18-02906-E

Debra Smetana
ktMINE
940 West Adams
Suite 100
Chicago, IL 60607

U.S. Securities & Exchange Commission
Office of FOIA and Privacy Act Operations
100 F Street, NE
Mail Stop 2465
Washington, DC 20549-5100


Dear Sir or Madam:

Under the Freedom of Information Act (FOIA), please send the confidential portions (i.e. unredacted documents) corresponding to the expiration of the Confidential Treatment Order submitted under Rule 24b-2 of the following company

Exhibit 10.23 to the Form S-1 filed by Affymax, Inc. on 7/28/2006

We authorize $0 for search and review fees, as these documents have been previously requested. Please contact me if search will require additional fees beyond the above mentioned. My daytime phone number is (312) 667-0267

Sincerely,

Debra Smetana

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
STATION PLACE
100 F STREET, NE
WASHINGTON, DC 20549-2465

Office of FOIA Services

March 27, 2018

Ms. Debra Smetana
ktMine
940 West Adams, Suite 100
Chicago, IL 60607

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552
Request No. 18-02906-E

Dear Ms. Smetana:

This letter is in response to your request, dated and received in this Office on March 1, 2018, for Exhibit 10.23 to the Form S-1 filed by Affymax, Inc. on July 28, 2006.

The search for responsive records has resulted in the retrieval of 14 pages of records that may be responsive to your request. They are being provided to you with this letter.

If you have any questions, please contact me directly at andersonc@sec.gov or (202) 551-8315. You may also contact me at foiapa@sec.gov or (202) 551-7900. You also have the right to seek assistance from Ray J. McInerney as a FOIA Public Liaison or contact the Office of Government Information Services (OGIS) for dispute resolution services. OGIS can be reached at 1-877-684-6448 or Archives.gov or via e-mail at ogis@nara.gov.

Sincerely,

Clarissa Anderson

Clarissa Anderson
FOIA Research Specialist

Enclosure

[ ] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 OF THE SECURITIES ACT OF 1933, AS AMENDED.

**EXHIBIT 10.23**

Dr. Shawn Lee, Ph.D.
Chief Operating Officer
American Peptide Company
777 Evelyn Avenue
Sunnyvale, CA 94086

Re: Letter Agreement (the "Letter Agreement") between Affymax, Inc., with registered offices at 4001 Miranda Avenue, Palo Alto, CA, 94304, USA, ("Affymax"), and American Peptide Company, Inc., a California corporation with registered offices at 777 Evelyn Avenue, Sunnyvale, California ("APC").

9 October, 2003

Dear Dr. Lee:

As you know, Affymax and APC have agreed to negotiate with respect to a process development and supply agreement in which APC will manufacture and supply Affymax with Affymax's requirements for Affymax's proprietary peptide product Hematide through phase II clinical trials (the "Development and Supply Agreement"). To meet the tight timelines required for APC to deliver the first samples of such peptide drug substance to Affymax, APC will need to complete the initial feasibility and process development work before the parties expect to complete negotiating the defmitive Development and Supply Agreement; however, nothing in this Letter Agreement shall obligate either party to agree and enter into a definitive Development and Supply Agreement. Thus, to allow APC to begin process development work and deliver certain amounts of peptide Drug Substance while the parties negotiate the definitive Development and Supply Agreement, we have prepared this Letter Agreement, which confirms our recent discussions and understandings. We agree as follows:

**1. Definitions.** Capitalized terms used in this Letter Agreement (other than the headings of the Paragraphs), whether used in the singular or plural, shall have the meaning set forth below, or, if not listed below, the meaning as designated in the text of this Letter Agreement.

"cGMP" shall mean then-current good manufacturing practices required by: (i) by the provisions of 21 C.F.R., parts 210 and 211 and all applicable rules, regulations, orders and guidances (as the same may from time to time be amended); and (ii) the provisions of Chapter II of EC Commission Directive 91\356\EEC together with ICH Guideline UCH Q7A (Good Manufacturing Practice for Active Pharmaceutical Ingredients, November 16, 2000).

"CMC Documentation" shall mean the documentation of analytical methods and validation procedures related to the manufacture of the Drug Substance that is prepared in accordance with the Guidelines for Industry, Analytical Methods and Validation Procedures (Chemistry, Manufacturing and Controls documentation), as published by the Center for Drug Evaluation and

Research and the Center for Biologics Evaluation and Research in August 2000, and any finalized or successor guidelines thereto.

"Drug Substance" shall mean Affymax's EPO mimetic drug Drug Substance identified as Hematide and further defined in the specifications as [AF36205] ([30K PEG])."Drug Master File" or "DMF" shall mean appropriate DMF's, as defined by FDA's Guideline for Drug Master Files, September 1989 (http://www.fda.gov/cder/guidance/dmfhtm) and EMEA (http://www.emea.eu.int/pdfs/human/qwp/013402.pdf) appropriate to support Affymax's Investigational New Drug Application ("IND") for Drug Substance.

"Control" or "Controlled" shall mean with respect to any intellectual property, that a party owns or has a license to such intellectual property and has the ability to grant to the other party access, a license or a sublicense (as applicable) to such intellectual property as provided for herein without violating the terms of any agreement or other arrangements with any third party existing at the time such party would be first required hereunder to grant the other party such access, license or sublicense.

"Development Phase" shall have the meaning set forth in Paragraph 2.

"Effective Date" shall mean the date on which this Letter Agreement is signed by the representative of APC below.

"Feasibility Phase" shall have the meaning set forth in Paragraph 2.

"Interim Specifications" shall mean the specifications for Drug Substance as described in the quotation provided by APC in a letter of 17 July 2003 identified as Quotation Number 031707¬G2 and attached as Exhibit A.

"Know-How" shall mean all technical, scientific and other know-how, information, trade secrets, knowledge, ideas, inventions, concepts, formulae, procedures, methods, processes, protocols, techniques, materials and results of experimentation and testing, including without limitation, samples, data, and results (whether or not patentable), in each case that are developed or made by a party, either solely or jointly with the other party, in the course of performance of its obligations under this Letter Agreement. Know-How expressly excludes any Patents.

"Patents" shall mean: (i) all U.S. and non-U.S. patent applications; (ii) all provisionals, converted provisionals, divisionals, continuations and continuations-in-part thereto; and (iii) all patents, issuing from the foregoing in (i) and (ii), including without limitation all extensions, re-examinations, reissues, substitutions and inventors certificates; in each case that are conceived, reduced to practice, made or developed by a party, either solely or jointly with the other party, in the course of performance of its obligations under this Letter Agreement.

**2. Project; Committed Resources; Schedule.** Affymax and APC are entering into a development and manufacturing relationship (the "Project") in which APC shall produce and provide Affymax's requirements for initial clinical supplies of Drug Substance in full compliance with certain specifications to be determined by the parties in the course of the Project and as shown in Exhibit B, pages 1 and 2 (the "Clinical Specifications") and cGMP, all as further described below. APC shall commit to the Project appropriate personnel, including without

limitation experts in technical development, manufacturing, operations, quality control, quality assurance and regulatory affairs. Affymax shall commit such of its personnel or its agents with appropriate expertise to provide reasonable monitoring and technical consultation for the Project, as appropriate and agreed upon in writing by the parties. APC recognizes the importance of timely execution of the Project and accordingly shall give priority to the Project, assign adequate staffing and other resources and use all diligent, commercially reasonable efforts to maximize the potential of achieving successful completion of the Project according to the following schedule:

APC shall complete the set-up of the process for the production of at least one hundred (100) grams of cGMP-grade Drug Substance that is suitable for human clinical use and meeting the Clinical Specifications (the "Early-Stage Clinical Drug Substance"). The Early-Stage Clinical Drug Substance shall be delivered to Affymax or Affymax's designee(s) according to instructions from Affymax. APC shall ship to Affymax or Affymax's designee approximately [20 milligrams of unPEGylated dimer] as soon as possible following synthesis of the [unPEGylated dimer] and prior to release of Early Stage Clinical Drug Substance. APC shall release at least seventy-five (75) grams and any excess up to one hundred (100) grams total and ship approximately thirty (30) grams (or as otherwise specified by Affymax) of the first batch or lot of Early-Stage Clinical Drug Substance by November 28, 2003 and retain the remainder under GM? conditions suitable for subsequent shipment(s) for clinical use in humans. APC shall ship subsequent portions of the initial batch of Early-Stage Clinical Drug Substance within five (5) business days following receipt of written instructions from Affymax; if a shipment is delayed in excess of five (5) business days, APC shall pay to Affymax [five thousand (5,000)] U.S. Dollars for each additional business day of delay unless such delay can be shown to Affymax's satisfaction to be due to a valid and reasonable cause. Upon APC's release and delivery of the first batch of Early-Stage Clinical Drug Substance to Affymax and at Affymax's request, APC shall also provide to Affymax at such time a report describing the preparation of scale up, analytical methods, stability testing, validation and CMC Documentation (the "Development Phase Report"). The Development Phase Report shall be delivered to Affymax within 10 days of shipment of the first batch of Early-Stage Clinical Drug Substance.

APC shall prepare and deliver to Affymax within the time frame set forth on Exhibit B, and if requested by Affymax, submit to the appropriate US and foreign regulatory authorities, a drug master file ("DMF") for APC's manufacture of Drug Substance within 90 days of the initial release and shipment of Early Stage Clinical Drug Substance. APC shall also provide Affymax with a letter of access allowing Affymax and its sublicencee(s) to reference the DMF in Affymax's regulatory filings. The DMF shall be in compliance with requirements for drug master file submissions to the United States Food and Drug Administration (the "FDA"). The parties acknowledge that the stability data used or included in the DMF submission shall cover only such period as is available to APC at the time it is prepared. The parties shall consult and co-operate closely with each other in relation to the preparation of the DMF and any subsequent regulatory filings and inspections related thereto. A copy of any subsequent regulatory filings shall be provided to Affymax at the time of submission to the regulatory authorities.

**3. Cost.** The cost to Affymax shall be as specified in Section (A) of Quotation 031707-G2 attached as Appendix A for [AF37093 (30K PEG)]. APC will QC release an entire one hundred (100) gram single batch of Early-Stage Drug Substance, of which approximately 30 grams or portion thereof (as will be specified by Affymax) shall be delivered to Affymax or Affymax's

designee and the remainder of the batch retained by APC and delivered according to Affymax's subsequent instructions. The total cost of the Development Phase to Affymax shall be payable as follows: Affymax shall pay APC [three hundred thousand (300,000)] U.S. Dollars within thirty (30) days after the release of the initial one hundred (100) gram batch and Affymax's receipt of the initial approximately thirty (30) gram shipment of Early-Stage Clinical Drug Substance-conforming to specifications, however, the net initial payment shall be a net sum of [one hundred and fifty thousand (150,000)] U.S. Dollars in view of the non-refundable pre-payment of [ninety thousand (90,000)] U.S. Dollars paid by Affymax to APC pursuant to the letter agreement between the parties dated July 29, 2003 and additional non-refundable pre-payment of [sixty thousand (60,000)] U.S. Dollars pursuant to the letter memorandum of September 15, 2003, and which pre-payments shall be credited against the payment due; APC may invoice Affymax upon release and shipment of at least approximately thirty (30) grams of an at least one hundred (100) gram batch or lot of Early-Stage Clinical Drug Substance conforming to specifications, including receipt of all relevant documentation and Certificate(s) of Analysis. APC will deliver and invoice the Development Phase Report including the CMC Documentation and a copy of the DMF and related information and, upon receipt and acceptance by Affymax, Affymax shall pay [six thousand five hundred (6,500)] U.S. Dollars for said Development Phase Report and [ten thousand (10,000)] U.S. Dollars for said DMF, which APC may invoice upon submission of the DMF to the Food and Drug Administration and, if so instructed by Affymax, APC shall also submit or cause to be filed a DMF with the EMEA (European Medicines Evaluation Agency) and may invoice Affymax for an additional [ten thousand (10,000)] U.S. Dollars upon submission. If requested by Affymax, APC shall reasonably undertake to file DMF or similarly required documentation in other foreign regulatory authority offices and shall be reimbursed for reasonable costs plus an amount to be determined by the parties according to industry standards and not to exceed [ten thousand dollars (10,000)] per submission. Failure of APC to deliver the CMC Documentation and file the DMF with the US Food and Drug Administration within 90 days following the initial shipment of Early-Stage Clinical Drug Substance shall result in the payment due from Affymax to APC being reduced by [two percent (2%)] per business day for each day of delay commencing upon the 91st day following the date of initial shipment of the batch of Early-Stage Clinical Drug Substance. At Affymax's discretion and with the proviso that an analytical testing method will be identified by Affymax and acquired and implemented by APC prior to study initiation, APC will conduct a two-year stability study per ICH guidelines on the Early-Stage Clinical Drug Substance which would be fully prepaid by Affymax in a total amount of [twenty thousand (20,000)] U.S. Dollars upon initialization of the test protocol. Any additional analytical and process development activities to be performed by APC, if any, will be at reasonable cost according to industry standards, shall be determined by the parties and shall be agreed upon in writing signed by authorized representatives. All amounts due by one party hereunder shall be paid in dollars by wire transfer in immediately available funds to an account designated by the receiving party.

**4. Intellectual Property; Licenses.** Except to the extent provided in this Letter Agreement, neither Affymax nor APC grants any right, title or interest in any of its information, inventions, discoveries, processes, methods, compositions, formulae, procedures, protocols, improvements, techniques, data and intellectual property of any kind, whether or not copyrightable or patentable, that exist as of the Effective Date or are developed during the term of this Letter Agreement by a party independently of its performance pursuant to this Letter Agreement

("Non-Project Intellectual Property") to the other party and made independently of any work based on information disclosed under confidentiality by the other party.

During the term of this Letter Agreement, each party shall disclose promptly to the other party in writing all Patents and Know-How. The parties shall jointly own all Patents and Know-How that relate solely to general peptide synthesis technology ("Peptide Intellectual Property"), and each party hereby assigns to the other party any of such first party's right, title and interest in all Peptide Intellectual Property necessary to provide the other party with an one-half (1/2) undivided interest in and to such Peptide Intellectual Property. Affymax shall solely own all Patents and Know-How and other intellectual property based on the Drug Substance that does not relate solely to general peptide synthesis technology ("Project Intellectual Property"), and APC shall, and hereby does, assign to Affymax any and all of APC's right, title and interest in all Project Intellectual Property.

Each party hereby grants the other party a non-exclusive, fully paid-up, worldwide license with unrestricted right to sublicense under such party's Non-Project Intellectual Property that relates solely to the manufacture and use of Feasibility Drug Substance or Early-Stage Clinical Drug Substance and, in either case, is Controlled by such party solely as may be necessary for the parties to perform their obligations under this Letter Agreement, including obligations to any current or future sublicensee(s). Affymax hereby grants to APC a non-exclusive, fully paid-up, worldwide license under the Project Intellectual Property solely for APC to manufacture the Feasibility Drug Substance or Early-Stage Clinical Drug Substance for Affymax pursuant to this Letter Agreement.

**5. Work Plan.** As soon as practicable after entering into this Letter Agreement, Affymax and APC shall mutually agree in writing on a detailed work plan for the completion of the Feasibility Phase and Development Phase of the Project (the "Work Plan"). The Work Plan shall include without limitation scale-up, purification and process development work to be carried out by APC through the Development Phase.

**6. Project Team.** As soon as practicable after entering into this Letter Agreement, Affymax and APC shall form a committee (the "Project Team"), with each party designating two (2) members of the Project Team. The Project Team will be responsible for reviewing the progress of the Project under the Work Plan and to discuss and decide on any potential revisions of the Work Plan. The Project Team may make decision only by the unanimous consensus of all members. Decisions of the Project Team must be in writing. If the Project Team is unable to reach unanimous consensus on an issue, the final decision with respect to such issue shall be made by Affymax's Chief Operating Officer, however, after the BPR has been approved and released by APC's Quality Assurance Department, issues principally related to the manufacturing facility general operations and specifically related to compliance with current Good Manufacturing Practice (cGMP) for manufacture of Early-Stage Clinical Drug Substance shall be decided by APC's Chief Operating Officer. The Project Team shall have no authority to amend or waive compliance with this Letter Agreement.

**7. Facilities and Equipment.** APC shall dedicate exclusively to the Project: (i) the manufacturing suite identified as Room 306 for synthesis and Room 401 for purification; and (ii) the equipment at its facility at Vista, California.

**8. Compliance with Laws; Change in Manufacturing Process.** APC shall comply, and shall contractually require that its Affiliates comply, with all applicable supranational, national or local laws, rules or regulations ("Applicable Laws") in discharging APC's development, supply and manufacturing obligations. APC shall obtain Affymax's prior written approval before implementing any changes in the materials, equipment, process or procedures used to manufacture Drug Substance that would constitute a "major" change. A "major" change shall be any change that results in a change to a regulatory filing for the. Drug Substance under Applicable Law.

**9. Raw Materials Services; In-Process Testing.** APC shall provide to Affymax, in accordance with the Work Plan and cGMP, all ordering, testing, inventorying and releasing services for all raw materials used in the manufacture of the Drug Substance under this Letter Agreement. As part of the CMC Documentation, APC shall document the source and testing of all starting materials and vendors/sources, amino acid derivatives and resins used, chemical reagents, solvents, and polyethylene glycol.

**10. Delivery Terms.** APC shall deliver all Feasibility Drug Substance and/or Early-Stage Clinical Drug Substance shipped via World Courier or Fed Ex to Affymax, or its agent at Affymax's request. APC shall arrange for insurance and shipping of such Drug Substance at Affymax's reasonable expense.

**11. Testing, Acceptance and Rejection.** Upon Affymax's receipt of each batch of Early-Stage Clinical Drug Substance from APC, Affymax or its designee shall have thirty (30) days (the "Testing Period") to inspect each such batch to determine its compliance with APC's warranties in Paragraph 14 of this Letter Agreement. By the end of the Testing Period, Affymax shall notify APC in writing if Affymax accepts or rejects such batch based on such testing. If Affymax were to reject any batch of Early-Stage Clinical Drug Substance, APC shall immediately commence production of a replacement fifty (50) gram batch if so instructed by Affymax in writing using best efforts to complete production and release the replacement batch withyin six weeks of receiving Affymax's written instruction, and also shall promptly notify Affymax in writing if it either: (i) agrees with the rejection, in which event APC shall request in writing that Affymax either return or destroy the rejected batch of Early-Stage Clinical Drug Substance (at no additional cost to Affymax); or (ii) dispute Affymax's rejection. If APC disputes Affymax's rejection, the APC shall promptly provide Affymax with an equivalent amount of a replacement batch of Early-Stage Clinical Drug Substance (at no additional cost to Affymax), and the parties shall engage a mutually acceptable, third party laboratory to make a final and binding determination if Affymax's rejection was proper. The fees and expenses of such laboratory testing shall be borne entirely by the party against whom such findings are made. If such laboratory determines that such batch of Early-Stage Clinical Drug Substance is in compliance with the product specifications or has not been reasonably rejected, then such batch shall automatically be deemed to have been accepted by Affymax, and Affymax will pay the amount for the batch of Early-Stage Clinical Drug Substance initially rejected by Affymax, and any replacement Early-Stage Clinical Drug Substance provided by APC, in accordance with this Letter Agreement. If such laboratory determines that such batch of Early-Stage Clinical Drug Substance has been reasonably rejected, or if APC agrees with Affymax's initial rejection, then APC shall, at Affymax's sole option, either promptly replace the rejected batch of Early-Stage Clinical Drug Substance (at no additional cost to Affymax), if APC has not already done so per

Affymax's written instruction to commence immediate production of an additional fifty (50) gram batch upon notification of Affymax's rejection and undertaken best efforts to release and ship the additional fifty (50 gram batch within six weeks of receipt of said Affymax's written instruction, or refund Affymax for any amounts actually paid by Affymax for such rejected batch of Early-Stage Clinical Drug Substance.

**12. Access.** As soon as practicable after entering into this Letter Agreement, Affymax shall have the right to place one or more Affymax representatives at the APC manufacturing site upon reasonable prior notice and during regular business hours Affymax personnel shall have access to the area of the facility where the Drug Substance is developed and manufactured (according to APC's standard operating procedures) as well as have access to copies of batch records and any other documentation relating to development and manufacture of Product by APC under this Letter Agreement and shall be free to copy and use such documentation (except for batch records which may be inspected only on APC's premises) as reasonably required for any normal regulatory or business use relating to Drug Substance. Notwithstanding the provisions of Section 4 (Intellectual Property; Licenses), Affymax agrees to keep all information related to projects, trade secrets, business information, and all other information outside of the Affymax project confidential, whether acquired intentionally or unintentionally.

**13. Audits.** Affymax shall have the right to inspect APC's records relating to the development, supply and manufacture of Drug Substance no more than once in any six (6) month period; provided, however, that Affymax may have-the right-to conduct additional inspections if such--additional inspections are otherwise required under Applicable Laws or by applicable regulatory authorities. Affymax shall also have the right to conduct fmancial audits on financials related to development and manufacturing of the Drug Substance no more than once in any twelve (12) month period.

**14. Warranties.** APC warrants and covenants that for any quantity of Feasibility Drug Substance or Early-Stage Clinical Drug Substance delivered to Affymax: (i) APC shall manufacture such quantity in accordance with cGMP and Applicable Laws; (ii) the Feasibility Drug Substance supplied by APC to Affymax shall conform to the Interim Specifications at the time of delivery; and (iii) the Early-Stage Clinical Drug Substance supplied by APC to Affymax shall conform to the Clinical Specifications, as on Exhibit A pages 1 and 2 and further defined in Exhibit B at the time of delivery.

**15. Confidentiality.** Each party shall use commercially reasonable efforts to maintain all Confidential Information (defined below) disclosed to it by the other party in trust and confidence and not disclose any such Confidential Information to any third party without the prior written consent of such other party. Furthermore, each party covenants that it shall not use the Confidential Information of the other party except to perform its obligations under this letter Agreement. As used in this Letter Agreement, "Confidential Information" shall mean all proprietary information of a party, and any tangible embodiments thereof, provided by or on behalf of such party to the other party either in connection with the discussions and negotiations pertaining to this Letter Agreement or in the course of performing this Letter Agreement, except for any portion of such information or embodiment that, as demonstrated by competent written proof: (i) is publicly disclosed by the disclosing party, either before or after it becomes known to the receiving party; (ii) was known to the receiving party, without obligation to keep it

confidential, prior to when it was received from the disclosing party; (iii) is subsequently disclosed to the receiving party by a third party lawfully in possession thereof without obligation to keep it confidential; or (iv) has been publicly disclosed other than by the disclosing party and without breach of an obligation of confidentiality with respect thereto.

**16. Term and Termination.** The term of this agreement will commence upon the signing of this Letter Agreement and, unless and until superceded by the definitive Development and Supply Agreement, shall expire on 28 February 2004. Affymax may terminate the agreement without penalty or further obligation to APC if any of the following conditions occur: (i) APC has not produced and released the first batch or lot of Early-Stage Clinical Drug Substance meeting the Clinical Specifications from the Development Phase by_December 15, 2003 or (ii) APC has not met the performance milestones outlined in the Work Plan, including without limitation any delays by APC in providing Affymax with full cooperation and compliance for Affymax to file the CMC package.

Affymax may exercise its termination right under this Letter Agreement at any time the foregoing conditions in this Paragraph 16 arise by providing a written notice to APC, and the effective date of such termination shall be three (3) months from date that Affymax provides such notice. In the event of such a termination, Affymax will pay APC for any Drug Substance - ordered by Affymax during such three (3)-month period prior to termination in accordance with the forecasts provided by Affymax at a price equal to the then-current transfer price of Drug Substance for the first two (2) quarters contained in the forecast preceding such termination, and such payment shall be made within 30 days following delivery of the ordered Drug Substance. Affymax will also pay APC the total amount of any manufacturing-specific milestone payments that accrue during the three (3) months prior to the date such termination becomes effective.

**17. Yield Improvement.** APC shall use commercially reasonable efforts to identify and target potential areas of yield improvement relating to the performance of its obligations under this Letter Agreement and the Development and Supply Agreement. APC shall pass all cost savings resulting from such yield improvement to Affymax through a reduced cost of goods for manufacturing and supplying the Drug Substance.

**18. General Terms.** This Letter Agreement, and all Exhibits attached hereto and incorporated herein, embody the entire, final and complete agreement and understanding between the parties and replace and supersede all prior discussions and agreements between them with respect to its subject matter. Any claim, dispute or controversy relating to this Letter Agreement shall be governed under the laws of the State of California and any applicable Federal laws of the United States, without regard to any conflicts of laws provisions that would require the application of laws other than those of California. Furthermore, the parties agree that the United Nations Convention on Contracts for the International Sale of Goods shall be excluded from the application of governing law. If any provision of this Letter Agreement is found by a court of competent jurisdiction to be unenforceable, then such provision will be construed, to the extent feasible, so as to render the provision enforceable, and if no feasible interpretation would save such provision, it will be severed from the remainder of this Letter Agreement. The remainder of this Letter Agreement will remain in full force and effect, unless the severed provision is essential and material to the rights or benefits received by either party. In such event, the parties will negotiate, in good faith, and substitute a valid and enforceable

provision or agreement that most nearly implements the parties' intent in entering into this Letter Agreement. The failure of a party in any one (1) or more instances to insist upon strict performance of any of the terms and conditions of this Agreement shall not constitute a waiver or relinquishment, to any extent, of the right to assert or rely upon any such terms or conditions on any future occasion.

**19. Affiliates.** Each party may use Affiliates to perform such party's obligations under this Letter Agreement; provided, however, that such party contractually binds such Affiliate to the terms and conditions of this Agreement and the original party guarantees the performance of its Affiliate. "Affiliate" shall mean any other party that, directly or indirectly, through one (1) or more intermediaries, controls, is controlled by, or is under common control with such first party. For purposes of this definition only, "control" and, with correlative meanings, the terms "controlled by" and "under common control with" shall mean: (i) the possession, directly or indirectly, of the power to direct the management or policies of a party, whether through the ownership of voting securities or by contract relating to voting rights or corporate governance; or (ii) the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities or other ownership interest of a party; provided that, if local law restricts non-U.S. ownership, control will be established by direct or indirect ownership of the maximum ownership percentage that may, under such local law, be owned by non-U.S. interests.

**20. Development and Supply Agreement.** This Letter Agreement is intended to be binding upon the parties; provided, however, that the parties shall use commercially reasonable efforts to negotiate the definitive Development and Supply Agreement in good faith as soon as practicable after the execution of this Letter Agreement. The parties expressly understand, however, that in the event the parties do not enter into the definitive Development and Supply Agreement, then the terms of this Letter Agreement shall control and continue to be binding upon the parties. The definitive Development and Supply Agreement shall contain the provisions found in this Letter Agreement, as well as other provisions that are typically found in similar commercial development and supply agreements, including without limitation: a detailed work plan for the scale-up and commercial manufacturing phases of the Drug Substance; forecasting and ordering provisions; regulatory support rights; technology transfer provisions; second source rights; risk allocation and indemnification; insurance and risk allocation; and other terms typically contained in agreements governing similar development and supply of similar products. In addition, the definitive Development and Supply Agreement will contain a provision for the parties to negotiate in good faith a subsequent commercial supply agreement and the pricing basis thereunder.

To confirm your understanding and acceptance of this Letter Agreement on behalf of APC, please sign and return to me the original of this Letter Agreement, keeping a copy of the signed Letter Agreement for your records.

We look forward to continuing and expanding our productive relationship with APC.

Best regards,

/s/ Arlene M. Morris

Arlene M. Morris
Chief Executive Officer

Accepted and agreed on behalf of APC and its Affiliates:

By: /s/ Shawn Lee

Its.: Chief Operating Officer

Date: October 9, 2003

## Exhibit A

[Attach APC quote letter of 17 July 2003 identified as Quotation Number 031707-G2]

Chris Holmes, Ph.D.
Senior Director
Affymax Research Institute
4001 Miranda Ave.
Palo Alto, CA 94304
(650) 812-8700 Phone
(650) 424-0832 Fax
chris_holmes@Affymax.com

July 17, 2003

Quotation Number 031707-G2
Quotation expires in **30 days**.

Dear Dr. Holmes:

It is my pleasure to provide you with the following proposal for the synthesis of your peptide conjugate manufactured under cGMP conditions. Please note that the quantity is in gross weight. We can probably reduce the total lead time for delivery of the first 100g by 2-4 weeks by moving chemists down to Vista from Sunnyvale and working weekends and/or second shift. The extra cost for us will be about $100,000 over ten weeks. The GMP release of the peptide prior to conjugation will take 1 week and is in the timeline calculation which we have not had time to refine as yet. Please review the information and let me know if you have any questions. We will be available to discuss this with you next week at APS.

**A) Prices:**

| Product Number | Sequence | Purity By HPLC | Quantity Gross | Price (US$) | Delivery (wks) |
|---|---|---|---|---|---|
| TBD | [AF36205] | = or >[95%] | 100 g* | [$3,000/g]<br>[$4,000/g] | [14 wks]<br>[10-12-wks] |
| | | | 1kg | [$2,000/g] | [6 mos] |
| | | | 5kg | [$1,500/g] (est.) | [12 mos] |
| | *including PEG Raw Materials Costs [$162/g x 200g = $32,400] | | | | |

**B) Specifications for GMP Release of Peptide:**

| [Attribute | Specifications | Test Methods | Performed By/SOP |
|---|---|---|---|
| Appearance | White powder | Visual | APC/STP 50.004 |
| Purity | See above | RP-HPLC | APC/STP 50.011 |
| Amino Acid Composition | ±10% of theoretical | Amino acid analysis with Beckman 6300 | APC/STP 50.012 |
| Peptide Content | ≥ 80% | Amino acid analysis with Beckman 6300 | APC/STP 50.012 |
| Primary Counter Ion | Report | Ion Chromatography | APC/STP 50.036 |
| Water Content | ≥ 10% | Karl Fischer | APC/STP 50.006 |
| Molecular weight | MW ± 1.0 | Mass Spectral Analysis | APC/STP 50.022 |
| Free thiol | < 0.05% | Ellman's | APC/STP 50.041 |
| Storage recommendation | -15 or below | | |
| Certificate of Analysis | Provided with product] | | |

**C) Specifications for GMP Release of Conjugate: TBD**

**D) Terms:**

1. Under the terms of this proposal, American Peptide Company (APC) is proposing to provide the customer with the product mentioned above. APC will prepare and provide this compound as non-sterile lyophilized bulk. The manufacturing of this product will be performed under cGMP conditions.

2. This product will be labeled as; "Caution: New Drug Substance, for manufacturing, processing, or repackaging in the preparation of a new drug or new animal drug limited by Federal (or United States) law to investigational use only, as required by 21 CRF 312.6(a)."

3. APC will purify the product with a dedicated HPLC column in a GMP-dedicated cleanroom.

4. APC warrants that the product meets the product specifications agreed to by and between APC and the customer, as determined by the analytical methods described in the product specification section.

5. APC makes no warrantees direct or implied about the suitability of this product for any use by the customer. APC is not liable for any incidental, consequential or contingent damages arising from any use of this product.

6. APC can provide the appropriate documentation that may be required for preparing regulatory product submissions, such as IND's, upon request. The cost for preparation and delivery of documentation is not included in the cost of the delivery of the product.

7. Terms: Our terms are net 30 days (upon credit check), FOB Sunnyvale or Vista, California USA. Shipping, handling & insurance charges will be added to the invoice.

Sincerely Yours,

Jim Hampton
VP Business Development
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**Exhibit B**

**Product**

| Product Number | Sequence | Purity By HPLC | Quantity Gross | Price (US$) | Delivery (wks) |
|---|---|---|---|---|---|
| 322662 | [AF37093] | = or >[95%] | 100 g | [$3,000/g] | [12 wks] |

**Specifications for Release [AF37092] Intermediate:**

| Attribute | Specifications | | Test Methods |
|---|---|---|---|
| [Appearance | White to Off-White powder | | Visual |
| Purity | ≥ 95% | | RP-HPLC |
| Amino Acid Composition | Thr 1.40 – 2.20<br>Gln 1.80 – 2.20<br>Pro 3.60 – 4.40<br>Gly 5/40 – 6.60<br>Ala 1.0 – 2.20<br>Cys: detected<br>Val 1.80 – 2.20<br>Nal: detected | Ile 1.80 – 2.20<br>Leu 3.60 – 4.40<br>Lys 1.80 – 2.20<br>Arg 1.80 – 2.20<br>Sar 1.60 – 2.40<br>Met 1.60 – 2.40<br>Tyr 1.60 – 2.40<br>His 1.60 – 2.40 | Amino acid analysis with Beckman 6300 |
| Identity | Co-elutes with reference standard | | RP-HPLC |
| Peptide Content | ≥ 75% | | Amino acid analysis with Beckman 6300 |
| TFA Counter Ion | Report | | HPLC |
| Molecular weight | MW ± 2.0 | | Mass Spectral Analysis |
| Water | Report | | KF |
| Mass Balance | Report] | | |

**Specifications for GMP Release [AF37093]:**

| Attribute | Specifications | Test Methods |
|---|---|---|
| [Appearance | White to Off-White powder | Visual |
| Identity | Co-elutes with reference standard | RP-HPLC |
| Purity | ≥ 95% | RP-HPLC systems in TFA |
| Purity | ≥ 95%<br>AF37092 ≤ 1.0% | RP-HPLC system in TFAP |
| Peptide Content | ≥ 75% | Nitrogen Determination |
| Acetic Acid | ≤ 12% | RP-HPLC |
| Water Content | ≤ 10% | Karl Fischer |
| Molecular weight | MW (average) 30,000-40,000 | Mass Spectral Analysis |
| Mass Balance | 90 – 110% | AF37093 Content/HPLC purity + Acetate + Water + Residual Solvent content |
| Storage recommendation | | |
| Certificate of Analysis | ] | |

**Additional Specifications for [AF37093] for Information Only:**

| Attribute | Specification | Test Methods | Cost |
|---|---|---|---|
| [Total Residual Organic Solvents<br>Acetonitrile Content<br>Other Individual Solvents<br>Total Solvents | Report ALL<br><br>≤ 500ppm<br>≤ 500ppm<br>≤ 2,500ppm | Ion chromatography | $1,500<br>(3 week testing time) |
| Bacterial Endotoxins | Report | LAL | $450 |
| Microbial | Report | Aerobic count | $450 |
| Solubility | Report | TBD | |
| Heavy Metals | Report | TBD | TBD] |