EXHIBIT 10.25  
  
 MANUFACTURING AND SUPPLY AGREEMENT  
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 THIS MANUFACTURING AND SUPPLY AGREEMENT (the "Agreement") is made and  
entered into this 11 day of April, 2001 (the "Effective Date"), by and between  
CELGENE CORPORATION ("Celgene") and MIKART, INC. ("Mikart"). Mikart is a Georgia  
corporation with its principal place of business at 0000 Xxxxxxxxxxxxx Xxxxxx,  
Xxxxxxx, Xxxxxxx 00000. Celgene is a Delaware corporation with its principal  
place of business at 0 Xxxxxx Xxxx Xxxxx, Xxxxxx, Xxx Xxxxxx 00000.  
  
 BACKGROUND:  
  
 Subject to the terms and conditions contained in this Agreement,  
Celgene desires to engage Mikart to manufacture the "Product" (as hereinafter  
defined) for commercial distribution by Celgene, and Mikart desires to accept  
such appointment.  
  
 In consideration of the foregoing premise, and mutual covenants and  
obligations set forth herein, Celgene and Mikart hereby agree as follows:  
  
 ARTICLE 1  
 DEFINITIONS  
 -----------  
  
 The following words, terms and phrases, when used herein, shall have  
the following respective meanings.  
  
 1.1 "API" shall mean the active pharmaceutical ingredient d-threo  
methylphenidate HCl.  
  
 1.2 "Batch" shall mean the quantity of two million (2,000,000) tablets  
of the Product in the 2.5 mg, 5 mg or 10 mg strengths.  
  
 1.3 "Contract Year" shall mean a twelve (12) consecutive month period  
after the Qualification Date and during the Term of this Agreement. The first  
Contract Year shall commence as of the Qualification Date, and subsequent  
Contract Years shall commence on each anniversary of the Qualification Date.  
  
 1.4 "FDA" shall mean the United States Food and Drug Administration or  
any successor agency thereof.  
  
 1.5 "Master Batch Record" shall mean the document containing the  
formulas, manufacturing process and analytical test methods for the Product set  
forth in Exhibit A.  
  
 1.6 "Product" shall mean d-threo-methylphenidate HCl tablets in 2.5 mg,  
5 mg and 10 mg strengths.  
  
  
  
 1.7 "Qualification Date" shall mean the date on which Mikart  
satisfactorily completes its validation pursuant to Article 2 of this Agreement.  
  
 1.8 "Raw Materials" shall mean the excipients necessary for  
manufacturing and packaging operations (exclusive of the API) as listed in the  
Master Batch Record.  
  
 1.9 "Specifications" shall mean the specifications for the  
manufacturing, packaging and labeling of the Product described on Exhibit B  
attached hereto and incorporated herein by reference.  
  
 1.10 "Territory" shall mean the United States of America and its  
territories and such other locations as may be designated by the parties hereto.  
  
 1.11 "Test" or "Testing" shall mean the analytical procedures, as  
applicable for Raw Materials, API, in-process materials and Product set forth in  
the Specifications.  
  
 ARTICLE 2  
 VALIDATION  
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 2.1 VALIDATION. Celgene and Mikart acknowledge that Mikart must  
validate three (3) Batches of each of the 2.5 mg, 5 mg and 10 mg strengths of  
the Product prior to selling any of the Product to Celgene. Mikart shall conduct  
such validation on three (3) Batches of each of the 2.5 mg, 5 mg and 10 mg  
strengths of the Product and, thereafter, Celgene shall be obligated to purchase  
such Batches in accordance with the terms of this Agreement. Such Batches shall  
be part of, and shall be applied to, Celgene's minimum purchase requirements  
within the first Contract Year. Celgene shall review and authorize both the  
validation protocols and validation reports.  
  
 ARTICLE 3  
 MANUFACTURE  
 -----------  
  
 3.1 LIMITED WARRANTIES. Mikart hereby represents and warrants to  
Celgene that all Product manufactured and sold to Celgene hereunder shall  
conform to the Specifications and shall be free of all defects in materials and  
workmanship. All Product, when manufactured, packaged and sold to Celgene, shall  
comply with all applicable federal, state and local laws, rules and regulations  
in the Territory, including without limitation the current Good Manufacturing  
Practices as published and amended from time to time by the FDA, and Mikart's  
manufacturing and storage facilities shall comply with all applicable federal,  
state and local laws, rules and regulations in the Territory. EXCEPT AS SET  
FORTH IN THIS SECTION 3.1 AND SECTION 10.1, MIKART MAKES NO OTHER  
REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, REGARDING THE PRODUCTS  
MANUFACTURED BY IT HEREUNDER AND SPECIFICALLY DISCLAIMS ALL SUCH OTHER  
REPRESENTATIONS AND WARRANTIES, INCLUDING, WITHOUT LIMITATION, THE IMPLIED  
WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. With  
respect to each Batch of a Product manufactured hereunder, this Section 3.1  
shall remain effective until the expiration date noted on such Product.  
  
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 3.2 QUALITY CONTROL  
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 (a) Mikart will perform, at Mikart's expense, quality control  
 Testing on the Product in accordance with normal industry standards to  
 determine whether such Product conforms to the Specifications.  
 Contemporaneously with each shipment of Product hereunder, Mikart will  
 provide Celgene with a certificate of analysis with respect to such  
 Product. In addition, Mikart will perform, at Celgene's expense, any  
 and all other testing relating to the Product which is reasonably  
 requested by Celgene and promptly provide Celgene with the results  
 thereof; provided, however, Celgene shall not be responsible for the  
 expenses associated with any such testing which shows that such Product  
 does not meet the Specifications.  
  
 (b) In addition, Mikart shall be responsible for conducting an  
 ongoing stability program for the Product as required by federal law.  
  
 (c) Mikart will, upon the reasonable request of Celgene, assay any  
 Product returned to Celgene by a third party purchaser. Celgene shall  
 reimburse Mikart for the costs of any such assay unless the results  
 thereof prove the cause of return is as a result of Mikart's negligence  
 or willful misconduct or the failure of such Product to comply with the  
 limited warranties contained in Section 3.1 hereof.  
  
 (d) In the event that any Batch is subject to a recall, Celgene, at  
 its expense, shall conduct the recall, except that Mikart shall  
 reimburse Celgene for the costs of such recall (including reimbursing  
 Celgene for the Product at the invoice prices paid by Celgene  
 therefore) in the Territory to the extent such recall results from the  
 manufacture, packaging or storage of such Product by Mikart.  
  
 (e) Each party hereto shall promptly notify the other of any recall  
 of either Product which has been directed by it or by any governmental  
 or regulatory entity or agency for any reason whatsoever. Such notice  
 shall identify the reason for the recall and all relevant details  
 thereof.  
  
 (f) Each party hereto shall notify the other within twenty-four  
 hours via fax, with a copy via U.S. Mail within five calendar days, of  
 all notices received by it from the FDA during the Term of this  
 Agreement relating to the design, manufacture, packaging, shipping,  
 storage or sale of the Product.  
  
 (g) Upon the reasonable advance request of Celgene, Mikart shall  
 permit a representative of Celgene and its Licensee (Novartis Pharma,  
 AG) to inspect its facilities where the Product is manufactured,  
 packaged and stored.  
  
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 3.3 PACKAGING MATERIALS. Mikart shall order from time to time, at  
Celgene's request and expense, labels, package inserts and other packaging  
materials in sufficient quantities to permit the packaging of the Product  
ordered by Celgene from time to time hereunder. Mikart shall not be responsible  
for any packaging labels, package inserts and any other packaging materials, to  
the extent that such packaging contains the Specifications, instructions,  
directions and/or warnings, and all such packaging labels, package inserts and  
other packaging materials, relating to the Specifications, instructions,  
directions and/or warnings, shall be the sole responsibility of Celgene.  
  
 3.4 API  
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 (a) API Delivery. At least ninety (90) days prior to Celgene's  
 first firm purchase order submitted under Section 4.2, Celgene shall  
 identify the source of the API to Mikart and shall furnish the API to  
 Mikart, free of charge, in such quantities as are necessary to enable  
 Mikart to manufacture the Products ordered. Celgene or its designee  
 will ship to Mikart the API released with a certificate of analysis for  
 the API.  
  
 (b) API Segregation. Mikart shall keep all API segregated from  
 other materials within its reasonable control so as to maintain the  
 integrity of the substance and shall not allow any samples of the  
 substance to be used or Tested by any party not under its direct  
 supervisory control for any purposes. Mikart shall perform only such  
 Tests and analysis as it deems necessary for this Agreement and shall  
 maintain the confidentiality of such Test results in compliance with  
 Section 11.1 below. The API shall remain the property of Celgene until  
 used by Mikart in the Processing.  
  
 (c) API Verification. Mikart shall verify the quantity and quality  
 of all API received by Mikart according to the methods and procedures  
 set forth in the Specifications within sixty (60) days of receipt by  
 Mikart of the API. Within such sixty (60) day period, Mikart shall  
 inform Celgene in writing of any discrepancies in the quantity and/or  
 quality of the API received and the documents accompanying each  
 shipment of the API.  
  
 (d) Timely API Discrepancy. If Mikart notifies Celgene of a  
 discrepancy in the quantity or quality of the API within such sixty  
 (60) day period, Celgene shall endeavor in good faith to ship  
 additional API within the time period necessary for Mikart to  
 manufacture Commercial Product in accordance with the completion date  
 for delivery of Commercial Product pursuant to the applicable purchase  
 order.  
  
 (e) Legal Notice of Discrepancy, or API Damage. If Mikart fails to  
 inform Celgene of any discrepancy in the quantity or quality of the API  
 within such sixty (60) day period or if there is damage to the API  
 within the foregoing sixty (60) day period and Mikart cannot  
 demonstrate that such damage occurred prior to delivery to Mikart or if  
 any such damage is the result of Mikart's failure to handle the API in  
 accordance with the terms of this Agreement, then Mikart shall (i) at  
 Mikart's option return the API to Celgene or dispose of same according  
 to Celgene's instructions and (ii) at Celgene's option, either (A)  
 purchase from Celgene replacement API for a value equal to Celgene's  
 then current API cost for the API that is lost, damaged or destroyed,  
 or (B) credit Celgene on it's next invoice for an amount equal to  
 Celgene's then-current cost for such API.  
  
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 (f) Other API Damage or Loss. Mikart shall assume responsibility  
 and liability for, and shall defend, indemnify and hold Celgene  
 harmless from and against, any loss of or damage to the API while  
 Mikart has custody and control over the API, In-Process Materials  
 and/or the finished Commercial Product. Such responsibility and  
 liability shall commence upon Mikart's receipt of the API at Mikart's  
 manufacturing facility and end upon the delivery of the Commercial  
 Product to a common carrier at the manufacturing facility for shipment  
 to Celgene. Without limiting the generality of the foregoing, lost or  
 damaged API shall be disposed of and replaced or credited as provided  
 in Section 3.1(e).  
  
 3.5 SUPPLY AND PURCHASE OBLIGATIONS. During the Term of this Agreement,  
Mikart shall manufacture and supply Products exclusively for Celgene. Celgene  
shall purchase at least fifty percent (50%) of its requirements of Products from  
Mikart pursuant to Section 4.1 below and subject to Section 4.2 below unless  
Mikart fails to supply conforming Products for any two (2) out of four (4)  
consecutive calendar quarters.  
  
 ARTICLE 4  
 ORDERS AND SALES  
 ----------------  
  
 4.1 FORECASTS. Commencing on the Qualification Date, and thereafter at  
least thirty (30) days prior to the commencement of each calender quarter,  
Celgene shall provide Mikart with a non-binding, rolling twelve (12) month  
forecast of its requirements for the Product.  
  
 4.2 PURCHASE ORDERS. Celgene shall place its orders for the Product no  
later than ninety (90) days prior to the requested delivery date using  
separately numbered, written purchase orders. Each purchase order must be for  
one or more full Batches. Purchase orders shall be transmitted to Mikart via  
U.S. mail, private courier, or facsimile transmission. Each purchase order shall  
include complete and accurate information with respect to the requested Product,  
quantity, sizes, shipment dates, shipment method and delivery destination.  
Mikart shall promptly notify Celgene upon its receipt of any purchase orders  
containing shipment dates which need to be rescheduled, and Mikart and Celgene  
shall work together in good faith to schedule a new shipment date for such order  
(which shall not be later than thirty (30) days after the date requested by  
Celgene).  
  
 ARTICLE 5  
 PRICES, TERMS OF PAYMENT  
 ------------------------  
  
 5.1 PRICE. The prices to be paid for the Product by Celgene to Mikart  
for shipments made during the first year after the Effective Date (if any) shall  
be set forth below for the following strengths of the Product:  
  
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 SIZE PRICE  
 100 tables of 2.5 mg $3.59  
 100 tablets of 5 mg $3.59  
 100 tables of 10 mg $3.59  
  
 5.2 PRICE ADJUSTMENTS. Mikart shall have the right to increase the  
prices charged for the Product pursuant to Section 5.1 hereof during each year  
after the Effective Date to reflect any increase in the costs of goods or  
services necessary to manufacture the Product ("Total Product Costs"). Mikart  
shall provide Celgene with documented evidence of any such cost increases and  
shall use its reasonable efforts to prevent any such cost increases from  
occurring. In the event that Mikart seeks to increase the prices charged for the  
Product pursuant to Section 5.1 hereof by more than five percent (5%) during any  
one (1) year after the Effective Date to reflect an increase in Total Product  
Costs, Mikart shall provide written notice to Celgene explaining the reason(s)  
for such additional price increase prior to any price increase becoming  
effective. Celgene shall have thirty (30) days from the date of the written  
notice to accept the additional price increase or to terminate the Agreement,  
provided that such notice of termination must be made in writing to Mikart.  
  
 5.3 PAYMENT TERMS. Mikart shall invoice Celgene for the price of the  
Product sold at the time of shipment, and Celgene shall pay each such invoice  
within thirty (30) days after its receipt thereof.  
  
 ARTICLE 6  
 SHIPPING, DEFECTS, RETURNS  
 --------------------------  
  
 6.1 SHIPPING. Mikart will ship all Product ordered hereunder to Celgene  
f.o.b. Mikart's manufacturing facility, at which point the risk of loss for such  
Product will pass to Celgene. Mikart shall ship the Product to the location  
designated by Celgene on its purchase order. The parties agree that the method  
and route of shipment are at Mikart's discretion unless Celgene furnishes Mikart  
instructions with the purchase order. Celgene agrees to pay all costs of  
shipping and any costs of freight insurance obtained by Mikart at the request of  
Celgene. Mikart agrees to provide reasonable support to assist Celgene in  
pursuing any claims it may have against carriers.  
  
 6.2 NOTIFICATION OF DEFECTS. Celgene shall notify Mikart in writing as  
soon as reasonably practicable after delivery to Celgene of any non-conforming  
Product containing obvious defects in such Product discoverable without  
affecting the integrity of such Product's packaging (but in any event within  
twenty (20) days after delivery) and within thirty (30) days of the earlier of  
its discovery or its notification by a third party of any defects not  
discoverable without affecting the integrity of such Product's packaging.  
Celgene shall be responsible for its costs to inspect all Product, unless such  
inspection reveals a defect caused by Mikart's manufacture and/or packaging of  
the Product, in which event Mikart will reimburse or credit Celgene for the  
commercially reasonable cost of such inspection.  
  
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 6.3 RETURNS. Mikart shall accept for return and replacement or credit  
(at invoiced cost plus the freight cost from Mikart's manufacturing facility to  
Celgene or Celgene's customer(s) to the place of delivery) any Product sold to  
Celgene under this Agreement which does not conform with the warranties set  
forth herein and for which proper notice has been given in accordance with  
Section 6.2. Mikart shall assume the risk of loss in transit associated with  
such returns. Celgene shall provide Mikart with five (5) days written notice via  
facsimile prior to shipping any such returns.  
  
 ARTICLE 7  
 REJECTION AND CURES  
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 7.1 REJECTION. The Master Batch Records and each corresponding Batch  
shall be accepted as conforming, complete and accurate unless Celgene notifies  
Mikart in writing within thirty (30) business days of delivery of such Master  
Batch Records and Batches that Celgene has determined that either the Batches  
(or any portion thereof) do not conform to the Specifications or that the Master  
Batch Records are not complete, setting forth the specific basis for rejection  
(the "Rejection Notice"). In the event that Mikart disputes the basis for  
rejection contained in the Rejection Notice, Mikart shall notify Celgene of such  
dispute via facsimile within ten (10) business days of receipt of the Rejection  
Notice (the "Dispute Notice"). In the event that Mikart does not timely dispute  
the contents of the Rejection Notice, the Rejection notice shall be deemed  
accepted by Mikart and the incomplete Master Batch Records or non-conforming  
Batch (or any non-conforming portion thereof), as the case may be, shall be  
cured in accordance with the provisions of Section 7.3.  
  
 7.2 DISPUTE. Upon Celgene's receipt of a Dispute Notice, if the parties  
are thereafter unable to agree in good faith within thirty (30) days as to  
whether the relevant Master Batch Records are complete or the Batches (or any  
portion thereof) conform to the Specifications, the parties, in good faith,  
shall promptly agree upon and engage an independent, reputable and mutually  
acceptable laboratory that is qualified to conduct the appropriate Test  
method(s) to resolve such dispute (the "Laboratory"). The Test results obtained  
by the Laboratory shall be final and controlling. The costs and fees charged by  
the Laboratory shall be borne by the prevailing party. Incomplete Master Batch  
Records and Batches (or any portion thereof) that are determined by the  
Laboratory not to conform to the Specifications shall be cured in accordance  
with the provisions of Section 7.3.  
  
 7.3 CURES  
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 (a) If, prior to Celgene's acceptance thereof, it is determined that a  
 Master Batch Record is deficient, Mikart shall correct such  
 deficiency within forty-five (45) business days of such  
 determination.  
  
 (b) If prior to Celgene's acceptance thereof, it is determined that a  
 Batch (or a portion thereof) does not conform to the  
 Specifications, Mikart shall replace such non-conforming Batch (or  
 non-conforming portion thereof) within forty-five (45) business  
 days of such determination. Mikart shall bear all additional  
 shipping and transportation costs necessary to replace such  
 non-conforming Batch (or non-conforming portion thereof). The  
 costs of the API necessary to manufacturing such replacement Batch  
 (or portion thereof) (the "Additional API Costs") shall be paid  
 according to the following:  
  
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 (i) Celgene shall bear the cost for API in the event of a  
 non-conforming Batch when that non-conforming Batch was produced  
 (a) in the specified facilities, (b) using approved equipment, (c)  
 using the validated manufacturing process and (d) with no  
 deviation from cGMPs or applicable Standard Operating Procedures;  
 and  
  
 (ii) Mikart shall bear the cost of API in the event of a  
 non-conforming Batch when that non-conforming Batch was produced  
 by any deviation from (a) use of specified facilities, (b) uses of  
 specified, approved equipment (or mechanical failure of specified,  
 approved equipment), (c) the validated manufacturing process and  
 (d) cGMP or applicable Standard Operating Procedures.  
  
 ARTICLE 8  
 TERM AND TERMINATION  
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 8.1 TERM. Unless earlier terminated in accordance with the provisions  
hereof, the Term of this Agreement shall commence on the Effective Date and  
shall thereafter continue in effect until the forth (4th) anniversary of the  
Qualification Date (the "Initial Term"). At the end of the Initial Term and each  
subsequent "Renewal Term" (as hereinafter defined), the Term of this Agreement  
shall be automatically renewed and extended for a one (1) year period (a  
"Renewal Term"), unless either party delivers a written termination notice to  
the other party at least six (6) months prior to the end of the Initial Term or  
the then current Renewal Term, as the case may be. The Initial Term and any  
Renewal Terms shall be referred to herein collectively as the "Term."  
  
 8.2 TERMINATION. Either party may terminate this Agreement on written  
notice to the other party, effective immediately if:  
  
 (a) the other party commits a material breach of any of its  
 obligations hereunder which is not cured within sixty (60) days of  
 written notice from the other party specifying the breach;  
  
 (b) the other party is dissolved or liquidated, files or has filed  
 against it a petition under any bankruptcy or insolvency law, makes an  
 assignment for the benefit of its creditors, has a receiver appointed  
 for all or substantially all of its property, or has a petition under  
 any bankruptcy or insolvency law filed against it which is not  
 dismissed within sixty (60) days; or  
  
 (c) the Qualification Date has not occurred within two (2) years  
 after the Effective Date  
  
 (d) product withdrawal by Celgene, FDA or DEA  
  
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Such right of termination shall be in addition to any other remedy a  
non-defaulting party may have at law or in equity due to the other party's  
breach of is obligations hereunder.  
  
 8.3 CHANGED CIRCUMSTANCES. In the event that the market for the Product  
materially changes or either party, in good faith, believes that a material  
change in such party's circumstances beyond their control has occurred which  
materially affects its ability to perform its obligations pursuant to this  
Agreement, the parties hereto shall, in good faith, negotiate towards mutually  
acceptable revisions to this Agreement to address the impact of such material  
changes; provided, however, the terms of this Agreement shall continue in full  
force and effect unless and until the parties hereto agree otherwise.  
  
 8.4 FORCE MAJEURE  
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 (a) The failure of either of the parties hereto to perform any  
 obligation under this Agreement solely by reason of any cause beyond  
 its control (and due to no fault of its own), including, without  
 limitation, acts of God, acts of government, riots, wars, strikes and  
 accidents in transportation, shall not be deemed to be a breach of this  
 Agreement, provided, however, that the party so prevented from  
 complying herewith shall continued to take all actions within its  
 power, including payment of outstanding invoices, to comply as fully as  
 possible herewith.  
  
 (b) If, due to force majeure, Mikart is prevented or expected to  
 be prevented from supplying Celgene with the Product for a period  
 exceeding one hundred twenty (120) days, then Celgene shall have the  
 right to terminate this Agreement with immediate effect and upon the  
 request of Celgene at Celgene's expense, Mikart will provide reasonable  
 assistance in establishing or locating a new manufacturer for the  
 Product. Likewise, should Celgene be unable to purchase the Product for  
 a period exceeding one hundred twenty (120) days, then Mikart shall  
 have the right to terminate this Agreement, provided Celgene shall  
 remain obligated to pay to Mikart any amounts owed hereunder for  
 Product ordered prior to such termination.  
  
 8.5 SPECIAL TERMINATION. Notwithstanding anything else contained herein  
to the contrary, but subject to Section 8.6, in the event Celgene fails in any  
Contract Year to meet its annual purchase requirements set forth in Section 3.5  
hereof for any reason other than a breach of this Agreement by Mikart, or  
Mikart's inability to supply Celgene, then Mikart shall have the right to  
terminate this Agreement effective immediately by delivering written notice  
thereof to Celgene.  
  
 8.6 POST-TERMINATION OBLIGATIONS  
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 (a) Notwithstanding anything else contained herein to the  
 contrary, following any termination or expiration of this Agreement,  
 Celgene shall purchase from Mikart (at the most recent applicable price  
 therefore) Mikart's remaining inventory of the Product, such amount not  
 to exceed Celgene's forecasted requirements for the Product, pursuant  
 to Section 4.1 hereof, for the three (3) months immediately following  
 the termination or expiration of this Agreement.  
  
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 (b) Upon any expiration or termination of this Agreement (other  
 than by Celgene pursuant to Section 8.2(a)), Celgene shall grant Mikart  
 at least sixty (60) days to produce all open orders in house in  
 accordance with the conditions of the open orders and this Agreement.  
  
 ARTICLE 9  
 INDEMNIFICATION AND INSURANCE  
 -----------------------------  
  
 9.1 INDEMNIFICATION. Mikart hereby indemnifies and agrees to defend and  
hold Celgene harmless from and against any and all losses, claims, damages,  
liabilities, costs and expenses (including, without limitation, attorneys' fees  
and court costs) (collectively, "Losses") incurred by Celgene as a result of any  
breach of this Agreement by Mikart, the manufacture or storage of any Product by  
Mikart, or Mikart's willful misconduct or gross negligence. Celgene hereby  
indemnifies and agrees to defend and hold Mikart harmless from and against any  
and all Losses incurred by Mikart as a result of any breach of this Agreement  
by Celgene, the storage, sale or distribution of the Product by Celgene, any  
Product labeling, Specifications, instructions, directions, warnings, pamphlets  
or other information provided by Celgene or any other Losses incurred by Mikart  
that are a result of the delivery, sale or use of the Product other than those  
Losses that are the result of any breach of this Agreement by Mikart, the  
manufacture or storage of the Product by Mikart or Mikart's willful misconduct  
or gross negligence.  
  
 9.2 INSURANCE. Mikart shall maintain with a financially sound and  
reputable insurer from the date of the first purchase of Product through the  
remainder of the Term of this Agreement comprehensive general liability  
insurance, including, without limitation, product liability insurance with  
liability limits of at least $3,000,000 per occurrence and in the aggregate.  
Celgene shall maintain with a financially sound and reputable insurer from the  
date of the first purchase of the Product through the remainder of the Term of  
this Agreement comprehensive general liability insurance, including, without  
limitation, product liability insurance with liability limits of at least  
$3,000,000 per occurrence and in the aggregate. Each party hereto shall also  
name the other party as an additional insured party on its policy and provide  
the other party with such evidence thereof as is reasonably requested by the  
other party from time to time.  
  
 ARTICLE 10  
 WARRANTIES AND REPRESENTATIONS OF THE PARTIES  
 ---------------------------------------------  
  
 10.1 ADDITIONAL REPRESENTATIONS AND WARRANTIES OF MIKART. Mikart hereby  
additionally represents and warrants to Celgene the following:  
  
 (a) Mikart is a corporation duly organized and existing in good  
 standing under the laws of the State of Georgia;  
  
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 (b) There are no material adverse claims pending or, to the best  
 of Mikart's knowledge, threatened against Mikart by any entity with  
 respect to the Product,  
  
 (c) Mikart is neither a party to nor otherwise bound by any  
 agreement or instrument which prohibits or prevents it from performing  
 its obligations under this Agreement; and  
  
 (d) Mikart's manufacturing, packaging and storage facilities  
 comply in all material respects with all applicable federal, state and  
 local laws, rules and regulations in the Territory. The Product shall,  
 at the time it is shipped to Celgene,  
  
 (i) Not be adulterated or misbranded within the meaning of  
 the Federal Food, Drug and Cosmetic Act (FFDCA) or within the  
 meaning of any applicable state or municipal law;  
  
 (ii) Not be articles that may not, under Section 505 of the  
 FFDCA or any other provision of the FFDCA or any other applicable  
 law, statute or regulation, be introduced into interstate  
 commerce,  
  
 (iii) Have been manufactured, processed and packed in  
 accordance with all requirements under the FFDCA (including drug  
 establishment registration and applicable good manufacturing  
 practice) or under any other applicable laws, rules or regulations  
 of the United States; and  
  
 (iv) Conform to the Specifications for the Products as  
 documented on the Master Batch Record.  
  
 10.2 ADDITIONAL REPRESENTATIONS AND WARRANTIES OF CELGENE. Celgene  
hereby additionally represents and warrants to Mikart the following:  
  
 (a) Celgene is a corporation duly organized and existing under the  
 laws of the State of Delaware;  
  
 (b) There are no material adverse claims pending or, to the best  
 of Celgene's knowledge, threatened against Celgene by any entity with  
 respect to the Product, and  
  
 (c) Celgene is neither a party to nor otherwise bound by any  
 agreement or instrument which prohibits or prevents it from performing  
 its obligations under this Agreement and Celgene, by entering into and  
 performing this Agreement, will not infringe (nor cause Mikart to  
 infringe) the trademark, copyright, patent or other intellectual  
 property rights of any third party.  
  
  
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 ARTICLE 11  
 CONFIDENTIALITY AND NON-SOLICITATION OF PERSONNEL  
 -------------------------------------------------  
  
 11.1 CONFIDENTIALITY. Each party hereto acknowledges that it has been  
and will be exposed to certain "Confidential Information" and "Trade Secrets"  
(both as hereinafter defined) of the other party in connection with the  
transactions contemplated by this Agreement and that its unauthorized use or  
disclosure of such information or data could cause immediate and irreparable  
harm to such other party. Accordingly, except to the extent that it is necessary  
to use such information or data to perform its obligations under this Agreement,  
neither party shall, without the express prior written consent of the other  
party, redistribute, market, publish, disclose or divulge to any person or  
entity, or use or modify for use, directly or indirectly, in any way for any  
person or entity, (a) any of the other party's Confidential Information during  
the Term of this Agreement and for a period of five (5) years after any  
expiration or termination of this Agreement, and (b) any of the other party's  
Trade Secrets at any time during which such information constitutes a trade  
secret under applicable law. For purposes hereof, "Confidential Information"  
shall mean all competitively sensitive, non-public information (other than  
"Trade Secrets) of or about a party which is not generally known by or available  
to such party's competitors, and "Trade Secrets" shall mean "Trade Secrets" as  
defined under applicable law.  
  
 11.2 NON-SOLICITATION OF PERSONNEL. Neither party hereto shall, without  
the prior written consent of the other party, either directly or indirectly,  
alone or in conjunction with any other person or entity, solicit or attempt to  
solicit any "key or material" employee, consultant, contractor or personnel of  
such other party to terminate, alter or lessen his or her affiliation with such  
other party at any time during the Term of this Agreement and for a period of  
one (1) year thereafter.  
  
 ARTICLE 12  
 ARBITRATION OF DISPUTES  
 -----------------------  
  
 All disputes arising out of or in connection with the interpretation,  
application or enforcement of this Agreement shall be settled by final and  
binding arbitration. Such arbitration shall be conducted in a mutually  
convenient location within an approximately equal geographic distance between  
the addresses of the parties, pursuant to the commercial arbitration rules of  
the American Arbitration Association in effect at the time the arbitration is  
commenced. The decision of the arbitrators, which may include interest, shall be  
final and binding on the parties hereto and may be entered and enforced in any  
court of competent jurisdiction by any party. The arbitration shall be pursued  
and brought to conclusion as rapidly as possible. The prevailing party in the  
arbitration proceeding shall be awarded reasonable attorneys' fees, expert  
witness costs and expenses, and all other costs and expenses incurred in  
connection with such proceeding, unless the arbitrators shall for good cause  
determine otherwise.  
  
 ARTICLE 13  
 NOTICES  
 -------  
  
 13.1 DELIVERY. All notices, consents, requests and other communications  
hereunder shall be in writing and shall be sent by hand delivery, by certified  
or registered mail (return-receipt requested), or by a recognized national  
overnight courier service as set forth below.  
  
 12  
  
  
  
 If to Mikart: Mikart, Inc.  
 0000 Xxxxxxxxxxxxx Xxxxxx  
 Xxxxxxx, Xxxxxxx 00000  
 Attention: Xxxxx X. XxXxxxxx  
  
 If to Celgene: Celgene Corporation  
 0 Xxxxxx Xxxx Xxxxx  
 Xxxxxx, Xxx Xxxxxx 00000  
 Attention: Xxxxxx X. Day Jr.  
 Senior Vice President, Planning and Business  
 Development  
  
 With a copy to: Proskauer Rose, LLP  
 0000 Xxxxxxxx  
 Xxx Xxxx, XX 00000-0000  
 Attn: Xxxxxx X. Xxxxxxx  
  
 13.2 EFFECTIVE TIME. Notices delivered pursuant hereto shall be deemed  
given: (a) at the time delivered, if personally delivered; (b) at the time  
received, if mailed; and (c) one (1) business day after timely delivery to the  
courier, if by overnight courier service.  
  
 13.3 CHANGES. Either party hereto may change the address to which  
notice is to be sent by written notice to the other party in accordance with the  
provisions of this Article 13.  
  
 ARTICLE 14  
 MISCELLANEOUS  
 -------------  
  
 14.1 SEVERABILITY. If any provision of this Agreement is held to be  
invalid, illegal or unenforceable, the validity, legality and enforceability of  
the remaining provisions shall not in any way be affected or impaired, and the  
parties shall use their best efforts to substitute a valid, legal and  
enforceable provision, which, insofar as practical, implements the purpose of  
this Agreement.  
  
 14.2 COUNTERPARTS. This Agreement may be executed in one or more  
counterparts, each of which shall be deemed an original, but all of which  
together shall be deemed one and the same instrument.  
  
 14.3 GOVERNING LAW. This Agreement shall be governed by, and any matter  
of dispute arising out of this Agreement shall be determined by, the laws of the  
State of Delaware.  
  
14.4 HEADINGS; GENDER. "Article," "Section" and other headings contained in this  
Agreement are for reference purposes only and shall not affect in any way the  
meaning or interpretation of this Agreement. All personal pronouns used in this  
Agreement shall include the other genders, whether used in the masculine,  
feminine or neuter gender, and the singular shall include the plural and vice  
versa, whenever and as often as may be appropriate.  
  
 13  
  
  
  
 14.5 ENTIRE AGREEMENT. This Agreement represents the entire agreement  
of the parties with respect to its subject matter. Any and all prior discussions  
or agreements with respect hereto are merged into and superseded by the terms of  
this Agreement. This Agreement may be modified or amended only in writing signed  
by both parties which expressly refers to this Agreement and states an intention  
to modify or amend it. No such amendment or modification shall be effected by  
use of any purchase order, acknowledgment, invoice or other form of either party  
and in the event of conflict between the terms of this Agreement and any such  
form, the terms of this Agreement shall control.  
  
 14.6 NO ASSIGNMENT. Neither party shall, without the prior written  
consent (not to be unreasonably withheld or delayed) of the other party having  
been obtained, assign or transfer this Agreement to any person or entity, in  
whole or in part, provided that, each party may assigned or transfer this  
Agreement to any Affiliate or to any successor by merger of such party or its  
pharmaceutical business to which this Agreement relates, or upon a sale of all  
or substantially all of such parties assets, or the assets of its pharmaceutical  
business to which this Agreement relates, and provided further that Celgene may  
assign this Agreement to Novartis Pharmaceuticals, AG, in each case, without the  
prior written consent of the other party hereto. This Agreement is entered into  
solely for the benefit of the parties hereto and not for the benefit of any  
other persons or entities. No other persons or entities may enforce it for their  
benefit nor shall they have any claim or remedy for its breach.  
  
 14.7 BINDING EFFECT. This Agreement shall be binding upon and shall  
inure to the benefit of the parties hereto and their respective successors,  
heirs, representatives and permitted assigns.  
  
 14.8 INTERPRETATION. This Agreement was fully negotiated by both  
parties hereto and shall not be construed more strongly against either party  
hereto regardless of which party is responsible for its preparation.  
  
 14.9 NO CONSEQUENTIAL DAMAGES. Neither party to this Agreement shall  
have any liability to the other party for any consequential or indirect damages  
arising out of any breach of this Agreement including, without limitation, loss  
of profit, loss of use or business stoppage.  
  
 14.10 FURTHER ASSURANCES. Upon the reasonable request of the other  
party, each party hereto agrees to take any and all actions necessary or  
appropriate to give effect to the terms set forth in this Agreement.  
  
 14  
  
  
  
 IN WITNESS WHEREOF, the parties hereto have caused their duly  
authorized representatives to execute this Agreement as of the day and year  
first above written.  
  
 "Mikart"  
  
 MIKART, INC.  
  
  
 By /s/ Xxxxx X. XxXxxxxx  
 -----------------------------------  
 Xxxxx X. XxXxxxxx, President  
  
  
 "Celgene"  
  
 CELGENE CORPORATION  
  
  
  
 By /s/ Xxx X. Xxxxx, PhD  
 -----------------------------------  
 Xxx X. Xxxxx, PhD  
 President & COO  
  
  
  
  
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