Appendix C: Importer Supporting Documentation

Premier Mid-America

February 26, 2024

Center for Drug Evaluation and Research
Food and Drug Administration
10001 New Hampshire Avenue
Hillandale Building, 4th Floor
Silver Spring, MD 20993

RE: Name and Address Importer, Contact Information for Responsible Individuals

Name of Importer: Premier Pharmaceuticals Mid-America, LLC. (DBA Premier Mid-America or PMA)

Address of SIP Sponsor: 2231 Venture Dr, Bowling Green, OH, 43402

Responsible Individuals:

Name	Redacted
Jacob Fuchs, President	
Adrian Constance, Executive Vice President	Redacted
Tanner Wollan, Vice President of Strategy	Redacted
Eric Pollex, General Manager	Redacted

Sincerely,

Jacob Fuchs
President

COLORADO
Department of Health Care Policy & Financing

303 East 17th Avenue
Denver, CO 80203

Colorado's Drug Importation Program

NON-CONFLICT OF INTEREST AND DISCLOSURE AGREEMENT

As an individual involved in the Colorado Drug Importation Program with the Department of Health Care Policy and Financing ("HCPF"), I understand that I will be responsible for parts of the program as defined in statute and the rule. By signing this document, I attest and agree that:

1. I have read this Non-Conflict of Interest and Disclosure Agreement in its entirety, and I have had the opportunity to consult with independent legal counsel regarding its contents, its meaning, the information I provide herein, and the legal significance of the Agreement and of my disclosure of any and information herein or related to it the Agreement.

2. I do not have any Actual Individual Conflicts of Interest, unmitigated Potential Individual Conflicts of Interest, or unmitigated Perceived or Apparent Conflicts of Interest, as described in Appendix A

3. I have disclosed all Potential Individual Conflicts of Interest related to this and any circumstances that could be perceived as creating bias.

4. I have provided a complete disclosure of any past criminal convictions or violations of State, Federal, or Canadian laws regarding drugs or devices as outlined by 21 Code of Federal Regulations Section 251.3(2) and shown in Appendix B.

5. I have listed below any Organization principal(s), any shareholder(s) who owns 10 percent or more of outstanding stock in the Organization, any Organization directors or officers, and any facility manager or designated representative of such a manager.

_____

_____

_____

6. Please list all disciplinary actions imposed against the Organization and any Workers of the Organization for the previous seven (7) years. Indicate 'N/A' if there are no disciplinary actions to report.

Date of Action	Party to any Action	Comments

I, FIRST MIDDLE LAST, have disclosed all affiliations with any person or organization that I have reason to believe may affect decisions related to this project or matter. I understand that I am not to participate on any matters relevant to my conflict(s) of interest as specified herein. I also further understand that if I fail to disclose any conflict(s) of interest, my participation in this project or matter will be terminated.

_____
Printed Name

_____
Signature

_____
Date

Appendix A

1. **Definitions.** For the purposes of this attestation, the following terms shall have the meanings ascribed to them below:
   a. **Actual Individual Conflict of Interest.** A situation where a financial, personal, or familial interest materially affects the Worker's duties to put the interest of the state first and compromises a Worker's objectivity, professional judgment, professional integrity, and/or ability to perform his or her duties.
   b. **Potential Individual Conflict of Interest.** A situation where a financial, personal, or familial interest could materially affect the Worker's duties to put the interest of the state first and may compromise a Worker's objectivity, professional judgment, professional integrity, and/or ability to perform his or her duties.
   c. **Perceived or Apparent Conflict of Interest** A situation where a financial, personal, or familial interest appears that it could materially affect the Worker's duties to put the interest of the state first and may appear to compromise a Worker's objectivity, professional judgment, professional integrity, and/or ability to perform his or her duties; even if no conflict of interest exists.
   d. **Organizational Conflict of Interest.** Organizational Conflict of Interest arises when an organization that receives funds from the State of Colorado, carries out part of a federal or state program as a Subrecipient, has a parent, affiliate, or subsidiary organization, and is unable or potentially unable to be impartial in conducting a procurement action involving a related organization.
   e. **Individual.** A natural person.
   f. **Organization.** Includes multiple individuals and includes all forms of legal organization.
   g. **Subrecipient.** An Individual or Organization that receives federal or state funds from the State of Colorado to carry out all or part of a federal or state program.
   h. **Worker.** Managers, supervisors, permanent full-time and part-time employees, temporary employees, contractors, applicants, volunteers, interns and for the purposes of this policy, include any individual whose close association with the employee is the equivalent of a family relationship.

2. **Applicability of this Agreement.** This agreement applies to all employees of registered partners of the State of Colorado State Importation Program. This applies and covers all Workers, and any individual who conducts business for and on behalf of the State of Colorado. Organizational Conflict of Interest: Any Subrecipient that receives federal or State funds from the State of Colorado State Importation Program shall be held to this agreement through their relationship with the partner.

3. **Consequences for Non-Compliance with this Agreement.** Any violation of this agreement will result in the immediate termination of a contract for the Partner (Organization)

Initials:_____

Appendix B

1. Include an attestation and information statement containing a complete disclosure of any past criminal convictions or violations of State, Federal, or Canadian laws regarding drugs or devices against or by the responsible individual(s), Foreign Seller, or Importer or an attestation that the responsible individual(s), Foreign Seller, or Importer has not been involved in, or convicted of, any such violations. Such attestation and information statement must include principals, any shareholder who owns 10 percent or more of outstanding stock in any non-publicly held corporation, directors, officers, and any facility manager or designated representative of such manager.

2. Include a list of all disciplinary actions, to include the date of and parties to any action imposed against the responsible individual(s), Foreign Seller, or Importer by State, Federal, or Canadian regulatory bodies, including any such actions against the principals, owners, directors, officers, quality unit, or any facility manager or designated representative of such manager for the previous 7 years prior to submission of the SIP Proposal.

Premier Pharma Premier Mid-America

Colorado's Drug Importation Program

Confidentiality Agreement

DEFINITIONS

"Confidential Information" (CI) means any and all information about a Party, whatever its form or medium (whether written, oral, electronic, graphic or otherwise), disclosed directly or indirectly by that Party to the other Party including but not limited to: technical information (including but not limited to know-how, techniques, methods, materials and components, information tools, software development, trade secrets, technology, inventions, improvements, research results, product design information, and other intellectual property information or data); record programs (and source code therefor), proposals, plans, programs, analyses, compilations, forecasts, studies or other documents prepared by a Party or by the Parties jointly related to the Purpose including without limitation the terms of this Agreement; business models; financial information and analyses; marketing, sales and promotion plans; product development or extension plans; product pricing, margins and profitability; financing and capital plans; customer and supplier lists; and company structure, owners, management and employees. In addition to the general categories described above, "Confidential Information" also includes all information received to perform required laboratory statutory testing under 21 CFR 251.16, including testing protocols, certificates of analyses, manufacturer developed samples of reference standards, formulation information of any Health Canada HBFP-approved drug subject to Colorado's State Importation Program (SIP) pursuant to section 804 of the Federal Food, Drug, and Cosmetic Act, stability-indicating assay(s), FDA-approved drug specifications and standards, analytical procedures and methods for acceptance criteria, laboratory records, data, and testing results of any drug to be imported under an SIP, any forms created or completed for submission of data to FDA related to testing and importation of a drug under an SIP, any other information supplied by a manufacturer to authenticate a prescription drug being tested or to confirm labeling compliance, any trade secrets or commercial or financial information that a manufacturer supplies for the purposes of testing in accordance with the Food Drug and Cosmetic Act or the Final Rule implementing FDA's Section 804 Importation Program.

"Disclosing Party" means a Party to this Agreement who discloses Confidential Information to the other Party or to a Related Person of other Party.

"Purpose" means the importation of Canadian pharmaceutical drugs for sale to Colorado participating pharmacies and other entities pursuant to Colorado's SIP.

"Receiving Party" means a Party to this Agreement who receives Confidential Information from the other Party or from a Related Person of other Party.

"Related Persons" means a Party's directors, officers, employees, agents and/or consultants, and the directors, officers, employees, agents and/or consultants of any parent, subsidiary, or other affiliate of the Party.

CONFIDENTIAL INFORMATION

Use of Confidential Information. The Receiving Party shall not use, or authorize the use of, Confidential Information received from the Disclosing Party except solely for the Purpose in connection with the discussions conducted between the Parties hereunder. It is understood and agreed by the Parties that the Purpose shall not include the practice of any method, process or other technology disclosed in the Confidential Information (whether for research, commercial or any other purposes), except as the Parties may otherwise expressly agree in writing.

Obligations of Non-Disclosure.

(i) The Receiving Party shall (i) hold in strict confidence all Confidential Information received from the Disclosing Party hereunder, (ii) not disclose or authorize the disclosure of any such Confidential Information, and (iii) not permit or assist, by acquiescence or otherwise, any third party to access, reveal, publish, use or disclose, directly or indirectly, any such Confidential Information; provided, however, the Receiving Party may disclose such Confidential Information on a need-to-know basis to the Receiving Party's Related Persons who are bound by confidentiality obligations no less restrictive than those contained herein and only to the extent necessary to accomplish the Purpose. The Receiving Party shall promptly advise the Disclosing Party in writing of any unauthorized use or disclosure of Confidential Information of which the Receiving Party becomes aware and shall provide reasonable assistance to the Disclosing Party to stop such unauthorized use or disclosure.

(ii) The Receiving Party agrees that (i) the Receiving Party shall be liable for the acts and omissions of its Related Persons with respect to the Confidential Information disclosed, and (ii) all acts and omissions of the Receiving Party's Related Persons shall be deemed to be the acts and omissions of the Receiving Party.

(iii) The Receiving Party shall not (i) alter, decompile, disassemble, reverse engineer, or otherwise modify any Confidential Information; or (ii) remove any

copyright notice, trademark notice, and/or other proprietary legend or indication of confidentiality set forth on or contained in any of the Confidential Information.

Protection of Confidential Information. The Receiving Party shall take security precautions equal to or greater than the security precautions the Receiving Party employs to protect its own Confidential Information, but in no event less than reasonable security precautions necessary to protect from disclosure and to keep confidential the Confidential Information of the Disclosing Party.

Exceptions to Non-Use and Non-Disclosure. Except as limited by the FDCA and FDA regulations governing Colorado's SIP, the Receiving Party's obligations respecting confidentiality under this Agreement shall not apply to any of the Confidential Information of the Disclosing Party that the Receiving Party can demonstrate: (i) was in the public domain at the time of disclosure to it; (ii) after disclosure to it, is published or otherwise becomes part of the public domain through no fault of the Receiving Party; (iii) the Confidential Information was in the possession of the Receiving Party at the time of disclosure to it without being subject to any obligation of confidentiality; (iv) was received from a third party who, to the Receiving Party's knowledge, had a lawful right to disclose such information to it; (v) was independently developed by the Receiving Party without reference to the Confidential Information; or (vi) was required to be disclosed to order of a court of competent jurisdiction and/or any regulatory body having jurisdiction over the Receiving Party or any of its Related Persons. In the case of any disclosure pursuant to clause (v) of this Section 3.3, to the extent legally permissible, the Receiving Party will give prior notice to the Disclosing Party of the required disclosure and will use commercially reasonable efforts to obtain, or reasonably assist the Disclosing Party in obtaining a protective order covering such disclosure.

For the avoidance of doubt, any disclosures made under this subsection shall be strictly limited to the information covered by the applicable subsection, and any Confidential Information not specifically covered by the exceptions in those subsections shall be redacted prior to disclosure of the relevant documents or materials.

Return of Materials. Upon written request of the Disclosing Party, all documents and other tangible things containing or representing the Confidential Information of the Disclosing Party shall be destroyed or promptly returned to the Disclosing Party; however, the Parties may each retain a copy of the other's Confidential Information solely for purposes of ensuring compliance with this Agreement and providing evidence of the Confidential Information received. In addition, upon the Disclosing Party's request the Receiving Party shall promptly deliver to the Disclosing Party, or delete, erase or otherwise destroy, all communications, notes, memoranda, analyses, writings and other tangible and intangible works created or prepared by or for the Receiving Party with respect to or containing any of the Confidential Information. If such works are deleted, erased or otherwise destroyed, the Receiving Party shall certify to the Disclosing Party in writing such deletion, erasure or destruction has occurred. Notwithstanding such return, delivery or destruction of Confidential Information, the Receiving Party shall continue to be bound by all its obligations hereunder. Notwithstanding the generality of the foregoing, nothing contained herein shall be construed as requiring the destruction

of system wide back-up materials which may incidentally contain or have reference to Confidential Information.

The provisions of this Agreement shall apply during the period of disclosure and consideration and for a period of ten (10) years thereafter.

The provisions of the Agreement are necessary for the protection of the business and goodwill of the parties and are considered by the parties to be reasonable for such purpose. Recipient admits for all purposes that any violation of this Agreement may constitute an irreparable injury to Disclosing Party for which monetary damages provide an inadequate remedy. As such, in addition to any other remedy to which Disclosing Party may be entitled at law or in equity, Disclosing Party shall also be entitled to seek injunctive relief to prevent breaches of any provision of this Agreement and to specifically enforce the terms and provisions hereof.

Venue, Governing Law. This Agreement shall be construed and enforced in accordance with the laws of the State of Colorado without regard to the choice of law thereof. Venue for any legal action relating to this Agreement shall lie in a court of competent jurisdiction located in Denver County, Colorado.

Assignment. This Agreement is a personal, indivisible, nontransferable agreement and may not without the written consent of the other Party be assigned or transferred, except to an affiliate, in whole or in part.

Representations of the Parties. The Parties represent and warrant that each possesses the legal authority to enter into this Agreement. Additionally, the Parties represent that the person or persons signing and executing this Agreement on behalf of such Party, has been fully authorized to execute this Agreement on its behalf and to bind the Party validly and legally to all terms, obligations, and provisions herein.

Binding. This Agreement is expressly subject to and shall not become effective or binding on any Party hereto until it has been fully executed by all Parties.

No Warranty. EACH PARTY ACKNOWLEDGES AND AGREES THAT ALL CONFIDENTIAL INFORMATION IS PROVIDED ON AN "AS IS" BASIS AND THAT NEITHER PARTY NOR ANY OF ITS RELATED PERSONS HAS MADE OR WILL MAKE ANY WARRANTY WHATSOEVER, EXPRESS, IMPLIED OR OTHERWISE, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE, ENFORCEABILITY OR NON-INFRINGEMENT.

Remedies. Each Party acknowledges that the Confidential Information disclosed and/or made available to the Receiving Party hereunder is valuable to the Disclosing Party and that any threatened or actual breach of this Agreement would cause irreparable injury to the Disclosing Party (and/or Related Persons and/or clients of the Disclosing Party) for which monetary damages would be inadequate. Accordingly, in the event of a breach or threatened breach of this Agreement, the Disclosing Party shall be entitled to seek equitable relief, including without limitation, injunction and specific performance. Each Party hereby waives any requirements for security or posting of any bond

Initials:_____

in connection with such relief. No specification in this Agreement of any particular remedy shall be construed as a waiver or prohibition of any other remedies at law or in equity a Party may have in the event of a breach or threatened breach of this Agreement.

Counterparts. This Agreement may be executed by electronic means (including .PDF) and in any number of counterparts, each of which when executed and delivered, shall constitute an original, but all of which together shall constitute one agreement binding on all parties, notwithstanding that all parties are not signatories to the same counterpart.

Waiver. No failure or delay by Disclosing Party or Recipient in exercising any right, power, or privilege under this Agreement shall act as a waiver thereof. Any amendments or modifications to this Agreement must be in writing and signed by the parties.

Entire Agreement. This Agreement contains the entire understanding between the parties with respect to the subject matter and supersedes all prior and contemporaneous agreements, negotiations, correspondence, undertakings and understandings, oral or written, relating to such subject matter.

The parties executing this document agree with all aspects of this confidentiality agreement. I also further understand that if I breach this agreement, my participation in this project or matter will be terminated.

Premier Pharmaceuticals	**Company**
_____	_____
Printed Name	Printed Name
_____	_____
Signature	Signature
_____	_____
Date	Date

Initials:_____

IDAHO

IDAHO STATE BOARD OF PHARMACY
1199 SHORELINE LN, SUITE 303
BOISE, ID 83702
PHONE: 208-334-2356
FAX: 208-334-3536

FACILITY
Premier Pharmaceuticals LLC
1111 S Orchard Suite 204
Boise, ID 83705
2084211719
Owner: Jacob Fuchs

LICENSE
License No:
License Type: Wholesale Distributor

Inspection Type:	Initial	**Inspection Date:**	3/27/2019
Result:	Pass		

Notes:
Remarks: No Controls.

Checklist Results	
27.01.01.022.02 BOARD INSPECTIONS	
Question	**Answer**
27.01.01.022.02.. - Inspections. Prior to the commencement of business, as applicable, and thereafter at regular intervals, upon presentation of appropriate identification, registrants and licensees must permit the Board or its compliance officers to enter and inspect the premises and to audit the records of each drug outlet for compliance with laws enforced by or under the Board's jurisdiction.	reviewed
27.01.06.041 - FACILITY REQUIREMENTS	
Question	**Answer**
27.01.06.041 - Facilities where drugs are stored, warehoused, handled, held, offered, marketed, or displayed for wholesale distribution must:	True
27.01.06.041.01 - Minimum Physical Standards. Be of suitable size, construction, and location to accommodate cleaning, maintenance, and proper operations;	Compliant
27.01.06.041.02 - Minimum Environmental Standards. Have adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;	Compliant
27.01.06.041.03 - Quarantine. Have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, or adulterated or that are in immediate or sealed secondary containers that have been opened;	Compliant
27.01.06.041.04 - Maintenance Requirements. Be maintained in a clean and orderly condition	Compliant
27.01.06.041.05 - Pest Controls. Be free from infestation by insects, rodents, birds, or vermin of any kind	Compliant
27.01.06.042 - FACILITY SECURITY REQUIREMENTS	
Question	**Answer**
27.01.06.042 - Facilities used for wholesale drug distribution must be secure from unauthorized entry, as follows:	Not Answered
27.01.06.042.01 - Access from Outside. Access from outside the premises must be kept to a minimum and well controlled;	Compliant
27.01.06.042.02 - Perimeter Lighting. The outside perimeter of the premises must be well lighted;	Compliant
27.01.06.042.03 - Authorized Entry. Entry into areas where drugs are held must be limited to authorized personnel;	Compliant
27.01.06.042.04 - Alarm Systems. Facilities must be equipped with an alarm system to detect entry after hours	Compliant
27.01.06.042.05 - Security Systems. Facilities must be equipped with security systems sufficient to protect against theft, diversion, and record tampering	Compliant
27.01.06.043 / 044 - DRUG STORAGE & SHIPMENT RQMTS	
Question	**Answer**
27.01.06.043 - Drugs must be stored at temperatures and under conditions required by the labeling of the drugs, if any, or by current requirements of the USP-NF, to preserve product identity, strength, quality, and purity. Temperature and humidity recording equipment, devices, or logs must document proper storage of drugs.	Compliant
27.01.06.044.01 - Examination on Receipt. Each shipping container must be visually examined on receipt for identity and to avoid acceptance of drugs that are contaminated or otherwise unfit for distribution.	Compliant
27.01.06.044.02 - Outgoing Shipment Inspections. Outgoing shipments must be inspected to verify the accuracy and product integrity of the shipment contents.	Compliant
27.01.06.045 - QUARANTINE	
Question	**Answer**

27.01.06.045 - Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated must be physically separated from other drugs in a designated quarantine area until destroyed or returned to the original manufacturer or third party returns processor.	Compliant
27.01.06.045.01 -Container Adulteration. Used drugs and those whose immediate or sealed outer or sealed secondary containers have been opened are adulterated and must be quarantine	Compliant
27.01.06.045.02 -Other Conditions Requiring Quarantine. Drugs must be quarantined under any condition that causes doubt as to a drug's safety, identity, strength, quality, or purity unless under examination, testing, or other investigation the drug is proven to meet required standards.	Compliant
27.01.06.046 -RECORDKEEPING REQUIREMENTS	
Question	**Answer**
27.01.06.046 -Wholesalers and other entities engaged in wholesale drug distribution must establish and maintain inventories and records of transactions pertaining to the receipt and distribution or other disposition of drugs.	Compliant
27.01.06.046.01 - Record Contents. The records must include at least:	viewed shipping document set up
27.01.06.046.01.a - The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;	Compliant
27.01.06.046.01.b - The identity and quantity of the drugs received and distributed or disposed of;	Compliant
27.01.06.046.01.c - The dates of receipt and distribution or other disposition of the drugs.	Compliant
27.01.06.046.02 - Records Maintenance. Records may be maintained in an immediately retrievable manner at the inspection site or in a readily retrievable manner at a central location.	Compliant
27.01.06.047.01 - PERSONNEL	
Question	**Answer**
27.01.06.047.01 - Responsible Person Designees. A wholesaler must establish and maintain a list of officers, directors, managers, a designated representative, and other persons responsible for wholesale drug distribution, storage, and handling and must include a description of each individual's duties and a summary of their qualifications.	Compliant
27.01.06.047.02 -Adequate Personnel. A wholesaler must employ personnel in sufficient numbers and with adequate education, training, and experience to safely and lawfully engage in wholesale drug distribution activities.	Compliant
27.01.06.048 - POLICIES AND PROCEDURES	
Question	**Answer**
27.01.06.048 - Wholesalers must adopt policies and procedures for the receipt, security, storage, inventory, and distribution of drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, for correcting errors and inaccuracies in inventories, and as necessary to ensure compliance with the following:	Not Answered
27.01.06.048.01 - Distribution of Oldest Approved Stock First. The oldest approved stock of a drug product must be distributed first except if extraordinary circumstances require a temporary deviation.	Compliant
27.01.06.048.02 - Recalls and Withdrawals. Drugs must be recalled or withdrawn upon: (a) A request by the FDA or other local, state, or federal law enforcement or other government agency, including the Board; (b) A voluntary action by a manufacturer to remove defective or potentially defective drugs from the market; or (c) An action undertaken to promote public health and safety by replacing existing merchandise with an improved product or a new package design.	Compliant
27.01.06.048.03 - Crisis Preparation. Wholesalers must prepare for, protect against, and competently handle a crisis affecting the security or operation of a facility, including a fire, flood, or other natural disaster, a strike, or other situations of local, state, or national emergency.	Compliant
27.01.06.030.05.. - DRUG DISTRIBUTION	
Question	**Answer**
27.01.06.030.02.a. - Drug product only to a person licensed by the appropriate state licensing agency to dispense, conduct research with or independently administer such drugs;	Compliant
27.01.06.030.02.b. - Scheduled controlled substances only to a person who has been issued a valid controlled substance registration by the DEA and the Board, unless exempt by state or federal law;	Not Applicable
27.01.06.030.02.c. - Federally required transaction documentation, including transaction information, transaction history, and transaction statements with each distribution; and	Compliant
27.01.06.030.02.d. - Drug product only to the registered address of the authorized receiving person. Delivery to a hospital pharmacy receiving area satisfies this requirement, provided that authorized receiving personnel sign for receipt at the time of delivery.	Compliant
27.01.06.030.03.a. - The date of the transaction;	Compliant
27.01.06.030.03.b. - The name, address, and DEA registration number of the distributing dispenser;	Compliant
27.01.06.030.03.c. - The name, address, and DEA registration number of the receiving dispenser;	Compliant
27.01.06.030.03.d. - The drug name, strength, and quantity for each product distributed; and	Compliant
27.01.06.030.03.e. - The signature of the person receiving the drugs.	Compliant
27.01.06.030.04.. - Monitoring Purchase Activity. An authorized distributor must have adequate processes in place for monitoring purchase activity of customers and identifying suspicious ordering patterns that identify potential diversion or criminal activity related to controlled substances such as orders of unusual size, orders deviating substantially from a normal pattern, orders for drugs that are outside of the prescriber's scope of practice, and orders of unusual frequency.	Compliant
27.01.06.030.05.. - Reporting. An authorized distributor must report specified data on controlled substances distributed at least monthly to the Board in a form and manner prescribed by the Board, except when distributing intracompany.	Compliant
27.01.01.022.04 BOARD INSPECTIONS REVIEW / DEFICIE	
Question	**Answer**
27.01.01.022.03 - Inspection Deficiencies. Deficiencies noted must be promptly remedied, and if requested, the Board office notified of corrective measures. If required, one (1) follow-up inspection may be performed by the Board at no cost. For additional follow-up inspections, the drug outlet will be charged actual travel and personnel costs incurred in the inspection and must pay within ninety (90) days of inspection.	reviewed
27.01.01.022.04 BOARD INSPECTIONS REVIEW - Inspection Reports. Inspection reports must be reviewed with the Board inspector and signed by an agent of the drug outlet upon completion of the exit interview.	signed by Jacob Fuchs

THE UNDERSIGNED LICENSEE OR REPRESENTATIVE AT THE TIME OF INSPECTION ACKNOWLEDGES RECEIPT OF THIS INSPECTION REPORT.

Compliance Officer	3/27/2019 Date/Time	Signature of Owner/Representative

IDAHO

IDAHO STATE BOARD OF PHARMACY
1199 SHORELINE LN, SUITE 303
BOISE, ID 83702
PHONE: 208-334-2356
FAX: 208-334-3536

FACILITY
Premier Pharmaceuticals LLC
7259 W Franklin Rd
Boise, ID 83709
2086390241
Owner: Jacob Fuchs

LICENSE
License No:
License Type: Wholesale Distributor

Inspection Type:	Initial	**Inspection Date:**	2/14/2020
Result:	Pass		

Notes:
Remarks: No controlled substances. GSA class V safe on site not in use.

Checklist Results	
27.01.01.103. BOARD INSPECTIONS AND INVESTIGATIONS	
Question	**Answer**
27.01.01.103.02. Inspections. Prior to the commencement of business, as applicable, and thereafter at regular intervals, registrants and licensees must permit the Board or its compliance officers to enter and inspect the premises and to audit the records of each drug outlet for compliance with laws enforced by or under the Board's jurisdiction. (7-1-18)	True
27.01.01.230.01. New Drug Outlet Inspections. Prior to approving the issuance of a new license or registration,	True
27.01.01.300. DRUG OUTLETS: MINIMUM FACILITY STAND	
Question	**Answer**
27.01.01.300.01. Security and Privacy. A drug outlet must be constructed and equipped with adequate security to protect its equipment, records and supply of drugs, devices and other restricted sale items from unauthorized access, acquisition or use. All protected health information must be stored and maintained in accordance with HIPAA. (7-1-18)	Compliant
27.01.01.300.02. Controlled Substance Storage. Drug outlets that dispense prescription drugs must store controlled substances in accordance with federal law. (7-1-18)	Compliant
27.01.01.300.03. Authorized Access to the Restricted Drug Storage Area. Access to the restricted drug storage area must be limited to authorized personnel. (7-1-18)	Compliant
27.01.01.500. RECORDKEEPING: MAINTENANCE AND INVEN	
Question	**Answer**
27.01.01.500.01. Records Maintenance and Retention Requirement. Unless an alternative standard is stated for a specified record type, form, or format, records required to evidence compliance with statutes or rules enforced by the Board must be maintained and retained in a readily retrievable form and location for at least three (3) years from the date of the transaction. (7-1-18)	Compliant
27.01.01.500.07. Electronic Records Storage. Records may be electronically stored and maintained if they remain legible and are in a readily retrievable format, and if federal law does not require them to be kept in a hard copy format. (7-1-18)	Compliant
27.01.01.103.03. Inspection Deficiencies.	
Question	**Answer**
27.01.01.103.03. Inspection Deficiencies. Deficiencies noted must be promptly remedied, and if requested, the Board office notified of corrective measures. One (1) follow-up inspection may be performed by the Board at no cost. For additional follow-up inspections, the drug outlet will be charged actual travel and personnel costs incurred in the inspection to be paid within ninety (90) days of inspection. (7-1-18)	n/a
27.01.01.103.04. Inspection Reports. Inspection reports must be reviewed with the Board inspector and signed by an agent of the drug outlet upon completion of the exit interview. (7-1-18)	Jacob Fuchs

THE UNDERSIGNED LICENSEE OR REPRESENTATIVE AT THE TIME OF INSPECTION ACKNOWLEDGES RECEIPT OF THIS INSPECTION REPORT.

Compliance Officer	2/14/2020 Date/Time	Signature of Owner/Representative

IDAHO

IDAHO STATE BOARD OF PHARMACY
1199 SHORELINE LN, SUITE 303
BOISE, ID 83702
PHONE: 208-334-2356
FAX: 208-334-3536

FACILITY
Premier Pharmaceuticals LLC
7259 W Franklin Rd
Boise, ID 83709
2086390241

LICENSE
License No: W57324
License Type: Wholesale Distributor

Inspection Type:	Annual	**Inspection Date:**	3/22/2022
Result:	Completed		

Notes:
Remarks: First shipment of CS invoiced 10/13/21 and distributed immediately after. No Schedule II drugs. limited schedule III, IV (Testosterone is only scheduled drug on site) Drug was in the unlocked safe in unlocked room that also serves as storage for non-controlled drugs. Concerned that the safe holding testosterone was not locked upon arrival - CS security must show -Title 21 CFR 1301.71 (b)(11) The adequacy of supervision over employees having access to manufacturing and storage areas; The Safe to remain locked at all times with limited access when CS are in current inventory.

Checklist Results	
24.36.01.103. BOARD INSPECTIONS AND INVESTIGATIONS	
Question	**Answer**
24.36.01.103.01. Records Subject to Board Inspection. Records created, maintained, or retained by Board licensees or registrants in compliance with statutes or rules enforced by the Board must be made available for inspection upon request by Board inspectors or authorized agents. It is unlawful to refuse to permit or to obstruct a Board inspection. (7-1-18)	True
24.36.01.103.02. Inspections. Prior to the commencement of business, as applicable, and thereafter at regular intervals, registrants and licensees must permit the Board or its compliance officers to enter and inspect the premises and to audit the records of each drug outlet for compliance with laws enforced by or under the Board's jurisdiction. (7-1-18)	True
24.36.01.300. DRUG OUTLETS: MINIMUM FACILITY STAND	
Question	**Answer**
24.36.01.300.01. Security and Privacy. A drug outlet must be constructed and equipped with adequate security to protect its equipment, records and supply of drugs, devices and other restricted sale items from unauthorized access, acquisition or use. All protected health information must be stored and maintained in accordance with HIPAA. (7-1-18)	Compliant
24.36.01.300.02. Controlled Substance Storage. Drug outlets that dispense prescription drugs must store controlled substances in accordance with federal law. (7-1-18)	Non Compliant
24.36.01.300.03. Authorized Access to the Restricted Drug Storage Area. Access to the restricted drug storage area must be limited to authorized personnel. (7-1-18)	Compliant
24.36.01.104.10. Substandard, Misbranded, Adulterated, or Expired Products. Manufacturing, compounding, delivering, distributing, dispensing, or permitting to be manufactured, compounded, delivered, distributed or dispensed substandard, misbranded, or adulterated drugs or preparations or those made using secret formulas. Failing to remove expired drugs from stock	Compliant
24.36.01.500. RECORDKEEPING: MAINTENANCE AND INVEN	
Question	**Answer**
24.36.01.500.01. Records Maintenance and Retention Requirement. Unless an alternative standard is stated for a specified record type, form, or format, records required to evidence compliance with statutes or rules enforced by the Board must be maintained and retained in a readily retrievable form and location for at least three (3) years from the date of the transaction. (7-1-18)	Compliant
24.36.01.500.03. Inventory Records. Each drug outlet must maintain a current, complete and accurate record of each controlled substance manufactured, imported, received, ordered, sold, delivered, exported, dispensed or otherwise disposed of by the registrant. Drug outlets must maintain inventories and records in accordance with federal law. An annual inventory must be conducted at each registered location no later than seven (7) days after the date of the most recent inventory in a form and manner that satisfies the inventory requirements of federal law. Drugs stored outside a drug outlet in accordance with these rules must be regularly inventoried and inspected to ensure that they are properly stored, secured, and accounted for. Additional inventories are necessary when required by federal law. (7-1-18)	Compliant
24.36.01.500.05. Drug Distributor Records. Wholesalers and other entities engaged in wholesale drug distribution must maintain inventories and records or transactions pertaining to the receipt and distribution or other disposition of drugs in accordance with federal law. The records must include at least: (4-11-19	
24.36.01.500.05.a. The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped; (4-11-19)	Compliant
24.36.01.500.05.b. The identity and quantity of the drugs received and distributed or disposed of; (4-11-19)	Compliant
24.36.01.500.05.c. The dates of receipt and distribution or other disposition of the drugs; and (4-11-19)	Compliant

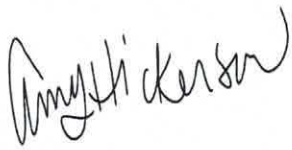
24.36.01.500.05.d. Controlled substance distribution invoices, in the form and including the requirements of federal law. (4-11-19)	Compliant

24.36.01.103.03. Inspection Deficiencies.

Question	Answer
24.36.01.103.03. Inspection Deficiencies. Deficiencies noted must be promptly remedied, and if requested, the Board office notified of corrective measures. One (1) follow-up inspection may be performed by the Board at no cost. For additional follow-up inspections, the drug outlet will be charged actual travel and personnel costs incurred in the inspection to be paid within ninety (90) days of inspection. (7-1-18)	submit response to CS storage security
24.36.01.103.04. Inspection Reports. Inspection reports must be reviewed with the Board inspector and signed by an agent of the drug outlet upon completion of the exit interview. (7-1-18) [Discussed with]	Jacob
Deficiencies- Education of Code and Rule provided?	Yes
Deficiencies- Issued Warning to Drug Oulet -Possible Discipline?	No
Disclaimer - Any items not discussed specifically by compliance officer on this inspection does not constitute compliance nor approval.	True

Violation Code	Violation Date	Date Resolved	Remarks
24.36.01.300.02. Controlled Substance Storage	3/22/2022 12:00:00 AM		Safe storing CS must remain locked and limit access. No camera or security measure documenting entry into area where CS are stored.

THE UNDERSIGNED LICENSEE OR REPRESENTATIVE AT THE TIME OF INSPECTION ACKNOWLEDGES RECEIPT OF THIS INSPECTION REPORT.



Compliance Officer

3/22/2022

Date/Time

Signature of Owner/Representative

---------- Forwarded message ---------
From: **Amy Hickerson** <Amy.Hickerson@dopl.idaho.gov>
Date: Thu, Aug 18, 2022 at 5:31 PM
Subject: follow up inspection
To: Jacob Fuchs <jacob@premierpharma.com>

Jacob,

I have marked the violation recorded on 3/22/2022 as resolved as of today, 8/18/2022, based on my observations of the new location of the safe that includes badge access and cameras. You may want to save this email and attach it to your previous inspection.

Amy Hickerson

Drug Compliance Officer

Division of Occupational and Professional Licenses

Health Professions - Board of Pharmacy

Office: 208-334-2356 Mobile: 208-861-0241

IDAHO

IDAHO STATE BOARD OF PHARMACY
1199 SHORELINE LN, SUITE 303
BOISE, ID 83702
PHONE: 208-334-2356
FAX: 208-334-3536

FACILITY
Premier Pharmaceuticals LLC
7259 W Franklin Rd
Jacob Fuchs
Boise, ID 83709
2086390241

LICENSE
License No: W57324
License Type: Wholesale Distributor

Inspection Type:	Annual	**Inspection Date:**	2/14/2023
Result:	Finalized		

Notes:
Remarks: Seller and Recipient DEA # to be included on invoice document provided to client. Verified DEA was in computer for account set up, this information did not transfer over to packing slip/invoice/pick ticket

Checklist Results

24.36.01.103. BOARD INSPECTIONS AND INVESTIGATIONS

Question	Answer
24.36.01.103.01. Records Subject to Board Inspection. Records created, maintained, or retained by Board licensees or registrants in compliance with statutes or rules enforced by the Board must be made available for inspection upon request by Board inspectors or authorized agents. It is unlawful to refuse to permit or to obstruct a Board inspection. (7-1-18)	True
24.36.01.103.02. Inspections. Prior to the commencement of business, as applicable, and thereafter at regular intervals, registrants and licensees must permit the Board or its compliance officers to enter and inspect the premises and to audit the records of each drug outlet for compliance with laws enforced by or under the Board's jurisdiction. (7-1-18)	True

24.36.01.300. DRUG OUTLETS: MINIMUM FACILITY STAND

Question	Answer
24.36.01.300.01. Security and Privacy. A drug outlet must be constructed and equipped with adequate security to protect its equipment, records and supply of drugs, devices and other restricted sale items from unauthorized access, acquisition or use. All protected health information must be stored and maintained in accordance with HIPAA. (7-1-18)	Compliant
24.36.01.300.02. Controlled Substance Storage. Drug outlets that dispense prescription drugs must store controlled substances in accordance with federal law. (7-1-18)	Compliant
24.36.01.300.03. Authorized Access to the Restricted Drug Storage Area. Access to the restricted drug storage area must be limited to authorized personnel. (7-1-18)	Compliant
24.36.01.104.10. Substandard, Misbranded, Adulterated, or Expired Products. Manufacturing, compounding, delivering, distributing, dispensing, or permitting to be manufactured, compounded, delivered, distributed or dispensed substandard, misbranded, or adulterated drugs or preparations or those made using secret formulas. Failing to remove expired drugs from stock	Compliant

24.36.01.500. RECORDKEEPING: MAINTENANCE AND INVEN

Question	Answer
24.36.01.500.01. Records Maintenance and Retention Requirement. Unless an alternative standard is stated for a specified record type, form, or format, records required to evidence compliance with statutes or rules enforced by the Board must be maintained and retained in a readily retrievable form and location for at least three (3) years from the date of the transaction. (7-1-18)	Compliant
24.36.01.500.03. Inventory Records. Each drug outlet must maintain a current, complete and accurate record of each controlled substance manufactured, imported, received, ordered, sold, delivered, exported, dispensed or otherwise disposed of by the registrant. Drug outlets must maintain inventories and records in accordance with federal law. An annual inventory must be conducted at each registered location no later than seven (7) days after the date of the most recent inventory in a form and manner that satisfies the inventory requirements of federal law. Drugs stored outside a drug outlet in accordance with these rules must be regularly inventoried and inspected to ensure that they are properly stored, secured, and accounted for. Additional inventories are necessary when required by federal law. (7-1-18)	Compliant
24.36.01.500.05. Drug Distributor Records. Wholesalers and other entities engaged in wholesale drug distribution must maintain inventories and records or transactions pertaining to the receipt and distribution or other disposition of drugs in accordance with federal law. The records must include at least: (4-11-19	Compliant
24.36.01.500.05.a. The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped; (4-11-19)	Compliant
24.36.01.500.05.b. The identity and quantity of the drugs received and distributed or disposed of; (4-11-19)	Compliant
24.36.01.500.05.c. The dates of receipt and distribution or other disposition of the drugs; and (4-11-19)	Compliant
24.36.01.500.05.d. Controlled substance distribution invoices, in the form and including the requirements of federal law. (4-11-19)	Compliant

24.36.01.103.03. Inspection Deficiencies.	
Question	**Answer**
24.36.01.103.03. Inspection Deficiencies. Deficiencies noted must be promptly remedied, and if requested, the Board office notified of corrective measures. One (1) follow-up inspection may be performed by the Board at no cost. For additional follow-up inspections, the drug outlet will be charged actual travel and personnel costs incurred in the inspection to be paid within ninety (90) days of inspection. (7-1-18)	follow up with updated invoice within 2 weeks
24.36.01.103.04. Inspection Reports. Inspection reports must be reviewed with the Board inspector and signed by an agent of the drug outlet upon completion of the exit interview. (7-1-18) [Discussed with]	Jacob
Deficiencies- Education of Code and Rule provided?	Not Answered
Deficiencies- Issued Warning to Drug Oulet -Possible Discipline?	Not Answered
Disclaimer - Any items not discussed specifically by compliance officer on this inspection does not constitute compliance nor approval.	True

THE UNDERSIGNED LICENSEE OR REPRESENTATIVE AT THE TIME OF INSPECTION ACKNOWLEDGES RECEIPT OF THIS INSPECTION REPORT.

Compliance Officer

2/14/2023

Date/Time

Signature of Owner/Representative

Licensee Details

This is a primary source verification website offered by the Idaho State Board of Pharmacy.

Demographic Information

Facility Name: Premier Pharmaceuticals LLC

Ownership Type: Limited Liability

Physical Address

Street Address: 7259 W Franklin Rd

Fax:

Phone: 2086390241

City: Boise

Zip: 83709

State: ID

County: Ada

Country: United States

License Information

DBA: Premier Pharmaceuticals LLC

Lic #: W57324

Type: Wholesale Distributor

Status: Active

Orig. Issued Date: 2/21/2020

Expiry: 12/31/2024

Effective: 2/21/2020

Status Reason: License Issuance

Status Date: 2/21/2020

Renewed: 11/30/2023

Method: Change of Address

Disciplinary Action

Disciplinary Action is indicated above in red, if the section is BLANK no action exists for this record.

Board Orders

No Related Documents

State of Ohio Board of Pharmacy

77 South High Street, 17th Floor, Columbus, Ohio 43215-6126
(614) 466-4143 | Fax (614) 752-4836 | http://www.pharmacy.ohio.gov

License APP-000740608

Premier Pharmaceuticals Mid-america Llc

2231 Venture Dr
Bowling Green, OH 43402-7501
Wood County

Wholesaler - Category 3

Wholesale Drug Distributor

October 19, 2023

License APP-000740608 - Premier Pharmaceuticals Mid-america Llc

Full

State of Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215-6126
(614) 466-4143 | Fax (614) 752-4836
http://www.pharmacy.ohio.gov

Completed by David Rivera
Start 10/19/2023 10:00 AM
End 10/19/2023 11:15 AM

Organization

Name
Premier Pharmaceuticals Mid-america Llc

License Type
Wholesaler - Category 3

Category

License Number
APP-000740608

Business Type
FS - Full Service

DEA Number

Responsible Person
Amy Nusbaum

Hours of Operation
M-F 8a-5p

Contact

Address
2231 Venture Dr
Bowling Green, OH 43402-7501
Wood County

Primary Number
(419) 318-3566

Fax Number

Website

Personnel

Name	Initials	Position	I.D. No.	Phone	Email
Amy Nusbaum		Responsible Person		(734) 735-1186	amy@premierpharma.com

1) Initial Inspection Information

2) Were multiple inspection guides used during this inspection?

No

3) Facility Description

Observation
Freestanding office park-like warehouse. No attached suites or buildings.

2) Licensing

1) Is the license current, signed, and on-site available for viewing at the time of inspection?

Yes

2) The responsible person on the license is correct, and appropriate for the licensed location.

Yes

3) The facility has a current DEA certificate.

No

Observation
Will obtain after obtaining state license.

3) Security

1) Dangerous drugs are stored in a secure area with access by authorized personnel only?

Yes

Observation
Only RP has access to controlled substance cage and CII safe. Policy is in place for person to temporary have access when RP is on leave.

3) Adequate systems are in place to detect and deter drug diversion and to prevent unauthorized access to drug stock.

Yes

Observation
Cleaning company has no access to the building after hours, must be let in by staff during open hours. Only clean office area of building, not allowed into warehouse where drugs are present.

4) Minimum Standards/Cleanliness

1) The facility was observed clean, well-lighted, well-ventilated and in an orderly condition for the storage of drugs and devices.

Yes

5) Refrigeration

1) Storage areas for refrigerated drugs are maintained at temperatures that insure the integrity of drugs.

Yes

3) Storage areas for refrigerated and frozen drugs contain only those items required to be stored under the specified temperatures.

Yes

4) Refrigerators and freezers are properly maintained and defrosted as necessary to ensure the integrity of drugs stored within.

Yes

6) References

1) The licensee is able to access current federal and state drug laws and rules.

Yes

8) Drug Purchases

1) Wholesale and Terminal Distributors of Dangerous Drugs utilized by the licensee include:

Other:

Observation
Direct from manufacturers.

2) The licensee has a policy/procedure in place to verify the TDDD/WDDD of the distributor/wholesaler prior to purchsing dangerous drugs or controlled substances from them.

Yes

4) The facility purchases non-patient specific compounded drug products from an in-state pharmacy for direct administration by a prescriber.

No

8) The facility purchases schedule II controlled substances using the following ordering procedures.

The facility orders schedule II controlled substances using an electronic ordering method.

10) Drug Records and Inventories

1) The facility maintains all drug records on-site for a period of three years.

Yes

4) The facility maintains an annual inventory of controlled substances in accordance with OAC 4729-9-14.

Yes

5) The facility maintains records of controlled substances received, administered, dispensed or used other than by prescription separately from all other records of the registrant, and in a readily retrievable format.

Yes

6) The facility conducts routine audits of controlled substances on-hand.

Yes

7) Theft or loss of dangerous drugs, controlled substances and/or drug documents has been reported to the Ohio State Board of Pharmacy.

Yes

Observation
Any theft or loss of dangerous drugs must be reported by law to the Ohio State Board of Pharmacy and local law enforcement immediately upon discovery. Notify the DEA if controlled substances were involved.

Theft or loss must be reported verbally to the Ohio State Board of Pharmacy (614-466-4143) or a local Pharmacy Board Employee immediately upon discovery and in writing to the Ohio State Board of Pharmacy (dea106reporting@pharmacy.ohio.gov) within 30 days of the discovery of the theft or loss.

11) Adulterated/Expired Drugs

1) The facility has a policy/procedure to regularly check drug stock for expired/adulterated products and to remove them from stock areas.

Yes

2) Adulterated/expired drugs are stored in a separate and secure area apart from the storage of drugs used for dispensing and administration.

Yes

3) In a facility licensed as a terminal distributor of dangerous drugs, adulterated/expired drugs are stored no longer than 1 year from the date of adulteration/expiration.

Yes

4) In a facility licensed as a wholesale distributor of dangerous drugs, adulterated/expired drugs are stored no longer than 2 years from the date of adulteration/expiration.

Yes

12) Drug Destruction

1) Controlled substances are destroyed in a manner consistent with 21 C.F.R. 1317.

Yes

Observation
All adulterated products are sent back to manufacturers for replacement.

4) The facility is registered with the DEA as an authorized collector of non-registrant controlled substances.

No

13) OARRS

1) The facility is not required to report to Ohio's Dangerous Drug Data Base (OARRS).

This is a category II facility. No reportable drugs are permitted on site.

Observation
At the moment, no drugs are currently on site.

14) Wholesale Facilities

1) The facility is of suitable size and construction to facilitate cleaning, maintenance and proper operations.

Yes

2) The facility maintains a quarantine area for adulterated drugs.

Yes

3) The facility is secure from unauthorized entry.

Yes

4) The facility is equipped with an alarm system to detect unauthorized entry after hours.

Yes

Observation
Individual codes for each employee.

5) Dangerous drugs are stored at appropriate temperatures.

Yes

6) Shipping containers are visually examined to prevent the acceptance or delivery of contaminated dangerous drugs.

Yes

7) The facility has established and maintains inventories and records of all transactions regarding the receipt distribution and other disposition of dangerous drugs.

Yes

9) The facility has a system in place to identify and report suspicious orders for drugs to the Ohio State Board of Pharmacy.

Yes

11) The facility maintains written policies and procedures for the receipt, security, storage, inventory and distribution of dangerous drugs.

Yes

12) Employees have appropriate education and/or experience to assume responsibility for positions related to compliance with licensing regulations.

Yes

13) Facilities making a wholesale sale of controlled substances possess a license as a wholesale distributor of dangerous drugs and a license as a wholesaler or manufacturer of controlled substances.

Yes

14) The wholesaler conducts an inventory of controlled substances in accordance with OAC 4729-9-16 and applicable federal laws.

Yes

Observation
Quarterly, but will designate one as their Annual CS Inventory.

15) The facility is registered to submit wholesale sales of controlled substances and gabapentin to OARRS,

No

Observation
Using the following link, please register an account on OARRS and report all wholesales of controlled substances AND gabapentin:
https://www.ohiopmp.gov/Documents/General/WHOLESALE_DISTRIBUTORS/Instructions%20for%20Reporting%20Wholesale%20Transactions,%20Suspicious%20Orders%20and%20Customers%20to%20OARRS.pdf
Wholesale sales of controlled substances must be reported to OARRS. All wholesale drug sale information is required to be submitted during the first through the fifteenth day of each month. Information must be consecutive and inclusive from the last date/time information was submitted. Information must be submitted no later than 45 days after the date of the wholesale sale.
(OAC 4729-37-03) The following entities are required to submit the specified dispensing and wholesale sale information to the board of pharmacy for the drug database:
(C) All wholesalers licensed as a wholesale distributor of dangerous drugs that sell drugs identified in rule 4729-37-02 of the Administrative Code at wholesaleshall report those drug transactions.
(OAC 4729-37-07)
(D) All wholesale drug sale information required to be submitted to the board of pharmacy pursuant to rules 4729-37-02 and 4729-37-04 of the Administrative Code must be submitted monthly as follows:
(1) During the first through the fifteenth day of each month; and
(2) The information shall be consecutive and inclusive from the last date and time information was submitted and shall be reported no later than forty-five days after the date of the wholesale sale.

16) Substance Abuse and Mental Health Resources for Healthcare Professionals

1) Substance Abuse and Mental Health Resources for Healthcare Professionals

Observation

The healthcare profession is not immune to substance use disorder and mental health conditions. Such medical conditions impair a healthcare professional's competency, ability, and judgment. Substance use disorder and/or mental health conditions that are left untreated may not only cause a healthcare professional to risk their career but may also endanger the life of a patient.

These medical conditions can be effectively treated, and it is possible for healthcare professionals that are in treatment or recovery to return to practice.

The State of Ohio Boar of Pharmacy encourages all healthcare professionals who may be struggling with substance use disorder or mental health condition to seek help. The following are resources that can assist healthcare professionals in getting help: (the resources listed here are for informational purposes only and do not constitute an endorsement by the State of Ohio Board of Pharmacy. They do not represent a complete list of the resources available)

Ohio Careline 1-800-720-9616, emotional support, with referral to other resources if needed.
Crisis text line, text "4hope" to 741 741 to speak with a crisis counselor.
Treatment Bridge 1-877-275-6364, for addiction and mental health srevices.
National Suicide prevention dial 988, or call 1-800-273-8255.
Ohio Domestic Violence Network 1-800-934-9840
Pharmacist Rehabilitation Organization (www.ohiopro.org) for pharmacists and pharmacy interns.
Ohio Physicians Health Program (www.ophp.org)

19) Inspection Affirmation

1) Inspection Affirmation

Observation

As the person in charge, at the time of this inspection, I affirm that I have reviewed this inspection report with the Specialist/Agent, and understand its content. If this inspection report requires a written response of corrective action, the response shall be provided to the Ohio State Board of Pharmacy within 30 days of this inspection. I understand that if I am not the Responsible Person documented on this site's Ohio TDDD license, I will ensure the Responsible Person is notified of this inspection report and any corrective actions required. Responses can be emailed (with a copy of the inspection report) to writtenresponse@pharmacy.ohio.gov or they may be mailed to 77 South High Street, 17th Floor, Columbus, Ohio 43215.

Summary

No Issue Found

Reviewed by Amy Nusbaum

(signature)

STATE OF OHIO
BOARD OF PHARMACY

LICENSE TO DISTRIBUTE DANGEROUS DRUGS

The entity named below is duly licensed, and is entitled to conduct business in the state of Ohio until June 30, 2025.

Premier Pharmaceuticals Mid-America LLC

Premier Mid-America

2231 Venture Dr

Bowling Green, OH 43402-7501

License Number: 0132000157

Wholesaler - Category 3

Expiration Date: June 30, 2025

CLASS: Wholesaler - Category 3
BUSINESS TYPE: FS – Full Service

Responsible Person – Print, sign and keep license in a readily retrievable location at the address listed on this license.

Responsible Person Name (Print)	Signature of Responsible Person
AMY NUSBAUM	

Any change of responsible person must be reported within ten days of the effective date of the appointment of the new responsible person via Service Request on your Ohio eLicense Dashboard - https://elicense.ohio.gov/oh_homepage.

State of Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215
T: 614/466-4143 | F: 614/752-4836 | licensing@pharmacy.ohio.gov

Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

Drug Establishments Current Registration Site

New Search (default.cfm)

Search Results for **Premier Pharmaceuticals Mid-America**

CSVExcel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Premier Pharmaceuticals Mid-America LLC		127175467	RELABEL; REPACK;	2231 Venture Drive, Bowling Green, Ohio (OH) 43402, United States (USA)	12/31/2024

Showing 1 to 1 of 1 entries
Previous1Next
Data Current through: Wednesday, Jan 31, 2024

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

FDA

Wholesale Distributor and Third-Party Logistics Providers Reporting

About this Database | Back to Search Page

Search Results for *"premier mid"*

Showing 1 to 2 of 2 entries Show 50 entries

Facility Name	Facility Type	License Number	License State	License Expiration Date	Reporting Year	Address	Facility Contact Name	Facility Contact Email
Premier Pharmaceuticals Mid-America, LLC DBA: **Premier Mid-America**	WDD	WHO.0008724	US-CO	10-31-2024	2023	2231 Venture Dr Bowling Green OH	Amy Nusbaum	amy@premierpharma.com

Facility Name	Facility Type	License Number	License State	License Expiration Date	Reporting Year	Address	Facility Contact Name	Facility Contact Email
Premier Pharmaceuticals Mid-America, LLC DBA: **Premier Mid-America**	WDD	0132000157	US-OH	06-30-2025	2023	2231 Venture Dr Bowling Green OH	Amy Nusbaum	amy@premierpharma.com

Previous 1 Next

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

Q LABS LLC.
1930 Radcliff Dr.
Cincinnati, OH 45204
Jeff Knowles Phone: 513-471-1300

BIOLOGICAL

Valid To: July 31, 2024 Certificate Number: 3026.02

In recognition of the successful completion of the A2LA evaluation process (including an assessment of the laboratory's compliance with the A2LA Food Testing Program Requirements, containing the 2018 "*AOAC International Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements, and Pharmaceuticals*"), accreditation is granted to this laboratory to perform the following tests on foods, feeds, and food additives:

Test	In-House Method	Test Method(s)
Quantitative Microbiology		
Aerobic Plate Count	10-GENM-METH-003	FDA/BAM (Chapter 3)
Bacillus cereus	10-GENM-METH-013	FDA/BAM (Chapter 14)
B. cereus Enumeration (Presumptive)	10-GENM-METH-074	ISO 7932
Bacillus coagulans GBI-30, 6086	10-GENM-METH-070	FCC
Clostridium perfringens	10-GENM-METH-030	FDA/BAM (Chapter 16)
Coliform Count in Food	10-GENM-METH-068	ISO 4832
Enterobacteriaceae Enumeration	10-GENM-METH-069	ISO 21528-1, ISO 21528-2
Enumeration of β–glucuronidase-Positive *Escherichia coli*	10-GENM-METH-109	ISO 16649-2
E. coli/Coliform – Petrifilm	10-GENM-METH-024	AOAC 991.14
Gluten Allergen	10-GENM-METH-090	RIDASCREEN Gliadin Assay
Lactic Acid Bacteria (LAB)	10-GENM-METH-018	Compendium of Methods for the Microbiological Examination of Foods (5th Edition)

Test	In-House Method	Test Method(s)
Staphylococcus aureus Count – Petrifilm	10-GENM-METH-059	AOAC 2003.07, 2003.08, 2003.11
TEMPO AC	10-GENM-METH-118	AOAC 121204
TEMPO EB	10-GENM-METH-116	AOAC 050801
TEMPO YM	10-GENM-METH-104	AOAC 041001
Total Microbial Count	10-GENM-METH-067	ISO 4833
Yeast & Mold	10-GENM-METH-026	FDA/BAM (Chapter 18)
Qualitative Microbiology		
Campylobacter	10-GENM-METH-073	ISO 10272-1
Confirmation and Identification using the Bruker MALDI-TOF Biotyper	10-MIDL-METH-001F	AOAC 2017.09, 2017.10
Cronobacter spp.	10-GENM-METH-103	ISO 22964:2017
E. coli O157:H7	10-GENM-METH-065	ISO 16654
E. coli O157:H7	10-GENM-METH-098	AOAC PTM # 031002
Listeria monocytogenes	10-GENM-METH-020	USDA MLG 8
L. monocytogenes – BAX PCR	10-GENM-METH-099	AOAC PTM # 121402
Listeria spp.	10-GENM-METH-061	ISO 11290-1
Listeria spp. – BAX PCR	10-GENM-METH-096	AOAC PTM # 081401
Listeria spp. – VIDAS LIS	10-GENM-METH-015	AOAC 999.06
Listeria spp. – VIDAS LPT	10-GENM-METH-106	AOAC 2013.10
Qualitative Detection of the Hepatitis A Virus by Real-Time PCR	10-VIRL-METH-002	ISO/TS 15216:2016, Part 2
Qualitative Detection of Norovirus GI and GII by Real-Time PCR	10-VIRL-METH-001	ISO/TS 15216:2016, Part 2
Salmonella	10-GENM-METH-006	FDA/BAM (Chapter 5)

Test	**In-House Method**	**Test Method(s)**
Salmonella	10-GENM-METH-062	ISO 6579
Salmonella – BAX PCR	10-GENM-METH-097	AOAC 2013.02
Salmonella – VIDAS SLM	10-GENM-METH-071	AOAC 2011.03
Salmonella – VIDAS SPT	10-GENM-METH-107	AOAC 2013.01
Vibrio spp.	10-GENM-METH-111	ISO 21872-1:2017
Legionella		
Biotecon *Legionella* Quantification Assay	10-GENM-METH-130	Biotecon Diagnostics Microproof *Legionella* Quantification Lyokit 5'Nuclease
Legionella Isolation from Environmental Samples (CDC)	10-GENM-METH-087	Centers for Disease Control and Prevention Document (01/2005)
Veriflow *Legionella* spp.	10-GENM-METH-117	(Veriflow) *Legionella* species test kit

Accredited Laboratory

A2LA has accredited

Q LABS LLC.

Cincinnati, OH

for technical competence in the field of

Biological Testing

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017 *General requirements for the competence of testing and calibration laboratories*. This laboratory also meets the requirements of A2LA *R204 - Specific Requirements - Food and Pharmaceutical Testing Laboratory Accreditation Program*. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (*refer to joint ISO-ILAC-IAF Communiqué dated April 2017*).

Presented this 9th day of September 2022.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 3026.02
Valid to July 31, 2024

For the tests to which this accreditation applies, please refer to the laboratory's Biological Scope of Accreditation.

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

Q LABS LLC.
1930 Radcliff Dr.
Cincinnati, OH 45204
Jeff Knowles Phone: 513-471-1300

CHEMICAL

Valid To: July 31, 2024 Certificate Number: 3026.01

In recognition of the successful completion of the A2LA evaluation process (including an assessment of the laboratory's compliance with the A2LA Food Testing Program Requirements, containing the 2018 "*AOAC International Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements, and Pharmaceuticals*"), accreditation is granted to this laboratory to perform the following tests on foods:

Test	In-House Method	Test Method(s)
Chromatography		
Cholesterol in Foods	15-GENC-METH-003	AOAC OMA 994.10 (Modified)
Wet Chemistry		
Ash in Foods	15-GENC-METH-009	AOAC OMA 923.03 (Modified)
Fat by Acid Hydrolysis in Foods	15-GENC-METH-006	AOAC OMA 922.06 (Modified), 950.54 (Modified), 933.05 (Modified), 935.38 (Modified)
Fat by Ether Extraction in Meat	15-GENC-METH-011	AOAC OMA 991.36 (Modified)
Moisture in Foods	15-GENC-METH-004	AOAC OMA 950.46B (Modified), 926.08 (Modified), 926.05 (Modified), 925.10 (Modified), 935.56 (Modified)
Protein in Foods	15-GENC-METH-010	AOAC OMA 981.10 (Modified)
Salt in Foods	15-GENC-METH-012	AOAC OMA 935.47 (Modified)

5202 Presidents Court, Suite 220 | Frederick, MD 21703-8398 | Phone: 301 644 3248 | Fax: 240 454 9449 | www.A2LA.org

Accredited Laboratory

A2LA has accredited

Q LABS LLC.

Cincinnati, OH

for technical competence in the field of

Chemical Testing

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017 *General requirements for the competence of testing and calibration laboratories*. This laboratory also meets the requirements of A2LA *R204 - Specific Requirements - Food and Pharmaceutical Testing Laboratory Accreditation Program*. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (refer *to joint ISO-ILAC-IAF Communiqué dated April 2017*).

Presented this 9th day of September 2022.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 3026.01
Valid to July 31, 2024

For the tests to which this accreditation applies, please refer to the laboratory's Chemical Scope of Accreditation.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6751 Steger Drive Cincinnati, OH 45237-3097 (513)679-2700 Fax:(513)679-2772	11/14/2019-11/21/2019*
	FEI NUMBER 1527260

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jeffrey A Rowe, President & Chief Executive Officer

FIRM NAME	STREET ADDRESS
Q Laboratories Inc	1911 Radcliff Dr
CITY, STATE, ZIP CODE, COUNTRY Cincinnati, OH 45204-1824	TYPE ESTABLISHMENT INSPECTED Control Laboratory

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically,

The SOP 20-ADMN-CGMP-0071, titled "Procedure for OOS Investigations of Analytical Results", effective August 13, 2018, states in section 5.4 investigations are documented and approved within 30 days of discovery.

During my review of OOS's, I observed the following OOS's were not closed within the allotted time frame:

19-010, 19-011, 19-052, 19-061, 19-062, 19-063, 19-095, 19-098, 19-102 and 19-110.

Additionally, the above OOS's did not have the written justification document, "A208, Investigation Extension Justification" authorizing the investigation to be extended as outlined in section 5.4 of the SOP.

---

*DATES OF INSPECTION

11/14/2019(Thu), 11/15/2019(Fri), 11/18/2019(Mon), 11/19/2019(Tue), 11/20/2019(Wed), 11/21/2019(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jon P Antoniou, Investigator	X Jon P Antoniou Investigator Signed By: Jon P. Antoniou -S3 Date Signed: 11-21-2019 10:15:19	11/21/2019

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."

November 22nd, 2019

Attn: Art Czabaniuk, Program Division Director
Division 3, Food and Drug Administration

Re: Observations made during a 2019 inspection of Q Labs LLC, 1911 Radcliff Dr., Cincinnati, OH 45204-1824 (FEI 1527260).

Mr. Czabaniuk,

The following is in response to a Form 483 observation made following an inspection of Q Labs, LLC conducted November 14th thru November 21st, 2019 by Consumer Safety Officer, Jon P. Antoniou from the Office of Pharmaceutical Quality Operations, Pharma Division 3.

Observation 1

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically,

The SOP 20-ADMN-CGMP-007, titled "Procedure for OOS Investigations of Analytical Results", effective August 13, 2018, state in section 5.4 investigations are documented and approved within 30 days of discovery.

During my review of OOS's, I observed the following OOS's were not closed within the allotted time frame:

19-010, 19-011, 19-052, 19-062, 19-063, 19-095, 19-098, 19-102 and 19-110.

Additionally, the above OOS's did not have the written justification document, "A208, Investigation Extension Justification" authorizing the investigation to be extended as outlined in section 5.4 of the SOP.

Response:

This observation had been made internally prior to the inspection by Mr. Antoniou, and a Non-Conformance Investigation (NC 19-142) had been opened to investigate and mitigate the outage. During the inspection, the NC was closed and Corrective and Preventative Action (CA 19-142) implemented. Copies of NC 19-142 and CA 19-142 (including supporting documentation) were provided to Mr. Antoniou during the inspection. An additional copy is attached here for your reference.

In summary, our investigation determined that, while investigations were being completed, they were not always being completed within the 30-day timeframe prescribed within our

SOP. We did conclude, however, that client contact was maintained throughout the investigation period to ensure clients were aware of any delay, and that, in many cases, the investigations were left open at the client's request to allow for additional hypothesis testing. However, in those instances, an Investigation Extension Justification (form A208) should have been written. It was determined that the most likely root cause for inconsistent filing of Investigation Extension Justification (form A208) was lack of a visible reminder to connect the need for extension requests with each individual investigation, as applicable.

To correct this outage, we have implemented two main corrective actions:

1. We have updated the Analytical and Microbiological investigation forms to include a space for investigation extensions to serve as a visible reminder to the investigator.

2. We have implemented weekly meetings between all QA personnel associated with investigations and the Director of Quality to discuss all open investigations, so that adequate resources can be assigned as necessary to ensure timely closure.

We will continue to monitor the effectiveness of these corrective and preventative actions to ensure their sustained effectiveness.

Best regards,

X

Jeffrey Rowe
President & CEO, Q Labs LLC

Site Master File

Table of Contents

1. Scope

This Site Master File (SMF) is a version-controlled document that describes the structure of Q Labs' organization, the site and facilities, the testing activities carried out, and the details of how the Quality Management System (QMS) functions to ensure data integrity.

2. Purpose

The purpose of this document is to provide an overview of the facilities and operations of Q Labs LLC located in Cincinnati, Ohio. This document describes the activities of the Company to demonstrate that it has a cGMP-compliant Quality System in place. The Quality Unit will review the Site Master File annually or any time the Company makes material changes to its operations.

3. Corporate Authorizations

Q Labs LLC is registered with the U.S. Food & Drug Administration (FDA) as a testing laboratory for pharmaceutical products, over-the-counter (OTC) drugs and cosmetic products. Since moving to electronic registration, FDA has begun utilizing Data Universal Numbering System (DUNS) numbers in combination with Facility Establishment Identifier (FEI) Numbers. DUNS Number for Q Labs is 080737501, and its FEI Number is 1527260. Q Labs LLC is current with its FDA registration as a drug establishment. The organization is currently ISO 17025 accredited through the A2LA accreditation body. The most recent FDA inspection was November 14-21, 2019. There are no unresolved regulatory issues. Registrations with applicable State and Federal regulatory agencies are current and in good standing.

4. Product Services

Q Labs LLC is a full-service contract testing laboratory for food, pharmaceutical, personal care products, cosmetic, medical device, animal health and dietary supplement industries. Testing services include microbiology, analytical chemistry, method development/validation and research & development support. Q Labs does not currently provide testing for Drug Enforcement Agency regulated products.

5. Facility Location Description

Q Labs facilities are located within the city limits of Cincinnati, Ohio. The testing laboratory site is bounded by residential neighborhoods, business sites and government property.

Q Labs currently operates at the following locations:

- **1911 Radcliff Drive, Cincinnati, Ohio, 45204** (30,000 ft2), on two levels to include microbiology and analytical chemistry laboratories.
- **1930 Radcliff Drive, Cincinnati, Ohio 45204** (15,000 ft_2), this building includes microbiology R&D, stability chambers, quality department, sales/marketing department, sample distribution and IT.
- **1920 Radcliff Drive, Cincinnati, Ohio 45204** (10,000 ft2), includes administrative support (executive offices, HR, finance, purchasing), facility engineering support, and receiving warehouse for supplies.

6. Company History

Q Laboratories was founded in 1966 by Herbert Quinn. The "Q" in the company name represents the founder. Mr. Quinn originally operated a small microbiology laboratory testing mostly water.
In 1985, Michael Knight, a former FDA investigator, bought the company from Mr. Quinn and moved it into a facility in the South Fairmount neighborhood of Cincinnati. Mr. Knight leveraged his FDA background to expand the services offered to include testing of food, pharmaceuticals, cosmetics and dietary supplements. He also opened the analytical chemistry department, implementing GMP quality standards throughout the operation.
With continued success, Q Laboratories eventually outgrew the South Fairmount facility and, in 1997, moved to 1400 Harrison Avenue. This lab building has a unique place in Cincinnati history. Built in 1911, it comprises over 14,000 square feet of space located in one of the city's oldest neighborhoods, just five minutes from downtown Cincinnati. The building originally housed the offices of the Herancourt Brewing Company, a now defunct brewery that operated in the early 20th century.
In 2000, the business was acquired by David Goins, who at that point served as the Laboratory Director. Growth continued and, in 2010, Q Laboratories opened a new 9,000 square foot addition which allowed for the expansion of laboratory space and a more efficient workflow.
Continued success has required another major facility expansion. In 2017, the company acquired investment capital and began construction of a new Q Laboratories campus – a 25,000 square foot administrative building along with a state-of-the-art, 30,000 square foot laboratory facility. The goal of this latest expansion: Enable Q Laboratories to continue to provide clients with cutting-edge scientific technologies capable of accommodating projects and sample volumes of virtually any size. The 1911 laboratory building was officially opened for business in May 2018.

7. Site Description

Each building is of suitable size, construction, and design to facilitate maintenance, cleaning, and operations. Space is adequate for orderly placement of equipment and testing of materials. Separate or defined areas are maintained to prevent contamination of products during receiving, and testing operations. Each building is maintained in a clean and sanitary condition. Commercial HVAC filtration systems are used to maintain the laboratory environments.

The buildings are adequately secured against entry of unauthorized personnel. Security controls include a 24-hour security system supported by security personnel. All employees are required to utilize badge

The buildings are adequately secured against entry of unauthorized personnel. Security controls include a 24-hour security system supported by security personnel. All employees are required to utilize badge access to enter the facility. A safety committee operates under the direction of the Chemical Hygiene Officer. The institutional biosafety committee operates under the direction of the Biological Safety Officer. Written policies for safety are established. First aid kits and fire extinguishers are suitably located throughout the buildings. Emergency evacuation maps are posted where necessary. Electronic copies of SDS are also maintained and may be accessed at each company computer through a desktop icon.

Openings to each building are protected against entry by rodents and other pests. Warehouse roll up doors are closed when not in use. HVAC filters in the laboratory area are inspected and changed every two months. There is adequate lighting in the laboratory areas to facilitate housekeeping, safety and operations.

Biological Safety Cabinets (BSC) with HEPA filtration are used for sample preparation in the GMP microbiology laboratory. The BSC are cleaned daily and the cleaning activity is recorded. There are 18 fume hoods and 4 acid hoods in the analytical chemistry area for sample preparation as applicable.

There are several separate laboratory areas for testing operations. The GMP microbiology laboratory has identified separate areas for sample preparation, antimicrobial effectiveness testing, and microbial identification to reduce the potential of contamination of samples. Food Microbiological testing is performed in a separate laboratory area from the GMP testing. The microbiology R&D laboratory is adequately separated from the routine laboratory testing areas. On the analytical chemistry floor, there are separate laboratory areas for food sample preparation, hazardous chemical storage, metals analysis, total organic carbon analysis, chromatography operations, mass spectroscopy operations and analytical R&D.

Staff amenities, including breakrooms and locker facilities, are separate from testing and quality control areas.

Restrooms are maintained and readily accessible in all buildings. They are properly lit and ventilated. Hand-washing facilities are provided and furnish soap, hand dryers, and running water at a suitable temperature. Laboratory personnel are required to remove and hang up their lab coats prior to entering the restroom.

Work instructions (masters) and standard operating procedures address processes for the maintenance of buildings and equipment. A documented environmental monitoring program is maintained. Pest control is addressed through an appropriate SOP. A pest control manual is maintained for each facility. Inspections are conducted by the facilities department. Exclusion measures are adequate for excluding pests from the buildings and for protecting against the contamination of samples. Insect light traps are installed at various locations in the facilities. Pest activity logs are in place. Exterior bait stations are in use.

8. Organization Charts & Department Staffing

Q Labs employs approximately 124 full-time employees and 21 part-time employees. The organization operates 7 days a week regarding routine microbiological testing and 5 days a week for analytical testing. Additional testing hours will be provided on an as contracted basis for client support.

9. Management Responsibilities

Jeff Rowe, President & CEO, is the most responsible person at Q Labs. Attachment 2 depicts the executive management organization.

There are an adequate number of supervisory and management employees with the necessary qualifications, training, or practical experience. There are organizational charts showing the key positions, as well as their areas of responsibility and lines of authority. Employees in responsible positions have written job descriptions describing their specific duties.

Key personnel include the persons nominated as responsible for Testing and Quality. Full-time personnel occupy key positions. Part-time employees are utilized for support functions within the laboratory and operational groups. Contracted labor is not employed at Q Labs. Personnel identified to perform Quality operations have the necessary independence and authority to ensure that Quality measures are employed in the testing all products. Laboratory personnel performing microbiological and analytical testing are suitably qualified.

Each laboratory have designated quality employees that facilitate data review, quality investigations, and procedural improvements. Q Labs has established the role of Metrologist with the focus on continuous improvement in maintenance, calibration, and qualification support of the laboratory equipment. The stability team lead is responsible for the stability chambers and the associated stability protocols. Document Control is supported by members of the Quality Assurance Unit responsible for controlling master testing forms, client procedures, SOPs and policies.

10. USP Purified Water System

Water used in the preparation of media for microbiological testing is purified to meet current USP requirements using deionization, UV sanitization, and filtration. The system was installed in 2018, has undergone qualification, and remains in a qualified state.

The water for the 1911 purified water system is supplied by the city of Cincinnati through the local municipal piping system. The city water passes through a softener, two carbon beds, two mixed resin beds, a 1-micron filter before it is treated by a UV lamp with bio filter. The purified water is transferred to the storage tank. The storage tank is fitted with a 0.2-micron vent filter. The water exits the storage tank through a pump to another mixed resin bed which is followed by a 1-micron filter. The water is

further treated by a UV lamp and bio filter before distribution to the points of use. The distribution loop circulates back to the storage tank. There are two continuously circulating water distribution lines, one line to the upper level for the chemistry area and one line to the lower level supplying the microbiology labs. Point-of-use (POU) drops are installed throughout each laboratory. The system is sampled monthly at beginning, middle, and end POU's. Chemical (TOC and Conductivity) and microbial alert and action levels are monitored and managed by Quality/Metrology.

The Milli Q purified water system located in the metals laboratory provides USP purified water for all testing performed in the chemistry laboratory area to include elemental analysis and chromatography. The system qualification was completed in September 2019.

11. Quality Management System

Q Labs has a documented Quality Management System (QMS), supported by management, that is well-established and maintained. Adequate resources are provided to achieve each aspect of the system.

- The Quality Management System ensures that managerial responsibilities are clearly defined, documented and exercised
- Testing operations are specified, and good manufacturing and good laboratory practices are followed
- Supplies meet required specifications
- Necessary controls on testing and data are carried out
- Final reports are not released before an authorized person has signed that each sample has been tested in accordance with documented procedures, meets required specifications, and meets all required Quality tests
- Appropriate storage conditions are maintained
- There is a procedure for conducting internal Quality System audits that appraise the effectiveness and application of the QMS.

A system of Quality Control is established to ensure that product testing complies with their required standards. Quality personnel approve all written procedures, tests, and examinations affecting GMP product quality reports.

Q Labs has established a quality manual, a set of Standard Operating Procedures (SOPs) and Masters (forms) to support the Quality Management System. The responsibilities and procedures applicable to the Quality Unit are described in SOP's and the quality manual.

Internal audits are conducted by representatives of the Quality Unit, with each department audited at a minimum of once each calendar year.

12. Resource Training

Employee training requirements are addressed in SOPs that detail job specific training, GMPs, and safety training for personnel. Department managers are responsible for training their employees. Internal training records are maintained by Quality to include the date and type of training, and person(s) trained. Personnel responsibilities related to confidentiality and undue pressure are reviewed annually with the employee.

13. Quality Control & Assurance

Testing supplies/materials are purchased from approved vendors that are periodically reviewed. Supplies are assigned an expiration date to ensure adequate control. Q Labs has established, written procedures for the receipt, identification, testing, and reporting of testing data. Each sample received is issued a Q Labs number (QL#) for traceability. The sample will be assigned to a trained analyst. The analyst will record the testing data on the appropriate master form. The data will be submitted to operations for typing the report. The typed report and raw data will be reviewed by Quality prior to obtaining the Laboratory Supervisors signature on the final report. Test samples are retained for 30 days prior to destruction. All data and associated paperwork are retained for 7 years.

The R&D Labs are responsible for method validations/verifications and GLP studies.

The GMP microbiology laboratory performs various microbial testing procedures on raw materials, bulk, and finished products from clients. Tests are performed against established specifications following validated customer-specified or USP Test Methods. Identification of bacteria, yeasts and mold are performed using the Bruker identification system. The majority of the media is prepared on site by the Media Lab and tested according to written instructions with documentation on the appropriate master. QC tests are conducted on prepared media. Purchased media plates are QC tested prior to use. Microbial testing of the purified water system is performed using membrane filtration and pour plate methods. Microbial alert and action levels are established. Test results are documented. Routine microbial test results for product release are recorded on both the sample master sheet as well as on the laboratory report that is sent to the client. Additional environmental testing is performed to monitor air and lab surface quality in the microbiological labs. Representative sites are sampled for air quality weekly while lab surfaces are sampled weekly to cover all sites within the month.

The analytical laboratory performs various physical and analytical testing procedures on raw materials, bulk, and finished products for clients. Tests are performed against established specifications and the results recorded. All testing is performed according to written Test Methods. Test data is recorded on a laboratory report that is sent to the client. The raw data is maintained for 7 years.

Laboratory management will notify the client and Q Labs Quality Unit of any out of specification (OOS) results in a timely manner of the discovery of the OOS result. Quality will perform an investigation to determine if laboratory error was the root cause. An investigation report will be issued to the client for further investigation and product disposition.

14. Stability

Q Labs provides ICH (International Conference on Harmonisation Regulations) compliant stability services and shelf life studies. The stability chambers are monitored utilizing continuous monitoring probes. Each chamber is mapped and certified annually. Studies may include weight loss, freeze/thaw, thermal cycling, or photostability depending on the product and container closure system. The testing and storage conditions will be outlined in the protocol prepared by the Stability Team Lead.

15. Third-Party Contracts

Q Labs only subcontracts its testing operations when the customer requests it or if the lab is temporarily unable to perform the test. The client must agree to have the test subcontracted. Q Labs will review and submit the final report to the client.

Q Labs utilizes a professional security service to provide the security services described above.

16. Document Control Procedures

Processes and associated activities in the testing of drug and personal care products are documented, and critical documents are subject to a system of document control. Employees are assigned to facilitate Document Control as part of the Quality Unit organization.

Documents are approved, signed and dated by appropriate and authorized persons. Master SOPs are maintained electronically, scanned into protected PDF format, and made available on the network "Documentation" drive. Responsibilities of Quality related to document control include establishing and maintaining Quality policies/procedures, as well as retiring and archiving obsolete procedure. Master documents used to document test data are controlled forms managed by Quality. SOPs are reviewed, at a minimum, every 3 years. The results of the review are recorded.

17. **Data Integrity Program**

The Data Integrity Program is intended to ensure the integrity of data, across the data lifecycle from creation through long-term archival, used to make safety, efficacy, quality and regulatory compliance decisions at this site. The Data Integrity Plan for Q Labs LLC is intended to align with current US FDA, Health Canada, MHRA, and World Health Organization guidelines for a risk-based approach and a data lifecycle concept as they pertain to data integrity and computerized systems validation.

Approved By: _____ 3.31.2022

August Smithmeyer, Director of Microbiology Operations — Date

Approved By: _____ 3-30-22

Jeff Knowles, VP Quality — Date

Approved By: _____ 3-30-22

Jeff Rowe, President and Chief Executive Officer — Date

REVISION HISTORY:

Rev	Date	Section	Changes
F	3/23/22	3	Updated Q Labs DUNS number to 080737501.
F	3/16/22	7	Changed that HVAC filters are inspected and changed semiannually.
F	3/16/22	8	Updated full-time employees to 124 and part-time employees to 21.
F	3/16/22	10	Changed "weekly to cover all POU within the month" to "monthly at beginning, Middle, and end POU's." Added "Quality/Metrology".
F	3/16/22	Entire Document	Updated approval to August Smithmeyer, Director of Microbiology Operations.

Q LABS SOP TOC

20-ADMN-POLI-004	Q Labs LLC Data Integrity Plan
20-ADMN-POLI-005	Site Master File
20-ADMN-ISO-001	Creation, Review, Approval & Distribution of SOPs and Forms
20-ADMN-ISO-002	Protection of Client's Confidentiality
20-ADMN-ISO-003	Subcontracting of Tests
20-ADMN-ISO-004	Ethical Conduct & Freedom from Undue Pressure & Conflicts of Interest
20-ADMN-ISO-005	Procurement
20-ADMN-ISO-006	Management Reviews
20-ADMN-ISO-007	Requirements of Equipment
20-ADMN-ISO-008	Control of Records
20-ADMN-ISO-009	Good Documentation Practices
20-ADMN-ISO-010	Investigation of Nonconforming Work
20-ADMN-ISO-011	Change Control
20-ADMN-ISO-012	Q Laboratories Quality System
20-ADMN-ISO-013	Training
20-ADMN-ISO-014	Corrective and Preventative Actions
20-ADMN-ISO-016	Quality Assurance Unit
20-ADMN-ISO-018	Inspection of Testing Facility/Visitor Policy
20-ADMN-ISO-019	Storage Requirements of Reagents and Chemicals
20-ADMN-ISO-020	Review of Requests and Contracts
20-ADMN-ISO-021	Reporting & Reviewing Test Results
20-ADMN-ISO-022	Traceability of Materials and Standards
20-ADMN-ISO-023	Method Development and Validation
20-ADMN-ISO-024	Deviations from Standard Test Methods & Q Laboratories Procedures
20-ADMN-ISO-025	Software Development, Modification and Validation
20-ADMN-ISO-028	Proficiency Testing Program
20-ADMN-ISO-029	Customer Feedback
20-ADMN-ISO-030	Control Charting and the Measuring of Uncertainty of Data for Microbiology
20-ADMN-ISO-035	Significant Figures and Rounding
20-ADMN-ISO-036	Pest Control Program
20-ADMN-ISO-037	Onboarding New Employees
20-ADMN-ISO-038	Blue Mountain Calibration Manager
20-ADMN-ISO-040	Control Charting and the Measuring Uncertainty of Data for Chemistry
20-ADMN-ISO-041	Quality Control Program
20-ADMN-ISO-042	Data Integrity
20-ADMN-ISO-043	Transfer of Samples
20-ADMN-ISO-045	Q Laboratories Deionized Water System, 1911 Radcliff
20-ADMN-ISO-046	Risk and Opportunity Management Using SWOT Analysis
20-ADMN-ISO-047	Maintenance and Calibration of Equipment
20-ADMN-CGMP-001	Conduct of CGMP Studies
20-ADMN-CGMP-002	Validation/Verification of GMP Methods
20-ADMN-CGMP-005	Stability Chambers and Stability Testing

20-ADMN-CGMP-006	Qualification of Laboratory Instruments
20-ADMN-CGMP-009	Inspection of Testing Facility by Regulatory Agencies
20-ADMN-CGMP-010	Guidelines for Analytical Method Transfer
20-ADMN-CGMP-011	Compliance of Laboratory Computer Systems to 21 CFR 11
20-ADMN-CGMP-012	Guidelines for Microbiology Method Transfer
20-ADMN-CGMP-013	Control of Master Data Sheets
20-ADMN-CGMP-014	OOS Investigations

Drug Establishments Current Registration Site Q Lab | FDA

Firm Name	FDA Establishmen	DUNS	Business Operations	Address	Registration Exp
Q Labs, LLC	1527260	080737501	ANALYSIS	1930 Radcliff Dr, Cincinnati, Ohio (OH) 45204, United States (USA)	12/31/2024

Q Laboratories

Quality Agreement

Q Laboratories
1930 Radcliff Dr.
Cincinnati, OH 45204
(also referred to as Contractor)

Authorization
Q Laboratories

Jayson Arling – President — Date 2-22-24

Jeff Knowles – Vice President, Quality — Date 2-22-24

Buyer Company Name – Premier Pharma

Name JACOB FUCHS Title Founder PRESIDENT — Date 2/5/24

Name ADRIAN CONSTANCE Title EVP — Date 2/5/24.

The action of approving this document indicates that the appropriate parties have reviewed the agreement to the complete content of this document.

THIS DOCUMENT WILL BECOME EFFECTIVE FROM THE DATE FINAL APPROVAL IS GIVEN BY THE BUYER AND CONTRACTOR.

Q Laboratories

TABLE OF CONTENTS

1.0 Scope of the Quality Agreement:

a) Q Laboratories has been appointed by Premier Pharma to perform monographed and/or method validated testing, physicochemical testing, microbiological testing, and stability storage under cGMP or GLP conditions as appropriate.

b) This Quality Agreement is not intended to supersede, modify or amend the Confidentiality Agreement in any respect.

c) This Quality Agreement is subject to US law and if it is translated into a language other than English, this version in English shall be controlling on all questions of interpretation.

2.0 Revision History:

Issued 1/15/2024

3.0 DEFINITIONS:
Except as otherwise defined below, the terms in this agreement shall have the meaning, if any, as defined within the US GMP Regulations.

a) "Q Labs" Q Laboratories referred to as Contractor- approved contract testing laboratory.

b) "Premier" Premier Pharma / Premier Mid-America referred to as Buyer, a cGMP regulated company.

c) "Competent Authority" means the applicable competent authority referred to by US and European cGMP Regulations.

d) "Parties" means Q Laboratories and Buyer and their permitted assigns and "Party" means any one of them or their permitted assigns, as the context requires.

e) "Quality Investigation" means any unplanned deviations that are raised during the laboratory testing for the product.

f) "Reference Sample" means a sample, stored for identification purposes, of a fully packaged unit from a batch of Finished Product.

g) "Primary Responsibilities" are defined between the Parties within the quality matrix, section 4, by the designators (R, I, C and NA) listed at the top of each section table, in the appropriate company column. NA delineates a responsibility as not applicable.

h) "Retention Sample" or "Retain sample" means a sample which is stored for the purpose of being analyzed should the need arise.

i) "Specifications" means those specifications for each Product provided by Contractor used to manufacture and test the Product.

j) Under General requirements and responsibility **(R)** = Responsible will be used to indicate which party would be responsible for performing or completing the task, likewise **(I)** = Inform will indicate which party would need to be informed, **(C)** = Consult would indicate that the party would act in consultation, and **(N/A)** = not applicable indicates that the activity does not apply to the designated party.

4.0 RESPONSIBILITIES

GENERAL REQUIREMENTS AND RESPONSIBILITIES
(R = responsible, I = inform, C = consult, N/A = not applicable)

Ref	Activity	Contractor	Buyer	Clarification of Responsibility
4.1	Preparation and update of Quality Agreement	R	R	Q Laboratories and Buyer are responsible for the preparation and regular review of this Quality Agreement.
		R	R	Except as otherwise expressly stated, the terms and conditions of the Quality Agreement remain in full force and effect.
		R	R	Contractor and Buyer have agreed to the Quality Agreement as a free-standing document and either company can propose changes to it. The change initiator shall communicate the change in writing prior to implementation. The initiator shall generate a draft revision. The draft revision will then be routed and approved without undue delay by the Buyer and the Contractor according to each Party's procedure. Upon completion of the review, Buyer will send Contractor two signed originals of the revised Agreement for Contractor's approval. Upon Contractor's approval, the Buyer will return one signed original to Contractor and retain the other.
		R	R	No change shall be made without written agreement of both parties, except as required by law or regulatory action.
		R	R	This Quality Agreement will be periodically reviewed and updated in accordance with each party's Standard Operating Procedures.
4.2	US cGMP / GLP and other applicable Health Authorities	R	R	Testing of Products shall be in accordance with the "The Rules Governing Medicinal Products" in the Good Manufacturing Practice provisions set forth in 21 CFR 58, 210, 211, 820 and Part 11, and other applicable regulatory or health authorities' provisions as amended from time to time. The generation and reporting of test data shall be in accordance with the Good Laboratory Practice and Good Manufacturing Practices provisions set forth in 21 CFR 58, 210, 211, 820 and Part 11, as appropriate
4.3	Subcontracting	R	C	The Contractor reserves the right to subcontract testing or other laboratory analysis to outside laboratories, provided that these outside testing laboratories are qualified using internal procedures. The Buyer must be notified and approve the subcontractor.

4.4	Documentation requirements	R	C	Contractor will prepare, provide and maintain Buyer's standard documentation requirements according to standard operating procedures and document control systems. Additional required documentation shall be provided by Contractor as agreed between Buyer and Contractor.
4.5	Key contacts/Buyer Visitation	I	I	See Appendix 2 to this Quality Agreement. The Buyer will be afforded the right on a limited basis and with a minimum of 7 days advanced notice, to have representatives present at Contractor premises whenever work is being conducted on behalf of the Buyer, *as long as presence does not violate confidentiality of other* Contractor *clients*, to assess compliance with quality requirements of the Buyer.
4.6	Electronic Records/Signatures	R	N/A	Electronic Records / Signatures: Contractor shall comply with 21 CFR Part 11 requirements regarding the use of electronic records / signatures involved in data generation.
4.7	Validation	R C	C R	Method validations will be performed, data compiled and documented as agreed between the Buyer and the Contractor. Buyer requests for additional qualifications and/or validations will be at Buyer's expense.

LABORATORY TESTING AND CONTROL

(R = responsible, I = inform, C = consult, N/A = not applicable)

Ref	Activity	Contractor	Buyer	Clarification of Responsibility
4.8	Site	R	I	Address(es) of approved site(s) of operation as Contractor: Q Laboratories, 1911 Radcliff Dr, Cincinnati OH, 45204 Q Laboratories, 1930 Radcliff Dr, Cincinnati OH, 45204
4.9	Documentation – Preparation	R	I	The contractor is responsible for the preparation and approval of laboratory documents.
4.10	Documentation – Retention	R	I	Contractor shall retain original documents in accordance with cGMP and local Standard Operating Procedures.
4.11	Specifications and Test methods for Starting Materials	I I	R R	The Buyer is responsible for the provision of specifications and test methods for samples. The Buyer is responsible for communicating any changes to specifications.
4.12	Specification and Test methods for Product	N/A	R	The Buyer is responsible for the approval of Finished Product Specifications and test methods for Product release.

4.13	Reference standards for Drug(s)	R	I	The Contractor is responsible for the supply of appropriate Reference standards, at cost to the Buyer, but will inform Buyer on any changes of supply or Reference standards.

4.14	Sampling and release for use of Bulk Product	I	R	Buyer is responsible for sampling and release of Bulk Product.
4.15	Warehousing	R	N/A	All samples provided to Contractor by Buyer are to be stored in accordance with the appropriate labeled storage conditions and in compliance with cGMP requirements or as otherwise agreed provided it is in accordance with US cGMP.
4.16	Waste management	R	N/A	Contractor shall comply with the current US Applicable Laws on waste management and waste disposal, and/or European legislation as appropriate.

QUALITY ASSURANCE

(R = responsible, I = inform, C = consult, N/A = not applicable)

Ref	Activity	Contractor	Buyer	Clarification of Responsibility
4.17	Inspection by a Competent Authority	R R	I I	Contractor will inform Buyer as soon as possible, not to exceed two consecutive business days, of any findings arising from routine inspections conducted by Competent Authorities of Contractor's facility, which may affect Buyer's Product. Contractor shall provide copies of inspection reports upon request by Buyer, which result in a finding that indicates a possible cGMP violation that affects or may affect the Products. Contractor will inform Buyer as soon as possible, not to exceed 2 business days, of any inspection by a Competent Authority of Contractor that may give rise to inspection of Buyer's facility.
4.18	Regulatory Inspections of Buyer	I C	R R	In the case of a request for an audit/inspection of Buyer's Facility from a Competent Authority having jurisdiction over the Product, Buyer shall permit representatives of the regulatory authority to enter Buyer's premises for inspection in relation to cGMP regulations. During an inspection the Buyer may contact the Contractor for assistance in addressing a question from the regulatory authority to include obtaining additional documentation of past testing that is within normal document retention periods.

4.19	Handling of cGMP Out Of Specification (OOS).	R R R	I C I	In the event of a cGMP out of specification (OOS), Contractor will notify Buyer as soon as possible, but within a timeframe not to exceed two (2) business days. Contractor shall have primary responsibility for the investigation with respect to laboratory analyses conducted, in accordance with agreed procedures with a target completion date of 30 calendar days. Contractor will consult with Buyer during the course of the investigation. Contractor will notify Buyer of extensions beyond the 30-day target completion.
4.20	Deviations (from the agreed processes or methods)	R	R	Contractor shall notify Buyer and obtain its prior approval for any planned deviations, which may affect the quality of the product.

REGULATORY
(R = responsible, I = inform, C = consult, N/A = not applicable)

Ref	Activity	Contractor	Buyer	Clarification of Responsibility
4.21	Technical Documentation	N/A N/A	N/A N/A	If applicable, Contractor or its agent is responsible for compiling and submitted all Technical Documentation to notify bodies and competent authorities for registrations outside the U.S. If applicable, Buyer will provide Contractor with all needed technical information to be able to complete the Dossier and international registrations, as appropriate and per Supply Agreement Drug substance characterization
4.22	Post inspection notification if Product quality is affected	R	I	Contractor will inform Buyer within two business days of any findings arising from routine inspections conducted by any recognized regulatory authority, including but not limited to, inspection by the FDA, which may affect Contractor's testing.

APPENDIX 1 – REQUIRED DOCUMENTS

DOCUMENT	FUNCTION
Purchase Order Request	Buyer includes with submitted sample(s) for identification, required testing and test method(s) to be performed by Contractor.
Sample Submission Form	Document used internally by Contractor to log incoming samples.
Final Report	Issued to Buyer by Contractor when testing has been completed, quality reviewed and accepted. Each report is identifiable by a "Q Labs Reference No.".

Q Laboratories

APPENDIX 2 – KEY CONTACTS

CONTRACTOR QUALITY MANAGEMENT

Name	Jeff Knowles
Phone	513-471-1300
Email	jknowles@qlaboratories.com

CONTRACTOR OPERATIONS MANAGEMENT

Name	August Smithmeyer
Phone	513-471-1300
Email	asmithmeyer@qlaboratories.com

BUYER QUALITY ASSURANCE MANAGER

Name	ADRIAN CONSTANCE
Phone	208-639-0241
Email	adrian@premierpharma.com

BUYER QUALITY CONTROL CONTACT

Name	
Phone	
Email	

BUYER QUALITY CONTROL LABORATORY MANAGER

Name	
Phone	
Email	

Q LABS, LLC
MUTUAL NONDISCLOSURE AGREEMENT

THIS MUTUAL NONDISCLOSURE AGREEMENT is made as of this 15th day of January, 2024 by and between Q LABS, LLC, an Ohio limited liability company ("Q Labs"), and Premier Pharma including Subsidiaries ("Customer").

WHEREAS, Q Labs is an independent, third party reference laboratory engaged in providing microbiological, analytical chemistry, and research and development testing services; and

WHEREAS, Customer desires to engage Q Labs to conduct certain microbiological, analytical chemistry and/or research and development studies and (the "Purpose"); and

WHEREAS, in connection with the Purpose, either or both of the parties (in each case, "the Disclosing Party") may disclose to the other party (the "Receiving Party") certain non-public and proprietary information about the Disclosing Party's business, the confidentiality of which the Disclosing Party wishes to protect and preserve.

NOW THEREFORE, in consideration of the mutual undertakings herein, and other good and valuable considerations, the receipt and sufficiency of which the parties each hereby acknowledges, the parties hereby agree as follows:

1. **Confidential Information**. For purposes of this Agreement "Confidential Information" shall mean all non-public and proprietary information so designated by the Disclosing Party prior to or upon its delivery to the Receiving Party including technical, scientific and financial information such as product compositions, formulae, specifications and samples; physical and chemical characteristics of compounds; product safety and efficacy data; technologies, know-how, techniques and methods; research, discoveries and inventions; market research studies and marketing plans; and all other matters protected by the Uniform Trade Secrets Act. Q Labs' test results, and its compilation of such test results, shall be deemed to be the Confidential Information of Customer. Notwithstanding the foregoing, Confidential Information shall not include information: (a) which is already in, or subsequently comes into, the public domain other than through a violation of this Agreement; (b) which is received by the Receiving Party on a non-confidential basis from a source other than the Disclosing Party, which source is not prohibited from disclosing such information by any legal, contractual or fiduciary obligation to the Disclosing Party; (c) which was already known by the Receiving Party at the time of receipt from the Disclosing Party as evidenced by the Receiving Party's records; or (d) which is developed by an employee, agent or consultant of the Receiving Party who did not have access to the Disclosing Party's Confidential Information.

2. **Ownership of Confidential Information**. The Receiving Party hereby confirms that, notwithstanding the disclosure to or use by the Receiving Party of any of the Disclosing Party's Confidential Information, all such Confidential Information at all times shall be remain the exclusive property of the Disclosing Party.

3. **Use of Confidential Information**. Any of the Disclosing Party's Confidential Information obtained by the Receiving Party shall be used by the Receiving Party solely for the Purpose and shall not be used by the Receiving Party or any of its employees for any other purpose or otherwise in any manner which is detrimental to the interests of the Disclosing Party or any of its affiliates. The Receiving Party shall keep the Disclosing Party's Confidential Information in strict confidence and may disclose such Confidential Information only to those of its employees who have a need to know such Confidential Information, who are informed by the Receiving Party of the confidential nature of such Confidential Information, and who agree to be bound by the confidentiality restrictions under this Agreement. The Receiving Party shall not disclose, make available or provide access to any of the Disclosing Party's Confidential Information to any other person or entity, and shall not directly or indirectly use such Confidential Information in whole or in part except for the Purpose. The Receiving Party shall be responsible for any use of the Disclosing Party's Confidential Information in violation of this Agreement by its employees and by any other persons or entities to which it has made such Confidential Information available.

4. **Return of Confidential Information.** When requested by the Disclosing Party, the Receiving Party promptly shall return (or at the Disclosing Party's request, destroy) all copies of the Disclosing Party's Confidential Information received by the Receiving Party and promptly shall destroy all summaries, analyses, excerpts, compilations or other documents prepared by the Receiving Party based on the Disclosing Party's Confidential Information; provided that Q Labs shall be entitled to retain, subject to the restrictions in this Agreement, one copy of its test results for regulatory compliance purposes. If destroyed, upon request of the Disclosing Party such destruction shall be certified in writing by an officer of the Receiving Party.

5. **Required Disclosure.** If the Receiving Party receives any court order, subpoena, discovery request or other legal directive to disclose any of the Disclosing Party's Confidential Information, the Receiving Party shall provide the Disclosing Party with prompt written notice of such directive so the Disclosing Party may seek an injunction, protective order or other appropriate remedy. In the event an injunction, protective order or other remedy is not obtained, the Receiving Party shall furnish only that portion of the Disclosing Party's Confidential Information and other information that it is legally obligated to disclose.

6. **Survival.** The Receiving Party's obligations under this Agreement shall remain in full force and effect for a period of five (5) years following the date of this Agreement.

7. **Remedies.** The Receiving Party acknowledges and agrees that any breach or threatened breach of this Agreement may result in irreparable harm to the Disclosing Party for which there may be no adequate remedy at law. Therefore, the Receiving Party agrees that in the event of any breach or threatened breach of this Agreement by the Receiving Party, the Disclosing Party shall be entitled, in addition to any other rights and remedies available to it, to seek ex parte, temporary, preliminary and permanent injunctive relief requiring the immediate return of all its Confidential Information in the possession of the Receiving Party or any third party, and enjoining the Receiving Party and any persons or entities to which it has made the Disclosing Party's Confidential Information available, from using such Confidential Information in violation of this Agreement, without showing or proving any actual damages have been sustained.

8. **No Legal Obligations.** Unless and until a definitive agreement or other contract has been entered into between the parties, neither of the parties hereto shall not be under any legal obligations of any kind whatsoever to the other with respect thereto by virtue of this Agreement except as expressly provided herein.

9. **Expenses.** In any proceeding which the Disclosing Party institutes against the Receiving Party to enforce this Agreement and in which the Disclosing Party is the prevailing party, the Disclosing Party shall be entitled, in addition to all its other right and remedies, to recover from the Receiving Party the litigation expenses, including reasonable attorneys' fees and court costs, incurred by the Disclosing Party in connection with such proceeding.

10. **Governing Law.** This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware.

11. **Entire Agreement.** This Agreement constitutes the entire agreement between the parties with respect to the subject matter hereof, and supersedes all prior written or oral negotiations and understandings.

12. **No Waiver.** The waiver of any breach of this Agreement shall not be deemed to be a waiver of any continuing or subsequent breach thereof.

13. **Binding Effect.** This Agreement shall be binding upon and inure to the benefit of the respective successors and assigns of the parties.

IN WITNESS WHEREOF, the duly authorized representative of each party has executed this Agreement as of the date first above written.

Q LABS, LLC

By: Daniel J Bowen
Digitally signed by Daniel J Bowen
DN: OU=Sales, O=Q Laboratories, CN=Daniel J Bowen, E=dbowen@qlaboratories.com
Reason: I am the author of this document
Location:
Date: 2024.02.22 11:18:31-08'00'
Foxit PDF Editor Version: 12.1.4

Title: VP Sales and Marketing

Premier Pharma ADRIAN CONSTANCE

By: _____

Title EVP

QUALITY AGREEMENT

SUPPLY OF PRODUCT UNDER THE SECTION 804 IMPORTATION PROGRAM (SIP).

Premier Pharmaceuticals Mid America LLC
2231 Venture Dr,
Bowling Green, OH 43402

hereinafter referred to as "SIP Importer", Contract Giver (CG)

and

AdiraMedica Inc.
2233 Argentia Rd,
Suite #302, Unit #306
Mississauga, Ontario, L5N 2X7, Canada

hereinafter referred to as "Foreign Seller", Contract Acceptor (CA)

1 SCOPE

This Quality Agreement ("Agreement") is made by and between Contract Giver (CG) located at 2231 Venture Dr, Bowling Green OH 43402and AdiraMedica Inc. the Contract Acceptor (AC) Contract Acceptor (CA)., located at 2233 Argentia Rd, Suite #302, Unit #306, Mississauga, Ontario, L5N 2X7, Canada.

This Agreement is for **CA** to act as the Foreign Seller and Drug Establishment License holder of the drug products listed in Attachment I and **CG** to act as the Importer as defined under the Section 804 Importation Program (SIP) of drug products listed in Attachment I.

As the Importer, **CG** has primary responsibility for all quality management over importation into the United States of America related to the products listed in Attachment I on behalf of the SIP Sponsor.

CA will be the Foreign Seller for the drug products listed in Attachment I, Current Product Listing.

For purposes of regulatory compliance, **Contract Acceptor (CA)** and **Contract Giver (CG)** enter into this Agreement to confirm that the CA will carry out all quality obligations in Canada that may be relevant hereunder, and **Contract Acceptor (CA)** acknowledges those quality obligations.

The purpose of this Agreement is to set forth the obligations of the parties regarding quality matters, related to the products imported by **Contract Giver (CG)** under the requirements of SIP.

The responsibility for ensuring this agreement is implemented, reviewed and revised as needed rests with the Quality Management of **Contract Acceptor (CA)** and **Contract Giver (CG)**.

Both parties have agreed to cooperate to ensure that the activities and responsibilities contemplated hereunder are carried out in full compliance with the relevant guidelines, policies and regulations set forth by the authorities in Canada and in the USA. In particular the current Good Manufacturing Practices, as set forth and amended form time to time by Health Canada and Federal Drug Administration (FDA).

2 DEFINITIONS

For purposes of this agreement, the following terms were used in this agreement and any Schedules to it, and shall, unless the context otherwise requires have the meanings herein ascribed:

Certificate of Analysis (CoA): A Certificate of Analysis is a document containing the name and address of the laboratory performing the test(s), name and specifications of the product(s), test(s) performed, test method(s) used, actual numerical results, approval date(s), signature of approver, and any other technical information deemed necessary for its proper use.

Certificate of Manufacture (CoM): Also referred to as a Certificate of Compliance (CoC). is a document issued by a Manufacturer or Marketing Authorization Holder to a distributor or importer that attests that a specific lot or batch of drug has been produced in accordance with its master production documents. Such certificates include a detailed summary of current batch documentation, with reference to respective dates of revision, manufacture, and packaging, and are signed and dated by the Manufacturer or Marketing Authorization Holder quality control department.

Drug Identification Number (DIN): An eight (8) digit numerical code assigned to each drug product marketed under the Canadian Food and Drugs Act and Regulations. The DIN identifies the following product characteristics: manufacturer, brand name, medicinal ingredient(s), strength of medicinal ingredient(s), pharmaceutical form, and route of product marketed under the Food and Drugs Act and Regulations.

cGMP: means the current edition of Code of Federal Regulations (FDA) and Health Canada's Health Products & Food Branch Inspectorate (HPFBI) Good Manufacturing Practices Guidelines.

Import: Means to import into USA a drug for the purpose of reprocessing and sale under the requirements of the SIP.

Manufacturer: The entity from where the Foreign Seller will source the drugs on behalf of the SIP Sponsor.

Marketing Authorization Holder (MAH): The DIN Product owner authorized to market the product in Canada.

Products: Drug products listed in Attachment I, Current Product Listing.

Package/Label: means to put a drug into its immediate container or to affix the inner or outer label of the drug under the requirement of the SIP.

QA: Quality Assurance department responsible for executing the quality systems to ensure product quality and regulatory compliance.

Record/Document Retention: An administrative program outlined in a standard operating procedure as required by regulations and by which an organization manages the retention periods of its records both paper and digital based on the guidelines provided in FDA or Health Canada regulations.

SIP & SIP Sponsor: Section 804 Importation Program. The SIP Sponsor is the entity which has applied and has been approved for the importation of DIN products.

Stability Program: This is typically a procedure which outlines the requirements to carry out the stability studies for each of the product sizes, dose forms and the various conditions to which they are exposed to. The requirements are based on the guidelines by FDA, Health Canada or other recognized entities such as ICH (The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use).

Stability Study: A stability study is an examination of a substance or product over a specified period of time to examine the effects under defined storage conditions monitoring the characteristics of this substance or product. This test essentially generates data to support the product's shelf life.

Test: Means to perform the tests, including any examinations, evaluations, and assessments, as specified in the Code of Federal Regulations of the FDA and the SIP requirements.

3PL: Third Party Logistics. (i.e. warehousing and distribution) providing services to the Foreign Seller (CA) and the SIP Sponsor.

3 CONFIDENTIALITY

CA and CG have addressed confidentiality in the separate Confidentiality Agreement. Excluded are disclosures of information necessary for regulatory authorities during inspections covered by this Agreement.

4 REGULATORY AFFAIRS INFORMATION

4.1 ESTABLISHMENT LICENSING

CA is responsible for all drug establishment licensing (DEL) requirements with Health Canada, including amendments, annual renewals for the purpose of wholesale activities.

CG is responsible for all drug establishment licensing requirements with FDA, including amendments, annual renewals for the purpose of importation activities.

5 GMP INSPECTION

CA shall notify **CG** of any regulatory inspections, including inspections that may impact products supplied to **CG.**

CG shall notify **CA** of any regulatory inspections, and their outcomes that may impact products supplied by **CA.**

On reasonable advance notice, and to the extent legally possible, **CG** and **SIP Sponsor** may audit **CA** every 2 years to ensure compliance to the SIP requirements..

Regulatory inspections shall take precedence over scheduled audits by either party.

6 GMP Quality Systems

CA shall ensure that all activities related to the SSI Labeling, storage, transportation and release of products listed in this Agreement follow Health Canada regulations for maintaining the marketing authorization (i.e. Drug Identification Numbers (DIN)) issued by Health Canada as well as the SIP requirements.

CG shall ensure that activities related to the importation and further processing of products supplied by **CA** will be in accordance with the **CG** Procedures and regulatory and SIP requirements.

CA personnel and any contractors and consultants used by **CA** responsible for wholesale activities of products shall have suitable education, training and experience.

CAs individual in charge of quality shall meet the Health Canada GMP requirements for wholesaled products.

The Delegation of Quality Responsibilities in listed in Attachment IV: *Delegation of Quality Responsibilities*.

6.1 Procedures

CA shall have procedures documenting the GMP quality system that include the following (if applicable to the activity):

- Change Control
- Product Complaints
- Deviations and Corrective Preventative (CAPA)
- Document Control
- Record Retention

6.2 GMP Documentation

CA agrees to ensure a Certificate of Manufacturing and Certificate of Analysis is generated and supplied for each supplied batch when permitted by the manufacturer or MAH.

CA shall prepare and maintain quality documentation required for disposition of product supplied to **CG.**

6.3 DATA INTEGRITY

CG and **CA** are responsible to ensure that all data recorded is accurate, controlled and safe from manipulation or loss, intentional or unintentional.

If electronic records and/or electronic signatures are used by **CA** and **CG,** they shall ensure that they to comply with the applicable Good Documentation Practice by U.S. FDA and Health Canada regulations and guidance documents.

6.4 RECORD RETENTION

CA and **CG** shall ensure that they retain the documents for at least the retention time specified in their applicable record retention procedures ensuring 6 years for documents listed in Attachment V. **Change Control**

CG shall notify **CA** regarding changes to products that may affect the Product marketing authorizations (e.g., manufacturer or MAH).

CG and CA agree to inform each other about any major changes that require a compliance, validation and/or regulatory review, that may interfere with the quality of the product.

CA shall ensure a formalized change control procedure to ensure that changes occur in a controlled and timely manner, including, but not limited to changes affecting:

- Storage requirements
- SSI Labelling
- Transportation
- Changes to packaging components.

CG shall have a formalized change control procedure to ensure that changes to importing processes/responsibilities occur in a controlled and timely manner.

6.5 SSI LABELLING

CA shall be responsible for the SSI labelling of the drug products supplied to **CG.**

CA shall ensure the drug products are labelled in accordance with GMPs and Procedural requirements.

CG undertakes to ensure that all packaging/labeling and testing processes shall meet the applicable cGMPs (US).

7 PRODUCT DISPOSITION

CA is responsible for the release of product for sale to **CG**, as the Importer. **CG** is responsible for the release of product for sale in the USA.

8 RETURNED PRODUCTS

CA is responsible to ensure that there is a written procedure describing the receipt, interim storage and final disposition of Products that are returned from customers

CA and their 3PL Provider are responsible to ensure that Products which have been returned from the market or are damaged at the 3PL Provider must be identified, clearly labelled and placed in an adequately segregated storage area (e.g. a secured quarantine cage) to avoid confusion with other Products and to prevent re-distribution or re-processing until a decision has been reached as to their disposition.

CG is responsible for managing product returns from the US market and is solely responsible for investigating and dispositioning the cause of the return. **CG** will ensure that returned products are not sent or returned to **CA**.

9 SECURITY AND COUNTERFEITING / THEFT

CG and CA are responsible to use their best efforts to prevent the theft or any non-authorized (re-)use of Product bearing applicable logo or brand name occurs. **CG and CA** shall take any necessary action to secure the product supply.

CA shall notify **CG** within five (5) business days in writing, after having received the appropriate information of any known incident or any suspicion of counterfeit or theft of product and shall help in any necessary investigation requested by **CG**.

10 STABILITY

CG shall ensure that stability studies are conducted in accordance with **CG** approved written procedures and regulatory commitments.

CG shall be responsible for the execution of the stability program (including sample collection, storage and testing) required supporting the shelf life of the products is provided with the approval of the marketing authorization holder or manufacturer.

CG will ensure stability study is performed of the marketed product within the USA in accordance with the applicable FDA Code of Federal Regulations

CG shall ensure that information on any stability failures is provided to **CA and the MAH or Manufacturer** within two (2) business days, so appropriate action can be taken.

11 RETENTION SAMPLES

CG shall ensure retention samples are maintained as outlined in **CGs** approved written procedures.

CG shall ensure that samples are retained under appropriate storage conditions, to comply with marketing authorization commitments.

12 STORAGE AND TRANSPORT CONDITIONS

CA agrees to ensure that all packaging components and finished product are received and stored under labeled storage conditions that do not interfere with the quality characteristics of the material or finished product.

CG shall ensure that products are shipped as per labeled storage conditions(i.e. temperature monitoring as required). This is to ensure that product quality is maintained and not exposed to conditions that may have an adverse effect on quality or stability of the product.

13 COMPLAINTS AND ADVERSE EVENTS

13.1 COMPLAINTS

CG shall establish a procedure that describes the communicating in writing of any product complaints for products supplied by **CA** within three (3) business days for any batches supplied to **CG**.

CA shall summarize and communicate in writing any product complaints requiring an investigation to **CG** within three (3) business days.

CG shall ensure that all product complaints are investigated for products supplied by **CA**. **CA** shall provide **CG** with a written report within thirty (30) business days after receiving complaint notification from **CG** If the final report is not available from **CA** within thirty (30) business days, an interim report will be provided to **CG** by **CA.**

13.2 ADVERSE EVENTS

CG will follow-up with FDA and the MAH or Manufacturer on adverse events and report them as required by the MAH or FDA.

14 RECALL

CA agrees to inform **CG** immediately of any decisions to recall a product supplied to **CG** or while in transit to **CG**. **CG** shall not proceed with any further processing of the recalled product.

CG agrees to inform **CA**, MAH or Manufacturer of any decision to recall a product supplied to **CG** within 2 working days.

Each party shall provide all supporting documentation related to the (potential) recalled product in a timely manner.

CA will support the MAH or Manufacturer's final decision whether to initiate a recall or a product withdrawal within in Canada.

It will be the responsibility of the **CG** to contact the FDA for the product recall for all products in USA.

CG and **CA** shall mutually agree on all communications concerning the recall or product withdrawal with FDA, as applicable.

CG and **CA** shall be responsible for coordinating all the necessary activities in connection with such recall or product withdrawal.

15 DESTRUCTION AND DISPOSAL

CG shall be responsible for coordinating and documenting all the necessary activities associated with destruction and disposal of rejected, returned, recalled or damaged product in USA.

CA shall be responsible for coordinating and documenting all the necessary activities associated with destruction and disposal of rejected, returned, recalled or damaged product in Canada.

CG and **CA** will maintain all destruction and disposal records and all other applicable documentation as required.

16 THIRD PARTY CONTRACTING

CA shall notify **CG** if there are any changes to the 3PL Provider. **CA** will maintain compliance evidence for any third-party contractors.

17 COMMUNICATION

CG and **CA** have identified key contact personnel, listed in Attachment II, *Key Contacts,* to ensure responsible individuals are fully informed and involved. Changes to key personnel or their designate shall be confirmed in writing and Attachment II, *Key Contacts* revised as necessary.

All communication shall be in writing as set forth below. To be effective, any verbal communication must be followed up in writing. Any notice or other communication shall be deemed sufficiently given if delivered by personal delivery or sent by confirmed email, acknowledged fax subsequently followed by a hard copy, or by courier or registered mail (return receipt requested), postage prepaid, addressed to:

In the case of **CA, AdiraMedica Inc.:**

Mr. Cal Bains
2233 Argentia Rd,
Suite #302, Unit #306
Mississauga,
Ontario, L5N 2X7,
Canada

and in the case of **Contract Giver (CG)**.

Mr. Adrian Constance
7259 W Franklin Road
Boise, ID 83709
United States>

18 QUALITY AGREEMENT REVISIONS

This Agreement may be revised as new products and/or requirements are added or deleted.

Any revisions to this document, excluding the Attachment I, *Current Product Listing*, shall be made in writing to the other party stating the reason for the revision and shall be agreed to by both parties prior to implementation of the revision.

19 TERMINATION OF QUALITY AGREEMENT

This Quality Agreement may be terminated in the event of any of the following:

- By either party for convenience by giving at least ninety (90) days prior written notice to the other party;
- With the mutual agreement of the parties. Such agreement will include a termination date, transition plan and financial considerations, if any, owing under the parties' separate agreements.

This Quality Agreement will also terminate automatically upon the termination or expiration of the parties' business relationship.

The terms and conditions of this Quality Agreement which by their nature or meaning survive termination of this Quality Agreement, including but not limited to provisions relating to Product Complaints, Product Returns and Product Recalls, shall so survive.

Attachments to this Agreement can be updated by agreement between **CA** and **CG**, independently of a revision of the overall Quality Agreement document.

Attachment I – Current Product Listing

Attachment II – Key Contacts.

Attachment III – Current Sub-Contracting List of Suppliers, outlines the sub-contracting partners.

Attachment IV – Delegation of Quality Responsibilities

Attachment V — Record Retention Responsibilities

Attachment VI – Revision History, outlines the revision history of this agreement

20 CONCLUDING PROVISIONS

The agreement comes into force when signed by the contracting parties.

In witness, whereof the parties have executed this agreement on the date and year first above written.

Premier, Contract Giver (CG)	
Name: Adrian Constance	**Position: CEO**
Signature: DocuSigned by: Adrian Constance Signer Name: Adrian Constance Signing Reason: I approve this document Signing Time: 2/22/2024 | 1:28:58 PM PST 0568C7A280384AEF8A9231DBB25D2DE4	**Date:** 2/22/2024

Premier, Contract Giver (CG)	
Name: Jacob Fuchs	**Position: Founder**
Signature: DocuSigned by: Jacob Fuchs Signer Name: Jacob Fuchs Signing Reason: I approve this document Signing Time: 2/22/2024 | 1:56:28 PM PST 88DC06F7A3404653854DDF0E53051F86	**Date:** 2/22/2024

Adira Medica Inc., Contract Acceptor (CA)	
Name: Arvind Bhandari	**Position:** President & CEO
Signature: DocuSigned by: Arvind Bhandari Signer Name: Arvind Bhandari Signing Reason: I approve this document Signing Time: 2/23/2024 | 11:22:43 AM PST 2902661CCFAE4DB499FC8A2547F21F55	**Date:** 2/23/2024

Adira Medica Inc., Contract Acceptor (CA)	
Name: Cal Bains	**Position:** Director, Business & Operations
Signature: DocuSigned by: Cal Bains Signer Name: Cal Bains Signing Reason: I approve this document Signing Time: 2/23/2024 | 8:38:10 AM PST B9858B33A1674032A6CAE7A5A7D02814	**Date:** 2/23/2024

Adira Medica Inc., Contract Acceptor (CA)	
Name: Ashwin Narotam	**Position:** Director, QA & RA
Signature: DocuSigned by: Ashwin Narotam Signer Name: Ashwin Narotam Signing Reason: I approve this document Signing Time: 2/23/2024 | 11:32:17 AM PST 1A3733570C6D4BCA89A32289A6DAFZ26	**Date:** 2/23/2024

21 ATTACHMENT I: CURRENT PRODUCT LISTING

Product Name	DIN	Dose Form	Strength	Size	MAH

Approved by:	Name	Signatures	Date
Premiere (CG)			
AdiraMedica Inc. (CA)			

22 ATTACHMENT II: KEY CONTACTS

CA – AdiraMedica Inc.

Name	Position	Areas of Responsibility	E Mail address & Telephone
Cal Bain	Director	Business & Operations	[redacted]
Arvind Bhandari	CEO	Global	[redacted]
Ashwin Narotam	Director	QA & RA	[redacted]

CG- Premier

Name	Position	Areas of Responsibility	E Mail address & Telephone
Adrian Constance	CEO	Business & Operations	[redacted]
Jacob Fuchs	Founder/ Advisor	Global	[redacted]
Tanner Wollan	Director	QA	[redacted]

23 ATTACHMENT III: CURRENT SUB-CONTRACTING LIST

Supplier	Activity
BioScript Logistics Inc.	Warehousing and Storage.

24 ATTACHMENT IV: DELEGATION OF QUALITY RESPONSIBILITIES

a) Licence to Provide the Specified Service

Responsibility	Contract Giver (CG)	Contract Acceptor (CA)
Maintain relevant licences and authorisations for importation of the Product contained in this Quality Agreement.	X	X
Maintain and provide relevant GMP compliance evidence to perform the obligations specified in this Quality Agreement.	X	X
CA will ensure that the Foreign Seller registration is reviewed and updated annually and that any changes are handled within 30 calendar days.		X

b) Testing and Specifications

Responsibility	Contract Giver (CG)	Contract Acceptor (CA)
Provide Certificate of Analysis or equivalent for each Product lot if available.		X
Provide Certificate of Manufacture for each Product lot if available.		X

c) Documentation

Responsibility	Contract Giver (CG)	Contract Acceptor (CA)
Ensure that the documentation for the Product SSI labelling complies with the GMP/cGMP and other relevant requirements for documentation control.	X	X
Ensure that the documentation for the Product storage, and distribution complies with the GMP / cGMP relevant requirements for documentation control.	X	X
Ensure that all records relating to **Contract Giver (CG)** business are appropriate, stored in a secure location and are maintained for a period of: Product expiry plus 2 years or 6 years, whichever is greater..	X	X

Responsibility	Contract Giver (CG)	Contract Acceptor (CA)
On a quarterly basis CA will initiate a written report pertaining to the SIP activities and submit to CG upon request. (1) Documentation specifying the manufacturer of each eligible prescription drug and the quantity of each lot of the eligible prescription drug(s) received by the CA from that manufacturer; (2) Documentation demonstrating that the eligible prescription drug was received by the CA from the manufacturer and subsequently picked up and shipped by the CG from CA warehouse to CG warehouse;		X
Prepare and complete SIP Pre-Import Request and forward to **CG**		X
CG will File the pre-import request form electronically to FDA	X	

d) Batch Release

Responsibility	Contract Giver (CG)	Contract Acceptor (CA)
Releasing of SSI labels and drug product supplied to **CA.**		X
QA Release of the final SSI labelled products to **CG.**		X
QA Release of Products after importation to USA.	X	
QA Release: Completed SSI Labelling Batch Documents, list of deviations, major changes and OOS results provided to **CA by 3PL** for each lot of Product supplied		X

e) Drug Supply Chain Security

Responsibility	Contract Giver (CG)	Contract Acceptor (CA)
Quarantine the illegitimate or suspect product upon determination that a product within its possession or control or due to a request for verification by the FDA.	X	X
Inform the CG, Manufacturer or MAH on the receipt of any suspect products.		X
Inform the CG, FDA or other involved parties the outcome of investigations pertaining to illegitimate products.		X

f) Sub-Contracting

Responsibility	Contract Giver (CG)	Contract Acceptor (CA)
Ensure that CA notifies **CG** of any changes or addition of third-party service providers (as listed in Attachment III) are used.	X	X
Provide evidence of qualification of sub-contractors.	X	X

g) Warehousing and Transportation

Responsibility	Contract Giver (CG)	Contract Acceptor (CA)
Storage of the Product under labelled storage conditions in approved and secure location in the warehouse.	X	X
Notifications of temperature excursions upon receipt of Product.	X	X
Investigation of temperature excursions and decision on disposition of affected product without any unnecessary delay.	X	X

h) Quality Audits

Responsibility	Contract Giver (CG)	Contract Acceptor (CA)
Contract Giver (CG) may audit **Contract Acceptor (CA)**and will announce with reasonable notice, taking into consideration the reason for the audit and its potential consequences.	**X**	
Provide the audit report within the agreed timeline (i.e.,30 calendar days).	X	
Provide the audit response indicating the corrective action plan for deficiencies (if any) noted during the audit within the agreed timeline (30 calendar days).		X

i) Complaints, Recalls and Returns

Responsibility	Contract Giver (CG)	Contract Acceptor (CA)
Report quality complaints relating to the Products in writing to t **Contract Acceptor** Quality Assurance within three (3) business days..	X	X
Ensure customer/patient can send any available complaint sample to CG QA representative and forwarded to **Contract Acceptor (CA)**, if applicable.	X	

Responsibility	Contract Giver (CG)	Contract Acceptor (CA)
Conduct investigation of product quality complaints relating to the Products and communication of the outcome to **Contract Acceptor (CA).**	X	
Return of product quality complaints to CA.	X	
Investigate complaints and returns, provide report to GG.		X
Injectables returned will not be restocked for resale.	X	X
Notification of recalls and market withdrawals relating to the Products.	X	X
Recalls and market withdrawals relating to the Products	X	X

j) Regulatory Requirements

Responsibility	Contract Giver (CG)	Contract Acceptor (CA)
Notification of changes which impacts product registration or licences to the regulatory authority as applicable.	X	X
Provide information to support regulatory submissions, as required.		X
Communication of regulatory authority approval/outcome.	X	X
Follow up and action conditions of approval.		X
Compliance with conditions of registration at all times.	X	X

k) Deviation Management

Responsibility	Contract Giver (CG)	Contract Acceptor (CA)
Have established written procedures for planned and unplanned deviations.	X	X

l) Change Control

Responsibility	Contract Giver (CG)	Contract Acceptor (CA)
Have established written procedures for Change control.	X	X

25 ATTACHMENT V: RECORD RETENTION RESPONSIBILITIES

The following outlines the documents to be retained by each party. The length of time for retention is according to the internal Retention procedures of each party or at a minimum of 6 years as per Section 804 Importation Program requirements.

Responsibility	Contract Giver (CG)	Contract Acceptor (CA)
	Provide and Approve	Review and maintain on file
Product Release • Executed Batch Records • Associated Deviations, Investigations, CAPA, • CofC, CofA, CofM	X	X
Complaints • Investigations and follow-up	X	X
Deviations • Deviation Report including root cause, risk assessment and complete investigation	X	X
Recalls • Recall Records and associated Investigations, Risk Assessment • Inventory Records	X	X
Change Controls • Change Control Records and supporting documentation	X	X
GMP Compliance Evidence • Regulatory Agency Inspection Report • Corrective Actions • Supporting SOPs • Quality Agreements	X	X

26 ATTACHMENT VI: REVISION HISTORY

Revision Number	Date Prepared	Reason for Change
0	Dec.18, 2023	New QA agreement.

MASTER SERVICE AGREEMENT

THIS MASTER SERVICE AGREEMENT ("Agreement") is made and entered into this 22nd day of February, 2024, (the, "Effective Date") by and between **DENVER HEALTH AND HOSPITAL AUTHORITY**, a body corporate and political subdivision of the State of Colorado, with offices located at 601 Broadway, Denver, Colorado 80204 ("DHHA"), on behalf of its division, **Rocky Mountain Poison & Drug Safety**, with a mailing address of 777 Bannock Street, Mail Code 0180, Denver, Colorado 80204 ("RMPDS") and; collectively known herein as (the "Provider") and **PREMIER PHARMACEUTICALS,** having a place of business at **2231 Venture Dr, Bowling Green, OH 43402** ("Company"). Each may be referred to as a "Party" and collectively the "Parties".

RECITALS:

WHEREAS, Provider provides contact center services, and other related services, including but not limited to medical information, safety reporting (adverse events and product quality complaints), clinical trials support, technical support and administrative support, medical writing, and pharmacovigilance and safety surveillance services (the, "Services"); and

WHEREAS, Provider has expert staff including nurses, pharmacists, physicians, scientists, and other non-medical program specialists (the, "Contact Center Providers") who provide both emergent and non-emergent services in a professional manner and Provider will use its best efforts to ensure that the individuals providing Services exercise their best judgment in performing the Services; and

WHEREAS, Company desires to receive Services from the Provider; and

WHEREAS Provider, desires to provide Company with these Services as described in this Agreement.

NOW, THEREFORE, in consideration of the mutual agreements hereinafter contained and subject to the terms and conditions herein stated, the parties agree as follows:

ARTICLE I
SERVICES, WORK ORDERS & CHANGE ORDERS

1.1 Services. Provider hereby agrees to provide to Company the Services identified and described in the Services section of each Work Order, as further defined below.

Provider shall perform the Services set forth in the applicable Work Order in compliance with (i) the provisions of this Agreement; and (ii) pursuant to the terms and conditions of the Work Order; and (iii) in accordance with Provider's policies and standard operating procedures mutually agreed upon by the Parties; and (iv) pursuant to the applicable federal, state and local laws, statutes, ordinances, guidelines and regulations, including but not limited to, the Federal Food, Drug and Cosmetic Act as amended, and the regulations of the United States Food and Drug Administration (the "FDA"), and ICH Good Clinical Practices (the, "Applicable Law"); and (v) Services shall be performed with due diligence and in a good and workmanlike manner in accordance with recognized industry standards. Each Work Order shall also be conducted in accordance with Applicable Law and applicable medical privacy laws and regulations including those pertaining to the protection of personal and protected health information.

1.2 Work Order. If the Parties reach an agreement to add new Services, Provider and Company shall execute a Work Order evidencing such Services. Each Work Order shall set forth in detail the responsibilities and obligations of the Parties, the fees and payment schedule, and as applicable, any deliverables, with respect to the Services to be provided by Provider. The Work Order, along with any applicable quality agreement, attachments, and exhibits, and this Agreement shall constitute the entire agreement for the Services. To the extent any terms set forth in a Work Order, unless otherwise stated, conflict with the terms set forth in this Agreement, the terms of the Work Order shall govern.

1.3 Change Orders. If Company requests any change to the Services for a particular Work Order that the Parties mutually agree upon and are not specifically provided for in the applicable Work Order, including without limitation, any change to the related protocol, it shall notify Provider in writing of such requested change.

Provider shall prepare an amendment to reflect the agreed upon change(s) to the Work Order, to include but not limited to, an estimate of any resulting adjustment to the timeline for the performance of the Services under the amended Work Order and to the payment schedule (whether

an increase, decrease or no effect). After an amendment change to the Work Order is fully executed, such action shall constitute an amendment to the applicable Work Order and the Services therein.

ARTICLE II
DATA COLLECTION AND REPORTING

2.1 Services will be conducted and reported to Company in a manner and time frame as mutually agreed upon by the Parties.

2.2 Case information will be entered into Provider's data base as outlined in applicable Standard Operating Procedure ("SOP"). Case information and any source documents will be forwarded to Company in a manner and frequency as mutually agreed upon by the Parties and as further detailed in the subsequent Work Order.

ARTICLE III
OBLIGATIONS OF COMPANY

3.1 Company must provide:

(i) Current list of Company product(s). The product list should be organized, if applicable, alphabetically by Company's divisions or product groupings.

(ii) Company shall provide updates to the product list as required.

(iii) Company shall ensure Provider has current Company contact information, to include: names, addresses, phone numbers, email addresses for telecommunications, technology, finance, operations, and other appropriate individuals.

(iv) As applicable, Company shall provide Provider with appropriate software licenses and access to Company databases, systems, and information necessary to provide Services.

ARTICLE IV
OBLIGATIONS OF PROVIDER

4.1 Provider must provide:

(i) Qualified staff to provide the Services to the Company pursuant to this Agreement.

(ii) Provider shall identify, develop, and maintain appropriate SOPs, SOW's, and other control documentation as applicable, regarding the Services under

the Work Order. All SOPs will be reviewed and approved by Company prior to dissemination for training.

(iii) Provider will deliver operational performance metrics as mutually agreed upon by the Parties. Ad hoc or custom reports are available at an additional cost upon the request of Company and mutual agreement of the Parties.

(iv) Provider shall ensure Company has current Provider contact information, to include: names, addresses, phone numbers, email addresses for telecommunications, technology, and other appropriate individuals.

ARTICLE V
CONFIDENTIALITY

5.1 Definition. As used in this Agreement, the term "Confidential Information" means (a) either Party's technical, marketing, product, business affairs information, including, without limitation, customers, prospects, pricing, clinical or other research, patent applications, regulatory data or plans, clinical data or plans, products, product plans, product candidates, markets, inventions, manufacturing processes, compounds, formulas and formulations, technology, designs, forecasts, market research, litigation matters, strategies, vendor agreements, equipment, finance or capitalization, and other proprietary and trade secret information, whether oral, graphic, written, electronic, or in machine readable form, and (b) all data, record formats, computer programs (and source code therefor), proposals, plans, programs, analysis, compilations, forecasts, studies, agreements or other documents prepared by a Party, or by the Parties jointly, related to any subject matter in this Agreement, including, without limitation, the terms of this Agreement.

5.2 Limitations. The term "Confidential Information" shall not include any information that: (i) is or becomes known or publicly available through no fault of the "Receiving Party"; (ii) is known by the Receiving Party at the time of disclosure, not subject to restriction; (iii) is independently developed by the Receiving Party without use of, reference to or reliance on the "Disclosing Party's" Confidential Information; or (iv) is lawfully obtained from a third party who has the right to make such disclosure.

5.3 Third-Party. Except as specifically permitted in this Agreement, neither Party will use or disclose Confidential Information of the other to any third party, except for the purpose described herein and only to those persons within the Disclosing Party and the Receiving Party and their necessary consultants, subcontractors, agents, and affiliates with a need to know. The

Receiving Party agrees that if it receives a subpoena or other government process that purports to require the production of any of the Confidential Information for use in an action or proceeding, the Receiving Party: (1) shall promptly inform the other Party or entity issuing such subpoena or other government process of the existence of this Agreement; (2) shall promptly inform the Disclosing Party of the receipt of such subpoena or other government process; and (3) shall not oppose any effort by the Disclosing Party to seek a protective order or to quash any such subpoena or other government process. If the Disclosing Party fails to intervene to seek a protective order or to quash said subpoena or other government process after being given notice and a reasonable opportunity to do so, or if such motion is denied by a court of competent jurisdiction, the Confidential Information may be produced, notwithstanding anything in this Agreement to the contrary. If any Confidential Information is ordered produced in an action or proceeding, it shall not lose its confidential status through such use, and the Receiving Party shall take all reasonable and necessary steps to protect its confidentiality during such use, to the extent possible.

5.4 Intellectual Property. If the Disclosing Party's intellectual property is or is threatened to be disclosed, the Disclosing Party will be entitled, if it so elects and without limitation of any other available remedy, to seek injunctive relief in any court of competent jurisdiction to enjoin or restrain such disclosure.

5.5 Ownership of Materials. Each Receiving Party agrees that all Confidential Information received is and will remain the property of the Disclosing Party and that such shall not be copied or reproduced without the express permission of the Disclosing Party, except for such copies as may be reasonably necessary to accomplish the purpose of this Agreement. Upon written request of the Disclosing Party, the Receiving Party shall immediately discontinue all use of all Confidential Information of the Disclosing Party, and shall, at the Disclosing Party's option, either destroy or return to the Disclosing Party all hard copies in its possession of such Confidential Information and any derivatives thereof (including all hard copies of any translation, modification, compilation, abridgement or other form in which the Confidential Information has been recast, transformed or adapted), and to delete all online electronic copies thereof; provided, however, that the Receiving Party may retain one (1) archival copy of the Confidential Information, which shall be used only in case of a dispute concerning this Agreement. Notwithstanding the foregoing, neither Party shall be required to destroy or alter any computer-based back-up files generated in

the normal course of its business, provided that such files are maintained confidential in accordance with the terms of this Agreement.

5.6 The Receiving Party agrees that it will maintain in confidence all Confidential Information. The Receiving Party shall take necessary and reasonable precautions to prevent such information from being disclosed to any unauthorized person, firm, or company. Upon disclosing Confidential Information to its officers and employees, necessary consultants, subcontractors, affiliates or agents, the Receiving Party shall advise same of the confidential nature thereof and shall take necessary and reasonable precautions to prevent the unauthorized disclosure of such information by such parties. The terms and obligations of this section shall survive the termination of this Agreement.

ARTICLE VI
TERM AND TERMINATION

6.1 Term. The term of this Agreement shall commence on the aforementioned Effective Date and shall continue in full force and effect for three (3) years (the, "Initial Term") and shall automatically renew for a successive term of three (3) years (the, "Renewal Term) until either Party elects not to renew, or terminates this Agreement and provides to the other Party a written notice of nonrenewal (the, "Termination Notice") ninety (90) days prior to the date of the expiration date of the then current term (the, "Termination"). If this Agreement is terminated, any and all Work Orders pursuant and subsequent to this Agreement shall also terminate at the Termination of this Agreement.

6.2 Termination. Unless otherwise specified in the applicable Work Order, this Agreement and/or any Work Order may be terminated: (i) by either Party at any time if one Party commits a material breach of its obligations hereunder (including Work Orders, amendments, attachments and exhibits), and the breaching Party fails to cure such breach within thirty (30) days of receipt of written notice of the alleged breach; or (ii) immediately by Provider in the event of a disclosure of any Confidential Information directly or indirectly to a third party other than as permitted by this Agreement or the applicable Work Order; or (iii) as additionally permitted in the applicable Work Order. Expiration or termination of any Work Order pursuant to this Section shall constitute the expiration or the termination of such Work Order only and shall not affect this

Agreement or any other Work Order under this Agreement. In the event of termination, Company shall pay Provider for Services performed through the termination date.

6.3 Wind Down. Upon the Notice of Termination or Termination of this Agreement, Provider shall cooperate with Company to provide for an orderly wind-down of all Services provided by Provider hereunder. In the case of termination of a Work Order, Provider shall cooperate with Company to provide for an orderly wind-down of all Services provided by Provider under such Work Order.

ARTICLE VII
PAYMENT OF SERVICES AND PASS-THROUGH COSTS

7.1 Charges for Services. Company shall pay Provider for all Services performed under this Agreement in accordance with the rates for Services and the payment schedule set forth in the applicable Work Order. Company shall also reimburse Provider for all out-of-pocket expenses incurred by Provider that are mutually agreed upon by the Parties and are incurred in connection with the performance of the Services (the, "Pass Through Costs").

Except as otherwise expressly provided in a Work Order, Provider shall submit to Company for each Work Order a monthly invoice describing in detail the charges for the Services and all Pass-Through Costs paid by Provider during the "Invoice Period".

7.2 Payments Company shall pay each monthly invoice within thirty (30) days of receipt thereof, unless otherwise specified in the applicable Work Order. Each payment shall reference the Provider's invoice number for which the Company is remitting payment. Payments received by Provider that do not reference Provider's invoice number shall be applied to any past due amounts in the order of the invoice date. All payments must be made payable to Denver Health and Hospital Authority, RMPDS and remitted to the following address:

Denver Health and Hospital Authority, RMPDS
P.O. Box 17093
Denver, Colorado
80217-0093
Tax ID# 84-1343242

7.3 Late Payment. If Company fails to timely pay any amount due pursuant to this Agreement and in accordance with the applicable Work Order within the Invoice Period other than those amounts that are the subject of a good faith dispute by Company, Company shall also pay a

late fee equal to one and one half percent (1.5%) per month (18% per annum) or the maximum charge permitted by applicable law, whichever is less, and all reasonable costs of collection, including, without limitation, reasonable attorneys' fees.

ARTICLE VIII
WARRANTIES, REPRESENTATIONS AND LIMITATIONS OF LIABILITY

8.1 No Inconsistent Obligations or Constraints upon Provider. Provider represents and warrants that it is qualified and permitted to enter into this Agreement and that the terms of this Agreement are not inconsistent with its other contractual arrangements. Provider warrants that it is not constrained by any existing agreement in providing the Services to be performed under this Agreement.

8.2 No Impairment; No Conflict. During the term of this Agreement, Provider warrants that it will not enter into any agreement to provide services that would in any way materially impair its ability to complete the Services in a timely fashion.

8.3 Disclaimer of Warranties. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER COMPANY NOR PROVIDER MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED, INCLUDING ANY EXPRESSED OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

8.4 Limitations of Liability. Each party hereto agrees to be responsible and assume liability for its own negligent or wrongful acts or omissions or those of its officers, employees or agents arising out of this Agreement to the full extent allowed by law and adjudicated by a court of competent jurisdiction; and in no event shall either Party be liable to the other Party for any indirect, incidental, special, or consequential damages, including, but not limited to, lost profits, or revenue, lost savings, loss of use of the licensed products, business interruption, or cost of substituted facilities, equipment, or services, whether or not such Party has been advised of the possibility of such damages, and whether any claim for recovery is based on theories of contract, negligence, or tort (including strict liability).

8.5 The Parties acknowledge that Provider is covered and self-insured under the *Colorado Governmental Immunity Act (CGIA) § 24-10-101, C.R.S. et seq.*, as applicable now or hereafter amended.

Notwithstanding any other provisions to the contrary, no term or condition of this contract shall be construed or interpreted as a waiver, express or implied, of any of the immunities, rights, benefits, protection or other provisions of the *Colorado Governmental immunity Act, CRS § 24-10-101 et. seq.*, as now or hereafter amended. The parties understand that liability for claims is controlled and limited by the provisions of *Colorado Governmental immunity Act, CRS §24-10-101 et. seq.*, as now or hereafter amended.

8.6 Company Liability - International Calls. With regard, and as applicable, to contacts which originate outside the United States, Company agrees to be responsible for and assume all liability for all such contacts and shall defend, indemnify and hold harmless Provider, its employees, officers, directors and agents from and against any and all claims, demands, causes of actions, proceedings, damages, losses and expenses resulting from Services provided as a result of any such call (collectively, the "Claims"), provided that such assumption of liability or indemnification shall not extend to Claims resulting directly or indirectly from the negligence, willful misconduct or fraud of, or from a breach of this Agreement committed by Provider. This indemnification shall survive the termination of this Agreement.

ARTICLE IX
DEBARMENT

9.1 Provider represents to the best of its knowledge that none of its directors, officers or employees providing services under this Agreement is a person debarred under *Code of Federal Regulations, Title 21, 1.284, Volume I Food and Drugs, Ch. I Food and Drug Administration Department of Health and Human Services, Subchapter A, Subpart A-C § 11.1-11.300, (Revised as of April 1, 2019).* Provider further agrees to notify Company immediately should any of its directors, officers or employees providing services under this Agreement become a debarred person during the term of this Agreement.

ARTICLE X
INTELLECTUAL PROPERTY

10.1 No License. Neither the operation of this Agreement, nor the delivery of any information to a Party hereto, shall be deemed to grant the receiving Party any right or license under any copyright, trademark right, patent right or any other proprietary right or to any know-how, technology or inventions of the disclosing Party, except as specifically provided herein.

10.2 Company Property. Provider will promptly disclose to Company all improvements, inventions, formulae, on behalf of its employees, agents or subcontractors, solely or jointly with Company, as a result of the performance of the Services under this Agreement that relates to the product that is the subject of any Work Order, is made using or incorporates Company's Confidential Information, or directly results from Provider's provision of the Services.

10.3 Provider Property. Company acknowledges that Provider may possess certain inventions, processes, technology, know-how, trade secrets, improvements, other intellectual property and other assets, including, without limitation, those related to data collection processes, data management processes, analytical methods, procedures and techniques, computer technical expertise and software (including codes) which have been independently developed by or for the Provider prior to the Effective Date without the benefit of, or access to, any information or materials provided by Company and do not relate to the composition of matter, method of using or method of administering any product that is the subject of a Work Order (collectively, the "Provider Property"). All Provider Property and improvements thereto, which are not specific to any Work Order, are the sole and exclusive property of Provider, and Company shall have no right, title, or interest therein.

Notwithstanding anything to the contrary, if applicable, Provider shall be the owner of any written materials produced pursuant to this Agreement and shall therefore also hold and/or own any copyright, trademark, registration, or other legal rights that may be obtained regarding, or associated with, such materials.

1

ARTICLE XI
INDEMNIFICATION

11.1 Company will defend, indemnify and hold harmless the Provider and its employees, officers, directors and agents from and against any and all claims, demands, causes of actions, proceedings, damages, losses and expenses resulting from the negligent or willful acts or omissions

of the Company, including the Company's employees, officers and agents. Company need not indemnify or hold the Provider harmless for damages or claims caused by sole negligence of the Provider or the Provider's employees or officers. This indemnification shall survive the termination of this Agreement. Provider cannot and by this Agreement does not agree to indemnify, hold harmless, exonerate, or assume the defense of Company or any other person or entity whatsoever, for any purpose whatsoever.

ARTICLE XII
PUBLICATION

12.1 Provider may not publish any articles or make any presentations relating to the Services provided to Company with respect to this Agreement or any Work Order, or referring to data, information or materials generated as part of the Services without the prior written consent of Company.

ARTICLE XIII
INSURANCE

13.1 Insurance. Each Party shall maintain, for the duration of this Agreement, insurance in an amount that is commercially reasonable to cover its obligations hereunder and, upon request, each Party will provide to the other Party a certificate of insurance showing that such insurance is in effect.

ARTICLE XIV
HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 (HIPPA)

14.1 Provider may receive or create from or on behalf of the Company, certain health or medical information Protected Health Information or "PHI" in connection with the performance of Services under this Agreement. Use or disclosure of PHI is subject to protection under state and federal law, including the *Health Insurance Portability and Accountability Act of 1996 and its corresponding privacy regulations (the "Privacy Rule"), as amended from time to time, as codified at 45 C.F.R. Parts 160 and 164* (the "Identifiable Data") and regulations promulgated thereunder by the U.S. Department of Health and Human Services ("Regulations").

14.2 As applicable, Provider shall (i) not use or further disclose information other than as permitted or required by this Agreement; (ii) not use or further disclose information in a manner that would violate the requirements of the HIPAA regulations; (iii) use appropriate safeguards to prevent use or disclosure other than as provided in the Agreement; (iv) report to the Company any use or disclosure not provided by this Agreement; (v) ensure that any subcontractors and agents to which Provider may provide PHI agree to the same restrictions and conditions as apply to Provider; (vi) make appropriate health information available upon individual request as appropriate; (vii) make its practices, book and records relating to the use and disclosure of PHI available to the U.S. Department of Health and Human Services; (viii) if feasible, return or destroy all PHI at the termination of the Agreement; and (ix) authorize Company to terminate this Agreement if Provider has violated a material term.

ARTICLE XV
RECORDS STORAGE

15.1 Record Maintenance. During the term of this Agreement, Provider shall maintain all materials and all other data obtained or generated by Provider in the course of providing the Services hereunder, including all computerized records and files as may be required by this Agreement and all Applicable Law. Provider shall cooperate with any reasonable internal review or audit by Company and promptly make available (at Provider's facilities, wherever Services are performed, or other mutually acceptable locations) to Company, the FDA or other regulatory agencies, for examination and duplication, during normal business hours and at mutually agreeable times, all documentation, data and information relating to this Agreement or subsequent Work Order(s). Provider shall maintain all materials and all other data obtained, generated, or collected by Provider in the course of providing the Services, including all computerized records and files, in a secure area, reasonably protected from fire, theft and destruction. Provider agrees to take reasonable steps that are requested by Company as a result of an audit to cure deficiencies in all documentation related to the Services. Audits conducted under this Article 15 shall be at the expense of Company.

15.2 Record Maintenance after Expiration or Termination. Upon the termination of this Agreement, all materials and all other data and information obtained or generated by Provider and its employees, officers, directors and agents in the course of providing the Services hereunder (the "Records") shall, at Company's option and unless stated otherwise in the applicable Work Order,

be (i) delivered to Company at its expense and risk to its offices identified herein in such form as is then currently in the possession of Provider, (ii) retained by Provider for Company for a period of three (3) years, or (iii) disposed of at Company' expense, as directed by written request of Company, unless the Records are otherwise required to be stored or maintained by Provider under Applicable Law. If Provider is required or requested to maintain and/or store the Records for a period beyond three (3) years after the termination or expiration of this Agreement, Company shall reimburse Provider for its maintenance and storage costs, which shall be no more than a commercially reasonable cost. In no event shall Provider dispose of Records without first giving Company sixty (60) days' prior written notice of its intent to dispose of the Records. Provider shall be entitled at its expense to retain copies of the Records reasonably necessary for regulatory purposes or to demonstrate the satisfaction of its obligations hereunder, all subject to the confidentiality obligations set forth in Article 5 above.

ARTICLE XVI
INSPECTIONS / AUDITS

16.1 Provider agrees to maintain financial records and other records documenting the Services provided under this Agreement. Provider also agrees to allow reasonable access to those records by the Company. Company may upon written request and mutual agreement of the Parties, conduct periodic audits of Provider to ensure compliance with the terms and conditions of this Agreement and subsequent Work Order(s).

16.2 Audits will be conducted per an agreed-upon Audit Standard Operating Procedure and audit agenda with a closing audit meeting conducted following completion of the audit by both the auditor and Provider to review any findings. In order for Provider to continue to improve Services, Company shall provide a copy of the final audit report to Provider.

16.3 Should Company opt to use a third-party auditor or contracted consultant to conduct an audit or review, Provider reserves the right to approve all third-party auditors or contracted consultants in advance to determine if any conflicts of interest exist and to secure a signed confidentiality non-disclosure agreement between Provider and the third-party auditor or contracted consultant.

16.4 At least ten (10) days prior to the audit, Company will provide Provider with the name, contact information and business information and/or website for the third-party auditor or

contracted consultant and a signed authorization that will allow Provider to disclose to this individual, Company's information relative to the Agreement. If Provider identifies a conflict of interest with the proposed third-party auditor or contracted consultant, Provider reserves the right to notify the Company and deny access to its files and systems by the third-party auditor or contracted consultant. Company and Provider will work together to agree upon an alternative third-party auditor or contracted consultant.

16.5 Company will be responsible for payment of the cost of any audit or subpoena, requiring information from Provider that is directly related to the Services to be provided hereunder. Provider staff and management time directly related to the audit or subpoena will be invoiced to the Company based on the hourly rates of the personnel involved in the audit or subpoena including pre and post audit or subpoena activity. The terms and provisions of this Article 16 shall survive the Termination or expiration of this Agreement.

ARTICLE XVII
EXAMINATION OF RECORDS

17.1 Company shall have the right at any time to review and inspect all such records, as referred to herein, maintained by Company. Company shall keep and maintain all such records for a period of at least three (3) years after the Termination of this Agreement.

ARTICLE XVIII
ANTI-KICKBACK

18.1 Provider and Company each agrees that the fees to be paid by Company to Provider hereunder reflects the fair market value for the Services and has been negotiated at arm's length and has not been determined in a manner which considers the volume or value of any referrals or other business otherwise generated between the Parties for which payment may be made in whole or in part. Provider is being compensated solely for the performance of the Services described in this Agreement, and nothing in this Agreement is intended, or should be construed as, a reward for past or an incentive for future decisions regarding the prescription, use, purchase or recommendation of Company's products or services. Company expects Provider and its employees, agents, and contractors to exercise their best and independent professional judgment regarding the care and treatment of individual patients.

ARTICLE XIX
GENERAL

19.1 Relationship of Parties. The Parties expressly acknowledge and agree that each Party's legal relationship to the other under this Agreement is as an independent contractor. Nothing in this Agreement shall be construed to place the Parties in the relations of partners or joint venturers, and neither Party shall have the power to obligate or bind the other in any manner whatsoever, except as specifically provided for herein.

19.2 Conflict of Interest. The Parties agree that no employee of Provider shall have any personal or beneficial interest whatsoever in the Services or property described herein during the Term of this Agreement. Company agrees not to directly solicit for hire or directly contract the services of any employee or officer of Provider without first obtaining prior written consent from the Provider.

19.3 No Waiver of Rights. No assent expressed or implied, to any breach of any one or more covenants, provisions, or conditions of the Agreement shall be construed as a waiver of any succeeding or other breach.

19.4 No Third-Party Beneficiaries. It is expressly understood and agreed that enforcement of the terms and conditions of this Agreement, and all rights of action relating to such enforcement shall be strictly reserved to the Parties and nothing contained in this Agreement shall give or allow any such claim or right of action by any other entity or third person. It is the express intention of the Parties that any person other than a Party to this Agreement receiving services or benefits under this Agreement shall be an incidental beneficiary only.

19.5 Assignment and Subcontracting. Company and Provider each agree not to assign, pledge, transfer, or subcontract their duties and rights in this Agreement, in whole or in part without first obtaining the prior written consent of the other Party. Any attempt by Company or Provider to assign, transfer, or subcontract their rights hereunder without such prior written consent shall, at the option of the non-assigning Party, terminate this Agreement and all rights of the assigning Party. Such prior written consent may be granted or denied at the sole and absolute discretion the Party whose consent is sought.

19.6 No Discrimination in Employment. In connection with the performance or work under this Agreement, each Party agrees to comply with laws applicable to hiring, discharge, promoting, demoting and discrimination in matters of compensation relating to any person otherwise qualified, solely because of race, color, religion, national origin, gender, gender identity or expression, age, military status, sexual orientation, marital status, or physical or mental disability.

19.7 General Data Protection Regulation and The California Consumer Privacy Act.

Each Party shall, and as applicable to either Party: (a) at its own costs, take all necessary measures to be compliant with the provisions of the *Regulation (EU) 2016/679 (General Data Protection Regulation) in the current version of the OJ L 119, 04.05.2016; cor. OJ L 127, 23.5.2018, GDPR* and *Title 1.81.5, The California Consumer Privacy Act of 2018, CCPA;* and (b) each Party is to be regarded as an independent data controller or data processor within the meaning of the GDPR and CCPA when it processes personal data for its own purposes in the field of its activities. This applies to the exchange of personal data from one Party to the other Party in the performance of this Agreement.

Each Party acknowledges the importance of complying with the GDPR and CCPA and each Party represents it has: (i) carefully assessed whether and to what extent the provisions of the GDPR and CCPA apply to its operations; and (ii) each Party has taken all necessary steps to comply with the provisions of the GDPR and CCPA where required.

In any event, national and international laws which are applicable under the GDPR and CCPA shall apply to this Agreement and each Party agrees to remain compliant with such laws.

19.8 Publicity. Each Party shall keep the terms of this Agreement confidential, provided that either Party may disclose the terms of this Agreement to the extent required by applicable law or any government regulatory agency or with the prior written consent of the other Party. Neither Party may issue a press release or otherwise make a public announcement upon execution of the Agreement stating the general nature of the relationship between the Parties and the assignment and transfers provided for herein, without the prior written consent of the other Party.

19.9 Severability. In the event any term, provision, covenant or restriction of this Agreement is held by a court of competent jurisdiction to be invalid, void or unenforceable, the remainder of the terms, provisions, covenants or restrictions of this Agreement shall remain in full

force and effect and shall in no way be affected, impaired or invalidated, and to the extent possible, the term, provision, covenant or restriction held to be invalid, void or unenforceable shall be amended or revised so as to make it valid and enforceable and give effect to the original intent of the Parties.

19.10 Notices. All notices, requests, claims, demands and other communications hereunder shall be in writing and shall be delivered to the respective Party as follows:

If to Provider:

Denver Health and Hospital Authority
Office of General Counsel
777 Bannock Street, M.C. 1919
Denver, Colorado 80204
Fax: 303-436-5073

With a copy to:

Rocky Mountain Poison & Drug Safety
777 Bannock Street, Mail Code 0180
Denver, Colorado 80204
Attn: Contracts Manager
Fax: 303-739-1446

If to Company:

Premier Pharmaceuticals LLC
7259 W Franklin Road
Boise, Idaho 83709
Attn: Adrian Constance
Fax: 208-609-4269

Said notice shall be delivered personally during normal business hours to the appropriate office, above, or by prepaid U.S. mail or other commercial mail service. Mailed notice shall be deemed effective three (3) days after deposit with the U.S. Postal Service or other commercial carrier with a tracking mechanism. The Parties may from time-to-time designate substitute addresses or persons where and to whom such notices are to be mailed or delivered but such substitutions shall not be effective until actual receipt of written notification.

19.11 Force Majeure. If any Party to this Agreement is rendered unable, wholly or in part, by an event of force majeure or any other cause not reasonably within its control, to perform

or comply with any material obligation or condition of this Agreement, such Party shall, upon giving notice and reasonably full particulars to the other Party, be relieved of such obligation or condition during the continuance of such inability. The term "force majeure" shall include acts of God, pandemics, the elements, fire, accidents, breakdowns, strikes and any other industrial, civil or public disturbance, inability to obtain or maintain telephonic communications because of power failure or failure by the telephone company, inability to obtain materials, supplies, permits or labor, and any laws, orders, rules, regulations, acts or restraints of any government or governmental body or authority, civil or military.

19.12 Non-Solicitation. During the term of this Agreement and for one (1) year thereafter, the Company shall not knowingly solicit or recruit for employment or hire any of Provider's employees. To "knowingly" solicit, recruit or hire within the meaning of this provision does not include, and therefore does not prohibit, solicitation, recruitment or hiring of a Provider employee by Company if the Provider employee was identified by Company solely because of the Provider employee's response to a general advertisement placed in the public domain.

19.13 Governing Law. This Agreement shall be construed and enforced in accordance with the laws of the State of Colorado, without regard to the choice of law thereof. Venue for any action arising hereunder shall lie in a court of competent jurisdiction in Denver, Colorado. This provision shall survive the termination of this Agreement.

19.14 Successors in Interest. This Agreement and the rights, interest and obligations hereunder shall be binding upon, inure to the benefit of, and be enforceable by the Parties and their respective successors and permitted assigns.

19.15 Dispute Resolution/Non-Binding Mediation. The Parties shall endeavor to resolve any dispute or claim arising out of or relating to this Agreement or to a breach, termination, or validity of this Agreement as follows: the Executive Officers or their designees, of each Party will meet to attempt to resolve such dispute by good faith negotiations. If the Executive Officers cannot resolve the dispute within thirty (30) days after a Party requests such a meeting, then each Party will attempt in good faith to settle the dispute by mediation pursuant to this Section. The mediation of any dispute is to be administered by The Mediation Association of Colorado, JAMS or such other mediator as may be mutually agreed to by the Parties. The Parties shall share the direct costs

of the mediator equally, but each Party shall be responsible for its own costs and expenses, including attorneys' fees, if any, relating to its participation in mediation. If mediation is unsuccessful within thirty (30) days after the Parties complete the mediation process pursuant to this Section, the Parties may then have recourse to the state and federal courts located within the State of Colorado.

19.16 Agreement as Complete Integration – Amendments. This Agreement contains the entire understanding between the Parties with respect to the subject matter and supersedes all prior and contemporaneous agreements, negotiations, correspondence, undertakings, and understandings, oral or written, relating to such subject matter. No amendment to or modification of this Agreement shall be effective unless it shall be in writing and signed by both Parties. No Party may waive any term, provision, covenant, or restriction of this Agreement except by duly signed writing referring to the specific provision to be waived.

19.17 Paragraph Headings. The captions set forth are for convenience of reference only and shall not be construed to define or limit the terms and provisions hereof.

19.18 Legal Authority. The Parties assure and guarantee that each of them possesses the legal authority, pursuant to any proper, appropriate, and official motion, resolution or action passed or taken, to enter into this Agreement. Additionally, the Parties assure and guarantee that the person or persons signing and executing this Agreement on behalf of such Party, has been fully authorized to execute this Agreement on its behalf and to bind the Party validly and legally to all terms, performance and provisions herein.

19.19 Execution of Agreement. This Agreement is expressly subject to and shall not become effective or binding on any Party hereto until it has been fully executed by all Parties.

19.20 Counterparts of Agreement. This Agreement may be executed in multiple, identical counterparts, each of which shall be deemed to be an original, and all of which, taken together, shall constitute one and the same instrument. Signatures to this Agreement transmitted by facsimile transmission, by electronic mail in "portable document format" (".pdf") form, or by any other electronic means intended to preserve the original graphic and pictorial appearance of the Agreement, shall have the same effect as physical delivery of the paper Agreement bearing the original signature.

19.21 Survival of Certain Agreement Provisions. The Parties agree that all terms, conditions and covenants of this Agreement, together with the exhibits and attachments hereto, which reasonably contemplate continued performance or compliance beyond the termination of this Agreement, and referred to, shall survive termination and shall continue to be enforceable as provided herein.

19.22 Capitalized Terms. All capitalized terms used herein and not otherwise defined in this Agreement will have the meanings set forth in the Agreement.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as of the Effective Date shown above.

PREMIER PHARMACEUTICALS

By _____

Adrian Constance
EVP

Date 02-22-2024

"COMPANY"

DENVER HEALTH AND HOSPITAL AUTHORITY
Employer Identification # 84-1343242

By DocuSigned by: Dr. Richard Dart
Signer Name: Dr. Richard Dart
Signing Reason: I approve this document
Signing Time: 2/24/2024 | 10:12:37 AM PST
BEF00B23FF0C4A9B81BF1CADC27AD247

Nancy Butler
Associate COO, RMPDS
Contract # RMPDS-R-MSA

Date 2/24/2024

"PROVIDER"