SIP Appendices List
February 27, 2024

A. SIP Sponsor

a. Name of Sponsor, Address, Responsible Individuals
b. Attestations/Conflict of Interest Forms for Responsible Individuals
c. Vendor Quality Manual*
d. Vendor Standard Operating Procedures*
    i. Non Conformance Procedure 5081-1
    ii. Corrective and Preventive Action Procedure - 5082-1
    iii. Partner Qualification Audit Procedure 5086-1
    iv. Procedures for SOPs 5085-1
    v. Partner Safety Report Recognition & Reporting 5099-1
    vi. Drug Evaluation 5180-1
    vii. Materials Training Form 5195-1
e. 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
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
c. Confidentiality Agreements for PMA & Q Labs

d. License, Registration
e. Inspectional History
f. Relabeler Name, Address, Registration
g. Qualified Lab Inspection History, Certifications, Registrations
h. 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-011 - Adverse Events - Quality Concerns, Cross Function Investigation
    vi. QMS-015 - Change Management System
    vii. VAL-019 - Temperature Control Validation
    viii. 804-001 - Pre-Import Request
    ix. 804-002 - Importation
    x. 804-003 - Receiving
    xi. 804-004 - Sampling and Statutory Testing
    xii. 804-005 - NDC Assignment
    xiii. 804-006 - Relabeling
    xiv. 804-007 - Recall Process Plan
    xv. 804-008 - Return Process Plan
    xvi. 804-009 - Employee Training & Certification
    xvii. 804-010 - Reporting
    xviii. 804-011 - Drug Supply Chain Security
    xix. 804-012 - Field Alert Reports
    xx. 804-048 - Material Specifications
    xxi. 804-049 - Batch Records
    xxii. 804-050 - Lot Disposition
i. Q Laboratories Quality Agreement & PMA
j. PMA and Adira Quality Agreement
k. Pharmacovigilance Master Services Agreement

D. Final Drug List

a. FDA Data List for All 24 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).