

**CALIFORNIA ALTERNATIVE ENERGY AND
ADVANCED TRANSPORTATION FINANCING AUTHORITY**

***Request to Approve a Time Extension for the
Initial Term of the Master Regulatory Agreement¹***

**PolyPeptide Laboratories, Inc.
Application No. 17-SM013**

Tuesday, September 15, 2020

Prepared By: *Stefani Carruth, Program Analyst*

SUMMARY

Applicant – PolyPeptide Laboratories, Inc.

Location – Torrance, Los Angeles County and San Diego, San Diego County

Industry – Peptide Pharmaceutical Manufacturing

Project – Peptide Pharmaceutical Manufacturing Facility Expansion (Advanced Manufacturing)

Total Amount Qualified Property Approved– \$12,750,000

Estimated Sales and Use Tax Exclusion Amount at Approval² – \$1,073,550

Amount of Time Requested –

- Nine months, until June 19, 2021 for the Initial Term of the Master Regulatory Agreement (three years and nine months from the date of initial CAEATFA Board approval)

Staff Recommendation – Approval

¹ All capitalized terms not defined in this document are defined in the Program’s statute and regulations.

² This amount is calculated based on the average statewide sales tax rate [of 8.36%/at the time of initial approval, which was 8.42%.

REQUEST

On September 19, 2017, the CAEATFA Board approved a sales and use tax exclusion (“STE”) for PolyPeptide Laboratories, Inc. (“PolyPeptide” or the “Applicant”) for the purchase of up to \$12,750,000 in Qualified Property to expand its existing peptide manufacturing facilities located in Torrance and San Diego (the “Project”). The Master Regulatory Agreement (“Agreement”) initial term provided the Applicant with three years from the date of Board Approval to utilize its STE award. The initial term of the Agreement can be extended by the Board upon a finding that an extension is in the public interest and advances the purposes of the Program.

As of July 30, 2020, PolyPeptide has used the STE to purchase approximately \$8,660,000 of Qualified Property (68% of the total Qualified Property approved). The Applicant is requesting to extend the Agreement initial term by nine months to accommodate delays with the City of Torrance Building Department, actual times for pre-engineering design being longer than estimated, as well as COVID-19.

According to the Applicant, the amount of time originally estimated to complete pre-engineering design ultimately did not align with the actual time frames required. Additionally, the Applicant stated that the plan check system with the City of Torrance Building Department was hacked which resulted in the plan checks being delayed. PolyPeptide also explains that the COVID-19 pandemic delayed equipment procurement and Project implementation activities by an additional four months.

THE APPLICANT

Polypeptide Laboratories, Inc. (or “Applicant”), founded in 1996, is a Delaware corporation headquartered in Torrance, California. Polypeptide manufactures pharmaceutical peptides on contract to biotechnology companies and research institutions. Many of the peptides they manufacture are used to treat rare, challenging, or life-threatening diseases, including cancer, muscular dystrophy, diabetes, and many others.

The major shareholders (10.0% or greater) of Polypeptide Laboratories, Inc. are:
Jane Salik

The corporate officers of Polypeptide Laboratories, Inc. are:
Jane Salik, CEO
Timothy Culbreath, President of U.S. Operations
Jan Fuhr Miller, CFO

THE PROJECT

Polypeptide entered into a large service contract to produce a peptide combatting a particular form of muscular dystrophy and plans to expand its Torrance and San Diego manufacturing facilities. The Applicant plans to add several new lab spaces and introduce large-scale synthesis, filtration, and purification equipment. Additionally, the Project will include a state-of-the-art

automated synthesizer, which is a relatively new technology for commercial peptide synthesis. The automated synthesizer will have the ability to be fully computer controlled, limiting mistakes by operators and helping to reduce raw material waste. PolyPeptide anticipates the Project will reduce its use of hazardous solvents per-unit of product produced, lower water intensity, and reduce production costs.

AGREEMENT INITIAL TERM EXTENSION REQUEST

PolyPeptide has requested that the initial term of the Agreement be extended from September 19, 2020 to June 19, 2021 in order to accommodate delays with the City of Torrance Building Department, pre-engineering design, as well as COVID-19.

Staff Evaluation

The Applicant explains that the estimated times did not align with the actual amount of time needed to complete pre-engineering. In an effort to avoid future delays related to time estimates and equipment purchases, PolyPeptide has hired a Senior Procurement Manager, who will be responsible for those tasks. Those tasks were previously handled by the engineering department, which was a factor in the initial delays. Another factor in the delays experienced is a computer system hack of the City of Torrance Building Department’s plan check system, which was not the fault of the Applicant, but delayed plan approvals. Additionally, PolyPeptide has experienced significant delays due to the COVID-19 pandemic, which Staff recognizes is a reality for many Applicants at this time, particularly for companies that rely on a global supply chain. According to the Applicant, the COVID-19 delays have set the Project back by approximately four months. PolyPeptide explains that a nine-month extension will allow the Applicant to finish purchasing several pieces of equipment that have manufacturing delivery times of three to eight months and require internal pre-engineering design work of an additional one to two months.

Based on this information, Staff believes extending the term of the Agreement will allow for the Project to be completed, and is therefore in the public interest and advances the purposes of the Program.

LEGAL QUESTIONNAIRE

Staff reviewed the Applicant’s responses to the questions contained in the Legal Status portion of the Application. The responses did not disclose any information that raises questions concerning the financial viability or legal integrity of this Applicant.

CAEATFA FEES

In accordance with the STE Program Regulations,³ the Applicant has paid an additional fee of \$500 because extending the initial term requires a modification to the Applicant’s Master Regulatory Agreement.

³ California Code of Regulations Title 4, Division 13, Section 10036

RECOMMENDATION

Staff recommends that the Board approve PolyPeptide Laboratories, Inc.'s request to extend the initial term of the Agreement by nine months to June 19, 2021 as it is in the public interest and advances the purposes of the Program.

Attachments

Attachment A: PolyPeptide Laboratories, Inc.'s letter requesting waiver (July 30, 2020)

Attachment B: PolyPeptide Laboratories, Inc.'s staff summary at the time of approval

**RESOLUTION APPROVING A TIME EXTENSION FOR
POLYPEPTIDE LABORATORIES, INC.'S INITIAL TERM FOR
THE MASTER REGULATORY AGREEMENT**

September 15, 2020

WHEREAS, on September 19, 2017 the California Alternative Energy and Advanced Transportation Financing Authority (the "Authority"), a public instrumentality of the State of California, approved a Sales Tax Exclusion ("STE") in the amount of \$12,750,000 of Qualified Property for PolyPeptide Laboratories, Inc. (the "Applicant"); and

WHEREAS, within three years of the approval by the Authority, the Applicant must make all purchases of the total amount of Qualified Property listed in the approval resolution (Regulations Section 10035(b)(1)); and

WHEREAS, upon a finding that it is in the public interest and advances the purposes of the Program, the Authority may waive the requirement that all purchases of Qualified Property be made within three years of Application approval (Regulations Section 10035(b)(1)(A)); and

WHEREAS, the Applicant has requested a waiver of the requirement to purchase all of the Qualified Property by September 19, 2020 due to unexpected delays in the Project timeline, extending the term by nine months to June 19, 2021; and

WHEREAS, granting the waiver will allow the Project to proceed and the state to receive the anticipated environmental and economic benefits that justified the initial approval of the Project in accordance with the law, thereby advancing both the public interest and the purposes of the Program.

NOW THEREFORE BE IT RESOLVED by the California Alternative Energy and Advanced Transportation Financing Authority, as follows:

Section 1. The Authority finds that it is in the public interest and advances the purposes of the Authority to extend the initial term of the Agreement to June 19, 2021.

Section 2. This resolution shall take effect immediately upon its passage.

Attachment A: PolyPeptide Laboratories, Inc’s Letter Requesting Waiver (July 30, 2020)

DOCUMENT: CAEATFA Extension Request		
WRITTEN BY: Zac Beyer		

COMPANY INFO:

The PolyPeptide Group
375 Maple Avenue, Torrance, CA 90503

REMARKS:

PolyPeptide Group formally requests a waiver for a time extension for its CAEATFA Master Regulatory agreement by a period of 9 months from its current expiration date of September 17, 2020.

This extension is necessary as PolyPeptide Group will not meet its initial term deadline specified in the MRA. This failure to meet the term deadline is rooted in the following key issues: original internal time estimations for pre-engineering design on equipment and projects were not reflective of actual times needed to complete such activities, the City of Torrance Building Department & plan check system was hacked in early 2020, shutting down plan check on projects that are pre-requisites to other projects listed in the MRA, and the global pandemic, COVID-19, effectively delayed all projects and equipment procurement activities by 4 months.

A 9-month extension will allow PolyPeptide Group to utilize CAEATFA for several equipments that have manufacturing delivery timelines of 3 and 8 months and require internal pre-engineering design work efforts of 1-2 months. These equipments include a Tray Lyophilizer (Item 23 on MRA), an R&D laboratory (Item 12 on MRA), and Large-Scale Automated Synthesizers (Item 22 on MRA).

Upon approval of its semi-annual report for January 1, 2020 – June 31, 2020, PolyPeptide Group has purchased \$8,660,000.00 of qualified property and therefore has a remainder \$4,090,000.00 of qualified property to purchase according to their master regulatory agreement.

PolyPeptide Group anticipates the remaining qualified property shall be purchased in the following periods upon approval of this extension request:

Q4, 2020: \$1,090,000

Q1, 2021: \$2,000,000

Q2, 2021: \$1,000,000

In support of meeting the new term deadline proposed by this extension request, PolyPeptide Group has hired a Senior Procurement Manager to support equipment purchases and negotiations with vendors/manufacturers/contractors. In the past, this task was handled by the Engineering department and would detract from the Engineering department’s ability to focus on pre-engineering design work for related projects.

Additionally, PolyPeptide Group has agreed with several customers to spend beyond the remaining \$4,090,000 in equipment purchases through 2020 in support of existing AND new batch manufacturing lines at the Torrance location.

DOCUMENT: CAEATFA Extension Request		
WRITTEN BY: Zac Beyer		

We appreciate your consideration for an extension.

Warm Regards,

PolyPeptide Group

Zachary Beyer 07/30/2020

Zachary Beyer
PPL – Engineering

CONFIDENTIAL

Attachment B: PolyPeptide Laboratories, Inc’s Staff Summary at the Time of Approval

**CALIFORNIA ALTERNATIVE ENERGY AND
ADVANCED TRANSPORTATION FINANCING AUTHORITY**

Request to Approve Project for Sales and Use Tax Exclusion (STE)⁴

**PolyPeptide Laboratories, Inc.
Application No. 17-SM013**

Tuesday, September 19, 2017

Prepared By: *Joel Schwartz, Blue Sky Consulting Group with Melanie Holman, Analyst*

SUMMARY

Applicant – PolyPeptide Laboratories, Inc.

Location – Torrance, Los Angeles County and San Diego, San Diego County

Industry – Peptide Pharmaceutical Manufacturing

Project – Expansion of Existing Peptide Pharmaceutical Manufacturing Facility (Advanced Manufacturing)

Value of Qualified Property – \$12,750,000

Estimated Sales and Use Tax Exclusion Amount⁵ – \$1,073,550

Application Score –

Fiscal Benefits Points:	956
<u>Environmental Benefits Points:</u>	<u>53</u>
Net Benefits Score:	1,009

<u>Additional Benefits Points:</u>	<u>129</u>
Total Score:	1,138

Staff Recommendation – Approval

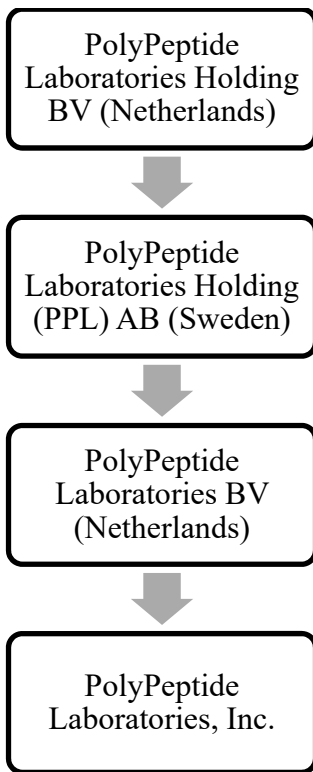
⁴ All capitalized terms not defined in this document are defined in the Program’s statute and regulations.

⁵ This amount is calculated based on the average statewide sales tax rate of 8.42%.

THE APPLICANT

PolyPeptide Laboratories, Inc. (or “Applicant”), a Delaware corporation, is a part of the PolyPeptide Group. PolyPeptide manufactures pharmaceutical peptides on contract to biotechnology companies and research institutions. According to the Applicant, many of the peptides the company manufactures are used to treat rare, challenging, or life threatening diseases, including cancer, muscular dystrophy, and diabetes.

The ownership structure of PolyPeptide Laboratories, Inc. is as follows:



The corporate officers of PolyPeptide Laboratories, Inc. are:

Timothy Culbreath, President of U.S. Operations

The corporate officers of PolyPeptide Holding AB are:

Jane Salik, Chief Executive Officer
Lars-Göran Peter Nilsson, Board Member
Jeffrey David Hobbs, Chairman of the Board
Erik Henricus Maria Schropp, Board Member
Jan Christensen, Global Sales and Marketing Director
Folke Flateland, Global Director of Process Excellence
Jan Fuhr Miller, Chief Financial Officer

THE PROJECT

PolyPeptide is requesting a sales and use tax exclusion to expand its existing peptide manufacturing facilities located in Torrance and San Diego (the “Project”). The Applicant represents it recently entered into a large service contract to produce a peptide combatting a particular form of muscular dystrophy, and with this expansion, the Applicant can begin to produce larger quantities of peptide active pharmaceutical ingredients. The Project will add several new lab spaces and introduce large-scale synthesis, filtration, and purification equipment. Additionally, the Project will include a state-of-the-art automated synthesizer, which is a relatively new technology for commercial peptide synthesis. According to the Applicant, the automated synthesizer will have the ability to be fully computer controlled, limiting mistakes by operators and helping to reduce raw material waste. Additionally, the Applicant represents the

Project will reduce the use of hazardous solvents per unit of product produced, and is anticipated to reduce water use.

ANTICIPATED COSTS OF QUALIFIED PROPERTY

The anticipated Qualified Property purchases are listed below:

New Quality Control labs	\$ 1,000,000
New production labs	2,000,000
Lab instruments	1,500,000
New Research & Development labs	1,000,000
New synthesis reactors	500,000
New Purification and Ultrafiltration equipment	2,500,000
Solvent Delivery Upgrades	2,000,000
Automated Synthesizers	1,500,000
Software upgrades	500,000
Environmental, Health & Safety upgrades	250,000
Total	<u>\$12,750,000</u>

Note: The Qualified Property purchases reported in the Application and shown here in staff's report are estimated costs. At the termination of the master regulatory agreement a finalized project equipment list will be prepared detailing the value of the Project equipment acquired and detailing the actual tax benefit realized pursuant to Revenue and Tax Code Section 6010.8. Variance from the costs shown in the Application and in this report may occur prior to the closing due to increased costs of certain components (of the Project) over original estimates, and other reasons. In addition, such costs may vary after closing due also to increased costs, as well as common design and equipment modifications during construction, differences in equipment due to future changes in law or regulation, or for other reasons.

TIMELINE

The project is scheduled to begin toward the end of 2017 at the Torrance facility, and be finished by late 2019. At the San Diego facility, the project is scheduled to begin early in 2018 and to be finished by early 2020.

PROJECT EVALUATION

NET BENEFITS

The total cost of the Qualified Property purchases is anticipated to be \$12,750,000 and the total net benefits are valued at -\$47,297 for the Project. Although the cumulative fiscal benefits fall short of the estimated sales and use tax exclusion amount, resulting in a negative net benefit, the Project has additional environmental and employment related benefits that are not quantifiable in fiscal terms. The Project received a Total Score of 1,138 points, which exceeds the required 1,000 point threshold, and a total Environmental Benefits Score of 53 points, which exceeds the 20 point threshold.

- A. Fiscal Benefits (956 points).** The net present value of the total fiscal benefits over the lifetime of the Qualified Property is derived from the Applicant's sales taxes, personal income taxes paid by the firm's employees, firm taxes on profits, property taxes and other indirect fiscal benefits of the Applicant which amounts to \$1,026,253 resulting in a Fiscal Benefits score of 956 points for the Project.
- B. Environmental Benefits (53 points).** The Project will result in an Environmental Benefits Score of 53. The Applicant received points in the following categories:
- 1. Environmental Sustainability Plan (20 of 20 points).** The Applicant will implement an environmental sustainability plan for its Project that it represents will result in energy efficiency programs, incentives for electric and hybrid cars, and exploration of solvent recycling programs to reduce hazardous waste.
 - 2. Energy Consumption (10 of 30 points).** The Applicant represents that its manufacturing process will result in a 10% reduction in energy consumption relative to the industry standard manufacturing process.
 - 3. Water Use (10 of 30 points).** The Applicant represents that its manufacturing process will result in a 10% reduction in water use relative to the industry standard manufacturing process.
 - 4. Hazardous Waste (13 of 30 points).** The Applicant represents that its manufacturing process will result in a 13% reduction in hazardous waste produced relative to the industry standard manufacturing process.
- C. Additional Benefits (129 points).** Applicants may earn additional points for their Total Score. The Applicant submitted information and received 129 additional points.
- 1. Permanent Jobs (45 of 75 points).** The Applicant represents that the Project will support a total of 225 permanent jobs at its Facilities. CAEATFA estimates that approximately seven of these jobs will be attributable to a marginal increase in jobs created due to the approved STE
 - 2. Construction Jobs (0 of 75 points).** The Applicant represents that the Project will support a total of 15 construction jobs at its Facilities. CAEATFA estimates that none of these jobs will be attributable to a marginal increase in jobs created due to the approved STE. Zero points were awarded because the marginal increase in jobs does not meet the required threshold.
 - 3. Unemployment (9 of 50 points).** The Applicant's Project is located in Los Angeles County, which has an average annual unemployment rate of 8.2%. This is above 110% of the statewide average annual unemployment rate which

was 7.5% in 2014, the dataset used in the application. This results in an Unemployment Score of 9 points for this Project.

4. **Research and Development Facilities (25 points)**. The Applicant has verified that it has a facility located in California that performs research and development functions related to industrial biotechnology.
5. **Workforce Partnerships (25 points)**. The Applicant has a partnership with El Camino College for the purpose of training the workers at the Facilities and/or for the purposes of assisting in the training of potential future workers.
6. **Industry Cluster (40 points)**. The industry associated with this Application has been identified by the Los Angeles County Economic Development Corporation as a biotechnology industry cluster of the region of the Project's location.

STATUS OF PERMITS/OTHER REQUIRED APPROVALS

PolyPeptide's existing facilities are already zoned for commercial manufacturing, so no additional zoning permits are required for the project. The Project will require inspections and verification of construction plans by city and county officials. PolyPeptide does not expect these requirements to cause any delays to the project schedule.

LEGAL QUESTIONNAIRE

Staff reviewed the Applicant's responses to the questions contained in the Legal Status portion of the Application. The responses did not disclose any information that raises questions concerning the financial viability or legal integrity of this Applicant.

CAEATFA FEES

In accordance with CAEATFA Regulations,⁶ the Applicant has paid CAEATFA an Application Fee of \$6,375 and will pay CAEATFA an Administrative Fee of \$51,000.

RECOMMENDATION

Staff recommends approval of Resolution No. 16-SM013 for PolyPeptide Laboratories. Inc.'s purchase of Qualified Property in an amount not to exceed \$12,750,000 anticipated to result in an approximate sales and use tax exclusion value of \$1,073,550.

⁶ California Code of Regulations Title 4, Division 13, Section 10036

RESOLUTION APPROVING AND AUTHORIZING EXECUTION OF A MASTER REGULATORY AGREEMENT WITH POLYPEPTIDE LABORATORIES, INC.

September 19, 2017

WHEREAS, the California Alternative Energy and Advanced Transportation Financing Authority (the “Authority” or “CAEATFA”) has received the Application of **PolyPeptide Laboratories, Inc.** (the “Applicant”), for financial assistance in the form of a master regulatory agreement (the “Agreement”) regarding tangible personal property utilized in an Advanced Manufacturing process or for the design, manufacture, production or assembly of Advanced Transportation Technologies or Alternative Source products, components, or systems (“Qualified Property”) as more particularly described in the staff summary and in the Applicant’s Application to the Authority (collectively, the “Project”); and

WHEREAS, the Applicant has requested the Authority to enter into the Agreement to acquire Project equipment with an estimated cost not to exceed \$12,750,000 over a period of three years; and

WHEREAS, the Applicant believes that this form of financial assistance will enable it to avail itself of the benefits of an exclusion from sales and use taxes relative to the Qualified Property pursuant to California Revenue and Taxation Code Section 6010.8; and

WHEREAS, approval of the terms of the Agreement and authority for the Executive Director, Deputy Executive Director, or Chair of the Authority to execute the necessary documents to effectuate the Agreement is now sought;

NOW, THEREFORE, BE IT RESOLVED by the California Alternative Energy and Advanced Transportation Financing Authority, as follows:

Section 1. The Project constitutes a “project” within the meaning of Public Resources Code Section 26003(a)(8)(B).

Section 2. The requested master regulatory agreement constitutes “financial assistance” within the meaning of Public Resources Code Section 26003(a)(6).

Section 3. The Applicant is a “participating party” within the meaning of Public Resources Code Section 26003(a)(7).

Section 4. The Executive Director, Deputy Executive Director, or Chair of the Authority (the “Authorized Signatories”) are hereby authorized for and on behalf of the Authority to approve any changes to the Project as the Executive Director shall deem appropriate, provided that the amount of the Qualified Property to be purchased may not be increased above the amount approved by the Authority.

Section 5. The proposed form of the Agreement between the Applicant and the Authority, as filed with the Authority prior to this meeting, is hereby approved. The Authorized Signatories

are hereby authorized and directed, for and on behalf and in the name of the Authority, to execute, acknowledge and deliver to the Applicant the Agreement in substantially the form filed with or approved by the Authority, with such insertions, deletions or changes therein as the Authorized Signatory executing the same may require or approve, and with particular information inserted therein in substantial conformance with the staff summary and in the Applicant's Application to the Authority, such approval to be conclusively evidenced by the execution and delivery thereof. The Authority understands and agrees that pursuant to the terms of the Agreement, the obligations of the Applicant may, under some circumstances, be carried out or assumed by a successor or assignee entity, or by an affiliate of the Applicant.

Section 6. Each of the Authorized Signatories, acting alone, is hereby authorized and directed to do any and all ministerial acts, including (without limitation) the execution and delivery of any and all documents and certificates they may deem necessary or advisable in order to consummate the Agreement and otherwise effectuate the purposes of this Resolution.

Section 7. The Applicant shall assure CAEATFA that all Qualified Property listed in the semi-annual reports pursuant to the Agreement shall be installed, maintained and operated in compliance with all applicable local, state and federal laws.

Section 8. The Agreement shall only apply to Qualified Property that the Applicant certifies will be installed, maintained and operated at facilities within the State of California.

Section 9. The adoption by the Authority of this Resolution for the Applicant shall not be referred to in any application before any governmental agency as evidence of the feasibility, practicality or suitability of the Project or in any application for any required permission or authority to acquire, construct or operate the Project.

Section 10. This Resolution is effective immediately and will remain in full force and effect unless the Regulatory Agreement, as defined in CAEATFA Regulations Section 10035(a), is not executed within thirty (30) days of the date of this Resolution. The Executive Director may extend the thirty days if necessary.