SIP Amended Appendices List[1]
March 11, 2025

A. SIP Sponsor

a. Name of Sponsor, Address, Responsible Individual(s)
b. Attestations/Conflict of Interest Forms for Responsible Individuals
   i. Kelly Swartzendruber
   ii. Vincent Giglierano
c. Vendor Quality Manual*
d. Quality Agreement*
e. Vendor Standard Operating Procedures*
   i. HCPF Regulatory Inspections 5079-1
   ii. HCPF Internal Audit Procedure 5080-1
   iii. Non Conformance Procedure 5081-1
   iv. Corrective and Preventive Action Procedure - 5082-1
   v. HCPF Planned Deviation Procedure - 5083-1
   vi. HCPF Documentation Control - 5084-1
   vii. Procedures for SOPs 5085-1
   viii. Partner Qualification Audit Procedure 5086-1
   ix. HCPF Management Review - 5088-1
   x. HCPF Complaint Procedure_5089-1
      1. Colorado Drug Importation Program Case Handling (COI SOP 4796-1)
      2. Colorado Drug Importation Program Transmission and Reconciliation (COI SOP 4797-1)
   xi. HPCF Record Retention and Disposition Procedure 5090-1
   xii. HCPF Compliance Management and Tools 5091-1
   xiii. HCPF Record Digitization 5092-1
   xiv. HCPF Training 5096-1
   xv. HPCF Risk Management - 5098-1
   xvi. Partner Safety Report Recognition & Reporting 5099-1
   xvii. Drug Evaluation 5180-1
   xviii. Materials Training Form 5195-1
f. Partner Checklists
   i. Foreign Seller
   ii. Importer
   iii. Qualified Lab

B. Foreign Seller

a. Name of Foreign Seller, Address, Responsible Individuals
b. Attestations/Conflict of Interest Form

[1]Updated documents are highlighted in blue font. Documents in black font were not submitted on March 10, 2025, and were submitted to FDA on August 28, 2024 and/or February 27 , 2024.

c. Certifications/Registrations -FDA and Website
    i. Drug Establishment Listing
    ii. Health Canada Inspectional History for Last 5 Years
    iii. FDA Foreign Seller Registration
d. Vendor Standard Operating Procedures*
    i. SOP-SIP 001 Labeling
    ii. SOP-SIP-002 Pre-Import Process
    iii. SOP SIP 002 Form
    iv. SOP SIP 002 Shipping Transfer
    v. SOP SIP 003 SIP Reporting
    vi. SOP SIP 004 Recall of Product
    vii. SOP SIP 004 Product Form
    viii. SOP SIP 005 Supply Chain Security
    ix. SOP SIP 018 Receiving, Storage, Pick, Pack, Shipping

C. Importer

a. Name of Importer, Address, Responsible Individuals
b. Attestations/Conflict of Interest Forms/Confidentiality Agreements (Premier Pharmaceuticals LLC. & Q Labs)
c. Premier Pharmaceuticals LLC. Idaho License, Registration, & Inspectional History, Colorado Wholesale License
d. Relabeler Name, Address, Registration
e. Qualified Lab Inspection History, Certifications, FDA Registrations
f. Vendor Standard Operating Procedures*
    i. OPS-028 - Inventory Management and Procedures, Accountability
    ii. OPS-037 - Inventory Count Process
    iii. OPS 039 - Return Process Plan
    iv. QMS-007 - Pharmaceutical Deviation Report System
    v. QMS-015 - Change Management System
    vi. VAL-019 - Temperature Control Validation
    vii. 804-001 - Pre-Import Request
    viii. 804-002 - Importation
    ix. 804-003 - Receiving
    x. 804-004 - Sampling and Statutory Testing
    xi. 804-005 - NDC Assignment
    xii. 804-006 - Relabeling
    xiii. 804-007 - Recall Process Plan
    xiv. 804-008 - Return Process Plan
    xv. 804-009 - Employee Training & Certification
    xvi. 804-010 - Reporting
    xvii. 804-011 - Drug Supply Chain Security
    xviii. 804-012 - Field Alert Reports
    xix. 804-013 - Adverse Events/Quality Concern Investigation Process/Cross Function Investigation

xx. 804-014 - Pharmaceutical Product Complaint Procedure
xxi. 804-048 - Material Specifications
xxii. 804-049 - Batch Records
xxiii. 804-050 - Lot Disposition

g. Q Laboratories Quality Agreement with Premier Pharmaceuticals LLC.
h. Premier Pharmaceuticals LLC. and AdiraMedica Quality Agreement
i. Pharmacovigilance Agreements
    i. Pharmacovigilance Master Services Agreement
    ii. Safety Data Exchange Agreement (SDEA)*
j. Pharmacovigilance Standard Operating Procedures (SOPs) & Work Instructions(WI)s*
    i. Pharmacovigilance Case Intake – 5107.3
    ii. Pharmacovigilance Aggregate Reporting – 5109.3
    iii. Pharmacovigilance Downtime Handling of Adverse Events – 5110.3
    iv. Pharmacovigilance MedDRA Coding Conventions and Dictionary Management – 5111.2
    v. Pharmacovigilance Quality Oversight – 5112.2
    vi. Pharmacovigilance Training – 5113.3
    vii. Pharmacovigilance Escalation of Safety Issues – 5118.3
    viii. Pharmacovigilance Safety Data Exchange Agreements – 5121.2
    ix. Pharmacovigilance Product Quality Complaints – 5123.3
    x. Pharmacovigilance Handling of Medical Information Inquiries - 5124.2
    xi. Pharmacovigilance Reconciliation – 5580.2
    xii. PV Outbound Communication Attempts - 5623
    xiii. PV Business Continuity Plan – 5630.1
    xiv. Pharmacovigilance Training Requirements by Job Function – 4414.4
    xv. Pharmacovigilance Training Verification Form – 4421.4
    xvi. MIQ Work Instruction 2543.13

D. Final Drug List

a. FDA Data List for All 20 Drugs
b. Labels for FDA Per drug
    i. Cover Page
    ii. Current FDA Approved Package Insert
    iii. Current Canadian Monograph
    iv. Proposed Package Insert
    v. Annotated Label Comparisons
    vi. Proposed Package Label
    vii. Orange Book Verification

E. Actuarial Cost Savings Analysis

F. Certification Reports

a. Foreign Seller
b. Importer
c. Relabeler

d. Lab

G. Enlarged Figure Library

a. Figure 2. Detailed Movement of Prescription Drugs
b. Figure 5. Legal Relationships
c. Figure 14. DSCSA Compliance
d. Figure 15 - SIP Drug Recall Map

H. **FDA Correspondence**

a. Guidance Request Letter 2022
b. FDA RFI to Colorado 3/2/23
c. Colorado Intent to Respond RFI 3/23/23
d. CO letter to FDA 5/17/23
e. Meeting Minutes from 6/16/23
f. Colorado letter to FDA 9/5/23
g. Manufacturer responses to Colorado (9/5/23)
h. FDA Response to Colorado 10/27/23
i. Colorado Response to FDA 10/30/23
j. HCPF to FDA Questions 11/29/23
k. FDA Response to Questions 1/22/24

I. Stakeholder Engagement

a. RFI Results
b. Consumer Survey Results
c. Stakeholder Meeting 1/10/23

*These documents describe internal processes and procedures that include security (building and system) information that is exempt from disclosure under Colorado Revised Statutes 24-72-204(2)(a)(VII)(A) and specialized and proprietary information on business operations that are trade secrets exempt from disclosure under 24-72-204(3)(a)(IV).