.

D. Section 15.0 of the Agreement is hereby amended by deleting NORAMCO's facsimile number contained therein and replacing it with the following: 302-761-2913.

F. Annex B of the Agreement is hereby deleted in its entirety and replaced with Annex B attached hereto.

G. This Amendment may not be amended or modified in any manner, except in writing signed by a duly authorized officer of each of the Parties. Except as set forth in this Amendment, all terms and conditions contained in the Agreement remain unchanged and in full force and effect.

I. This Amendment may be executed in one or more counterparts, each of which shall be deemed to be an original and all of which, when taken together, shall constitute one and the same instrument.

IN WITNESS WHEREOF, the parties' duly authorized respective representatives have executed this Amendment to the Agreement on the day and year first written above.

TEVA PHARMACEUTICALS USA, INC.	NORAMCO, INC.
By: Peg A Confrey	By: Leslie Storms
Name: PEG A. CONFREY	Name: Leslie Storms
Title: Purchasing Director	Title: Director, U.S. Marketing; Bus. Dvlpt
Date: Jan. 7, 2010	Date: 1/11/10
By: Michael J. Bogda	
Name: Michael J. Bogda	
Title: EVP US Tech Ops	
Date: 1/8/10	

LEGAL AFFAIRS

Supply Agreement
Annex B1

I. Oxycodone Hydrochloride

A. Noramco has converted its production of oxycodone hydrochloride to a process that is compliant with FDA requirements for potentially genotoxic impurities ("**Next Generation Process Oxycodone**").

B. The Base Price for purchases of Next Generation Process Oxycodone is two thousand three hundred dollars ($2,300/kilogram) for all volumes.

C. Noramco will retain the right to supply, at its sole discretion, oxycodone hydrochloride produced at either facility, Wilmington, DE or Athens, GA.

II. Codeine Phosphate

A. The Base Price shall be seven hundred and ninety-three dollars ($793) per kilogram.

B. Beginning on January 1, 2010, the Base Price shall be adjusted as follows:

i. (Base Price) times (0.35) times (Turkish Concentrated Poppy Straw price as of December 31, 2009) divided by (Turkish Concentrated Poppy Straw Price as of December 31, 2008).

ii. In subsequent years, "Turkish Concentrated Poppy Straw Price as of December 31, 2009" shall be replaced by the Turkish Concentrated Poppy Straw Price of the December 31 of the year preceding the adjustment.

iii. Regardless of above adjustment, in no event shall the adjusted base price for 2010 be greater than fifteen dollars ($15) over the 2009 base price.

C. Noramco expects to introduce a process change that would require Teva to submit a Changes Being Effected (CBE) supplement to the FDA with respect to Noramco's codeine phosphate. Teva may file with the FDA, at its sole discretion, the use of codeine phosphate produced with the process change. If Teva receives FDA approval to use codeine phosphate produced with the process change for all its Commercial Requirements, the Base Price for all codeine phosphate produced via the new process shall be reduced by twenty dollars ($20) per kilogram.

III. Hydrocodone Bitartrate

A. The Base Price for purchases of current generation process is two thousand six hundred dollars ($2,600) per kilogram for all volumes.

B. Noramco has converted its production of hydrocodone bitartrate to a process that is compliant with FDA requirements for potentially genotoxic impurities ("**Next Generation Process Hydrocodone**").

C. Teva agrees to file and qualify Noramco's Next Generation Hydrocodone for use in its Commercial Requirements and be prepared to receive next generation process for use in its Commercial Requirements in accordance with Article 2.1 of the Agreement no later than October 31, 2009.

D. The Base Price for purchases of Next Generation Process Hydrocodone is two thousand dollars ($2,000) per kilogram for all volumes.

E. Noramco will retain the right to supply, at its sole discretion, hydrocodone bitartrate produced at either facility, Wilmington, DE or Athens, GA.

EXHIBIT 9

#7490

NORAMCO, INC.
409 SILVERSIDE ROAD, SUITE 200 • WILMINGTON, DELAWARE 19809

September 7, 2004

Ms Sonal Patel
Amide Pharmaceutical
101 East Main Street
Little Falls, New Jersey 07424

Dear Ms Patel:

I have attached two signed copies of our Supply Agreement along with a "redlined" copy. Please sign the two copies and return one to:

Michael B. Kindergan
409 Silverside Road, Suite 200
Wilmington, DE 19809

I look forward to seeing you at your facility in the near future and to working with you over the years.

Sincerely,

Michael B. Kindergan

Encl.

SUPPLY AGREEMENT

THIS AGREEMENT is made as of September 7, 2004, ("Effective Date") by and between Noramco Inc. with its principal office at 500 Swedes Landing Road, Wilmington, Delaware 19801 and its Affiliates ("NORAMCO") and Amide Pharmaceutical, Inc, having its principal office at 101 East Main Street, Little Falls, New Jersey 07424 and its Affiliates ("AMIDE").

WITNESSETH

WHEREAS, AMIDE is a manufacturer and distributor of finished drug products, and

WHEREAS, NORAMCO is a manufacturer of bulk pharmaceuticals, including, oxycodone *hydrochloride for use in finished pharmaceutical products*, and

WHEREAS, AMIDE wishes to purchase bulk active ingredients from NORAMCO to use in the manufacture of finished drug products containing said active ingredient for distribution and sale throughout the United States.

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

ARTICLE 1.0 - DEFINITIONS

1.1 "Affiliate" of a party to this Agreement shall mean any corporation or partnership or other entity which directly or indirectly controls, is controlled by or is under common control with such party. "Control" shall mean the legal power to direct or cause the direction of the general management or partners of such entity whether through the ownership of voting securities, by contract or otherwise.

1.2 "Commercial Requirements" shall be the total purchases of Product during a calendar year.

1.3 "Forecasted Requirements" shall be AMIDE's expected requirements for Product during the periods defined in Article 4.

1.4 "Product" as used herein shall mean oxycodone hydrochloride in bulk form and meeting the Specifications.

1.5 "Qualification Date" shall be the first day in January following the Effective date of this Agreement.

1.6 "Specifications" as used herein shall mean the material specifications set forth in Exhibit A, attached hereto and made a part hereof.

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1.7 "Territory" as used herein shall mean the United States.

1.8 "DMF" as used herein shall mean the file maintained by the U.S. Food and Drug Administration ("FDA"), which contains information submitted by NORAMCO with respect to and oxycodone hydrochloride, its composition, manufacture, and packaging.

ARTICLE 2.0 - MANUFACTURE, PURCHASE AND SALE

2.1 NORAMCO shall manufacture, supply, and sell Product to AMIDE and AMIDE shall order and purchase Product from NORAMCO, all in accordance with the terms and conditions of this Agreement.

2.2 AMIDE shall purchase and NORAMCO shall supply at least Seventy Five Percent (75%) of AMIDE's ANDA Commercial Requirements for Product during the term of this Agreement.

2.3 NORAMCO shall manufacture, process, test, label and package the Product in accordance with applicable national, state, and local laws and regulations, including, but not limited to, United States law, local laws, and regulations.

ARTICLE 3.0 - TERMS OF PURCHASE

3.1 The Base Price @ 2004 to be paid by AMIDE to NORAMCO for Product shipped after July 31, 2004 is:

a) July 31 through December 31, 2004

Volume Tier	Incremental Price Per Kilogram
0 to 125 kg	$5,000
126 to 250 kg	$4,500
251+ kg	$4,000

b) After January 1, 2005

Volume Tier	Incremental Price Per Kilogram
0 to 187 kg	$5,000
188 to 350 kg	$4,500
351+ kg	$4,000

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The "Incremental Price Per Kilogram" is the price paid for each kilogram purchased during a calendar year within the "Volume Tier". For example if AMIDE purchases 350 kilograms during a calendar year after January 1, 2005, the total purchase cost would be the sum of:

187 kilograms times $5,000 per kilogram = $935,000
163 kilograms times $4,500 per kilogram = $733,500

Total purchases for the 350 kilograms purchased during the calendar year would be $1,668,500 The average purchase price for the year would thus be $4,767.14 per kilogram.

3.2 The Base Price @ 2004, as provided above, shall be adjusted on January 1, 2005 and, thereafter, annually on January 1st of each year.

The Base Price @ 2004 of Oxycodone shall be adjusted as follows:

(Base Price 2004) times (Producer Price Index of December 31, 2004 divided by Producer Price as of December 31, 2003)

3.3 NORAMCO may change its process to manufacture oxycodone hydrochloride in order to change the Specification by reducing the 14 dihydrocodeinone impurity. This change would be expected to require AMIDE to qualify use of oxycodone hydrochloride produced by the new process with the FDA on a prior approval basis. If NORAMCO implements this process change with no increase of the oxycodone hydrochloride prices in Paragraph 3.1 of this Agreement, AMIDE will qualify oxycodone hydrochloride produced via the new process in SKUs sufficient to fulfill its requirements in Paragraph 2.2 of this Agreement. If NORAMCO implements this process change with an increase of the oxycodone hydrochloride prices in Paragraph 3.1 of this Agreement, AMIDE may decline to qualify oxycodone hydrochloride produced via the new process at the higher prices. If AMIDE so declines to qualify the new process, NORAMCO or AMIDE may terminate the Agreement with six months notice.

3.4 Beginning January 1, 2006, if Amide receives a written offer to supply at least 75% of its Commercial Requirements for a price that is more than five percent (5%) lower than Noramco's Base Price (as may be adjusted pursuant to Section 3.2) from a third party qualified by the DEA to manufacture oxycodone hydrochloride and holding a current Type II DMF on file with the FDA, then AMIDE may notify NORAMCO in writing of such lower price. Noramco will have the option of matching the third party supplier's price within thirty (30) days. If Noramco chooses not to match the third party supplier's price within thirty (30) days, then Amide has the option of terminating the Agreement.

3.5 Should NORAMCO be unable to supply AMIDE's requirements for Product during any period during the term of this Agreement, AMIDE shall be permitted to purchase its requirements of Product during such period from third parties without violating this Agreement.

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3.6 NORAMCO shall pay the freight charges from the place of shipment to AMIDE.

3.7 NORAMCO shall bill AMIDE for each order of Product delivered. AMIDE shall pay each invoice within forty five (45) days of receipt.

ARTICLE 4.0 - FORECASTS

4.1 AMIDE shall furnish to NORAMCO during the month of August of each calendar year a written projection of its Forecasted Requirements for the succeeding calendar year.

AMIDE shall also furnish to NORAMCO during the first calendar month of each quarter a written projection of its Forecasted Requirements of Product for each of the next twelve (12) months.

4.2 The parties acknowledge that the foregoing forecasts are estimates and shall not be binding upon AMIDE unless and until confirmed in AMIDE's written purchase order.

ARTICLE 5.0 - PRODUCT ORDERS

5.1 Product shall be ordered on AMIDE's standard purchase order form accompanied by the associated Drug Enforcement Administration ("DEA") Form 222, which shall specifically reference this Agreement. The terms and conditions contained in the purchase order, to the extent that they are inconsistent or in conflict with the provisions of this Agreement, are hereby superseded.

5.2 AMIDE shall issue written purchase orders to NORAMCO at least forty-five (45) days prior to the requested delivery date. AMIDE's purchase orders shall be firm orders and shall designate the desired quantity of Product, the delivery date, and any special shipping instructions. NORAMCO shall be required to supply such quantities ordered, provided said quantities for any calendar quarter are no greater than thirty-five percent (35%) of the Potential Requirements for the next twelve (12) months per Article 4.1.

ARTICLE 6.0 - DELIVERY

6.1 NORAMCO shall cause the Product to be shipped to AMIDE or its designate in the quantities specified in AMIDE's purchase orders. Delivery shall be F.O.B. the place of shipment. NORAMCO shall bear the expense and cost of putting each order of Product into the possession of the carrier. Risk of loss shall pass to AMIDE upon receipt by AMIDE.

6.2 Prior to shipment, NORAMCO shall cause each lot of Product comprising the shipment to be tested for conformance with the Specifications and shall furnish to AMIDE the results of such testing including, but not limited to, a Certificates of Analysis with each shipment.

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6.3 NORAMCO shall also furnish AMIDE with a Material Safety Data Sheet for the Product and shall timely furnish material updates to the Material Safety Data Sheet as they occur.

ARTICLE 7.0 - INSPECTION

7.1 Upon receipt of each order of Product, AMIDE shall inspect the order to ascertain that the shipment conforms to the order and that it contains the designated quantity of Product.

7.2 AMIDE shall notify NORAMCO in writing within sixty (60) days after receipt of the shipment of any claim of shortage. AMIDE's failure to make any such claim within such period shall constitute a waiver of such claim.

7.3 AMIDE shall notify NORAMCO in writing within thirty (30) days after discovery of any Product claimed to be non-conforming to Specifications. NORAMCO shall promptly replace, at no additional cost to AMIDE, any Product which fails to meet Specifications as to which a timely notification pursuant to this paragraph is provided to NORAMCO.

ARTICLE 8.0 - REGULATORY MATTERS

8.1 AMIDE shall be responsible for obtaining and maintaining during the term of this Agreement all necessary governmental registrations or approvals, including all appropriate state, province or local registrations or approvals as required, for the manufacture and marketing within the Territory of finished drug products incorporating Product supplied by NORAMCO hereunder.

8.2 NORAMCO shall maintain updated DMFs in the Territory with the appropriate governmental authorities. NORAMCO shall grant to AMIDE a right of reference to the DMFs on file in the Territory and shall provide information to AMIDE concerning the composition, manufacture and packaging of Product as may be required by governmental authorities to enable AMIDE to obtain and maintain governmental registrations or approvals for the manufacture and marketing in the Territory of finished drug products incorporating Product supplied by NORAMCO hereunder. Further, NORAMCO will notify AMIDE of any material changes in the DMF process prior to implementation as required by the FDA "Guidelines for Drug Master Files" Section VIIA and applicable FDA regulations. Such changes may include, but are not limited to, modifications in production, testing or packaging procedures.

8.3 AMIDE shall have the right, upon reasonable notice to NORAMCO and during regular business hours, to inspect and audit the facilities being used by NORAMCO for production of Product to assure compliance by NORAMCO with applicable rules and regulations and with other provisions of this Agreement. AMIDE will provide NORAMCO written observations. NORAMCO will respond in writing to these observations.

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8.4 NORAMCO shall notify AMIDE of the following within three (3) business days:

a) Initiation of an inspection by the DEA or the FDA when the inspection scope includes the Product.

b) Receipt of notice from the DEA or FDA of formal agency regulatory actions.

ARTICLE 9.0 - WARRANTIES AND INDEMNIFICATION

9.1 NORAMCO warrants that the Product at the time of delivery to the carrier shall:

a. conform to the Specifications;
b. not be adulterated within the meaning of the U.S. Federal Food, Drug and Cosmetic Act or any other applicable law;
c. be in compliance with all applicable federal, state, provincial, and local laws and regulations.

9.2 NORAMCO warrants that it will manufacture Product in compliance with all applicable federal, state, provincial, and local laws including, but not limited to, cGMPs as applied to bulk pharmaceutical chemicals as regulated by the FDA as well as all applicable NORAMCO Standard Operating Procedures during the term of this Agreement.

9.3 NORAMCO shall indemnify and hold AMIDE, its directors, officers, and employees harmless against any and all liability, loss, damage, loss, cost, or expense resulting from any third party claim made or suit brought against AMIDE to the extent such (i) arises out of a claim of infringement of any patent or the unauthorized use of a trade secret resulting from the manufacture, sale or use of the Product or (ii) arises out of the distribution, use, or sale of the Product to the extent such activities or occurrences result from the acts or omissions of NORAMCO and are beyond the control of AMIDE. Upon proper notice of any such claim or suit, AMIDE shall immediately notify NORAMCO thereof and shall permit NORAMCO at its cost to handle and control the defense of such claim or suit. AMIDE shall have the right to participate in the defense of such claim or suit at its own expense.

ARTICLE 10.0 - CONFIDENTIAL INFORMATION

10.1 In carrying out the terms of this Agreement it may be necessary that one party disclose to the other certain information which is considered by the disclosing party to be proprietary and of a confidential nature. As used herein "Confidential Information" shall mean any and all information, know-how and data, technical or non-technical concerning any finished drug product or bulk active pharmaceutical ingredient, its manufacture, marketing and sale, which is disclosed and reduced to writing under this Agreement as set forth below and which AMIDE or NORAMCO identify as proprietary and confidential. Confidential Information shall include, but shall not be limited to plans, processes, compositions, formulations, specifications, samples, systems, techniques, analyses, production and quality control data, testing data, marketing and financial data, and such other information or data relating to any finished drug product or bulk active pharmaceutical ingredient or its manufacture, marketing or sale.

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10.2 The receiving party shall not use the Confidential Information for any purpose other than for purposes of performing its obligations under this Agreement and shall divulge the information only to those of its employees who have a need to know it as a part of the receiving party's obligations hereunder and said employees shall hold the information in confidence pursuant to this Agreement. The receiving party shall not disclose Confidential Information to any third party without the written consent of the disclosing party.

10.3 The obligations of confidentiality as provided herein shall terminate five (5) years from the expiration or termination of this Agreement and shall impose no obligation upon the receiving party with respect to any portion of the received information which (i) was known to or in the possession of the receiving party prior to the disclosure; or (ii) is or becomes publicly known through no fault attributable to the receiving party; or (iii) is provided to the receiving party from a source independent of the disclosing party which is not subject to a confidential or fiduciary relationship with the disclosing party concerning the information; or (iv) is generated by the receiving party independently of any disclosure from the disclosing party; or (v) is required by law to be disclosed to government officials who shall be informed of the confidential nature of such information.

10.4 Upon expiration or earlier termination of this Agreement, the receiving party shall, as the disclosing party may direct in writing, either destroy or return to the disclosing party all Confidential Information disclosed together with all copies thereof, provided, however, the receiving party may retain one archival copy thereof for the purpose of determining any continuing obligations of confidentiality.

ARTICLE 11.0 - TERM AND TERMINATION

11.1 This Agreement shall commence September 7, 2004 ("Effective Date") shall continue for an initial term of five years after the Qualification Date. Thereafter this Agreement shall be automatically renewed for successive terms of one year each unless terminated as of the end of the initial term or any renewal term by written notice from either party to the other given at least one year prior to the expiration of such initial term or renewal term.

11.2 Either party may terminate this Agreement for material breach if such material breach is not cured by the breaching party within thirty (30) days following written notice of such breach from the non-breaching party or the breaching party is not continuing to make all reasonable efforts, with due diligence, to remedy such breach beyond said thirty (30) days. Any termination of this Agreement in accordance with this provision shall be effective as of the date of receipt by the breaching party of a written notice of termination from the non-breaching party.

11.3 Termination of this Agreement shall not affect any rights or liabilities that may have accrued prior to the effective date of termination.

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11.4 The rights and obligations with respect to indemnification as provided in Article 9.0 and of confidentiality as provided in Article 10.0 shall survive the expiration or termination of this Agreement.

11.5 Notwithstanding the termination of this Agreement for any reason, each party hereto shall be entitled to recover any and all damages other than consequential damages which such party shall have sustained by reason of the breach by the other party hereto of any of the terms of this Agreement. Termination of this Agreement for any reason shall not release either party hereto from any liability which at such time has already accrued or which thereafter accrues from a breach or default prior to such expiration or termination, nor affect in any way the survival of any other right, duty or obligation of either party hereto which is expressly stated elsewhere in this Agreement to survive such termination.

ARTICLES 12.0 - NOTICES

12.1 Any notice required or permitted to be given herein shall be deemed to have been sufficiently delivered to either party if given by telephone, telex, or cable and confirmed by registered mail, postage prepaid, addressed as follows:

If to AMIDE: AMIDE Pharmaceuticals, Inc
101 East Main Street
Little Falls, New Jersey 07424
Attention: President with copy to Counsel

If to NORAMCO: NORAMCO, Inc.
500 Swedes Landing Road
Wilmington, DE 19801
Attention: Vice President Worldwide Bulk Analgesics

12.2 Either party may from time to time by notice served as set forth above designate a different address or a different or additional person to which all such notices or communications hereafter are to be given.

ARTICLE 13.0 - LEGAL REQUIREMENTS

13.1 All actions to be taken by the parties under this Agreement shall be taken in full compliance with all applicable laws and governmental regulations and the provisions of this Agreement shall be so construed to effectuate such compliance.

13.2 Anything herein to the contrary notwithstanding, neither party hereto shall be obligated to do any act pursuant to any provisions of this Agreement, when to do so would be inconsistent with any law, rule, ruling, regulation or order of any duly constituted governmental body having jurisdiction over either party.

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13.3 If any provision of this Agreement is determined to be illegal or unenforceable or incapable of construction consistent with legal or regulatory requirements, the enforceability of the other provisions of this Agreement shall not be affected and the parties will cooperate in agreeing upon some other method of performance which is consistent with the purposes and intents of this Agreement.

ARTICLE 14.0 - RELATIONSHIP OF THE PARTIES

14.1 Nothing contained in this Agreement shall be deemed to create a partnership or joint venture between the parties, and each of the parties shall be an independent contractor in all matters connected herewith. Except as expressly provided herein, neither of the parties hereto shall hold itself out as the agent of the other, nor shall either of the parties incur any indebtedness or obligation in the name of, or shall be binding on the other, without the prior written consent of the other.

ARTICLE 15.0 - DISPUTE RESOLUTION

15.1 The parties shall amicably discuss and negotiate any issues that are not specifically set forth herein. If any dispute should arise between the parties with respect to this Agreement, the parties shall first negotiate in good faith in an attempt to resolve such dispute prior to bringing any legal action.

15.2 In the event that a controversy or claim arising out of or relating to this Agreement cannot be amicably resolved by good faith negotiation between the parties, it shall be resolved by arbitration before a single arbitrator in accordance with the Commercial Arbitration Rules of the American Arbitration Association ("AAA") then pertaining (available at www.adr.org), except where those rules conflict with this provision, in which case this provision controls. Any court with jurisdiction shall enforce this clause and enter judgment on any award. The arbitrator shall be selected within twenty business days from commencement of the arbitration from the AAA's National Roster of Arbitrators pursuant to agreement or through selection procedures administered by the AAA. Within 45 days of initiation of arbitration, the parties shall reach agreement upon and thereafter follow procedures, including limits on discovery, assuring that the arbitration will be concluded and the award rendered within no more than eight months from selection of the arbitrator or, failing agreement, procedures meeting such time limits will be designed by the AAA and adhered to by the parties. The arbitration shall be held in New Jersey and the arbitrator shall apply the substantive law of New Jersey, except that the interpretation and enforcement of this arbitration provision shall be governed by the Federal Arbitration Act. Prior to commencement of arbitration, emergency relief is available from any court to avoid irreparable harm. The arbitrator shall not award either party punitive, exemplary, multiplied or consequential damages or attorney's fees or costs.

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Prior to commencement of arbitration, the parties must attempt to mediate their dispute using a professional mediator from AAA, the CPR Institute for Dispute Resolution, or like organization selected by agreement or, absent agreement, through selection procedures administered by the AAA. Within a period of 45 days after the request for mediation, the parties agree to convene with the mediator, with business representatives present, for at least one session to attempt to resolve the matter. In no event will mediation delay commencement of the arbitration for more than 45 days absent agreement of the parties or interfere with the availability of emergency relief.

ARTICLE 16.0 - FORCE MAJEURE

16.1 Neither party shall be considered in default or be liable to the other for any delay or failure in performance of any of its obligations hereunder if caused by circumstances beyond the control of the party, including but not limited to Acts of God, fire, civil unrest, strike, disruption utilities or other public services, flood, war, order of any court, or other causes which cannot be controlled by the party who failed to perform. Each party shall promptly notify the other should such circumstances occur and shall promptly take steps to remedy any delay or failure in performance upon removal of the circumstances causing such delay or failure.

ARTICLE 17.0 - WAIVER

17.1 The waiver by either party of a breach of any provisions of this Agreement shall not operate or be construed as a waiver of any subsequent breach.

ARTICLE 18.0 - ASSIGNMENT

18.1 This Agreement may not be assigned by either party without the prior written consent of the other which consent shall not be unreasonably withheld. Notwithstanding the foregoing, either NORAMCO or AMIDE may assign its rights and/or obligations hereunder to any of its Affiliates or in connection with any sale of the business to which this Agreement relates.

ARTICLE 19.0 - AMENDMENTS

19.1 No changes in or additions to this Agreement shall be binding unless specifically agreed to in writing and signed by the duly authorized representatives of the parties.

ARTICLE 20.0 - GOVERNING LAW

20.1 This Agreement and the rights and obligations of the parties hereto shall be governed by and construed in accordance with the internal substantive laws of the State of New Jersey, USA without giving effect to choice of law principles.

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ARTICLE 21.0 - ENTIRE AGREEMENT

21.1 This Agreement constitutes the complete and exclusive statement of the agreement between the parties and supersedes all proposals, oral or written, and all other communications between the parties relating to the subject matter of this Agreement.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed in duplicate by their duly authorized representatives as of the day and year first above written.

NORAMCO , Inc.	AMIDE Pharmaceutical, Inc.
By: Michael B Kindergan 9/7/04	By:
Name :Michael B. Kindergan	Name: Divya C. Patel
Title: Vice President Bulk Analgesics	Title: President

EXHIBIT 10

G001/3002

SUPPLY AGREEMENT

THIS SUPPLY AGREEMENT (this "Agreement") is made and entered into effective on and as of January 1, 2008, by and between Mallinckrodt Inc., a Covidien company ("Mallinckrodt"), and Cephalon Inc., 41 Moores Road, Frazer, PA 19355 (together with its affiliates and wholly owned subsidiaries Anesta Corporation and Cima Labs, "Cephalon").

WHEREAS, Cephalon has need of a certain bulk compound known as Fentanyl Citrate USP Mallinckrodt Code 1205 and or Code 1333 (hereinafter "Product") and is desirous of having Product manufactured by Mallinckrodt and of purchasing a substantial portion of its needs for the Product from Mallinckrodt, on the terms and conditions set forth herein; and

WHEREAS, Mallinckrodt is capable and desirous of undertaking the supply of Product for Cephalon in accordance with the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the promises, covenants and representations of the parties set forth herein, and other good and sufficient consideration receipt of which is hereby acknowledged, Cephalon and Mallinckrodt agree as follows:

1. Supply of Product.

(a) For the consideration provided herein and in accordance with all terms, conditions, representations, warranties and covenants set forth herein, and for the term hereof, Mallinckrodt shall provide Cephalon with such amounts of Product as Cephalon shall request. Cephalon, for its part, agrees that it shall purchase from Mallinckrodt, during every Contract Year during the term hereof, at least thirty percent (30%) of its requirements for Product; provided that and notwithstanding the immediately foregoing, for any Contract Year occurring after the Contract Year in which Cephalon receives approval from the U.S. Food and Drug Administration ("FDA") for its new drug application for the dosage pharmaceutical product known as Fentora®, Cephalon agrees that it shall purchase from Mallinckrodt up to forty percent (40%) of its requirements for Product. For purposes of the immediately preceding sentence and this Agreement in general, "Contract Year" shall mean and refer to each consecutive twelve (12) month period during the term hereof coinciding with calendar years. All Product supplied hereunder shall be manufactured by Mallinckrodt in accordance with current Good Manufacturing Practices ("cGMP") as determined by the FDA using the manufacturing process described in Mallinckrodt's batch records and the Drug

Master File for Product. If and as applicable, Mallinckrodt shall comply with the cGMP-equivalent requirements of those countries listed on Schedule A if and as Cephalon reasonably requests.

(b) The release specifications for the Product are described on Schedule B attached hereto (the "Specifications"), and such Specifications shall not be changed without a written amendment to this Agreement.

2. Raw Materials.

Subject to the provisions of Section 4 below, all raw materials and other resources required in connection with the manufacture and supply of the Product to be supplied hereunder shall be provided by Mallinckrodt at its cost and expense.

3. Quality Control.

(a) Mallinckrodt shall take all steps reasonably necessary to ensure that it has the facilities, equipment, instrumentation, resources and trained personnel to provide all raw materials, in-process and product assays, analysis and other testing including preparing, submitting and maintaining a Drug Master File for Product. Mallinckrodt shall provide a complete certificate of analysis for each lot of finished Product supplied hereunder at the time of shipment.

(b) Mallinckrodt shall maintain complete and accurate documentation of all validation data, stability testing data, batch records, quality control and laboratory testing and any other data required under cGMP or other FDA requirements.

(c) Mallinckrodt shall not engage in any act which causes any packaged and labeled Product manufactured by Mallinckrodt to become adulterated or misbranded within the meaning of the United States Federal Food, Drug and Cosmetic Act of 1938, as amended from time to time (the "FDCA"), and agrees that such Product shall not be adulterated or misbranded, within the meaning of the FDCA, when the Product is delivered to Cephalon.

(d) Mallinckrodt shall inform Cephalon of any changes related to any of the Drug Master Files related to the Product per the FDA's "Guidance for Industry" relevant to an NDA or ANDA. Pending agreement on the timing of implementation of any such changes, Mallinckrodt

agrees to continue to manufacture and supply to Cephalon unmodified Product under the terms and conditions of this Agreement; provided that, if any such changes are compendial changes or are required by government regulations Mallinckrodt will implement such changes after consultation with Cephalon but as and when Mallinckrodt deems reasonably necessary and the parties will in good faith discuss an appropriate transition plan relative to such changes to protect the interests of both parties to the extent possible under applicable circumstances, including but not limited to ensuring that delivery dates are not compromised by any Mallinckrodt implementation schedule.

(e) Mallinckrodt shall retain under proper storage conditions such samples of the Product as are required to comply with the stability sections of the Drug Master File for the Product. Mallinckrodt acknowledges and agrees that Cephalon is entitled to copies of all test specifications and methods as well as analytical methods validation documentation for Cephalon's files.

(f) In addition to the foregoing and in furtherance thereof, the parties agree to follow the quality procedures outlined in any Quality Agreement to be attached hereto. The final form of the Quality Agreement shall be negotiated by the parties in good faith, shall become a part of this Agreement and shall be attached hereto as Schedule C upon its execution. Notwithstanding any other provision hereof, in the event of any conflict or inconsistency between the terms of this Agreement and the terms of any Quality Agreement, the former shall prevail.

4. Compensation for Services Performed by Mallinckrodt.

(a) Cephalon shall pay Mallinckrodt, for Product to be produced and delivered in any particular Contract Year during the term hereof, the amount as follows ("Product Prices"):

(i) fifty dollars ($50.00) per gram during any Contract Year in which an amount of less than twenty (20) kilograms of Product is purchased and delivered, and

(ii) thirty six dollars ($36.00) per gram during any Contract Year in which the amount of Product purchased and delivered is greater than or equal to twenty (20) kilograms.

The Product Prices above shall apply to every gram purchased during any relevant Contract Year so long as the respective threshold amount of Product is purchased. The Product Prices set forth above shall be firm through the end of the second Contract Year (i.e.., the Contract Year ending on December 31, 2009), the date of December 31, 2009 being hereafter referred to as the "Adjustment Date". From and after the Adjustment Date, the Product Prices shall be adjusted upward to reflect increases in the cost to Mallinckrodt of all raw materials, directly associated regulatory compliance costs and all directly allocated labor (all of which costs are hereinafter referred to as "Product Costs"), in accordance with the following procedures. Within fifteen (15) days after the end of each Contract Year hereunder during the term hereof, Mallinckrodt will notify Cephalon in writing of the amount by which its Product Costs hereunder have increased during the immediately preceding Contract Year period and the adjusted Product Price to be charged for the Contract Year just commenced as a consequence of such increases ("Annual Adjustment Notice"). The amount of any increase in the Product Price (which is limited to no more than five percent (5%) for any single Contract Year) as set forth in any Annual Adjustment Notice shall be effective for all Product invoiced by Mallinckrodt to Cephalon in accordance herewith during the Contract Year for which such Annual Adjustment Notice is issued.

(b) At the time of shipment by Mallinckrodt to Cephalon of any lot of Product hereunder, Mallinckrodt shall submit to Cephalon an invoice setting forth the total amount of Product being shipped to Cephalon and the amount due to Mallinckrodt under Section 4(a), such amount due to Mallinckrodt to be calculated utilizing the Product Price related to the total estimated quantity of Product to be purchased and delivered during the then current Contract Year based on the most recent forecast submitted by Cephalon to Mallinckrodt pursuant to Section 5(a) below. Each such invoice shall also contain a certification that the Product for which Cephalon is being billed has been manufactured fully in conformance with applicable Specifications, cGMP and the requirements hereof. Any such invoice shall be payable by Cephalon within thirty (30) days after Cephalon's receipt of such invoice.

(c) If, at the end of any given Contract Year, the actual quantity of Product purchased and delivered in such Contract Year is such that the Product Price charged during the Contract Year requires adjustment based on the criteria set forth in Section 4(a) above, then within thirty (30) days after the end of such Contract Year, Mallinckrodt will issue a reconciling invoice setting forth either the additional amount due to Mallinckrodt or the overpayment made by Cephalon relative to such Contract Year. Any amount due by Cephalon on the reconciling invoice

shall be payable by Cephalon within thirty (30) days after receipt of such invoice. Any amount due to Cephalon on the reconciling invoice shall be payable by Mallinckrodt within thirty (30) days after receipt of such invoice.

(d) If during the term of this Agreement any government of a country in which Cephalon sells a dosage form of Product establishes a maximum price for any such dosage form, Mallinckrodt and Cephalon shall meet to discuss a mutually acceptable solution to Cephalon's market needs on the basis of documented evidence. In addition, the parties agree that should unanticipated or changed commercial or regulatory conditions cause either or both parties to experience economic hardship in connection with the performance of its or their obligations under the terms of this Agreement, the parties shall meet and attempt to reach agreement in good faith an equitable resolution of that hardship.

(e) Notwithstanding Section 4(a) set forth above, Cephalon shall have the right (through any independent agents or representative that are reasonably acceptable to Mallinckrodt and upon advance written notice to Mallinckrodt) from time to time during the existence of this Agreement and for a period of thirty (30) days after the termination or expiration hereof, but no more often than annually, to audit the books and records of Mallinckrodt to determine whether or not the amounts invoiced by Mallinckrodt to Cephalon in accordance with this section 4 are accurate and in particular (without limitation) whether or not the Product Costs reflected in any Annual Adjustment Notice have been reported and invoiced correctly by Mallinckrodt. In the event that, as consequence of any such audit or examination, Cephalon reasonably disagrees with any amounts invoiced by Mallinckrodt, Cephalon shall inform Mallinckrodt in writing and in reasonable detail of the amounts to be refunded and, unless and to the extent Mallinckrodt disputes the amounts set forth by Cephalon in any such notice, Mallinckrodt will refund to Cephalon any such undisputed amounts within twenty (20) days of the receipt of any such notice from Cephalon. In the event Mallinckrodt does dispute all or any portion of any refund claimed by Cephalon, Mallinckrodt will so notify Cephalon with such twenty (20) day period and the parties will attempt thereafter to resolve such dispute amicably and, if they cannot do so, the matter will be referred to an independent accounting firm acceptable to both Mallinckrodt and Cephalon, and the decision of such firm as to any Product Price adjustments or reimbursements to be made shall be final and binding on the parties, both as to the resolution of the dispute and the allocation of responsibility for the fees and expenses of such firm. Furthermore, if the prices Mallinckrodt charges are incorrect by more than five percent (5%) then Mallinckrodt shall be responsible for all associated audit fees by

the independent accounting firm, otherwise the expenses of such firm shall be for the account of Cephalon.

5. Forecasts, Order Placement and Delivery.

(a) Cephalon shall submit to Mallinckrodt, in writing and on or before the fifteenth (15th) day of every month during the term hereof, a forecast of the anticipated amounts of its orders for each Product hereunder during each of the next twelve (12) months. The forecast for the first three (3) months of that period will be considered to be firm and binding. The forecast for the last nine (9) months of that period will be non-binding and will be used by Mallinckrodt for production planning, but in all circumstances Cephalon shall act in good faith and with reasonable care to submit forecasts for Product which are as accurate as possible under the circumstances.

(b) Product shall be ordered by Cephalon only by written purchase order. Mallinckrodt shall not accept verbal orders of any kind for the production of Product. Any written purchase order will contain the following information: (i) the precise quantity of each Product desired, (ii) dates by which the ordered Product must be received, (iii) the anticipated shipping destination for any Product and (iv) such other information as Cephalon wishes to provide or that Mallinckrodt might find necessary or useful in completing a specific purchase order.

(c) Product shall be delivered F.C.A. by Mallinckrodt to the destination specified by Cephalon. Title to Product and risk of loss shall remain with Mallinckrodt until delivery to the destination specified by Cephalon in its purchase order at which time risk of loss and responsibility for the Product will transfer to Cephalon. Mallinckrodt shall be responsible to make such arrangements regarding the shipping of Product to such specified destinations as Cephalon shall reasonably request, all such shipping to be at Cephalon expense. Cephalon shall be responsible for any and all taxes or similar assessments that may be assessed with respect to any order for Product.

(d) If Mallinckrodt is unable to ship any quantity of Product ordered by Cephalon within sixty (60) days after the scheduled shipping date, regardless of the reason, then Cephalon will be permitted to purchase the same quantity of Product of like grade and quantity from another supplier on this occasion, and the amount of Product so purchased by Cephalon shall not be

considered as part of Cephalon's requirements for Product for the purpose of determining whether Cephalon has met its purchase obligation for any Contract Year as set forth in Section 1(a).

6. Acceptance and Rejection and Recalls.

(a) If Cephalon reasonably determines that any Product is defective in material or workmanship, not in conformance with applicable Specifications, is adulterated or misbranded, or is otherwise not in conformity with this Agreement (Product meeting any or all of such circumstances hereinafter referred to as "Defective Product"), then Cephalon, in addition to any other rights it may have under this Agreement, may reject and return the Defective Product to Mallinckrodt. At the time of any such rejection, Cephalon shall provide Mallinckrodt with a written notice describing in detail the circumstances surrounding the rejection and Cephalon's reasons therefor. If Mallinckrodt does not agree that Cephalon acted properly in rejecting Product, Mallinckrodt shall notify Cephalon in writing with twenty (20) days after Mallinckrodt receipt of any rejection notice from Cephalon, and if Mallinckrodt fails to notify Cephalon, Cephalon's rejection of product shall be deemed to be proper and such Product will be considered Defective Product for all purposes hereof. If Mallinckrodt does timely notify Cephalon of its disagreement, the parties will attempt to reach a mutually acceptable resolution of their differences within thirty (30) days of Mallinckrodt's notice to Cephalon. If the parties are unable to reach a resolution within such time frame, the matter will be submitted to an independent testing laboratory reasonably acceptable to both parties and both parties will accept as final the decision of such laboratory as to whether any given Product was properly rejected. If the parties or the independent laboratory (as applicable) determine that any given volume of Product was properly rejected by Cephalon, then Cephalon will, at Mallinckrodt's option, either return Defective Product to Mallinckrodt or destroy or dispose of it in the least expensive and most environmentally sound manner, and in any event, Mallinckrodt will be responsible for the costs of any such return, destruction or disposal. It is understood that Cephalon's sole remedies (in addition to destruction or disposal of the defective Product at Mallinckrodt's cost in accordance with the immediately proceeding sentence) in the event of Defective Product it has properly rejected will, at Cephalon's sole option, either be (i) the replacement by Mallinckrodt of rejected Product that has been returned or destroyed with Product that is not Defective Product or (ii) a full refund of any amount paid hereunder by Cephalon for such Defective Product. If the parties or the independent laboratory (as applicable) determine that any given product was not properly rejected, such product shall be deemed to have been accepted by Cephalon and Cephalon will promptly pay the full invoiced Product Price, if not already paid.

The costs and expenses of the independent testing laboratory shall be for the account and expense of the party whose judgment was not in correct as to whether Product was properly rejected.

(b) Any Product received by Cephalon from Mallinckrodt that has not been rejected by Cephalon within thirty (30) days after receipt shall be deemed to have been accepted, except where such Product contains a nonconformity that could not have been discovered by reasonable inspection, in which case Cephalon shall have an additional sixty (60) days after it discovers such nonconformity within which to reject such Product according to the procedure set forth in Section 6(a) above.

(c) If Cephalon reasonably decides to or is required to initiate a product recall, withdrawal or field correction with respect to, or if there is any governmental seizure of, its product containing any Product supplied hereunder, Cephalon shall notify Mallinckrodt promptly of the details regarding such action, including providing copies of all relevant documentation concerning such action. Mallinckrodt shall fully cooperate with and assist Cephalon in investigating any such situation and all regulatory contacts that are made and all activities concerning seizure, recall, withdrawal or field correction will be jointly coordinated by Cephalon and Mallinckrodt. The costs of the activities in this Section 6(d) shall be apportioned as set forth below in Section 6(d).

(d) If any such recall, withdrawal, field correction or seizure occurs due solely to (i) a failure of any Product sold by Mallinckrodt hereunder to conform to applicable Specifications (including, without limitation, it being adulterated or misbranded or is otherwise not in conformity with this Agreement) or any warranty or other requirement set forth in this Agreement, (ii) the failure by Mallinckrodt to comply in all material respects with any applicable law, rule, regulation, standard, court order or decree or (iii) the negligent, reckless or intentional wrongful act or omission of Mallinckrodt in connection with the manufacture of any Product hereunder, then Mallinckrodt shall bear the full cost and expense of any such seizure, recall, withdrawal or field correction. If any such recall, withdrawal, field correction or seizure occurs due solely to (A) any pharmaceutical product manufactured, sold or distributed by Cephalon that contains Product failing to conform to its applicable specifications for reasons other than those set forth in clause (i) above, (B) the failure of Cephalon to comply in all material respects with any applicable law, rule, regulation, standard, court order or decree or (C) the negligent, reckless or intentional wrongful act or omission of Cephalon, then Cephalon shall bear the full cost and expense of any such seizure, recall, withdrawal or field correction. If both Mallinckrodt and Cephalon contribute to the cause of a seizure, recall,

withdrawal or field correction, the cost and expenses thereof will be shared in proportion to each party's contribution to the problem.

7. Regulatory Compliance.

(a) Mallinckrodt shall comply in all material respects with all federal, state and local laws and regulations applicable to Mallinckrodt and the performance of its obligations hereunder.

(b) Mallinckrodt shall promptly furnish Cephalon with pertinent portions of all FDA and/or any foreign equivalent inspection reports and related correspondence directly related to and affecting its performance hereunder as and when such reports and correspondence become available to Mallinckrodt.

(c) Mallinckrodt shall notify Cephalon immediately of any warning (including any FDA Form 483), citation, indictment, claim, lawsuit or proceeding issued or instituted by any federal, foreign, state, local or foreign governmental entity or agency against Mallinckrodt or any of its affiliates or of any revocation of any license or permit issued to Mallinckrodt or any of its affiliates, to the extent that any such occurrence relates directly to Mallinckrodt's performance hereunder. Mallinckrodt shall promptly provide Cephalon with copies of the relevant portions of any documents or a written summary of any oral observations received by Mallinckrodt in connection with the matters set forth in this Section 7(c).

8. Adverse Event Reporting.

(a) Serious Adverse Events (as defined below in Section 8(b)) for the Product of which either party becomes aware shall be submitted to the other party within three (3) business days but no later than five (5) calendar days after the date the first-mentioned party first became aware of such Serious Adverse Event. Non-Serious Adverse Events (as defined below in Section 8(b)) for the Product that are reported to one party shall be submitted to the other party no more than one (1) month from the date received by the first mentioned party; *provided, however*, that medical and scientific judgment should be exercised in deciding whether expedited reporting is appropriate in other situations, such as important medical events that may not be immediately life-threatening or

result in death or hospitalization but may jeopardize the patient or may require intervention to prevent a Serious Adverse Event outcome.

(b) A "Serious Adverse Event" for the Product is defined as any untoward medical occurrence that at any dose for the Product (i) results in death, (ii) is life threatening, (iii) requires inpatient hospitalization or prolongation of existing hospitalization, (iv) results in persistent or significant disability/incapacity, (v) results in a congenital anomaly/birth defect, (vi) results in drug dependency or drug abuse, (vii) results in a cancerous condition, or (viii) is an overdose. A "Non-Serious Adverse Event" for the Product is defined as an untoward medical occurrence at any dose for the Product that is not a Serious Adverse Event.

(c) Mallinckrodt shall report all such Serious and Non-Serious Adverse Events involving the Product learned by it to:

Cephalon, Inc.
4745 Wiley Post Way
Salt Lake City, Utah 84116
Attn: Quality Department

(d) Cephalon shall report all such Serious and Non-Serious Adverse Events involving the Product learned by it to:

Mallinckrodt Inc.
c/o Pharmaceuticals Group
675 McDonnell Boulevard
Hazelwood, Missouri 63042
Attn: Nick Litzsinger
Global Business Director Bulk Narcotics

(e) All medical inquiries concerning the Product shall be handled by Cephalon's Medical Affairs Group. Mallinckrodt shall refer all routine medical information requests in writing to Cephalon as set forth in Section 8(c). Urgent medical information requests shall be referred by Mallinckrodt by telephone to (800) 896-5855.

9. Representations, Warranties and Covenants of Mallinckrodt.

(a) Mallinckrodt represents and warrants that all Product sold hereunder shall:

(i) be manufactured and packaged in compliance with cGMPs (including foreign equivalents thereof with respect to jurisdictions listed on Schedule A) applicable to the Product,

(ii) meet all applicable Specifications at the time the Product is delivered to Cephalon and (if properly stored and handled by Cephalon) during its shelf life; and

(iii) if properly stored and handled by Cephalon, have a minimum shelf life of two (2) years at the time the Product is delivered to Cephalon.

(b) Mallinckrodt represents and warrants to its knowledge, that the manufacture, use, export, importation or sale of the Product pursuant to this Agreement in its bulk form does not infringe, misappropriate or otherwise conflict with any intellectual property rights of any third party.

(c) Mallinckrodt represents and warrants that there is no claim, suit, proceeding or investigation pending or, to the knowledge of Mallinckrodt, threatened against Mallinckrodt or any of its affiliates which might prevent or interfere with Mallinckrodt's performance under this Agreement.

(d) Mallinckrodt represents and warrants to Cephalon that Product sold hereunder by Mallinckrodt shall not be:

(i) in violation of Sections 5 or 12 of the Federal Trade Commission Act or improperly labeled under applicable Federal Trade Commission Trade Practice Rules, or other similar foreign laws (for the countries set forth on Schedule A), as and to the extent applicable hereunder,

(ii) adulterated or misbranded within the meaning of the FDCA, as amended, or within the meaning of any applicable state or municipal law in which the definitions of adulteration and misbranding are substantially identical with those contained in the FDCA at the time the Product is delivered to Cephalon, or articles which may not under the provisions of Sections 404 or 505 of said Act be introduced into interstate commerce or which may not under substantially similar provisions of any state or municipal law be introduced into commerce,

(iii) manufactured or sold in violation of the federal Controlled Substances Act, as amended, or any similar legislation in the counties set forth on Schedule A, or applicable state law,

(iv) manufactured in violation of any applicable federal, state or local environmental law or regulation, or

(v) manufactured in violation of any agreement (commercial or otherwise), judgment, order or decree to which Mallinckrodt is a party.

(e) Mallinckrodt certifies that neither it nor any of its affiliates nor any member of their staff has been disqualified or debarred by the FDA or any other domestic regulatory authority, or any other applicable regulatory agency, for any purpose.

(f) Mallinckrodt warrants and represents that neither it nor any of its affiliates nor any member of their staff have been charged with or convicted under federal law for conduct relating to the development or approval, or otherwise relating to the regulation of any drug product under the Generic Drug Enforcement Act of 1992 or any other relevant statute, law or regulation.

(g) EXCEPT AS SET FORTH IN THIS SECTION 9 OR SPECIFICALLY SET FORTH ELSEWHERE IN THIS AGREEMENT, MALLINCKRODT MAKES NO OTHER WARRANTY OR REPRESENTATION, EXPRESS OR IMPLIED, CONCERNING ITS PERFORMANCE HEREUNDER, INCLUDING ANY WARRANTY OF MERCHANTABILITY

OR FITNESS FOR A PARTICULAR PURPOSE, WHICH WARRANTIES ARE HEREBY EXPRESSLY DISCLAIMED.

(h) Mallinckrodt hereby represents and warrants that it has all rights and licenses necessary to manufacture and sell the Product to Cephalon.

10. Facility Access.

Cephalon, through its employees, consultants or other representatives, will have the right during normal business hours and upon advance arrangement with Mallinckrodt to inspect Mallinckrodt's relevant manufacturing operations to determine whether or not Mallinckrodt is complying in all respects with its obligations hereunder. Cephalon agrees that all such inspections and audits shall be carried out in a manner calculated not to unreasonably interfere with Mallinckrodt's conduct of business and to ensure the continued confidentiality of Mallinckrodt's business and technical information. Further, Cephalon agrees to comply with all of Mallinckrodt's safety and security requirements during any visits to the Mallinckrodt facilities. Following an inspection by the FDA or any other applicable regulatory authority that will in any way affect the production of Product for supply to Cephalon, Mallinckrodt shall notify Cephalon in writing of any material issues that may be pertinent to the supply of Product(s) to Cephalon. The parties agree to cooperate in good faith and engage in active dialogue in an effort to resolve any issues resulting from any such inspections.

11. Force Majeure

Neither party to this Agreement shall be liable for or be in breach of any provision hereof for any failure or delay on its part to perform any obligation (other than the obligation to make payments when due) under any provision of this Agreement because of an event of "force majeure", including, but not limited to, any act of God, fire, flood, explosion, unusually severe weather, war, acts of terrorism, insurrection, riot, sabotage, labor unrest, strikes or work stoppages or any other cause whatsoever, whether similar or dissimilar to those enumerated herein, beyond any reasonable possibility of control of such party, if and only if the party affected shall have used all reasonable efforts under the circumstances to avoid such occurrence and to remedy it promptly if it shall have occurred. If an event of force majeure causes a failure or delay in performance hereunder by Mallinckrodt for more than one hundred eighty (180) continuous days, Cephalon, at

its option, may (i) terminate this Agreement effective upon written notice to Mallinckrodt or (ii) may extend the delivery or performance period by the amount of time during which such delivery or performance was omitted or delayed.

12. Relationship of parties

For all purposes hereof, Mallinckrodt shall be deemed to be an independent contractor and this Agreement shall not create an agency, partnership, joint venture, or employer/employee relationship between Cephalon and Mallinckrodt, and nothing hereunder shall be deemed to authorize either party hereto to act for, represent or bind the other or any of its affiliates except as expressly provided in this Agreement.

13. Confidentiality

(a) Each party shall maintain in confidence and not use or disclose to any third party, except as is specifically contemplated in this Agreement, and then only on a confidential basis satisfactory to both parties, any proprietary or confidential information of the other party, including (without limitation) business and technical information, experience or data regarding any facility, programs, laboratories, processes, products, costs, equipment operation or customers, relating to the manufacture or sale of Product hereunder. The foregoing obligations of confidentiality and non-use shall survive the termination or expiration of this Agreement for a period of five (5) years. Nothing herein shall prevent either party from disclosing any information required by statute or governmental regulations to be disclosed in a judicial or administrative proceeding after all reasonable legal remedies for maintaining such information in confidence have been practically exhausted or from using information which (i) has been published or has become part of the public domain other than by acts, omissions or fault of such party, (ii) was lawfully received by such party from a third party free of any obligation of confidence to such third party, (iii) a party can demonstrate from its records was already in its possession prior to receipt thereof, directly or indirectly, from the other party, or (iv) is independently developed by employees, agents or independent contractors of the receiving party or its affiliates without reference to or reliance upon the information furnished by the disclosing party, as evidenced by written records or other competent proof. The party asserting the applicability of one of the exclusions from the obligation of confidentiality set forth in the immediately preceding sentence shall have the burden of proving the applicability of any such exclusion in any particular circumstance.

(b) Each party acknowledges that any breach by it of the confidentiality obligations set forth in this Section 13 would cause the other party irreparable harm for which compensation by monetary damages would be inadequate and, therefore, the party that has been harmed by any such breach shall have the right to an injunction or decree for specific performance, in addition to any other rights and remedies such party may have at law or in equity.

(c) The receiving party shall also be entitled to disclose the other party's confidential information (i) that is required to be disclosed in compliance with applicable laws or regulations (including, without limitation, to comply with SEC, NASDAQ or stock exchange disclosure requirements) or by order of any governmental body or a court of competent jurisdiction, (ii) as may be necessary or appropriate in connection with the enforcement of this Agreement by judicial or other similar process or (iii) as may be necessary for the conduct of clinical studies, *provided* that the party disclosing such information shall promptly notify the other party and shall use commercially reasonable efforts to obtain confidential treatment of such information by the agency or court or other disclosee, and that, in the case of disclosures under clause (i), shall (A) provide the other party with prompt prior notice of the proposed disclosure such that the other party may seek a protective order or other appropriate remedy and (B) provide the other party with a copy of the proposed disclosure in sufficient time to allow reasonable opportunity to comment thereon.

(d) Nothing in this Section 13 shall be construed to create or imply any right or license under any patent rights, trademarks, copyrights or other intellectual property rights owned or controlled by a party or its affiliates except as may be expressly set forth in the other Sections of this Agreement.

(e) To the extent that any confidentiality obligations set forth in this Section 13 are the same or substantially the same as the confidentiality obligations set forth in a separate confidentiality agreement between the parties pertaining to the subject matter herein, the confidentiality obligations set forth in this Section 13 shall supercede such confidentiality agreement, shall govern any and all information disclosed by either party to the other pursuant thereto and shall be retroactively effective to the date of such confidentiality agreement.

14. Indemnification.

(a) Subject to the provisions of Sections 14(b) and 14(c), Mallinckrodt (on behalf of itself and its affiliates) hereby agrees to indemnify, defend and hold harmless Cephalon and its affiliates from and against any and all demands, claims, actions, causes of action, assessments, losses, damages, injuries, liabilities, costs and expenses, including without limitation, interest, penalties and reasonable attorneys' fees and expenses (collectively "Claims") resulting from, imposed upon or incurred by Cephalon or its affiliates, directly or indirectly related to, arising out of or resulting from third party claims in connection with:

(i) any breach or failure of any of the representations, warranties and covenants of Mallinckrodt contained herein, including (without limitation) any breach or failure by Mallinckrodt to perform any obligations contained herein, and

(ii) any failure of Mallinckrodt to observe or comply in all respects with any applicable laws, rules or regulations directly related to Mallinckrodt's performance hereunder.

(b) Subject to the provisions of Sections 14(a) and 14(c) hereof, Cephalon hereby agrees to indemnify, defend and hold harmless Mallinckrodt and its affiliates from and against any and all Damages asserted against, resulting to, imposed upon or incurred by Mallinckrodt, directly or indirectly related to, arising out of or resulting from third party claims in connection with:

(i) any failure of Cephalon to observe or comply in all respects with any applicable laws, rules or regulations directly related to Cephalon's performance hereunder, and

(ii) Cephalon's or Cephalon's agent's, distributor's or customer's use, processing, transportation, possession, disposal or sale of any dosage product manufactured by or for Cephalon that contains Product, and whether used alone or in combination with any other material.

(c) EXCEPT FOR ANY CLAIM FOR INDEMNITY UNDER SECTION 14(b)(ii) ABOVE, UNDER NO CIRCUMSTANCES SHALL EITHER PARTY BE LIABLE HEREUNDER FOR CONSEQUENTIAL, INDIRECT, EXEMPLARY OR SPECIAL DAMAGES OR ANY KIND (INCLUDING, WITHOUT LIMITATION, LOST PROFITS), WHETHER OR NOT IN ANY PARTICULAR CIRCUMSTANCE SUCH DAMAGES ARE FORESEEABLE AND WHETHER OR NOT THE RELEVANT PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

15. Term and Termination.

(a) Unless sooner terminated in accordance herewith, the initial term of this Agreement shall be for a period commencing on January 1, 2008, and ending on December 31, 2011 and shall be automatically renewed thereafter for successive twenty four (24) month periods unless either party shall provide written notice to the other party of its intent to terminate at least six (6) months prior to the end of the initial term or any renewal term.

(b) In addition to any other right of termination specifically provided for hereunder, this Agreement may be terminated by either party for cause upon written notice to the other. For purposes of the preceding sentence, "cause" shall mean (without limitation):

(i) any material breach of this Agreement by a party which shall go uncorrected for a period of thirty (30) days after written notice of such breach has been given to the defaulting party,

(ii) the institution by a party of voluntary proceedings in bankruptcy or under any insolvency law or law for the relief of debtors,

(iii) the making by a party of an assignment for the benefit of creditors or any dissolution or liquidation,

(iv) the filing of an involuntary petition under any bankruptcy or insolvency law against a party, unless such petition is dismissed or set aside within sixty (60) days from the date of its filing, or

(v) the appointment of a receiver or trustee for the assets or business of a party, unless such appointment is dismissed or set aside within sixty (60) days from the date of such appointment.

(c) The representations, warranties and covenants of the parties hereunder, which by their terms have effect after the termination or expiration hereof, and the parties' indemnification and confidentiality obligations shall survive termination or expiration of this Agreement in perpetuity unless otherwise expressly limited herein.

(d) In the event of any termination of this Agreement, for whatever reason, Mallinckrodt shall, notwithstanding the effective date of any termination, complete any orders for Product that were placed by Cephalon and accepted by Mallinckrodt prior to such date, and Cephalon shall pay Mallinckrodt for any Product produced in accordance with such orders at the then applicable Product Price in effect on the effective date of termination hereunder.

16. Binding Effect and Assignment.

This Agreement shall inure to the benefit of and be binding upon the parties hereto, their successors and assigns; provided, however, that neither party shall, without the prior written consent of the other party, assign or transfer any of its rights, benefits, obligations, or other interest under this Agreement to any other party, except that, without seeking the consent of either party, the other party may assign this Agreement to an affiliate or a successor in interest to the business associated with the Product, provided that such affiliate or successor acknowledges and agrees in writing to be bound by the terms of this Agreement. Any purported assignment that is not made in accordance with the terms herein shall be null and void.

17. Notice.

All notices, consents, approvals or other notifications required to be sent by one party to the other party hereunder shall be in writing and shall be deemed served upon the other party if delivered by hand or sent by United States registered or certified mail, postage prepaid, with return receipt requested, or by facsimile, air courier or telex, addressed to such other party at the address set out below, or the last address of such party as shall have been communicated to the other party. If a party changes its address, written notice shall be given promptly to the other party of the new address. Notice shall be deemed given on the day it is sent (in the case of delivery by method

other than hand delivery) or the date of delivery (in the case of delivery by hand) in accordance with the provisions of this paragraph. The addresses for notices are as follows:

If to Mallinckrodt:

Mallinckrodt Inc.
c/o Pharmaceuticals Group
675 McDonnell Boulevard
Hazelwood, Missouri 63042
Attn: Nick Litzsinger
Global Business Director Bulk Pharmaceuticals

with a copy to:

Mallinckrodt Inc.
675 McDonnell Boulevard
Hazelwood, Missouri 63042
Attn: C. Stephen Kriegh
Vice President - Legal

If to Cephalon:

Cephalon, Inc.
4745 Wiley Post Way
Salt Lake City, Utah 84116
Attn: Purchasing Department

with a copy to:

Cephalon, Inc.
41 Moores Rd.
Frazer, PA. 19355
Attn: Accounts Payable

18. Governing Law and Jurisdiction.

This Agreement shall be governed by and construed in accordance with the laws of the State of Missouri, without reference to its conflict of law provisions that might apply to the law of another jurisdiction.

19. Waiver.

The failure by any party to exercise any of its rights hereunder or to enforce any of the terms or conditions of this Agreement on any occasion shall not constitute or be deemed a waiver of that party's rights thereafter to exercise any rights hereunder or to enforce each and every term and condition of this Agreement.

20. Modifications.

This Agreement may not be amended or modified except by a writing specifically referring to this Agreement and executed by duly authorized representatives of both parties. The obligations of the parties are governed by the terms and conditions of this Agreement and none of the general terms and conditions of any Cephalon purchase order or any Mallinckrodt acknowledgment or any substantially similar documents of either party will in any case be controlling or supersede the provisions hereof.

21. Severability.

A determination that any portion of this Agreement is unenforceable or invalid shall not affect the enforceability or validity of any of the remaining portions hereof or of this Agreement as a whole. In the event that any part of any of the covenants, sections or provisions herein may be determined by a court of law or equity to be overly broad or against applicable precedent or public policy, thereby making such covenants, sections or provisions invalid or unenforceable, the parties shall attempt to reach agreement with respect to a valid and enforceable substitute for the deleted provisions, which shall be as close in its intent and effect as possible to the deleted portions.

22. Headings.

The parties agree that the section and article headings are inserted only for ease of reference, shall not be construed as part of this Agreement, and shall have no effect upon the construction or interpretation of any part hereof.

23. Counterparts.

This Agreement may be executed in several counterparts, and each executed counterpart shall be considered an original of this Agreement.

24. Entire Agreement.

This Agreement and its Schedules represent the entire agreement and understanding of the parties hereto with respect to their subject matter and supersede any and all prior agreements, understanding or discussions, whether written or oral, between the parties.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the day and year first above written.

CEPHALON, INC.

By: _____
Kenneth J. Fiorelli R.ph., Ph.D.
Vice President,
Worldwide Manufacturing Operations

MALLINCKRODT INC.

By: _____
Business Director
Bulk Narcotics

APPROVED AS TO LEGAL FORM
TCL
CEPHALON LEGAL DEPT.

SCHEDULE A

Foreign Jurisdictions to be listed

SCHEDULE B

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.

1 DESCRIPTION

1.1 Fentanyl Citrate Milled USP & Ph Eur

2 ITEM NUMBER

2.1 1901

3 SUPPLIER(S)

3.1 Approved suppliers as listed on the Approved and Certified Supplier List (FRM-0002054).

4 CERTIFICATE OF COMPLIANCE / ANALYSIS

4.1 Certificate of Compliance/Analysis is required with each new supplier lot. The certificate must include all relevant testing results and identify the product with its specific lot number.

5 EXPIRATION DATE

5.1 Three (3) years from the date of manufacture.

6 SAMPLING PLAN

6.1 As outlined in Sampling API for Analysis and Archive (SOP-0001827).

7 STORAGE

7.1 Store under dry conditions in a well closed, light resistant container at controlled room temperature (15 to 30°C) in a secure area with limited access.

8 MATERIAL HAZARDS / PRECAUTIONS

8.1 Fentanyl citrate is a potent opioid, Schedule II controlled substance. Great care should be taken to prevent inhaling particles or exposing skin and mucous membranes to the powder or solutions.

9 TESTS REQUIRED

9.1

U.S. Tests		
Characteristics	**Specifications**	**Methods**
Identification	IR spectrum matches USP RS	USP <197K>
Identification	UV spectrum matches USP RS	USP <197U>
Appearance	White to off-white powder Large plate-like particles are absent	TM-00140
Residue on ignition	NMT 0.5%	USP <281>
Heavy metals	NMT 0.002%	TM-00198 (equiv. To USP <231>)
Ordinary impurities	NMT 2.0%	TM-00207(equiv. To USP <466>, <621>)
Loss on drying USP	NMT 0.5%	TM-00173(equiv. To USP <731>)
Assay USP	98.0 to 102.0%	TM-00157(equiv. To USP)

9.2

Non-Compendial Tests		
Characteristics	**Specifications**	**Methods**
Particle size	D10 NLT 1.1 and NMT 2.5 µm D50 NLT 3.1 and NMT 7.1 µm D90 NLT 6.5 and NMT 18 µm Span (D90 – D10) / D50 NLT 1 and NMT 3	TM-00201
Phenethyl bromide (HPLC)	NMT 0.01% (w/w)	JM Method per DMF
Residual solvents (GC)	NMT 0.5% IPA	JM Method per DMF
Purity (HPLC)	98.0 to 102.0% (w/w, dried basis)	TM-00204
Impurities (HPLC)	Acetyl (*Ph. Eur.* Impurity C) NMT 0.15% FC 1001 (*Ph. Eur.* Impurity B) NMT 0.15% Individual unspecified NMT 0.10% Total impurities NMT 0.50%	JM Method per DMF
Metal impurities (ICP)	NMT 0.005% palladium	JM Method per DMF

Non-Compendial Tests		
Characteristics	**Specifications**	**Methods**
DSC (morphology)	Peak onset 147 to 153°C	TM-00150
Low level arylamines	Impurity B (*Ph. Eur. Impurity D*) NMT 0.01% Impurity A NMT 0.01% FC-1003 NMT 0.01%	MET-0002448

9.3

Non - U.S. Tests		
Characteristics	**Specifications**	**Methods**
Identification	Matches *Ph. Eur.* IR reference spectrum for fentanyl citrate	Absorption spectrophotometry, IR *Ph. Eur.* (2.2.24)
Appearance of solution	Clear, colorless	*Ph. Eur.* (2.2.1, 2.2.2)
Impurity "D" (PPA) Each impurity Total impurities	NMT 0.25% NMT 0.25% NMT 0.5%	*Ph. Eur.* (2.2.29)
Loss on drying	NMT 0.5%	TM-00173 (equiv. to *Ph. Eur.* 2.2.32)
Assay	NLT 99.0% and NMT 101.0%	TM-00158 (equiv. to *Ph. Eur.*)

10 REFERENCE DOCUMENTS

10.1 Current USP/NF

10.2 Johnson Matthey DMF

10.3 Appearance of Fentanyl Citrate, **(TM-00140)**

10.4 Differential Scanning Calorimetry (DSC) Analysis of Fentanyl Citrate, **(TM-00150)**

10.5 USP Assay for Fentanyl Citrate, **(TM-00157)**

10.6 Loss on Drying for Fentanyl Citrate, **(TM-00173)**

10.7 Heavy Metals Testing USP (Method II), **(TM-00198)**

10.8 Low Level Arylamines Testing of Johnson Matthey Fentanyl Citrate, **(MET-0002448)**

10.9 Current Ph Eur.

10.10 Particle Size Distribution of Fentanyl Citrate Dispersed in Fluid, (TM-00201)

10.11 USP Test for Ordinary Impurities in Fentanyl Citrate, (TM-00207)

10.12 Purity Testing of Johnson Matthey Fentanyl Citrate, (TM-00204)

10.13 EP Assay for Fentanyl Citrate, (TM-00158)

10.14 Sampling API for Analysis and Archive, (SOP-0001827)

10.15 Approved and Certified Supplier List, (FRM-0002054)

1 DESCRIPTION

1.1 Fentanyl Citrate Powder, Ph Eur & USP

2 ITEM NUMBER

2.1 0510

3 APPROVED SUPPLIER(S)

3.1 Approved supplier as listed on the Approved and Certified Supplier List (FRM-00260).

4 FORMULA (STRUCTURE)

4.1 $C_{22}H_{28}N_2O \cdot C_6H_8O_7$

5 MOLECULAR WEIGHT

5.1 528.60

6 CERTIFICATE OF COMPLIANCE / ANALYSIS

6.1 Certificate of Compliance/Analysis is required with each new supplier lot. The certificate must include all relevant testing results and identify the product with its specific lot number.

7 EXPIRATION DATE

7.1 Three (3) years from the date of manufacture.

8 SAMPLING PLAN

8.1 Identification amount: 2 g

8.2 Archived amount: 6 g

8.3 **NOTE:** Quantities listed reflect the minimum amount required.

9 STORAGE

9.1 Store under dry conditions in a well closed, light resistant container at controlled room temperature (15 to 30°C) in a secure area with limited access.

10 MATERIAL HAZARDS / PRECAUTIONS

10.1 Fentanyl citrate is a potent opioid, Schedule II controlled substance. Great care should be taken to prevent inhaling particles or exposing skin and mucous membranes to the powder or solutions.

11 REFERENCE STANDARDS

11.1 <11> USP Fentanyl Citrate RS

11.2 Ph Eur IR reference spectrum

12 TESTS REQUIRED

12.1

Non – U.S. Tests		
Characteristics	**Specifications**	**Methods**
Identification	Matches Ph. Eur IR ref. Spectrum of Fentanyl Citrate	Absorption spectrophotometry, IR Ph. Eur (2.2.24)
Appearance of solution	Clear colorless	Ph. Eur (2.2.1, 2.2.2)
Impurity "D" (PPA) Each Impurity Total Impurities	NMT 0.25% NMT 0.25% NMT 0.5%	Ph Eur (2.2.29)
Loss on drying	NMT 0.5%	TM-00173 (Equivalent to Ph Eur 2.2.32)
Assay	NLT 99.0% and NMT 101.0%	TM-00158 (Equivalent to Ph. Eur)
Residual Solvents	In compliance with CPMP/ICH/283/95	Ph.Eur 2.4.24

Particle Size (Alpine jet sieve method TM-00148)

Screen # (Mesh)	Particle Size (microns)	Specification
200	75	98% min through
450	32	70% min through
635	20	90% max through

12.2

U.S. Tests		
Characteristics	**Specifications**	**Methods**
Identification	IR spectrum matches USP RS UV spectrum matches USP RS	USP <197K> USP <197U>
Loss on drying	NMT 0.5%	TM-00173
Assay	NLT 98.0% and NMT 102.0%	TM-00157
Residue on ignition	NMT 0.5%	USP <281>
Heavy Metals	NMT 0.002%	TM-00198
Ordinary impurities	NMT 2.0%	TM-00207
Appearance	White to off-white powder Large, plate-like particles are absent	TM-00140
Assay PPA impurity Acetyl analog Pyruvyl analog Butyryl analog Fentanyl n-oxide Unknown related substances Total related substances	98.0 - 102.0% NMT 0.15% w/w NMT 0.15% w/w NMT 0.15% w/w NMT 0.15% w/w NMT 0.15% w/w NMT 0.10% w/w NMT 0.50% w/w	TM-00141
Differential scanning calorimetry (DSC)	Peak onset near 152°C	TM-00150

Particle Size

Characteristics	Specifications	Methods
D_{10}	NLT 0.5µm and NMT 2.0µm	TM-00159
D_{50}	NLT 3µm and NMT 14µm	
D_{90}	NLT 12µm and NMT 50µm	
Span	2.6 - 5.0	TM-00159

13 REFERENCES

13.1 Approved and Certified Supplier List, **(FRM-00260)**

13.2 Appearance of Fentanyl Citrate, **(TM-00140)**

13.3 Fentanyl Citrate USP Powder Assay and Related Substances, **(TM-00141)**

13.4 Particle Size Analysis of Fentanyl Citrate by Alpine Jet Sieve, **(TM-00148)**

13.5 Differential Scanning Calorimetry (DSC) Analysis of Fentanyl Citrate, **(TM-00150)**

13.6 USP Assay for Fentanyl Citrate, **(TM-00157)**

13.7 EP Assay for Fentanyl Citrate, **(TM-00158)**

13.8 Particle Size Distribution of Fentanyl Citrate Using the Mastersizer 2000, **(TM-00159)**

13.9 Loss on Drying for Fentanyl Citrate, **(TM-00173)**

13.10 Heavy Metals Testing USP (Method II), **(TM-00198)**

13.11 USP Test for Ordinary Impurities in Fentanyl Citrate, **(TM-00207)**

HISTORY OF CHANGES *(List the last two versions)*

Version	Change Tracking #	Initiator of Change	Effective Date	Short Detail of Change
02	SPEC326	K. Hartner	7/6/05	Section 12, Tests Required, Non-US and US testing was broken out into separate tables for easier reference. A U.S. particle size specification is added as dictated in a letter to the FDA on April 19, 2005 regarding NDA 20-747, Actiq (oral transmucosal fentanyl citrate), Amendment to S-021. The old specifications are kept since they are part of regulatory commitments outside the U.S. The new laser diffraction particle size specifications are D10, D50, D90, and Span, all of which will be determined by Test Method TM-00159. Additional changes made: Cephalon versions of compendial test methods have been produced for Loss on Drying and Assay. The methods are equivalent to compendial methods, so no change in testing is implied. Appearance and DSC are added to the Tests Required in the US Tests section in compliance with earlier commitments made to the FDA. A row has been added to this section for results obtained with test method TM-00141. This test method is a Cephalon version of a Mallinckrodt related substance method, and is required to confirm results on the vendor C of A.
03	SPEC395	J. Harwood	12/19/05	Updated to include the reference to the Approved and Certified Supplier List (FRM-00260). Updated the expiration date to be consistent with the suppliers recommended re-test date of 3 years. In section 12.2 under specifications for Heavy Metals 'NMT' was added.
04	SPEC466	K. Hartner	Refer to cover page	Mallinckrodt's related substance testing spec changed on May 2, 2006, therefore, the same changes are being made to our RMS. Change to the related substance specifications listed in the U.S. Tests table under method TM-00141. TM-00207 listed as the method for the "Ordinary Impurities" entry in the U.S. Tests table.

SCHEDULE C
QUALITY AGREEMENT

EXHIBIT 11

G0013002-02

AMENDED AND RESTATED SUPPLY AGREEMENT

THIS AMENDED AND RESTATED SUPPLY AGREEMENT ("Agreement") is made and entered into effective on and as of July 1, 2009, by and between Mallinckrodt Inc., a Covidien company ("Mallinckrodt"), and Cephalon, Inc., 41 Moores Road, Frazer, PA 19355 (together with its affiliates and wholly owned subsidiaries Anesta Corp. and CIMA LABS INC., "Cephalon"), with the purpose and effect of amending and restating that certain Supply Agreement between Mallinckrodt and Cephalon dated January 1, 2008 ("Prior Agreement") by providing for the supply of certain additional products.

WHEREAS, Cephalon has need of a certain bulk compound known as Fentanyl Citrate USP Mallinckrodt Code 1205 and/or Code 1333 (hereinafter "Product One") and is desirous of having Product One manufactured by Mallinckrodt and of purchasing a substantial portion of its needs for Product One from Mallinckrodt, on the terms and conditions set forth herein;

WHEREAS, Cephalon also has need of two (2) additional bulk compounds known respectively as Hydromorphone Hydrochloride USP Mallinckrodt Code 3245 ("Product Two") and Hydrocodone Bitartrate USP Mallinckrodt Code 1582 ("Product Three") and is also desirous of having Products Two and Three manufactured by Mallinckrodt and of purchasing a substantial portion of its needs for Products Two and Three from Mallinckrodt, on the terms and conditions set forth herein;

WHEREAS, Products One, Two and Three shall be known herein as "Products" when referred to jointly or as a "Product" when referred to individually and generically (rather than specifically); and

WHEREAS, Mallinckrodt is capable and desirous of undertaking the supply of Products for Cephalon in accordance with the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the promises, covenants and representations of the parties set forth herein, and other good and sufficient consideration receipt of which is hereby acknowledged, Cephalon and Mallinckrodt agree as follows:

1. Supply of Product.

(a) For the consideration provided herein and in accordance with all terms, conditions, representations, warranties and covenants set forth herein, and for the term hereof, Mallinckrodt shall provide Cephalon with such amounts of Products as Cephalon shall request. Cephalon agrees that it shall purchase from Mallinckrodt, during every Contract Year during the term hereof, at least thirty percent (30%) of its requirements for Product One; provided that and notwithstanding the immediately foregoing, for any Contract Year occurring after the Contract Year in which Cephalon receives approval from the U.S. Food and Drug Administration ("FDA") for its new drug application for the dosage pharmaceutical product known as Fentora®, Cephalon agrees that it shall purchase from Mallinckrodt at least forty percent (40%) of its requirements for Product One. Cephalon further agrees that it shall purchase from Mallinckrodt, during every Contract Year or Stub Period (as applicable), at least eighty percent (80%) of its requirements for Products Two and Three. For purposes of the two (2) immediately preceding sentences and this Agreement in general, "Contract Year" shall mean and refer to each consecutive twelve (12) month period during the term hereof coinciding with calendar years and "Stub Period" shall mean the last six (6) months of the calendar year 2009; provided, that the term Contract Year with reference to purchases of Product One by Cephalon may refer to calendar years occurring, in whole or in part before the date of this Agreement to reflect the fact that Cephalon has made purchases of Product One from Mallinckrodt during the eighteen (18) month period covered by the Prior Agreement. All Products supplied hereunder shall be manufactured by Mallinckrodt in accordance with current Good Manufacturing Practices ("cGMP") as determined by the FDA using the manufacturing process described in Mallinckrodt's batch records and the respective Drug Master File ("DMF") for each Product. If and as applicable, Mallinckrodt shall comply with the cGMP-equivalent requirements of those countries listed on Schedule A if and as Cephalon reasonably requests.

(b) The specifications for each of the Products are described on Schedule B attached hereto (the "Specifications"), and such Specifications shall not be changed without a written amendment to this Agreement.

2. Raw Materials.

Subject to the provisions of Section 4 below, all raw materials and other resources required in connection with the manufacture and supply of the Products to be supplied hereunder shall be provided by Mallinckrodt at its cost and expense.

3. Quality Control.

(a) Mallinckrodt shall take all steps reasonably necessary to ensure that it has the facilities, equipment, instrumentation, resources and trained personnel to provide all raw materials, in-process and product assays, analysis and other testing including preparing, submitting and maintaining a DMF for each Product. Mallinckrodt shall provide a complete certificate of analysis for each lot of finished Product supplied hereunder at the time of shipment. Mallinckrodt acknowledges and agrees that Cephalon shall be entitled to incorporate by reference the DMFs for these Products into any filings or document submissions made to the FDA or other government agencies or authorities.

(b) Mallinckrodt shall maintain complete and accurate documentation of all validation data, stability testing data, batch records, quality control and laboratory testing and any other data required under cGMP or other FDA requirements.

(c) Mallinckrodt shall not engage in any act which causes any packaged and labeled Product manufactured by Mallinckrodt to become adulterated or misbranded within the meaning of the United States Federal Food, Drug and Cosmetic Act of 1938, as amended from time to time (the "FDCA"), and agrees that Products shall not be adulterated or misbranded, within the meaning of the FDCA, when Products are delivered to Cephalon.

(d) Mallinckrodt shall inform Cephalon at least twelve (12) months in advance (unless a lesser time to implement any change is dictated by law) of any changes related to any of the DMFs related to any Product per the FDA's "Guidance for Industry" relevant to an NDA or ANDA. Pending agreement on the timing of implementation of any such changes, Mallinckrodt agrees to continue to manufacture and supply to Cephalon unmodified Products under the terms and conditions of this Agreement; provided that, if any such changes are compendial changes or are

required by government regulations Mallinckrodt will implement such changes after consultation with Cephalon but as and when Mallinckrodt deems reasonably necessary and the parties will in good faith discuss an appropriate transition plan relative to such changes to protect the interests of both parties to the extent possible under applicable circumstances, including but not limited to ensuring that delivery dates are not compromised by any Mallinckrodt implementation schedule.

(e) Mallinckrodt shall retain under proper storage conditions such samples of the Products as are required to comply with the stability sections of the DMF for each Product. Mallinckrodt acknowledges and agrees that Cephalon is entitled to copies of all test specifications and methods as well as analytical methods validation documentation for Cephalon's files.

(f) Mallinckrodt shall not, without the prior written approval of Cephalon, (i) change any test method or procedure for manufacturing the Products or (ii) sub-contract any part of the manufacturing process (including, without limitation, testing and stability control). The procedure for deviation and change control approval shall be set forth in the Quality Technical Agreement, as well as any additional standard operating procedures agreed upon in writing by Mallinckrodt and Cephalon from time to time. Mallinckrodt shall not change any vendor or supplier of critical materials or components used in the manufacture or testing of the Products, except as set forth in the Quality Technical Agreement.

(g) In addition to the foregoing and in furtherance thereof, the parties agree to follow the quality procedures outlined in any Quality Technical Agreement to be attached hereto (the "Quality Technical Agreement"). The final form of the Quality Technical Agreement shall be negotiated by the parties in good faith, shall become a part of this Agreement and shall be attached hereto as Schedule C upon its execution. Notwithstanding any other provision hereof, in the event of any conflict or inconsistency between the terms of this Agreement and the terms of any Quality Technical Agreement, the former shall prevail.

4. Compensation for Services Performed by Mallinckrodt.

(a) Cephalon shall pay Mallinckrodt, for Product One to be produced and delivered in any particular Contract Year during the term hereof, the following amount:

(i) fifty dollars ($50.00) per gram during any Contract Year in which an amount of less than twenty (20) kilograms of Product One is purchased and delivered, and

(ii) thirty six dollars ($36.00) per gram during any Contract Year in which the amount of Product One purchased and delivered is greater than or equal to twenty (20) kilograms.

The product prices set forth above in this Section 4(a) shall apply to every gram purchased during any relevant Contract Year so long as the respective threshold amount of Product is purchased.

(b) Cephalon shall pay Mallinckrodt for Product Two produced and delivered hereunder the amount of Thirteen Thousand Dollars ($13,000) per kilogram.

(c) Cephalon shall pay Mallinckrodt for Product Three produced and delivered hereunder the amount of Two Thousand Dollars ($2,000) per kilogram.

(d) The amounts set forth above for any Product shall hereinafter be referred to as the "Product Price(s)" for such Product. The Product Prices set forth above in subsection (a) of this Section 4 shall be firm through the end of the Contract Year coinciding with calendar year 2009 and the Product Prices set forth above in subsections (b) and (c) of this Section 4 shall be firm through the end of the Contract Year coinciding with the Calendar Year 2010, the date of December 31, 2009 (with respect to Product One) and the date of December 31, 2010 (with respect to Products Two and Three) being hereafter referred to herein, and with respect to any Product(s) as to which either such date is applicable, as the "Adjustment Date". From and after the Adjustment Date with respect to any given Product, the applicable Product Price shall be adjusted upward to reflect increases in the cost to Mallinckrodt of all raw materials, directly associated regulatory compliance costs and all directly allocated labor (all of which costs are hereinafter referred to as "Product Costs"), in accordance with the following procedures. Within fifteen (15) days after the end of each Contract Year hereunder during the term hereof, Mallinckrodt will notify Cephalon in writing of the amount by which its Product Costs with respect to any given Product hereunder have increased during the immediately preceding Contract Year or twelve (12) month period (as applicable) and the adjusted Product Price to be charged for the Contract Year just commenced as a consequence of such increases ("Annual Adjustment Notice"). The amount of any increase in any Product Price

(which is limited to no more than five percent (5%) for any single Contract Year) as set forth in any Annual Adjustment Notice shall be effective for all Product invoiced by Mallinckrodt to Cephalon in accordance herewith during the Contract Year for which such Annual Adjustment Notice is issued.

(e) At the time of shipment by Mallinckrodt to Cephalon of any lot or lots of Products hereunder, Mallinckrodt shall submit to Cephalon an invoice setting forth the total amount of each Product being shipped to Cephalon and the amount due to Mallinckrodt under Sections 4(a), 4(b) and/or 4(c) (as applicable), such amount due to Mallinckrodt with respect to Product One to be calculated utilizing the Product Price with respect to Product One related to the total estimated quantity of Product to be purchased and delivered during the then current Contract Year based on the most recent forecast submitted by Cephalon to Mallinckrodt for Product One pursuant to Section 5(a) below. Each such invoice shall also contain a certification that any Product for which Cephalon is being billed has been manufactured fully in conformance with applicable Specifications, cGMP and the requirements hereof. Any such invoice shall be payable by Cephalon within thirty (30) days after Cephalon's receipt of such invoice.

(f) If, at the end of any given Contract Year, the actual quantity of Product One purchased and delivered in such Contract Year is such that the Product Price charged during the Contract Year requires adjustment based on the criteria set forth in Section 4(a) above, then within thirty (30) days after the end of such Contract Year, Mallinckrodt will issue a reconciling invoice setting forth either the additional amount due to Mallinckrodt or the overpayment made by Cephalon relative to such Contract Year. Any amount due by Cephalon on the reconciling invoice shall be payable by Cephalon within thirty (30) days after receipt of such invoice. Any amount due to Cephalon on the reconciling invoice shall be payable by Mallinckrodt within thirty (30) days after receipt of such invoice.

(g) If during the term of this Agreement any government of a country in which Cephalon sells a dosage form of Product One establishes a maximum price for any such dosage form, Mallinckrodt and Cephalon shall meet to discuss a mutually acceptable solution to Cephalon's market needs on the basis of documented evidence. In addition, the parties agree that should unanticipated or changed commercial or regulatory conditions cause either or both parties to experience economic hardship in connection with the performance of its or their obligations under

the terms of this Agreement, the parties shall meet and attempt to reach agreement in good faith an equitable resolution of that hardship.

(h) Notwithstanding the preceding portions of this Section 4, Cephalon shall have the right (through any independent agents or representatives that are reasonably acceptable to Mallinckrodt and upon advance written notice to Mallinckrodt) from time to time during the existence of this Agreement and for a period of thirty (30) days after the termination or expiration hereof, but no more often than annually, to audit the books and records of Mallinckrodt to determine whether or not the amounts invoiced by Mallinckrodt to Cephalon in accordance with this section 4 are accurate and in particular (without limitation) whether or not the Product Costs reflected in any Annual Adjustment Notice for any Product have been reported and invoiced correctly by Mallinckrodt. In the event that, as consequence of any such audit or examination, Cephalon reasonably disagrees with any amounts invoiced by Mallinckrodt, Cephalon shall inform Mallinckrodt in writing and in reasonable detail of the amounts to be refunded and, unless and to the extent Mallinckrodt disputes the amounts set forth by Cephalon in any such notice, Mallinckrodt will refund to Cephalon any such undisputed amounts within twenty (20) days of the receipt of any such notice from Cephalon. In the event Mallinckrodt does dispute all or any portion of any refund claimed by Cephalon, Mallinckrodt will so notify Cephalon with such twenty (20) day period and the parties will attempt thereafter to resolve such dispute amicably and, if they cannot do so, the matter will be referred to an independent accounting firm acceptable to both Mallinckrodt and Cephalon, and the decision of such firm as to any Product Price adjustments or reimbursements to be made shall be final and binding on the parties, both as to the resolution of the dispute and the allocation of responsibility for the fees and expenses of such firm. Furthermore, if the prices Mallinckrodt charges are incorrect by more than five percent (5%) then Mallinckrodt shall be responsible for all associated audit fees by the independent accounting firm, otherwise the expenses of such firm shall be for the account of Cephalon.

5. Forecasts, Order Placement and Delivery.

(a) Cephalon shall submit to Mallinckrodt, in writing and on or before the fifteenth (15th) day of every month during the term hereof, a forecast of the anticipated amounts of its orders for each Product hereunder during each of the next twelve (12) months. The forecast for the first three (3) months of that period will be considered to be firm and binding. The forecast for the last nine (9) months of that period will be non-binding and will be used by Mallinckrodt for

production planning, but in all circumstances Cephalon shall act in good faith and with reasonable care to submit forecasts for each Product which are as accurate as possible under the circumstances.

(b) Products shall be ordered by Cephalon with sixty (60) days advance notice and only by written purchase order. Mallinckrodt shall not accept verbal orders of any kind for the production of Products. Any written purchase order will contain the following information: (i) the precise quantity of each Product desired, (ii) dates by which the ordered Product must be received, (iii) the anticipated shipping destination for any Product and (iv) such other information as Cephalon wishes to provide or that Mallinckrodt might find necessary or useful in completing a specific purchase order.

(c) Products shall be delivered F.C.A. by Mallinckrodt to the destination specified by Cephalon. Title to Product and risk of loss shall remain with Mallinckrodt until delivery to the destination specified by Cephalon in its purchase order at which time risk of loss and responsibility for the Products will transfer to Cephalon. Mallinckrodt shall be responsible to make such arrangements regarding the shipping of Products to such specified destinations as Cephalon shall reasonably request, all such shipping to be at Cephalon expense. Cephalon shall be responsible for any and all taxes or similar assessments that may be assessed with respect to any order for Products.

(d) If Mallinckrodt is unable to ship any quantity of any Product ordered by Cephalon within sixty (60) days after the scheduled shipping date, regardless of the reason, then Cephalon will be permitted to purchase the same quantity of that Product of like grade and quantity from another supplier on this occasion, and the amount of such Product so purchased by Cephalon shall not be considered as part of Cephalon's requirements for that Product for the purpose of determining whether Cephalon has met its purchase obligation for any Stub Period or Contract Year as applicable as set forth in Section 1(a).

6. Acceptance and Rejection and Recalls.

(a) If Cephalon reasonably determines that any Product is defective in material or workmanship, not in conformance with applicable Specifications, is adulterated or misbranded, or is otherwise not in conformity with this Agreement (Product meeting any or all of such circumstances hereinafter referred to as "Defective Product"), then Cephalon, in addition to any

other rights it may have under this Agreement, may reject and return the Defective Product to Mallinckrodt. At the time of any such rejection, Cephalon shall provide Mallinckrodt with a written notice describing in detail the circumstances surrounding the rejection and Cephalon's reasons therefor. If Mallinckrodt does not agree that Cephalon acted properly in rejecting any such Product, Mallinckrodt shall notify Cephalon in writing with twenty (20) days after Mallinckrodt receipt of any rejection notice from Cephalon, and if Mallinckrodt fails to notify Cephalon, Cephalon's rejection of product shall be deemed to be proper and such Product will be considered Defective Product for all purposes hereof. If Mallinckrodt does timely notify Cephalon of its disagreement, the parties will attempt to reach a mutually acceptable resolution of their differences within thirty (30) days of Mallinckrodt's notice to Cephalon. If the parties are unable to reach a resolution within such time frame, the matter will be submitted to an independent testing laboratory reasonably acceptable to both parties and both parties will accept as final the decision of such laboratory as to whether any given Product was properly rejected. If the parties or the independent laboratory (as applicable) determine that any given volume of Product was properly rejected by Cephalon, then Cephalon will, at Mallinckrodt's option, either return Defective Product to Mallinckrodt or destroy or dispose of it in the least expensive and most environmentally sound manner, and in any event, Mallinckrodt will be responsible for the costs of any such return, destruction or disposal. It is understood that Cephalon's sole remedies (in addition to destruction or disposal of the Defective Product at Mallinckrodt's cost in accordance with the immediately proceeding sentence) in the event of Defective Product it has properly rejected will, at Cephalon's sole option, either be (i) the replacement by Mallinckrodt of rejected Product that has been returned or destroyed with Product that is not Defective Product or (ii) a full refund of any amount paid hereunder by Cephalon for such Defective Product. If the parties or the independent laboratory (as applicable) determine that any given Product was not properly rejected, such Product shall be deemed to have been accepted by Cephalon and Cephalon will promptly pay the full invoiced Product Price, if not already paid. The costs and expenses of the independent testing laboratory shall be for the account and expense of the party whose judgment was not in correct as to whether any Product was properly rejected.

(b) Any Product received by Cephalon from Mallinckrodt that has not been rejected by Cephalon within thirty (30) days after receipt shall be deemed to have been accepted, except where such Product contains a nonconformity that could not have been discovered by reasonable inspection, in which case Cephalon shall have an additional sixty (60) days after it discovers such nonconformity within which to reject such Product according to the procedure set forth in Section 6(a) above.

(c) If Cephalon reasonably decides to or is required to initiate a product recall, withdrawal or field correction with respect to, or if there is any governmental seizure of, its product containing any Product supplied hereunder, Cephalon shall notify Mallinckrodt promptly of the details regarding such action, including providing copies of all relevant documentation concerning such action. Mallinckrodt shall fully cooperate with and assist Cephalon in investigating any such situation and all regulatory contacts that are made and all activities concerning seizure, recall, withdrawal or field correction will be jointly coordinated by Cephalon and Mallinckrodt. The costs of the activities in this Section 6(c) shall be apportioned as set forth below in Section 6(d).

(d) If any such recall, withdrawal, field correction or seizure occurs due solely to (i) a failure of any Product sold by Mallinckrodt hereunder to conform to applicable Specifications (including, without limitation, it being adulterated or misbranded or is otherwise not in conformity with this Agreement) or any warranty or other requirement set forth in this Agreement, (ii) the failure by Mallinckrodt to comply in all material respects with any applicable law, rule, regulation, standard, court order or decree or (iii) the negligent, reckless or intentional wrongful act or omission of Mallinckrodt in connection with the manufacture of any Product hereunder, then Mallinckrodt shall bear the full cost and expense of any such seizure, recall, withdrawal or field correction. If any such recall, withdrawal, field correction or seizure occurs due solely to (A) any pharmaceutical product manufactured, sold or distributed by Cephalon that contains Product failing to conform to its applicable specifications for reasons other than those set forth in clause (i) above, (B) the failure of Cephalon to comply in all material respects with any applicable law, rule, regulation, standard, court order or decree or (C) the negligent, reckless or intentional wrongful act or omission of Cephalon, then Cephalon shall bear the full cost and expense of any such seizure, recall, withdrawal or field correction. If both Mallinckrodt and Cephalon contribute to the cause of a seizure, recall, withdrawal or field correction, the cost and expenses thereof will be shared in proportion to each party's contribution to the problem.

7. Regulatory Compliance.

(a) Mallinckrodt shall comply in all material respects with all federal, state and local laws and regulations applicable to Mallinckrodt and the performance of its obligations hereunder.

(b) Mallinckrodt shall promptly furnish Cephalon with pertinent portions of all FDA and/or any foreign equivalent inspection reports and related correspondence directly related to and affecting its performance hereunder as and when such reports and correspondence become available to Mallinckrodt.

(c) Mallinckrodt shall notify Cephalon immediately of any warning (including any FDA Form 483), citation, indictment, claim, lawsuit or proceeding issued or instituted by any federal, foreign, state, local or foreign governmental entity or agency against Mallinckrodt or any of its affiliates or of any revocation of any license or permit issued to Mallinckrodt or any of its affiliates, to the extent that any such occurrence relates directly to Mallinckrodt's performance hereunder. Mallinckrodt shall promptly provide Cephalon with copies of the relevant portions of any documents or a written summary of any oral observations received by Mallinckrodt in connection with the matters set forth in this Section 7(c).

8. Adverse Event Reporting.

(a) Serious Adverse Events (as defined below in Section 8(b)) for any Product of which either party becomes aware shall be submitted to the other party within three (3) business days but no later than five (5) calendar days after the date the first-mentioned party first became aware of such Serious Adverse Event. Non-Serious Adverse Events (as defined below in Section 8(b)) for any Product that are reported to one party shall be submitted to the other party no more than one (1) month from the date received by the first mentioned party; *provided, however*, that medical and scientific judgment should be exercised in deciding whether expedited reporting is appropriate in other situations, such as important medical events that may not be immediately life-threatening or result in death or hospitalization but may jeopardize the patient or may require intervention to prevent a Serious Adverse Event outcome.

(b) A "Serious Adverse Event" for the Product is defined as any untoward medical occurrence that at any dose for a Product (i) results in death, (ii) is life threatening, (iii) requires inpatient hospitalization or prolongation of existing hospitalization, (iv) results in persistent or significant disability/incapacity, (v) results in a congenital anomaly/birth defect, (vi) results in drug dependency or drug abuse, (vii) results in a cancerous condition, or (viii) is an overdose. A "Non-Serious Adverse Event" for a Product is defined as an untoward medical occurrence at any dose for that Product that is not a Serious Adverse Event.

(c) Mallinckrodt shall report all such Serious and Non-Serious Adverse Events involving any Product learned by it to:

Cephalon, Inc.
4745 Wiley Post Way
Salt Lake City, Utah 84116
Attn: Quality Department

(d) Cephalon shall report all such Serious and Non-Serious Adverse Events involving any Product learned by it to:

Mallinckrodt Inc.
c/o Pharmaceuticals Group
675 McDonnell Boulevard
Hazelwood, Missouri 63042
Attn: Nick Litzsinger
Global Business Director Bulk Narcotics

(e) All medical inquiries concerning any Product shall be handled by Cephalon's Medical Affairs Group. Mallinckrodt shall refer all routine medical information requests in writing to Cephalon as set forth in Section 8(c). Urgent medical information requests shall be referred by Mallinckrodt by telephone to (800) 896-5855.

9. Representations, Warranties and Covenants of Mallinckrodt.

(a) Mallinckrodt represents and warrants that all Products sold hereunder shall:

(i) be manufactured and packaged in compliance with cGMPs (including foreign equivalents thereof with respect to jurisdictions listed on Schedule A) applicable to the Product in question,

(ii) meet all applicable Specifications at the time the Product is delivered to Cephalon and (if properly stored and handled by Cephalon) during its shelf life; and

(iii) if properly stored and handled by Cephalon, have a minimum shelf life of two (2) years at the time the Product is delivered to Cephalon.

(b) Mallinckrodt represents and warrants, to its knowledge, that the manufacture, use, export, importation or sale of any Product pursuant to this Agreement in its bulk form does not infringe, misappropriate or otherwise conflict with any intellectual property rights of any third party.

(c) Mallinckrodt represents and warrants that there is no claim, suit, proceeding or investigation pending or, to the knowledge of Mallinckrodt, threatened against Mallinckrodt or any of its affiliates which might prevent or interfere with Mallinckrodt's performance under this Agreement.

(d) Mallinckrodt represents and warrants to Cephalon that any Product sold hereunder by Mallinckrodt shall not be:

(i) in violation of Sections 5 or 12 of the Federal Trade Commission Act or improperly labeled under applicable Federal Trade Commission Trade Practice Rules, or other similar foreign laws (for the countries set forth on Schedule A), as and to the extent applicable hereunder,

(ii) adulterated or misbranded within the meaning of the FDCA, as amended, or within the meaning of any applicable state or municipal law in which the definitions of adulteration and misbranding are substantially identical with those contained in the FDCA at the time the Product is delivered to Cephalon, or articles which may not under the provisions of Sections 404 or 505 of said Act be introduced into interstate commerce or which may not under substantially similar provisions of any state or municipal law be introduced into commerce,

(iii) manufactured or sold in violation of the federal Controlled Substances Act, as amended, or any similar legislation in the counties set forth on Schedule A, or applicable state law,

(iv) manufactured in violation of any applicable federal, state or local environmental law or regulation, or

(v) manufactured in violation of any agreement (commercial or otherwise), judgment, order or decree to which Mallinckrodt is a party.

(e) Mallinckrodt certifies that neither it nor any of its affiliates nor any member of their staff has been disqualified or debarred by the FDA or any other domestic regulatory authority, or any other applicable regulatory agency, for any purpose.

(f) Mallinckrodt warrants and represents that neither it nor any of its affiliates nor any member of their staff have been charged with or convicted under federal law for conduct relating to the development or approval, or otherwise relating to the regulation of any drug product under the Generic Drug Enforcement Act of 1992 or any other relevant statute, law or regulation.

(g) EXCEPT AS SET FORTH IN THIS SECTION 9 OR SPECIFICALLY SET FORTH ELSEWHERE IN THIS AGREEMENT, MALLINCKRODT MAKES NO OTHER WARRANTY OR REPRESENTATION, EXPRESS OR IMPLIED, CONCERNING ITS PERFORMANCE HEREUNDER, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WHICH WARRANTIES ARE HEREBY EXPRESSLY DISCLAIMED.

(h) Mallinckrodt hereby represents and warrants that it has all rights and licenses necessary to manufacture and sell the Products to Cephalon.

10. Facility Access.

Cephalon, through its employees, consultants or other representatives, will have the right during normal business hours and upon advance arrangement with Mallinckrodt to inspect Mallinckrodt's relevant manufacturing operations to determine whether or not Mallinckrodt is complying in all respects with its obligations hereunder. Cephalon agrees that all such inspections and audits shall be carried out in a manner calculated not to unreasonably interfere with Mallinckrodt's conduct of business and to ensure the continued confidentiality of Mallinckrodt's business and technical information. Further, Cephalon agrees to comply with all of Mallinckrodt's safety and security requirements during any visits to the Mallinckrodt facilities. Following an inspection by the FDA or any other applicable regulatory authority that will in any way affect the production of Product for supply to Cephalon, Mallinckrodt shall notify Cephalon in writing of any material issues that may be pertinent to the supply of Product(s) to Cephalon. The parties agree to cooperate in good faith and engage in active dialogue in an effort to resolve any issues resulting from any such inspections.

11. Force Majeure

Neither party to this Agreement shall be liable for or be in breach of any provision hereof for any failure or delay on its part to perform any obligation (other than the obligation to make payments when due) under any provision of this Agreement because of an event of "force majeure", including, but not limited to, any act of God, fire, flood, explosion, unusually severe weather, war, acts of terrorism, insurrection, riot, sabotage, labor unrest, strikes or work stoppages or any other cause whatsoever, whether similar or dissimilar to those enumerated herein, beyond any reasonable possibility of control of such party, if and only if the party affected shall have used all reasonable efforts under the circumstances to avoid such occurrence and to remedy it promptly if it shall have occurred. If an event of force majeure causes a failure or delay in performance hereunder by Mallinckrodt for more than one hundred eighty (180) continuous days, Cephalon, at its option, may (i) terminate this Agreement effective upon written notice to Mallinckrodt or (ii) may extend the delivery or performance period by the amount of time during which such delivery or performance was omitted or delayed.

12. Relationship of Parties

For all purposes hereof, Mallinckrodt shall be deemed to be an independent contractor and this Agreement shall not create an agency, partnership, joint venture, or employer/employee relationship between Cephalon and Mallinckrodt, and nothing hereunder shall be deemed to authorize either party hereto to act for, represent or bind the other or any of its affiliates except as expressly provided in this Agreement.

13. Confidentiality

(a) Each party shall maintain in confidence and not use or disclose to any third party, except as is specifically contemplated in this Agreement, and then only on a confidential basis satisfactory to both parties, any proprietary or confidential information of the other party, including (without limitation) business and technical information, experience or data regarding any facility, programs, laboratories, processes, products, costs, equipment operation or customers, relating to the manufacture or sale of Products hereunder. The foregoing obligations of confidentiality and non-use shall survive the termination or expiration of this Agreement for a period of five (5) years. Nothing herein shall prevent either party from disclosing any information required by statute or governmental regulations to be disclosed in a judicial or administrative proceeding after all reasonable legal remedies for maintaining such information in confidence have been practically exhausted or from using information which (i) has been published or has become part of the public domain other than by acts, omissions or fault of such party, (ii) was lawfully received by such party from a third party free of any obligation of confidence to such third party, (iii) a party can demonstrate from its records was already in its possession prior to receipt thereof, directly or indirectly, from the other party, or (iv) is independently developed by employees, agents or independent contractors of the receiving party or its affiliates without reference to or reliance upon the information furnished by the disclosing party, as evidenced by written records or other competent proof. The party asserting the applicability of one of the exclusions from the obligation of confidentiality set forth in the immediately preceding sentence shall have the burden of proving the applicability of any such exclusion in any particular circumstance.

(b) Each party acknowledges that any breach by it of the confidentiality obligations set forth in this Section 13 would cause the other party irreparable harm for which compensation by monetary damages would be inadequate and, therefore, the party that has been

harmed by any such breach shall have the right to an injunction or decree for specific performance, in addition to any other rights and remedies such party may have at law or in equity.

(c) The receiving party shall also be entitled to disclose the other party's confidential information (i) that is required to be disclosed in compliance with applicable laws or regulations (including, without limitation, to comply with SEC, NASDAQ or stock exchange disclosure requirements) or by order of any governmental body or a court of competent jurisdiction, (ii) as may be necessary or appropriate in connection with the enforcement of this Agreement by judicial or other similar process or (iii) as may be necessary for the conduct of clinical studies, *provided* that the party disclosing such information shall promptly notify the other party and shall use commercially reasonable efforts to obtain confidential treatment of such information by the agency or court or other disclosee, and that, in the case of disclosures under clause (i), shall (A) provide the other party with prompt prior notice of the proposed disclosure such that the other party may seek a protective order or other appropriate remedy and (B) provide the other party with a copy of the proposed disclosure in sufficient time to allow reasonable opportunity to comment thereon.

(d) Nothing in this Section 13 shall be construed to create or imply any right or license under any patent rights, trademarks, copyrights or other intellectual property rights owned or controlled by a party or its affiliates except as may be expressly set forth in the other Sections of this Agreement.

(e) To the extent that any confidentiality obligations set forth in this Section 13 are the same or substantially the same as the confidentiality obligations set forth in a separate confidentiality agreement between the parties pertaining to the subject matter herein, the confidentiality obligations set forth in this Section 13 shall supercede such confidentiality agreement, shall govern any and all information disclosed by either party to the other pursuant thereto and shall be retroactively effective to the date of such confidentiality agreement.

14. Indemnification.

(a) Subject to the provisions of Sections 14(b) and 14(c), Mallinckrodt (on behalf of itself and its affiliates) hereby agrees to indemnify, defend and hold harmless Cephalon and its affiliates from and against any and all demands, claims, actions, causes of action,

assessments, losses, damages, injuries, liabilities, costs and expenses, including without limitation, interest, penalties and reasonable attorneys' fees and expenses (collectively "Damages") resulting from, imposed upon or incurred by Cephalon or its affiliates, directly or indirectly related to, arising out of or resulting from third party claims in connection with:

(i) any breach or failure of any of the representations, warranties and covenants of Mallinckrodt contained herein, including (without limitation) any breach or failure by Mallinckrodt to perform any obligations contained herein, and

(ii) any failure of Mallinckrodt to observe or comply in all respects with any applicable laws, rules or regulations directly related to Mallinckrodt's performance hereunder.

(b) Subject to the provisions of Sections 14(a) and 14(c) hereof, Cephalon hereby agrees to indemnify, defend and hold harmless Mallinckrodt and its affiliates from and against any and all Damages asserted against, resulting to, imposed upon or incurred by Mallinckrodt, directly or indirectly related to, arising out of or resulting from third party claims in connection with:

(i) any failure of Cephalon to observe or comply in all respects with any applicable laws, rules or regulations directly related to Cephalon's performance hereunder, and

(ii) Cephalon's or Cephalon's agent's, distributor's or customer's use, processing, transportation, possession, disposal, marketing, distribution or sale of any dosage product manufactured by or for Cephalon that contains any Product, and whether used alone or in combination with any other material.

(c) EXCEPT FOR ANY CLAIM FOR INDEMNITY UNDER SECTION 14(b)(ii) ABOVE, UNDER NO CIRCUMSTANCES SHALL EITHER PARTY BE LIABLE HEREUNDER FOR CONSEQUENTIAL, INDIRECT, EXEMPLARY OR SPECIAL DAMAGES OR ANY KIND (INCLUDING, WITHOUT LIMITATION, LOST PROFITS), WHETHER OR

NOT IN ANY PARTICULAR CIRCUMSTANCE SUCH DAMAGES ARE FORESEEABLE AND WHETHER OR NOT THE RELEVANT PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

15. Term and Termination.

(a) Unless sooner terminated in accordance herewith, the initial term of this Agreement shall be for a period commencing on July 1, 2009 and ending on December 31, 2011 and shall be automatically renewed thereafter for successive twenty four (24) month periods unless either party shall provide written notice to the other party of its intent to terminate at least six (6) months prior to the end of the initial term or any renewal term.

(b) In addition to any other right of termination specifically provided for hereunder, this Agreement may be terminated by either party for cause upon written notice to the other. For purposes of the preceding sentence, "cause" shall mean (without limitation):

(i) any material breach of this Agreement by a party which shall go uncorrected for a period of thirty (30) days after written notice of such breach has been given to the defaulting party,

(ii) the institution by a party of voluntary proceedings in bankruptcy or under any insolvency law or law for the relief of debtors,

(iii) the making by a party of an assignment for the benefit of creditors or any dissolution or liquidation,

(iv) the filing of an involuntary petition under any bankruptcy or insolvency law against a party, unless such petition is dismissed or set aside within sixty (60) days from the date of its filing, or

(v) the appointment of a receiver or trustee for the assets or business of a party, unless such appointment is dismissed or set aside within sixty (60) days from the date of such appointment.

(c) The representations, warranties and covenants of the parties hereunder, which by their terms have effect after the termination or expiration hereof, and the parties' indemnification and confidentiality obligations shall survive termination or expiration of this Agreement in perpetuity unless otherwise expressly limited herein.

(d) In the event of any termination of this Agreement, for whatever reason, Mallinckrodt shall, notwithstanding the effective date of any termination, complete any orders for Products that were placed by Cephalon and accepted by Mallinckrodt prior to such date, and Cephalon shall pay Mallinckrodt for any Product produced in accordance with such orders at the then applicable Product Price in effect on the effective date of termination hereunder.

16. Binding Effect and Assignment.

This Agreement shall inure to the benefit of and be binding upon the parties hereto, their successors and assigns; provided, however, that neither party shall, without the prior written consent of the other party, assign or transfer any of its rights, benefits, obligations, or other interest under this Agreement to any other party, except that, without seeking the consent of either party, the other party may assign this Agreement to an affiliate or a successor in interest to the business associated with the Product, provided that such affiliate or successor acknowledges and agrees in writing to be bound by the terms of this Agreement. Any purported assignment that is not made in accordance with the terms herein shall be null and void.

17. Notice.

All notices, consents, approvals or other notifications required to be sent by one party to the other party hereunder shall be in writing and shall be deemed served upon the other party if delivered by hand or sent by United States registered or certified mail, postage prepaid, with return receipt requested, or by facsimile, air courier or telex, addressed to such other party at the address set out below, or the last address of such party as shall have been communicated to the other party. If a party changes its address, written notice shall be given promptly to the other party of the new address. Notice shall be deemed given on the day it is sent (in the case of delivery by method other than hand delivery) or the date of delivery (in the case of delivery by hand) in accordance with the provisions of this paragraph. The addresses for notices are as follows:

If to Mallinckrodt:

Mallinckrodt Inc.
c/o Pharmaceuticals Group
675 McDonnell Boulevard
Hazelwood, Missouri 63042
Attn: Nick Litzsinger
Global Business Director Bulk Pharmaceuticals

with a copy to:

Mallinckrodt Inc.
675 McDonnell Boulevard
Hazelwood, Missouri 63042
Attn: C. Stephen Kriegh
Vice President - Legal

If to Cephalon:

Cephalon, Inc.
4745 Wiley Post Way
Salt Lake City, Utah 84116
Attn: Purchasing Department

with a copy to:

Cephalon, Inc.
41 Moores Rd.
Frazer, PA. 19355
Attn: Accounts Payable

18. Governing Law and Jurisdiction.

This Agreement shall be governed by and construed in accordance with the laws of the State of Missouri, without reference to its conflict of law provisions that might apply to the law of another jurisdiction.

19. Waiver.

The failure by any party to exercise any of its rights hereunder or to enforce any of the terms or conditions of this Agreement on any occasion shall not constitute or be deemed a waiver of that party's rights thereafter to exercise any rights hereunder or to enforce each and every term and condition of this Agreement.

20. Modifications.

This Agreement may not be amended or modified except by a writing specifically referring to this Agreement and executed by duly authorized representatives of both parties. The obligations of the parties are governed by the terms and conditions of this Agreement and none of the general terms and conditions of any Cephalon purchase order or any Mallinckrodt acknowledgment or any substantially similar documents of either party will in any case be controlling or supersede the provisions hereof.

21. Severability.

A determination that any portion of this Agreement is unenforceable or invalid shall not affect the enforceability or validity of any of the remaining portions hereof or of this Agreement as a whole. In the event that any part of any of the covenants, sections or provisions herein may be determined by a court of law or equity to be overly broad or against applicable precedent or public policy, thereby making such covenants, sections or provisions invalid or unenforceable, the parties shall attempt to reach agreement with respect to a valid and enforceable substitute for the deleted provisions, which shall be as close in its intent and effect as possible to the deleted portions.

22. Headings.

The parties agree that the section and article headings are inserted only for ease of reference, shall not be construed as part of this Agreement, and shall have no effect upon the construction or interpretation of any part hereof.

24. Entire Agreement.

This Agreement and its Schedules represent the entire agreement and understanding of the parties hereto with respect to their subject matter and supersede any and all prior agreements, understanding or discussions, whether written or oral, between the parties.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the day and year first above written.

CEPHALON, INC.

By: _____
Kenneth J. Fiorelli R.ph., Ph.D.
Vice President,
Worldwide Manufacturing Operations

MALLINCKRODT INC.

By: _____
Allyne F. Montano
Senior Product Manager,
Bulk Pharmaceuticals

APPROVED AS TO LEGAL FORM
BCS
CEPHALON LEGAL DEPT.

SCHEDULE A

Foreign Jurisdictions to be listed as and when applicable.

SCHEDULE B

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

SPECIFICATIONS FOR PRODUCT ONE

Raw Material Specification	DOCUMENT NO.	VERSION	STATUS	EFFECTIVE DATE
	RMS-1901	6.0	Effective	12-Jun-2007
Cephalon	TITLE: Fentanyl Citrate Milled USP & Ph Eur			

1 DESCRIPTION

1.1 Fentanyl Citrate Milled USP & Ph Eur

2 ITEM NUMBER

2.1 1901

3 SUPPLIER(S)

3.1 Approved suppliers as listed on the Approved and Certified Supplier List (FRM-0002054).

4 CERTIFICATE OF COMPLIANCE / ANALYSIS

4.1 Certificate of Compliance/Analysis is required with each new supplier lot. The certificate must include all relevant testing results and identify the product with its specific lot number.

5 EXPIRATION DATE

5.1 Three (3) years from the date of manufacture.

6 SAMPLING PLAN

6.1 As outlined in Sampling API for Analysis and Archive (SOP-0001827).

7 STORAGE

7.1 Store under dry conditions in a well closed, light resistant container at controlled room temperature (15 to 30°C) in a secure area with limited access.

8 MATERIAL HAZARDS / PRECAUTIONS

8.1 Fentanyl citrate is a potent opioid, Schedule II controlled substance. Great care should be taken to prevent inhaling particles or exposing skin and mucous membranes to the powder or solutions.

9 TESTS REQUIRED

9.1

U.S. Tests		
Characteristics	**Specifications**	**Methods**
Identification	IR spectrum matches USP RS	USP <197K>
Identification	UV spectrum matches USP RS	USP <197U>
Appearance	White to off-white powder Large plate-like particles are absent	TM-00140
Residue on ignition	NMT 0.5%	USP <281>
Heavy metals	NMT 0.002%	TM-00198 (equiv. To USP <231>)
Ordinary impurities	NMT 2.0%	TM-00207(equiv. To USP <466>, <621>)
Loss on drying USP	NMT 0.5%	TM-00173(equiv. To USP <731>)
Assay USP	98.0 to 102.0%	TM-00157(equiv. To USP)

9.2

Non-Compendial Tests		
Characteristics	**Specifications**	**Methods**
Particle size	D10 NLT 1.1 and NMT 2.5 µm D50 NLT 3.1 and NMT 7.1 µm D90 NLT 6.5 and NMT 18 µm Span (D90 – D10) / D50 NLT 1 and NMT 3	TM-00201
Phenethyl bromide (HPLC)	NMT 0.01% (w/w)	JM Method per DMF
Residual solvents (GC)	NMT 0.5% IPA	JM Method per DMF
Purity (HPLC)	*98.0 to 102.0% (w/w, dried basis)*	*TM-00204*
Impurities (HPLC)	Acetyl (*Ph. Eur.* Impurity C) NMT 0.15% FC 1001 (*Ph. Eur.* Impurity B) NMT 0.15% Individual unspecified NMT 0.10% Total impurities NMT 0.50%	*JM Method per DMF*
Metal impurities (ICP)	NMT 0.005% palladium	JM Method per DMF

Non-Compendial Tests		
Characteristics	**Specifications**	**Methods**
DSC (morphology)	Peak onset 147 to 153°C	TM-00150
Low level arylamines	Impurity B (*Ph. Eur. Impurity D*) NMT 0.01% Impurity A NMT 0.01% FC-1003 NMT 0.01%	MET-0002448

9.3

Non - U.S. Tests		
Characteristics	**Specifications**	**Methods**
Identification	Matches *Ph. Eur.* IR reference spectrum for fentanyl citrate	Absorption spectrophotometry, IR *Ph. Eur.* (2.2.24)
Appearance of solution	Clear, colorless	*Ph. Eur.* (2.2.1, 2.2.2)
Impurity "D" (PPA) Each impurity Total impurities	NMT 0.25% NMT 0.25% NMT 0.5%	*Ph. Eur.* (2.2.29)
Loss on drying	NMT 0.5%	TM-00173 (equiv. to *Ph. Eur.* 2.2.32)
Assay	NLT 99.0% and NMT 101.0%	*TM-00158 (equiv. to Ph. Eur.)*

10 REFERENCE DOCUMENTS

10.1 Current USP/NF

10.2 Johnson Matthey DMF

10.3 Appearance of Fentanyl Citrate, (TM-00140)

10.4 Differential Scanning Calorimetry (DSC) Analysis of Fentanyl Citrate, (TM-00150)

10.5 USP Assay for Fentanyl Citrate, (TM-00157)

10.6 Loss on Drying for Fentanyl Citrate, (TM-00173)

10.7 Heavy Metals Testing USP (Method II), (TM-00198)

10.8 Low Level Arylamines Testing of Johnson Matthey Fentanyl Citrate. (MET-0002448)

10.9 Current Ph Eur.

10.10 Particle Size Distribution of Fentanyl Citrate Dispersed in Fluid, (TM-00201)

10.11 USP Test for Ordinary Impurities in Fentanyl Citrate, (TM-00207)

10.12 Purity Testing of Johnson Matthey Fentanyl Citrate, (TM-00204)

10.13 EP Assay for Fentanyl Citrate, (TM-00158)

10.14 Sampling API for Analysis and Archive, (SOP-0001827)

10.15 Approved and Certified Supplier List, (FRM-0002054)

1 DESCRIPTION

1.1 Fentanyl Citrate Powder, Ph Eur & USP

2 ITEM NUMBER

2.1 0510

3 APPROVED SUPPLIER(S)

3.1 Approved supplier as listed on the Approved and Certified Supplier List (FRM-00260).

4 FORMULA (STRUCTURE)

4.1 $C_{22}H_{28}N_2O \cdot C_6H_8O_7$

5 MOLECULAR WEIGHT

5.1 528.60

6 CERTIFICATE OF COMPLIANCE / ANALYSIS

6.1 Certificate of Compliance/Analysis is required with each new supplier lot. The certificate must include all relevant testing results and identify the product with its specific lot number.

7 EXPIRATION DATE

7.1 Three (3) years from the date of manufacture.

8 SAMPLING PLAN

8.1 Identification amount: 2 g

8.2 Archived amount: 6 g

8.3 **NOTE:** Quantities listed reflect the minimum amount required.

9 STORAGE

9.1 Store under dry conditions in a well closed, light resistant container at controlled room temperature (15 to 30°C) in a secure area with limited access.

10 MATERIAL HAZARDS / PRECAUTIONS

10.1 Fentanyl citrate is a potent opioid, Schedule II controlled substance. Great care should be taken to prevent inhaling particles or exposing skin and mucous membranes to the powder or solutions.

11 REFERENCE STANDARDS

11.1 <11> USP Fentanyl Citrate RS

11.2 Ph Eur IR reference spectrum

12 TESTS REQUIRED

12.1

Non – U.S. Tests		
Characteristics	**Specifications**	**Methods**
Identification	Matches Ph. Eur IR ref. Spectrum of Fentanyl Citrate	Absorption spectrophotometry, IR Ph. Eur (2.2.24)
Appearance of solution	Clear colorless	Ph. Eur (2.2.1, 2.2.2)
Impurity "D" (PPA) Each Impurity Total Impurities	NMT 0.25% NMT 0.25% NMT 0.5%	Ph Eur (2.2.29)
Loss on drying	NMT 0.5%	TM-00173 (Equivalent to Ph Eur 2.2.32)
Assay	NLT 99.0% and NMT 101.0%	TM-00158 (Equivalent to Ph. Eur)
Residual Solvents	In compliance with CPMP/ICH/283/95	Ph.Eur 2.4.24

Particle Size (Alpine Jet sieve method TM-00148)

Screen # (Mesh)	Particle Size (microns)	Specification
200	75	98% min through
450	32	70% min through
635	20	90% max through

12.2

U.S. Tests		
Characteristics	**Specifications**	**Methods**
Identification	IR spectrum matches USP RS UV spectrum matches USP RS	USP <197K> USP <197U>
Loss on drying	NMT 0.5%	TM-00173
Assay	NLT 98.0% and NMT 102.0%	TM-00157
Residue on ignition Heavy Metals Ordinary impurities	NMT 0.5% NMT 0.002% NMT 2.0%	USP <281> TM-00198 TM-00207
Appearance	White to off-white powder Large, plate-like particles are absent	TM-00140
Assay PPA impurity Acetyl analog Pyruvyl analog Butyryl analog Fentanyl n-oxide Unknown related substances Total related substances	98.0 - 102.0% NMT 0.15% w/w NMT 0.15% w/w NMT 0.15% w/w NMT 0.15% w/w NMT 0.15% w/w NMT 0.10% w/w NMT 0.50% w/w	TM-00141
Differential scanning calorimetry (DSC)	Peak onset near 152°C	TM-00150

Particle Size

Characteristics	Specifications	Methods
D_{10}	NLT 0.5µm and NMT 2.0µm	TM-00159
D_{50}	NLT 3µm and NMT 14µm	
D_{90}	NLT 12µm and NMT 50µm	
Span	2.6 - 5.0	TM-00159

13 REFERENCES

13.1 Approved and Certified Supplier List, **(FRM-00260)**

13.2 Appearance of Fentanyl Citrate, **(TM-00140)**

13.3 Fentanyl Citrate USP Powder Assay and Related Substances, **(TM-00141)**

13.4 Particle Size Analysis of Fentanyl Citrate by Alpine Jet Sieve, **(TM-00148)**

13.5 Differential Scanning Calorimetry (DSC) Analysis of Fentanyl Citrate, **(TM-00150)**

13.6 USP Assay for Fentanyl Citrate, **(TM-00157)**

13.7 EP Assay for Fentanyl Citrate, **(TM-00158)**

13.8 Particle Size Distribution of Fentanyl Citrate Using the Mastersizer 2000, **(TM-00159)**

13.9 Loss on Drying for Fentanyl Citrate, **(TM-00173)**

13.10 Heavy Metals Testing USP (Method II), **(TM-00198)**

13.11 USP Test for Ordinary Impurities in Fentanyl Citrate, **(TM-00207)**

HISTORY OF CHANGES *(List the last two versions)*

Version	Change Tracking #	Initiator of Change	Effective Date	Short Detail of Change
02	SPEC326	K. Harmer	7/5/05	Section 12, Tests Required, Non-US and US testing was broken out into seperate tables for easier reference. A U.S. particle size specification is added as dictated in a letter to the FDA on April 19, 2005 regarding NDA 20-747, Actiq (oral transmucosal fentanyl citrate), Amendment to S-021. The old specifications are kept since they are part of regulatory commitments outside the U.S. The new laser diffraction particle size specifications are D10, D50, D90, and Span, all of which will be determined by Test Method TM-00119. Additional changes made: Cephalon versions of compendial test methods have been produced for Loss on Drying and Assay. The methods are equivalent to compendial methods, so no change in testing is implied. Appearance and DSC are added to the Tests Required in the US Tests section in compliance with earlier commitments made to the FDA. A row has been added to this section for results obtained with test method TM-00141. This test method is a Cephalon version of a Mallinckrodt related substance method, and is required to confirm results on the vendor C of A.
03	SPEC395	J. Harwood	12/19/05	Updated to include the reference to the Approved and Certified Supplier List (FRM-00260). Updated the expiration date to be consistent with the suppliers recommended re-test date of 3 years. In section 12.2 under specifications for Heavy Metals 'NMT' was added.
04	SPEC466	K. Harmer	Refer to cover page	Mallinckrodt's related substance testing spec changed on May 2, 2006, therefore, the same changes are being made to our RMS. Change to the related substance specifications listed in the U.S. Tests table under method TM-00141. TM-00207 listed as the method for the "Ordinary Impurities" entry in the U.S. Tests table.

SPECIFICATIONS FOR PRODUCT TWO

Mallinckrodt Specification for Hydromorphone Hydrochloride, USP - Code 3245 (04/16/09)

TESTS	LIMITS
Appearance	white to off-white powder
Identification A (IR) (USP)	matches reference standard
Identification B (UV) (USP)	3.0% max absorptivities difference
Identification C (Chloride) (USP)	white precipitate
Specific Rotation (25°C) (USP)	-136° to -139°
Acidity (USP)	0.30 mL max
Loss on Drying (USP)	1.5% max
Residue on Ignition (USP)	0.3% max
Sulfate (USP)	no turbidity
Ordinary Impurities (TLC) (USP)	2.0% max
Organic Volatile Impurities (equal to USP)	
1,4-Dioxane	meets USP requirements
Methylene Chloride	meets USP requirements
Trichloroethylene	meets USP requirements
Residual Solvents	
Chloroform	3 ppm max
Isopropanol	5000 ppm max
Assay (Titration)(dried basis)(USP)	98.0 - 101.0%
Assay (HPLC) (dried basis)	
Hydromorphone Hydrochloride	98.0 – 102.0% w/w
Related Substances	
2,2' - Bishydromorphone	0.50% w/w max
7,8' - Bishydromorphone	0.50% w/w max
Other related substances (each)	0.50% w/w max
Unknown related substances (each)	0.10% w/w max
Total related substances	2.0% w/w max
Morphinone (HPLC)	0.15% w/w max
Sieve US Standard No. 200	20% max retained

SPECIFICATIONS FOR PRODUCT THREE

Mallinckrodt Specification for Hydrocodone Bitartrate, USP Crystals – Code 1582 (2/03/09)

Appearance	Fine white or slightly yellow white powder
Solubility	Clear Solution
Color test (optical density)	0.31 max
Identification A (IR) (USP)	Matches Standard
Identification B (UV) (USP)	Matches Standard (Absorptivites 3% max difference)
Specific Rotation (as is basis) (25°C) (USP)	-79° to -84°
pH (USP)	3.2 - 3.8
Loss on drying (105°C) (USP)	7.5 - 12.0%
Residue on ignition (USP)	0.1% max
Chloride (Cl) (USP)	No opalescence
Ordinary Impurities (TLC) (USP)	2.0% max
Organic volatile impurities (OVI) (USP)	Meets USP requirements
Assay (HPLC) (equal to USP) Hydrocodone Bitartrate (dried basis)	98.0 - 102.0% w/w
Related Substances:	
Dihydrocodeine Bitartrate (Parzone® Bitartrate)	0.15% w/w max
Hydrocodone Aldol Dimer Bitartrate	0.15% w/w max
7-Cyclohexenyl Hydrocodone Bitartrate	0.15% w/w max
Hydrocodone Diol Bitartrate	0.15% w/w max
Unknown related substances (each)	0.10% w/w max
Total related substances	1.5% w/w max
Residual Solvents (USP)	
Alcohols (total)	1.0% max
Methanol	0.30% max
Ethanol	0.80% max
Sieve Tests	
US Standard No. 20	1% max retained
US Standard No. 45	3% max retained
US Standard No. 200	25% max retained

SCHEDULE C

QUALITY TECHNICAL AGREEMENT

[See attached Quality Technical Agreement dated August 3, 2004]

EXHIBIT 12

G0013002-03

Cephalon

January 12, 2010

Mallinckrodt Inc.
c/o Pharmaceuticals Group
675 McDonnell Boulevard
Hazelwood, Missouri 63042
Attention: Nick Litzsinger

Re: Amendment No. 1 to Amended and Restated Agreement

Dear Nick:

This letter is to confirm our mutual understanding concerning an amendment to that certain Amended and Restated Supply Agreement dated as of July 1, 2009 (the "Restated Agreement") by and between Mallinckrodt Inc. ("Mallinckrodt") and Cephalon, Inc. (together with its affiliates and wholly owned subsidiaries Anesta Corp. and CIMA LABS INC., "Cephalon"). The Restated Agreement replaced that certain Supply Agreement dated January 1, 2008 (the "Original Agreement") by and between Mallinckrodt and Cephalon. All terms not otherwise defined herein are used as defined in the Restated Agreement.

As you know, the parties recently discovered that outdated Specifications for Product One were included in Schedule B to the Restated Agreement at the time executed copies of the Restated Agreement were exchanged by the parties. The Specifications for Product One effective February 2009, under which the parties had been operating pursuant to the Original Agreement until July 1, 2009, should have been attached to the Restated Agreement.

The purpose of this Amendment is to provide the correct Specifications for Product One without changing the Specifications for Product Two and Product Three. However, in order to minimize any uncertainty in the future, Schedule B shall be replaced in its entirety.

The Restated Agreement is hereby amended as follows, effective as of July 1, 2009:

1. Schedule B to the Restated Agreement is hereby deleted in its entirety and replaced with the Schedule B attached hereto as Exhibit A (the "Corrected Schedule B").

2. The parties agree and confirm that any Product made and/or delivered pursuant to the Restated Agreement after July 1, 2009 shall be subject to the Specifications set forth in the Corrected Schedule B.

3. Except as amended hereby, the Restated Agreement remains in full force and effect.

If the foregoing accurately reflects your understanding as to these matters, please indicate your agreement in the space provided below, and return one fully-executed original to Cephalon.

Very truly yours,

CEPHALON, INC.

By: K. M. Feld
Name:
Title:

KENNETH M. FELD
VICE PRESIDENT
WORLDWIDE PROC. DEV.

ACKNOWLEDGED AND AGREED:

MALLINCKRODT INC.

By:
Name: NICK LITZINGER
Title: GLOBAL DIRECTOR BULK NARCOTICS

APPROVED AS TO LEGAL FORM
BCS
CEPHALON LEGAL DEPT.

EXHIBIT A

Raw Material Specification	DOCUMENT NO.	VERSION	STATUS	EFFECTIVE DATE
	RMS-1901	7.0	Effective	10-Feb-2009
Cephalon	TITLE: Fentanyl Citrate Milled USP & Ph Eur			

OWNING FUNCTION: Quality Control
OWNING SUBFUNCTION: Analytical

APPROVALS

Approver	Meaning	Approval Date (GMT)
Childs Joey	Affected Area Approval	22-Jan-2009 04:21:15 PM
Hartner Ken	Author Approval	22-Jan-2009 06:10:07 PM
Bemis Paul	QA Approval	26-Jan-2009 09:29:06 PM
Chugg Nick	Affected Area Approval	06-Feb-2009 09:41:57 PM

1 DESCRIPTION

1.1 FENTANYL CITRATE MILLED, USP/PH EUR

2 ITEM NUMBER

2.1 00010565

3 SUPPLIER(S)

3.1 Approved suppliers as listed on the Approved and Certified Supplier List (FRM-0002054).

4 CERTIFICATE OF COMPLIANCE / ANALYSIS

4.1 Certificate of Compliance/Analysis is required with each new supplier lot. The certificate must include all relevant testing results and identify the product with its specific lot number.

5 EXPIRATION DATE

5.1 Three (3) years from the date of manufacture.

6 SAMPLING PLAN

6.1 As outlined in Sampling API for Analysis and Archive (SOP-0001827).

7 STORAGE

7.1 Store under dry conditions in a well closed, light resistant container at controlled room temperature (15 to 30°C) in a secure area with limited access.

8 MATERIAL HAZARDS / PRECAUTIONS

8.1 Fentanyl citrate is a potent opioid, Schedule II controlled substance. Great care should be taken to prevent inhaling particles or exposing skin and mucous membranes to the powder or solutions.

9 TESTS REQUIRED

9.1

Non - U.S. Tests		
Characteristics	**Specifications**	**Methods**
Identification	Matches *Ph. Eur.* IR reference spectrum for fentanyl citrate	Absorption spectrophotometry, IR *Ph. Eur.* (2.2.24)
Appearance	White to off-white powder Larger plate-like particles are absent	TM-00140
Appearance of solution	Clear, colorless	*Ph. Eur.* (2.2.1, 2.2.2)
Impurity "D" (PPA) Each specified impurity Any other impurity Total impurities	NMT 0.25% NMT 0.25% NMT 0.10% NMT 0.5%	MET-0004301 (equiv. to *Ph. Eur.* 2.2.29)
Loss on drying	NMT 0.5%	TM-00173 (equiv. to *Ph. Eur.* 2.2.32)
Assay	NLT 99.0% and NMT 101.0%	TM-00158 (equiv. to *Ph. Eur.*)
Particle size	D10 NMT 3 µm *D50 NMT 14 µm* D90 NMT 50 µm	TM-00159

9.2

U.S. Tests		
Characteristics	**Specifications**	**Methods**
Identification	IR spectrum matches *USP RS*	*USP <197K>*
Identification	UV spectrum matches USP RS	USP <197U>
Appearance	White to off-white powder Large plate-like particles are absent	TM-00140
Residue on ignition	NMT 0.5%	USP <281>
Heavy metals	*NMT 0.002%*	TM-00198 (equiv. To USP <231>)
Ordinary impurities	NMT 2.0%	TM-00207(equiv. To USP <466>, <621>)

U.S. Tests		
Characteristics	**Specifications**	**Methods**
Loss on drying USP	NMT 0.5%	TM-00173(equiv. To USP <731>)
Assay USP	98.0 to 102.0%	TM-00157(equiv. To USP)

9.3

Non-Compendial Tests (Performed for US and non-US product)		
Characteristics	**Specifications**	**Methods**
Particle size	D10 NLT 1.1 and NMT 2.5 µm D50 NLT 3.1 and NMT 7.1 µm D90 NLT 6.5 and NMT 18 µm Span (D90 – D10) / D50 NLT 1 and NMT 3	TM-00201
Phenethyl bromide (HPLC)	NMT 0.01% (w/w)	JM Method per DMF
Residual solvents (GC)	NMT 0.5% IPA	JM Method per DMF
Purity (HPLC)	98.0 to 102.0% (w/w. dried basis)	TM-00204
Impurities (HPLC)	Acetyl (*Ph. Eur.* Impurity C) NMT 0.15% FC 1001 (*Ph. Eur.* Impurity B) NMT 0.15% Individual unspecified NMT 0.10% Total impurities NMT 0.50%	MET-0002549
Metal impurities (ICP)	NMT 0.005% palladium	JM Method per DMF
DSC (morphology)	Peak onset 147 to 153°C	TM-00150
Low level arylamines	Impurity B (*Ph. Eur. Impurity D*) NMT 0.01% Impurity A NMT 0.01% FC-1003 NMT 0.01%	MET-0002448

10 REFERENCE DOCUMENTS

10.1 Current USP/NF

10.2 Johnson Matthey DMF

10.3 Appearance of Fentanyl Citrate, **(TM-00140)**

10.4 Differential Scanning Calorimetry (DSC) Analysis of Fentanyl Citrate, **(TM-00150)**

10.5 USP Assay for Fentanyl Citrate, **(TM-00157)**

10.6 Loss on Drying for Fentanyl Citrate, **(TM-00173)**

10.7 Heavy Metals Testing USP (Method II). **(TM-00198)**

10.8 Low Level Arylamines Testing of Johnson Matthey Fentanyl Citrate, **(MET-0002448)**

10.9 Current Ph Eur.

10.10 Particle Size Distribution of Fentanyl Citrate Dispersed in Fluid. **(TM-00201)**

10.11 USP Test for Ordinary Impurities in Fentanyl Citrate, **(TM-00207)**

10.12 Purity Testing of Johnson Matthey Fentanyl Citrate, **(TM-00204)**

10.13 EP Assay for Fentanyl Citrate, **(TM-00158)**

10.14 Sampling API for Analysis and Archive. **(SOP-0001827)**

10.15 Approved and Certified Supplier List, **(FRM-0002054)**

10.16 Impurities Testing of Johnson Matthey Fentanyl Citrate, **(MET-0002549)**

10.17 Particle Size Distribution of Fentanyl Citrate Using the Mastersizer 2000, **(TM-00159)**

10.18 Fentanyl Citrate Related Substances per Ph Eur, **(MET-0004301)**

HISTORY OF CHANGES *(List the last two versions)*

Version	Initiator of Change	Effective Date	Short Detail of Change
5.0	K. Hartner	3/6/07	(Ver 4.0 was approved but not made effective. Changes had to be made to the document after it had been sent to approval. The document was cancelled and pulled back to draft as version 5.0. All changes made to 4.0 were accepted and are in the current document.) The correction to the published document is removal of test method numbers MET-0002549 and MET-0002448. These methods are not published yet, so inclusion of them in this RMS was premature.
6.0	S. Jenkins	06/12/07	When Ph Eur tests were included in version 4.0 the description was never updated. The description was updated to include Ph Eur. Also added the in-house test method MET-0002448 for low level of arylamines, which is equivalent to JM DMF. Added reference to equivalent methods found in the USP for clarification.
7.0	K. Hartner	Refer to cover page	SAP description and item number inserted. Referenced internal method (MET-0004301) for Ph Eur impurities, equivalent to 2.2.29. Addition of Ph Eur specification of NMT 0.10% for "any other impurity", complies with ICH requirements and the request of EU regulatory authorities. Addition of a new particle size spec for non-US tests per PR17184 / 17482: part of EU filing for use of JM material in Actiq. Inclusion of MET-0002549 for non-compendial Impurities (HPLC) test, equivalent to the JM method referred to previously. Appearance added to non-US tests.

OWNING FUNCTION: Quality Control
OWNING SUBFUNCTION: Analytical

APPROVALS

Approver	Meaning	Approval Date (GMT)
Childs Joey	Affected Area Approval	22-Jan-2009 04:20:39 PM
Hartner Ken	Author Approval	22-Jan-2009 06:11:31 PM
Bemis Paul	QA Approval	26-Jan-2009 09:29:30 PM
Chugg Nick	Affected Area Approval	06-Feb-2009 09:41:41 PM

1 DESCRIPTION

1.1 FENTANYL CITRATE POWDER, USP/PH EUR

2 ITEM NUMBER

2.1 00010566

3 APPROVED SUPPLIER(S)

3.1 Approved supplier as listed on the Approved and Certified Supplier List (FRM-0002054).

4 FORMULA (STRUCTURE)

4.1 $C_{22}H_{28}N_2O \cdot C_6H_8O_7$

5 MOLECULAR WEIGHT

5.1 528.60

6 CERTIFICATE OF COMPLIANCE / ANALYSIS

6.1 Certificate of Compliance/Analysis is required with each new supplier lot. The certificate must include all relevant testing results and identify the product with its specific lot number.

7 EXPIRATION DATE

7.1 Three (3) years from the date of manufacture.

8 SAMPLING PLAN

8.1 As outlined in Sampling API for Analysis and Archive, (SOP-0001827).

9 STORAGE

9.1 Store under dry conditions in a well closed, light resistant container at controlled room temperature (15 to 30°C) in a secure area with limited access.

10 MATERIAL HAZARDS / PRECAUTIONS

10.1 Fentanyl citrate is a potent opioid, Schedule II controlled substance. Great care should be taken to prevent inhaling particles or exposing skin and mucous membranes to the powder or solutions.

11 REFERENCE STANDARDS

11.1 <11> USP Fentanyl Citrate RS

11.2 Ph Eur IR reference spectrum

12 TESTS REQUIRED

12.1

Non – U.S. Tests		
Characteristics	**Specifications**	**Methods**
Identification	Matches Ph. Eur IR ref. Spectrum of Fentanyl Citrate	Absorption spectrophotometry. IR Ph. Eur (2.2.24)
Appearance	White to off-white powder Large plate-like particles are absent	TM-00140
Appearance of solution	Clear colorless	Ph. Eur (2.2.1, 2.2.2)
Impurity "D" (PPA) Each specified impurity Any other impurity Total Impurities	NMT 0.25% NMT 0.25% NMT 0.10% NMT 0.5%	MET-0004301 (Equivalent to Ph Eur 2.2.29)
Loss on drying	NMT 0.5%	TM-00173 (Equivalent to Ph Eur 2.2.32)
Assay	NLT 99.0% and NMT 101.0%	TM-00158 (Equivalent to Ph. Eur)
Residual Solvents	In compliance with *CPMP/ICH/283/95*	Ph.Eur 2.4.24

Non-US Particle Size

Characteristics	Specifications	Methods
D_{10}	NMT 3µm	TM-00159
D_{50}	NMT 14µm	
D_{90}	NMT 50µm	

Particle Size (Alpine jet sieve method TM-00148)

Screen # (Mesh)	Particle Size (microns)	Specification
200	75	98% min through
450	32	70% min through
635	20	90% max through

12.2

U.S. Tests		
Characteristics	**Specifications**	**Methods**
Identification	IR spectrum matches USP RS	USP <197K>
	UV spectrum matches USP RS	USP <197U>
Loss on drying	NMT 0.5%	TM-00173
Assay	NLT 98.0% and NMT 102.0%	TM-00157
Residue on ignition	NMT 0.5	USP <281>
Heavy Metals	NMT 0.002%	TM -00198
Ordinary impurities	NMT 2.0%	TM-00207
Appearance	White to off-white powder Large plate-like particles are absent	TM-00140
Assay	98.0 - 102.0%	TM-00141
PPA impurity	NMT 0.15% w/w	
Acetyl analog	NMT 0.15% w/w	
Pyruvyl analog	NMT 0.15% w/w	
Butyryl analog	NMT 0.15% w/w	
Fentanyl n-oxide	NMT 0.15% w/w	
Unknown related substances	NMT 0.10% w/w	
Total related substances	NMT 0.50% w/w	
Differential scanning calorimetry (DSC)	Peak onset near 152°C	TM-00150
Residual Solvents	2-propanol ≤ 0.5%	USP <467>

US Particle Size

Characteristics	Specifications	Methods
D_{10}	NLT 0.5µm and NMT 2.0µm	TM-00159
D_{50}	NLT 3µm and NMT 14µm	
D_{90}	NLT 12µm and NMT 50µm	
Span	2.6 - 5.0	TM-00159

13 REFERENCES

13.1 Approved and Certified Supplier List, **(FRM-0002054)**

13.2 Appearance of Fentanyl Citrate, **(TM-00140)**

13.3 Fentanyl Citrate USP Powder Assay and Related Substances, **(TM-00141)**

13.4 Particle Size Analysis of Fentanyl Citrate by Alpine Jet Sieve, **(TM-00148)**

13.5 Differential Scanning Calorimetry (DSC) Analysis of Fentanyl Citrate, **(TM-00150)**

13.6 USP Assay for Fentanyl Citrate, **(TM-00157)**

13.7 EP Assay for Fentanyl Citrate, **(TM-00158)**

13.8 Particle Size Distribution of Fentanyl Citrate Using the Mastersizer 2000, **(TM-00159)**

13.9 Loss on Drying for Fentanyl Citrate, **(TM-00173)**

13.10 Heavy Metals Testing USP (Method II), **(TM-00198)**

13.11 USP Test for Ordinary Impurities in Fentanyl Citrate, **(TM-00207)**

13.12 Sampling API for Analysis and Archive, **(SOP-0001827)**

13.13 Fentanyl Citrate Related Substances per Ph Eur, **(MET-0004301)**

HISTORY OF CHANGES *(List the last two versions)*

Version	Change Tracking #	Initiator of Change	Effective Date	Short Detail of Change
03	SPEC395	J. Harwood	12/19/05	Updated to include the reference to the Approved and Certified Supplier List (FRM-00260). Updated the expiration date to be consistent with the suppliers recommended re-test date of 3 years. In section 12.2 under specifications for Heavy Metals 'NMT' was added.
04	SPEC466	K. Hartner	07/13/06	Mallinckrodt's related substance testing spec changed on May 2, 2006, therefore, the same changes are being made to our RMS. Change to the related substance specifications listed in the U.S. Tests table under method TM-00141. TM-00207 listed as the method for the "Ordinary Impurities" entry in the U.S. Tests table.
5.0	n/a	K. Hartner	Refer to cover page.	Periodic Review. Sampling SOP and supplier form updated to current number. SAP item number and description inserted. Addition of Ph Eur specification of NMT 0.10% for "any *other* impurity", complies with ICH requirements and the request of EU regulatory authorities. Referenced internal method for non-US impurities, equivalent to Ph Eur 2.2.29. Addition of a new particle size spec for non-US tests per PR17184 / 17482. Added US testing for residual solvents for compliance to change in USP <467>. PR16385. Appearance added to non-US tests.