CALIFORNIA ALTERNATIVE ENERGY AND ADVANCED TRANSPORTATION FINANCING AUTHORITY

Request to Approve a Time Extension for the Initial Term of the Master Regulatory Agreement[1]

Boehringer Ingelheim Fremont, Inc.
Application No. 17-SM043

Tuesday, April 21, 2020

Prepared By: *Xee Moua, Program Analyst*

SUMMARY

Applicant – Boehringer Ingelheim Fremont, Inc.

Location – Fremont, Alameda County

Industry – Biopharmaceutical

Project – Biopharmaceutical Manufacturing Facility Expansion (Advanced Manufacturing)

Total Amount Qualified Property Approved– $214,040,484

Estimated Sales and Use Tax Exclusion Amount at Approval[2] **–** $18,022,209

Amount of Time Requested –

- Three years, until May 16, 2023 for the Initial Term of the Master Regulatory Agreement (Three years from the date of initial CAEATFA Board approval)

Staff Recommendation – Approval

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[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%.

REQUEST

On May 16, 2017, the CAEATFA Board approved a sales and use tax exclusion ("STE") for Boehringer Ingelheim Fremont, Inc. ("Boehringer" or the "Applicant") for the purchase of up to $214,040,484 in Qualified Property to expand its biopharmaceutical manufacturing facility in Fremont (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.

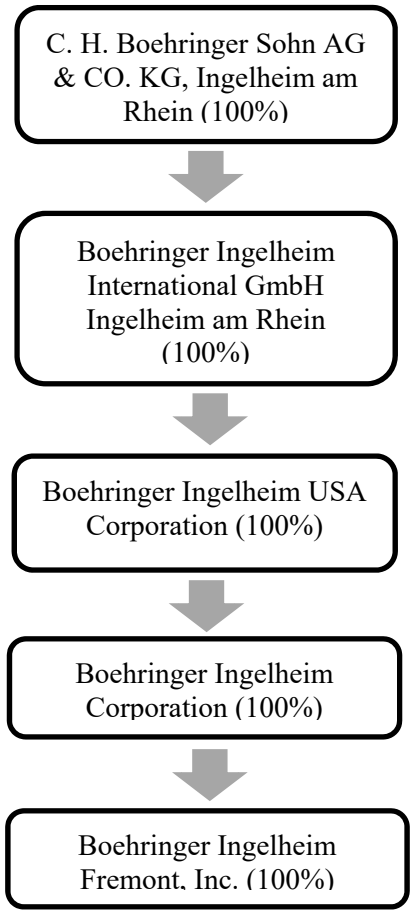
As of March 9, 2020, Boehringer has used the STE award to purchase approximately $104.5 million of Qualified Property (49% of the total Qualified Property approved) and began production in November 2018. The Applicant is requesting to extend the Agreement initial term by three years to accommodate permitting and building delays.

As described by the Applicant, its inability to secure project permits have led to delayed construction, Qualified Property purchases, and production. According to Boehringer, the Project requires specialized units to help adequately store production materials before manufacturing operations can be initiated. However, because of permitting delays with PG&E and the City of Fremont, the structures have not been built as anticipated and a new timetable had to be established. To expedite the permitting process, Boehringer states it has been working closely with the related localities, energy providers, and Governor's office to help identify and rectify the issues. Furthermore, Boehringer states that global trade issues have also contributed to delays in making and receiving purchases from foreign vendors. Boehringer represents that its new timeline involves expending approximately $37.6 million of the approved Qualified Property in 2020, $31.7 million in 2021, $23 million in 2022, and any remaining STE amount through May 2023 should the extension request become approved.

THE APPLICANT

Boehringer Ingelheim Fremont, Inc. is a Delaware Corporation incorporated in 2011. The Company is a subsidiary of C.H. Boehringer Sohn AG & CO. KG, Ingelheim am Rhein, a leading biopharmaceutical contract manufacturer with worldwide operations.

The ownership structure of Boehringer is as follows:



The corporate officers of Boehringer are:

Dr. Wolfgang Baiker, President and Chief Executive Officer

Christian Orth, Senior Vice President and Chief Financial Officer

Sheila Denton, Senior Vice President, General Counsel and Secretary

Paula Wittmayer, Assistant Secretary

Howard Korn, Assistant Treasurer

THE PROJECT

The Applicant requested a sales and use tax exclusion to expand its biopharmaceutical manufacturing facility in Fremont. Boehringer currently has two 12,000L bioreactors, and will add a third 12,000L bioreactor and a 3,000L Media feed tank through the expansion. This will allow the Company to increase commercial manufacturing. The Project will produce both biologics (genetically engineered proteins derived from genes) and biosimilars (a biologic medical product that is nearly identical to an FDA-approved biologic). The Applicant represents that this type of biotechnology is achieved by the manipulation of gene expression in an

organism such that it expresses large amounts of a recombinant gene. This includes the transcription of the recombinant DNA to messenger RNA (mRNA), the translation of mRNA into polypeptide chains, which are ultimately folded into functional proteins and may be targeted to specific subcellular or extracellular locations. The products produced at the Boehringer facility will be used in other pharmaceutical products to treat cancer. However, Boehringer does not know which specific biologics and biosimilars will be produced at the facility at this time, because the facility will be producing products that are used by other biopharmaceutical manufacturers in their final products. Several different biologics and biosimilars are expected to be produced by the facility, and the majority have already been approved by the Food and Drug Administration.

The Project will utilize state-of-the-art equipment due to the complexity of biologic manufacturing. Cells are grown for a specified amount of time, and transferred to a large container to undergo fermentation. Then, media is added to help the cells grow in a specific manner. Once this step is complete, the cells secrete the desired protein or antibody. During this process, the cells go through multiple purification steps using filters and resins to remove impurities such as viruses, cell debris, and other minerals and undesirable elements. At the end of the purification process, the product is suitable for human use. The manufacturing process steps will be controlled by a validated Distributed Control System and Laboratory Information Management System and are monitored and evaluated on a routine basis using statistical analysis and trending software. In addition, the Applicant's electronic systems are capable of keeping electronic manufacturing batch records, which guarantees that the complete history of each batch is easily accessible and comprehensive.

AGREEMENT INITIAL TERM EXTENSION REQUEST

Boehringer has requested that the initial term of the Agreement be extended from May 16, 2020 to May 16, 2023 to accommodate permitting and building delays.

Staff Evaluation

According to the Applicant, it has not been able to complete the Project due to extensive permitting as well as trade issues beyond its control. Boehringer is currently working closely with the localities, with assistance from the Governor's office, to ensure it obtains the necessary permits, and it projects to spend the remainder of its award over the next three years. Boehringer states it has increased its manufacturing capabilities by 150%, and it has contractual agreements with its customers to ensure its products are manufactured in a timely manner.

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 purpose 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 CAEATFA 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.

RECOMMENDATION

Staff recommends that the Board approve Boehringer's request to extend the initial term of the Agreement by three years to May 16, 2023 as it is in the public interest and advances the purpose of the program.

Attachments

Attachment A: Boehringer Ingelheim Fremont, Inc.'s letter requesting waiver (March 26, 2020)
Attachment B: Boehringer Ingelheim Fremont, Inc.'s staff summary at the time of approval

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

RESOLUTION APPROVING A TIME EXTENSION FOR BOEHRINGER INGELHEIM FREMONT, INC.'S INITIAL TERM FOR THE MASTER REGULATORY AGREEMENT

April 21, 2020

WHEREAS, on May 16, 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 $214,040,484 of Qualified Property for **Boehringer Ingelheim Fremont, 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 within three years by May 16, 2020 due to unexpected delays in the Project timeline, extending the term three years to May 16, 2023; 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 May 16, 2023.

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

Attachment A: Boehringer Ingelheim Fremont, Inc.'s Letter Requesting Waiver (March 26, 2020)

Boehringer Ingelheim

Howard Korn
Site Finance Lead
Boehringer Ingelheim Fremont, Inc.
6755 Kaiser Drive, Fremont CA, 94555

March 26, 2020

CAEATFA
915 Capitol Mall Room 538
Sacramento, CA 94814

Dear CAEATFA,

Boehringer Ingelheim would respectfully request an extension of our award that is set to expire on May 16, 2020. Our 2017 award was designed to help with our expansion at our biotechnology facility. Unfortunately due to a number of issues outside of our control, we are asking another 3-year term till 2023 to meet our milestones.

While our Fremont facility continues to spend funds and expand, we have had a number of hiccups along the way that has delayed our purchasing abilities. As has been well-documented with state and local entities, we have had a number of permit delays that have had a rolling effect to postpone purchase abilities. Many of our large purchases require specialized storage. The delay on permits from the city, state, county and energy providers has deferred construction, which has in turn inhibited our ability to store such products. As a global company with purchases around the world, the international trade concerns have added to such delays.

We have increased our manufacturing capabilities by 150%, which is helping bring lifesaving treatments to patients around the world. We continue to use these funds for additional manufacturing capabilities and storage to store both raw materials and finished products before the biologics can be dispersed through the pharmaceutical supply chain.

Lastly, the site has undergone a complete leadership change since our award, with a new site head and financial department who had zero knowledge of the award or its intricacies.

To date we have spent $104,549,663.07. We have projections to spend $37,630,000 in 2020, $31.685,000 in 2021, $22,960,200 in 2022. That leaves us with a delta of $12,274,463 that we plan to spend till our term ends in May 2023.

We have been working closely with the localities and the Governor's office to help us in expediting outstanding permits to ensure that our materials can be stored adequately. As a contract manufacturer, we have contractual agreements to ensure that products are manufactured in a timely manner. As such, there are multiple pressures on the site to make this new deadline happen.

Thank you very much for your consideration.

Sincerely,

Howard Korn

Attachment B: Boehringer Ingelheim Fremont, 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]

Boehringer Ingelheim Fremont, Inc.
Application No. 17-SM043

May 16, 2017

Prepared By: *Ellen Hildebrand, Analyst*

SUMMARY

Applicant – Boehringer Ingelheim Fremont, Inc.

Location – Fremont, Alameda

Industry – Biopharmaceutical

Project – Biopharmaceutical Manufacturing Facility Expansion (Advanced Manufacturing)

Value of Qualified Property – $214,040,484

Estimated Sales and Use Tax Exclusion Amount[5] – $18,022,209

Application Score[6] –

Fiscal Benefits Points:	3,262
Environmental Benefits Points:	140
Net Benefits Score:	**3,402**
Additional Benefits Points:	95
Total Score:	**3,497**

Staff Recommendation – Approval

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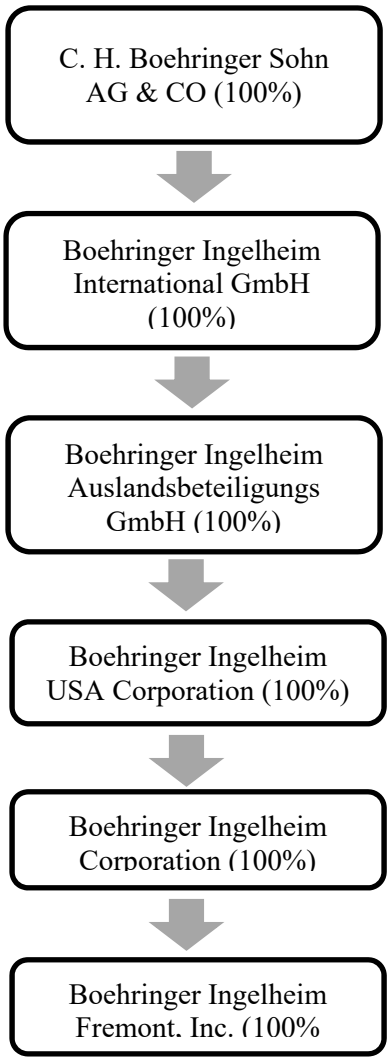
[4] All capitalized terms not defined in this document are defined in the Program's statute and regulations.
[5] This amount is calculated based on the average statewide sales tax rate of 8.42%.

THE APPLICANT

Boehringer Ingelheim Fremont, Inc., ("Boehringer", the "Applicant", or the "Company") is a Delaware Corporation incorporated in 2011. The Company is a subsidiary of C.H. Boehringer Sohn AG & CO, a leading biopharmaceutical contract manufacturer with worldwide operations.

The ownership structure of Boehringer is as follows:



The corporate officers of Boehringer are:

Jens Vogel, President and Chief Executive Officer

Christian Orth, Senior Vice President and Chief Financial Officer

Desiree Ralls-Morrison, Senior Vice President, General Counsel and Secretary

Paula Wittmayer, Assistant Secretary

Kyung Lee, Assistant Treasurer

THE PROJECT

The Applicant is requesting a sales and use tax exclusion to expand their biopharmaceutical manufacturing facility in Fremont (the "Project"). Boehringer currently has two 12,000L bioreactors, and will add a third 12,000L bioreactor and a 3,000L Media feed tank through the expansion. This will allow the Company to increase commercial manufacturing. The Project will produce both biologics (genetically engineered proteins derived from genes) and biosimilars

(a biologic medical product that is nearly identical to an FDA-approved biologic). The Applicant represents that this type of biotechnology is achieved by the manipulation of gene expression in an organism such that it expresses large amounts of a recombinant gene. This includes the transcription of the recombinant DNA to messenger RNA (mRNA), the translation of mRNA into polypeptide chains, which are ultimately folded into functional proteins and may be targeted to specific subcellular or extracellular locations. The products produced at the Boehringer facility will be used in other pharmaceutical products to treat cancer. However, Boehringer does not know which specific biologics and biosimilars will be produced at the facility at this time, because the facility will be producing products that are used by other biopharmaceutical manufacturers in their final products. Several different biologics and biosimilars are expected to be produced by the facility, and the majority have already been approved by the Food and Drug Administration.

The Project will utilize state-of-the-art equipment due to the complexity of biologic manufacturing. Cells are grown for a specified amount of time, and transferred to a large container to undergo fermentation. Then, media is added to help the cells grow in a specific manner. Once this step is complete, the cells secrete the desired protein or antibody. During this process, the cells go through multiple purification steps using filters and resins to remove impurities such as viruses, cell debris, and other minerals and undesirable elements. At the end of the purification process, the product is suitable for human use. The manufacturing process steps will be controlled by a validated Distributed Control System and Laboratory Information Management System and are monitored and evaluated on a routine basis using statistical analysis and trending software. In addition, the Applicant's electronic systems are capable of keeping electronic manufacturing batch records, which guarantees that the complete history of each batch is easily accessible and comprehensive.

ANTICIPATED COSTS OF QUALIFIED PROPERTY

The anticipated Qualified Property purchases are listed below:

Physical Project Structure & Demolition		$ 3,743,353
Process Equipment and Materials & Spare Parts		10,297,131
Cell Culture Media		70,000,000
Resins for Purification		70,000,000
Tangential Flow Filters		20,000,000
Excipients and Other Chemicals		20,000,000
Other Materials for Manufacturing		20,000,000
	Total	**$214,040,484**

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

Boehringer expects to make significant Qualified Property purchases in the second half of 2017 and first half of 2018. The Project is expected to be complete and operational in summer 2018.

PROJECT EVALUATION

NET BENEFITS

The total cost of the Qualified Property purchases is anticipated to be $214,040,484 and the total net benefits are valued at $40,764,795 for the Project. The Project received a Total Score of 3,497 points, which exceeds the required 1,000 point threshold and a total Environmental Benefits Score of 140 points, which exceeds the 20 point threshold.

A. Fiscal Benefits (3,262 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 $58,787,003 resulting in a Fiscal Benefits score of 3,262 points for the Project.

B. Environmental Benefits (140 points). The Project will result in an Environmental Benefits Score of 140 points. 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 tracking of air emissions, water use, energy use, solid waste, and hazardous waste.

2. **Energy Consumption (30 of 30 points).** The Applicant represents that its manufacturing process will result in a 35% reduction in energy consumption relative to the industry standard manufacturing process.

3. **Water Use (30 of 30 points).** The Applicant represents that its manufacturing process will result in a 30% reduction in water use relative to the industry standard manufacturing process.

4. **Solid Waste (30 of 30 points).** The Applicant represents that its manufacturing process will result in a 30% reduction in solid waste produced relative to the industry standard manufacturing process.

5. **Air Pollutants (30 of 30 points).** The Applicant represents that its manufacturing process will result in a 30% reduction in air pollutants produced relative to the industry standard manufacturing process.

C. Additional Benefits (70 points). Applicants may earn additional points for their Total Score. The applicant submitted information and received 95 additional points.

1. **Permanent Jobs (20 of 75 points).** The Applicant represents that the Project will support a total of 717 permanent jobs at its Facility. CAEATFA estimates that approximately 13 of these jobs will be attributable to a marginal increase in jobs created due to the approved STE resulting in a Permanent Jobs Score of 20 points for the Project.

2. **Construction Jobs (0 of 75 points).** The Applicant represents that the Project will support a total of 30 construction jobs at its Facility. CAEATFA estimates that approximately one 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. **Research and Development Facilities (25 points).** The Applicant has verified that it has a facility located in Fremont, California that performs research and development functions related to biopharmaceutical manufacturing process.

4. **Industry Cluster (25 points).** The industry associated with this Application has been identified by the State of California's Employment Development Department as an industry cluster of the region of the Project's location.

STATUS OF PERMITS/OTHER REQUIRED APPROVALS

Boehringer's expansion will require building and fire permits, which have not been submitted at this stage of the planning process. The Applicant represents that they will submit a construction permit to the City of Fremont in early July.

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,[7] the Applicant has paid CAEATFA an Application Fee of $10,000 and will pay CAEATFA an Administrative Fee of up to $350,000.

[7] California Code of Regulations Title 4, Division 13, Section 10036

RECOMMENDATION

Staff recommends approval of Resolution No. 17-SM043 for Boehringer Ingelheim Fremont, Inc.'s purchase of Qualified Property in an amount not to exceed $214,040,484 anticipated to result in an approximate sales and use tax exclusion value of $18,022,209.

RESOLUTION APPROVING AND AUTHORIZING EXECUTION OF A MASTER REGULATORY AGREEMENT WITH BOEHRINGER INGELHEIM FREMONT, INC.

May 16, 2017

WHEREAS, the California Alternative Energy and Advanced Transportation Financing Authority (the "Authority" or "CAEATFA") has received the Application of **Boehringer Ingelheim Fremont, 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 $214,040,484 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.