Exhibit 10.6  
  
THE SYMBOL ‘\*\*\*’ IS USED THROUGHOUT THIS EXHIBIT TO INDICATE THAT A PORTION OF THE EXHIBIT HAS BEEN OMITTED AS CONFIDENTIAL.  
 Confidential  
  
  
  
  
  
  
Manufacturing and Supply Agreement  
  
  
  
by and among  
  
Angiotech Pharmaceuticals, Inc.  
  
Angiotech International, GmbH  
  
Cohesion Technologies, Inc.  
  
and  
  
Xxxxxx Healthcare Corporation  
  
Xxxxxx Healthcare, S.A.  
  
  
  
  
  
  
  
   
 CONFIDENTIAL  
  
  
  
Manufacturing and Supply Agreement  
  
This Manufacturing and Supply Agreement (“Manufacturing Agreement”), dated as of April 1, 2003 (“Effective Date”) is entered into by and among:  
Angiotech Pharmaceuticals, Inc. (“Angiotech”), a British Columbia corporation with principal offices at 0000 Xxxxxxx Xxxxxx, Xxxxxxxxx, Xxxxxxx Xxxxxxxx, Xxxxxx X0X 0X0;  
Angiotech International GmbH (“Angiotech International”), which is organized and existing under the laws of Switzerland, and is a wholly-owned subsidiary (and an “Affiliate” as defined herein) of Angiotech;  
Cohesion Technologies, Inc. (“Cohesion”), a Delaware corporation with principal offices at 0000 Xxxxx Xxxxx, Xxxx Xxxx, Xxxxxxxxxx 00000, and a wholly-owned subsidiary (and an “Affiliate” as defined herein) of Angiotech. (Angiotech, Angiotech International and Cohesion shall be collectively referred to herein as “AAC”);  
Xxxxxx Healthcare Corporation (“Xxxxxx Healthcare”), a Delaware corporation with principal offices at Xxx Xxxxxx Xxxxxxx, Xxxxxxxxx, Xxxxxxxx 00000; and  
Xxxxxx Healthcare, S.A. (“BHSA”), which is organized and existing under the laws of Switzerland (Xxxxxx Healthcare and BHSA shall be collectively referred to herein as “Baxter”).  
RECITALS  
WHEREAS, Angiotech has acquired Cohesion which Controls certain biosurgical products, and particularly the CoSeal Sealant Unit, CoSeal Adhesion Prevention Unit (each as defined below) and their components, as well as certain CoSeal Accessory(ies);  
WHEREAS, Baxter has substantial expertise in distributing and commercializing medical products and devices worldwide, and through the Distribution and License Agreement (as defined herein) has acquired exclusive rights to exploit the CoSeal Sealant Unit in the Sealant Territory; exclusive rights to exploit the CoSeal Adhesion Prevention Unit in the Adhesion Prevention Territory; exclusive rights to exploit certain CoSeal Accessory(ies) in the Territory for use with CoSeal Unit(s); and an option to obtain (a) exclusive rights to exploit the CoSeal Sealant Unit in Japan, and (b) exclusive rights to exploit the CoSeal Adhesion Prevention Unit in the United States;  
WHEREAS, the Distribution and License Agreement contemplates that Baxter will manufacture and supply for clinical and commercial purposes the CoSeal Sealant Products and the CoSeal Adhesion Prevention Products solely for use, testing and sale as a component of a CoSeal Unit, and the CoSeal Accessories solely to sell for use with a CoSeal Unit; and  
WHEREAS, AAC wishes to convey such manufacturing and supply rights to Baxter.  
  
1  
CONFIDENTIAL  
 NOW, THEREFORE, in consideration of the premises and mutual covenants hereinafter set forth, the sufficiency of which is hereby acknowledged, AAC and Baxter (individually referred to as “Party” and collectively as “Parties”) hereby agree as follows:  
Article 1  
Definitions  
Any capitalized terms not defined in this Manufacturing Agreement shall have the meaning given such term(s) in the Distribution and License Agreement. Any references in this Manufacturing Agreement to “Sections” shall refer to Sections of this Manufacturing Agreement, unless specified to be referring to Sections of the Distribution and License Agreement. For purposes of this Manufacturing Agreement, the following capitalized terms, whether used in the singular or plural, shall have the following meanings:  
1.1  
“AAC Manufacturing Know-How” shall mean information, trade secrets, data, materials and formulations, together with all Improvements, that are Controlled by AAC or its Affiliates; and (a) that are in existence as of the Effective Date, or that arise thereafter until the date of Successful Completion of Manufacturing Technology Transfer, and (i) are used for the manufacture of CoSeal Accessory(ies), Product(s) or CoSeal Units by AAC prior to the Successful Completion of Manufacturing Technology Transfer, and (ii) are transferred to Baxter; and (b) that are in existence as of the date of Successful Completion of Manufacturing Technology Transfer or that arise thereafter until expiration or termination of this Manufacturing Agreement, and (i) are necessary or used for the manufacture of CoSeal Accessory(ies), Product(s) or CoSeal Units by AAC, and (ii) are transferred to Baxter at the sole option of AAC. AAC Manufacturing Know-How shall expressly include AAC’s or its Affiliates’ communications with any Regulatory Authority regarding the CoSeal Accessory(ies), Products or the CoSeal Units or components thereof; provided, however, that such communications shall continue to be accorded the status of Confidential Information of AAC under this Manufacturing Agreement.  
1.2  
“AAC Manufacturing Patents” shall mean (a) the Patents Controlled by AAC and its Affiliates from the Effective Date until the date of Successful Completion of Manufacturing Technology Transfer having one or more valid and unexpired claims (i) that cover one or more CoSeal Accessory(ies), Products or CoSeal Units, or (ii) that cover processes directed to making one or more CoSeal Accessory(ies), Products or CoSeal Units, and (b) all Patent applications filed and Patents obtained for AAC’s or its Affiliates’ Improvements directly relating to the CoSeal Sealant Product, the CoSeal Adhesion Prevention Product, or any CoSeal Unit that are discovered, conceived or reduced to practice by AAC and/or its Affiliates (or on their behalf) under the Distribution and License Agreement during its term, but excluding Joint Patents. For purposes of this Manufacturing Agreement, the phrase “valid and unexpired claim” shall mean a composition of matter, method or device claim (or equivalent thereof) of an issued and unexpired Patent, or a composition of matter, method or device claim (or equivalent thereof) of a pending application within the Patents in the Territory covering a CoSeal Accessory(ies), Product(s) or a CoSeal Unit(s), which (y) has not been revoked or held unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal; and (z) has not been abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer or otherwise.   
 2  
CONFIDENTIAL  
  
AAC Manufacturing Patents shall expressly include the Patents owned or Controlled by AAC that are set forth in Schedule 1.2, as it may be amended by the Parties from time to time. For the purposes of Patent prosecution and maintenance, AAC Manufacturing Patents shall be considered AAC Patents under Article 10 of the Distribution and License Agreement.  
1.3  
“Baxter Manufacturing Know-How” shall mean information, trade secrets, data, materials and formulations together with all Improvements: (a) that are Controlled by Baxter or its Affiliates during the term of this Manufacturing Agreement; and (b) that are transferred to AAC at the sole option of Baxter and are necessary or used for the manufacturing of CoSeal Accessory(ies), Product(s) or CoSeal Unit(s) by Baxter. Baxter Manufacturing Know-How shall expressly include Xxxxxx’x or its Affiliates’ communications with any Regulatory Authority regarding the CoSeal Accessory(ies), Products or the CoSeal Units or components thereof; provided, however, that such communications shall continue to be accorded the status of Confidential Information of Baxter under this Manufacturing Agreement.  
1.4  
“Baxter Manufacturing Patents” shall mean Patent applications filed and Patents obtained that are directly related to the manufacture of CoSeal Accessory(ies), Products, CoSeal Units or Improvements, and that are discovered, conceived or reduced to practice by Baxter and/or its Affiliates (or on their behalf) during the term of this Manufacturing Agreement, but excluding Joint Patents.  
1.5  
“Baxter Supply Agreement” shall mean an agreement setting forth the terms under which Baxter shall manufacture and supply a product for AAC pursuant to Section 4.2.  
1.6  
“Commercialization Date” shall mean, with reference to a CoSeal Unit in existence as of the Effective Date, the occurrence of either of the following events without regard to order: (a) with regard to the United States, the date of FDA approval to manufacture at a manufacturing facility by or on behalf of Baxter, but excluding an AAC facility, or (b) with regard to the European Union, the date of the acceptance of the change notification by the notified body. The first of these events to occur shall be referred to herein as the “First Commercialization Date,” and the second of these events to occur shall be referred to herein as the “Second Commercialization Date.”  
1.7  
 “Deliver” or “Delivery,” with respect to CoSeal Accessory(ies) and CoSeal Units, shall mean, and shall take place upon, the transfer of possession of such CoSeal Accessory or CoSeal Unit to a carrier F.O.B at the place of manufacture, or F.O.B at the place of final sterilization, if any, of such CoSeal Accessory or CoSeal Unit.  
1.8  
“Distribution and License Agreement” shall mean the Distribution and License Agreement among the Parties, dated as of the same date as this Manufacturing Agreement.  
1.9  
“Manufacturing Agreement” shall mean this Manufacturing and Supply Agreement together with all exhibits, schedules, and appendices attached to this Manufacturing and Supply Agreement, all as respectively amended, modified or supplemented by the Parties in accordance with the terms of this Manufacturing and Supply Agreement.  
 3  
CONFIDENTIAL  
  
1.10  
“Non-Licensed Product” shall mean any product for which Baxter has not acquired sales, marketing and distribution rights pursuant to the Distribution and License Agreement.  
1.11  
“Specification(s)” means the requirements, standards, quality control testing and other attributes pertaining to a Product or a CoSeal Unit, as set forth in Schedule 1.11, along with any valid amendments or modifications thereto.  
1.12  
“Successful Completion of Manufacturing Technology Transfer” shall mean the day after the completion of three (3) consecutive successful validation runs of the first CoSeal Unit that are performed by or on behalf of Baxter.  
Article 2  
Grant of Manufacturing Rights  
2.1  
CoSeal Sealant Product and CoSeal Adhesion Prevention Product Exclusive Manufacturing Rights.  
(a)  
CoSeal Sealant Product. Subject to the terms and conditions of this Manufacturing Agreement, AAC hereby grants to Baxter and its Affiliates, and Baxter, on behalf of itself and its Affiliates, hereby accepts:  
  
(i) a sole and exclusive (even as to AAC and its Affiliates) license, with right to sublicense in accordance with Section 2.4, under AAC Manufacturing Patents to make and have made the CoSeal Sealant Products, for the purpose of assembly into CoSeal Sealant Units, in the Sealant Territory.  
  
(ii) a non-exclusive license under AAC Manufacturing Know-How, with right to sublicense as set forth in Section 2.4, to make and have made the CoSeal Sealant Products, for the purpose of assembly into CoSeal Sealant Units, in the Sealant Territory during the term of this Manufacturing Agreement. Upon expiration or termination of this Manufacturing Agreement, the license granted in this Section 2.1(a)(ii) shall be deemed paid in full and irrevocable with regard to all AAC Manufacturing Know-How transferred to Baxter under this Section 2.1(a)(ii) during the term of this Manufacturing Agreement.  
  
(b)  
CoSeal Adhesion Prevention Product. Subject to the terms and conditions of this Manufacturing Agreement, AAC hereby grants to Baxter and its Affiliates, and Baxter, on behalf of itself and its Affiliates, hereby accepts:  
  
(i) a sole and exclusive (even as to AAC and its Affiliates) license, with right to sublicense in accordance with Section 2.4, under AAC Manufacturing Patents to make and have made the CoSeal Adhesion Prevention Products, for the purpose of assembly into CoSeal Adhesion Prevention Units, in the Adhesion Prevention Territory and the United States.  
  
(ii)  
a non-exclusive license under AAC Manufacturing Know-How, with right to sublicense as set forth in Section 2.4, to make and have made the CoSeal Adhesion Prevention Products, for the purpose of assembly into CoSeal Adhesion Prevention Units, in the Adhesion Prevention Territory and the United States. Upon expiration or termination of this  
 4  
CONFIDENTIAL  
  
Manufacturing Agreement, the license granted in this Section 2.1(b)(ii) shall be deemed paid in full and irrevocable with regard to all AAC Manufacturing Know-How transferred to Baxter under this Section 2.1(b)(ii) during the term of this Manufacturing Agreement.  
  
(c)  
CoSeal Devices and CoSeal Accessories. Subject to the terms and conditions of this Manufacturing Agreement, AAC hereby grants to Baxter and its Affiliates, and Baxter, on behalf of itself and its Affiliates, hereby accepts:  
  
(i) a sole and exclusive (even as to AAC and its Affiliates) license, with right to sublicense in accordance with Section 2.4, under AAC Manufacturing Patents to make and have made the CoSeal Devices, for the purpose of assembly into CoSeal Units, and the CoSeal Accessories in the Field in the Territory.  
  
(ii) a non-exclusive license under AAC Manufacturing Know-How, with right to sublicense as set forth in Section 2.4, to make and have made the CoSeal Device(s) , for the purpose of assembly into CoSeal Units, and the CoSeal Accessory(ies) in the Field in the Territory. Upon expiration or termination of this Manufacturing Agreement, the license granted in this Section 2.1(c)(ii) shall be deemed paid in full and irrevocable with regard to all AAC Manufacturing Know-How transferred to Baxter under this Section 2.1(c)(ii) during the term of this Manufacturing Agreement.  
  
(d)  
Limitations. The license grants to Baxter pursuant to this Section 2.1 under AAC Manufacturing Patents, AAC Manufacturing Know-How, and AAC Trademarks to make and have made Products and CoSeal Devices shall be exercisable solely for the purpose of (i) including Products or CoSeal Devices as components of CoSeal Units, and (ii) selling the CoSeal Accessory(ies) for use with a CoSeal Unit.  
2.2  
Grant Back of Rights to AAC.  
(a)  
CoSeal Sealant Unit(s) and Components Thereof. Subject to the terms and conditions of this Manufacturing Agreement, Baxter hereby grants to AAC and its Affiliates, and AAC, on behalf of itself and its Affiliates, hereby accepts, a fully paid-up, irrevocable, non-exclusive license under the rights granted to Baxter in this Article 2, with the right to grant sublicenses, under AAC Manufacturing Patents, AAC Trademarks, and AAC Manufacturing Know-How that are in existence on the Effective Date, or that arise thereafter until the date of Successful Completion of Manufacturing Technology Transfer, to make and have made the CoSeal Sealant Unit(s) and components thereof in the Sealant Territory in the following instances:  
  
(i)  
from the Effective Date until the Second Commercialization Date, for the purpose of fulfilling its obligations under this Manufacturing Agreement, and thereafter only for the purpose of acting as a source of supply of CoSeal Sealant Unit(s) to Baxter; and  
  
(ii)  
at all times for all purposes other than sales, marketing and distribution of the CoSeal Sealant Unit(s).  
  
(b)  
CoSeal Adhesion Prevention Unit(s) and Components Thereof. Subject to the terms and conditions of this Manufacturing Agreement, Baxter hereby grants to AAC and its  
 5  
CONFIDENTIAL  
  
Affiliates, and AAC, on behalf of itself and its Affiliates, hereby accepts, a fully paid-up, irrevocable, non-exclusive license under the rights granted to Baxter in this Article 2, with the right to grant sublicenses, under AAC Manufacturing Patents, AAC Trademarks, and AAC Manufacturing Know-How that are in existence on the Effective Date, or that arise thereafter until the date of Successful Completion of Manufacturing Technology Transfer, to make and have made the CoSeal Adhesion Prevention Unit(s) and components thereof in the Adhesion Prevention Territory in the following instances:  
  
(i)  
from the Effective Date until the Second Commercialization Date, for the purpose of fulfilling its obligations under this Manufacturing Agreement, and thereafter only for the purpose of acting as a source of supply of CoSeal Adhesion Prevention Unit(s) to Baxter;  
  
(ii)  
for the purpose of marketing, selling and distributing the Adhesion Prevention Unit(s), in the event that Baxter fails to exercise the CoSeal Adhesion Prevention Option, as described in the Distribution and License Agreement, and no agreement is reached by the Parties under Section 4.4 after Xxxxxx'x election to continue to retain its exclusive manufacturing rights under Section 2.6; and  
  
(iii)  
at all times for all purposes other than sales, marketing and distribution of the CoSeal Adhesion Prevention Unit.  
  
(c)  
CoSeal Accessory(ies). Subject to the terms and conditions of this Manufacturing Agreement, Baxter hereby grants to AAC and its Affiliates, and AAC, on behalf of itself and its Affiliates, hereby accepts, a fully paid-up, irrevocable, non-exclusive license under the rights granted to Baxter in this Article 2, with the right to grant sublicenses, under AAC Manufacturing Patents, AAC Trademarks, and AAC Manufacturing Know-How that are in existence on the Effective Date, or that arise thereafter until the date of Successful Completion of Manufacturing Technology Transfer, to make and have made the CoSeal Accessory(ies) and components thereof in the Field in the Territory in the following instances:  
  
(i)  
from the Effective Date until the Second Commercialization Date, for the purpose of fulfilling its obligations under this Manufacturing Agreement, and thereafter only for the purpose of acting as a source of supply of CoSeal Accessory(ies) to Baxter;  
  
(ii)  
at all times for all purposes other than sales, marketing and distribution of the CoSeal Accessory(ies) for use with a CoSeal Unit(s); and  
  
(iii)  
at all times for all purposes in connection with a CoSeal Unit(s) for which AAC has sales, marketing and distribution rights.  
  
2.3  
CoSeal Devices and CoSeal Accessories Exclusive Manufacturing Rights. With respect to CoSeal Devices, as of the date of Successful Completion of Manufacturing Technology Transfer, and with respect to CoSeal Accessories, as of the Effective Date, Baxter, at its sole option, shall have the right to: (a) receive an assignment of such agreements as AAC may have with Third Party CoSeal Device or Third Party CoSeal Accessory(ies) manufacturers, subject to any required consents and the effective assumption of such agreements by Baxter; (b) negotiate new agreements with such Third Party CoSeal Device or Third Party CoSeal  
 6  
CONFIDENTIAL  
  
Accessory(ies) manufacturers; (c) use Third Party CoSeal Device or Third Party CoSeal Accessory(ies) manufacturers of Xxxxxx’x choosing; (d) manufacture the CoSeal Device(s) or CoSeal Accessory(ies) at a facility by or on behalf of Baxter; and/or (e) with the consent of AAC, have AAC continue to purchase CoSeal Devices or CoSeal Accessory(ies) on behalf of Baxter. In the event that Baxter elects to receive an assignment of agreements under this Section 2.3(a), then AAC may obtain such CoSeal Device(s) or CoSeal Accessory(ies) from Baxter [\*\*\*] for the term of the applicable agreement (including any renewals or extensions) or the term of any renegotiated agreement between Baxter and such Third Party CoSeal Device or CoSeal Accessory(ies) manufacturer. In the event that Baxter elects to interact directly with such Third Party CoSeal Device manufacturers or Third Party CoSeal Accessory(ies) manufacturers under this Section 2.3(b) or (c), and Baxter does not receive an assignment under this Section 2.3(a), or Baxter elects to manufacture CoSeal Device(s) or CoSeal Accessory(ies) itself under this Section 2.3(d), then AAC may obtain such CoSeal Device(s) or CoSeal Accessory(ies) from Baxter [\*\*\*]  
  
2.4  
Sublicense. Baxter and its Affiliates shall have the right to grant a sublicense under the licenses granted to Baxter and its Affiliates hereunder in connection with the performance of Xxxxxx’x manufacturing obligations under this Manufacturing Agreement, upon fulfillment of the following conditions: (a) that Baxter obtain the prior written consent of AAC before executing any such sublicense agreement, which consent shall not be unreasonably withheld or delayed; (b) that Baxter shall provide a copy of any such executed sublicense agreement to AAC within ten (10) Business Days after execution; and (c) that the execution and delivery by Baxter of such sublicense agreement to any Third Party shall not in any way diminish, reduce or eliminate any of Xxxxxx’x obligations under this Manufacturing Agreement, and Baxter shall remain liable for such obligations. Baxter shall obtain contractual undertakings from every sublicensee that will provide that the rights of such sublicensee shall terminate upon termination of this Manufacturing Agreement.  
  
2.5  
Ownership of Intellectual Property; Retention of Certain Rights. AAC retains all rights to all AAC Manufacturing Patents, AAC Trademarks, and AAC Manufacturing Know-How, to the extent such rights are not expressly granted to Baxter herein or in the Distribution and License Agreement. These retained rights expressly include the right to develop, have developed, make, have made, use, have used, offer for sale, sell, have sold, market, have marketed, distribute, have distributed, import, export, and otherwise fully exploit and commercialize (a) Non-Licensed Products throughout the Territory at all times and (b) the CoSeal Accessories, the CoSeal Devices, the Products and the CoSeal Units for the purpose of exercising its retained rights regarding Non-Licensed Products at all times.  
  
2.6  
Option to Manufacture If Distribution Rights Are Terminated.   
(a)  
Termination of CoSeal Sealant Unit Distribution Rights. In the event that Xxxxxx’x rights to market, distribute and sell the CoSeal Sealant Unit are terminated under the Distribution and License Agreement by AAC or by Baxter, then Baxter, at its option, may elect to retain, or terminate, its exclusive manufacturing rights with respect to both the CoSeal Sealant Unit and the CoSeal Adhesion Prevention Unit. Baxter shall have ninety (90) days from the date of termination of its rights by AAC under the Distribution and License Agreement to decide whether it wishes to continue to retain its exclusive manufacturing rights with respect to both the  
 7  
CONFIDENTIAL  
  
CoSeal Sealant Unit and the CoSeal Adhesion Prevention Unit. If Baxter elects to continue to retain its exclusive manufacturing rights, Baxter shall provide written notice of such election to AAC within such ninety (90) day period. If (i) Baxter elects to terminate its exclusive manufacturing rights pursuant to this Section 2.6(a), or (ii) Baxter fails to provide written notice of such election pursuant to this Section 2.6(a), then the exclusive manufacturing rights with respect to such CoSeal Sealant Units and CoSeal Adhesion Prevention Units shall revert to AAC without further action by the Parties, and Baxter shall act promptly to facilitate the transfer of its then current manufacturing technology used to manufacture the CoSeal Sealant Units, CoSeal Adhesion Prevention Units, CoSeal Accessories, and components of the CoSeal Units to AAC. Such transfer to AAC of Xxxxxx’x manufacturing technology used to manufacture the CoSeal Sealant Units, CoSeal Adhesion Prevention Units, CoSeal Accessories, and components of the CoSeal Units shall be conducted at AAC’s sole expense, in accordance with a transitional period plan that is consistent with the responsibilities and timelines included with the transitional period plan prepared pursuant to Section 4.1(a)(v). In no event shall Xxxxxx’x responsibilities relating to this transfer of Xxxxxx’x manufacturing technology be less than AAC’s obligations and responsibilities under the transitional period plan prepared pursuant to Section 4.1(a)(v) and as set forth under Section 3.3 (including no less than two thousand eighty (2080) personnel work hours at no cost to AAC, other than reimbursement to Baxter of out-of-pocket expenses related thereto). Notwithstanding the foregoing, if Xxxxxx’x CoSeal Sealant Unit distribution rights are terminated by Baxter for reason other than AAC’s uncured material breach under Section 14.3 of the Distribution and License Agreement, Baxter will pay all such manufacturing technology transfer costs. In no event shall Xxxxxx’x obligations under this Section 2.6(a) to transfer manufacturing technology exceed eighteen (18) months after (i) the date that Baxter provides written notice to AAC of Xxxxxx’x election to terminate its exclusive CoSeal Sealant Unit and CoSeal Adhesion Prevention Unit manufacturing rights, or (ii) in the absence of such written notice, the expiration of the ninety (90) day notice period set forth in this Section 2.6(a), whichever occurs first.  
  
(b)  
Termination of CoSeal Adhesion Prevention Unit Distribution Rights. In the event that Xxxxxx’x rights to market, distribute and sell the CoSeal Adhesion Prevention Unit are terminated under the Distribution and License Agreement by AAC or by Baxter (or Baxter does not exercise the Adhesion Prevention Option), then AAC, at its option, may choose to manufacture the CoSeal Adhesion Prevention Unit or may elect to allow Baxter to retain its exclusive manufacturing rights with respect to the CoSeal Adhesion Prevention Unit, but in either event Baxter shall retain its exclusive manufacturing rights with respect to the CoSeal Sealant Unit. AAC shall have ninety (90) days from the date of termination of Xxxxxx’x rights under the Distribution and License Agreement to decide whether it wishes to manufacture the CoSeal Adhesion Prevention Unit. If AAC elects to manufacture the CoSeal Adhesion Prevention Unit, it shall provide written notice of such election to Baxter within such ninety (90) day period. If AAC elects to allow Baxter to retain exclusive manufacturing rights under this Section 2.6(b), then the exclusive manufacturing rights with respect to such CoSeal Adhesion Prevention Unit shall remain with Baxter without further action by the Parties. If (i) AAC elects to manufacture the CoSeal Adhesion Prevention Unit pursuant to this Section 2.6(b), or (ii) AAC fails to provide written notice of its election to manufacture the CoSeal Adhesion Prevention Unit pursuant to this Section 2.6(b), then the exclusive manufacturing rights with respect to such CoSeal Adhesion Prevention Unit shall revert to AAC without further action by the Parties, and Baxter shall act promptly to facilitate the transfer of its then current manufacturing technology  
 8  
CONFIDENTIAL  
  
used to manufacture the CoSeal Accessories, the CoSeal Adhesion Prevention Unit and components of the CoSeal Adhesion Prevention Unit to AAC. Such transfer to AAC of Xxxxxx’x manufacturing technology used to manufacture the CoSeal Accessories, the CoSeal Adhesion Prevention Unit and components of the CoSeal Adhesion Prevention Unit shall be conducted at AAC’s sole expense, in accordance with a transitional period plan that is consistent with the responsibilities and timelines included with the transitional period plan prepared pursuant to Section 4.1(a)(v). In no event shall Xxxxxx’x responsibilities relating to this transfer of Xxxxxx’x manufacturing technology be less than AAC’s obligations and responsibilities under the transitional period plan prepared pursuant to Section 4.1(a)(v) and as set forth under Section 3.3 (including no less than two thousand eighty (2080) personnel work hours at no cost to AAC, other than reimbursement to Baxter of out-of-pocket expenses related thereto). Notwithstanding the foregoing, if Xxxxxx’x CoSeal Adhesion Prevention Unit distribution rights are terminated by Baxter for reason other than AAC’s uncured material breach under Section 14.3 of the Distribution and License Agreement, Baxter will pay all such manufacturing technology transfer costs. In no event shall Xxxxxx’x obligations under this Paragraph 2.6(b) to transfer manufacturing technology exceed eighteen (18) months after (i) the date that AAC provides written notice to Baxter of AAC’s election to manufacture the CoSeal Adhesion Prevention Unit, or (ii) in the absence of such written notice, the expiration of the ninety (90) day notice period set forth in this Section 2.6(b), whichever occurs first.  
  
2.7  
Sharing of Know-How. During the term of this Manufacturing Agreement, Baxter, at its sole option, may (but shall not have the obligation to) transfer to AAC Baxter Manufacturing Know-How, and AAC shall have the right to use such Baxter Manufacturing Know-How in conjunction with Non-Licensed Products. After the date of Successful Completion of Manufacturing Technology Transfer, AAC, at its sole option, may (but shall not have the obligation to) transfer to Baxter AAC Manufacturing Know-How, and Baxter shall have the right to use such AAC Manufacturing Know-How in conjunction with CoSeal Accessories, Products and CoSeal Units. Any transfer under this Section 2.7 shall not be effective until the content of such transfer has been set forth or confirmed in writing and signed by both Parties.  
  
Article 3  
Technology Transfer  
3.1  
Technology Transfer. The Parties shall cooperate to expedite transfer of Cohesion’s Product and CoSeal Unit manufacturing technology from the Cohesion facility to a facility designated by Baxter, where manufacturing will be conducted by or on behalf of Baxter. AAC will make employees of appropriate skill and experience reasonably available to Baxter to facilitate such transfer pursuant to Section 3.3. AAC and Baxter will cooperate to minimize the expenses associated with such transfer and to ensure that the transfer of such Product and CoSeal Unit manufacturing is effectively coordinated.  
  
3.2  
Hiring of Employees. Baxter shall have the right, but not the obligation, to hire such Cohesion employees, including but not limited to manufacturing, quality assurance, quality control and regulatory employees, as are needed to facilitate the transfer of Product and CoSeal Unit manufacturing to Xxxxxx’x facility. Any such hiring decisions, and the terms thereof, shall be solely at Xxxxxx’x discretion. AAC shall assist Baxter in making its hire/no hire decision regarding employees by providing Baxter with a list of key employees that have been designated  
 9  
CONFIDENTIAL  
  
by AAC as available for hiring by Baxter, including information regarding job titles, job descriptions, salary and benefit information, as well as access to such individuals for interviews and direct evaluations by Baxter. Notwithstanding the foregoing, Baxter expressly agrees not to solicit for employment any AAC employees, other than those identified on such list of key employees, without AAC’s prior written consent, provided however, that nothing herein shall prohibit Baxter from hiring any AAC employees who respond to industry-wide or general employment solicitations, advertised employment opportunities, or other available employment opportunities at Baxter.  
  
3.3  
Costs of Technology Transfer. Except for such costs to be borne by AAC as set forth herein, Baxter shall be solely responsible for any and all costs associated with the transfer of manufacturing of Products and CoSeal Units from the Cohesion facility to the facility where Products and CoSeal Units are to be manufactured by or on behalf of Baxter. To facilitate the transfer, AAC shall provide up to two thousand eighty (2080) personnel work hours at no cost to Baxter, other than reimbursement to AAC of out-of-pocket expenses related thereto. Xxxxxx shall pay to AAC [\*\*\*] per personnel work hour, plus reimbursement to AAC of related out-of-pocket expenses, for any personnel work hours of assistance requested by Xxxxxx and agreed to be provided by AAC in excess of two thousand eighty (2080) personnel work hours. AAC shall be responsible for all costs associated with Cohesion’s termination of manufacturing the Product and the CoSeal Unit at the Cohesion facility (including severance payments to employees).  
  
3.4  
Delivery of Raw Materials and Finished Goods Following Commercialization Date. Following each Commercialization Date, AAC and Xxxxxx shall determine an appropriate allocation between them relating to inventory of raw materials and finished goods on hand at AAC. AAC shall deliver to such location in the United States such allocation of inventory of raw materials and finished goods as the Program Directors have reasonably agreed should be transferred to Xxxxxx pursuant to Section 3.1(a) of the Distribution and License Agreement. Xxxxxx shall reimburse to AAC its cost for any such raw material transferred to Xxxxxx.  
  
3.5  
Batch Records and Data. Upon request, within thirty (30) days following Delivery, AAC shall provide (and shall require any Third Party manufacturer to provide) Xxxxxx with properly completed copies of batch records prepared in accordance with the Specifications and applicable laws; provided, however, that if testing reveals an “out-of-Specification” result, AAC (or the Third Party manufacturer, as the case may be) shall provide such batch records within ten (10) days following resolution of the “out-of-Specification” result. The Parties agree that AAC shall provide these records to Xxxxxx solely for the purpose of assisting with manufacturing technology transfer, and Xxxxxx shall not bear the responsibility for correction of any “out-of-Specification” results.  
Article 4  
Manufacture and Supply  
4.1  
Manufacture of the CoSeal Units.  
(a)  
Effective Date to Second Commercialization Date. With respect to CoSeal Units, from the Effective Date until the Second Commercialization Date, and with  
 10  
CONFIDENTIAL  
  
respect to CoSeal Accessories, from the Effective Date until the later of six (6) months after the Effective Date or the date of Successful Completion of Manufacturing Technology Transfer, AAC will be responsible for supplying Xxxxxx with CoSeal Accessories and CoSeal Units under the following terms and conditions:  
  
(i)  
Forecasting. In accordance with Section 4.1(a), the CoSeal Accessories (unless Xxxxxx elects to obtain its own supply of CoSeal Accessories pursuant to Section 2.3) and CoSeal Units shall be supplied by AAC to Xxxxxx. On or before the first day of each calendar month, Xxxxxx shall furnish to AAC a written twelve (12) month rolling forecast of the quantities of CoSeal Accessories and CoSeal Units that Xxxxxx estimates it will order from AAC during such twelve (12) month forecast period (the “Forecast”; the first of which is attached hereto as Schedule 4.1). The first three (3) months of each Forecast shall constitute a binding order for the quantities of CoSeal Accessories and CoSeal Units specified therein (the “Firm Commitment”), and the following nine (9) months of the Forecast shall be non-binding, good faith estimates. Thereafter, until the Second Commercialization Date, Xxxxxx’x sole legal remedy for AAC’s failure to provide a given CoSeal Unit(s) according to the Forecast shall be either suspension of Xxxxxx’x Minimum Sales requirements for the given CoSeal Unit(s) for that calendar year, or a downward adjustment of Xxxxxx’x Minimum Sales requirements for the given CoSeal Unit(s) for that calendar year that is equal to the sales that would be attributable to the given CoSeal Unit(s) that AAC failed to provide. The Program Directors shall determine which of the two remedies (i.e., suspension or adjustment) shall apply.  
  
(ii)  
Purchase Orders. On or before the first (1st) day of each calendar month, Xxxxxx shall submit a purchase order for the Firm Commitment portion of the Forecast, as to which no purchase order has been previously submitted, which specifies the actual quantities of CoSeal Accessories and CoSeal Units to be delivered to Xxxxxx hereunder and the requested shipping dates for each order (“Purchase Order”). Xxxxxx shall submit each Purchase Order to AAC at least sixty (60) days in advance of the shipment date requested in the Purchase Order. For example, a Purchase Order placed on January 1st will request shipping dates during the month of March or at least sixty (60) days after January 1st. In the event of a conflict between the terms of any Purchase Order and this Manufacturing Agreement, this Manufacturing Agreement shall control. In any given month, Xxxxxx shall not submit a Purchase Order with respect to any month contained within the Firm Commitment for less than [\*\*\*] of the amount forecasted one (1) month earlier for such month, nor shall AAC be obligated to accept a Purchase Order to the extent that it exceeds by more than [\*\*\*] the amount forecasted one (1) month earlier for such month. For example, the Firm Commitment included in a January 1st forecast includes the months of January, February and March. The Firm Commitment for the month of March must be no less than [\*\*\*] of the amount forecasted for March in the December 1st forecast or one (1) month earlier than the January 1st forecast. Likewise, the Firm Commitment for the month of March must be no greater than [\*\*\*] of the amount forecasted for March in the December 1st forecast or one (1) month earlier than the January 1st forecast. Notwithstanding the foregoing, once AAC accepts a Purchase Order that failed to meet such requirements, it shall not thereafter reject such Purchase Order for such failure. All Purchase Orders shall reflect orders of a size that the Parties have agreed are within the reasonably anticipated capacity of Cohesion.  
 11  
CONFIDENTIAL  
  
(iii)  
Raw Material or Capacity Shortage. In the event that AAC is unable to supply Xxxxxx with CoSeal Accessories or CoSeal Units in the quantities ordered by Xxxxxx in accordance with Section 4.1(a)(ii), due to AAC’s insufficient supplies of raw materials for Products or CoSeal Units or other manufacturing capacity constraints, AAC shall use Commercially Reasonable Efforts to equitably allocate available raw materials or manufacturing capacity, as the case may be, in a manner consistent with the Parties’ anticipated needs. Notwithstanding the foregoing, AAC shall allocate manufacturing capacity and raw materials first to the manufacture of CoSeal Units for commercial sale.  
  
(iv)  
Xxxxxx Modification or Cancellation. Xxxxxx may request modification of the delivery date, Specifications or quantity of CoSeal Accessories or CoSeal Units in a Purchase Order only by submitting a written change order to AAC. Such change order shall be effective and binding against AAC only upon written or deemed acceptance by AAC, not to be unreasonably withheld or delayed. Notwithstanding the foregoing, Xxxxxx shall remain responsible for the Firm Commitment portion of the Forecast. AAC shall notify Xxxxxx of its approval or rejection of any such change order within ten (10) days after receipt thereof; provided, however, that AAC’s failure to so notify Xxxxxx within such ten (10) day period, (A) with respect to a requested modification of the delivery date or quantity of CoSeal Accessories or CoSeal Units in a Purchase Order, shall be deemed to be an acceptance of such change order if AAC received actual notice of such requested modification, and (B) with respect to a requested modification of the Specifications, shall be deemed to be a rejection of such change order.  
  
(v)  
Transitional Period Plan. Within ninety (90) days after the Effective Date, the Parties shall negotiate in good faith and devise a transitional period plan which will set forth, among other things, the Parties’ responsibilities relating to the manufacture of the CoSeal Accessories, Products and CoSeal Units during the transfer of manufacturing technology from AAC to Xxxxxx, the time frame for such transfer, and the Parties’ mutually determined collaborative and comprehensive plan that will ensure a supply of CoSeal Accessories and a smooth transition of manufacturing of the Products and CoSeal Units from AAC to Xxxxxx.  
  
(b)  
Second Commercialization Date to Termination of Xxxxxx’x Manufacturing Rights. From the Second Commercialization Date until the date of expiration or early termination of this Manufacturing Agreement (in whole or in part), where such expiration or early termination results in the loss of Xxxxxx’x right to manufacture and/or supply CoSeal Accessories, Products and CoSeal Units, Xxxxxx will be responsible for manufacture of Xxxxxx’x entire requirements for commercial supply of such CoSeal Accessories, Products and CoSeal Units.  
4.2  
Manufacture by Xxxxxx for AAC.   
(a)  
Pre-Commercialization Supply. If, following the Second Commercialization Date, AAC requests that Xxxxxx supply to AAC formulations of the Products for AAC’s research or clinical trial activities, Xxxxxx may, in its sole discretion, agree to provide AAC with then current formulations of the Products, at a price to be negotiated by the Parties, in amounts that are forecasted in the same manner as set forth in Sections 4.1(a)(i), (ii) and (iv), and  
 12  
CONFIDENTIAL  
  
in accordance with such other terms as are agreed to by the Parties and set forth in a Xxxxxx Supply Agreement.  
 (b)  
Commercial Supply. If, following the second Commercialization Date, AAC requests that Xxxxxx supply to AAC a Non-Licensed Product containing the CoSeal Ingredients or formulations of the Products for inclusion as part of a Non-Licensed Product for AAC’s commercialization of such Non-Licensed Product, Xxxxxx, in its sole discretion, may supply AAC with such Non-Licensed Product in amounts that are forecasted in the same manner as set forth in Sections 4.1(a)(i), (ii) and (iv), and in accordance with such other terms as are agreed to by the Parties and set forth in a Xxxxxx Supply Agreement. The terms and conditions of such Xxxxxx Supply Agreement, including transfer price and forecasted amounts, shall be negotiated by the Parties in good faith at least nine (9) months prior to the date that AAC expects to obtain its first Regulatory Approval of such Non-Licensed Product.  
 4.3  
CoSeal Unit Manufacturing Procedures, Standards and Compliance with Laws. All CoSeal Accessories and CoSeal Units used for pre-clinical, clinical and commercial purposes will be manufactured, tested and released by the Parties according to current good manufacturing practices (“GMPs”), standards, and applicable corresponding laws in the Territory for the production of the CoSeal Accessories and CoSeal Units. During the time in which it is responsible for manufacturing the CoSeal Accessories or CoSeal Units(s), each Party will be fully responsible for maintaining its facilities and procedures, and for ensuring that any Third Party used by such Party for manufacturing CoSeal Accessories or CoSeal Units or components thereof maintains its facilities and procedures, in compliance with current GMPs, standards and applicable corresponding laws.  
  
4.4  
Transfer Price if Xxxxxx Elects To Manufacture, But Does Not Distribute, Product; Inventory. If Xxxxxx retains its exclusive manufacturing rights with respect to a CoSeal Unit in accordance with Section 2.6, the Parties will negotiate in good faith a mutually acceptable transfer price for such CoSeal Units that are manufactured by Xxxxxx and distributed by AAC (or its Third Party distributor).  
  
4.5  
Rights and Obligations after Transfer of Manufacturing. Where Xxxxxx, during the term of this Agreement or by termination or expiration of this Agreement, is obligated to transfer manufacturing technology and Xxxxxx Manufacturing Know-How pertaining to any CoSeal Accessories, Product or CoSeal Unit hereunder from Xxxxxx to AAC (or to a Third Party manufacturer identified by AAC) to enable AAC (or such Third Party manufacturer) to manufacture and/or supply such CoSeal Accessories, Product or CoSeal Unit, Xxxxxx will use its Commercially Reasonable Efforts to effect such transfer fully and efficiently. In such event, Xxxxxx shall continue to manufacture and supply CoSeal Accessories, Product or CoSeal Unit to AAC according to AAC’s current forecasts for such CoSeal Accessories, Product or CoSeal Unit, until such time that AAC (or such Third Party manufacturer) is able to independently manufacture such CoSeal Accessories, Product or CoSeal Unit in amounts needed by AAC. However, in no event shall Xxxxxx be required to continue to supply AAC for a period of more than eighteen (18) months after (a) with respect to a transfer pursuant to Section 2.6(a), (i) the date that Xxxxxx provides written notice to AAC of Xxxxxx’x election to terminate its exclusive CoSeal Sealant Unit and CoSeal Adhesion Prevention Unit manufacturing rights, or (ii) in the absence of such written notice, the expiration of the ninety (90) day notice period set forth in  
 13  
CONFIDENTIAL  
  
Section 2.6(a), whichever occurs first; (b) with respect to a transfer pursuant to Section 2.6(b), (i) the date that AAC provides written notice to Xxxxxx of AAC’s election to manufacture the CoSeal Adhesion Prevention Unit, or (ii) in the absence of such written notice, the expiration of the ninety (90) day notice period set forth in Section 2.6(b), whichever occurs first; (c) with respect to a transfer following termination of this Manufacturing Agreement pursuant to Section 10.3, the expiration of the thirty (30) day cure period; and (d) with respect to a transfer pursuant to Section 10.4, the date that AAC receives written notice from Xxxxxx of Xxxxxx’x election to discontinue manufacturing either of the CoSeal Units. The Parties will negotiate in good faith a mutually acceptable transfer price for such CoSeal Units that are manufactured by Xxxxxx and distributed by AAC (or its Third Party distributor).  
  
4.6  
Certificate of Analysis. AAC shall deliver to Xxxxxx with fulfillment of each CoSeal Unit order a certificate of analysis confirming that such order meets the Specifications applicable to such CoSeal Unit (each, a “Certificate of Analysis”) and a certificate of compliance of such order. AAC shall test batches Delivered hereunder in accordance with agreed upon standard testing and inspection protocols, which shall in any event be consistent with generally accepted standards in the medical device industry as then in effect. Xxxxxx shall be responsible for reasonable inspection of each order for physical damage in shipping and shortage. Within twenty-one (21) days after receipt of each order of CoSeal Unit, together with AAC's Certificate of Analysis and certificate of compliance pertaining to each such order, Xxxxxx shall notify AAC if, in Xxxxxx'x determination, such order fails to conform to the Specifications. Xxxxxx shall provide notice of rejection of the applicable order to AAC within such twenty-one (21) day period. Orders not rejected within such twenty-one (21) day period in a written notice of rejection sent to AAC shall be deemed to have been accepted by Xxxxxx. Once Xxxxxx accepts an order of CoSeal Unit, it shall not have the right to reject such order thereafter. If Xxxxxx determines that such order does not conform to Specifications, it shall send to AAC, via overnight delivery service or certified mail, return receipt requested, within such twenty-one (21) day period a written notice of rejection of the order, along with a sample of the rejected order to the VP, Manufacturing at the following address: Cohesion Technologies, Inc., 0000 Xxxxx Xxxxx, Xxxx Xxxx, XX 00000. If AAC agrees that the order is defective or non-conforming, it will, at its option (a) replace, whether through reprocessing or otherwise, such order, or (b) reimburse Xxxxxx its out-of-pocket costs in destroying such order. Furthermore, AAC shall pay for the shipping cost associated with the delivery of the replacement order, if any. If AAC does not agree with Xxxxxx'x determination that such order is defective or non-conforming, then after reasonable efforts to resolve the disagreement, either Party may submit a sample from the order to a mutually agreed upon independent Third Party laboratory for resolution of the dispute. The independent laboratory’s results shall be final and binding. Unless otherwise agreed to by the Parties in writing, the costs associated with such testing and review shall be borne by the Party against whom the independent laboratory rules. For purposes of this Section 4.6, the twenty-one (21) day period shall commence on the date of Xxxxxx’x receipt of the order and the related Certificate of Analysis.  
  
4.7  
Replacement of Defective Item. In accordance with the terms set forth in this Manufacturing Agreement, AAC shall replace, whether through reprocessing or otherwise, at its sole expense, all items that do not comply or are found not to comply with the Specifications (“Defective Item”), or shall credit Xxxxxx for amounts already paid for the Defective Item. EXCEPT IN THE EVENT OF A XXXXXX THIRD PARTY  
 14  
CONFIDENTIAL  
  
CLAIM OR AAC THIRD PARTY CLAIM, AS SET FORTH IN ARTICLE 11, THE OBLIGATION OF AAC TO REPLACE DEFECTIVE ITEMS IN ACCORDANCE WITH THE SPECIFICATIONS OR APPLICABLE LAWS SHALL BE XXXXXX’X SOLE AND EXCLUSIVE REMEDY UNDER THIS MANUFACTURING AGREEMENT FOR DEFECTIVE ITEMS, AND IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED.  
  
4.8  
Delivery. AAC shall tender CoSeal Accessory and CoSeal Unit for delivery, F.O.B. the place of manufacture (or as otherwise designated by AAC), whether at the site of a Third Party manufacturer or otherwise, as the case may be, in accordance with the Specifications and addressed to the shipping address specified by Xxxxxx. Xxxxxx shall provide AAC with standard shipping instructions at least two (2) months prior to the first requested shipping date hereunder; thereafter, such shipping instructions may be changed upon reasonable written notice to AAC. AAC shall not Deliver any batch of CoSeal Unit prior to completion of quality control testing by AAC without the consent of Xxxxxx, which consent shall not be unreasonably withheld or delayed. Xxxxxx shall be responsible for all costs and risk of loss associated with the shipping materials (from and after Delivery), shipping instructions and the CoSeal Units from and after Delivery.  
  
Article 5  
Records; Regulatory Matters  
5.1  
Recordkeeping. AAC shall maintain (and shall require any Third Party manufacturer to maintain) true and accurate books, records, test and laboratory data, reports and all other information relating to manufacturing under this Manufacturing Agreement, including all information required to be maintained by applicable laws. Such information shall be maintained in forms, notebooks and records for a period of at least two (2) years from the relevant finished CoSeal Unit expiration date, or longer if required under applicable laws.  
  
5.2  
Regulatory Responsibility and Compliance.  
(a)  
AAC agrees to use Commercially Reasonable Efforts to cause, (i) within six (6) months after the Effective Date, the transfer of title and ownership to Xxxxxx of Regulatory Approvals and related Regulatory Filings which are owned by AAC and are filed, issued and in full force and effect as of the Effective Date, and (ii) within six (6) months after obtaining Regulatory Approval for the each of the [\*\*\*], [\*\*\*] or [\*\*\*] indications, the transfer of title and ownership to Xxxxxx of Regulatory Approvals and related Regulatory Filings, licenses or permits for such approved indication.  
  
(b)  
AAC shall be responsible for obtaining and maintaining any establishment licenses or permits required by the FDA, by applicable laws or by Regulatory Authorities that pertain to its CoSeal Unit manufacturing facility. AAC hereby grants to Xxxxxx the right to reference such establishment files for the purpose of obtaining and maintaining Regulatory Approval.  
  
5.3  
Governmental Inspections and Requests. AAC shall advise Xxxxxx within three (3) Business Days if an authorized agent of any Regulatory Authority visits a facility where manufacturing activity with respect to CoSeal Devices or CoSeal Units takes place, where the  
 15  
CONFIDENTIAL  
  
interest of the Regulatory Authority is specifically related to manufacturing activity with respect to CoSeal Devices or CoSeal Units (and shall require any Third Party manufacturers to do the same within five (5) Business Days with respect to their facilities). In such circumstance, AAC shall furnish (and shall require any Third Party manufacturer to furnish) to Xxxxxx a copy of sections of the report by such Regulatory Authority which are specifically related to the CoSeal Devices or CoSeal Units within ten (10) days of receipt of such report. Further, upon receipt of a Regulatory Authority written request to inspect a manufacturing facility or the manufacturing facilities of a Third Party manufacturer, or to audit AAC’s (or its Third Party manufacturer’s) books and records with respect to manufacturing of CoSeal Devices or CoSeal Units under this Manufacturing Agreement, AAC shall notify Xxxxxx thereof within three (3) Business Days (and require any Third Party manufacturer to notify Xxxxxx within five (5) Business Days thereof), and shall provide (and require any Third Party manufacturer to provide) Xxxxxx with a copy of any written document received from such Regulatory Authority. AAC shall provide Xxxxxx with notice of any such non-written inspection request from a Regulatory Authority which specifically relates to the CoSeal Devices or CoSeal Units as promptly as reasonably practicable under the circumstances. AAC shall also provide to Xxxxxx such notice as is reasonably practicable under the circumstances of any action by a Regulatory Authority, resulting from an inspection of a facility where manufacturing activity with respect to CoSeal Devices or CoSeal Units takes place, which is reasonably anticipated to materially affect AAC’s ability to perform its obligations under this Manufacturing Agreement. Nothing in this Section 5.3 shall require AAC to submit to Xxxxxx any books, records, data or information relating to the manufacture or distribution of any products not covered under this Manufacturing Agreement or the Distribution and License Agreement.  
  
5.4  
Recall and Field Corrective Action. This Section 5.4 shall govern recall arising after the Effective Date from the CoSeal Accessories and CoSeal Units manufactured by AAC (or on its behalf by a Third Party) for Xxxxxx. In the event that AAC believes a recall, field alert, CoSeal Accessory or CoSeal Unit withdrawal, or field corrective action may be necessary with regard to any CoSeal Accessory or CoSeal Unit provided to Xxxxxx under this Manufacturing Agreement, AAC shall immediately notify Xxxxxx in writing. In the event that Xxxxxx believes a recall, field alert, CoSeal Accessory or CoSeal Unit withdrawal, or field corrective action may be necessary with regard to any CoSeal Accessory or CoSeal Unit provided by AAC under this Manufacturing Agreement, Xxxxxx shall immediately notify AAC in writing. Xxxxxx shall provide reasonable cooperation and assistance to AAC. Notwithstanding Sections 4.7 and 4.8, the cost of any such recall, field alert, CoSeal Accessory or CoSeal Unit withdrawal, or field corrective action shall be borne by AAC, unless such recall, field alert, CoSeal Accessory or CoSeal Unit withdrawal, or field corrective action is caused in material part by Xxxxxx'x breach of its obligations under this Manufacturing Agreement, the Distribution and License Agreement (including obligations regarding advertising, distribution and storage of the CoSeal Units) or applicable laws, or by its willful misconduct; then such cost shall be borne by Xxxxxx to the extent such recall, field alert, CoSeal Accessory or CoSeal Unit withdrawal, or field corrective action was due to such causes. For purposes of this Section 5.4, the Party bearing the costs of any recall, field alert, CoSeal Accessory or CoSeal Unit withdrawal, or field corrective action shall only be required to reimburse the other Party for reasonable, actual and documented out-of-pocket costs incurred by such other Party for such recall, field alert, CoSeal Accessory or CoSeal Unit withdrawal, or  
 16  
CONFIDENTIAL  
  
field corrective action (including costs of retrieving CoSeal Accessory or CoSeal Unit already delivered to customers, costs and expenses such other Party is required to pay for notification, shipping and handling charges, and all other costs reasonably related to such recall, field alert, CoSeal Accessory or CoSeal Unit withdrawal, or field corrective action), and the cost to replace, or the actual replacement of, the CoSeal Accessory or CoSeal Unit.  
  
5.5  
Quality Agreement. Upon the transfer of responsibility for all permits and licenses required by any Regulatory Authority with respect to CoSeal Accessories or CoSeal Units under this Manufacturing Agreement, including any product licenses, applications and amendments in connection therewith, the Parties shall execute a quality agreement, which will reflect the division of quality responsibilities while a CoSeal Accessory or CoSeal Unit is made by AAC for Xxxxxx (“Quality Agreement”). AAC shall use Commercially Reasonable Efforts to comply with the Quality Agreement, but in any event shall comply with applicable laws. In the event of a conflict between the terms of this Manufacturing Agreement and the Quality Agreement, this Manufacturing Agreement shall control, but AAC shall in any event comply with applicable laws. The failure of a Party to comply with a requirement of the Quality Agreement shall not be actionable, unless it constitutes a material breach of this Manufacturing Agreement or the Distribution and License Agreement, or a material violation of law of any jurisdiction in which CoSeal Accessories or CoSeal Units are distributed.  
  
5.6  
Quality, Environmental, Heath and Safety Audits. AAC shall permit Xxxxxx'x personnel, upon reasonable notice, at reasonable intervals, and for reasonable duration during regular business hours, to visit the facility where any CoSeal Accessory, Product or CoSeal Unit is manufactured, tested, or stored by, or on behalf of, AAC; or to audit compliance with this Manufacturing Agreement, including but not limited to the Specifications, GMPs, or applicable laws; provided, however, that such audits shall be conducted not more than once in any twelve (12) month period, other than "for cause" audits, which Xxxxxx shall be entitled to conduct following the implementation of measures in response to Form 483’s delivered by the FDA to AAC pertaining to the manufacture of a CoSeal Accessory, Product or CoSeal Unit.  
  
All information obtained by Xxxxxx in any such review, including without limitation the findings and results related thereto, shall be deemed AAC Confidential Information. AAC will have responsibility to audit its permitted subcontractors and suppliers at reasonable intervals for compliance with (a) the Specifications, (b) current GMPs, and (c) applicable laws. Xxxxxx shall have the right to confirm audits of subcontractors and suppliers of AAC for any CoSeal Accessory, Product, or CoSeal Unit manufactured under this Manufacturing Agreement.  
5.7  
Complaints and Adverse Events. The Party responsible for all permits and licenses required by any Regulatory Authority with respect to a given CoSeal Accessory(ies) or CoSeal Unit(s) under this Manufacturing Agreement, including any product licenses, applications and amendments in connection therewith, shall be responsible for evaluating and investigating complaints and for reporting all Adverse Events to Regulatory Authorities in the applicable Territory. If the responsible Party becomes aware of any Adverse Event, it shall evaluate, investigate and determine the necessity of reporting all information in its possession regarding such Adverse Event as soon as practicable, in order to fulfill regulatory reporting obligations within the time frames required by Regulatory Authorities and law; provided, however, that AAC shall not be required to communicate with customers of Xxxxxx. The Parties  
 17  
CONFIDENTIAL  
  
will comply with all applicable reporting laws, rules and regulations governing Adverse Events. Xxxxxx and AAC agree to supply all complaint information (including Adverse Event information) to the responsible Party within five (5) Business Days of learning of a complaint or event; to cooperate with investigations and corrective actions; and to comply with all applicable reporting laws, rules and regulations governing Adverse Events.  
  
5.8  
Compliance. The obligations of AAC and Xxxxxx set forth in this Article 5 are intended to comply with the laws, rules and regulations of each country in the Territory in which the CoSeal Accessory or CoSeal Units are distributed and sold. The requirements of this Article 5 shall therefore be construed and interpreted to comply with all such laws, rules and regulations. To the extent provisions of this Article 5 do not adequately reflect any such law, rule or regulation, such provisions shall be revised to the extent reasonably necessary to make such provisions legal and valid in accordance with such laws, rules and regulations.  
  
Article 6  
Payments  
6.1  
Technology Transfer Timing and Fee. The Parties will commence the transfer of manufacturing technology pertaining to the Products and CoSeal Units as soon as possible, but not later than thirty (30) days after the Effective Date, and anticipate that transfer of manufacturing of the Products or CoSeal Units from the Cohesion facility to a facility where the Products or CoSeal Units will be manufactured by or on behalf of Xxxxxx will be completed by September 30, 2004. Within fifteen (15) days of the date of the Successful Completion of Manufacturing Technology Transfer of the first Product or corresponding CoSeal Unit, Xxxxxx will pay to Cohesion [\*\*\*]. Within fifteen (15) days after the first Commercialization Date, Xxxxxx will pay to Cohesion the sum of [\*\*\*], and within fifteen (15) days after the second Commercialization Date, Xxxxxx will pay to Cohesion an additional [\*\*\*].  
  
6.2  
Currency. Unless otherwise agreed by the Parties in writing, all amounts paid by Xxxxxx under this Manufacturing Agreement shall be paid to Cohesion or its designee in Dollars by wire transfer to a financial institution to be designated by Cohesion. Written or electronic notice of each such transaction shall be promptly provided to such financial employee or officer as is designated by AAC. Subject to Section 6.4, such payments shall be without deduction of collection, wire transfer or other charges, and, specifically, without deduction of withholding or similar taxes or other government imposed fees or taxes, except only as permitted in the definition of Net Sales in Section 1.37 of the Distribution and License Agreement.  
  
6.3  
Interest Due. In case of any delay in payment by Xxxxxx to Cohesion or its designee, interest on the overdue payment shall accrue at an annual interest rate equal to the lesser of: (a) the prime rate as reported in the Money Rates set forth in The Wall Street Journal, plus three (3) percentage points, as determined for each month on the last Business Day of the previous month, or (b) the maximum amount permitted by law, in either instance assessed from the date that payment was initially due. The foregoing interest shall be due from Xxxxxx without any special notice, and shall be in addition to any other remedies that AAC may have pursuant to this Manufacturing Agreement.  
 18  
CONFIDENTIAL  
  
6.4  
Taxes. The Parties agree that any taxes that either Party is required by law to withhold from amounts payable to the other Party under this Manufacturing Agreement (whether under this Article 6 or otherwise) shall be deducted by the paying Party from the amounts paid to the non-paying Party hereunder at the rate(s) required by applicable law, and shall be promptly paid to the appropriate governmental authority on behalf of the non-paying Party. The paying Party shall promptly provide to the non-paying Party receipts from the government or taxing authority evidencing payment of such taxes, if available, or other written proof of payment if official receipts are not available, and shall provide reasonable assistance to the non-paying Party to obtain tax credits therefor.  
  
Article 7  
Representations and Warranties  
7.1  
Representations and Warranties of AAC.   
(a)  
Authorization. AAC, jointly and severally, represents, warrants and covenants that:  
(i)  
this Manufacturing Agreement has been duly executed and delivered by AAC and constitutes a valid and binding obligation of AAC, enforceable against AAC in accordance with its terms, except as enforceability may be limited by bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other laws relating to or affecting creditors’ rights generally and by general equitable principles;  
  
(ii)  
the execution, delivery and performance of this Manufacturing Agreement have been duly authorized by all necessary action on the part of AAC, its officers and directors and does not conflict with any agreement, instrument or understanding, oral or written, to which AAC is a party or by which it may be bound, and, to the best of its knowledge, does not violate any material law or regulation of any court, governmental body or administrative or other agency having authority over it;  
  
(iii)  
AAC has full power and authority to perform the obligations set forth herein, and that AAC is not subject to any order, decree or injunction by a court of competent jurisdiction which may prevent or materially delay the consummation of the transactions contemplated by this Manufacturing Agreement;  
  
(iv)  
AAC is duly organized, validly existing and in good standing under the laws of the jurisdiction where it is organized; and  
  
(v)  
AAC Controls the AAC Manufacturing Patents set forth in Schedule 1.2.  
  
(b)  
AAC’s Rights (CoSeal Ingredients and Product(s)). As of the Effective Date, AAC, jointly and severally, represents and warrants, with respect only to CoSeal Ingredients and Product(s) as they are configured in the CoSeal Sealant Unit (both the formulation marketed as of the Effective Date and the “premix” formulation) and the CoSeal Adhesion Prevention Unit as of the Effective Date, that to its knowledge, upon reasonable inquiry, the granting of the licenses to Xxxxxx hereunder does not conflict with any contractual  
 19  
CONFIDENTIAL  
  
obligation of AAC to any Third Party, except as set forth in Schedule 2.1(b) of the Distribution and License Agreement.  
  
(c)  
AAC’s Rights (CoSeal Ingredients, CoSeal Accessories, Product(s), CoSeal Devices, and CoSeal Units). As of the Effective Date, AAC, jointly and severally, represents and warrants, with respect only to CoSeal Ingredients, CoSeal Devices, and Product(s) as they are configured in CoSeal Units as of the Effective Date, and CoSeal Accessories and CoSeal Units as of the Effective Date, that Schedule 1.2 contains the full and complete list of all material AAC Manufacturing Patents relating to CoSeal Accessory(ies), Products(s), CoSeal Device(s) and CoSeal Unit(s) Controlled by AAC as of the Effective Date, which Control by AAC as of the Effective Date is subject to those Third Party Rights granted prior to the Effective Date in those agreements set forth in Schedule 2.1(b) of the Distribution and License Agreement and to research use only rights and limited non-commercial rights granted to Third Parties pursuant to material transfer agreements or feasibility study agreements.  
  
The sole remedy for inadvertent failure to include an AAC Manufacturing Patent on Schedule 1.2 shall be amendment of such schedule to include the omitted AAC Manufacturing Patent, and such omission shall not be deemed a material breach by AAC of the representations and warranties set forth in this Section 7.1(c).  
(d)  
No Conflicting Agreements. AAC, jointly and severally, represents and warrants that it has not to its knowledge granted, and during the term of this Manufacturing Agreement will not grant, any right to a Third Party in the Field in the Territory, except as set forth in Schedule 2.1(b) of the Distribution and License Agreement, that would conflict with the licenses and rights granted to Xxxxxx hereunder.  
  
(e)  
No Proceedings or Challenges; Non-Infringement. As of the Effective Date, to AAC’s actual knowledge, upon reasonable inquiry, there are no proceedings before any court, administrative tribunal or other authority commenced, pending or threatened which would challenge the validity of AAC Manufacturing Patents or assert a right or interest of a Third Party in AAC Manufacturing Patents or any portion thereof. As of the Effective Date, to AAC’s actual knowledge, upon reasonable inquiry, AAC is not aware of, nor has any Third Party asserted, any claim, notice, or concern about the potential infringement of any Third Party proprietary rights as a result of the manufacture, use, offer to sell, sale, importation or distribution of Product(s).  
  
(f)  
No Dominant Patents. As of the Effective Date, to AAC’s actual knowledge and with respect only to CoSeal Ingredients, Product(s), CoSeal Devices and CoSeal Units as of the Effective Date, there are no Patents owned or Controlled by AAC that are dominant to the AAC Manufacturing Patents licensed to Xxxxxx hereunder. With the exception of Patents covering [\*\*\*] or any other component of an Improvement as a separate entity (for instance, apart from its use within such Improvement), should any such Patents that are owned or Controlled by AAC become known to AAC, such Patents shall be deemed “AAC Manufacturing Patents” for the purposes of this Manufacturing Agreement, AAC shall notify Xxxxxx in writing of such Patents and Schedule 1.2 shall be amended to include such Patents.  
 20  
CONFIDENTIAL  
  
7.2  
Representations and Warranties of Xxxxxx.  
(a)  
Authorization. Xxxxxx, jointly and severally, represents, warrants and covenants that:  
(i)  
this Manufacturing Agreement has been duly executed and delivered by Xxxxxx and constitutes a valid and binding obligation of Xxxxxx, enforceable against Xxxxxx in accordance with its terms, except as enforceability may be limited by bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other laws relating to or affecting creditors’ rights generally and by general equitable principles;  
  
(ii)  
the execution, delivery and performance of this Manufacturing Agreement by Xxxxxx have been duly authorized by all necessary action on the part of Xxxxxx, its officers and directors, and does not conflict with any agreement, instrument or understanding, oral or written, to which Xxxxxx is a party or by which it may be bound, and, to the best of its knowledge, does not violate any material law or regulation of any court, governmental body or administrative or other agency having authority over it;  
  
(iii)  
Xxxxxx has full power and authority to perform the obligations set forth herein, and that Xxxxxx is not subject to any order, decree or injunction by a court of competent jurisdiction which may prevent or materially delay the consummation of the transactions contemplated by this Manufacturing Agreement; and  
  
(iv)  
Xxxxxx is duly organized, validly existing and in good standing under the laws of the jurisdiction where it is organized.  
  
(b)  
No Impairing Agreements. Xxxxxx, jointly and severally, represents, warrants and covenants that, during the term of this Manufacturing Agreement, it will not knowingly enter into any agreements, oral or written, that would in any way impair its ability to fulfill its obligations under this Manufacturing Agreement.  
(c)  
No Dominant Patents. If Xxxxxx has any dominant Patent that was filed before the Effective Date or during the term of this Manufacturing Agreement that contains claims that would cover the CoSeal Ingredients for use in the Field, Product(s) for use in the Field, CoSeal Devices(s) for use in the Field, or CoSeal Unit(s) for use in the Field, then Xxxxxx shall not assert such dominant Patent against AAC or its licensees during the term of this Manufacturing Agreement in any manner, and will make no claim under this Manufacturing Agreement for additional compensation.  
  
Article 8  
Limitations on Representations and Warranties  
8.1  
Limitations on Representations and Warranties  
THE LIMITED WARRANTIES CONTAINED IN ARTICLE 7 ARE THE SOLE WARRANTIES GIVEN BY THE PARTIES HEREUNDER, AND ARE MADE EXPRESSLY IN LIEU OF AND EXCLUDE ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OR OTHERWISE, AND ALL OTHER EXPRESS OR IMPLIED REPRESENTATIONS AND WARRANTIES PROVIDED BY  
 21  
CONFIDENTIAL  
  
COMMON LAW, STATUTE OR OTHERWISE ARE HEREBY DISCLAIMED BY BOTH PARTIES. IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR INDIRECT, PUNITIVE, SPECIAL, CONSEQUENTIAL OR EXEMPLARY DAMAGES OF ANY KIND, INCLUDING WITHOUT LIMITATION, LOSS OF PROFITS AND LOSS OR INTERRUPTION OF BUSINESS. THE FOREGOING PROVISION SHALL NOT BE CONSTRUED TO LIMIT A PARTY'S INDEMNIFICATION OBLIGATION UNDER THIS MANUFACTURING AGREEMENT FOR THIRD PARTY CLAIMS WHICH MAY INCLUDE CONSEQUENTIAL, PUNITIVE OR OTHER TYPES OF DAMAGES.  
Article 9  
Confidentiality  
9.1  
Confidentiality.   
(a)  
No Disclosure or Use. During the term of this Manufacturing Agreement, and for a period of three (3) years thereafter, each Party shall keep confidential all information received from the other Party (the “Confidential Information”), and shall not disclose or use such Confidential Information without the other Party’s written consent, except to the extent contemplated by this Manufacturing Agreement. This restriction shall not, however, prevent disclosure of such Confidential Information if and to the extent that disclosure is required by law; provided that the disclosing Party informs the other Party without delay of any such requirement, in order to allow such other Party to object to such disclosure and to seek an appropriate protective order or similar protection prior to disclosure.  
  
(b)  
No Misappropriation. The Parties agree that the transfer of intellectual property rights and of rights in regulatory documentation by one Party to the other Party pursuant to this Manufacturing Agreement shall not, to the actual knowledge of the transferring Party, misappropriate the proprietary or trade secret information of a Third Party.  
  
9.2  
Exceptions.   
The above obligations shall not apply, or shall cease to apply, to Confidential Information of the disclosing Party which:  
  
(a)  
is now, or hereafter becomes, through no act or failure to act on the part of the receiving Party, generally known or available;  
  
(b)  
is known by the receiving Party at the time of receiving such Confidential Information, as evidenced by its written records;  
  
(c)  
is hereafter furnished to the receiving Party by a Third Party, as a matter of right and without restriction on disclosure;  
  
(d)  
is independently developed by the receiving Party without resort to the Confidential Information of the disclosing Party or any breach of this Article 9;  
  
(e)  
is entered into evidence in a legal proceeding or submitted for use in a dispute resolution proceeding to enforce one or more rights of a Party under this Manufacturing Agreement; provided that the receiving Party shall give the disclosing Party prompt written  
 22  
CONFIDENTIAL  
  
notice and sufficient opportunity to object to such use or disclosure, or to request confidential treatment of the Confidential Information; or  
(f)  
is the subject of a written permission to disclose provided by the disclosing Party.  
9.3  
Permitted Disclosures.   
(a)  
Each Party may disclose Confidential Information: (i) for the purpose of preparing, filing, prosecuting and maintaining Patents; (ii) for obtaining Regulatory Approvals; (iii) for the manufacture, marketing, distribution or sale of CoSeal Unit(s); or (iv) to any individuals that are required by law, contract or otherwise not to use or disclose such Confidential Information except as permitted by this Manufacturing Agreement. Each Party will use at least the same standard of care as it uses to protect proprietary or confidential information of its own to ensure that such individuals do not disclose or make any unauthorized use of the Confidential Information.  
(b)  
In order to exploit rights retained by or granted to the Parties under this Manufacturing Agreement, each Party may publish or publicly present any research or other data which may involve the disclosure of Confidential Information; provided that the publishing Party agrees to furnish the non-publishing Party with copies of any proposed oral, written, graphic or electronic public disclosure prior to submission for publication or presentation. The non-publishing Party shall then have forty five (45) days to review such contemplated publication or presentation. At the end of the forty five (45) day period, the publishing Party may proceed with the contemplated publication or presentation unless (i) the non-publishing Party reasonably requests additional time to fully protect its intellectual property rights, in which case any such contemplated publication or presentation containing the details of a patentable invention must be withheld by the publishing Party for an additional period of forty five (45) days or until a patent application is filed thereon by the non-publishing Party, whichever is earlier in time; or (ii) the non-publishing Party reasonably requests that trade secret information or other Confidential Information of the non-publishing Party be redacted from the contemplated publication or presentation, in which case any such request shall be honored by the publishing Party.  
9.4  
Disclosure of Manufacturing Agreement. Except as required by law, neither AAC nor Xxxxxx shall release to any Third Party or publish in any way any Confidential Information with respect to the terms of this Manufacturing Agreement or concerning their cooperation without the prior written consent of the other Party, which consent will not be unreasonably withheld or delayed; provided; however, that either Party may disclose the terms of this Manufacturing Agreement to the extent required to comply with applicable laws, including without limitation: (a) any instance where a Party must comply with the rules and regulations promulgated by the U.S. Securities and Exchange Commission, a stock reporting organization (i.e., the New York Stock Exchange) or similar authorities in other jurisdictions, and (b) any instance where a Party becomes legally compelled (by deposition, interrogatory, request for documents, subpoena, civil investigative demand or similar process). Notwithstanding any other provision of this Manufacturing Agreement, each Party may disclose the terms of this Manufacturing Agreement (y) to its legal counsel or (z) to lenders, investment bankers, attorneys, financial advisors and other financial institutions of its choice solely for purposes of  
 23  
CONFIDENTIAL  
  
financing the business operations of such Party, or to a potential acquirer of all or substantially all of the assets or equity interests of such Party (A) upon the written consent of the other Party, or (B) if the Party disclosing such terms obtains a signed confidentiality agreement with such intended recipient with respect to such Confidential Information, upon terms substantially similar to those contained in this Article 9.  
  
9.5  
Press Release. Within twenty (20) Business Days after execution of this Manufacturing Agreement, either or both of the Parties may issue a press release pertaining to the execution of this Manufacturing Agreement. Any such press release will recite language that has been mutually agreed upon by the Parties. Except as otherwise required by law, applicable governmental regulations or New York Stock Exchange rules, without the prior written agreement of the Parties, neither Party will issue any other press release concerning the terms or existence of this Manufacturing Agreement.  
  
9.6  
Confidential Information of Each Party. The Parties agree that the material financial terms of the Manufacturing Agreement shall be considered the Confidential Information of both Parties.  
  
9.7  
Employee Obligations. Each Party shall undertake to ensure that all of its employees who have access to Confidential Information are under obligations of confidentiality to such Party.  
9.8  
Prior Confidentiality Agreements.   
The Parties and/or their Affiliates are parties to the following Confidentiality Agreements:  
(a)  
Mutual Confidentiality Agreement by and between Xxxxxx Healthcare and Angiotech, dated as of October 15, 2002;  
  
(b)  
Letter Agreement by and between Xxxxxx International, Inc. and Cohesion, dated as of September 6, 2002 (the "Letter Agreement");  
  
(c)  
Amendment to the Letter Agreement by and between Xxxxxx Healthcare, Cohesion, and Angiotech, dated as of January 31, 2003; and  
  
(d)  
CoSeal Units Distribution Agreement by and between Angiotech, Cohesion and Xxxxxx Healthcare, dated February 25, 2003 (the above agreements set forth in this Section 9.8, collectively, the “Prior Confidentiality Agreements”).  
  
The Prior Confidentiality Agreements shall govern disclosures made among the Parties and their Affiliates up to the Effective Date according to their respective terms, and this Manufacturing Agreement shall govern disclosures made on and after the Effective Date under this Manufacturing Agreement.  
  
24  
CONFIDENTIAL  
 9.9  
Confidential Information upon Expiration or Termination.   
 Upon expiration or termination of this Manufacturing Agreement, each Party shall cease to use or disclose Confidential Information for any purpose, except for use or disclosure that is permitted under this Manufacturing Agreement after expiration or termination of this Manufacturing Agreement.  
Article 10  
Term and Termination  
10.1  
Term.   
(a)  
Term. The term of this Manufacturing Agreement shall be the longer of: (i) ten (10) years from the Effective Date, or (ii) the expiration date of the last to expire AAC Patent listed on Schedule 1.3 of the Distribution and License Agreement, as it may be amended by the Parties from time to time; provided, however, that in no event shall the term of this Manufacturing Agreement exceed thirty (30) years.  
  
(b)  
Accrued Obligations. Except where explicitly provided elsewhere herein, termination of this Manufacturing Agreement for any reason, or expiration of this Manufacturing Agreement, will not affect: (i) obligations of the Parties, including any payments which have accrued as of the date of termination or expiration, or (ii) rights and obligations of the Parties at law or in equity which, from the context thereof, are intended to survive termination or expiration of this Manufacturing Agreement; nor prejudice any Party’s right to obtain performance of any obligation then due and owing.  
  
10.2  
Termination for Insolvency. Either Party may terminate this Manufacturing Agreement immediately upon delivery of written notice to the other Party: (a) upon the institution by or against the other Party of insolvency, receivership or bankruptcy proceedings or any other proceedings for the settlement of the other Party’s debts; provided, however, with respect to involuntary proceedings, that such proceedings are not dismissed within thirty (30) days; (b) upon the other Party’s making an assignment for the benefit of creditors; or (c) upon the other Party’s dissolution or ceasing to do business. All licenses granted under this Manufacturing Agreement, whether by Xxxxxx or AAC, shall be deemed to be the grant of licenses of "Intellectual Property" under Section 365(n) of the United States Bankruptcy Code, as amended. Should either Party elect to terminate this Manufacturing Agreement pursuant to this Section 10.2, Xxxxxx’x sole obligations shall be to cease manufacture and sale of the Product, subject to the sell-off period provided in the Distribution and License Agreement and to facilitate the transfer of manufacturing technology to AAC (or a Third Party designated by AAC), if requested to do so by AAC or an officer of the bankruptcy court within thirty (30) days of receipt or delivery of the notice to terminate. Such transfer of manufacturing technology to AAC shall be at the sole expense of AAC. Where termination is effected pursuant to this Section 10.2, Xxxxxx shall have no continuing obligation to supply product under this Manufacturing Agreement after the thirty (30) day termination period.  
  
10.3  
Termination for Material Breach. Either Party may terminate this Manufacturing Agreement upon thirty (30) days prior written notice to the other Party upon a material breach by the other Party of any of its obligations under this Manufacturing Agreement (and such obligations specifically include a failure by a Party to pay any amount owing under  
 25  
CONFIDENTIAL  
  
this Manufacturing Agreement); provided, however, that such termination shall become effective only if the breaching Party shall fail to: (a) remedy or cure the breach within such thirty (30) day period, or initiate a remedy or cure within such period if it is not practicable to complete the cure in such period; or (b) within thirty (30) days after the date of the non-breaching Party’s written notice of material breach, provide written notice of the breaching Party’s dispute of the alleged breach or failure to cure and its invocation of the dispute resolution provisions set forth in Article 12. If the non-breaching Party elects not to terminate this Manufacturing Agreement pursuant to this Section 10.3, then the non-breaching Party shall be entitled to seek, subject to Sections 12.2 and 12.3, any equitable remedies and damages permitted by law, except to the extent otherwise limited by this Manufacturing Agreement.  
  
10.4  
Xxxxxx’x Termination of Manufacturing. Xxxxxx, at its sole option, shall have the right for any or no reason to terminate its manufacturing rights under this Manufacturing Agreement. If Xxxxxx elects to discontinue manufacturing either of the CoSeal Units, Xxxxxx shall promptly provide written notice to AAC of its election not to manufacture such CoSeal Unit and this Manufacturing Agreement shall terminate, subject to Xxxxxx'x obligation to continue to manufacture CoSeal Accessories, Products and CoSeal Units for the benefit of AAC for a period not to exceed eighteen (18) months from the date that AAC receives such written notice from Xxxxxx pursuant to this Section 10.4. Within ten (10) Business Days after AAC’s receipt of such written notice, the Parties shall commence the transfer of manufacturing technology used to manufacture CoSeal Accessories, CoSeal Devices, Products and CoSeal Units to AAC (or to Third Party manufacturers identified by AAC). Such transfer shall be conducted at Xxxxxx’x sole expense, in accordance with a transitional period plan that is consistent with the responsibilities and timelines included with the transitional period plan prepared pursuant to Section 4.1(a)(v). In no event shall Xxxxxx’x responsibilities relating to this transfer of Xxxxxx’x manufacturing technology be less than AAC’s obligations and responsibilities under the transitional period plan prepared pursuant to Section 4.1(a)(v) and as set forth under Section 3.3 (including no less than two thousand eighty (2080) personnel work hours at no cost to AAC, other than reimbursement to Xxxxxx of out-of-pocket expenses related thereto). In addition, the Distribution and License Agreement shall also terminate in its entirety as of the effective termination date applicable to this Manufacturing Agreement, subject to Xxxxxx’x inventory sell off rights pursuant to Section 14.8 of the Distribution and License Agreement.  
  
10.5  
Effect of Expiration or Termination.   
(a)  
License of Rights to AAC As Applied to Marketed CoSeal Units, CoSeal Accessories and Components Thereof.   
  
(i)  
Expiration or Termination of Manufacturing Agreement. Upon expiration or termination of this Manufacturing Agreement, Xxxxxx shall grant to AAC a fully paid up, royalty free and irrevocable right and license under the Xxxxxx Manufacturing Patents, Xxxxxx Trademarks and Xxxxxx Manufacturing Know-How existing as of the date of such expiration or termination, such that AAC has all necessary or useful rights and licenses (including the right to sublicense) under such Xxxxxx Manufacturing Patents, Xxxxxx Trademarks and Xxxxxx Manufacturing Know-How to manufacture (itself or through contractually bound Third Party(ies) of AAC) Product(s), CoSeal Device(s) or CoSeal Unit(s) which are being sold  
 26  
CONFIDENTIAL  
  
or offered for sale in the Field under the Distribution and License Agreement for indications approved in the Field at the date of termination or expiration.  
  
(ii)  
Termination of CoSeal Adhesion Prevention Unit Rights. After Xxxxxx’x exercise of its CoSeal Adhesion Prevention Option, in the event that Xxxxxx’x right to manufacture the CoSeal Adhesion Prevention Unit is terminated and if this Manufacturing Agreement otherwise continues in full force and effect, then Xxxxxx shall xxxxx to AAC a fully paid up, royalty free and irrevocable right and license under the Xxxxxx Manufacturing Patents, Xxxxxx Trademarks and Xxxxxx Manufacturing Know-How existing as of the date of termination of Xxxxxx’x rights to manufacture the CoSeal Adhesion Prevention Unit, such that AAC has all necessary or useful rights and licenses (including the right to sublicense) under such Xxxxxx Manufacturing Patents, Xxxxxx Trademarks and Xxxxxx Manufacturing Know-How to manufacture (itself or through contractually bound Third Party(ies) of AAC) the CoSeal Adhesion Prevention Product(s), CoSeal Adhesion Prevention Device(s) or CoSeal Adhesion Prevention Unit(s) which are being sold or offered for sale in the Field under the Distribution and License Agreement for indications approved in the Field at the date of termination of Xxxxxx’x right to manufacture the CoSeal Adhesion Prevention Unit.  
  
(b)  
Covenant by Xxxxxx not to Xxx AAC for Manufacture of Marketed CoSeal Units and CoSeal Accessories.   
  
(i)  
Expiration or Termination of Manufacturing Agreement. Upon expiration or termination of this Manufacturing Agreement (other than termination by Xxxxxx for breach hereof by AAC), Xxxxxx and Affiliates (and their respective successors and assigns) covenant not to xxx (either at the time of, or subsequent to expiration or termination of this Manufacturing Agreement):  
  
(A) AAC,  
  
(B) any contractually bound Third Party licensee of AAC or Affiliate licensee of AAC, or  
  
(C) any Third Party(ies) that is/are a contractually bound sublicensee(s) of such Third Party licensee or Affiliate licensee,  
  
under the Patents Controlled by Xxxxxx existing as of the date of such expiration or termination, for any manufacture by AAC and Affiliates (and their respective successors and assigns) or by any such Third Party licensee or sublicensee of CoSeal Accessories, Product(s), CoSeal Device(s) or CoSeal Unit(s) which are being sold or offered for sale in the Field under the Distribution and License Agreement for indications approved in the Field at the date of expiration or termination (“CoSeal Covenant Subject Matter”). For the avoidance of doubt, Xxxxxx and its Affiliates (and their respective successors and assigns) shall not assert at any time after the date of such expiration or termination, and shall take no steps to assert after the date of such expiration or termination, any Patents Controlled by Xxxxxx that cover the CoSeal Covenant Subject Matter against AAC or any such Third Party licensee or Affiliate licensee or any of their  
 27  
CONFIDENTIAL  
  
sublicensees, for any use, marketing, distribution, sale, offer for sale, export or import of the CoSeal Covenant Subject Matter in accordance with this Section 10.5(b)(i).  
  
(ii)  
Termination of CoSeal Adhesion Prevention Unit Rights. After Xxxxxx’x exercise of its CoSeal Adhesion Prevention Option, in the event that Xxxxxx’x right to manufacture the CoSeal Adhesion Prevention Unit is terminated and if this Manufacturing Agreement otherwise continues in full force and effect, then Xxxxxx and Affiliates (and their respective successors and assigns) covenant not to xxx (either at the time of, or subsequent to termination of Xxxxxx’x right to manufacture the CoSeal Adhesion Prevention Unit):  
  
(A) AAC,  
  
(B) any contractually bound Third Party licensee of AAC or Affiliate license of AAC, or  
  
(C) any Third Party(ies) that is/are a contractually bound sublicensee(s) of such Third Party licensee or Affiliate licensee,  
  
under the Patents Controlled by Xxxxxx existing as of the date of such termination, for any manufacture by AAC and Affiliates (and their respective successors and assigns) or by any such Third Party licensee or sublicensee of CoSeal Accessories, CoSeal Adhesion Prevention Product(s), CoSeal Adhesion Prevention Device(s) or CoSeal Adhesion Prevention Unit(s) which are being sold or offered for sale in the Field under the Distribution and License Agreement for indications approved in the Field at the date of termination of Xxxxxx’x right to manufacture the CoSeal Adhesion Prevention Unit (“CoSeal Adhesion Prevention Covenant Subject Matter”). For the avoidance of doubt, Xxxxxx and its Affiliates (and their respective successors and assigns) shall not assert at any time after the date of such expiration or termination, and shall take no steps to assert after the date of such expiration or termination, any Patents Controlled by Xxxxxx that cover the CoSeal Adhesion Prevention Covenant Subject Matter against AAC or any such Third Party licensee, Affiliate licensee or any of their sublicensees, for any use, marketing, distribution, sale, offer for sale, export or import of the CoSeal Covenant Subject Matter in accordance with this Section 10.5(b)(ii).  
  
(c)  
License of Rights to AAC As Applied to Other Products, CoSeal Units for Additional Indications, Other Devices, and Processes. With respect to rights and licenses not set forth in Section 10.5(a), upon expiration or termination of this Manufacturing Agreement, and subject to negotiation of a royalty (if applicable) and a license agreement acceptable to the Parties, Xxxxxx shall xxxxx to AAC:  
  
(i)  
one or more royalty-bearing, non-exclusive right(s) and license(s) (negotiated in good faith by the Parties for a period not to exceed ninety (90) days)under Patents Controlled by Xxxxxx and Xxxxxx Trademarks: (A) existing as of the date of such expiration or termination, such that AAC has all necessary or used rights and licenses (including the right to sublicense) under such Patents Controlled by Xxxxxx and Xxxxxx Trademarks to manufacture (itself or through contractually bound Third Party(ies)) such Products and devices as are sold or offered for sale in conjunction with Drug-Loaded Products or such CoSeal Unit(s) which are  
 28  
CONFIDENTIAL  
  
intended to be sold or offered for sale for indications approved subsequent to the date of termination or expiration, and (B) having one or more valid and unexpired claims or marks that cover one or more of such Products, devices or CoSeal Unit(s) or that cover processes directed to making or using one or more of such Products, devices or CoSeal Units, and  
  
(ii)  
a fully paid up, royalty-free, irrevocable, non-exclusive license (with a right to sublicense) under the Xxxxxx Manufacturing Know-How existing as of the date of termination or expiration, to manufacture (itself or through contractually bound Third Party(ies) of AAC) such Products and devices as are sold or offered for sale in conjunction with Drug-Loaded Products or such CoSeal Unit(s) which are intended to be sold or offered for sale for indications (as well as related processes) in development at the date of termination or expiration.  
  
(d)  
License of Rights to AAC upon Termination of CoSeal Adhesion Prevention Rights. With respect to rights and licenses not set forth in Section 10.5(a), after Xxxxxx’x exercise of its CoSeal Adhesion Prevention Option, in the event that Xxxxxx’x right to manufacture the CoSeal Adhesion Prevention Unit is terminated and if this Manufacturing Agreement otherwise continues in full force and effect, and subject to negotiation of a royalty (if applicable) and a license agreement acceptable to the Parties, Baxter shall grant to AAC:  
  
(i)  
one or more royalty-bearing, non exclusive right(s) and license(s) (negotiated in good faith by the Parties for a period not to exceed ninety (90) days) under Patents Controlled by Xxxxxx and Xxxxxx Trademarks: (A) existing as of the date of such expiration or termination, such that AAC has all necessary or useful rights and licenses (including the right to sublicense) under such Patents Controlled by Xxxxxx and Xxxxxx Trademarks to manufacture (itself or through contractually bound Third Party(ies)) such CoSeal Adhesion Prevention Products and devices as are sold or offered for sale in conjunction with Drug-Loaded Products or such CoSeal Adhesion Prevention Unit(s) which are intended to be sold or offered for sale for indications approved subsequent to the date of termination or expiration, and (B) having one or more valid and unexpired claims or marks that cover one or more of such CoSeal Adhesion Prevention Products, devices or CoSeal Adhesion Prevention Unit(s) or that cover processes directed to making or using one or more of such CoSeal Adhesion Prevention Products, devices or CoSeal Adhesion Prevention Units, and  
  
(ii)  
a fully paid up, royalty-free, irrevocable, non-exclusive license (with a right to sublicense) under the Baxter Manufacturing Know-How existing as of the date of termination of Xxxxxx’x manufacturing rights to the CoSeal Adhesion Prevention Product, to manufacture (itself or through contractually bound Third Party(ies) of AAC) such CoSeal Adhesion Prevention Products and devices as are sold or offered for sale in conjunction with Drug-Loaded Products or such CoSeal Adhesion Prevention Unit(s) which are intended to be sold or offered for sale for indications (as well as related processes) in development at the date of termination of Xxxxxx’x right to manufacture the CoSeal Adhesion Prevention Unit.  
  
(d)  
Information. In the event of termination of this Manufacturing Agreement for any reason other than AAC’s uncured material breach of this Agreement, Baxter shall make customer information reasonably available to AAC that is comparable to the customer  
 29  
CONFIDENTIAL  
  
information provided by AAC to Baxter pursuant to Section 8.1(b) of the Distribution and License Agreement.  
(e)  
Additional Obligations. Upon expiration or termination of this Manufacturing Agreement (or termination of a Party’s rights and obligations with respect to a given CoSeal Unit) by either Party, Baxter shall deliver to AAC (or to its designee, as permitted under the applicable law) all Regulatory Approvals (including all supporting data, quality system records and information) for such CoSeal Unit(s), including CoSeal Accessory(ies), in the Territory as of the effective date of the termination. In the event of termination by AAC or termination by Baxter for material breach by AAC, such transfer shall be at AAC’s sole expense. Except as set forth in Section 10.2, in the event of termination by Baxter or termination by AAC for material breach by Baxter, such transfer shall be at the Xxxxxx’x sole expense.  
  
10.6  
Inventory. Notwithstanding the foregoing, upon early termination of this Manufacturing Agreement (so long as this termination is not for reason of Xxxxxx’x uncured material breach), and further upon the terminating Party’s election, Baxter shall be allowed to complete all work in process under the provisions specified in the Section 14.8 of the Distribution and License Agreement.  
  
Article 11  
Product Liability, Indemnification and Insurance  
11.1  
Responsibility and Control. Baxter and AAC shall each be solely responsible for the safety of its own employees, agents, Affiliates or independent contractors with respect to its performance under this Manufacturing Agreement, and each shall hold the other Party harmless with regard to any liability for damages or personal injuries resulting from acts of its respective employees, agents, Affiliates or independent contractors.  
11.2  
Baxter Right to Indemnification. AAC shall defend, indemnify, and hold harmless Baxter, its Affiliates, successors, and assigns and their respective directors, officers, employees, agents, and independent contractors (collectively the "Baxter Indemnitees") from and against any and all liabilities, damages, losses, settlements, claims, actions, suits, judgments, interest, penalties, fines, costs, or expenses (including, without limitation reasonable attorneys' fees) (any of the foregoing, "Section 11.2 Damages") incurred or asserted against any Baxter Indemnitee of whatever kind or nature including, without limitation, any claim or liability based upon negligence, warranty, strict liability, or violation of governmental regulation, or otherwise arising from or occurring as a result of a claim or demand made by a Third Party against any Baxter Indemnitee (a "Baxter Third Party Claim") because of (a) the manufacture, packaging, testing, labeling, storage, handling, or delivery of any, Product or CoSeal Unit by or on behalf of AAC, or attributes of any Product or CoSeal Unit, including but not limited to the immunogenicity, toxicity, teratogenicity, carcinogenicity, or inherent risk of the use or administration of any Product or CoSeal Unit; (b) the material breach by AAC of its representations, warranties, or obligations under this Manufacturing Agreement; (c) the violation of any applicable law by AAC; or (d) the negligence or willful misconduct of AAC, its employees, other agents, independent contractors, sublicensees or Affiliates in connection with this Manufacturing Agreement (clauses (a) through (d) being the "AAC Activities"); provided, however, that AAC shall have no such obligation to defend, indemnify, or hold harmless the  
 30  
CONFIDENTIAL  
  
Baxter Indemnitees against a Baxter Third Party Claim to the extent any Section 11.2 Damages are based upon, or are the result of, or arise from, Baxter Activities (as defined below). The indemnification provided under clause (a) of this Section 11.2, shall apply only to Products manufactured by AAC. The indemnification provided under clauses (b) through (d) of this Section 11.2, shall be applicable during the term of this Manufacturing Agreement.  
11.3  
AAC Right to Indemnification. Baxter shall defend, indemnify, and hold harmless AAC, its Affiliates, successors, and assigns and their respective directors, officers, employees, agents, and independent contractors (collectively the "AAC Indemnitees") from and against any and all liabilities, damages, losses, settlements, claims, actions, suits, judgments, interest, penalties, fines, costs, or expenses (including, without limitation, reasonable attorneys' fees) (any of the foregoing, "Section 11.3 Damages") incurred or asserted against any AAC Indemnitee of whatever kind or nature including, without limitation, any claim or liability based upon negligence, warranty, strict liability, or violation of governmental regulation, or otherwise arising from or occurring as a result of a claim or demand made by a Third Party against any AAC Indemnitee (an "AAC Third Party Claim") because of (a) the manufacture, packaging, testing, labeling, storage, handling, or delivery of any Product or CoSeal Unit by or on behalf of Baxter, or attributes of any Product or CoSeal Unit, including but not limited to the immunogenicity, toxicity, teratogenicity, carcinogenicity, or inherent risk of the use or administration of any Product or CoSeal Unit; (b) the material breach by Baxter of its representations, warranties, or obligations under this Manufacturing Agreement, (c) the violation of any applicable law by Baxter, or (d) the negligence or willful misconduct of Baxter, its employees, other agents, independent contractors, sublicensees or Affiliates in connection with this Manufacturing Agreement (clauses (a) through (d) being the "Baxter Activities"); provided, however, that Baxter shall have no such obligation to defend, indemnify, or hold harmless the AAC Indemnitees against an AAC Third Party Claim to the extent any Section 11.3 Damages are based upon, or are the result of, or arise from, AAC Activities. The indemnification provided under clause (a) of this Section 11.3, shall apply only to Products manufactured by or on behalf of Baxter, other than by AAC under this Manufacturing Agreement. The indemnification provided under clauses (b) through (d) of this Section 11.3, shall be applicable during the term of this Manufacturing Agreement.   
11.4  
Indemnification Procedures. Promptly after receipt by a Baxter Indemnitee or an AAC Indemnitee (together or individually, an “Indemnitee”) of notice of any pending or threatened claim against it (an “Action”), such Indemnitee shall give written notice to the Party to whom the Indemnitee is entitled to look for indemnification pursuant to this Article 11 (the “Indemnifying Party”) of the commencement thereof. The failure to so notify the Indemnifying Party shall not relieve it of any liability that it may have to any Indemnitee hereunder, except to the extent the Indemnifying Party demonstrates that it is prejudiced thereby. In case any Action that is subject to indemnification under Section 11.2 or Section 11.3 shall be brought against an Indemnitee and it shall give written notice to the Indemnifying Party of the commencement thereof, the Indemnifying Party shall be entitled to participate therein and, if it so desires, to assume the defense thereof with counsel reasonably satisfactory to such Indemnitee and, after notice from the Indemnifying Party to the Indemnitee of its election to assume the defense thereof, the Indemnifying Party shall not be liable to such Indemnitee under this Article 11 for any fees of other counsel or any other expenses, in each case subsequently incurred by such Indemnitee in connection with the defense thereof. Notwithstanding an Indemnifying Party’s  
 31  
CONFIDENTIAL  
  
election to assume the defense of any such Action that is subject to indemnification under Section 11.2 or Section 11.3, the Indemnitee shall have the right to employ separate counsel and to participate in the defense of such Action at its own expense. If an Indemnifying Party assumes the defense of such Action, no compromise or settlement thereof may be effected by the Indemnifying Party without the Indemnitee’s written consent, which consent shall not be unreasonably withheld or delayed, unless (a) there is no finding or admission of any violation of law or any violation of the rights of any Third Party and no effect on any other claims that may be made against the Indemnitee and (b) the sole relief provided is monetary damages that are paid in full by the Indemnifying Party.  
  
11.5  
Compliance. The Parties shall comply fully with all applicable laws and regulations in connection with their respective activities under this Manufacturing Agreement.  
11.6  
Baxter Insurance.  
(a)  
Baxter shall, until expiration of the last batch of CoSeal Unit sold under the Distribution and License Agreement, or of Product or CoSeal Unit manufactured hereunder, by Baxter, its Affiliates and sublicensees, obtain and maintain at its own cost and expense, any combination of insurance or self-insurance, at Xxxxxx’x sole discretion, for its commercial liability, including, but not limited to, product liability and contractual liability insurance, with respect to its activities hereunder.  
  
(b)  
Such insurance or self-insurance shall be in such amounts and subject to such deductibles as the Parties may agree based upon standards prevailing in the industry at the time, but under no circumstances shall be less than: (i) Four Million Dollars ($4,000,000) per occurrence for damage, injury and/or death to persons prior to Regulatory Authority approval of a CoSeal Unit; (ii) Ten Million Dollars ($10,000,000) per occurrence for damage, injury and/or death to persons after Regulatory Authority approval of a CoSeal Unit; or One Million Dollars ($1,000,000) per occurrence for damage/or injury to property. Such insurance or self-insurance shall be written to cover claims incurred, discovered, manifested, or made in connection with clinical development and commercial sale of CoSeal Units in the Territory. Upon written request of AAC, Baxter shall provide to AAC copies of its Certificates of Insurance.  
11.7  
AAC Insurance.   
(a)  
AAC shall, until expiration of the last batch of Product or CoSeal Unit sold or manufactured by AAC, its Affiliates, and sublicensees for Baxter under this Manufacturing Agreement, obtain and maintain at its own cost and expense, any combination of insurance or self-insurance, at AAC’s sole discretion, for its commercial liability, including, but not limited to, product liability and contractual liability insurance, with respect to its activities hereunder.   
  
(b)  
Such insurance or self-insurance shall be in such amounts and subject to such deductibles as the Parties may agree based upon standards prevailing in the industry at the time, but under no circumstances shall be less than: (i) Four Million Dollars ($4,000,000) per occurrence for damage, injury and/or death to persons prior to Regulatory Authority approval of a CoSeal Unit; (ii) Ten Million Dollars ($10,000,000) per occurrence for damage, injury and/or  
 32  
CONFIDENTIAL  
  
death to persons after Regulatory Authority approval of a CoSeal Unit; or One Million Dollars ($1,000,000) per occurrence for damage/or injury to property. Such insurance or self-insurance shall be written to cover claims incurred, discovered, manifested, or made in connection with clinical development and commercial sale of CoSeal Units in the Territory. Upon the written request of Baxter, AAC shall provide to Baxter copies of its Certificates of Insurance.  
11.8  
Method of Insurance.All insurance required of either Party under this Manufacturing Agreement shall, at each Parties’ discretion with respect to its insurance, be through self-insurance or a combination of self-insurance and commercially placed insurance. Where the Party uses commercially placed insurance, such insurance shall (i) be issued by reputable, financially sound companies; (ii) provide that the insurance company will endeavor to provide at least thirty (30) days notice of cancellation of coverage, non-renewal or material change of coverage to both Baxter and AAC, but its failure to do so shall impose no penalty or additional obligations under this Manufacturing Agreement; and (iii) contain a severability of interest or separation of the insureds provision, affording defense and coverage for an insured in the event of a claim brought by another insured.  
  
11.9  
Additional Requirements. All of the foregoing liability policies shall be primary and non-contributory and contain a waiver of subrogation in favor of the other Party or the other Party’s designee.   
  
11.10  
No Limitation. Nothing in this Article 11 regarding insurance coverage amounts shall be deemed or interpreted as a limitation on the indemnities set forth in this Manufacturing Agreement.  
  
Article 12  
Miscellaneous Provisions  
12.1  
Governing Law. This Manufacturing Agreement shall be governed, interpreted and construed in accordance with the laws of New York, without regard to conflict of laws principles thereof.   
  
12.2  
Escalation of Dispute Resolution. The Parties shall attempt to settle any dispute through good faith negotiations in the spirit of mutual cooperation between business executives with authority to resolve the dispute. Prior to taking action as provided in Section 12.3 of this Manufacturing Agreement, the Parties shall first submit such dispute to Angiotech’s Chief Executive Officer and to Xxxxxx’x General Manager of the BioSurgery Business (“Heads”) for resolution. The Heads to whom any dispute is submitted shall attempt to resolve the dispute through good faith negotiations over a reasonable period, not to exceed fifteen (15) Business Days in the aggregate unless otherwise agreed upon by the Heads. Such fifteen (15) Business Day period shall be deemed to commence on the date the dispute was submitted to the Heads. All negotiations pursuant to this Section 12.2 shall be confidential and shall be treated as compromise and settlement negotiations for purposes of applicable rules of evidence.  
  
12.3  
Arbitration. Any dispute that is not resolved by negotiations pursuant to Section 12.2 shall, upon the submission of the written request of either Party to the other Party, be resolved by binding arbitration before a three person panel of Arbitrators (the “Panel”),  
 33  
CONFIDENTIAL  
  
conducted in accordance with the Rules of CPR Institute for Dispute Resolution, except to the extent that such rules are inconsistent with this Manufacturing Agreement. Each Party shall select its own Arbitrator (a “Party Arbitrator”) and shall notify the other Party of its selection within fifteen (15) Business Days after receipt of the written request for binding arbitration. However, neither Party may select as a Party Arbitrator any Third Party who is currently engaged to provide non-arbitration related legal services to such Party or that has derived more than ten percent (10%) of its revenues from non-arbitration related legal services provided to such Party within the past twelve (12) months. The Party Arbitrators shall then mutually select a third Arbitrator (a “Neutral Arbitrator”) in accordance with the Rules of the CPR Institute for Dispute Resolution. Such Neutral Arbitrator may not be currently engaged by either Party and may not have derived more than ten percent (10%) of its revenues from services provided to either Party within the past twelve (12) months. Each member of the Panel shall be free of any subject matter conflict and conflict with a Party. The Panel shall resolve the dispute in accordance with this Manufacturing Agreement and the substantive rules of law (but not the rules of procedure) that would be applied by a federal court sitting at the site of the arbitration. The arbitration shall take place in Chicago, Illinois if initiated by AAC, and in Seattle, Washington if initiated by Baxter. The arbitration shall be governed by the United States Arbitration Act, 9 U.S.C. §§ 1-16. Except as set forth in this Manufacturing Agreement, the Panel is not empowered to award damages in excess of compensatory damages. The Panel has no power or authority, under the CPR Rules for Non-Administered Arbitration or otherwise, to relieve the Parties from their agreement hereunder to arbitrate, or otherwise to amend or disregard any provision of this Manufacturing Agreement, including the provisions of this Section 12.3. The award of the Panel shall be the sole and exclusive remedy of the Parties, and shall be enforceable in any court of competent jurisdiction, subject only to revocation on grounds of fraud or clear bias on the part of any member of the Panel. The statute of limitations of the State of New York, applicable to the commencement of a lawsuit, shall apply to the commencement of an arbitration under this Section 12.3, except that no defenses shall be available based upon the passage of time during any negotiation or mediation pursuant to Section 12.2.  
  
12.4  
Waiver. The failure on the part of AAC or Baxter to exercise or enforce any rights conferred upon it hereunder shall not be deemed to be a waiver of any such rights and shall not operate to bar the exercise or enforcement thereof at any time or times thereafter. The observance of any term of this Manufacturing Agreement may be waived (either generally or in a particular instance, and either retroactively or prospectively) by the Party entitled to enforce such term, but any such waiver shall be effective only if set forth in a writing signed by the Party against whom such waiver is to be asserted.  
  
12.5  
Force Majeure. Neither Party shall be held liable or responsible to the other Party, nor be deemed to have defaulted under or breached this Manufacturing Agreement, for failure or delay in fulfilling or performing any term of this Manufacturing Agreement, other than an obligation to make a payment, when such failure or delay is caused by or results from fire, floods, earthquakes, embargoes, prohibitions or interventions, war, acts of war (whether war be declared or not), acts of terrorism, insurrections, riots, civil commotions, strikes, lockouts, acts of God, or any other cause beyond the reasonable control of the affected Party (hereinafter a “Force Majeure”). Nothing in this provision shall be interpreted to restrict either Party from exercising  
 34  
CONFIDENTIAL  
  
its rights to terminate this Manufacturing Agreement pursuant to its terms during such periods of Force Majeure.  
  
12.6  
Severability. It is the intention of the Parties to comply with all applicable laws, domestic or foreign, in connection with the performance of its obligations hereunder. In the event that any provision of this Manufacturing Agreement, or any part hereof, is found invalid or unenforceable, the remainder of this Manufacturing Agreement will be binding on the Parties hereto, and will be construed as if the invalid or unenforceable provision or part thereof had been deleted, and this Manufacturing Agreement shall be deemed modified to the extent necessary to render the surviving provisions enforceable to the fullest extent permitted by law.  
  
12.7  
Survival. The following Articles and Sections shall survive termination or expiration of this Manufacturing Agreement, with such limitations as are noted: Article 1, to the extent definitions are embodied in the following listed Articles and Sections of this Manufacturing Agreement; Sections 2.1(a)(ii), 2.1(b)(ii), 2.1(c)(ii), 4.5, 5.1, 5.4 (as applicable), 5.7, and 5.8; Articles 8 and 9; Sections 10.1(b), 10.5 and 10.6; and Articles 11 and 12 (excluding Section 12.8).  
  
12.8  
Government Acts. In the event that any act, regulation, directive, or law of a government, including its departments, agencies or courts, (a “Government Act”) should make impossible or prohibit, restrain, modify or limit any material act or obligation of AAC or Baxter under this Manufacturing Agreement, the Party, not so affected shall have the right, at its option, to suspend or terminate this Manufacturing Agreement. Such right of suspension or termination may be exercised as to the country which committed the Government Act only if after thirty (30) days of good faith negotiations between the Parties, the Parties cannot agree to make such modifications to this Manufacturing Agreement as may be necessary to fairly address the Government Act.  
  
12.9  
Government Approvals. Each Party will use commercially reasonable efforts to obtain any government approval required to enable this Manufacturing Agreement to become effective, or to enable any payment hereunder to be made, or enable any other obligation hereunder to be observed or performed. Each Party will keep the other Party informed of its progress in obtaining any such governmental approvals.  
  
12.10  
Assignment. This Manufacturing Agreement may not be assigned in part or in whole, or delegated in whole or in part, by either Party without the prior written consent of the other Party; provided, however, that either Party may assign this Manufacturing Agreement, without the consent of the other Party, (a) in part or in whole to any of its Affiliates, if the assigning Party remains liable for the full performance of its Affiliates’ obligations hereunder, or (b) in connection with the transfer or sale of all or substantially all of its assets or business to which this Manufacturing Agreement relates, or in the event of its merger or consolidation with, acquisition by, or sale to another company. The Parties acknowledge that Baxter may elect to assign to one or more Third Parties, on a country-by-country or region-by-region basis, certain of its rights and to delegate certain of its obligations under this Manufacturing Agreement; provided, however, that Baxter may not assign such rights or delegate such obligations in the United States, Europe or Japan to a Third Party without AAC’s prior written consent. In all cases, (x) the assigning or delegating Party shall provide the other Party with prompt written  
 35  
CONFIDENTIAL  
  
notice of any such assignment or delegation; (y) the assignee or delegatee shall accept such assignment or delegation in writing and agree to the related obligations of such assignment or delegation; and (z) and (z) the assignment or delegation shall not in any way diminish, reduce or eliminate any of the assigning or delegating Party’s obligations under this Distribution and License Agreement, and such Party shall remain liable for all such obligations. Any purported assignment or delegation in contravention of this Section 12.10 shall, at the option of the non-assigning or non-delegating Party, be null and void and of no effect. Unless the Parties otherwise agree in writing, no assignment or delegation shall release either Party from responsibility for the performance of any accrued obligation of such Party hereunder. The grant of a sublicense pursuant to Section 2.4 of this Manufacturing Agreement shall not be deemed an assignment or delegation under this Manufacturing Agreement.  
  
12.11  
Binding Agreement. This Manufacturing Agreement shall be binding upon and inure to the benefit of all successors and permitted assigns of the Parties.  
  
12.12s  
Counterparts. This Manufacturing Agreement may be executed by original or facsimile signature in several counterparts, all of which shall be deemed to be originals, and all of which shall constitute one and the same Manufacturing Agreement.  
  
12.13  
No Agency. Nothing herein contained shall be deemed to create an agency, joint venture, amalgamation, partnership or similar relationship between AAC and Baxter. Notwithstanding any of the provisions of this Manufacturing Agreement, neither Party shall at any time enter into, incur, or hold itself out to Third Parties as having authority to enter into or incur, on behalf of the other Party, any commitment, expense, or liability whatsoever, and all such commitments, expenses and liabilities undertaken or incurred by one Party in connection with or relating to the development, manufacture or sale of CoSeal Unit(s) or components thereof shall be undertaken, incurred or paid exclusively by that Party, and not as an agent or representative of the other Party.  
  
12.14  
Notice. All communications between the Parties with respect to any of the provisions of this Manufacturing Agreement will be sent to the addresses set forth below, or to such other addresses as designated by one Party to the other Party by notice pursuant hereto, by internationally recognized courier or by prepaid, certified air mail (which shall be deemed received by the other Party on the seventh (7th) Business Day following deposit in the mails), or by facsimile transmission or other electronic means of communication (which shall be deemed received when transmitted), with confirmation by letter sent at or before the close of business the next following Business Day:  
  
If to AAC, at:  
Angiotech Pharmaceuticals, Inc.  
0000 Xxxxxxx Xxxxxx  
Xxxxxxxxx, Xxxxxxx Xxxxxxxx, XXXXXX X0X 0X0  
Attention: Chief Business Officer  
36  
CONFIDENTIAL  
 with a copy to:  
Angiotech Pharmaceuticals, Inc.  
0000 Xxxxxxx Xxxxxx  
Xxxxxxxxx, Xxxxxxx Xxxxxxxx, XXXXXX X0X 0X0  
Attention: General Counsel  
If to Baxter, at:  
Xxxxxx Healthcare Corporation  
0000 Xxxx Xxxx Xxxx  
Xxxxxxxx XXXX-0X  
Xxxxxxxxx, Xxxxxxxx 00000  
Attention: President, Venture Management  
with copies to:  
Xxxxxx Healthcare Corporation  
Xxx Xxxxxx Xxxxxxx  
Xxxxxxxxx, Xxxxxxxx 00000  
Attention: General Counsel  
Xxxxxx Healthcare Corporation  
Attn: Associate General Counsel of Baxter BioScience  
Xxx Xxxxxx Xxx  
Xxxxxxxx Xxxxxxx, XX 00000  
12.15  
Headings. The Article, Section and subsection headings are for convenience only and will not be deemed to affect in any way the language of the provisions to which they refer.  
  
12.16  
Authority. The undersigned represent that they are authorized to sign this Manufacturing Agreement on behalf of the Parties hereto.  
12.17  
No Implied Licenses. Nothing in this Manufacturing Agreement shall be construed as granting either Party by implication, estoppel or otherwise, any license rights which are not expressly set forth herein.  
12.18  
Entire Agreement. This Manufacturing Agreement, including the Schedules appended hereto, together with the Distribution and License Agreement which is hereby incorporated by reference as if fully set forth herein, contains the entire understanding of the Parties relating to the matters referred to herein, and may only be amended by a written document, duly executed on behalf of the respective Parties.  
<Signature Page Follows>  
  
  
37  
CONFIDENTIAL  
  
   
  
  
IN WITNESS WHEREOF, the Parties hereto have caused this Manufacturing Agreement to be executed by their duly authorized representatives effective as of the day and year first above written, although actually signed on the dates set forth below.  
Xxxxxxxxx, Xxxxxxx Xxxxxxxx  
Xxxxxxxxx, Xxxxxxxx  
Angiotech Pharmaceuticals, Inc.  
Xxxxxx Healthcare Corporation  
  
  
/s/ Xxxxxxx X. Xxxxxx  
/s/ Xxxxxxx Xxxxx  
Xx. Xxxxxxx X. Xxxxxx  
Xxxxxxx Xxxxx  
President and Chief Executive Officer  
Vice President & General Manager  
Biosurgery  
  
Date April 18, 2003  
Date April 18, 2003  
  
  
   
Angiotech International, Inc.  
Xxxxxx Healthcare, S. A.  
  
  
  
/s/ Xxxxx X. XxXxxxxxx  
/s/ Xxxxxxx Xxxxx  
Xxxxx X. XxXxxxxxx  
Xxxxxxx Xxxxx  
Managing Officer  
Under Power of Attorney  
from Xxxxxx Healthcare, S.A.  
  
Date April 18, 2003  
Date April 18, 2003  
  
  
  
Cohesion Technologies, Inc.  
  
  
  
/s/ Xxxxxx X. Xxxxxxxx  
Xxxxxx X. Xxxxxxxx  
Secretary  
  
Date April 18, 2003  
  
  
  
  
   
38  
CONFIDENTIAL  
  
SCHEDULE 1.2  
  
AAC MANUFACTURING PATENTS  
  
Patent Family  
  
Patent Number  
  
Title  
  
Dates  
International Patents  
and Applications  
(per patent family)  
1  
5,874,500  
CROSSLINKED POLYMER COMPOSITIONS AND METHODS FOR THEIR USE  
Issued 2/23/99  
Filed 12/18/96  
Off of ’500 Patent  
Australia 717660 (issued)  
Canada 2239775 (pending)  
Europe 96944824.0 (published)  
Japan 9-522938 (pending)  
  
Off of ’889 Patent  
WIPO 02/19122 (published)  
6,051,648  
CROSSLINKED POLYMER COMPOSITIONS AND METHODS FOR THEIR USE  
Issued 4/18/00  
Filed 1/13/99  
09/932,536  
CROSSLINKED POLYMER COMPOSITIONS AND METHODS FOR THEIR USE  
Filed 11/27/01  
(allowed)  
6,458,889  
COMPOSITIONS AND SYSTEMS FOR FORMING CROSSLINKED BIOMATERIALS AND ASSOCIATED METHODS OF PREPARATION AND USE  
Issued 10/1/02  
Filed 06/15/01  
 2  
6,312,725  
RAPID GELLING BIOCOMPATIBLE POLYMER COMPOSITION (THIOL PEGS)  
Issued 11/6/01  
Filed 04/16/99  
Japan 2000-611963 9 (published)  
10/012,263  
RAPID-GELLING BIOCOMPATIBLE POLYMER COMPOSITION AND ASSOCIATED METHODS OF PREPARATION AND USE  
Filed 11/05/01  
 3  
5,162,430  
COLLAGEN-POLYMER CONJUGATES  
Issued 11/10/92  
Filed 11/14/89  
Xxxxxxxxx 000000 (xxxxxx)  
Xxxxx 0000000 (issued)  
France 444157 (issued)  
Germany 68928754.2 (issued)  
Italy 444157 (issued)  
UK 444157 (issued)  
5,304,595  
COLLAGEN-POLYMER CONJUGATES  
Issued 04/19/94  
Filed 12/30/92  
5,264,214  
COMPOSITION FOR BONE REPAIR  
Issued 11/23/93  
Filed 08/14/92  
5,324,775  
BIOLOGICALLY INERT, BIOCOMPATIBLE-POLYMER CONJUGATES  
Issued 06/28/94  
Filed 07/02/92  
5,565,519  
CLEAR, CHEMICALLY MODIFIED COLLAGEN-POLYMER CONJUGATES FOR OPHTHALMIC APPLICATIONS  
Issued 10/15/96  
Filed 11/3/93  
 4  
6,495,127  
COMPOSITIONS AND SYSTEMS FOR FORMING HIGH STRENGTH MEDICAL SEALANTS, AND ASSOCIATED METHODS OF PREPARATION AND USE  
Issued 12/1702  
Filed 08/28/00  
Europe 00959535.6 (published)  
Japan 2001 - 520763 (pending)  
  
  
  
  
   
39  
CONFIDENTIAL  
  
  
SCHEDULE 1.2  
AAC MANUFACTURING PATENTS  
(continued)  
  
  
Patent Family  
  
Patent Number  
  
Title  
  
Dates  
International Patents  
and Applications  
(per patent family)  
5  
6,165,489  
CROSSLINKED COLLAGEN COMPOSITIONS FOR IN SITU ADMINISTRATION  
Issued 12/26/00  
Filed 04/28/99  
None  
 6  
5,614,587  
COLLAGEN-BASED BIOADHESIVE COMPOSITIONS  
Issued 03/25/97  
Filed 06/07/95  
Canada 2172906 (pending)  
Europe 96108503.2 (published)  
Japan 8-139317 (published)  
 7  
6,328,229  
LOW VOLUME MIXING SPRAY HEAD FOR MIXING AND DISPENSING OF TWO REACTIVE FLUID COMPONENTS  
Issued 12/11/01  
Filed 12/18/98  
None  
 8  
5,643,464  
PROCESS FOR PREPARING A STERILE, DRY CROSSLINKING AGENT  
Issued 07/01/97  
Filed 06/30/95  
None  
 9  
5,968,018  
CELL SEPARATION DEVICE AND IN-LINE ORIFICE MIXER SYSTEM  
Issued 10/19/99  
Filed 10/30/96  
Japan 10-520756 (published)  
  
  
  
  
   
40  
CONFIDENTIAL  
  
   
  
  
SCHEDULE 1.11  
SPECIFICATIONS  
  
See Attached [\*\*\*] and [\*\*\*] Material Safety Data Sheets and additional information pertaining to [\*\*\*] and [\*\*\*], individually and as combined.  
  
  
  
   
41  
CONFIDENTIAL  
  
   
  
  
[\*\*\*] MATERIAL SAFETY DATA SHEET  
  
------------------------------------------------------------------------------  
  
SUPPLIER/MANUFACTURER NAME & ADDRESS  
  
Raylo Chemicals Inc., A Xxxxxxx Fine Chemicals Co.  
0000 Xxxxxx Xxxx  
Xxxxxxxx, Xxxxxxx, Xxxxxx  
X0X 0X0  
  
Phone No:  
(000) 000-0000  
Fax No:  
(000) 000-0000  
  
24-HOUR EMERGENCY PHONE NO: (000) 000-0000  
------------------------------------------------------------------------------  
  
------------------------------------------------------------------------------  
1 - PRODUCT IDENTIFICATION  
------------------------------------------------------------------------------  
PRODUCT NAME: [\*\*\*]  
  
FORMULA: [\*\*\*]  
  
FORMULA WT: [\*\*\*]  
  
COMMON SYNONYMS: [\*\*\*]  
  
PRODUCT NUMBER: [\*\*\*]  
  
CHEMICAL FAMILY: [\*\*\*]  
  
CAS NO.: Not available  
  
NIOSH/RTECS NO.: Not available  
  
CREATION DATE: February 8, 2001  
 REVISION DATE: N/A  
  
------------------------------------------------------------------------------  
2 - COMPOSITION/INFORMATION ON INGREDIENTS  
------------------------------------------------------------------------------  
 Hazardous Ingredients  
Wt. %  
CAS NO.  
  
[\*\*\*]  
 42  
CONFIDENTIAL  
  
[\*\*\*] MATERIAL SAFETY DATA SHEET  
   
------------------------------------------------------------------------------  
3 - PHYSICAL DATA  
------------------------------------------------------------------------------  
  
BOILING POINT (°C): Not available  
 VAPOR PRESSURE (MM HG): Not available  
  
MELTING POINT (°C): [\*\*\*]  
  
VAPOR DENSITY (AIR=1): Not available  
  
SPECIFIC GRAVITY (Kg/L): Not available  
(H2O=1)   
  
EVAPORATION RATE: (SLOWER/FASTER/EQUAL TO BUTYL ACETATE) N/A  
   
  
SOLUBILITY (H2O) (ml/g): [\*\*\*]  
  
APPEARANCE & ODOR: [\*\*\*]  
  
  
------------------------------------------------------------------------------  
4 - FIRE AND EXPLOSION HAZARD DATA  
------------------------------------------------------------------------------  
  
FLASH POINT (CLOSED CUP): Not available  
  
NFPA 704M RATING: Not available  
  
FLAMMABLE LIMITS: UPPER – N/A  
%  
LOWER – N/A %  
  
FIRE EXTINGUISHING MEDIA: Dry chemicals, foam. DO NOT USE WATER.  
  
SPECIAL FIRE-FIGHTING PROCEDURES: wear self-contained breathing apparatus and full protective gear.  
  
UNUSUAL FIRE & EXPLOSION HAZARDS: Reacts with water.   
  
TOXIC GASES PRODUCED: Not available  
  
  
  
  
   
43  
CONFIDENTIAL  
  
[\*\*\*] MATERIAL SAFETY DATA SHEET  
  
------------------------------------------------------------------------------  
5 - HEALTH HAZARD DATA  
------------------------------------------------------------------------------  
To the best of our knowledge the chemical, physical and toxicological properties of this product have not been fully investigated. Exercise due care, handle as a chemical which is toxic.   
  
THRESHOLD LIMIT VALUE (TLV/TWA):  
Not available  
(PPM)  
  
PERMISSIBLE EXPOSURE LIMIT (PEL):  
Not available  
 (PPM)  
  
TOXICITY: LD50/ OTHER  
(ORAL-RAT)(MG/KG)  
Not available  
  
  
CARCINOGENICITY:   
NTP:  
IARC:  
 Z LIST:   
OSHA REG: N/A  
  
  
EFFECTS OF OVEREXPOSURE: N/A  
 TARGET ORGANS: Not available  
 MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE: Not available  
 ROUTES OF ENTRY: Inhalation, Skin Absorption, Ingestion  
  
EMERGENCY AND FIRST AID PROCEDURES  
  
Skin Contact:  
Immediately wash skin with copious amounts of water for at least 15 minutes while removing contaminated clothing. If irritation persists, SEEK MEDICAL ATTENTION.  
  
Eye Contact:  
Immediately flush the eyes with copious amounts of water for at least 15 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. If irritation persists, SEEK MEDICAL ATTENTION.  
  
Inhalation:  
Remove to fresh air, rest and keep warm. In severe cases or if symptoms persist, SEEK MEDICAL ATTENTION.  
  
Ingestion:  
Wash out mouth with copious amounts of water for at least 15 minutes. DO NOT induce vomiting. SEEK MEDICAL ATTENTION.  
  
  
  
   
44  
CONFIDENTIAL  
  
  
  
[\*\*\*] MATERIAL SAFETY DATA SHEET  
  
  
------------------------------------------------------------------------------  
6 - REACTIVITY DATA  
------------------------------------------------------------------------------  
  
STABILITY:  
[\*\*\*]  
  
  
HAZARDOUS POLYMERIZATION: [\*\*\*]  
  
CONDITIONS TO AVOID: Not available  
  
INCOMPATIBLES: [\*\*\*]  
  
DECOMPOSITION PRODUCTS: [\*\*\*]  
  
  
------------------------------------------------------------------------------  
7 - SPILL AND DISPOSAL PROCEDURES  
------------------------------------------------------------------------------  
  
STEPS TO BE TAKEN IN THE EVENT OF A SPILL OR DISCHARGE:  
  
Evacuate unnecessary persons from the area. Wear appropriate safety equipment. Provide thorough ventilation to remove dusts and vapors. Sweep up material and hold for proper disposal. DO NOT USE WATER.  
   
DISPOSAL PROCEDURE:  
  
If approved, may be burnt in a chemical incinerator equipped with an afterburner and scrubber. Comply with all federal, provincial and local regulations.  
   
EPA HAZARDOUS WASTE NUMBER:  
  
  
------------------------------------------------------------------------------  
8 - PROTECTIVE EQUIPMENT  
------------------------------------------------------------------------------  
-  
VENTILATION Handle in a well-ventilated area.  
  
RESPIRATORY PROTECTION: NIOSH approved dust/mist respirator.  
 EYE/SKIN PROTECTION: Safety glasses/ goggles and protective gloves.  
  
  
  
   
45  
CONFIDENTIAL  
  
  
[\*\*\*] MATERIAL SAFETY DATA SHEET  
  
  
------------------------------------------------------------------------------  
9 - STORAGE AND HANDLING PRECAUTIONS  
------------------------------------------------------------------------------  
  
SPECIAL PRECAUTIONS: Not available  
  
------------------------------------------------------------------------------  
10 - TRANSPORTATION DATA AND ADDITIONAL INFORMATION  
------------------------------------------------------------------------------  
  
DOMESTIC (D.O.T.): [\*\*\*]  
  
PROPER SHIPPING NAME: N/A  
  
HAZARD CLASS: N/A  
  
UN/NA: [\*\*\*]  
  
PACKING GROUP: N/A  
------------------------------------------------------------------------------  
11 - PREPARATION DATE OF MSDS  
------------------------------------------------------------------------------  
  
Prepared By: Xxxx Xxxxx  
  
Phone:  
(000) 000-0000  
  
Date: February 8, 2001  
  
Date Printed: February 15, 2001  
  
Version: One  
  
NOTE:  
1.  
Only selected Registry of Toxic Effects of Chemical Substances (RTECS) data is presented here. See entry in RTECS for complete information.  
  
2.  
The burden of safe use of our materials must rest with the user. We cannot assume responsibility for the completeness or accuracy of any information supplied by us concerning the hazards or recommended use of the chemicals.  
  
  
  
   
46  
CONFIDENTIAL  
  
[\*\*\*] MATERIAL SAFETY DATA SHEET  
  
------------------------------------------------------------------------------  
  
SUPPLIER/MANUFACTURER NAME & ADDRESS  
  
Raylo Chemicals Inc., A Xxxxxxx Fine Chemicals Co.  
0000 Xxxxxx Xxxx  
Xxxxxxxx, Xxxxxxx, Xxxxxx  
X0X 0X0  
  
Phone No:  
(000) 000-0000  
Fax No:  
(000) 000-0000  
  
24-HOUR EMERGENCY PHONE NO: (000) 000-0000  
------------------------------------------------------------------------------  
  
------------------------------------------------------------------------------  
1 - PRODUCT IDENTIFICATION  
------------------------------------------------------------------------------  
  
PRODUCT NAME: [\*\*\*]  
  
FORMULA: [\*\*\*]  
FORMULA WT: [\*\*\*]  
  
COMMON SYNONYMS: [\*\*\*]  
  
PRODUCT NUMBER: [\*\*\*]  
  
CHEMICAL FAMILY: [\*\*\*]  
  
CAS NO.: N/A  
  
NIOSH/RTECS NO.:  
N/A  
  
CREATION DATE: February 8th, 2001  
 REVISION DATE: N/A  
  
------------------------------------------------------------------------------  
2 - COMPOSITION/INFORMATION ON INGREDIENTS  
------------------------------------------------------------------------------  
 Hazardous Ingredients  
Wt. %  
 CAS NO.  
  
[\*\*\*]  
  
  
  
   
47  
CONFIDENTIAL  
  
  
[\*\*\*] MATERIAL SAFETY DATA SHEET  
  
------------------------------------------------------------------------------  
3 - PHYSICAL DATA  
------------------------------------------------------------------------------  
  
BOILING POINT (°C): Not available  
 VAPOR PRESSURE (MM HG): Not available  
  
MELTING POINT (°C): [\*\*\*]  
  
VAPOR DENSITY (AIR=1): Not available  
  
SPECIFIC GRAVITY (Kg/L): Not available  
(H2O=1)   
  
EVAPORATION RATE: (SLOWER/FASTER/EQUAL TO BUTYL ACETATE) Not available  
   
  
SOLUBILITY (H2O) (ml/g): [\*\*\*]  
  
APPEARANCE & ODOR: [\*\*\*]  
  
  
------------------------------------------------------------------------------  
4 - FIRE AND EXPLOSION HAZARD DATA  
------------------------------------------------------------------------------  
  
FLASH POINT (CLOSED CUP): Not available  
  
NFPA 704M RATING: Not available  
  
FLAMMABLE LIMITS: UPPER – N/A  
%  
LOWER – N/A  
%  
  
FIRE EXTINGUISHING MEDIA: Dry chemicals, foam.  
 SPECIAL FIRE-FIGHTING PROCEDURES: Wear full protective clothing & NIOSH approved self contained breathing apparatus .  
  
UNUSUAL FIRE & EXPLOSION HAZARDS: Not available  
  
TOXIC GASES PRODUCED: Not available  
  
  
  
   
48  
CONFIDENTIAL  
  
  
[\*\*\*] MATERIAL SAFETY DATA SHEET  
  
------------------------------------------------------------------------------  
5 - HEALTH HAZARD DATA  
------------------------------------------------------------------------------  
To the best of our knowledge the chemical, physical and toxicological properties of this product have not been fully investigated. Exercise due care, handle as a chemical which is toxic.   
  
THRESHOLD LIMIT VALUE (TLV/TWA):  
N/A  
(PPM) Not available  
  
PERMISSIBLE EXPOSURE LIMIT (PEL):  
N/A  
 (PPM) Not available  
  
TOXICITY: LD50/ OTHER  
(ORAL-RAT)(MG/KG): Not available  
  
  
CARCINOGENICITY:   
NTP:  
N/A  
IARC:  
N/A  
 Z LIST: N/A OSHA REG: N/A  
  
EFFECTS OF OVEREXPOSURE: Not available  
  
TARGET ORGANS: Not available  
 MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE: Not available  
 ROUTES OF ENTRY: Not available  
  
EMERGENCY AND FIRST AID PROCEDURES  
  
Skin Contact:  
Immediately wash skin with copious amounts of water for at least 15 minutes while removing contaminated clothing. If irritation persists, SEEK MEDICAL ATTENTION.  
  
Eye Contact:  
Immediately flush the eyes with copious amounts of water for at least 15 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. If irritation persists, SEEK MEDICAL ATTENTION.  
  
Inhalation:  
Remove to fresh air, rest and keep warm. In severe cases or if symptoms persist, SEEK MEDICAL ATTENTION.  
  
Ingestion:  
Wash out mouth with copious amounts of water for at least 15 minutes. DO NOT induce vomiting. SEEK MEDICAL ATTENTION.  
  
  
  
   
49  
CONFIDENTIAL  
  
  
  
[\*\*\*] MATERIAL SAFETY DATA SHEET  
  
------------------------------------------------------------------------------  
6 - REACTIVITY DATA  
------------------------------------------------------------------------------  
  
STABILITY:  
[\*\*\*]  
  
 HAZARDOUS POLYMERIZATION: [\*\*\*]  
  
CONDITIONS TO AVOID: Not available  
  
INCOMPATIBLES: [\*\*\*]  
  
DECOMPOSITION PRODUCTS: [\*\*\*]  
  
  
------------------------------------------------------------------------------  
7 - SPILL AND DISPOSAL PROCEDURES  
------------------------------------------------------------------------------  
  
STEPS TO BE TAKEN IN THE EVENT OF A SPILL OR DISCHARGE:  
  
Evacuate unnecessary persons from the area. Wear appropriate safety equipment. Provide thorough ventilation to remove dusts and vapors. Sweep up material and hold for proper disposal.   
   
DISPOSAL PROCEDURE:  
  
If approved, may be burnt in a chemical incinerator equipped with an afterburner and scrubber. Comply with all federal, provincial and local regulations.  
   
EPA HAZARDOUS WASTE NUMBER: N/A  
  
------------------------------------------------------------------------------  
8 - PROTECTIVE EQUIPMENT  
------------------------------------------------------------------------------  
  
VENTILATION: Handle in a well-ventilated area, i.e. fume hood.  
  
RESPIRATORY PROTECTION: NNIOSH approved dust/mist respirator with chemical goggles  
  
EYE/SKIN PROTECTION: Chemical safety goggles, coveralls, and protective gloves.  
  
  
  
   
50  
CONFIDENTIAL  
  
  
COH206 MATERIAL SAFETY DATA SHEET  
  
  
------------------------------------------------------------------------------  
9 - STORAGE AND HANDLING PRECAUTIONS  
------------------------------------------------------------------------------  
  
SPECIAL PRECAUTIONS: N/A  
  
------------------------------------------------------------------------------  
10 - TRANSPORTATION DATA AND ADDITIONAL INFORMATION  
------------------------------------------------------------------------------  
  
DOMESTIC (D.O.T.): [\*\*\*]  
  
PROPER SHIPPING NAME: N/A  
  
HAZARD CLASS: N/A  
  
UN/NA: [\*\*\*]  
  
PACKING GROUP: N/A  
------------------------------------------------------------------------------  
11 - PREPARATION DATE OF MSDS  
------------------------------------------------------------------------------  
  
Prepared By: Xxxx Xxxxx  
  
Phone:  
(000) 000-0000  
  
Date: February 8th, 2001  
  
Date Printed: February 15, 2001  
  
Version: One  
  
NOTE:  
  
2.  
Only selected Registry of Toxic Effects of Chemical Substances (RTECS) data is presented here. See entry in RTECS for complete information.  
  
2.  
The burden of safe use of our materials must rest with the user. We cannot assume responsibility for the completeness or accuracy of any information supplied by us concerning the hazards or recommended use of the chemicals.  
  
  
  
   
51  
CONFIDENTIAL  
  
  
  
  
 Molecular Formula  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
  
[\*\*\*]  
  
  
  
   
52  
CONFIDENTIAL  
  
  
  
 Chemical Name  
Chemical Abstracts Service Number  
Trade Name  
Average Molecular Weight (Mw)  
Molecular Weight Distribution Mw/Mn  
(GPC)  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
  
 Weight (g)  
Viscosity (cP)  
Color  
pH  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
  
  
  
  
   
 53  
CONFIDENTIAL  
   
  
  
  
SCHEDULE 4.1  
FORECAST – COSEAL SEALANT PRODUCT  
(TO BE ADDED BY XXXXXX)  
  
  
  
  
 54