

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549  
FORM 10-Q/A  
Amendment No. 1**

(Mark One)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2018

or

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
Commission file number 001-10865



**AMAG Pharmaceuticals, Inc.**  
(Exact Name of Registrant as Specified in Its Charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**04-2742593**

(I.R.S. Employer  
Identification No.)

**1100 Winter Street  
Waltham, Massachusetts**

(Address of principal executive offices)

**02451**

(Zip Code)

**(617) 498-3300**

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. **Yes**  **No**

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). **Yes**  **No**

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). **Yes**  **No**

As of December 18, 2018, there were 34,606,760 shares of the registrant's Common Stock, par value \$0.01 per share, outstanding.

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#### **EXPLANATORY NOTE - EXHIBIT FILING ONLY**

AMAG Pharmaceuticals, Inc. (the “Company”) is filing this Amendment No. 1 (this “Amendment”) to its Quarterly Report on Form 10-Q for the quarter ended June 30, 2018 (the “Form 10-Q”), originally filed on August 3, 2018. This Amendment is an exhibit-only filing in response to comments received from the Securities and Exchange Commission (the “Commission”) regarding a request for confidential treatment of certain portions of Exhibits 10.7 and 10.8 originally filed with the Form 10-Q. This Amendment is being filed solely to re-file Exhibits 10.7 and 10.8 based on Commission comments in order to restore certain redacted information in such exhibits that was subject to a confidential treatment request. In addition, as required by Rule 12b-15 under the Securities Exchange Act of 1934, as amended, new certifications by our principal executive officer and principal financial officer are filed as exhibits to this Amendment.

This Amendment is limited in scope to the items identified above and should be read in conjunction with the Form 10-Q. This Amendment does not reflect events occurring after the filing of the Form 10-Q and no revisions are being made to the Company’s financial statements pursuant to this Amendment. Other than the filing of the information identified above, this Amendment does not modify or update the disclosure in the Form 10-Q in any way.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

AMAG PHARMACEUTICALS, INC.

By: /s/ William K. Heiden  
William K. Heiden  
*President and Chief Executive Officer*  
*(Principal Executive Officer)*

Date: December 21, 2018

By: /s/ Edward Myles  
Edward Myles  
*Executive Vice President of Finance, Chief Financial Officer and Treasurer*  
*(Principal Financial Officer)*

Date: December 21, 2018

**Item 6. Exhibits:**

<b>Exhibit Number</b>	<b>Description</b>
2.1	<a href="#"><u>Stock Purchase Agreement, dated June 14, 2018, by and among AMAG Pharmaceuticals, Inc., CBR Acquisition Holdings Corp. and GI Chill Acquisition LLC (incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed June 15, 2018 File No. 001-10865)</u></a>
10.1*	<a href="#"><u>AMAG Pharmaceuticals, Inc.'s Amended and Restated Non-Employee Director Compensation Policy</u></a>
10.2	<a href="#"><u>AMAG Pharmaceuticals, Inc. Fourth Amended and Restated 2007 Equity Incentive Plan, as amended (incorporated herein by reference to Appendix A to the Registrant's Definitive Proxy Statement on Schedule 14A filed April 25, 2018, File No. 001-10865)</u></a>
10.3	<a href="#"><u>AMAG Pharmaceuticals, Inc. First Amendment to 2015 Employee Stock Purchase Plan (incorporated herein by reference to Appendix B to the Registrant's Definitive Proxy Statement on Schedule 14A filed April 25, 2018, File No. 001-10865)</u></a>
10.4*	<a href="#"><u>Form of Restricted Stock Unit Agreement for AMAG Pharmaceuticals, Inc. Employees under AMAG Pharmaceuticals, Inc.'s Fourth Amended and Restated 2007 Equity Incentive Plan and the Lumara Health Inc. Amended and Restated 2013 Incentive Compensation Plan</u></a>
10.5*	<a href="#"><u>Form of Restricted Stock Unit Agreement for Non-Employee Directors under AMAG Pharmaceuticals, Inc.'s Fourth Amended and Restated 2007 Equity Incentive Plan</u></a>
10.6*	<a href="#"><u>Form of Restricted Stock Unit Agreement - Non-Plan Inducement Grant</u></a>
10.7+#	<a href="#"><u>Distribution and Supply Agreement, dated December 20, 2017, by and between AMAG Pharmaceuticals, Inc. and Prasco, LLC</u></a>
10.8+#	<a href="#"><u>Commercial Supply Agreement, dated June 4, 2018, by and between AMAG Pharmaceuticals, Inc. and SAFIC, Inc.</u></a>
31.1+	<a href="#"><u>Certification Pursuant to Rule 13a-14(a)/15d-14(a) of the Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u></a>
31.2+	<a href="#"><u>Certification Pursuant to Rule 13a-14(a)/15d-14(a) of the Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u></a>
32.1++	<a href="#"><u>Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u></a>
32.2++	<a href="#"><u>Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u></a>
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

\* Previously filed with the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2018, as filed on August 3, 2018.

+ Filed herewith.

# Confidential treatment has been requested for certain information contained in this exhibit, which information was omitted by means of redacting a portion of the text and replacing it with [\*\*\*]. This exhibit has been filed separately with the SEC without any redactions pursuant to a Confidential Treatment Request under Rule 24b-2 of the Securities and Exchange Act of 1934, as amended.

++ Furnished herewith.

\*\*\* INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

**Execution Version**

**Exhibit 10.7**

**Authorized Generic of Makena® (hydroxyprogesterone caproate injection)**

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**DISTRIBUTION AND SUPPLY AGREEMENT**

**BY AND BETWEEN**

**AMAG PHARMACEUTICALS, INC.**

**AND**

**PRASCO, LLC**

**DATED AS OF DECEMBER 20, 2017**

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## DISTRIBUTION AND SUPPLY AGREEMENT

**This Distribution and Supply Agreement** (this “**Agreement**”) is made as of December 20, 2017 (the “**Effective Date**”), by and between AMAG Pharmaceuticals, Inc., a Delaware corporation with offices located at 1100 Winter Street, Waltham, Massachusetts 02451 (hereinafter referred to as “**Manufacturer**” and “**AMAG**”), and Prasco, LLC, a Ohio limited liability company with offices located at 6125 Commerce Court, Mason, Ohio 45040 (hereinafter referred to as “**Distributor**” and “**Prasco**”) and is to be effective as of the Effective Date. Manufacturer and Distributor are each referred to herein as a “**Party**” and, collectively, as the “**Parties**.”

### RECITALS

WHEREAS, Manufacturer may supply, and Distributor may purchase, distribute and sell, the Products in the Territory in accordance with the terms of this Agreement.

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

### ARTICLE 1 DEFINITIONS

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

**1.1 “Act”** shall mean the United States Federal Food, Drug, and Cosmetic Act, as amended from time to time, and the rules, regulations and guidelines promulgated thereunder.

**1.2 “Affiliate”** of a Party shall mean a Person that controls, is controlled by, or is under common control with a Party. For the purposes of this definition, the word “control” (including, with correlative meaning, the terms “controlled by” or “under common control with”) means the actual power, either directly or indirectly through one or more intermediaries, to direct the management and policies of such Person, whether by the ownership of fifty percent (50%) or more of the voting interest of such Person (it being understood that the direct or indirect ownership of a lesser percentage of such interest shall not necessarily preclude the existence of control), or by contract or otherwise.

**1.3 “AG Product”** shall mean a hydroxyprogesterone caproate injection supplied in (i) 250 mg/mL preservative free in 1 mL single dose glass vial in a single unit carton bundled with four in each tray or pack, and (ii) 250 mg/mL in 5 mL multidose glass vial in a single unit carton, each in Manufactured form and sold under AMAG’s NDA.

**1.4 “Agreement”** shall have the meaning assigned to such term in the Preamble.

**1.5 “Allowance for Distribution and Marketing”** shall mean [\*\*\*].

**1.6 “AMAG Party”** shall have the meaning assigned to such term in Section 9.1(b).

**1.7 “AMAG’s NDA”** shall mean NDA No. 21-945, and all supplements filed pursuant to the requirements of FDA, including all documents, data and other information concerning Makena which are necessary for the Regulatory Approval of Makena.

**1.8 “Bailment Agreement”** has the meaning given in Section 6.1(b).

**1.9 “Bailment Product”** has the meaning given in Section 6.1(b).

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

**1.11 “Branded Product”** means branded product Makena® sold by Manufacturer under the Trademark.

**1.12 “Brand Fee”** means the “Annual Fee on Branded Prescription Pharmaceutical Manufacturers and Importers” pursuant to Section 9008 of the Patient Protection and Affordable Care Act of 2010, and any amendments thereto, that is owed by Distributor relating to the sale of Products if the orphan drug status of the Product changes, and shall be calculated on an accrual basis based on sales of the Products during a period to the relevant government programs.

**1.13 “Business Day”** shall mean any day other than a Saturday, Sunday or a day on which banks in New York, New York are authorized or required by law to close.

**1.14 “Calendar Quarter”** shall mean each three-month period starting on January 1, April 1, July 1, and October 1 of each calendar year.

**1.15 “cGMP”** shall mean all applicable standards relating to manufacturing practices for fine chemicals, active pharmaceutical ingredients, intermediates, bulk products or finished pharmaceutical products, including the principles detailed in the U.S. current Good Manufacturing Practices, 21 C.F.R. Parts 210 and 211.

**1.16 “Change in Control”** shall mean (i) the liquidation or dissolution of a Party or the sale or other transfer by a Party (excluding transfers to Affiliates) of all or substantially all of its assets, or (ii) the occurrence of a tender offer, stock purchase, other stock acquisition, merger, consolidation, recapitalization, reverse split, sale or transfer of assets or other transaction, as a result of which any person, entity or group (a) becomes the beneficial owner, directly or indirectly, of securities of a Party representing more than fifty percent (50%) of the ordinary shares of such Party or representing more than fifty percent (50%) of the combined voting power

with respect to the election of directors (or members of any other governing body) of such Party's then outstanding securities, or (b) obtains the ability to appoint a majority of the Board of Directors (or other governing body) of a Party, or obtains the ability to direct the operations or management of a Party or any successor to the business of a Party.

**1.17 "Claim"** shall have the meaning assigned to such term in Section 9.1(a).

**1.18 "Commencement Date"** shall have the meaning assigned to such term in Section 2.1(b).

**1.19 "Commencement Notice"** shall have the meaning assigned to such term in Section 2.1(b).

**1.20 "Commercially Reasonable Efforts"** shall mean, with respect to the efforts to be expended by any Party with respect to any objective, those reasonable, diligent, good faith efforts to accomplish such objective as such Party would normally use to accomplish a similar objective under similar circumstances. "Commercially Reasonable Efforts" with respect to a Product shall mean those efforts and resources normally used by such Party with respect to a product owned or controlled by such Party, or to which such Party has similar rights, which product is of similar market potential and is at a similar stage in its life as is the Product, taking into account issues of safety, efficacy, product profile, the competitiveness of the marketplace, the proprietary position of the Product, the regulatory structure involved, profitability of the Product and other relevant commercial factors. Without limiting the foregoing, Commercially Reasonable Efforts requires, with respect to such obligations, that the Party: (a) promptly assign responsibility for such obligation to specific employee(s) who are held accountable for progress and monitor such progress on an on-going basis, (b) set annual objectives for carrying out such obligations, and (c) allocate resources designed to advance progress with respect to such objectives.

**1.21 "Competitive Product"** shall mean [\*\*\*].

**1.22 "Compound"** shall mean hydroxyprogesterone caproate.

**1.23 "Confidential Information"** shall mean, with respect to a Party, all proprietary information of any kind whatsoever (including without limitation, materials, data, compilations, formulae, models, patent disclosures, procedures, processes, projections, protocols, results of experimentation and testing, specifications, strategies, techniques and all non-public intellectual property rights) or other information (whether or not patentable) disclosed by a Party to the other Party regarding a Party's know how, products, business information or objectives, regardless of whether such information is written, oral, electronic or other form and regardless of whether such information is specifically designated as confidential. This Agreement and the terms and conditions hereof shall be considered "Confidential Information".

**1.24 "Designated Officers"** shall have the meaning assigned to such term in Section 12.15.

**1.25 "Disclosing Party"** shall have the meaning assigned to such term in Section 11.1.



1.26 “**Distributor**” shall have the meaning assigned to such term in the Preamble.

1.27 “**Distributor Label Information**” shall mean the artwork, layout, content and design provided or included in the Product Labeling, other than the content of the Makena Label.

1.28 “**Distributor Party**” shall have the meaning assigned to such term in Section 9.1(a).

1.29 “**Event of Default**” shall have the meaning assigned to such term in Section 10.3.

1.30 “**Failure to Supply Charges**” shall mean [\*\*\*].

1.31 “**FDA**” shall mean the United States Food and Drug Administration and any agency under its control or any successor agency thereto.

1.32 “**FDA Notice**” shall have the meaning assigned to such term in Section 10.5(a).

1.33 “**Firm Order**” shall have the meaning assigned to such term in Section 5.1(c).

1.34 “**Firm Order Period**” shall have the meaning assigned to such term in Section 5.1(c).

1.35 “**Firm Order Quantity**” shall have the meaning assigned to such term in Section 5.1(c).

1.36 “**First Commercial Sale**” shall mean the date of Distributor’s first sale of Product to a Third Party, including without limitation to retail chains, pharmaceutical wholesalers, or managed care providers.

1.37 “**Force Majeure Event**” shall have the meaning assigned to such term in Section 10.6.

1.38 “**GAAP**” shall mean generally accepted accounting principles in effect in the United States from time to time, consistently applied.

1.39 “**Generic Equivalent Product**” shall mean a Competitive Product approved by the FDA.

1.40 “**Initial Launch Quantities**” shall have the meaning assigned to such term in Section 5.1(b).

1.41 “**Initial Term**” shall have the meaning assigned to such term in Section 10.1.

1.42 “**Invoice Supply Price**” shall mean, for Products delivered to Distributor, [\*\*\*].

1.43 “**Label**” shall mean any Package labeling designed and used with the Product, including the package insert for the Product that is approved by FDA, and “**Labeled**” or “**Labeling**” shall have the correlated meaning.

[\*\*\*] INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

**1.44 “Launch Quantities”** shall have the meaning assigned to such term in Section 5.1(b).

**1.45 “Losses”** shall mean any liabilities, damages, costs or expenses, including reasonable attorneys’ fees and expert fees, incurred by any Party that arise from any claim, lawsuit or other action by a Third Party.

**1.46 “Makena”** shall mean the branded pharmaceutical product that contains the Compound as its sole active ingredient which is approved for Marketing in the Territory pursuant to AMAG’s NDA and sold under the Trademark.

**1.47 “Manufacture”** shall mean all activities related to the manufacturing and/or production of the Product, or any ingredient thereof including, but not limited to, manufacturing and procuring Compound or supplies for development, manufacturing product for commercial sale, packaging, labeling, in-process and finished product testing, including QC Testing, release of product or any component or ingredient thereof, quality assurance activities related to development, manufacturing and release of product, ongoing stability tests and regulatory activities related to any of the foregoing, and **“Manufactured”** and **“Manufacturing”** shall have the correlated meaning.

**1.48 “Manufacturer”** shall have the meaning assigned to such term in the Preamble.

**1.49 “Manufacturing Costs”** shall mean [\*\*\*].

The current Manufacturing Costs are set forth on Exhibit 1.49.

**1.50 “Market”** shall mean to distribute, promote, advertise (if applicable), market, offer to sell and sell, to a Third Party and **“Marketing”** and **“Marketed”** shall have the correlated meaning.

**1.51 “Modified Firm Order Quantity”** shall have the meaning assigned to such term in Section 5.1(c).

**1.52 “NDA”** shall mean a New Drug Application filed with FDA pursuant to Section 505 of the Act (21 U.S.C. Section 355), or the applicable regulations (21 CFR Part 314), including any supplements, amendments or modifications submitted to or required by FDA or any successor application or procedure for approval to Market a pharmaceutical product.

**1.53 “NDC#”** shall mean a unique 3-segment number that identifies the labeler/vendor, the product and the trade package size.

**1.54 “Net Distributable Profits”** for any period means [\*\*\*]. Notwithstanding the foregoing, it is understood that Net Distributable Profits for a particular period may be adjusted in the future (but not to less than zero) for any quarterly period in connection with adjustments to the accrual amounts for such period as actual amounts and/or more definite information becomes known in accordance with Section 3.4.

[\*\*\*] INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

**1.55 “Net Sales”** means [\*\*\*].

**1.56 “Non-performing Party”** shall have the meaning assigned to such term in Section 10.6.

**1.57 “Notice”** shall have the meaning assigned to such term in Section 12.8.

**1.58 “Package”** shall mean all containers, including bottles, cartons, shipping cases or any other matter used in packaging or accompanying a product, and “Packaged” or “Packaging” shall have the correlated meaning.

**1.59 “Party”** and “Parties” shall have the meaning assigned to such terms in the Preamble.

**1.60 “Performing Party”** shall have the meaning assigned to such term in Section 10.6.

**1.61 “Person”** shall mean any individual, corporation, partnership, limited liability company, joint venture, association, trust, unincorporated organization or other legal Person or entity.

**1.62 “Pharmacovigilance Agreement”** shall mean the pharmacovigilance agreement entered into by the Parties within [\*\*\*] following the Effective Date of this Agreement, which agreement shall be on terms that comply with ICH guidelines, including: (i) providing detailed procedures regarding the maintenance of core safety information and the exchange of safety data relating to the Compound, Products, and Makena in the Territory within appropriate timeframes and in an appropriate format to enable Manufacturer to meet both expedited and periodic regulatory reporting requirements; and (ii) ensuring compliance with the reporting requirements of all applicable regulatory authorities in the Territory for the reporting of safety data in accordance with standards stipulated in the ICH guidelines, and all applicable regulatory and legal requirements regarding the management of safety data.

**1.63 “Pre-booking Activities”** shall mean the activities set forth on Exhibit 1.63.

**1.64 “Pre-booking Date”** shall have the meaning assigned to such term in Section 2.1(b).

**1.65 “Products”** shall mean the AG Products supplied to Distributor under this Agreement, each sold under Distributor’s NDC# and trade dress.

**1.66 “Product Claims”** shall have the meaning assigned to such term in Section 6.6(a).

**1.67 “Product Listing”** shall mean filing with FDA a list of drugs in commercial distribution as required by law.

**1.68 “Promotional Materials”** shall have the meaning assigned to such term in Section 2.4.

**1.69 “QC Testing”** shall include all quality control tests and other inspections required by applicable cGMP standards and AMAG’s NDA for each lot of Product delivered to Distributor.

**1.70 “Quality Agreement”** shall mean the quality agreement entered into by the Parties within [\*\*\*] following the Effective Date of this Agreement, which sets forth the respective responsibilities of Manufacturer and Distributor to ensure that the manufacture, quality control, release, storage, distribution, and reporting obligations for the Product comply with good manufacturing practices as set forth in 21 CFR 210 and 211 and with the Product marking authorization held by the Manufacturer.

**1.71 “Recipient”** shall have the meaning assigned to such term in Section 11.1.

**1.72 “Regulatory Approval”** shall mean final Marketing approval by FDA for the Marketing of a pharmaceutical product in the Territory

**1.73 “Remaining Supply Price”** shall have the meaning assigned to such term in Section 3.4.

**1.74 “Rolling Forecast”** shall have the meaning assigned to such term in Section 5.1(a).

**1.75 “Shelf Stock Adjustment”** shall mean the customary practice of providing a purchaser of generic product an adjustment to the net purchase price for on-hand inventory in response to the lowering of the purchase price for the generic product.

**1.76 “SKU”** means a given package configuration of a given strength of the Products, as may be changed by Manufacturer upon notice to Distributor.

**1.77 “Specifications”** shall mean the specifications for the Products contained in AMAG’s NDA.

**1.78 “Supply Interruption”** shall have the meaning assigned to such term in Section 5.2(c).

**1.79 “Supply Price”** shall mean [\*\*\*].

**1.80 “Term”** shall have the meaning assigned to such term in Section 10.1.

**1.81 “Territory”** shall mean the [\*\*\*].

**1.82 “Third Party” or “Third Parties”** shall mean any Person or entity other than a Party or its Affiliates.

1.83 “**Trademark**” shall mean the Manufacturer’s trademark Makena®.

## ARTICLE 2 DISTRIBUTION RIGHTS AND OBLIGATIONS

### 2.1 Commencement Date; First Commercial Sale.

(a) At any time after the Effective Date, Manufacturer may elect to authorize Distributor to commence the Marketing of a SKU under this Agreement. Manufacturer shall have the sole right and discretion to determine if and when to authorize Distributor to commence Marketing the SKU.

(b) If Manufacturer decides to authorize Distributor to commence Marketing a SKU, Manufacturer shall provide Distributor with written notice specifying a date for Distributor to commence selling and distributing the SKU and a date for Distributor to begin Pre-booking Activities for such SKU. A notice delivered by Manufacturer under this Section 2.1(b) is referred to herein as a “**Commencement Notice**,” the date specified in a Commencement Notice for Distributor to commence the selling and distribution of a SKU is referred to herein as the “**Commencement Date**,” and the date specified in a Commencement Notice or in a separate written pre-booking notice for Distributor to commence the Pre-booking Activities is referred to herein as the “**Pre-booking Date**”.

(c) Effective as of the Pre-booking Date for a SKU, Manufacturer grants to Distributor an exclusive, non-sublicensable, nontransferable license under the NDA for the Branded Product to perform the Pre-booking Activities for such SKU in the Territory in accordance with the terms of this Agreement. Effective as of the Commencement Date for a SKU, Manufacturer grants to Distributor an exclusive, non-sublicensable, nontransferable license under the NDA for the Branded Product to Market such SKU of the Product in the Territory as a generic product subject to and in accordance with the terms of this Agreement. Distributor shall Market the Product in the Territory as a generic product commencing as of the Commencement Date, in accordance with this Agreement. Prior to the Pre-booking Date, Distributor shall have no right to distribute, Market, promote or sell the Product, engage in Pre-booking Activities, make any public statements, or inform any Third Parties regarding Distributor’s right or ability to distribute, or sell the Products. Prior to the Commencement Date, Distributor shall have no right to distribute or sell the Product.

(d) Manufacturer may elect to supply Distributor with some or all of the Launch Quantities of each SKU under the Bailment Agreement prior to the Commencement Date for such SKU. In any event, upon delivery of the Commencement Notice for a SKU, Manufacturer shall promptly supply Launch Quantities of such SKU to Distributor, to the extent not previously supplied under the Bailment Agreement.

## 2.2 Commercial Exploitation.

(a) Distributor shall \*\*\* Market the Product in the Territory in accordance with this Agreement. Distributor shall not Market the Product through a Third Party or Affiliate without the prior written consent of Manufacturer. Except for Marketing activities, Distributor shall be entitled to carry out all other obligations under this Agreement through one or more of its Affiliates, but any such arrangement shall not limit Distributor's obligations and liability with respect thereto under this Agreement.

(b) Distributor shall \*\*\* have the First Commercial Sale for a SKU be within \*\*\* of the later of \*\*\*. No later than \*\*\* after the First Commercial Sale of a SKU, Distributor shall give written notice to Manufacturer specifying the date of the First Commercial Sale of such SKU.

(c) Distributor shall \*\*\* in entering into contracts, establishing the terms of sale and Marketing decisions (except as set forth in Section 2.2(c), 2.2(e) 2.4, and 2.5) for the Products, including without limitation the price to its customers, \*\*\*; provided that Distributor's contracts and terms of sale for the Products shall be consistent in all material respects with industry standards for other similar products (e.g., using similar distribution channels) distributed by Distributor, including with respect to returns, credits, discounts, rebates and adjustments. In addition, Distributor will not use the Products as a "loss leader" or as part of a bundle, basket or group sale with sales of its other products that would result in financially disadvantaging the Product relative to such other products.

(d) In Marketing the Products, Distributor (i) shall not use any trademarks or trade names owned or licensed by Manufacturer, and (ii) shall identify itself as the distributor of the Product using its "Prasco" trade name and trade dress. Within \*\*\* of the Effective Date, Manufacturer shall provide Distributor with final labeling and packaging artwork, including the graphics and artwork for the Packaging and Labeling components for Distributor's approval. All trademarks, trade names and packaging graphics and artwork on the Labeling and Packaging shall comply with regulatory or other governmental agency guidance or directives. In no event shall Distributor identify the Products in any way that is deemed by Manufacturer to be confusingly similar to the trade name Makena.

(e) Distributor shall not, directly or indirectly, (i) solicit or accept orders for sales of any Products to any existing or prospective customer outside the Territory, (ii) deliver or tender (or cause to be delivered or tendered) any Products outside of the Territory, or (iii) sell any Products to, or solicit any sales from, a customer if Distributor \*\*\* that such customer intends to resell the Product outside of the Territory. If Distributor becomes aware, after reasonable inquiry, of any circumstance where there is a reason to believe that Products are being, or will be, distributed or redistributed outside the Territory by a customer of Distributor, Distributor shall promptly notify Manufacturer, and Distributor shall promptly \*\*\* stop the sale or distribution of Products outside the Territory, including, without limitation, terminating future sales of

Product to any such customer until such time that Distributor and/or Manufacturer receives reasonable assurances from such customer that such activity has stopped and a Party has communicated such reasonable assurance to the other Party. Distributor shall not sell or otherwise transfer Products to an Affiliate for subsequent Marketing or resale by such Affiliate.

### **2.3 Distribution Obligations.**

(a) Distributor shall: (i) store, handle and distribute its inventory of the Products, including Bailment Product, in clean and sanitary conditions as required to maintain the quality and traceability of the Product, and in accordance with FDA approved labeling for the Product; (ii) not alter the Products in any manner; (iii) comply with the Act and all other applicable federal, state and local food, health and other relevant laws, rules and regulations within the Territory in connection with the storage, handling, and distribution of the Product; and (iv) not Market the Products in any manner which is inconsistent with FDA approved labeling of the Product or applicable laws, rules and regulations (including without limitation, 21 CFR Sections 201 and 801), or otherwise not make any false or misleading representations to customers or others regarding the Product.

(b) Distributor shall Market the Products using only an NDC# that reflects Distributor as the distributing and selling party.

(c) Distributor shall not Market the Products under any brand name or private label.

(d) Distributor (or Distributor's designee) shall at all times maintain its inventory of Product under proper storage conditions in compliance with all applicable laws, rules and regulations and in accordance with Exhibit 2.3(d) and the Quality Agreement.

**2.4 Promotional Materials.** Distributor will not use any Promotional Materials (as defined below) in connection with the Marketing, sale or distribution of the Product without Manufacturer's prior written approval. Distributor may [\*\*\*]. For purposes of this Agreement, "**Promotional Materials**" includes all labeling, advertising and reminder materials (including trade show graphics) as defined in 21 CFR Section 200.200 and Section 202.1(e)(2), as well as any other applicable provisions of the Act or applicable laws, rules or regulations. For the avoidance of doubt, [\*\*\*] or as otherwise required by applicable law; provided, however, that [\*\*\*].

**2.5 Sampling.** Distributor shall not provide any samples of the Products to any Third Party.

**2.6 Rebate Processing.**

(a) \*\*\* will be solely responsible for all federal, state and local government and private purchasing, pricing or reimbursement programs with respect to the Product, including taking all necessary and proper steps to execute agreements and file other appropriate reports and other documents with governmental and private entities and \*\*\* shall provide reasonable assistance to \*\*\* to effectuate same. \*\*\* will be solely responsible for payment and processing of all rebates, and for providing pricing and price disclosures, whether required by contract or local, state or federal law, for the Product sold by Distributor.

(b) Manufacturer is required to refer to Product sales made by Distributor in Manufacturer's government price reports. As such, Distributor will provide Manufacturer with aggregate sales figures for Product sales made by Distributor and the related Net Sales by product NDC#. The foregoing requirement shall be satisfied by Distributor providing the monthly reports contemplated by Section 3.5(a)(ii). Manufacturer shall use any data or information relating to pricing that Distributor provides under this Section 2.6 or otherwise for the limited purpose of complying with legal price reporting requirements and for no other purpose. Manufacturer shall not use any such data or information in connection with its sales, Marketing or contract operations and hereby represents and warrants to Distributor that such data and information will not be disclosed among Manufacturer's personnel for any purpose other than for government price reporting.

**2.7 Manufacturer's Reservation of Rights.** Except as expressly provided in this Agreement, nothing contained in this Agreement shall grant (or be construed as granting) to Distributor any right, title or interest in, to, or under AMAG's NDA or any other NDA held in the name of Manufacturer or its Affiliates, or any supplement thereto, or any intellectual property right owned or controlled by Manufacturer or its Affiliates. Manufacturer is not granting to Distributor any right, title or interest, whether express or implied, under any intellectual property right or other right that Manufacturer or its Affiliates may own or otherwise control. Nothing contained in this Agreement is intended to limit or restrict Manufacturer's ability to manufacture, use, license, Market, or otherwise exploit the Branded Product. Manufacturer shall be permitted in its sole discretion to Market the Branded Product itself or through an Affiliate and to grant Third Parties the right to Market the Branded Product and to supply Branded Product to those Third Parties during the Term. Following the Term (but, for clarity, not during the Term), Manufacturer shall be permitted in its sole discretion to Market the AG Product itself or through an Affiliate and to grant Third Parties the right to Market the AG Product and to supply AG Product to those Third Parties.

**2.8 Limitation on a Competing Product.** During the Term, except with respect to the Product pursuant to this Agreement or any other product supplied by Manufacturer or its Affiliates to Distributor or its Affiliates, \*\*\*].

**2.9 Management.** Distributor and Manufacturer shall establish an Executive Committee with \*\*\*] to discuss important issues related to this Agreement, \*\*\*].



### ARTICLE 3 FINANCIAL PROVISIONS

**3.1 Supply Price.** Following the Commencement Date, and during the remaining Term, Distributor shall pay Manufacturer the Supply Price for the Product.

**3.2 Invoice Supply Price.**

(a) The current Manufacturing Costs for each SKU is set forth in Exhibit 1.49, and each such price shall be subject to adjustment in accordance with Section 3.2(b) [\*\*\*].

(b) If the Manufacturing Costs have increased or decreased during any calendar year (for example, but without limitation, as a result of a change in cost of manufacturing process or a decrease in volume [\*\*\*]), or Manufacturer provides documentation of an increase or decrease in Manufacturing Costs during the coming calendar year, Manufacturer shall give Distributor prior written notice of the change, [\*\*\*].

**3.3 Payment of Invoice Supply Price.** Manufacturer shall invoice Distributor for the Invoice Supply Price together with, or promptly after, each shipment of Product to Distributor. Distributor shall pay Manufacturer's invoices: (A) [\*\*\*], and (B) within [\*\*\*] from the date of invoice for shipments of such Product thereafter. [\*\*\*].

**3.4 Remaining Supply Price.**

(a) Following the first Commencement Date, and during the remaining Term, Distributor shall pay Manufacturer an amount [\*\*\*] (the "**Remaining Supply Price**") and shall make such payments in accordance with Section 3.5. For purposes hereof, a "quarter" is measured as follows with respect to each SKU of the Products that has a different date of First Commercial Sale: (i) for the first quarter, the stub period beginning on the date of the First Commercial Sale and ending on the last day of the Calendar Quarter (March 31, June 30, September 30, or December 31) in which the First Commercial Sale occurs; (ii) for the next succeeding quarters, the full Calendar Quarter period; and (iii) for the final quarter, the stub period beginning on the first day of the Calendar Quarter and ending on the termination or expiration of this Agreement in its entirety or with respect to a particular SKU of the Products. Notwithstanding the foregoing, if the First Commercial Sale occurs on a date that makes the first stub period less than two months, then for purposes of this Agreement, the "first quarter" shall be the period beginning on the date of the First Commercial Sale and ending on the last day of the first full Calendar Quarter after the stub period.

(b) The Parties acknowledge that [\*\*\*]. Accordingly, on an ongoing basis, Distributor shall revise accrual estimates based on actual amounts or updated information, compare those revised accrual estimates to existing accruals, and adjust accruals accordingly. Within [\*\*\*] after the end of each Calendar Quarter, Distributor shall provide to Manufacturer (in accordance with the Accrual Rollforward Report included in Exhibit 3.4(b)) a rollforward of

accrual activity during the previous Calendar Quarter, provided that no accrual shall be adjusted more than [\*\*\*] after it was originally reported. Such rollforward shall show accruals at the beginning of the period, additions to accruals, actual charges against such accruals, any adjustments to accruals deemed necessary by Distributor, and ending accruals held by Distributor at the end of the Calendar Quarter. Any adjustments, both additions to and reductions from the existing accruals, shall be included in the computation of Net Sales or Net Distributable Profits (as applicable) for the same Calendar Quarter.

(c) Upon the expiration or termination of this Agreement, Distributor shall continue to provide Manufacturer with an Accrual Rollforward Report as provided above until all adjustments to existing accruals are determined, provided that the final Accrual Rollforward Report shall be provided no later than the earlier of (i) [\*\*\*] after the last expiry date of the Product sold by Distributor, or (ii) [\*\*\*] after the last date Product is sold by Distributor, or such sooner time as all accruals have been resolved with actual information. Within [\*\*\*] after Distributor delivers each such Accrual Rollforward Report, (i) if Distributor reports a decrease in amounts previously accrued, Distributor shall pay Manufacturer the resulting increase in the Remaining Supply Price, and (ii) if Distributor reports an increase in amounts previously accrued, Manufacturer shall pay Distributor the resulting decrease in the Remaining Supply Price. Nothing contained herein shall require Manufacturer to pay any disputed amounts set forth in such report or notice, or otherwise constitute a waiver of any right of Manufacturer to dispute the amounts set forth in such report or notice.

**3.5 Payment of Remaining Supply Price.** During the period commencing after the First Commercial Sale of a Product and continuing thereafter until the end of the Calendar Quarter following the Calendar Quarter in which this Agreement terminates or expires (or such longer period as Distributor may be entitled to sell inventory pursuant to Sections 10.7 and 10.9(a)):

(a) Within [\*\*\*] after the end of each calendar month, following the first delivery of Product or Bailment Product to Distributor, Distributor shall deliver to Manufacturer a written report, showing with respect to the immediately preceding month (i) inventory of Product or Bailment Product, as applicable, on a SKU-by-SKU basis in Distributor's distribution facilities as of the first and last days of such month, and units of Product or Bailment Product, as applicable, received and shipped during such month and as projected months of supply inventory (all in accordance with the report included in Exhibit 3.5(a)(i)), and (ii) an estimated calculation of the Net Sales, Net Distributable Profits, and the Remaining Supply Price made in accordance with the Quarterly Report included in Exhibit 3.5(a)(ii). As Products are sold, the inventory included on the Quarterly Report shall reflect the inventory with the oldest dating.

(b) Within [\*\*\*] after the end of each Calendar Quarter, Distributor shall submit to Manufacturer a written report setting forth its reasonable good faith estimates of the items set forth in Section 3.5(c) in order to allow Manufacturer to comply with internal reporting obligations.

(c) Within [\*\*\*] after the end of each Calendar Quarter, Distributor shall submit to Manufacturer a Quarterly Report in the form of Exhibit 3.5(a)(ii), completed with

respect to the prior Calendar Quarter. Simultaneously with the delivery of such written report, Distributor shall remit the total amount due to Manufacturer for the Remaining Supply Price for such Calendar Quarter.

(d) Manufacturer may dispute any amounts reflected on a Quarterly Report or Accrual Rollforward Report, [\*\*\*]. Manufacturer shall notify Distributor in writing of each disputed item, specifying the amount thereof in dispute and setting forth, in reasonable detail, the basis for such dispute, within [\*\*\*] of Distributor's delivery of the Quarterly Report or Accrual Rollforward Report, as applicable. In the event of such a dispute, Manufacturer and Distributor shall attempt to reconcile their differences. If Manufacturer and Distributor are unable to resolve any such dispute within [\*\*\*].

### **3.6 Taxes and Withholding; Brand Fee.**

(a) Except as set forth in Section 3.6(b), Distributor shall make all payments to Manufacturer under this Agreement without any deduction or withholding for, or on account of, any tax.

(b) This Section sets forth the understanding and intentions of Manufacturer and Distributor relating to the treatment of the Brand Fee, if any. [\*\*\*]. The Parties further acknowledge that the reimbursed portion of the Brand Fee, if any, will be accounted for consistent with the "cost reimbursement doctrine," generally recognized by the courts and the Internal Revenue Service, under which expenditures subject to a right to reimbursement at the time incurred are reported net of the reimbursement. In furtherance of the intent of the parties, Manufacturer and Distributor agree to and acknowledge the following:

[\*\*\*].

**3.7 Payments.** All amounts hereunder, including, without limitation, the Invoice Supply Price and the Remaining Supply Price to Manufacturer hereunder shall be (i) expressed and paid in U.S. dollars, and (ii) made by wire transfer to the credit of such bank account as shall be designated in advance by Manufacturer through written instructions signed by the Manufacturer.

**3.8 Maintenance of Records; Audit.** Each Party shall maintain, and shall direct its Affiliates to maintain, complete, and accurate books and records in connection with, as applicable, its Manufacture, purchase, handling, Marketing, sale, distribution, return, and destruction of all Product hereunder, as necessary to allow the accurate calculation consistent with GAAP of the amounts due from Distributor to Manufacturer (including the Manufacturing Cost, Invoice Supply Price, Remaining Supply Price and all items used in the calculation thereof), the reporting obligations set forth herein, and compliance with the terms of this Agreement. Each Party shall maintain such books and records for a period of at least [\*\*\*] after the end of the calendar year in which they were generated, or for such longer period as may be required by law, rule, or regulation. [\*\*\*] per calendar year and with respect to any additional audit as provided in Sections 3.5(d) and 5.2(d), each Party shall have the right upon reasonable

notice and at a time mutually agreed by the Parties, [\*\*\*], to engage an independent accounting firm [\*\*\*] to examine in confidence the relevant books and records of the other Party as may be reasonably necessary to determine or verify, as applicable, the amounts due from Distributor to Manufacturer (including the Manufacturing Cost, Invoice Supply Price, Remaining Supply Price and all items used in the calculation thereof, including any Failure to Supply Charges under Section 5.2(c)), the financial reporting obligations of the other Party contemplated herein, and compliance by the other Party with its financial obligations hereunder. The Party whose books and records are being examined shall make such books and records available, during normal business hours at the facility(ies) where such books and records are maintained. Each such examination shall be limited to pertinent books and records for any year ending not more than [\*\*\*] before the date of request, provided that neither Party shall be permitted to audit the same period of time more than once. Before permitting such independent accounting firm to have access to such books and records, the Party being examined may require such independent accounting firm and its personnel involved in such audit to sign a confidentiality agreement [\*\*\*] as to any Confidential Information which is to be provided to such accounting firm or to which such accounting firm will have access while conducting the audit under this Section. The independent accounting firm will prepare and provide to each Party a written report stating whether the reports submitted by the Parties, as applicable, and amounts paid are correct or incorrect and the amounts of any discrepancies. In the event either Party's auditors believe there is a discrepancy in the calculation of the amounts due from Distributor to Manufacturer (including the Manufacturing Cost, Invoice Supply Price, Remaining Supply Price and all items used in the calculation thereof, including any Failure to Supply Charges under Section 5.2(c)), that Party's auditors shall be entitled to take copies or extracts from such records, books of account, information and data during any review or audit. [\*\*\*]. If there was an underpayment by Distributor hereunder, unless disputed by Distributor in accordance with Section 12.15, Distributor shall promptly (but in no event later than [\*\*\*] after its receipt of the independent auditor's report so concluding) make payment to Manufacturer of any shortfall by wire transfer in U.S. dollars. If there was an overpayment by Distributor hereunder, unless disputed by Manufacturer in accordance with Section 12.15, Manufacturer shall promptly (but in no event later than [\*\*\*] after Manufacturer's receipt of the independent auditor's report so concluding) refund to Distributor the excess amount by wire transfer in U.S. dollars. In the event of any underpayment by Distributor or over charge of the Invoice Supply Price by Manufacturer resulting in a cumulative discrepancy during any calendar year in excess of the greater of [\*\*\*].

**3.9 Interest on Late Payments.** If any undisputed payment under this Agreement is late, interest shall accrue on the past due amount at a rate equal to the lesser of (a) [\*\*\*], and (b) the maximum rate permitted by law.

## **ARTICLE 4 REGULATORY; COOPERATION**

### **4.1 Regulatory Filings; Communications with a Regulatory Agency.**

(a) Manufacturer will have control over, and authority and responsibility for, monitoring and coordinating all maintenance of, regulatory actions with respect to, and communications and filings with and submissions to, FDA or any regulatory agency with respect to Makena and the Manufacturing, supply, distribution and sale of the Product under this Agreement

(b) Manufacturer will have control over, and authority and responsibility for, monitoring, coordinating, and making all filings with FDA required for Product Listing for the Product, as well as reporting of Adverse Drug Experiences and Adverse Events. Manufacturer shall use Commercially Reasonable Efforts to make such filings with applicable regulatory agencies as necessary for Manufacturer to carry out its obligations under this Agreement. In the case of the Product Listing, Distributor shall reasonably assist Manufacturer in preparing the required form for filing by Manufacturer. Manufacturer represents and warrants to Distributor that it will timely file with FDA a Product Listing form showing Distributor as the distributor of the Product.

(c) Distributor shall be solely responsible for communications and filings with and submissions to any regulatory agency or other federal, state or local governmental authority concerning Product sales, prices, discounts, rebates, fees, charge-backs, and other payments associated with Distributor's Marketing, distribution and sale of Product under this Agreement, including, without limitation, all reporting, and disclosure obligations under the Medicaid Drug Rebate Program (e.g., Monthly and Quarterly Average Manufacturer Price, Baseline Average Manufacturer Price, and Rebate Per Unit), Medicare Part B (Quarterly Average Sales Price), the Veteran's HealthCare Act 602 (Public Health Service 340B Quarterly Ceiling Price), the Veteran's HealthCare Act 603 (Quarterly and Annual Non-Federal Average Manufacturer Price and Federal Ceiling Price), Best Price, Federal Supply Schedule Contract Prices and Tricare Retail Pharmacy Refunds and Medicare Part D. Distributor shall also cooperate fully with Manufacturer and shall supply all data and information reasonably requested by Manufacturer within [\*\*\*] (or such other amount of time as mutually agreed or proscribed by such federal, state or local governmental authority or governmental requirement) to enable Manufacturer to comply with any applicable federal, state or local reporting and disclosure requirements concerning Manufacturer's supply of Product to Distributor under this Agreement.

(d) Concurrent with the execution and delivery of this Agreement, Manufacturer shall provide to Distributor information regarding the [\*\*\*] for the first full quarter following launch of the Branded Product (and the date of such first full quarter), which may be used by Distributor solely in connection with Distributor's government reporting obligations relating to the Product. In addition, upon request by Distributor, Manufacturer shall provide any other information reasonably requested by Distributor to enable Distributor to comply with any

Applicable Laws concerning Distributor's marketing and distribution of the Product in accordance with this Agreement.

**4.2 Distributor's Communications with FDA or a Governmental Agency.** If Distributor reasonably concludes that it is necessary or advisable for Distributor to communicate with FDA or a regulatory agency regarding Distributor's activities under this Agreement, then before such communication Distributor shall (to the extent practicable) so advise Manufacturer and, if applicable, provide Manufacturer with copies of all proposed correspondence between Distributor and the applicable entity. Distributor shall provide Manufacturer with copies of all correspondence, documents and materials received from or provided to FDA or a regulatory agency concerning the Product or any activities under this Agreement at least [\*\*\*] after receipt or before the submission of such correspondence, documents, or materials (unless a shorter period is required in the reasonable discretion of Distributor due to applicable law or a requirement of FDA or a regulatory agency). Manufacturer shall promptly respond to Distributor regarding any such proposed correspondence or communications; provided that, in the event Distributor has used Commercially Reasonable Efforts to confirm Manufacturer's receipt of such correspondence and Manufacturer does not respond within [\*\*\*] of receipt of such correspondence, Manufacturer shall be deemed to have approved such correspondence or communications in the form presented to Manufacturer. Distributor shall consult with Manufacturer and adopt all reasonable suggestions and recommendations of Manufacturer concerning any meeting or written or oral communication with FDA or a regulatory agency.

**4.3 Cooperation.** Each Party shall provide the other with all reasonable assistance and take all actions reasonably needed to enable such other Party to comply with any law, rule or regulation applicable to such other Party's activities under this Agreement. Except as otherwise provided in Article 7, such assistance and actions shall include, without limitation, informing the other Party within [\*\*\*] of receiving any information that:

- (a) raises any material concerns regarding the safety or efficacy of any Product;
- (b) is reasonably likely to lead to a recall or market withdrawal of or other corrective action with respect to the Product in the Territory; or
- (c) concerns any investigation, inspection, detention, seizure or injunction involving any Product by any governmental entity or regulatory agency in the Territory.

Manufacturer and Distributor shall, in each such case, adhere to the executed Quality Agreement requirements to jointly determine whether subsequent notification to any government entity or regulatory agency is required, and [\*\*\*]. Notwithstanding anything in this Agreement to the contrary, Manufacturer shall not be obligated to supply Distributor with the Products until the Quality Agreement is executed by the Parties. [\*\*\*]. Furthermore, each Party shall inform the other Party within [\*\*\*] and provide such other Party with all reasonable assistance after receiving any information that indicates or suggests a potential material liability for either Party to Third Parties arising from or in connection with the Product.

## ARTICLE 5 SUPPLY, ORDERING, AND FORECASTS

### 5.1 Forecasts; Purchase Orders; Launch Quantities.

(a) Within \*\*\* of the Effective Date (or such later date as the Parties may mutually agree) and within the first \*\*\* of each calendar month following the First Commercial Sale, Distributor shall provide to Manufacturer a non-binding (subject to Section 5.1(c)), good faith written estimate (each a “**Rolling Forecast**”) by month of Distributor’s reasonably anticipated quantity requirements for Product by SKU. Distributor’s first Rolling Forecast for each SKU of the Products shall cover the \*\*\* period starting with the calendar month following the month in which the First Commercial Sale shall occur for such SKU, and each subsequent Rolling Forecast shall cover the \*\*\* period starting with the calendar month following the month in which Distributor provides such Rolling Forecast to Manufacturer. For example, \*\*\*. Within \*\*\* of receipt of the Rolling Forecast, Manufacturer shall confirm to Distributor in writing Manufacturer’s acceptance of the Rolling Forecast. If within such \*\*\* period Manufacturer notifies Distributor of a problem with the Rolling Forecast, including a reasonable determination that (i) the quantities of Product in the Rolling Forecast, or any month(s) therein, exceeds the amount necessary for Distributor to meet demand for the Product, (ii) Manufacturer cannot supply the full quantities of Product in the Rolling Forecast, or (iii) if the Rolling Forecast does not comply with the requirements of Sections 5.1(d) or 5.1(f), the Parties shall cooperate in resolving such problems relating to the supply of Products under this Agreement.

(b) Within \*\*\* of the Effective Date, Distributor shall submit binding purchase orders to Manufacturer for the quantities of Product sufficient to meet demand during the \*\*\* of the first Rolling Forecast (the “**Launch Quantities**”). Manufacturer shall use Commercially Reasonable Efforts to deliver the quantities specified on Exhibit 5.1(b) hereto (which will be the quantities specified in the first month of the Rolling Forecast) as Bailment Product (the “**Initial Launch Quantities**”) on or before the Commencement Date. In the event that the launch scenario is different from the assumptions identified on Exhibit 5.1(b) (e.g., fewer competitors launch a Competing Product) as of the Commencement Date, the Parties shall discuss in good faith revisions to the Initial Launch Quantities and/or Rolling Forecast in light of such circumstances.

(c) Accompanying each Rolling Forecast, Distributor shall place monthly purchase orders (each a “**Firm Order**”) for Product for \*\*\* period of each Rolling Forecast being the “**Firm Order Period**”) by written or electronic purchase order to Manufacturer (or by any other means agreed to by the Parties). Each purchase order shall specify the quantity and type of each Product to be delivered and the desired delivery dates in the applicable month (the “**Firm Order Quantity**”). The purchase orders submitted by Distributor, or required to be submitted by Distributor hereunder, shall represent a binding obligation upon Distributor and may not be cancelled or adjusted in any manner except by written consent of Manufacturer. Manufacturer shall acknowledge Distributor’s purchase order(s) within \*\*\* of Manufacturer’s receipt of the purchase order(s). Within \*\*\* of receipt of the purchase order for the Firm Order

Period, Manufacturer shall confirm to Distributor in writing Manufacturer's acceptance of the Firm Order Quantity or its modification of the Firm Order Quantity pursuant to the following provisions. If the Firm Order does not comply with the order limitations in Section 5.1(d), Manufacturer may modify, [\*\*\*], the quantity of Product to be supplied to Distributor (a "**Modified Firm Order Quantity**") and shall provide notification of such to Distributor. Upon acceptance by Manufacturer, an accepted Firm Order Quantity or Modified Firm Order Quantity is binding upon Manufacturer such that Manufacturer shall use Commercially Reasonable Efforts to timely deliver to Distributor such quantity of Product.

(d) The Rolling Forecasts and purchase orders for Firm Order Periods shall comply with the increments and minimum order quantities for the Products set forth on Exhibit 5.1(d) hereto, which may be amended by written notice from Manufacturer from time to time. [\*\*\*].

(e) Distributor shall be required to purchase at a minimum [\*\*\*], except that if (i) (A) the Commencement Date does not occur within six (6) months of the Effective Date, (B) [\*\*\*], or (C) [\*\*\*], and, in any such case, Distributor reasonably determines that such circumstances have reduced the potential market share of the Product and that as a result Distributor's Rolling Forecast for Launch Quantities are likely to exceed the demand of Distributor's customers for such Launch Quantities or (ii) there is a Supply Interruption and Distributor reasonably determines that the failure has reduced or is reasonably likely to reduce the demand of Distributor's customers for the Product, then in each case, Distributor may by written notice to Manufacturer, as promptly as practical and, in any event, within [\*\*\*] after Distributor's determination under clause (i) or Manufacturer's failure and Distributor's reasonable determination under clause (ii), reduce Distributor's binding commitments under purchase orders then in effect to reflect such actual or expected reduction in demand, and Distributor may also reduce future Rolling Forecasts to reflect such actual or expected reduction in demand.

(f) Manufacturer shall not be required to accept any Rolling Forecast for Products in which (i) there is any change to any month in the Firm Order Period, (ii) there is a change (increasing or decreasing) of more than [\*\*\*] in any month for the [\*\*\*], in each case in quantity of units of Products contained in the immediately preceding Rolling Forecast. [\*\*\*].

(g) Manufacturer shall use its [\*\*\*].

(h) [\*\*\*].

## 5.2 Delivery; Delays; Supply Interruption.

(a) Any shipment delivered that is within plus or minus [\*\*\*] of the quantity ordered will be considered as meeting such order quantity, and any shipment delivered on a date within [\*\*\*] of the delivery date specified on the purchase order will be considered as delivered on time. In the event any delivery is less than [\*\*\*] of an [\*\*\*], as applicable, Manufacturer shall be deemed as meeting such order quantity if, as of the delivery date specified in the purchase order, Distributor has sufficient inventory of the Product to cover the shortfall (measured by the



difference between the actual delivery amount and [\*\*\*] of an accepted Firm Order Quantity or Modified Firm Order Quantity, as applicable) in the quantity delivered.

(b) In the event that any Product supply will be delayed, in whole or in part, more than [\*\*\*], Manufacturer will notify Distributor of such late supply as soon as possible and promptly thereafter agree with Distributor, such agreement not to be unreasonably withheld, on a later date for supply that is intended to accommodate the delay, taking into consideration Manufacturing and product availability constraints outside of Manufacturer's reasonable control. In no event shall a delivery delay alter Manufacturer's obligation to supply the amount of Product subject to a purchase order issued by Distributor and accepted by Manufacturer for the Firm Order Period.

(c) In the event that Manufacturer fails (except due to a Force Majeure Event) with respect to either (i) [\*\*\*] to deliver at least [\*\*\*] of each of the Firm Order Quantities or Modified Firm Order Quantities for such periods [\*\*\*] within [\*\*\*] of the applicable delivery date, or (ii) with respect to [\*\*\*] to deliver at least [\*\*\*] of the Firm Order Quantity or Modified Firm Order Quantity for such period within [\*\*\*] of the delivery date (either being a "**Supply Interruption**"), and as a direct result of such Supply Interruption Distributor incurs any Failure to Supply Charges, [\*\*\*]. A Supply Interruption shall be deemed resolved when Manufacturer has either filled all delinquent purchase orders from Distributor or delivered enough Product to enable Distributor to supply all unfilled customer orders and satisfy Distributor's minimum Safety Stock requirements.

During the Term and subject to the performance by Manufacturer of its obligations to supply the Product, Distributor shall use [\*\*\*] to maintain no less than [\*\*\*] safety stock inventory, which safety stock level shall be measured as the forecasted daily inventory level at the time of the Supply Interruption. During a Supply Interruption and during any period before a Supply Interruption is anticipated to occur, Distributor shall [\*\*\*]. In addition, and notwithstanding anything in this Agreement to the contrary, to the extent that Distributor fails to [\*\*\*]. Failure to Supply Charges subject to reimbursement under this Section [\*\*\*].

(d) Distributor shall provide to Manufacturer a report calculating any Failure to Supply Charges, which shall include [\*\*\*] before [\*\*\*]. Manufacturer may dispute any amounts reflected on a Failure to Supply Charges report, but only on the basis that the amounts were not correctly calculated. Manufacturer shall notify Distributor in writing of each disputed item, specifying the amount thereof in dispute and setting forth, in reasonable detail, the basis for such dispute, within [\*\*\*] of receipt of the documentation specified in this Section 5.2(d). In the event of such a dispute, Manufacturer and Distributor shall attempt to reconcile their differences. If Manufacturer and Distributor are unable to resolve any such dispute within [\*\*\*] after Manufacturer's delivery of its notice of dispute to Distributor, [\*\*\*].

## ARTICLE 6 DELIVERY TERMS

### 6.1 Delivery Terms; Title Passage.

(a) Except with respect to Bailment Product, (i) Manufacturer shall deliver all quantities of Products to Distributor [\*\*\*] Manufacturer's or its subcontractor's manufacturing facility, warehouse or such other facility mutually agreed to by the Parties, (ii) [\*\*\*], and (iii) Distributor shall be responsible for all freight, insurance, handling, fees, taxes and other costs associated with the shipment of Products, as well as all export licenses, import licenses and customs formalities for the import and export of goods.

(b) From time to time prior to the Commencement Date for each SKU, Manufacturer may ship Distributor quantities of such SKU under bailment (the "**Bailment Product**") on the terms of the Bailment Agreement between the Parties dated as of the date of this Agreement (the "**Bailment Agreement**"). The Bailment Agreement shall govern the terms of shipment, freight and insurance costs, title, and risk of loss of Products shipped to Distributor's warehouse pursuant to the Bailment Agreement. [\*\*\*].

**6.2 Packaging & Labeling.** All Product supplied to Distributor hereunder shall be in finished packaged form which complies with AMAG's NDA and all applicable law, including future requirements of the Drug Supply Chain Security Act at the time of delivery of Products to Distributor. Manufacturer shall, [\*\*\*] produce all Packaging and Labeling materials to be used for the Product (including print-ready artwork with Distributor's NDC#). Upon completion of the design for the Packaging and Labeling, Manufacturer shall provide Distributor with a sample for Distributor's approval. Any changes to the Packaging and Labeling specifications requested by Distributor shall require the prior written consent of Manufacturer, which shall not be unreasonably withheld, conditioned or delayed. If Manufacturer consents to such changes, [\*\*\*]. Distributor shall clearly identify that the Product is manufactured for Manufacturer on all packaging materials unless otherwise requested by Manufacturer.

**6.3 Shipping Documentation.** Each delivery of Product shall be accompanied by a packing slip that describes the Product and shows Distributor's purchase order number for the Product being delivered. Manufacturer shall supply with each delivery all documentation required by the Quality Agreement including, but not limited to, a certificate of compliance for each lot of the Product included in the delivery.

**6.4 Governing Terms.** To the extent there is any conflict or inconsistency between this Agreement, the Bailment Agreement and any purchase order, purchase order release or any similar business document, the terms of this Agreement shall govern and control. Any other document which shall conflict with or be in addition to the terms and conditions of this Agreement is hereby rejected (unless the Parties shall have mutually agreed to the contrary in writing in respect of a particular instance). Notwithstanding the foregoing, in the event of any conflicts between this Agreement and the Quality Agreement regarding quality-related activities, the Quality Agreement shall govern and control.

**6.5 Marketing Costs.** Except as expressly set forth in this Agreement, [\*\*\*] shall be solely responsible for all costs and expenses related to the Marketing, sale and distribution of Product in the Territory.

**6.6 Acceptance and Rejection and Product Defects.**

(a) **Defective Product Claims Generally.** Delivery of any Product by Manufacturer to Distributor shall constitute a certification by Manufacturer that such Product conforms to the representations and warranties made by Manufacturer in this Agreement. Distributor shall (i) have [\*\*\*] after receipt of each delivery of Product to determine if such Product conforms to such warranties and to accept or reject any of such Product that fails to conform to such warranties, (ii) submit any claims for failure to conform (“**Product Claims**”) in writing to Manufacturer within such [\*\*\*] period describing in reasonable detail the nonconforming characteristics of the Product, and (iii) be deemed to have accepted any Product if it fails to submit a Product Claim during such [\*\*\*] period.

(b) **Disputed Defective Product Claims.** If Distributor submits a Product Claim and Manufacturer notifies Distributor in writing that Manufacturer does not agree with the Product Claim within [\*\*\*] after it receives the Product Claim, the Parties shall submit the Product in question to a [\*\*\*] independent Third Party that has the capability of testing the Product to determine whether the Product complies with the warranties in Section 6.7(a), which independent Third Party will make such determination within [\*\*\*] after submission of the Product thereto by the Parties. The determination of such independent party shall be binding on the Parties. [\*\*\*].

(c) **Remedies for Defective Products.** If Manufacturer agrees with the Product Claim, then Manufacturer shall (a) instruct Distributor whether to return or destroy the Product in question, and (b) at Manufacturer’s option either (i) credit Distributor the Supply Price for the Product in question as promptly as possible (but in any event within [\*\*\*]), or (ii) provide Distributor with replacement Product as promptly as possible using Commercially Reasonable Efforts as agreed by the Parties, but in any event within [\*\*\*] after Distributor submitted its Product Claim to Manufacturer pursuant to Section 6.6(a) or (y) in the event Manufacturer disputes a Product Claim, [\*\*\*] after the Parties resolved such dispute pursuant to Section 6.6(b). [\*\*\*].

**6.7 Product Warranty.**

(a) **Warranty Generally; Minimum Dating.** Manufacturer warrants that (x) upon delivery to Distributor’s warehouse under the Bailment Agreement of all Bailment Product supplied to Distributor pursuant to the Bailment Agreement, and (y) upon delivery at the shipping point of all other Products supplied to Distributor in accordance with Section 6.1(a), upon delivery by Manufacturer, all Product Manufactured and/or supplied to Distributor (i) shall comply with the Specifications, this Agreement and the Quality Agreement, (ii) shall have been manufactured in compliance with all applicable laws, rules and regulations, including without limitation, cGMP requirements, (iii) shall not be adulterated or misbranded within the meaning of the Act, and (iv) may be introduced into interstate commerce pursuant to the Act. All Product

Manufactured and/or supplied by Manufacturer shall, upon receipt by Distributor or its designee, have dating of not less than [\*\*\*] of shelf-life for such Product, except that Bailment Product and Initial Launch Quantities shall have dating of not less than [\*\*\*] prior to expiration as of the date title to such Bailment Product transfers to Distributor under the Bailment Agreement. Supply of any Product having shorter dating shall be subject to the written consent of Distributor, which shall not be unreasonably withheld.

(b) Warranty Exceptions. Warranty claims shall not apply to damaged or non-conforming Product to the extent such damage or non-conformity is caused by Distributor's negligence, handling or storage that is not in accordance with the Specifications, cGMP or FDA approved Product Labeling, or failure to comply with its obligations under Section 2.3.

6.8 [\*\*\*].

## ARTICLE 7 PHARMACOVIGILANCE; RECALLS

7.1 Pharmacovigilance. Manufacturer shall be solely responsible for maintaining the safety database for Products and for the pharmacovigilance surveillance and timely reporting of all relevant adverse drug reactions and experiences, Product quality, Product complaints and safety data relating to the Compound, Products, and Makena to the appropriate regulatory authorities in the Territory. Distributor shall cooperate with Manufacturer in fulfilling those responsibilities in accordance with the terms of the Pharmacovigilance Agreement. Notwithstanding anything in this Agreement to the contrary, Distributor shall not be permitted to Market the Products until the Pharmacovigilance Agreement is executed by the Parties. Except as required by applicable laws, rules, or regulations, Distributor shall not disclose any information concerning any adverse drug reactions or experiences or any complaint concerning any Product to any Third Party without the prior written consent of Manufacturer.

### 7.2 Recalls.

(a) FDA Required Recall. If a recall of any Product sold by or on behalf of Distributor is required or recommended by FDA, or if a recall, suspension or other withdrawal of any Product sold by or on behalf of Distributor is deemed advisable by Manufacturer, such recall, suspension or withdrawal shall be implemented and administered by the Parties in a manner that is appropriate and reasonable under the circumstances and in conformity with accepted trade practices and any requests, recommendations, or orders of FDA. Each Party shall cooperate with the other Party to effectuate such recall, suspension or other withdrawal as specified in the Quality Agreement and all field alerts shall be the responsibility of Manufacturer. As soon as reasonably practicable, but in no event more than [\*\*\*] after the decision to implement a recall, Distributor shall provide Manufacturer all information in Distributor's possession or control reasonably necessary for Manufacturer to comply with FDA reporting requirements.

[\*\*\*] INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

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

(c) Recall Costs and Expenses. [\*\*\*] shall pay all Recall Costs and Expenses in connection with a recall, suspension or withdrawal under this Section 7.2, except that [\*\*\*] shall bear such Recall Costs and Expenses to the extent such recall, suspension, or withdrawal is implemented as a result of [\*\*\*] negligence or breach of its obligations under this Agreement. As used in this Section 7.2, the term “**Recall Costs and Expenses**” means only: [\*\*\*].

(d) Distributor shall establish a track and trace and recall system which will enable Distributor to trace the Products to the first consignee and, to the extent reasonably possible, to identify, as quickly as possible, customers within the Territory who have been supplied with Products, and to recall such Products from such customers.

(e) Cooperation. Each Party shall cooperate with the other Party to effectuate any such recall or other withdrawal as specified in the Quality Agreement.

**7.3 Information**. As soon as reasonably practicable, but in no event more than [\*\*\*] after Manufacturer’s written request, Distributor shall provide Manufacturer all information in Distributor’s possession or control reasonably necessary for Manufacturer to comply with FDA reporting requirements. This Section shall not apply to Adverse Drug Experiences or Safety Information which shall be governed by Section 7.1.

## **ARTICLE 8 REPRESENTATIONS AND WARRANTIES**

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

(a) it is an entity duly organized, validly existing and in good standing under the laws of the state or country of its incorporation and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;

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

(c) the entering into of this Agreement by Manufacturer shall not (i) violate any provision of law, statute, rule or regulation or any ruling, writ, injunction, order, judgment or decree of any court, administrative agency or other governmental body to which Manufacturer is

subject, or (ii) conflict with or result in any breach of any of the terms, conditions or provisions of, any agreement to which Manufacturer or any of its Affiliates is a party or by which it or its Affiliates or any of its or their properties or assets is bound or affected;

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

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

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

(g) the facilities where the Product is Manufactured conforms, and shall continue to conform throughout the Term, in all respects to applicable laws governing such facilities;

(h) it will timely file the Label for the Product as a supplement to AMAG's NDA; and

(i) it will maintain a stability testing program in full compliance with AMAG's NDA.

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

(a) it is a limited liability company duly organized, validly existing and in good standing under the laws of the state or country of its formation and has full limited liability company power and authority to enter into this Agreement and to carry out the provisions hereof;

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

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

**8.3 Debarment and Exclusion.** Each Party represents and warrants that neither it, nor any of its employees or agents performing hereunder, have ever been, are currently, or are the subject of a proceeding that could lead to it or such employees or agents becoming, as applicable, a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual or a Convicted Entity or Convicted Individual. Each Party further covenants, represents and warrants that if, during the term of this Agreement, it, or any of its employees or agents performing

hereunder, become or are the subject of a proceeding that could lead to a Person becoming, as applicable, a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual or a Convicted Entity or Convicted Individual, the Party in question shall promptly notify the other Party, and the Parties will promptly discuss necessary measures to avoid such a circumstance from affecting a Party's performance hereunder. For purposes of this provision, the following definitions shall apply:

A "Debarred Individual" is an individual who has been debarred by FDA pursuant to 21 U.S.C. §335a (a) or (b) from providing services in any capacity to a Person that has an approved or pending drug or injectable product application.

A "Debarred Entity" is a corporation, partnership or association that has been debarred by FDA pursuant to 21 U.S.C. §335a (a) or (b) from submitting or assisting in the submission of any abbreviated drug application, or a subsidiary or affiliate of a Debarred Entity.

An "Excluded Individual" or "Excluded Entity" is (i) an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal health care programs such as Medicare or Medicaid by the Office of the Inspector General (OIG/HHS) of the U.S. Department of Health and Human Services, or (ii) is an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal procurement and non-procurement programs, including those produced by the U.S. General Services Administration (GSA).

A "Convicted Individual" or "Convicted Entity" is an individual or entity, as applicable, who has been convicted of a criminal offense that falls within the ambit of 21 U.S.C. §335a (a) or 42 U.S.C. §1320a - 7(a), but has not yet been excluded, debarred, suspended or otherwise declared ineligible.

#### **8.4 Disclaimer of Warranties.**

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

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

#### **8.5 Limitations of Liabilities.**

(a) EXCEPT AND ONLY TO THE EXTENT OF \*\*\*, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY LOST PROFITS (INCLUDING, WITHOUT LIMITATION, DISTRIBUTOR'S LOST PROFITS FROM THE

RESALE OF PRODUCT) SPECIAL, INDIRECT, PUNITIVE, OR CONSEQUENTIAL DAMAGES OF ANY KIND (INCLUDING, WITHOUT LIMITATION, LOST PROFITS, BUSINESS, OR GOODWILL) IN CONNECTION WITH THIS AGREEMENT.

(b) The limitation of liability set forth in this Section 8.5 reflects a deliberate and bargained for allocation of risks between Distributor and Manufacturer and is intended to be independent of any exclusive remedies available under this Agreement, including any failure of such remedies to achieve their essential purpose.

(c) The Parties acknowledge that the limitations of liability set forth in this Section 8.5 are an essential element of this Agreement between the Parties and that the Parties would not have entered into this Agreement without such limitations of liability.

## ARTICLE 9 INDEMNIFICATION

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

(a) Manufacturer's Indemnification Obligations. Manufacturer shall defend, indemnify and hold harmless each of Distributor and its Affiliates and its and their directors, officers, employees and contractors ("**Distributor Party**") from and against any and all Losses arising from, relating to or in connection with (i) any Third Party claim, lawsuit, investigation, proceeding, regulatory action, or other cause of action ("**Claim**") resulting from any breach of this Agreement, negligent acts or negligent omissions to act, or willful misconduct of any AMAG Party in connection with the performance of its obligations under this Agreement; (ii) except to the extent subject to indemnification by Distributor pursuant to Section 9.1(b)(iii), any Claim for personal injury or property damage based on or arising out of the use, Manufacturing or Marketing of Makena or the use or Manufacturing of the Product; (iii) Manufacturer's failure to Manufacture, store or release Product for shipment in accordance with applicable laws, regulations, AMAG's NDA or this Agreement; (iv) the breach by Manufacturer of any of its representations or warranties contained in this Agreement; (v) any claim that the Product Label (including the information in the Makena Label, but excluding the Distributor's Label information) contains any false or misleading statements or representations or omits information necessary to adequately warn consumers of the risks inherent in the Product; (vi) any governmental investigation or proceeding (administrative or otherwise) or Third Party claim relating to a potential or actual settlement agreement between Manufacturer and a Third Party that plans to market or is marketing a Generic Equivalent Product; or (vii) any misuse by a AMAG Party of Distributor's company name or logo or other trademark; except, in each case, to the extent that the Losses are caused by the negligence, breach of the terms of this Agreement, or willful misconduct of a Distributor Party. Failure to Supply Charges shall not be subject to indemnification by Manufacturer under this Article 9.



(b) Distributor's Indemnification Obligations. Distributor shall defend, indemnify and hold harmless each of Manufacturer and its Affiliates and its and their directors, officers, employees and contractors (“**AMAG Party**”) from and against any Losses arising from or in connection with: (i) any Claim resulting from any breach of this Agreement, negligent acts or negligent omissions to act, or willful misconduct of any Distributor Party in connection with the performance of its obligations under this Agreement; (ii) any Claim for personal injury or property damage based on or arising out of the Marketing of the Product by Manufacturer or the failure of Distributor to store or ship Product in accordance with applicable laws, regulations or this Agreement, to the extent that such liability is a result of the acts or failure to act of Distributor, its Affiliates, or its employees, agents, partners or contractors; (iii) the breach by Distributor of any of its representations or warranties contained in this Agreement; or (iv) any misuse by the Distributor Parties of Manufacturer's company name or logo or other trademark; except, in each case, to the extent that the Losses are caused by the negligence, breach of the terms of this Agreement, or willful misconduct of a AMAG Party.

**9.2** Procedures. As soon as a Party becomes aware of the possibility of a claim involving indemnification hereunder, the indemnified Party shall give the indemnifying Party prompt written notice in writing and shall permit the indemnifying Party to have control over the defense of such claim or suit. The indemnified Party agrees to provide all reasonable information and assistance to the indemnifying Party in such defense. No such claims shall be settled other than by the Party defending the same, and then only with the consent of the other Party, which shall not be unreasonably withheld or delayed; provided, however, that the indemnified Party shall have no obligation to consent to any settlement of any such claim which imposes on the indemnified Party any liability or obligation which cannot be assumed and performed in full by the indemnifying Party. In the event that a claim for indemnification is brought or made against both Parties, then each Party will have the right to be represented by counsel at its own expense.

## **ARTICLE 10 TERM AND TERMINATION**

**10.1** Term. This Agreement shall commence as of the Effective Date and shall continue for a period of four (4) years after the Commencement Date, unless terminated earlier as provided below (the “**Initial Term**”). This Agreement will automatically renew for additional one (1) year terms (together with the Initial Term, the “**Term**”) unless either Party elects not to renew this Agreement by written notice to the other Party, which notice must be provided at least nine (9) months prior to the expiration of the Term.

### **10.2** Termination of Agreement by Manufacturer.

(a) Prior to Commencement Date. Manufacturer may terminate this Agreement at any time prior to the Commencement Date for any reason upon written notice to Distributor; [\*\*\*].

(b) Convenience. After the [\*\*\*] period following the First Commercial Sale of the Product, Manufacturer may terminate this Agreement at any time for any reason upon [\*\*\*] written notice to Distributor.

(c) Distributor Change in Control. If Distributor becomes subject to any Change in Control, Distributor shall so notify Manufacturer, in writing, within thirty (30) days. Manufacturer may terminate this Agreement upon [\*\*\*] written notice to Distributor after a Change in Control of Distributor, which notice of termination must be given no later than (i) [\*\*\*] after Distributor gives Manufacturer written notice of the Change in Control, or (ii) if notice is not provided by Distributor, at any time within [\*\*\*] following Manufacturer becoming aware of such Change in Control.

**10.3 Termination by Non-Defaulting Party upon Event of Default**. Upon the occurrence of an Event of Default, in addition to all rights and remedies provided by applicable law, the non-defaulting Party in its sole discretion may terminate this Agreement upon [\*\*\*] prior written notice to the defaulting Party. For purposes of this Section 10.3, the occurrence of any one or more of the following acts, events or occurrences shall constitute an “**Event of Default**” under this Agreement: (a) [\*\*\*]; or (b) either Party fails to cure any material breach of its obligations under this Agreement, within [\*\*\*] after written notice of the breach from the other Party, provided that all financial obligations hereunder shall be deemed material for purposes of this Section 10.5.

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

**10.5 Termination Upon FDA Notice**.

(a) Either Party may terminate this Agreement by written notice to the other Party if FDA has notified either Party in writing (an “**FDA Notice**”) that Distributor’s Marketing, distributing, offering to sell, or selling the Product which meets the Specifications would constitute a violation of the Act or applicable regulations thereunder. In the event a Party seeks to trigger this termination right, the terminating Party shall provide the other Party [\*\*\*] written notice of its intention to terminate this Agreement. Upon receipt of the FDA Notice, Distributor shall cease Marketing, promoting and selling the Product, and the Parties shall work together in good faith to overcome the basis of the FDA Notice during such [\*\*\*] period. This Agreement shall automatically terminate at the end of such [\*\*\*] period unless the Parties mutually agree that issues raised in the FDA Notice have been resolved.

(b) Either Party may terminate this Agreement immediately upon written notice to the other Party, if there is a final administrative or judicial decision from which no appeal has been or can be taken (other than a petition to the United States Supreme Court for a writ of certiorari) finding that this Agreement violates applicable law; provided that, prior to termination, the Parties shall engage in good faith discussions to

revise the Agreement, if possible, to preserve the basic commercial terms of the Agreement and comply with applicable law .

**10.6 Force Majeure Events.** If either Party is prevented from performing any of its obligations hereunder, except for payment obligations, due to any cause which is beyond the non-performing Party's (the "**Non-performing Party**") reasonable control, including fire, explosion, flood or other acts of God; acts, regulations, or laws of any government; war (whether or not declared), civil commotion or terrorist act; strike or lock-out; or failure of public utilities (a "**Force Majeure Event**"), such Non-performing Party shall not be liable for breach of this Agreement with respect to such non-performance to the extent any such non-performance is due to a Force Majeure Event. Such non-performance will be excused to the extent affected by the Force Majeure Event and for as long as such event shall be continuing, provided that the Non-performing Party gives immediate written notice to the other Party (the "**Performing Party**") of the Force Majeure Event. Such Non-performing Party shall exercise all Commercially Reasonable Efforts to eliminate the Force Majeure Event and to resume performance of its affected obligations as soon as practicable, and the Parties shall use commercially reasonable efforts to mitigate any damages. Should the Force Majeure Event continue unabated for a period of [\*\*\*] or more, the Parties shall enter into good faith discussions with a view to alleviating its effects or to agreeing upon such alternative arrangements as may be fair and reasonable having regard to the circumstances prevailing at that time, and if such discussions do not result in a new or modified agreement within [\*\*\*] following commencement thereof, the Performing Party may terminate this Agreement upon written notice to the Non-performing Party.

**10.7 Termination Upon Lack of Commercial Viability.** If at any time during the term of this Agreement Distributor or Manufacturer reasonably determine that due to an event, change or circumstance outside of its reasonable control, the continued sale and distribution of the Product is no longer commercial viable [\*\*\*], then Distributor or Manufacturer may provide written notice (the "**Supply Notice**") to the other Party of such determination and, if applicable, a calculation of an [\*\*\*] necessary for the continued distribution and sale of the Product to remain commercially viable. Any such Supply Notice shall be accompanied with reasonable documentation supporting [\*\*\*] after the delivery of the Supply Notice, Distributor and Manufacturer fail to negotiate an adjustment to the Invoice Supply Price and other terms that would be necessary for the continued distribution and sale of the Product to remain commercially viable, which may include a retroactive price adjustment for inventory then held by Distributor, either Party shall have the right to terminate this Agreement upon [\*\*\*] prior written notice delivered within [\*\*\*] after such [\*\*\*] period.

**10.8 Purchase Orders; Sell-off.** Upon either Party giving notice of termination of this Agreement with such termination being effective prior to the expiration of the Term, any outstanding Firm Order shall be automatically cancelled, and Manufacturer shall have no further obligation to supply Product to Distributor, provided that, [\*\*\*], Distributor may, at its sole discretion, accept delivery of, and pay Manufacturer for, all of such already finished Product under the terms of this Agreement, and (iii) Distributor shall be authorized and permitted to sell any inventory of Product during the [\*\*\*] period immediately following the end of the Term

subject to its obligations to share profits with Manufacturer pursuant to this Agreement. If Distributor has not sold all such remaining inventory before the expiration of the sell-off period, Distributor shall, at Manufacturer's sole discretion and instruction, either return such excess inventory to Manufacturer, at its sole cost and expense and, except as otherwise provided in this Agreement, without payment therefor by Manufacturer, or destroy such excess inventory and provide to Manufacturer a certification, executed by one of its authorized officers, that such excess inventory has been destroyed.

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

**10.10 Obligations Following Expiration of this Agreement.**

(a) Purchase Orders; Sell-off. Provided that this Agreement has not been terminated by either Party pursuant to Sections 10.2-10.7, of this Agreement and provided the First Commercial Sale has occurred, (a) Manufacturer shall be obligated to supply Distributor with any Product that is the subject of a purchase order calling for delivery of the Product prior to the end of the Term and that has not been delivered as of the end of the Term, and (b) Distributor shall be permitted to sell any inventory of Product during the [\*\*\*] period immediately following the end of the Term subject to its obligations to share profits with Manufacturer pursuant to this Agreement. If Distributor has not sold all such remaining inventory before the expiration of the sell-off period, Distributor shall, at Manufacturer's sole discretion and instruction, either return such excess inventory to Manufacturer, at its sole cost and expense and without payment therefor by Manufacturer, or destroy such excess inventory and provide to Manufacturer a certification, executed by one of its authorized officers, that such excess inventory has been destroyed.

(b) Failure to Supply Charges. Except with respect to a termination of this Agreement by Distributor pursuant [\*\*\*].

**10.11 Effects of Termination.** Upon the expiration or termination of this Agreement, (a) this Agreement shall thereafter have no effect, except as provided in Section 12.2, (b) except as otherwise set forth herein, payment obligations that have accrued and have been invoiced before the date of expiration or termination shall remain due and payable in accordance with the terms of this Agreement, and payment obligations that have accrued but have not been invoiced as of the date of expiration or termination shall be invoiced and paid in full within [\*\*\*] of receipt of such invoice, (c) all rights granted by Manufacturer to Distributor shall immediately cease (except with respect to any applicable sell-off period under Sections 10.8 or 10.10(a)), and (d) except as otherwise set forth herein, neither Party shall be relieved from liability for any breach

of any representation, warranty or agreement hereunder occurring before such expiration or termination.

## **ARTICLE 11 CONFIDENTIALITY, PUBLIC ANNOUNCEMENTS AND DISCLOSURE**

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

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

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

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

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

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

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

(a) Prosecute or defend litigation;

(b) Effectively exercise its rights and obligations under this Agreement;

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

[\*\*\*] INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

(d) its Affiliates, and its and their employees, consultants, contractors and agents; or

(e) potential and actual investors, acquirors, licensees and other financial or commercial partners solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition or collaboration,.

In the event a Recipient shall deem it necessary to disclose, pursuant to this Section 11.2, Confidential Information of the Disclosing Party, the Recipient (i) shall in the case of disclosures pursuant to Sections 11.2(a)-(c), to the extent possible, give reasonable advance notice of such disclosure to the Disclosing Party, (ii) shall use reasonable efforts to minimize the scope of such disclosure, and (iii) shall cooperate with the Disclosing Party to take reasonable measures to ensure confidential treatment of such information, including, but not limited to, by ensuring that the Third Party to whom the Confidential Information is disclosed to is subject to obligations to maintain such information in confidence and to use it only for the purposes for which it is disclosed.

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

**11.4 Public Announcements.** Following the Commencement Date, either Party may issue a press release or make a public announcement or statement (including, without limitation, a presentation to investor meetings) concerning the existence or terms of this Agreement, and the disclosing Party shall (i) provide [\*\*\*] advance notice and text of such press release, public announcement or statement to the other Party, and (ii) obtain the written approval of the other Party, [\*\*\*] on the nature, text and timing of such press release, public announcement or statement. In addition, Manufacturer may issue a press release at any time without notice to, or consent of, Distributor. Either Party shall have the right to make any public announcement or other disclosure required by applicable law after such Party has provided to the other Party a copy of such announcement or disclosure [\*\*\*] in advance of making such announcement or disclosure and an opportunity to comment thereon (to the extent legally permitted). The disclosing Party shall reasonably consider the other Party's comments. Each Party agrees that it shall cooperate fully with the other with respect to all disclosures regarding this Agreement to the Securities Exchange Commission (in accordance with Section 11.3) and any other governmental or regulatory agencies, including requests for confidential treatment of proprietary information of either Party included in any such disclosure. Once any written statement is approved for disclosure by the Parties or information is otherwise made public in accordance with this Section 11.4 after the Commencement Date, either Party may make a subsequent public disclosure of the

same contents of such statement in the same context as such statement without further approval of the other Party. Notwithstanding anything to the contrary contained herein, in no event shall either Party disclose any financial information of the other, without the prior written consent of such other Party (to the extent legally permitted), unless such financial information already has been publicly disclosed by the Party owning the financial information or otherwise has been made part of the public domain by no breach of a Party of its obligations under this Section 11.4.

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

## **ARTICLE 12 MISCELLANEOUS**

**12.1 Insurance.** Each Party shall procure and maintain in full force and effect at its own expense during the term of this Agreement and, provided a First Commercial Sale has occurred, for a period of [\*\*\*] following the termination or expiration of this Agreement, a program of insurance which includes the minimum required insurance described in Exhibit 12.1. Such insurance shall be provided by an insurer with an [\*\*\*]. Each Party shall provide the other Party with a certificate of insurance evidencing such coverage upon request of the other Party. On such certificate of insurance, each Party shall cause the other Party to be listed as an "additional insured" as required by agreement. Such "additional insured" status shall be limited to instances where there is an indemnifiable claim pursuant to the terms of this Agreement or the Bailment Agreement. In the event of a claim for which there is an indemnification obligation, and for which the indemnified Party is deemed an "additional insured," the indemnifying Party's insurance shall be deemed primary and non-contributory with any insurance maintained by the indemnified Party.

**12.2 Survival.** The provisions of Sections 2.4-2.6, 3.4 - 3.9, 5.2(c) and (d), 6.7, 6.8, 8.4 and 8.5, and Articles 4, 7, 9, 10, 11 and 12 and those provisions of this Agreement dealing with rights and obligations after termination of this Agreement shall survive termination of this Agreement to the extent necessary to give effect to such provisions.

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

**12.4 Binding Effect; Benefits; Assignment.**

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

(b) Subject to Section 12.4(c) and Section 12.4(d), this Agreement shall not be assignable by either Party without the prior written consent of the other Party, except that a Party shall be permitted to assign this Agreement without the prior written consent of the other Party to a Person acquiring all or substantially all of such Party's assets or voting stock. Such assignment shall be subject to the assignee agreeing in writing to assume the benefits and obligations of this Agreement. A Party shall provide the other Party with prompt notice of any such sale, or other Change of Control of such Party promptly following consummation thereof.

(c) Manufacturer shall be entitled, without the prior written consent of Distributor, to assign all of its rights, duties, restrictions and obligations under this Agreement to an Affiliate; provided the Affiliate expressly assumes in writing those rights, duties, restrictions and obligations of Manufacturer under this Agreement and Manufacturer expressly agrees in writing to continue to be bound by the duties, restrictions and obligations of Manufacturer under this Agreement.

(d) Distributor may, with the prior written consent of Manufacturer, assign all of its rights, duties, restrictions and obligations under this Agreement to an Affiliate; provided the Affiliate expressly assumes in writing those rights, duties, restrictions and obligations of Distributor under this Agreement and Distributor expressly agrees in writing to continue to be bound by the duties, restrictions and obligations of Distributor under this Agreement.

(e) Any purported assignment of this Agreement in violation of the foregoing shall be null and void *ab initio* and of no force or effect.

**12.5 Entire Agreement; Amendments.** This Agreement, including all Exhibits, the Bailment Agreement, the Pharmacovigilance Agreement, and Quality Agreement constitute the entire agreement between the Parties with respect to the subject matter of this Agreement, and all prior agreements, understandings, promises and representations, whether written or oral, with respect thereto are superseded hereby. Each of the Parties acknowledges that in deciding to enter into this Agreement and to consummate the transaction contemplated hereby none of them has relied upon any statements or representations, written or oral, other than those explicitly set forth herein or therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties hereto unless reduced to writing and signed by the respective authorized officers of the Parties.

**12.6 Severability.** In the event that any one or more of the provisions (or any part thereof) contained in this Agreement or in any other instrument referred to herein, will, for any



reason, be held to be invalid, illegal or unenforceable in any respect, the remaining provisions of this Agreement will remain in full force and effect. If any of the terms or provisions of this Agreement are in conflict with any applicable statute or rule of law, then such terms or provisions will be deemed inoperative to the extent that they may conflict therewith and will be deemed to be modified to conform with such statute or rule of law. In the event that the terms and conditions of this Agreement are materially altered as a result of this Section 12.6, the Parties will renegotiate the terms and conditions of this Agreement to resolve any inequities.

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

**12.8 Notices.** Any notice, request, consent or communication (collectively, a “**Notice**”) under this Agreement shall be effective if it is in writing and (i) personally delivered, (ii) sent by certified or registered mail, postage prepaid, return receipt requested, (iii) sent by an internationally recognized overnight delivery service, with delivery confirmed, or (iv) sent by facsimile or electronic mail, with receipt confirmed and hard copy delivered by regular mail; addressed as set forth in this Section 12.8 or to such other address as shall be furnished by either Party hereto to the other Party hereto. A Notice shall be deemed to have been given as of (i) the date when personally delivered, (ii) [\*\*\*] after being deposited with the United States Postal Service, certified or registered mail, properly addressed, return receipt requested, postage prepaid, (iii) two Business Days after being delivered to said overnight delivery service properly addressed, or (iv) immediately upon receiving confirmation of receipt of the facsimile or electronic mail, as the case may be.

If to **Manufacturer:** [\*\*\*]

If to **Distributor:**[\*\*\*]

**12.9 Waivers.** No failure or delay by either Party in exercising any right or remedy provided by law under or pursuant to this Agreement shall impair such right or remedy or operate or be construed as a waiver or variation of it or preclude its exercise at any subsequent time and no single or partial exercise of any such right or remedy shall preclude any other or further exercise of it or the exercise of any other right or remedy.

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

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

**12.12 Construction.** The Parties expressly agree that any rule of construction to the effect that ambiguities are to be resolved against the drafting Party shall not be applied in the construction or interpretation of this Agreement. The language in all parts of this Agreement shall be construed, in all cases, according to its fair meaning. The words “hereof,” “herein,” “hereto” and “hereunder” and words of similar import, when used in this Agreement, shall refer to this Agreement as a whole and not to any particular provision of this Agreement. The terms defined in the singular shall have a comparable meaning when used in the plural, and vice versa. Whenever used herein, the words “include,” “includes” and “including” shall mean “include, without limitation,” “includes, without limitation” and “including, without limitation,” respectively. The masculine, feminine or neuter gender and the singular or plural number shall each be deemed to include the others whenever the context so indicates.

**12.13 Governing Law and Jurisdiction.** This Agreement shall be governed by the laws of the State of New York without regard to the conflicts of law provisions thereof. The Parties irrevocably agree that the federal district courts in the State of New York shall have exclusive jurisdiction to deal with any disputes arising out of or in connection with this Agreement and that, accordingly, any proceedings arising out of or in connection with this Agreement shall be brought in the United States District Court for the Southern District of New York. Notwithstanding the foregoing, if there is any dispute for which the federal district courts in the Southern District of New York do not have subject matter jurisdiction, the state courts in New York, shall have jurisdiction. In connection with any dispute arising out of it in connection with this Agreement, each Party hereby expressly consents and submits to the personal jurisdiction of the federal and state courts in County, City, and State of New York. Each Party hereto agrees that **A RIGHT TO TRIAL BY JURY IS HEREBY WAIVED** any that such proceeding will be conducted solely in the English language.

**12.14 Expenses.** Each Party will pay all of its own fees and expenses (including all legal, accounting and other advisory fees) incurred in connection with the negotiation and execution of this Agreement and the arrangements contemplated hereby, except as specifically provided herein.

**12.15 Informal Dispute Resolution.** Unless otherwise expressly provided for herein, any claim or controversy between the Parties arising out of or relating to the execution, interpretation and performance of this Agreement (including the validity, scope and enforceability of this provision) will be identified in writing and presented to the other Party. Within [\*\*\*] after delivery of such notice of dispute, the Chief Executive Officer of Manufacturer and [\*\*\*] (or another executive of a Party or an Affiliate designated by such [\*\*\*], as applicable) (the “**Designated Officers**”) will meet (either in person or via telephone conference) at a mutually acceptable time and place, and thereafter as often as they reasonably deem necessary, to attempt to resolve the dispute in good faith. All reasonable requests for information made by one Party to another will be honored. All negotiations pursuant to this clause are confidential and will be

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treated as compromise and settlement negotiations for purposes of applicable rules of evidence. If such Designated Officers cannot resolve such dispute within \*\*\* after such initial meeting, then each Party reserves its right to any and all remedies available under law or equity with respect to any other dispute. Notwithstanding anything to the contrary herein, each Party may seek immediate or other equitable relief against the other Party at any time to enforce their proprietary rights in confidential information or other intellectual property rights.

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IN WITNESS WHEREOF, the undersigned have executed this Agreement as of the date hereof.

**AMAG PHARMACEUTICALS, INC.**

By: /s/ William K. Heiden  
Name: William K. Heiden  
Title: President and Chief Executive Officer

**PRASCO, LLC**

By: \*\*\*  
Name: \*\*\*  
Title: \*\*\*

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*[Signature Page to Distribution and Supply Agreement]*

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**EXHIBIT 1.49**

**MANUFACTURING COSTS**

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**EXHIBIT 1.63**

**DESCRIPTION OF PRE-BOOKING ACTIVITIES**

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**EXHIBIT 2.3(d)**

**STORAGE AND SHIPPING REQUIREMENTS**

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**EXHIBIT 3.4(a)**

**PERCENTAGE OF NET DISTRIBUTABLE PROFITS**

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**EXHIBIT 3.4(b)**

**ACCRUAL ROLLFORWARD REPORT**

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**EXHIBIT 3.5(a)(i)**

**INVENTORY ACTIVITY REPORT**

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**EXHIBIT 3.5(a)(ii)**  
**QUARTERLY REPORT**

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**EXHIBIT 5.1(b)**

**INITIAL LAUNCH QUANTITIES**

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**EXHIBIT 5.1(d)**

**INCREMENTAL ORDER SIZES**

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**MINIMUM ORDERS**

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**EXHIBIT 12.1**

**INSURANCE**

\*\*\*

**COMMERCIAL SUPPLY AGREEMENT  
ACTIVE PHARMACEUTICAL INGREDIENT**

This Commercial Supply Agreement (this "Agreement"), effective as of the 4<sup>th</sup> day of June, 2018 (the "Effective Date"), is entered into by and between:

AMAG Pharmaceuticals, Inc., a company incorporated under the laws of State of Delaware, with its principal office located at 1100 Winter Street, Waltham, MA 02451 ("Company"); and

SAFC, Inc., a company organized under the laws of Wisconsin, with its corporate headquarters located at 3050 Spruce Street, St. Louis, Missouri 63103 ("SAFC").

Company and SAFC are hereinafter sometimes referred to separately as a "Party" or together as the "Parties".

**RECITALS**

WHEREAS, Company is a biopharmaceutical company engaged in the research and development of products, including the API and the Finished Product (as such terms are hereinafter defined), that utilizes its proprietary technology for the development and commercialization of a therapeutic hormone medicine used to lower the risk of preterm birth in women who are pregnant with one baby and who have previously delivered one baby too early (preterm);

WHEREAS, SAFC develops, manufactures and sells a broad range of biochemicals and organic chemicals globally for use in pharmaceutical development and as APIs, and key components in pharmaceutical manufacturing;

WHEREAS, Company desires to engage SAFC to manufacture the API at commercial scale for use in the Finished Product; and

WHEREAS, SAFC is willing to manufacture and supply to Company the API upon the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the above premises and the mutual covenants and agreements contained herein, the Parties hereby agree as follows:

**1. Definitions and Interpretation**

1.1 "Active Pharmaceutical Ingredient" or "API" means hydroxyprogesterone caproate (HPC).

1.2 "Affiliate" means any entity controlling, controlled by or under common control with either Party hereto. For purpose of this definition, "control" means ownership of over fifty percent (50%) of the equity capital, the outstanding voting securities or other ownership interest of an entity, or the right to receive over fifty percent (50%) of the profits or earnings of an entity. In the case of non-stock organizations, the term "control" means the power to control the distribution of profits.

1.3 "Analytical Methods" means the set of validated analytical methods related to the Manufacturing of the API as set forth on Appendix 4 hereto.

1.4 "API Requirements" has the meaning set forth in Section 4.1 hereof.

1.5 "Batch" means the API that results from a single Manufacturing process, inclusive of Materials.

1.6 "Batch Record" and "Master Batch Record" have the meanings assigned to such terms in the Quality Agreement.

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1.7 "Commencement Date" means the date Company issues its initial binding written purchase order for the commercial supply of API under Section 3.2 below.

1.8 "Commercial Forecast" has the meaning set forth in Section 3.1 hereof.

1.9 "Confidential Information" means with respect to each Party in its capacity as a disclosing party (collectively, "Disclosing Parties," and each a "Disclosing Party") any information disclosed to the other Party (the "Receiving Party") (in any form, tangible or intangible), including, without limitation, information concerning or relating to any business plans, products, trade secret processes or methodologies, intellectual property, design specifications, finances, customers, suppliers, employees, operation and/or business, technical documents and other proprietary rights and information; which: (a) is identified by the Disclosing Party at the time of disclosure as being of a confidential nature or that is marked as confidential; or (b) would lead a reasonable person, under the circumstances, to understand that such information is confidential or proprietary in nature, regardless of whether so marked; and provided further, that, regardless of whether so marked, all information regarding SAFC's operations, methods, and pricing disclosed by SAFC to Company in connection with this Agreement shall be deemed "Confidential Information" of SAFC and all API, API structure, Specifications, related documents, materials, raw materials, product, product specifications, processes, operations, methods, Master Batch Record, and all and any other documentation, information, templates, and biological, chemical or other materials furnished to SAFC by or on behalf of Company or developed in the course of Manufacturing API other than SAFC Property (collectively, with all associated intellectual property rights) shall be deemed "Confidential Information" of the Company. For clarification, Company will not receive the original of the Master Batch Record.

1.10 "Current Good Manufacturing Practices" or "cGMP" means all Laws and standards relating to the Manufacture of API, including the then current Manufacturing practices for fine chemicals, active pharmaceutical ingredients, intermediates or bulk products as established by the principles detailed in the guidance documents developed by the International Conference on Harmonization, (b) the U.S. Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.), (c) relevant United States regulations in Title 21 of the United States Code of Federal Regulations (including Parts 11, 210, and 211), (d) EC Directive 2003/94 EC of October 8, 2003, (e) the EC Guide to Good Manufacturing Practice Parts I and II, and (f) all additional Regulatory Agency documents that replace, amend, modify, supplant or complement any of the foregoing.

1.11 "Deviation" has the meaning set forth in the Quality Agreement.

1.12 "EMEA" means the European Medicines Agency of the European Union, and any successor thereto.

1.13 "Facility" means (a) SAFC's facility located at [\*\*\*], as well as (b) such other facility where API may be Manufactured as approved by Company in writing.

1.14 "Failure to Supply" has the meaning set forth in Section 2.11(a) hereof.

1.15 "FDA" means the United States Food and Drug Administration, and any successor thereto.

1.16 "Finished Product" means the finished dosage form drug product that contains the API.

1.17 "Laboratory" has the meaning set forth in Section 4.2 hereof.

1.18 "Latent Defect" means any deficiency (meaning any API that fails to meet the representations, warranties or other quality requirements set forth in this Agreement) that is not determinable upon a reasonable inspection of the API (based on physical inspection, identity test and review of the certificate of analysis).

1.19 "Law" means the laws, ordinances, rules, regulations, requirements and lawful orders of any federal, state, local, national or supranational public authority, including child labor laws, whether existing at present or later enacted that may be in effect from time to time, in each case applicable to the performance of this Agreement and/or the Manufacture of API.

1.20 "Manufacture", "Manufacturing" or "Manufactured" means all activities related to the manufacturing of the API, or any ingredient thereof, to be undertaken by SAFC in accordance with the terms and conditions of this Agreement



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and the Quality Agreement, which may include receipt (including testing) and storage of Materials, manufacturing the API for development or commercial sale, packaging the API, in-process and final testing and release of the API (or any component or ingredient thereof), quality assurance activities related to manufacturing, warehousing, release of the API, and regulatory activities related to any of the foregoing.

1.21 "Manufacturing Process" means the instructions, Specifications (as well as specifications for raw materials and excipients), formulae, procedures, tests and standards developed, established and described by Company for Manufacturing API.

1.22 "Marks" has the meaning set forth in Section 11.4 hereof.

1.23 "Materials" means all raw materials, components, and other potential substance-contacting items necessary for, or otherwise used in, the Manufacture of API pursuant to this Agreement, as applicable.

1.24 "Minimum Lead Time" has the meaning set forth in Section 3.2(c) hereof.

1.25 "OOS" (Out of Specification) has the meaning set forth in the Quality Agreement.

1.26 "Quality Agreement" means the Quality Agreement between Company and SAFC attached hereto and incorporated herein by reference as Appendix 1.

1.27 "Records" means SAFC's records related to the performance of this Agreement, which shall include Manufacturing documents, Batch Records, test results, financial records, reports, correspondence, memoranda, and any other similar documentation related to the performance of this Agreement.

1.28 "Regulatory Agency" has the meaning set forth in the Quality Agreement.

1.29 "Specifications" means the Manufacturing specifications for the API as set forth in Appendix 2 hereto and/or in the Quality Agreement, as such specifications may be modified from time to time by Company (and in the case of any such modifications, Company shall provide such modifications to SAFC, and the Specifications shall thereafter be deemed to be so modified within a reasonable time without the need to amend this Agreement or the Quality Agreement, as applicable).

1.30 "Term" has the meaning set forth in Section 9.1 hereof.

## **2. Manufacture and Supply of API**

2.1 General Conditions of Supply. During the Term, SAFC shall Manufacture at the Facility and supply API to Company, and Company shall purchase API from SAFC in such quantities as set forth in Section 2.9 below, subject to the limitations and requirements set forth herein.

2.2 Specifications. At all times during the Term, SAFC shall Manufacture the API in accordance with cGMPs, Laws, the Specifications and the Quality Agreement.

2.3 Quality Control and Release. SAFC shall conduct quality control(s) and release(s) of API (including preparing documentation) in accordance with the Quality Agreement. Company shall have the right to reject API that does not meet the quality control and release testing requirements agreed upon in the Quality Agreement.

2.4 Inspections. Inspections of the Facilities shall be conducted as specified in the Quality Agreement or as required by the applicable Regulatory Agency.

2.5 Change Control Program. The Specifications and Manufacturing Process shall be changed as set forth in the Quality Agreement. Notwithstanding anything herein or in the Quality Agreement to the contrary, any change control procedures described in the Quality Agreement and any changes implemented pursuant to such change control procedures shall, in each instance, comply with the Laws (including cGMPs). Further, for any such change, SAFC shall ensure that all

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API Manufactured following such change meets the Specifications as amended by such change, and provide Company with all information with respect to the Manufacture of the API in connection with such change needed to amend any regulatory filings maintained with respect to the subject Finished Product. Company and SAFC shall mutually agree on the allocation of costs of implementing the foregoing changes.

2.6 Manufacturing at Facility. Supplier shall Manufacture all API supplied under this Agreement at the Facility. Manufacturing of API may not be relocated from the Facility without Company's prior written consent, provided that such consent shall not be unreasonably withheld.

2.7 Subcontracting. Prior to engaging a given Affiliate or third party to perform any Manufacturing activities under this Agreement, SAFC shall notify Company thereof and discuss such subcontracting with Company; provided that in all cases, SAFC shall not subcontract any of its obligations under this Agreement, including any obligations to Manufacture API, to an Affiliate or third party without the prior written consent of Company and that such consent shall not be unreasonably withheld. With respect to any subcontracting (including to an Affiliate or a third party), SAFC shall remain fully responsible and liable for all obligations under this Agreement, and fully guarantees and warrants the performance (in accordance with this Agreement) of any responsibilities so subcontracted, and assumes full vicarious liability for such activities performed by any subcontractor. Without limiting the foregoing, SAFC shall cause any and all such subcontractors to comply with the applicable terms and conditions of this Agreement (including intellectual property ownership provisions and any and all audit and inspection rights). Any subcontracting of any Manufacturing or other activities under this Agreement shall be subject to the other applicable terms and conditions of this Agreement, in each case, to the extent applicable.

2.8 Safety of API. Each Party shall immediately notify the other Party of any unusual health or environmental occurrence relating to API. Each Party shall advise the other Party immediately of any safety or toxicity problems of which it becomes aware regarding API manufactured under this Agreement.

2.9 Purchase Commitment.

(a) During the Term and upon the terms and subject to the conditions of this Agreement, and as long as SAFC can demonstrate to Company's reasonable satisfaction that SAFC: (i) provides conforming Product in accordance with the terms of this Agreement and (ii) can meet the Commercial Assurance (as defined below in Sec. 3.1) production levels, Company undertakes to purchase from SAFC not less than [\*\*\*] of API ("Minimum Percentage Requirement"). The Parties acknowledge that Company placed and SAFC manufactured API for the Work Order dated October 17, 2017 under purchase order 80319 dated November 6, 2017 and Proposal dated March 7, 2018 under purchase order 80767 dated March 16, 2018. The Parties agree that the terms of this Agreement shall apply to the Manufacture of API pursuant only to Purchase Order 80767, however both Purchase Orders 80319 and 80767 shall apply towards the Minimum Percentage Requirement. [\*\*\*]. Company agrees to cooperate in a prompt and timely manner with SAFC in any investigation and resolution of any quality issues with the API to enable SAFC to remedy any such issue. [\*\*\*]. For clarity, API that is to be used for clinical purposes shall not be included when calculating Total Commercial Volume Requirements.

(b) At any time and from time to time during the Term, if SAFC believes that Company is not purchasing the Minimum Percentage Requirement, it will provide Company with written notice requesting that Company provide sufficient documentation demonstrating such purchases. Company shall have [\*\*\*] after such notice to provide this documentation. If Company does not provide such documentation within this [\*\*\*] period or if such documentation does not demonstrate, to SAFC's reasonable satisfaction, that Company purchased the Minimum Percentage Requirement based on Company's demand forecast, the Parties will engage in good faith discussions for a period of an additional [\*\*\*] in an effort to resolve the disagreement. If the Parties do not reach a mutually acceptable agreement within the foregoing [\*\*\*] discussion period, then either Party may refer the matter to be resolved by binding arbitration. The arbitration shall be conducted in accordance with the Commercial Arbitration Rules of the American Arbitration Association in effect at the time of the arbitration to the extent that both Parties are domestic United States companies or in accordance with the International Arbitration Rules of the American Arbitration Association in effect at the time of the arbitration to the extent that one of the Parties is not a domestic United States company, except, in each instance, as such rules may be modified herein or by mutual agreement of the Parties. The seat of the arbitration shall be New York City, New York, USA, and it shall be conducted in the English language.

## 2.1 Delay.

(a) If SAFC is or will be unable, for any reason (including an event of Force Majeure under Section 11.17 hereof), to supply the API in accordance with the quantities and/or delivery dates specified by Company in a purchase order received and accepted by SAFC (provided that such quantities are within the Commercial Forecast and such delivery dates meet the Minimum Lead Time requirements herein) (“Failure to Supply”), SAFC shall immediately upon discovery notify Company in writing of such circumstance. Within [\*\*\*] of such Failure to Supply, SAFC shall notify Company of the cause of such failure and shall propose a plan of remediation.

(b) If such Failure to Supply will continue or does continue for a period of [\*\*\*], and SAFC is unable to Manufacture the API in quantities necessary to cure the Failure to Supply within [\*\*\*] after the initial Failure to Supply, then any quantities of API ordered by Company from an alternative supplier of API shall be considered ordered under this Agreement for purposes of calculating whether Company has ordered the Minimum Percentage Requirement.

(c) SAFC shall promptly notify Company when SAFC can resume supply of API in accordance with this Agreement and provide Company with a firm date for delivery of the API in accordance with Company’s needs.

## 3. **Forecasts, Release, Purchase Orders, Delivery and Storage**

3.1 Forecasts. Reasonably in advance of the Commencement Date, Company shall determine its initial estimated purchases of the API from SAFC under this Agreement. Starting shortly after the Effective Date, Company shall deliver to SAFC a written, non-binding, rolling [\*\*\*] forecast of quantities of API to be purchased (the “Commercial Forecast”), provided that the first [\*\*\*] of each such Commercial Forecast shall be binding for Company to purchase and SAFC to Manufacture. Further, SAFC shall provide reasonable assurance in writing to Company of SAFC’s ability and capacity to meet not less than [\*\*\*] of the then current non-binding portion of the Commercial Forecast (as updated from time to time by Company) (“Commercial Assurance”). The Commercial Forecast shall cover each of the next succeeding [\*\*\*]. After delivery of the initial Commercial Forecast, the Commercial Forecast shall be updated by Company on a calendar quarterly basis, which update shall include the next successive calendar quarter added to the last period of the previous Commercial Forecast. Although the last [\*\*\*] of the Commercial Forecast is non-binding, Company understands that SAFC shall use the Commercial Forecast for planning purposes (including raw material acquisitions and investment in equipment and other resources) in order to make available the production capacity required to Manufacture and supply the forecasted amounts of the API within the time frames specified therein and reciprocally SAFC understands that Company has relied on SAFC’s Commercial Assurance in its production and manufacturing arrangements.

## 3.2 Initial Commercial Supply; Purchase Orders.

(a) Company issued Purchase Order 80767 for its initial purchase of API hereunder.

(b) All purchase orders for API hereunder shall be in minimum batch sizes of [\*\*\*] each.

(c) All purchase orders for API subsequent to the initial purchase order must be issued at least [\*\*\*] prior to the requested delivery of API thereunder or such shorter time as may be agreed upon by the Parties in writing. The minimum number of days between the date of a purchase order and the date of delivery of API under this Section 3.2(c) above shall be referred to hereinafter as the “Minimum Lead Time”.

(d) Within [\*\*\*] of receipt of a purchase order, SAFC shall notify Company in writing if it accepts the purchase order; provided that it is understood that SAFC must accept a purchase order if it does not exceed the binding portion of the Commercial Forecast and meets the Minimum Lead Time. If SAFC fails to respond within [\*\*\*] of receipt of the purchase order, Company shall follow up with SAFC to determine whether SAFC is in receipt of the purchase order. SAFC shall confirm its receipt of Company’s purchase order within [\*\*\*] following an inquiry made by Company pursuant to the previous sentence.

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(e) If a purchase order exceeds the binding portion of the Commercial Forecast or does not meet the Minimum Lead Time, SAFC may reject such purchase order if SAFC reasonably determines that it cannot, using commercially reasonable efforts, ship the amount of API ordered by the requested delivery date. If SAFC accepts such purchase order, it will be required to fill such excess and/or accommodate such shorter lead-time.

(f) For each purchase of API, the purchase order shall specify: (i) an identification of the API ordered; (ii) quantity requested; (iii) the requested delivery date; and (iv) shipping instructions and address.

(g) Each purchase order shall give rise to a contract for the purchase of the API under the terms and conditions set forth in this Agreement, to the exclusion of any additional or contrary terms set forth in any purchase order or invoice, unless otherwise explicitly agreed to in writing by the Parties.

3.3 Cancellation or Deferral. Without prejudice to the Minimum Percentage Requirements, Company may cancel or defer any purchase order, in whole or in part, without penalty, provided that such cancellation or deferral notice is received by SAFC prior to SAFC's commencement of the actual Manufacture of the applicable API pursuant to such purchase order. If Company cancels or defers a purchase order, in whole or in part, with less than the aforementioned notice, Company shall reimburse SAFC for the reasonable, non-cancellable, out of pocket costs incurred by SAFC as a result of such cancellation or deferral by Company (and in connection therewith, the Parties shall discuss in good faith and agree to the amount of such costs), provided that SAFC shall use its commercially reasonable efforts to minimize such costs.

3.4 Release of API. SAFC shall notify Company when all of the following activities have been completed: (i) the Manufacture of the API is complete, (ii) all Manufacturing records have been reviewed, (iii) all Deviations have been adequately reviewed and approved, and (iv) the API has been released by SAFC in accordance with the Quality Agreement. SAFC shall use commercially reasonable efforts to target a release date for the API that is [\*\*\*] after Manufacturing is complete. If this target cannot be achieved for a batch, SAFC shall notify Company of the reason and a new target release date. SAFC shall deliver all documents required by the Quality Agreement to Company after SAFC's release of each Batch.

3.5 Delivery, Title and Risk of Loss. All API supplied by SAFC shall be delivered FCA SAFC's shipping point within the meaning of Incoterms 2010. Delivery of the API to the carrier at such SAFC shipping point shall constitute delivery to Company. Title to and risk of loss of the API sold hereunder shall pass to Company or its designee when the API is delivered to the carrier at SAFC's shipping point. The Parties recognise the importance of timely delivery and SAFC will use commercially reasonable best efforts to fulfil its delivery obligations.

3.6 Packaging. SAFC will preserve, package, handle, and pack all API to protect the API from loss or damage, in conformance with standard commercial practices, the Specifications, the Quality Agreement and Laws, including cGMPs.

3.7 Storage. SAFC shall hold all API under the storage conditions established pursuant to the Quality Agreement and in accordance with Laws, including cGMP. SAFC shall store the API for a period not to exceed [\*\*\*], at its own cost, after the requested delivery date set forth in the purchase order. Any API held by SAFC beyond [\*\*\*] from the requested delivery date shall be subject to a SAFC's standard storage charges, as such storage charges are communicated to Company reasonably in advance of the end of such [\*\*\*].

#### **4. Rejection, Defects and Non-Conforming Goods**

4.1 Nonconforming API. Within [\*\*\*] from the date SAFC delivers API (including all release documentation) to Company or to a third party designated by Company, Company shall have the right to inspect and test the API to determine whether such API at the time of delivery did not meet the representations, warranties or covenants specified in Section 6.2(b) (collectively the "API Requirements"). Any claim by Company that API does not conform to the API Requirements shall be made in writing to SAFC within such [\*\*\*] period and shall be accompanied by a detailed report of analysis prepared by or on behalf of Company. Notwithstanding the foregoing, if a defect in the API is a Latent Defect, then such [\*\*\*] time period shall not apply; provided that Company shall have the obligation to provide such

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notification to SAFC in writing within [\*\*\*] after Company's discovery of such Latent Defect (or within [\*\*\*] after Company is notified in writing by a third party of such Latent Defect, if later) but in no case later than [\*\*\*] after the date SAFC delivers API (including all release documentation) to Company or to a third party designated by Company; provided, however, that if SAFC receives stability data that establishes a shelf life of greater than or equal to [\*\*\*] from the date of Manufacture of the API, then the notification period for a Latent Defect shall be no later than [\*\*\*] from the date of Manufacture of the API.

4.2 Dispute Concerning Fulfilment of API Requirements. In the event of a dispute concerning the fulfilment of API Requirements, Company and SAFC shall agree on an independent testing laboratory of recognized standing in the industry selected by SAFC and approved by Company (which approval shall not be unreasonably withheld) ("Laboratory") to determine whether any such API met the API Requirements. The findings of the Laboratory shall be binding. The expenses related to such testing shall be borne by SAFC only if the testing confirms that API Requirements are not fulfilled, and otherwise by Company. During any period that the Parties are in dispute regarding the conformity of the API, SAFC shall, if requested by Company, replace such quantity of API, and Company shall pay for both the original shipment of API and the replacement shipment of API if the Laboratory confirms the conformity of the original shipment.

4.3 Remedies for Non-Conforming Product. If any API delivered to Company fails to conform to API Requirements, SAFC, [\*\*\*] within a commercially reasonable period not to exceed [\*\*\*] from the date that Company notifies SAFC of such nonconformity. In addition, if the API is determined not to have met the API Requirements, SAFC shall [\*\*\*]. Pursuant to written directions from SAFC, Company shall either return the nonconforming API to SAFC or destroy it, in each case, at SAFC's expense. If Company is directed to destroy nonconforming API, then Company shall provide SAFC a certificate certifying such destruction. Except for SAFC's indemnification obligations in respect of third party claims under Section 6.8 below, the remedy under this Section 4.3 shall be Company's exclusive remedy and SAFC's sole liability for any claim that API fails to conform to the API Requirements. Deviations and OOS. The Parties shall cooperate with each other upon request in the investigation and response to any API concerns relating to Deviations and OOS, which may relate to SAFC's role in the Manufacture of API (in addition to complying with the corresponding provisions in the Quality Agreement). Further, SAFC shall share with Company any quality assurance or quality control analyses performed or identified trends relating to safety and quality of the API or its Manufacturing process.

## 5. Sales Prices and Terms of Payment

5.1 Currency. Except as otherwise expressly indicated, all references to "\$" or "dollars" in this Agreement refer to the currency of the United States of America.

5.2 Sales Prices. The sales prices for API Manufactured under this Agreement and released by SAFC's quality assurance department shall be the prices set forth in Appendix 3. The prices are to be understood as packaged and ready for further processing at the facility of Company or of a third party designated in writing by Company, excluding costs of shipping, insurance and freight and further excluding applicable sales or other taxes (which will be applied as set forth in Section 5.6 hereof). Except as otherwise expressly indicated, all prices are listed in United States Dollars.

5.3 Invoices and Payments. SAFC shall invoice Company at the time of delivery (or partial delivery) of the API. All undisputed payments are due in full within [\*\*\*] from the date of receipt of the SAFC invoice. Undisputed payments shall be made to SAFC in accordance with the instructions on the invoice; provided, that, in the event of a conflict between an invoice and the terms of this Agreement, this Agreement shall control and any additional terms set forth in an invoice shall be null and void. Except as otherwise expressly indicated, all undisputed payments hereunder shall be made in United States Dollars.

5.4 Overdue Payments. Company shall pay interest on all past-due amounts (except those subject to a bona fide dispute) at a rate of interest equal to the lesser of [\*\*\*] per month or the maximum rate permitted by Law.

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5.5 Price Adjustment. Notwithstanding any other provision of this Agreement to the contrary, no more than once each calendar year of the Term following the first year of the Term, with [\*\*\*] prior written notice to Company (“Price Adjustment Period”), and in addition to any other price adjustment that may be permitted by this Agreement or otherwise agreed to by the Parties, SAFC may adjust the pricing applicable to Company’s purchases of API for such calendar year by an amount not to exceed [\*\*\*] from the Effective Date or the date of the last increase pursuant to this Section 5.5, to the date of such written notice to Company; provided that any price adjustment shall apply only to purchase orders submitted following the Price Adjustment Period.

#### 5.6 Taxes.

(a) If Company must withhold from any payment to SAFC under this Agreement any taxes required to be withheld by Company under the applicable laws of any country, state, territory or jurisdiction, such amount shall be paid to the appropriate taxing authorities. Upon request, Company shall provide SAFC with documentation of such withholding as is reasonably available to allow SAFC to document such tax withholdings for purposes of claiming tax credits and similar benefits.

(b) Any use tax, sales tax, value added tax, excise tax, duty, custom, inspection or testing fee, or any other tax, fee or charge of any nature whatsoever imposed by any governmental authority on or measured by the transactions between Company and SAFC (except any amounts imposed based upon or attributable to SAFC’s income) shall be paid by Company in addition to any other amounts due hereunder.

### **6. Recall, Warranties, Indemnification and Insurance**

#### 6.1 Recall.

(a) As between the Parties, Company shall have the sole and absolute discretion as to whether to institute a recall or withdrawal of Finished Product or API (whether instituted at the request of a Regulatory Agency or voluntarily instituted by Company for any reason). Notwithstanding anything to the contrary contained herein, SAFC shall have no right to institute any recall or withdrawal of any Finished Product or API. SAFC agrees to abide by all decisions of Company to recall or withdraw Finished Product or API.

(b) Company shall be responsible for conducting any recall arising out of, related to or in connection with this Agreement (including without limitation any recall of any Finished Product. SAFC shall co-operate with and give all reasonable assistance to Company in conducting any such recall to the extent it relates to the API. Subject to Section 11.5 below, SAFC shall bear the reasonably incurred cost and expense of a recall or withdrawal to the extent such recall results from SAFC’s negligence or willful misconduct or breach of this Agreement or the Quality Agreement; provided, however, if such recall or similar action is also the result of Company’s breach of its representations, warranties or obligations hereunder or under the Quality Agreement or also results from Company’s negligence or willful misconduct, then SAFC’s liability for such recall shall be reduced proportionately by the damages or losses attributable to Company. Otherwise, Company shall bear all costs and expenses associated with any such recall. In the event of a recall or similar action, each Party shall use commercially reasonable efforts to mitigate the costs associated therewith.

(c) In the case of a dispute as to the existence or level of nonconforming API in connection with a recall under this Section 6.1, the matter shall be referred to the Laboratory in accordance with Section 4.2 above. The decision of the Laboratory shall be final and binding on the Parties.

#### 6.2 SAFC Representations and Warranties. SAFC hereby represents, warrants and covenants as follows:

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(a) (i) The execution, delivery and performance of this Agreement does not conflict with, violate or breach any agreement to which SAFC is a party or SAFC's constituent documents, (ii) SAFC is not prohibited or limited by any law or agreement (to which it is a party) from entering into this Agreement and (iii) the performance of this Agreement will not create any legal conflict with any other business or activity engaged in by SAFC;

(b) The API at the time of delivery shall (i) have been Manufactured and delivered in compliance with, and shall meet, the Specifications, (ii) be Manufactured in accordance with all Laws (including cGMPs) in effect on the day of delivery, (iii) will conform to the Quality Agreement and the Specifications; (iv) not be adulterated or misbranded within the meaning of the U.S. Federal Food, Drug and Cosmetic Act (the "Act"), or any similar Law of any other jurisdiction, and (v) not be an article that may not, under the provisions of the Act, or any similar Law of any other jurisdiction, be introduced into stream of commerce;

(c) SAFC will have obtained and maintained in effect all such approvals and permits as may be required under applicable laws, rules, regulations and requirements to operate the Manufacturing facility for the API for the purposes of Manufacturing API under the Quality Agreement and under this Agreement;

(d) SAFC will not in the course of performing the Manufacturing obligations hereunder, infringe or misappropriate any intellectual property of any other person, provided, however, that this warranty does not apply to SAFC's use of any Company Confidential Information used solely in accordance with the terms of this Agreement or the Quality Agreement or other written instructions provided by Company in accordance with the Quality Agreement and used by SAFC in Manufacturing API hereunder.

(e) SAFC shall not disclose to Company any trade secrets or confidential or proprietary information of any third party without the consent of such third party.

(f) SAFC agrees that federal securities law may prohibit it, its affiliates and its representatives from purchasing or selling any securities of the Company while it is in possession of material, non-public information of the Company, and that it will not disclose any material, non-public information, directly or indirectly, to any party for the purpose of encouraging such party to trade in the Company's securities and that it will comply at all times with the applicable Federal Securities Laws and regulations.

### 6.3 Regulatory Violations.

(a) SAFC represents and warrants that it does not and will not, and its Affiliates do not and will not, knowingly use in any capacity the services of any person or entity debarred under Section 306 of the Federal Food, Drug, and Cosmetic Act named on the FDA Debarment List (Drug Product Applications) ([http://www.fda.gov/ora/compliance\\_ref/debar/](http://www.fda.gov/ora/compliance_ref/debar/)), or otherwise debarred under the corresponding Laws of another jurisdiction. Where permissible by local Laws, notably regulation on personal data protection, SAFC will as soon as practically possible disclose in writing to Company any information which comes to its attention and indicates that the statement in the preceding sentence is or may be incorrect. SAFC shall notify Company in writing as soon as practically possible if any Violation (as defined below) occurs or comes to its attention at any time during the Term. If a Violation exists with respect to any of SAFC's officers, directors, Key Employees, or Subcontractors, SAFC shall promptly remove such individual(s) or entities from performing any service, function or capacity related to this Agreement. Company shall also have the right, in its sole discretion, to terminate this Agreement immediately in the event of any such Violation, if such Violation (i) is not cured by SAFC within [\*\*\*] after receipt of a notification of such Violation from Company or (ii) cannot be cured by SAFC.

(b) SAFC represents and warrants that SAFC, its Affiliates and their respective officers and directors, and employees in the Manufacture of API, have not been, and will not be, in Violation. SAFC shall notify Company in writing as soon as practically possible if any such Violation occurs or comes to its attention. Company shall have the right, in its sole discretion, to terminate this Agreement and/or any purchase order immediately in the event of any such Violation. The term "Violation" shall mean that either SAFC or its Affiliates or, to SAFC's knowledge any of their respective officers, directors, or employees Manufacturing API has been: (1) convicted of any of the felonies identified among the exclusion authorities listed on the U.S. Department of Health and Human Services, Office of Inspector General (OIG) website,

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including 42 U.S.C. 1320a-7(a) (<https://oig.hhs.gov/exclusions/authorities.asp> ); (2) identified in the OIG List of Excluded Individuals/Entities (LEIE) database (<https://oig.hhs.gov/exclusions/authorities.asp> ) or the U.S. General Services Administration's list of Parties Excluded from Federal Programs (<http://www.sam.gov> ); or (3) listed by any US Federal agency as being suspended, debarred, excluded, or otherwise ineligible to participate in Federal procurement or non-procurement programs, including under 21 U.S.C. 335a ([http://www.fda.gov/ora/compliance\\_ref/debar/](http://www.fda.gov/ora/compliance_ref/debar/)); or (4) listed on the SDN LIST (including owned by 50% or more by a person listed on the SDN List), the U.S. Commerce Department's Denied Persons List (<http://www.bis.doc.gov/dpl/thedeniallist.asp>) and Entity List (<http://www.bis.doc.gov/entities/default.htm>), or the Consolidated List of Persons, Groups and Entities Subject to EU Financial Sanctions ([http://ec.europa.eu/external\\_relations/cfsp/sanctions/list/version4/global/e\\_ctlview.html](http://ec.europa.eu/external_relations/cfsp/sanctions/list/version4/global/e_ctlview.html)).

6.4 No Contaminants. SAFC hereby declares and covenants that as of the Effective Date of this Agreement it is not, and during the Term shall not, produce, package, label, warehouse, quality control test (including in-process, release and stability testing), release or ship any chemical entity classified as penicillins or other beta-lactam antibiotics such as cephalosporins, carbapenems or monobactams; biological preparations containing live viruses or microorganisms, in the Facility.

#### 6.5 Company Representations and Warranties.

(a) Company represents and warrants that (i) the execution, delivery and performance of this Agreement does not conflict with, violate or breach any agreement to which Company is a party or Company's constituent documents, (ii) Company is not prohibited or limited by any law or agreement to which it is a party from entering into this Agreement and (iii) the performance of this Agreement will not create any conflict with any other business or activity engaged in by Company.

(b) Company represents and warrants that (i) Company has all rights, permissions and licenses required to enter into and perform its obligations under this Agreement, (ii) any intellectual property of Company provided to SAFC under or in connection with this Agreement does not, and will not infringe any patent or other proprietary right of any third party if used in accordance with the terms of the Agreement, Quality Agreement, and any written instructions provided by Company; and (iii) Company shall not disclose to SAFC any trade secrets or confidential or proprietary information of any third party without the consent of such third party.

(c) Company agrees that federal securities law may prohibit it, its affiliates and its representatives from purchasing or selling any securities of SAFC while it is in possession of material, non-public information of SAFC, and that it will not disclose any material, non-public information, directly or indirectly, to any party for the purpose of encouraging such party to trade in SAFC's securities and that it will comply at all times with the applicable Federal Securities Laws and regulations.

6.6 Disclaimer. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, THE PARTIES ACKNOWLEDGE AND AGREE THAT NEITHER PARTY IS MAKING ANY REPRESENTATIONS OR WARRANTIES OF ANY KIND WHATSOEVER, EITHER EXPRESS OR IMPLIED, WRITTEN OR ORAL, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY, WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE, OR WARRANTY OF NON-INFRINGEMENT, WHETHER ARISING BY LAW, COURSE OF DEALING, COURSE OF PERFORMANCE, USAGE OF TRADE OR OTHERWISE, ALL OF WHICH ARE EXPRESSLY DISCLAIMED.

6.7 Company Indemnification. Company shall indemnify, defend and hold harmless SAFC, its Affiliates and its or their directors, officers and employees from and against all liabilities, losses, damages, fines, penalties, costs and expenses (including without limitation reasonable attorneys' fees) (collectively, "Losses"), arising from any third party claim, action or demand ("Third Party Claim"), to which SAFC is or may become subject to the extent relating to or arising out of or are alleged or claimed to relate to or arise out of or in connection with:



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- (a) any breach by Company of any of its (or any of its Affiliate's) obligations or representations and warranties under this Agreement;
  - (b) any negligent act or omission or willful misconduct by Company, its Affiliates or its or their directors, officers, employees, agents or subcontractors related to its activities under this Agreement and the Quality Agreement, or related to the API or the Finished Product;
  - (c) the labeling, marketing, distribution, offer for sale or sale by Company of the API or the Finished Product (or any other product, good or service in connection with this Agreement);
  - (d) the use and/or consumption of the API, or the use and/or consumption of Finished Product, in each case by Company, any of its Affiliates or any of its or their officers, directors, employees, agents, subcontractors or licensees;
  - (e) the infringement by the Finished Product, the API and/or the Company's use of the API and/or the Finished Product of any intellectual property or other proprietary rights of any third party, except to the extent the method of Manufacture of API, or any part thereof, infringes, misappropriates, or otherwise violates the intellectual property rights of or any confidentiality or non-use obligations to any third party (other than a claim to the extent that such claim is based on any know-how or other intellectual property provided by Company);
  - (f) SAFC following any of Company's Specifications in the Manufacture of the API provided in accordance with the Quality Agreement];
- or
- (g) any violation of any applicable law or regulation by Company, its Affiliates or its or their officers, directors, employees, agents or subcontractors in the performance of its obligations under this Agreement;

in each case except that Company shall have no obligation to indemnify, defend, and/or hold harmless SAFC, its Affiliates and its or their directors, officers and employees for any Losses or Third Party Claims to the extent that SAFC has an obligation to indemnify Company with respect to such Losses or Third Party Claims pursuant to Section 6.8.

6.8 SAFC Indemnification. SAFC shall indemnify, defend and hold harmless Company, its Affiliates and its or their directors, officers and employees from and against all Losses arising from any Third Party Claim to which Company is or may become subject to the extent relating to or arising out of or are alleged or claimed to relate to or arise out of or in connection with:

- (a) any breach by SAFC of any of its obligations or representations and warranties under this Agreement or the Quality Agreement;
- (b) any negligent act or omission or willful misconduct by SAFC, its Affiliates or its or their directors, officers, employees, agents or subcontractors related to its activities under this Agreement and the Quality Agreement;
- (c) any claim that the SAFC Property used by SAFC to Manufacture API for Company infringes, misappropriates, or otherwise violates the intellectual property rights of, or any confidentiality or non-use obligations to, any third party (other than to the extent that such claim is based on any know-how or other intellectual property provided by Company); or
- (d) any violation of any applicable law or regulation by SAFC, its Affiliates or its or their officers, directors, employees, agents or subcontractors in the performance of its obligations under this Agreement;

in each case except that SAFC shall have no obligation to indemnify, defend, and/or hold harmless Company, its Affiliates and its or their directors, officers and employees for any Losses or Third Party Claims to the extent

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that Company has an obligation to indemnify SAFC with respect to such Losses or Third Party Claims pursuant to Section 6.7(a) or (b) above.

**6.9 Indemnification Procedure.** Either Party intending to seek indemnification from the other Party under Sections 6.7 or 6.8 above, as the case may be, shall: (a) give the other Party prompt notice of any such claim or lawsuit; (b) indicate the estimated amount of damages claimed in such claim or lawsuit (if reasonably practicable); (c) provide a copy of the claim or lawsuit served upon it, and (d) fully cooperate with the other Party and its legal representatives in the investigation and defense of any matter which is the subject of indemnification. A Party against whom indemnification is claimed is referred to as an “Indemnitor” and a Party claiming indemnification is referred to as an “Indemnitee”. Any Indemnitee shall have the right to employ separate counsel in any such Third Party Claim and to participate in the defense thereof, but the fees and expenses of such counsel shall not be entitled to indemnity hereunder unless (i) the Indemnitor shall have failed, within a reasonable time after having been notified by the Indemnitee of the existence of such Third Party Claim as provided in this Section 6.9, to assume and continue to conduct the defense of such Third Party Claim, (ii) the employment of such counsel has been specifically authorized by the Indemnitor, or (iii) the representation of the Indemnitee by counsel provided by the Indemnitor would be inappropriate due to actual or potential conflicting interests between them, including situations in which there are one or more material legal defenses available to the Indemnitee that are not available to Indemnitor. No Indemnitor shall, without the written consent of the Indemnitee, effect the settlement or compromise of, or consent to the entry of any judgment with respect to, any pending or threatened action or claim in respect of which indemnification may be sought hereunder (whether or not the Indemnitee is an actual or potential party to such action or claim) unless such settlement, compromise or judgment (a) includes an unconditional release of the Indemnitee from all liability arising out of such action or claim and (b) does not include a statement as to, or an admission of, fault, culpability or a failure to act, by or on behalf of the Indemnitee. In no event will an Indemnitee consent to the entry of any judgment or enter into any settlement with respect to any Third Party Claim without the prior written consent of the Indemnitor which consent shall not be unreasonably withheld. Notwithstanding the foregoing, the failure to give timely notice to the Indemnitor shall not release the Indemnitor from any liability to the Indemnitee to the extent the Indemnitee is not materially prejudiced thereby.

**6.10 Company Insurance.** Without limiting its liability under this Agreement (except as may be otherwise expressly provided in this Agreement), during the Term and for [\*\*\*] after the expiration or termination of this Agreement, Company shall obtain and maintain commercial general liability/product liability insurance with limits of not less than [\*\*\*] per occurrence for general liability and product liability. With respect to all insurance coverage required under this Section 6.10, (i) Company shall, promptly upon SAFC’s request, furnish SAFC with certificates of insurance evidencing such insurance and (ii) all policies shall include provisions for at least [\*\*\*] prior written notice of cancellation. Such insurance required by this Section 6.10 shall extend coverage to SAFC via a broad form vendor endorsement feature.

**6.11 SAFC Insurance.** Without limiting its liability under this Agreement (except as may be otherwise expressly provided in this Agreement), during the Term and for [\*\*\*] after the expiration or termination of this Agreement, SAFC shall obtain and maintain commercial general liability/product liability insurance (including through self-insurance) with limits of not less than [\*\*\*] per occurrence for general liability and product liability. With respect to all insurance coverage required under this Section 6.11, (i) SAFC shall, promptly upon Company's request, furnish Company with certificates of insurance evidencing such insurance or other similar evidence if self-insured and (ii) all policies shall include provisions for at least [\*\*\*] prior written notice of cancellation. Company shall be named as an additional insured under the policies of insurance required by this Section 6.11.

## **7. Regulatory Matters; Compliance with Laws**

**7.1 Regulation of Manufacturing Process.** If SAFC is required by the FDA, EMA, or any other Regulatory Agency to validate or re-validate Manufacturing processes that will impact the Manufacturing of API, SAFC shall notify Company and consult with Company regarding the required activities. SAFC shall be responsible for the costs of any such

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validation or re-validation that is required due to the non-compliance of the SAFC Manufacturing facility with cGMPs; otherwise any such costs shall be borne by Company provided SAFC obtains Company's advance written consent prior to incurring such costs.

7.2 Correspondence. SAFC will notify Company (pursuant to the Quality Agreement) promptly upon receipt of any correspondence from a Regulatory Agency, which relates to the API. In addition, SAFC shall provide to the Regulatory Agencies all documents and information requested by such authority, and shall submit to all inquiries, audits and inspections by the Regulatory Agencies.

7.3 Compliance with Laws; Authorizations. In performing this Agreement, each Party shall (i) comply with all Laws and (ii) obtain and maintain all releases, licenses, permits or other authorization required by any governmental body or authority.

7.4 Regulatory Filings. SAFC shall be responsible for preparing documents to support marketing authorizations or other filing submissions for API, as reasonably required by Company, and shall provide a copy of such documents to Company for review prior to submission to a Regulatory Agency by Company. SAFC shall continue to provide all such documents reasonably requested by Company for maintenance of Company's marketing authorizations or other filing submissions. SAFC shall continue to provide ongoing support reasonably requested by Company for marketing authorization for the Finished Products. SAFC shall be responsible, at its cost, for receiving and maintaining any Facility licenses, authorizations, accreditations, permits and/or registrations granted or filed with a governmental authority, including those required for Manufacture of API. SAFC shall also provide Company with all applicable data and other information and certifications related to the Manufacture of API in order for Company to provide the foregoing to any applicable governmental authority. For clarity, Company shall be permitted to share information provided by SAFC under this Section 7.4 with Affiliates and third parties (including sublicensees and governmental authorities) and such Affiliates and third parties shall be entitled to use such information in support for API or Finished Product.

7.5 Waste. In connection with the Manufacture of API pursuant to this Agreement, SAFC shall be solely responsible for maintaining safety procedures in connection with the Manufacture of API and for the generation, treatment, storage and/or disposal of waste relating thereto, all of which shall comply with all Law, including all applicable environmental and occupational safety and health requirements in the jurisdiction of the Facility.

## **8. Confidentiality; Intellectual Property**

8.1 Confidentiality Obligations. In the course of the performance of this Agreement, each Party may, from time to time, disclose its Confidential Information (the "Disclosing Party") to the other Party or its Affiliates (the "Receiving Party"). Except as expressly permitted otherwise by the terms of this Agreement, Receiving Party shall: (i) maintain in confidence and not disclose the Confidential Information of Disclosing Party to any third party, except on a need-to-know basis to Receiving Party's (or its Affiliates') employees and agents to the extent such disclosure is reasonably necessary in connection with Receiving Party's (or its Affiliates') activities as expressly authorized by this Agreement and upon obligations of confidentiality similar to those set forth herein; and (ii) not use or grant the use of the Confidential Information of the Disclosing Party for any purpose other than the performance of Receiving Party's obligations hereunder. The Receiving Party shall be solely responsible for informing the foregoing persons and entities of the terms of this Agreement, and Disclosing Party's Confidential Information disclosed to any of the foregoing persons or entities shall be subject to the terms of this Agreement. The Receiving Party shall be liable for any breach of the provisions of this Agreement by any of its Affiliates, employees, attorneys, officers, advisers and agents.

8.2 Exceptions. The provisions of Section 8.1 above shall not apply to any Confidential Information of the Disclosing Party that can be shown by competent evidence by the Receiving Party:

(a) To have been known to or in the possession of the Receiving Party without any separate obligation of confidentiality before the date of its actual receipt from the Disclosing Party;

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(b) To be or to have become readily available to the public other than through any act or omission of the Receiving Party in breach of any confidentiality obligations owed to the Disclosing Party;

(c) To have been disclosed to the Receiving Party, other than under an obligation of confidentiality, by a third party which is not known to the Receiving Party to have had an obligation to the Disclosing Party not to disclose such information to others; or

(d) To have been subsequently independently developed by the receiving Party without use of or reference or access to the Disclosing Party's Confidential Information.

8.3 Disclosure Required by Law. In the event that the Receiving Party is required by judicial or administrative process to disclose Confidential Information, the receiving Party, to the extent permitted by Law, shall promptly notify the Disclosing Party and allow the Disclosing Party a reasonable time to oppose such process or seek a protective order.

8.4 Survival of Confidentiality Obligations. The confidentiality and non-disclosure obligations imposed by this Agreement shall expire with respect to any particular item of a Disclosing Party's Confidential Information on the [\*\*\*] anniversary of the date of disclosure of such Confidential Information (and in the case of trade secrets, until such time as such trade secrets are no longer accorded trade secret status under Delaware law).

8.5 Return of Confidential Information. Each Receiving Party agrees to either destroy or return all Confidential Information received from a Disclosing Party at the request of the Disclosing Party, except that a Receiving Party may retain in its confidential files one copy of written Confidential Information of the Disclosing Party for compliance purposes only.

8.6 Equitable Relief. Each Party acknowledges, understands and agrees that a breach of this Article 8 may cause irreparable injury to a Disclosing Party, and that no adequate or complete remedy at law may be available to the Disclosing Party for such breach. Accordingly, the Parties agree that the Disclosing Party may seek enforcement of this Agreement by injunction.

8.7 Inventions. SAFC shall keep complete, accurate and dated records of the Manufacturing performed under this Agreement and the data and results thereof. Any discovery, improvement, process, formula, data, information, invention, know-how, trade secret, procedure, device, or other intellectual property, whether or not protectable under patent, trademark, copyright or similar laws, including any enhancement in the manufacture, formulation, ingredients, preparation, presentation, means of delivery, dosage or packaging of a compound or product or any discovery or development of a new indication for a compound or product created, conceived, discovered, developed, reduced to practice or otherwise made by or on behalf of either Party or jointly by or on behalf of the Parties that (i) relate to the API or any derivatives thereof or other compounds related thereto (including the making, manufacture or use of any of the foregoing), or (ii) are derived from, based on or arise from the use of the Specifications or any Confidential Information of Company or relate to the Manufacturing Process or otherwise arise from the performance of the Services (each, a "Company Invention") will be deemed the property of Company and will be owned solely by Company. Company shall own all right, title and interest in and to any and all Company Inventions and any and all work outputs and reports prepared by SAFC. SAFC shall, and shall cause its Affiliates to, promptly disclose in writing to Company the discovery, development, making, conception or reduction to practice of any Company Invention and shall and does hereby, and shall cause its Affiliates, employees, agents, subcontractors to, assign to Company any and all right, title or interest SAFC or its Affiliates may have in or to any Company Invention. SAFC will promptly and fully disclose to Company all such records and Company Inventions. Such records shall also identify the names of SAFC's employees, officers or Affiliates who performed the work. The Company Inventions and the work outputs and reports shall be considered Confidential Information of Company. SAFC agrees that it shall not publish or present any information related to the Confidential Information of Company, the API or the results thereof or any Company Inventions without the prior written consent of Company. Notwithstanding the foregoing, Company acknowledges that SAFC possesses certain inventions, processes, know-how, trade secrets, improvements, other intellectual properties and other assets, including but not limited to analytical methods, procedures and techniques, procedure manuals, personnel data, financial information, computer technical expertise and software, which have been independently developed by SAFC and which relate to its business or operations (collectively "SAFC Property"). Company and SAFC agree that SAFC Property includes improvements, enhancements and modifications thereto which are used, improved, modified or developed by SAFC under or during the term of this Agreement and which are and shall remain the sole and exclusive

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property of SAFC subject to Section 8.8(b) below and provided such improvements, enhancements and modifications thereto do not incorporate or rely upon Company Confidential Information or Company Inventions.

## 8.8 Licenses.

(a) During the Term, Company hereby grants to SAFC a royalty-free, non-exclusive license under any know-how, trade secrets, copyrights, designs, databases, discoveries, improvements and/or inventions (whether patentable or not) related to the API or the Manufacture of the API that are owned or controlled by Company and that are useful for SAFC's performance of its obligations under this Agreement, but only for such purposes and only to the extent useful for SAFC to perform its obligations under this Agreement.

(b) SAFC must identify and obtain Company's approval prior to inclusion of any SAFC Property into the API. To the extent any SAFC Property is incorporated into or otherwise necessary to Manufacture or use API, SAFC shall grant, and hereby does grant, to Company a non-exclusive, worldwide and fully-paid right and license under any such SAFC Property to the extent necessary or useful for Company to Manufacture, use and otherwise commercialize API and Finished Product.

## 9. **Term and Termination**

9.1 Term. The initial term of this Agreement shall commence as of the Effective Date and shall continue in full force and effect until the third (3<sup>rd</sup>) yearly anniversary of the Commencement Date, unless earlier terminated as provided in Sections 9.2 or 9.3 below or elsewhere as provided in this Agreement. Thereafter the Agreement shall be renewed automatically for additional two (2) year terms, unless cancelled by one of the Parties upon at least twelve (12) months prior written notice. The initial term and any renewal term(s) shall be referred to herein as the "Term".

9.2 Termination. Notwithstanding the provisions of Section 9.1 above, the Parties may terminate this Agreement in the event of either of the following:

(a) Termination for Material Breach. Either Party may terminate this Agreement by written notice at a date set in the notice (allowing at least [\*\*\*] for cure) in the event of a material breach of this Agreement by the other Party; provided that the breaching Party fails to cure such breach within [\*\*\*] from the date of such notice.

(b) Insolvency. If either Party shall become insolvent or shall make or seek to make an arrangement with, or an assignment for the benefit of creditors, or if proceedings in voluntary or involuntary bankruptcy shall be instituted by, on behalf of or against such Party, or if a receiver or trustee of such Party's assets shall be appointed, or bankruptcy proceedings begin, the other Party may terminate this Agreement, as may be permitted by the applicable Laws, with immediate effect; provided, that in the case of an involuntary proceeding, such other Party may not terminate this Agreement if the petition is dismissed within [\*\*\*] of filing.

## 9.3 Rights and Obligations Upon Termination.

(a) Return of Inventory and Confidential Information. In the event of any termination: (i) SAFC shall return to Company all Company property at Company's expense, unless such termination shall have been as a result of a breach of this Agreement by SAFC in accordance with Section 9.2(a), in which case such property shall be returned at SAFC's expense; and (ii) each Party shall return all Confidential Information of the other Party and shall make no further use of such Confidential Information without the prior written consent of the other Party; except that each Party may retain one (1) copy of the other Party's Confidential Information in confidence for purposes of ensuring compliance with this Agreement and complying with applicable laws.

(b) Payments. Termination of this Agreement shall not release either Party from the obligation to make payment of all amounts then due and payable. Upon termination of this Agreement by SAFC pursuant to Section

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9.2(a), Company shall take delivery and pay for all API that is subject to an open purchase order (to the extent such API when delivered conforms to the API Requirements), pay all monies due and owing pursuant to this Agreement and reimburse SAFC for its costs for all material, work in process, finished API and all other outstanding inventory (meaning all raw materials that are specifically required and purchased by SAFC for the Manufacture of the API) to the extent that such items were reasonably acquired by SAFC to meet its obligations hereunder in a timely manner, and make such other payments to SAFC as may be set forth in Appendix 3 hereto.

(c) Technology Transfer. Upon the expiration or termination of this Agreement, at the election and reasonable expense of Company, SAFC shall assist Company in effecting a smooth transition to an alternate supplier(s) for the Manufacture of API. In such an event, the Parties shall discuss in good faith the scope of SAFC's assistance in the technology transfer and reasonable costs payable to SAFC for providing such assistance. The scope of assistance and related costs and expenses shall be reduced to writing in an Amendment pursuant to Section 11.14 of this Agreement, if during the Term, or in a separate written agreement executed by both Parties. Without limiting the generality of the foregoing, the scope of the technology transfer may include: (i) allowing representatives of Company (and/or its designees) to observe the Manufacturing Process at the Facilities, on a mutually convenient timetable, (ii) supplying analytical test methods and other testing know-how including method validation reasonably required to perform release testing or other testing as may be required by the applicable Regulatory Agency, (iii) providing Company (and/or its designees) with appropriate quantities of reference standards and samples related to API in order to facilitate its testing, (iv) providing to Company (and/or its designees) copies of updates or changes (after the Effective Date) to all processes, protocols, procedures, methods, tests and other know-how, relating to the Manufacturing of API, and (v) making available to Company (and/or its designees) via telephone or email, on a mutually convenient timetable, reasonable technical assistance with respect to the Manufacture of API.

(d) SAFC acknowledges and agrees that, during and after the Term, SAFC shall not use the Manufacturing Process, Specifications or any other Confidential Information of Company or Company Invention to manufacture for or supply to any third party any API. Notwithstanding the foregoing, nothing in this Agreement shall prohibit SAFC from using SAFC Property or general knowledge that is not Company Inventions or Confidential Information of Company in the manufacture or supply of any API or other product to any third party, provided it does not violate any of the terms or conditions in this Agreement.

9.4 Surviving obligations. Termination or expiration of this Agreement shall not affect any accrued rights or obligations of either Party. The terms of Sections 1, 2.8, 4.1 through 4.4, 5.4, 6.1, 6.4, 6.6 through 6.11, 7.2, 8, 9.3, 9.4, , 10 and 11 of this Agreement shall survive termination of this Agreement.

## **10. Governing Law; Dispute Resolution**

10.1 Governing Law. This Agreement shall be governed by, interpreted and construed in accordance with, the laws of the [\*\*\*], without regard to its conflict of law provisions. The U.N. Convention on International Sales of Goods shall not apply to this Agreement.

10.2 Good Faith Meeting. In the event of any dispute arising between the Parties concerning this Agreement, Company and SAFC agree that in the first place they shall promptly meet for good faith discussions in an attempt to negotiate an amicable solution.

## **11. Miscellaneous**

11.1 Conditional Effectiveness. The effectiveness of this Agreement is conditioned upon Company and SAFC duly executing and delivering the Quality Agreement.

11.2 Publicity. Any public announcement or similar publicity with respect to this Agreement will be issued, if at all, at such times and in such manner as shall be mutually agreed in writing by the Parties.

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11.3 Use of Names. SAFC shall not use the name of Company, its Affiliates, or the names of their employees or representatives in any advertising materials or in any publication without prior written consent of Company. Company shall not use the name of SAFC, its Affiliates, or the names of their employees or representatives in any advertising materials or in any publication without prior written consent of SAFC. Notwithstanding the foregoing, Company shall be entitled to identify SAFC as the source of the API in any regulatory submission without SAFC's prior written consent.

11.4 Marks. Each Party reserves all rights to any name, trademark, service mark or logo ("Marks") it may have or hereafter acquire. Neither Party shall by this Agreement obtain any right, title or interest in or to any Marks of the other Party or its Affiliates. Accordingly, neither Party shall use any Marks confusingly similar to or likely to cause confusion with the Marks of the other or of any other person or entity. Each use by a Party of any Marks of the other Party, whether in advertising or marketing materials, websites, company announcements or offering circulars, informational materials, public events, or otherwise, shall be subject to the prior written approval of the other Party.

11.5 Limitation of Liability.

(a) NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES (SUCH AS LOST PROFITS) OR ANY SPECIAL OR PUNITIVE DAMAGES ARISING OUT OF THE PERFORMANCE OF THIS AGREEMENT OR THE QUALITY AGREEMENT, WHETHER BASED ON CONTRACT, NEGLIGENCE, STRICT LIABILITY, OTHER TORT OR OTHERWISE AND REGARDLESS OF WHETHER ANY PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. FOR PURPOSES OF THIS WAIVER, ANY LIABILITY INCURRED BY EITHER PARTY AS A RESULT OF ANY THIRD PARTY CLAIM IS NOT CONSIDERED AN INDIRECT DAMAGE.; AND

(b) NOTWITHSTANDING ANY PROVISION OF THIS AGREEMENT TO THE CONTRARY, EXCEPT AS SET FORTH IN SECTION 11.5(d) BELOW, MAXIMUM AGGREGATE LIABILITY OF SAFC AND ITS AFFILIATES TO THE COMPANY AND ITS AFFILIATES FOR A CAUSE OF ACTION (OR RELATED CAUSES OF ACTION) ARISING OUT OF OR RELATED TO THIS AGREEMENT, THE QUALITY AGREEMENT AND/OR THE DELIVERY OF THE API SHALL NOT EXCEED THE AMOUNT ACTUALLY PAID BY COMPANY TO SAFC PURSUANT TO THIS AGREEMENT FOR THE API DURING THE [\*\*\*] PERIOD IMMEDIATELY PRECEDING THE CLAIM (OR IN THE CASE OF RELATED CAUSES OF ACTION – THE FIRST CLAIM) GIVING RISE TO THE LIABILITY.

(c) The foregoing limitations in Section 11.5(a) and (b) above shall survive notwithstanding any failure of essential purpose of a limited remedy.

(d) NOTWITHSTANDING THE FOREGOING OR ANYTHING WRITTEN IN THIS AGREEMENT TO THE CONTRARY, NOTHING IN THIS SECTION 11.5 OR OTHERWISE IN THE AGREEMENT, IS INTENDED TO LIMIT OR RESTRICT AND SHALL NOT APPLY TO DAMAGES AVAILABLE FOR [\*\*\*].

11.6 Assignment; Successors; Subcontractors; Third-Party Beneficiaries.

(a) Neither Party may assign or otherwise transfer any of its rights or obligations under this Agreement without the prior written consent of the other Party, which will not be unreasonably withheld, except that either Party may assign, in whole or in part, without such consent any of its rights or obligations under this Agreement (i) to any Affiliate of such Party, provided that any such assignment to an Affiliate shall not relieve the assigning Party as the primary obligor hereunder, or (ii) in connection with the merger, consolidation or sale of the stock or substantially all of the assets of such Party relating to the performance of this Agreement. Any assignment in violation of this Section 11.6(a) shall be null and void.

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(b) Subject to the preceding subsection (a), this Agreement will apply to, be binding in all respects upon, and inure to the benefit of the successors and permitted assigns of the Parties.

(c) Nothing expressed or referred to in this Agreement will be construed to give any person other than the Parties any legal or equitable right, remedy or claim under or with respect to this Agreement or any provision of this Agreement. This Agreement and all of its provisions and conditions are for the sole and exclusive benefit of the Parties to this Agreement and their successors and assigns.

11.7 Transactions Outside Scope of Agreement. Other than as expressly provided for otherwise in this Agreement, this Agreement shall in no way limit or restrict the ability of either Party or any Affiliate of such Party to offer its products or services to any other person.

11.8 No Transfer of Rights. No transfer, grant or license of rights under any patent or copyright or to any intellectual property, proprietary information and/or trade secret is made or is to be implied by this Agreement except as may be expressly stated otherwise herein.

11.9 Independent Contractors. The Parties undertake to carry out this Agreement as independent contractors. No franchise, partnership, joint venture or relationship of principal and agent is intended by this Agreement. Neither Party is authorized, in the name of or on behalf of the other Party, to incur any obligation, receive any benefit or right or otherwise bind the other Party. All employees, agents, representatives and contractors of a Party are solely those of such Party and no acts thereof will be binding upon the other Party.

11.10 Waiver. The failure or the delay of any Party hereto to enforce at any time any provision of this Agreement shall not be construed to be a waiver of such provision or of the right of such Party thereafter to enforce such provision. No waiver of any breach of this Agreement shall be held to constitute a waiver of any other or subsequent breach of this Agreement.

11.11 Severability. Should any provision of this Agreement become void or be cancelled, then the other provisions shall remain in full force and effect. If a provision of this Agreement should be void or should be declared void, then the Parties will attempt to replace it by another valid provision or will leave the provision unreplaced by mutual consent. Any provision of this Agreement held invalid or unenforceable only in part or degree will remain in full force and effect to the extent not held invalid or unenforceable.

11.12 Appendices. All appendices attached hereto are hereby incorporated in and made a part of this Agreement as if fully set forth herein.

11.13 Entire Agreement. This Agreement, including all appendices hereto, contains the final, complete and exclusive agreement of the Parties relative to the subject matter hereof and supersedes all prior and contemporaneous understandings and agreements relating to its subject matter.

11.14 Amendment. This Agreement shall not be deemed or construed to be modified, amended, rescinded, cancelled or waived, in whole or in part, except by written amendment signed by the Parties hereto.

11.15 Notices. All notices, consents, waivers and other communications under this Agreement must be in writing and will be deemed to have been duly given when (i) delivered by hand (with written confirmation of receipt), (ii) sent by facsimile (with written confirmation of transmission), (iii) when received by the addressee if sent by registered or certified mail (return receipt requested) or if sent by an internationally recognized overnight delivery service, in each case to the appropriate addresses or facsimile numbers set forth below (or to such other addresses and facsimile numbers as a Party may designate by notice to the other Party):



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If to Company: AMAG Pharmaceuticals, Inc.  
1100 Winter Street  
Waltham, MA 02451  
Attention: VP, Technical Operations

With a copy to: AMAG Pharmaceuticals, Inc.  
1100 Winter Street  
Waltham, MA 02451  
Attention: General Counsel

If to SAFC: SAFC, Inc.  
645 Science Drive  
Madison, WI 53711  
Attention: Site Director

With a copy to: EMD Millipore Corporation  
Legal Department  
400 Summit Drive  
Burlington, MA 01803  
Attention: General Counsel

11.16 Section Headings: Construction. The headings of Sections in this Agreement are provided for convenience only and will not affect its construction or interpretation. Unless otherwise expressly provided, the word “including” does not limit the preceding words or terms.

11.17 Force Majeure. Any events that are beyond the reasonable control of a Party to prevent or overcome, such as fire, flood, war, strike, civil unrest, terrorism, natural catastrophes, government acts and regulations, embargos, epidemics, disruptions in the national transportation system, and raw material, energy or water shortages, will free the affected Party for the duration of the event from its obligations (other than the obligation to make payments of money) under this Agreement. As soon as there is an indication of an event of force majeure, the affected Party will advise the other Party within [\*\*\*] or as soon as practical of the effect of such event on this Agreement and about the measures to be taken to mitigate such effect. The Parties are obligated to mitigate damages and to resume the fulfilment of their contractual obligations as quickly as possible. Notwithstanding anything to the contrary in this Agreement, if a force majeure persists for more than [\*\*\*], then the Party not affected by such force majeure may terminate this Agreement by written notice to the other Party, with immediate effect.

11.18 Expenses. Except as otherwise expressly provided in this Agreement, in the appendices hereto or in any agreement or other document expressly referenced herein and forming a part hereof, including the Quality Agreement, each Party to this Agreement will bear its respective expenses incurred in connection the performance of its obligations hereunder. In the event of termination of this Agreement, the obligation of each Party to pay its own expenses will be subject to any rights of a Party arising from a breach of this Agreement by the other.

11.19 Counterparts. This Agreement may be executed in one or more counterparts, each of which will be deemed to be an original copy of this Agreement and all of which, when taken together, will be deemed to constitute one and the same agreement.

11.20 Governing Language. The validity, interpretation, construction and performance of this Agreement shall be in accordance with the English language. If this Agreement is translated into another language and there is a conflict between the non-English version and the English version, then the English version shall control. Notwithstanding anything

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to the contrary in this Agreement or in any other document or agreement, in the event of a conflict between this Agreement and the Quality Agreement, the Quality Agreement shall govern and control with respect to quality-related matters; and this Agreement shall govern and control with respect to all other matters.

[Signature Page Follows]

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IN WITNESS WHEREOF, the Parties intending to be bound by the terms and conditions hereof have caused this Agreement to be signed effective as of the Effective Date by their duly authorized representatives.

**SAFC, Inc.**

**AMAG Pharmaceuticals, Inc.**

By: /s/ Michael Trasatti

By: /s/ William K. Heiden

Name: Michael Trasatti

Name: William K. Heiden

Title: VP PharmaProcessing Americas

Title: President and CEO

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**APPENDIX 1**

**QUALITY AGREEMENT**

Quality Agreement between Company and SAFC, as amended, supplemented or restated from time to time (actual version).

\*\*\*

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**APPENDIX 2**

**SPECIFICATIONS**

\*\*\*

**APPENDIX 3**

**PRICING**

[\*\*\*]

## CERTIFICATIONS

I, William K. Heiden, certify that:

1. I have reviewed this Amendment No. 1 to Quarterly Report on Form 10-Q of AMAG Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: December 21, 2018

/s/ William K. Heiden

\_\_\_\_\_  
William K. Heiden

President and Chief Executive Officer  
(Principal Executive Officer)

## CERTIFICATIONS

I, Edward Myles, certify that:

1. I have reviewed this Amendment No. 1 to Quarterly Report on Form 10-Q of AMAG Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: December 21, 2018

/s/ Edward Myles

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Edward Myles

Executive Vice President of Finance, Chief Financial Officer and Treasurer  
(Principal Financial Officer)



**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with Amendment No. 1 to the Quarterly Report of AMAG Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, William K. Heiden, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ William K. Heiden

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William K. Heiden

*President and Chief Executive Officer*

*(Principal Executive Officer)*

December 21, 2018

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with Amendment No. 1 to the Quarterly Report of AMAG Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Edward Myles, Executive Vice President of Finance, Chief Financial Officer and Treasurer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Edward Myles

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Edward Myles

*Executive Vice President of Finance, Chief Financial Officer and Treasurer  
(Principal Financial Officer)*

December 21, 2018