Appendix A: SIP Sponsor Supporting Documentation

COLORADO
Department of Health Care Policy & Financing

303 E. 17th Avenue
Denver, CO 80203

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 of SIP Sponsor, Contact Information for Responsible Individuals

Name of SIP Sponsor: Colorado Department of Health Care Policy & Financing

Address of SIP Sponsor: 303 E. 17th Avenue, Denver, Colorado 80203

Responsible Individuals:

Name	Contact Information
Kelly Swartzendruber, Drug Importation Program Manager	Kelly.Swartzendruber@state.co.us 303-866-3632

Sincerely,

Kelly Swartzendruber

Kelly Swartzendruber, PharmD.
Drug Importation Program Manager
Pharmacy Office

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.

COLORADO
Department of Health Care Policy & Financing

Foreign Seller Compliance Checklist

DCN: HCPF FORM 5198.1
Effective Date: 23Feb2024

General Information					
Foreign Seller Name:					
Phone:		Website:			
Foreign Seller Address:					
Primary Contact Name and Title:		Email:		Phone:	
Completed By:		Date:			
Title:					

INSTRUCTIONS:

Please attach a copy of any relevant documents to support the questions in this assessment such as SOPs, Quality Manual etc. to the *last page* of this document.

Foreign Seller Quality Self-Assessment

Question	Yes	No	N/A	Comments / Explanation
1. Does your company maintain a documented quality management system? *251.3(e)(15)(iii)*	☐	☐	☐	
2. Do you have a Quality Manual? *251.3(e)(15)(iii)*	☐	☐	☐	
3. Do you have formal, documented policies, procedures and work instructions or other documentation for managing quality related issues? *251.3(e)(15)(iii)*	☐	☐	☐	
4. Do you have a system to control quality related documents in regard to their creation, revision, approval and implementation? Is a documented procedure available? Briefly describe relevant processes. *251.3(e)(15)(iii)*	☐	☐	☐	
5. Is there a policy or procedure to identify training needs of employees? *251.3(e)(15)(iii)*	☐	☐	☐	
6. Are employee training records maintained? *251.3(e)(15)(iii)*	☐	☐	☐	

7. Do you have a system to evaluate your suppliers? *251.3(e)(15)(iii)*	☐	☐	☐	
8. How do you measure the quality performance of your suppliers? *251.3(e)(15)(iii)*	☐	☐	☐	
9. Do you have processes/procedures in place for raising deviations and management of corrective and preventive actions? *251.3(e)(15)(iii)*	☐	☐	☐	
10. Do you have a process to identify/control nonconformances? *251.3(e)(15)(iii)*	☐	☐	☐	
11. Do you have adequate and documented procedures to address nonconformance? *251.3(e)(15)(iii)*	☐	☐	☐	
12. Do you have processes/procedures in place for raising deviations and management of corrective and preventive actions? *251.3(e)(15)(iii)*	☐	☐	☐	
13. Do you have an internal audit program? *251.3(e)(15)(iii)*	☐	☐	☐	
14. Do you have an audit schedule? *251.3(e)(15)(iii)*	☐	☐	☐	
15. Do you report on audit outcomes? *251.3(e)(15)(iii)*	☐	☐	☐	
16. Is there follow-up to ensure acceptable corrective action for audit findings? *251.3(e)(15)(iii)*	☐	☐	☐	
17. Do you have a Business Continuity/Disaster Recovery Plan to ensure your company is able to operate and fulfill contractual obligations? Briefly describe your key actions for business continuity and disaster planning. *251.3(e)(15)(iii)*	☐	☐	☐	
Confirm that the following requirements are available for review	Yes	No	N/A	**Comments** / Explanation
1. Health Canada Drug Establishment License and any other relevant Canadian or regional operations license(s). *251.3(d)(8), 251.5(c)(3)*	☐	☐	☐	
2. Unique Facility Identifier *251.5(c)(3)*	☐	☐	☐	
3. Health Canada Inspection history for the past 5 years *251.3(e)(4)(i)*	☐	☐	☐	
4. Registration with the FDA as a Foreign Seller *251.9(a)ff, 251.10(a)(1)-(3), 251.10(b)(1)-(3)*	☐	☐	☐	

5. Specific designee for Official Contact. List information in comments. *251.11(a)(1)-(2)*	☐	☐	☐	
6. Specific designee for US agent. List information in comments. *251.11(b)(1)ff*	☐	☐	☐	
7. Records of disposition of illegitimate foreign product(s) for at least 6 years after disposition *251.14(c)(2)(iv)*	☐	☐	☐	
8. Documentation specifying the manufacturer and quantity of each lot of the eligible prescription drug(s) received from the manufacturer. *251.19(d)(1)*	☐	☐	☐	
9. Records of shipment to the Importer under Section 804 and documentation that shipment was received directly from the manufacturer. *251.5(c)(4)(v)*	☐	☐	☐	
10. Documentation that the quantity ordered from the manufacturer does not exceed the quantity shipped to the Importer for the Section 804 program. *251.5(c)(4)(vi), 251.19(d)(2), 251.19(d)(3)*	☐	☐	☐	
11. Records associating SSI with the DIN and all records received from the manufacturer for 6 years after receipt *251.14(c)(4)(iv)*	☐	☐	☐	

Reference	Section 804 Requirement	List SOP(s) that meet Requirement or provide comments / explanation
251.3(e)(15)(iii), 251.3(e)(15)(iv)	How does the Foreign Seller ensure that all appropriate personnel are trained to the requirements and processes as it pertains to Section 804? What records are maintained?	
251.5(c)(4)(xiii)(B), 251.5(c)(4)(xiii)(C),	What items are provided to whom for the Pre-Import request and how is the information gathered verified?	
251.3(e)(11)(i), 251.14(a)(4), 251.14(d)(5)	How do the storage, handling, and distribution practices of supply chain participants, including transportation	

	providers meet the requirements outlined?	
251.5(c)(4)(vii), 251.5(c)(4)(xiii)(A), 251.14(a)(2), 251.14(a)(3), 251.14(c)(4)(i), 251.14(c)(4)(ii), 251.14(c)(4)(iii), 251.14(c)(4)(iv), 251.14(d)(5), 251.14(d)(2)	How are products received from the Canadian manufacturer verified and prepared for importation?	
251.3(e)(11)(ii), 251.14(a)(1), 251.14(a)(4), 251.14(a)(5), 251.19(d)(2)	Describe the flow of product through the Foreign Seller starting from order to US importation as it pertains to Section 804 and how supply chain security is ensured at each step.	
251.3(e)(11)(ii), 251.5(c)(4)(v), 251.14(c)(6)ff,	What is provided to the Importer as it pertains to supply chain security and timelines on when required/relevant information is delivered?	
251.14(c)(1)(i), 251.14(c)(1)(i)(A), 251.14(c)(1)(i)(B), 251.14(c)(1)(i)(C), 251.14(c)(3), 251.14(c)(7)	How is a suspect product identified, investigated, and reported to all relevant parties?	
251.14(c)(1)(ii), 251.14(c)(1)(ii)(A), 251.14(c)(1)(ii)(B), 251.14(c)(1)(ii)(C), 251.14(c)(2)(i) 251.14(c)(2)(ii) 251.14(c)(2)(iii), 251.14(c)(3), 251.14(c)(7), 251.18(e)(2)	How is an illegitimate foreign product identified, handled? How are relevant parties notified and updated?	
251.3(e)(13), 251.14(c)(3), 251.14(c)(7), 251.18(e)(2), 251.18(e)(3)ff, 251.18(e)(4)(ii), 251.18(e)(5)	How are recalls monitored, communicated, and handled? Explain how you cooperate with the SIP Sponsor's recall plan.	

251.14(c)(5)	Describe the process for completing requests for verification. Include intake source, timelines, communication method	
251.11(b)(2), 251.14(c)(1)(i)(C), 251.14(c)(2)(i), 251.14(c)(2)(ii), 251.14(c)(2)(iii), 251.14(c)(3), 251.18(e)(4)(ii), 251.19(h)	Describe communication plan to and from the FDA. Include method of communication and timeline.	

Please list the attachments being provided here, as applicable:	
Certifications:	
Quality Manual:	
List any documents/certifications relevant to Section 804 not otherwise listed:	

References from Section 804 of the FD&C Act Final Rule:

251.3(d)(7)	The name and address of the Foreign Seller;
251.3(d)(8)	A copy of the Foreign Seller's Health Canada Drug Establishment License;
251.3(e)(1)	Identify the SIP Sponsor, including any co-sponsors, identify the responsible individual(s), and identify the applicant that holds the approved NDA or ANDA for each eligible prescription drug's FDA-approved counterpart, the manufacturer(s) of the finished dosage form and the active ingredient or ingredients of each eligible prescription drug that the SIP Sponsor seeks to import, if known or reasonably known, the **Foreign Seller**, if known or reasonably known, and the Importer, and **explain the legal relationship**, if any, of each of these entities to the SIP Sponsor.
251.3(e)(2)	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**.
251.3(e)(3)	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.
251.3(e)(4)(i)	The **Health Canada inspectional history for the Foreign Seller** for the previous 5 years or, if the Foreign Seller has been licensed for less than 5 years, for the duration of its period of licensure; and
251.3(e)(10)	Explain how the SIP Sponsor will ensure that all the participants in the SIP comply with the requirements of section 804 of the Federal Food, Drug, and Cosmetic Act and this part.
251.3(e)(11)(i)	**Storage, handling, and distribution practices of supply chain participants, including transportation providers**, meet the requirements of part 205 of this chapter and do not affect the quality or impinge on the security of the eligible prescription drugs;
251.3(e)(11)(ii)	**Supply chain is secure**;

251.3(e)(13)	Include the **SIP's recall plan**, including an explanation of how the SIP Sponsor will obtain recall or market withdrawal information and how it will ensure that **recall or market withdrawal information is shared among the SIP Sponsor, the Foreign Seller**, the Importer, and FDA and provided to the manufacturer.
251.3(e)(15)(iii)	The creation of written **compliance policies, procedures, and protocols**
251.3(e)(15)(iv)	The provision of **education and training** to ensure that Foreign Sellers, Importers, qualifying laboratories, and their employees understand their compliance-related obligations
251.5(c)(3)	Identification of the Foreign Seller, including the name of the Foreign Seller; business address; unique facility identifier; any license numbers issued by Health Canada or a provincial regulatory body; and the name, email address, and phone number of a contact person
251.5(c)(4)(v)	**Copies of the invoice and any other documents** related to the manufacturer's sale of the drug to the Foreign Seller that was provided by the manufacturer to the Importer, and **copies of the same documents provided by the Foreign Seller to the Importer**
251.5(c)(4)(vi)	**Quantity**, listed separately by dosage form, strength, batch and lot or control number assigned by the manufacturer to the eligible prescription drug intended to be imported under this Pre-Import Request, **compared to the quantity of each batch and lot or control number originally received by the Foreign** Seller from the manufacturer, and the date of such receipt.
251.5(c)(4)(vii)	**Expiration date** of the HFPB-approved drug, listed by lot or control number assigned by the manufacturer
251.5(c)(4)(xiii)(A)	**Location** of the eligible prescription drugs in Canada and **anticipated date of shipment** (date the eligible prescription drug(s) leave their location in Canada);
251.5(c)(4)(xiii)(B)	**Name, address, email address, and telephone number of the Foreign Seller**
251.5(c)(4)(xiii)(C)	Anticipated **date of export** from Canada and **Canadian port of exportation**
251.9(a)ff	Any Foreign Seller(s) designated in a SIP Proposal must be **registered** with FDA before FDA will authorize the SIP Proposal.
251.10(a)(1)-(3)	Expedited updates. A Foreign Seller must **update** its registration information no later than 30 calendar days after
251.10(b)(1)-(3)	**Annual review and update of registration information**. A Foreign Seller must review and update all registration information required under § 251.9

251.11(a)(1)-(2)	Official contact. A Foreign Seller subject to the registration requirements of this part must designate an **official contact**. The official contact is responsible for:
251.11(b)(1)ff	A Foreign Seller must designate a single **U.S. agent**. The U.S. agent must reside or maintain a place of business in the United States and may not be a mailbox, answering machine or service, or other place where a person acting as the U.S. agent is not physically present. The U.S. agent is responsible for
251.11(b)(2)	**FDA may provide certain information and/or documents to the U.S. agent**. The provision of information and/or documents by FDA to the U.S. agent is equivalent to providing the same information and/or documents to the Foreign Seller.
251.14(a)(1)	Each drug imported under the SIP is **HPFB-approved** and **labeled for sale in Canada** by the manufacturer before it reaches the Foreign Seller
251.14(a)(2)	For each drug that is imported under the SIP and that is **manufactured outside Canada**, the drug was **authorized for import into Canada by the manufacturer and was not transshipped through Canada for sale in another country**
251.14(a)(3)	For each drug imported under the SIP, the **drug was sold by the manufacturer directly to a Foreign Seller**;
251.14(a)(4)	For each drug imported under the SIP, the **Foreign Seller ships the drug directly to the Importer** in the United States
251.14(a)(5)	For each drug imported under the SIP, the Foreign Seller identified in the SIP **meets applicable supply chain security requirements of this part**
251.14(c)(1)	A Foreign Seller must have systems in place to
251.14(c)(1)(i)	Determine whether a drug in its possession or control that it intends to sell to the Importer under a SIP is a **suspect foreign product**. Upon making a determination that a drug in its possession or control is a suspect foreign product, or upon receiving a request for verification from FDA that the Foreign Seller has determined that a product within its possession or control is a suspect foreign product, a Foreign Seller must
251.14(c)(1)(i)(A)	Quarantine such product within its possession or control until such product is cleared or dispositioned
251.14(c)(1)(i)(B)	Promptly **conduct an investigation**, in coordination with the Importer and the manufacturer, as applicable, to determine whether the product is an illegitimate foreign product, and **verify the product at the package level, including the SSI**; and

251.14(c)(1)(i)(C)	If the Foreign Seller makes the determination that a suspect foreign product is not an illegitimate foreign product, promptly **notify FDA of such determination** for those products that FDA has requested verification.
251.14(c)(1)(ii)	Determine whether a drug in its possession or control that it intends to sell to the Importer under a SIP is an **illegitimate foreign product**. Upon making a determination that a drug in its possession or control is an illegitimate foreign product, the Foreign Seller must:
251.14(c)(1)(ii)(A)	Quarantine such product within the possession or control of the Foreign Seller from product intended for distribution until such product is dispositioned;
251.14(c)(1)(ii)(B)	Disposition the illegitimate foreign product within the possession or control of the Foreign Seller;
251.14(c)(1)(ii)(C)	Take reasonable and appropriate steps to **assist** a manufacturer or Importer to disposition an illegitimate product not in the possession or control of the Foreign Seller; and
251.14(c)(1)(ii)(D)	**Retain a sample** of the product for further physical examination or laboratory analysis of the product by the manufacturer or FDA (or other appropriate Federal or State official) upon request by FDA (or other appropriate Federal or State official), as necessary and appropriate.
251.14(c)(2)(i)	Upon determining that a product in the possession or control of the Foreign Seller is an illegitimate foreign product, the Foreign Seller **must notify FDA** and the Importer that the Foreign Seller received such illegitimate product **not later than 24 hours** after making such determination.
251.14(c)(2)(ii)	Upon the receipt of a notification from the manufacturer, FDA, the Importer or other wholesale distributor, or dispenser that a determination has been made that a product that had been sold by the Foreign Seller is an illegitimate foreign product, a Foreign Seller must **identify all illegitimate foreign product subject to such notification** that is in the possession or control of the Foreign Seller, including any product that is subsequently received, and perform the activities to investigate the product described in paragraph (c)(1) of this section.
251.14(c)(2)(iii)	Upon making a determination, in consultation with FDA, that a notification is no longer necessary, a Foreign Seller **must promptly notify** the Importer and person who sent the notification that the notification is terminated.
251.14(c)(2)(iv)	A Foreign Seller **must keep records of the disposition** of an illegitimate foreign product for not less than 6 years after the conclusion of the disposition.

251.14(c)(3)	Upon request by FDA, or other appropriate Federal or State official, in the event of a recall or for purposes of **investigating a suspect foreign product or an illegitimate foreign product**, a Foreign Seller must promptly provide the official with information about its **transactions** with the manufacturer and the Importer.
251.14(c)(4)	A Foreign Seller, **upon receiving a shipment** of eligible prescription drugs from the manufacturer, must
251.14(c)(4)(i)	**Separate** the portion of drugs intended for sale to the Importer located in the United States, and store such portion separately from that portion of product intended for sale in the Canadian market;
251.14(c)(4)(ii)	**Assign an SSI** to each package and homogenous case intended for sale to the Importer in the United States, **unless each such package and homogenous case displayed a manufacturer-affixed or imprinted product identifier**, as such term is defined in section 581(14) of the Federal Food, Drug, and Cosmetic Act, at the time of receipt by the Foreign Seller;
251.14(c)(4)(iii)	Affix or imprint the SSI **on each package and homogenous case** intended for sale to the Importer in the United States. Such SSI must be located on **blank space** on the package or homogenous case and must not obscure any labeling for the Canadian market, including the DIN; and
251.14(c)(4)(iv)	**Keep records associating the SSI with the DIN and all the records** the Foreign Seller received from the manufacturer upon receipt of the original shipment intended for the Canadian market for not less than **6 years**.
251.14(c)(5)	Upon receiving a **request for verification** from the Importer or other authorized repackager, wholesale distributor, or dispenser that is in possession or control of a product such person believes to be distributed by such Foreign Seller, a Foreign Seller must, **not later than 24 hours** after receiving the request for verification, or in such other reasonable time as determined by the FDA based on the circumstances of the request, notify the person making the request whether the SSI that is the subject of the request corresponds to the SSI affixed or imprinted by the Foreign Seller. If a Foreign Seller responding to a request for verification identifies an SSI that does not correspond to that SSI affixed or imprinted by the Foreign Seller, the Foreign Seller **must treat such product as suspect foreign product and conduct an investigation** as described in paragraph (c)(1) of this section. If the Foreign Seller determines the product is an illegitimate foreign product, the Foreign Seller must advise the person making the request of such determination at the time such Foreign Seller responds to the request for verification.

251.14(c)(6)ff	For each transaction between the Foreign Seller and the Importer for an eligible prescription drug, the Foreign Seller must provide: (i) A statement that the Foreign Seller purchased the product directly from the manufacturer; (ii) The proprietary name (if any) and the established name of the product; (iii) The strength and dosage form of the product; (iv) The container size; (v) The number of containers; (vi) The lot number of the product assigned by the manufacturer; (vii) The date of the transaction; (viii) The date of the shipment, if more than 24 hours after the date of the transaction; (ix) The business name and address of the person associated with the Foreign Seller from whom ownership is being transferred; (x) The business name and address of the person associated with the Importer to whom ownership is being transferred; (xi) The SSI for each package and homogenous case of product; and (xii) The Canadian DIN for each product transferred.
251.14(c)(7)	Upon a request by FDA, or other appropriate Federal or State official, in the event of a recall or for purposes of investigating a suspect foreign product or an illegitimate foreign product, the Foreign Seller must promptly provide the official with information about its transactions with the manufacturer and the Importer.
251.18(e)(2)	If FDA, the SIP Sponsor, the Foreign Seller, the Importer, or the manufacturer determines that a recall is warranted, the SIP Sponsor must effectuate the recall in accordance with its written recall plan under paragraph (e)(3) of this section.
251.18(e)(3)ff	A SIP must have a written recall plan that describes the procedures to perform a recall of the product and specifies who will be responsible for performing the procedures. The recall plan must cover recalls mandated or requested by FDA and recalls initiated by the SIP Sponsor, the Foreign Seller, the Importer, or the manufacturer. The recall plan must include sufficient procedures for the SIP Sponsor to:
251.18(e)(4)(ii)	The Foreign Seller must provide to FDA, upon request, information about its **transactions** of the recalled drug with the manufacturer and the Importer.
251.18(e)(5)	The Foreign Seller and Importer **must cooperate** with any recalls, including recalls initiated by the SIP Sponsor, FDA, the Foreign Seller, the Importer, or the drug's manufacturer.
251.19(d)(1)	**Documentation** from the Foreign Seller specifying the **manufacturer** of each eligible prescription drug and the **quantity of each lot** of the eligible prescription drug(s) received by the Foreign Seller from that manufacturer;

251.19(d)(2)	Documentation demonstrating that the eligible prescription drug was received by the Foreign Seller from the manufacturer and subsequently shipped by the Foreign Seller to the Importer;
251.19(d)(3)	Documentation of the quantity of each lot of the eligible prescription drug(s) received by the Foreign Seller, demonstrating that the quantity being imported into the United States is not more than the quantity that was received by the Foreign Seller; and
251.19(h)	A SIP Sponsor must submit a report to FDA within **10 calendar days**, in electronic format via the ESG or to an alternative transmission point identified by FDA, regarding any applicable **criminal conviction, violation of law, or disciplinary action** as described in § 251.3(e)(2) and (3).

COLORADO
Department of Health Care Policy & Financing

Importer Compliance Checklist Form

DCN: HCPF FORM 5197.1
Effective Date: 23Feb2024

General Information					
Importer Name:					
Business Type:					
Phone:		Website:			
Importer Address:					
Primary Contact Name and Title:		Email:		Phone:	
Completed By:		Date:			
Title:					

INSTRUCTIONS: Please attach a copy of any relevant documents to support the questions in this assessment such as SOPs, Quality Manual etc. to the *last page* of this document.

Importer Quality Self-Assessment

Question	Yes	No	N/A	Comments / Explanation
1. Does the Importer also perform the relabeling activities? If no, please indicate name and contact information for the FDA-registered relabeler. *251.3(d)(10), 251.5(c)(4)(xiii)(E), 251.5(c)(4)(xiii)(F)(2)*	☐	☐	☐	
2. Does your company maintain a documented quality management system? *251.3(e)(15)(iii)*	☐	☐	☐	
3. Do you have a Quality Manual? *251.3(e)(15)(iii)*	☐	☐	☐	
4. Do you have formal, documented policies, procedures and work instructions or other documentation for managing quality related issues? *251.3(e)(15)(iii)*	☐	☐	☐	
5. Do you have a system to control quality related documents in regard to their creation, revision, approval and implementation? Is a documented procedure available? Briefly describe relevant processes. *251.3(e)(15)(iii)*	☐	☐	☐	

6. Is there a policy or procedure to identify training needs of employees? *251.3(e)(15)(iv)*	☐	☐	☐	
7. Are employee training records maintained? *251.3(e)(15)(iv)*	☐	☐	☐	
8. Do you have a system to evaluate your suppliers? *251.3(e)(15)(iii)*	☐	☐	☐	
9. How do you measure the quality performance of your suppliers? *251.3(e)(15)(iii)*	☐	☐	☐	
10. Do you have processes/procedures in place for raising deviations and management of corrective and preventive actions? *251.3(e)(15)(iii)*	☐	☐	☐	
11. Do you have a process to identify/control nonconformances? *251.3(e)(15)(iii)*	☐	☐	☐	
12. Do you have adequate and documented procedures to address nonconformance? *251.3(e)(15)(iii)*	☐	☐	☐	
13. Do you have processes/procedures in place for raising deviations and management of corrective and preventive actions? *251.3(e)(15)(iii)*	☐	☐	☐	
14. Do you have an internal audit program? *251.3(e)(15)(iii), 251.7(b)*	☐	☐	☐	
15. Do you have an audit schedule? *251.3(e)(15)(iii), 251.7(b)*	☐	☐	☐	
16. Do you report on audit outcomes? *251.3(e)(15)(iii), 251.7(b)*	☐	☐	☐	
17. Is there follow-up to ensure acceptable corrective action for audit findings? *251.3(e)(15)(iii), 251.7(b)*	☐	☐	☐	
18. Do you have a Business Continuity/Disaster Recovery Plan to ensure your company is able to operate and fulfill contractual obligations? Briefly describe your key actions for business continuity and disaster planning. *251.3(e)(15)(iii)*	☐	☐	☐	
Confirm that the following requirements are available for review	Yes	No	N/A	Comments / Explanation
1. Adequate evidence of FDA labeler registration and FDA inspection history. (Applicable if Importer is also relabeler) *251.3(d)(10), 251.5(c)(4)(xiii)(E), 251.5(c)(4)(xiii)(F)(1), 251.12(b)(1)*	☐	☐	☐	
2. FDA labeler code *251.12(b)(1-2)*				

3. State and Federal Inspection history for the Importer for at least the last 5 years. *251.3(e)(4)(ii)*	☐	☐	☐	
4. Unique facility identifier or FDA establishment identification number. *251.5(c)(1), 251.5(c)(4)(xiii)(E)*	☐	☐	☐	
5. Records of association of the product identifier to the SSI and Canadian DIN of imported product for at least 6 years prior. *251.14(d)(3)(ii), 251.14(d)(3)(iii), 251.14(d)(4)*	☐	☐	☐	

Reference	Section 804 Requirement	List SOP(s) that meet Requirement or provide comments / explanation
251.3(e)(15)(iii), 251.3(e)(15)(iv)	How does the Importer ensure that all appropriate personnel are trained to the requirements and processes as it pertains to Section 804? What records are maintained?	
251.5(a), 251.5(c)(3), 251.5(c)(4), 251.5(c)(4)(i), 251.5(c)(4)(ii), 251.5(c)(4)(ii)(A-C), 251.5(c)(4)(iii), 251.5(c)(4)(iv), 251.5(c)(4)(v), 251.5(c)(4)(vi), 251.5(c)(4)(vii), 251.5(c)(4)(viii), 251.5(c)(4)(ix), 251.5(c)(4)(x), 251.5(c)(4)(xii)(A-E), 251.5(e)(1), 251.13(b)(1)(i)	What information is gathered for the Pre-Import request? How is the information collected and verified to meet the requirements of Section 804?	
251.5(b), 251.5(d), 251.5(c)(4)(xiii)(F)(3), 251.5(c)(4)(xiii)(A-D), 251.5(e)(1-2), 251.8(d)	How is the Pre-Import request information collected and submitted to the FDA? What conditions warrant resubmission? Include what information is gathered internally, requested from the manufacturer, and from other partners. Include timelines for all processes.	

251.5(c)(4)(xi), 251.5(c)(4)(xi)(A-C), 251.5(c)(4)(xii), 251.16(a), 251.16(b), 251.16(c), 251.16(f), 251.16(g), 251.16(h)(1), 251.17(d)(1-3), 251.17(e)(1-3), 251.17(f), 251.17(g)	How will samples be selected and tested? How does the process change or not change if the manufacturer completes testing? How will results of the testing be communicated to relevant parties including the FDA?	
251.3(e)(11)(i), 251.14(a)(4), 251.3(e)(11)(ii), 251.5(c)(4)(xiii)(E), 251.5(c)(4)(xiii)(F)(4)	How do the storage, handling, and distribution practices of supply chain participants, including transportation providers meet the requirements outlined in Section 804?	
251.5(c)(4)(xiii)(F)(4), 251.12(a)(5), 251.12(a)(6), 251.17(a-d)	Explain the process of entry into the United States of product received from the Foreign Seller. Include what documentation is submitted to whom, how the products are held, and how products are released for entry.	
251.3(e)(11)(iii), 251.12(a)(2-4)	How are products that are received from the Foreign Seller verified?	
251.12(a)(1, 251.12(b)(1)), 251.12(b)(2), 251.13(b)(1), 251.13(c), 251.13(d), 251.14(d)(2), 251.14(d)(3), 251.14(d)(3)(i), 251.17(a-d)	Describe the flow of product through relabeling starting from the assignment of the NDC until the product is verified to meet all FDA labeling requirements. Include criteria and manner in which a supplemental labeling proposal would be submitted to the FDA.	
251.13(b)(4), 251.13(b)(4)(i), 251.13(b)(4)(ii),	How are products checked and verified as meeting FDA	

251.13(b)(4)(iii), 251.13(b)(4)(iv), 251.13(b)(4)(v), 251.13(b)(4)(vi), 251.13(b)(4)(vii), 251.13(c)	standards? Must include check procedures for the drug enclosure, carton, and all relevant documentation that accompanies the product.	
251.12(b)(3), 251.13(a), 251.14(b), 251.14(d)(1)	Describe what records are kept for each drug that is eligible for relabeling. Outline what records need to be obtained from other parties and how those records are requested and maintained.	
251.14(b), 251.14(d)(1), 251.14(d)(2), 251.14(d)(3), 251.14(d)(3)(i)	Explain the process of assigning a unique product identifier and each step contributes to overall supply chain security. Include what records are kept, how they are kept, and how they can be accessed.	
251.14(d)(6), 251.14(d)(7), 251.14(d)(7)(i-iv)	Describe all processes in place to ensure that requirements of section 582 as outlined by section 804 are met.	
251.3(e)(11)(iv), 251.12(a)(7,)251.18(b), 251.18(c), 251.18(d)(1-3), 251.18(d)(3)(i), 251.18(d)(3)(ii), 251.18(d)(4), 251.18(d)(5), 251.18(d)(6), 251.18(d)(6)(i)(A-B), 251.18(d)(6)(ii)(A-F), 251.18(d)(6)(ii)(E)(1-2) 251.18(d)(6)(ii)(F)(1-2), 251.18(d)(10), 251.18(d)(11)(i), 251.18(d)(11)(ii)	How will adverse event information be captured, checked for completion, and submitted to the FDA? Include categorizations and timelines for submissions for both ICSRs and field reports. Include how patient privacy will be protected.	
251.3(e)(11)(iv), 251.12(a)(7), 251.18(d)(1), 251.18(d)(8)(i-iii), 251.18(d)(9)	How will each individual involved in the importation program be trained to identify	

	and report adverse events? What records are kept and for how long?	
251.3(e)(13), 251.18(e)(2), 251.18(e)(3)ff, 251.18(e)(4), 251.18(e)(4)(i), 251.18(e)(5)	Describe how all responsibilities of the Importer as described by the overall recall plan have been met. Include how notifications of a recall are received and disseminated, what procedures are in place to ensure recalled drug is not released into distribution.	
251.14(a)(7)	How are drugs dispositioned? What requirements need to be met? What records are kept and for how long?	
251.19(c), 251.19(d)(2), 251.19(d)(4), 251.19(e)ff, 251.19(f), 251.19(h)	What information is provided to the SIP Sponsor for quarterly reports? How is that information gathered/maintained and verified before provision?	

Please list the attachments being provided here, as applicable:	
Certifications:	
Quality Manual:	
List any documents/certifications relevant to Section 804 not otherwise listed:	

References from Section 804 of the FD&C Act Final Rule:

251.3(d)(9)	The name and address of the **Importer**;
251.3(d)(10)	The name and address of the **FDA-registered repackager or relabeler**, if different from the Importer, that will relabel the eligible prescription drugs (including any limited repackaging in accordance with the requirements in this part), along with **adequate evidence of registration and of satisfactory resolution of any objectionable conditions or practices identified during its most recent FDA inspection**, if applicable; and
251.3(e)(1)	Identify the SIP Sponsor, including any co-sponsors, identify the responsible individual(s), and identify the applicant that holds the approved NDA or ANDA for each eligible prescription drug's FDA-approved counterpart, the manufacturer(s) of the finished dosage form and the active ingredient or ingredients of each eligible prescription drug that the SIP Sponsor seeks to import, if known or reasonably known, the **Foreign Seller**, if known or reasonably known, and the Importer, and **explain the legal relationship**, if any, of each of these entities to the SIP Sponsor.
251.3(e)(2)	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**.
251.3(e)(3)	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.
251.3(e)(4)(ii)	The **State and Federal inspectional history for the Importer** for the previous **5 years** or, if the Importer has been licensed for less than 5 years, for the duration of its period of licensure.
251.3(e)(10)	Explain how the SIP Sponsor will ensure that all the participants in the SIP comply with the requirements of section 804 of the Federal Food, Drug, and Cosmetic Act and this part.

251.3(e)(11)(i)	**Storage, handling, and distribution practices of supply chain participants, including transportation providers**, meet the requirements of part 205 of this chapter and do not affect the quality or impinge on the security of the eligible prescription drugs;
251.3(e)(11)(ii)	**Supply chain is secure**;
251.3(e)(11)(iii)	Importer **screens** the eligible prescription drugs it imports for **evidence that they are adulterated, counterfeit, damaged, tampered with, expired, suspect foreign product, or illegitimate foreign product**; and
251.3(e)(11)(iv)	Importer **fulfills its responsibilities to submit adverse event, field alert, and other reports** required by the SIP, the Federal Food, Drug, and Cosmetic Act, or this part.
251.3(e)(13)	Include the **SIP's recall plan**, including an explanation of how the SIP Sponsor will obtain recall or market withdrawal information and how it will ensure that **recall or market withdrawal information is shared among the SIP Sponsor, the Foreign Seller**, the Importer, and FDA and provided to the manufacturer.
251.3(e)(15)(iii)	The creation of written **compliance policies, procedures, and protocols**
251.3(e)(15)(iv)	The provision of **education and training** to ensure that Foreign Sellers, Importers, qualifying laboratories, and their employees understand their compliance-related obligations
251.5(a)	An eligible prescription drug **may not be imported or offered for import** under this part unless the **Importer has filed a Pre-Import Request** for that drug in accordance with this section and **FDA has granted** the Pre-Import Request.
251.5(b)	The **Importer must submit a complete Pre-Import Request** in electronic format via the ESG, or to an alternative transmission point identified by FDA, **at least 30 calendar days prior to the scheduled date of arrival or entry for consumption**, whichever occurs first, of an eligible prescription drug **covered under an authorized SIP**.
251.5(c)(1)	**Identification of the Importer**, including **Importer name**; **business type** (wholesale distributor or pharmacist); **U.S. license number**(s) and State(s) of license; **business address**; **unique facility identifier** if required to register with FDA as an establishment under section 510 of the Federal Food, Drug, and Cosmetic Act or **FDA establishment identification number** if not required to register under section 510 of the Federal Food, Drug, and Cosmetic Act; and the **name, email address, and phone number of a contact person**.
251.5(c)(2)	**Identification of the FDA-authorized SIP**, including the **name of the SIP**, if any; the **name or names of the SIP Sponsor and co-sponsors**, if any; **business address; and the name, email address, and phone number of a contact person**.

251.5(c)(3)	**Identification of the Foreign Seller**, including the **name of the Foreign Seller; business address; unique facility identifier; any license numbers issued by Health Canada or a provincial regulatory body**; and the **name, email address, and phone number of a contact person**.
251.5(c)(4)	**Identification and description of each drug** covered by the Pre-Import Request, including, for each drug, the following information:
251.5(c)(4)(i)	**Established and proprietary name of the HPFB-approved drug**, as applicable; **DIN**; and **complete product description, including strength, description of dosage form, and route(s) of administration**.
251.5(c)(4)(ii)	**Active pharmaceutical ingredient** (API) information, including:
251.5(c)(4)(ii)(A)	**Name of API**;
251.5(c)(4)(ii)(B)	**Manufacturer of API** and its **unique facility identifier**; and
251.5(c)(4)(ii)(C)	**Amount of API** and **unit measure** in the eligible prescription drug;
251.5(c)(4)(iii)	**Established name and proprietary name**, as applicable, of the **FDA-approved counterpart drug** and **NDA** or **ANDA number**.
251.5(c)(4)(iv)	**Manufacturer of the eligible prescription drug** with the **business address and unique facility identifier**.
251.5(c)(4)(v)	**Copies of the invoice and any other documents** related to the **manufacturer's sale of the drug to the Foreign Seller** that was provided by the **manufacturer** to the **Importer**, and **copies of the same documents provided by the Foreign Seller to the Importer**.
251.5(c)(4)(vi)	**Quantity, listed separately by dosage form, strength, batch** and **lot** or **control number** assigned by the **manufacturer** to the eligible prescription drug intended to be imported under this Pre-Import Request, **compared to the quantity of each batch and lot or control number originally received by the Foreign Seller from the manufacturer**, and the **date of such receipt**.
251.5(c)(4)(vii)	**Expiration date of the HFPB-approved drug**, listed by **lot** or control number assigned by the **manufacturer**.
251.5(c)(4)(viii)	**Expiration date to be assigned to the eligible prescription drug** when **relabeled** by the **Importer** with a **complete description of how that expiration date was determined** using the **manufacturer's stability studies** in accordance with the FDA-approved NDA or ANDA.
251.5(c)(4)(ix)	**NDC** proposed for assignment by the **Importer**.

251.5(c)(4)(x)	**FDA product code** for the eligible prescription drug(s) to be imported.
251.5(c)(4)(xi)	Unless the manufacturer has notified the Importer that it intends to conduct the required testing as provided in § 251.16(e), a **Statutory Testing** plan that includes:
251.5(c)(4)(xi)(A)	A **description** of how the **samples** will be **selected** from a shipment for the Statutory Testing;
251.5(c)(4)(xi)(B)	The **name and location of the qualifying laboratory** in the United States that will conduct the Statutory Testing; and
251.5(c)(4)(xi)(C)	A **description of the testing method(s)** that will be used to conduct the Statutory Testing.
251.5(c)(4)(xii)	**Attestation and information statement** from the **manufacturer** that establishes that the drug proposed for import, but for the fact that it bears the HPFB-approved labeling, **meets the conditions in the FDA-approved NDA or ANDA**, including any process-related or other requirements for which compliance cannot be established through laboratory testing. Accordingly, the attestation and information statement must include, at a minimum:
251.5(c)(4)(xii)(A)	**Confirmation** that the HPFB-approved drug has the **active ingredient**(s), **active ingredient source**(s) (including **manufacturing facility or facilities**), **inactive ingredient**(s), **dosage form**, **strength**(s), and **route**(s) of administration **described in the FDA-approved drug's NDA or ANDA**.
251.5(c)(4)(xii)(B)	**Confirmation** that the HPFB-approved drug **conforms to the specifications** in the FDA-approved drug's NDA or ANDA regarding the **quality of the drug substance**(s), drug product, intermediates, raw materials, reagents, components, in-process materials, container closure systems, and other materials used in the production of the drug.
251.5(c)(4)(xii)(C)	**Confirmation** that the HPFB-approved drug was **manufactured** in accordance with the conditions described in the FDA-approved drug's NDA or ANDA, including with regard to the facilities and manufacturing lines that are used, and in compliance with current good manufacturing practice requirements set forth in **section 501** of the Federal Food, Drug, and Cosmetic Act and **parts 4** (if a combination product), **210**, and **211** of this chapter.
251.5(c)(4)(xii)(D)	**Original date of manufacture** or the **date used to calculate the labeled expiration date** based on the HPFB-approved or scientifically validated expiration period, the expiration period set forth in the FDA-approved drug's NDA or ANDA, and any other **information needed to label the drug with an expiration date within the expiration dating period determined by stability studies in the FDA-approved NDA or ANDA**.
251.5(c)(4)(xii)(E)	**Information needed to confirm that the labeling of the prescription drug complies with labeling requirements** under the Federal Food, Drug, and Cosmetic Act.

251.5(c)(4)(xiii)	**Information** related to the **importation**, including
251.5(c)(4)(xiii)(A)	**Location** of the eligible prescription drugs in **Canada** and **anticipated date of shipment** (date the eligible prescription drug(s) leave their location in Canada);
251.5(c)(4)(xiii)(B)	**Name, address, email address, and telephone number of the Foreign Seller**;
251.5(c)(4)(xiii)(C)	Anticipated **date of export** from Canada and **Canadian port of exportation**;
251.5(c)(4)(xiii)(D)	**Anticipated date and approximate time of arrival at the port authorized by FDA to import eligible prescription drugs** under section 804 of the Federal Food, Drug, and Cosmetic Act;
251.5(c)(4)(xiii)(E)	The **name, address, unique facility identifier or FDA establishment identification number, and telephone number of the secured warehouse, location** within a specific **foreign trade zone**, or other **secure distribution facility** controlled by or under contract with the **Importer** where the eligible prescription drug will be **stored pending testing, relabeling,** and **FDA determination of admissibility**;
251.5(c)(4)(xiii)(F)	**Information** regarding the **facility** where the **relabeling** and any **repackaging** allowed under the authorized SIP will occur for the eligible prescription drug, including:
251.5(c)(4)(xiii)(F)(1)	The **facility's unique facility identifier**;
251.5(c)(4)(xiii)(F)(2)	The facility's **name, address, and FDA establishment identifier number**;
251.5(c)(4)(xiii)(F)(3)	The **anticipated date** the relabeling and any limited repackaging will be **completed**; and
251.5(c)(4)(xiii)(F)(4)	Information about **where the relabeled drug will be stored pending distribution**, including the **FDA establishment identification number of the storage facility**, if available.
251.5(d)	The **manufacturer must provide** the **attestation and information statement** described in paragraph (c)(4)(xii) of this section to the Importer within **30 calendar days** of **receiving** the **Importer's request**. If the manufacturer cannot provide the attestation and information statement, it **must notify FDA and the Importer of its inability to provide the attestation and information statement** and **articulate** with **specificity** the **reason**(s) why it cannot provide the attestation and information statement.
251.5(e)(1)	The **Importer must provide** the **executed batch record**, including the **certificate of analysis**, for **at least one recently manufactured**, commercial-scale batch of the **HPFB-approved drug**, and **at least one recently manufactured**, commercial-scale batch of the

	FDA-approved drug that was **produced for and released for distribution to the U.S. market under an NDA or ANDA**.
251.5(e)(2)	The **manufacturer must provide** these records to the **Importer**, within **30 calendar days** of receiving the **Importer's request**, for **each manufacturing line** that the manufacturer used to produce either or both of the drugs.
251.7(b)	**SIP Sponsors** and other **SIP participants must agree** to **submit** to **audits** of their books and records and inspections of their facilities as a condition of participation in a SIP. If a **SIP Sponsor, manufacturer, Foreign Seller, Importer, qualifying laboratory, or other participant** in the supply chain **delays, denies, or limits an inspection**, or **refuses** to permit entry, inspection, or audit of its facility or its records, **FDA may suspend the SIP**, in whole or in part, immediately.
251.8(d)	If FDA authorizes **changes** to a SIP, the **Importer must submit a new Pre-Import Request** in accordance with § 251.5.
251.12(a)(1)	In accordance with the procedures set forth in § 207.33 of this chapter, **proposing an NDC for assignment** for each eligible prescription drug imported pursuant to this part
251.12(a)(2)	**Examining the Canadian labeling of a sample of each shipment** of eligible prescription drugs to **verify that the labeling is that of the HPFB-approved drug**, and **attesting** that such examination has been conducted through reports to FDA required under this part;
251.12(a)(3)	**Screening** eligible prescription drugs for **evidence that they are adulterated, counterfeit, damaged, tampered with, expired, suspect foreign product, or illegitimate foreign product**;
251.12(a)(4)	**Ensuring** the eligible prescription drug is **relabeled** with the required U.S. labeling, including the **container and carton labeling**; **Prescribing Information**; and **patient labeling**, such as Medication Guides, Instruction for Use documents, and patient package inserts, in accordance with §§ 251.13 and 251.14(d);
251.12(a)(5)	**Arranging for an entry** to be submitted in accordance with § 251.17;
251.12(a)(6)	**Collecting and submitting the information and documentation to FDA** about the imported drug(s) pursuant to section 804(d) of the Federal Food, Drug, and Cosmetic Act, in addition to **information about the Foreign Seller**, as set forth in § 251.19; and
251.12(a)(7)	**Submitting the adverse event, field alert, and other reports**, and **complying with drug recalls**, in accordance with § 251.18.

251.12(b)(1)	**Register with FDA as a repackager or relabeler** under section 510(b) of the Federal Food, Drug, and Cosmetic Act, in accordance with § 207.25 of this chapter;
251.12(b)(2)	Obtain a **labeler code from FDA** and **propose an NDC** for each eligible prescription drug pursuant to § 207.33 of this chapter; and
251.12(b)(3)	**List** each eligible prescription drug pursuant to § 207.53 of this chapter.
251.13(a)	**Upon the request** of a **SIP Sponsor** or **Importer**, the **manufacturer** of an eligible prescription drug **must provide** an **Importer written authorization for the Importer to use**, at no cost, the **FDA-approved labeling for the drug**. If the manufacturer fails to do so within **30 calendar days** of receiving the Importer's request, FDA **may** deem this **authorization to have been given**.
251.13(b)	In addition to the **exemption** provided in subpart D of part 201 of this chapter, an eligible prescription drug imported for purposes of this part **is exempt** from section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act if **all** the following conditions are met:
251.13(b)(1)	The **Importer** or the **manufacturer certifies** that the **drug meets all labeling requirements** under the Federal Food, Drug, and Cosmetic Act, including the requirements of this part. The **Importer** of an eligible prescription drug **must** either:
251.13(b)(1)(i)	**Propose an NDC** for the drug following the procedures in § 207.33 of this chapter and **list** the drug following the procedures in § 207.53 of this chapter; or
251.13(b)(2)	The drug **must** be
251.13(b)(2)(i)	In the **possession** of a person (or his or her agents or employees), including **Foreign Sellers** and **Importers, regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of prescription drugs**;
251.13(b)(3)	The **drug is to be dispensed** in accordance with section 503(b) of the Federal Food, Drug, and Cosmetic Act.
251.13(b)(4)	At the time the drug is **sold** or **dispensed**, the **labeling of the drug must** be the same as the **FDA-approved labeling** under the applicable **NDA or ANDA**, except that the labeling **must bear conspicuously**:
251.13(b)(4)(i)	The **Importer's NDC** for the eligible prescription drug, and such **NDC must replace any other NDC** otherwise appearing on the label of the FDA-approved drug;
251.13(b)(4)(ii)	The **lot number** assigned by the **manufacturer** of the eligible prescription drug, on the **carton labeling** and on the **container label**;
251.13(b)(4)(iii)	The **name and place of business of the Importer**;

251.13(b)(4)(iv)	The **statement**: "[This drug was/These drugs were] imported from Canada without the authorization of [Name of Applicant] under the [Name of SIP Sponsor] Section 804 Importation Program." If the SIP maintains a website, the statement could also include the **website address**. This statement **must** appear in the **HOW SUPPLIED/STORAGE AND HANDLING** section for products subject to §§ 201.56(d) and 201.57 of this chapter, or in the **HOW SUPPLIED** section for products subject to §§ 201.56(e) and 201.80 of this chapter. The **statement** also **must** be included on the **immediate container label and outside package**;
251.13(b)(4)(v)	For products subject to §§ 201.56(d) and 201.57(c)(17)(iii) of this chapter, the NDC(s) assigned to the eligible prescription drug in accordance with the procedures in § 207.33 of this chapter must be included in the **HOW SUPPLIED/STORAGE AND HANDLING** section **in place** of the **NDC(s) assigned to the FDA-approved versions of the drug**. The NDC(s) also **must** be included on the **immediate container label** and **outside package**;
251.13(b)(4)(vi)	For products subject to §§ 201.56(d) and 201.57(a)(11)(ii) of this chapter, the **Adverse Reaction Contact Reporting Statement** under the **Adverse Reactions** heading in the **Highlights** of **Prescribing Information**. This statement **must** include the **Importer's name** and the **telephone number** of the **firm** to **provide a structured process for reporting suspected adverse events**; and
251.13(b)(4)(vii)	For products subject to §§ 201.56(e) and 201.80(k)(3) of this chapter, the **NDC(s) assigned to the eligible prescription drug** in accordance with the procedures in § 207.33 of this chapter. The NDC(s) **must** be included in the **HOW SUPPLIED** section **in place of the NDC(s) assigned to the FDA-approved versions of the drug**. The NDC(s) also **must** be included on the **immediate container label** and **outside package**.
251.13(c)	The **Importer** is **responsible** for **relabeling the drug**, or **arranging** for it to be relabeled, to meet the requirements of this part. The relabeling and associated limited repackaging activities must meet applicable requirements, including applicable **current good manufacturing practice requirements** under parts 210 and 211 of this chapter. Except for repackaging that is necessary to perform the relabeling described in this part, **further repackaging of drugs imported pursuant to a SIP is prohibited. Repackaging the container closure of a drug is not permitted under this part**.
251.13(d)	The **Importer may** submit to FDA, in **electronic format** via the ESG or to an alternative transmission point identified by FDA, under § 251.8, a **supplemental proposal to modify the labeling** of an eligible prescription drug, for **example** if the eligible prescription drug's **container is too small** to fit the additional information required by this section.
251.14(a)(4)	For **each drug** imported under the SIP, the **Foreign Seller ships the drug directly to the Importer** in the United States;

251.14(a)(6)	The **Importer** identified in the SIP **meets the applicable requirements of this part** and in sections 582(c) and (d) of the Federal Food, Drug, and Cosmetic Act; and
251.14(a)(7)	**Returned** eligible prescription drugs **are properly dispositioned in**, and **not exported** from, the United States.
251.14(b)	**Manufacturer**. For **each transaction** of the eligible prescription drug, the **manufacturer must provide** to the **Importer**, within **30 calendar days** of receiving the **Importer's request**, a **copy** of **all transaction documents** that were provided from the **manufacturer** to the **Foreign Seller**.
251.14(d)(1)	An **Importer** of an eligible prescription drug **must purchase the drug directly** from a **Foreign Seller** in Canada.
251.14(d)(2)	Upon **receipt of an eligible prescription drug in a transaction** from the **Foreign Seller**, an **Importer must facilitate** the **affixation** or **imprinting** of a **product identifier**, as defined in section 581(14) of the Federal Food, Drug, and Cosmetic Act, for **all eligible prescription drugs**. The **Importer must ensure** that such **affixation** or **imprinting** occurs at the same time the **product is relabeled** with the **required U.S.-approved labeling** for the drug product and, **except for repackaging necessary to perform the relabeling described in this part, cannot otherwise relabel or repackage the product**. The **Importer may affix** or **imprint** the product identifier, or the Importer **may contract** with an **entity registered with FDA** under part 207 of this chapter to accomplish such relabeling, provided that the entity does not otherwise relabel or repackage the product, except for repackaging that is necessary to perform the relabeling described in this part. **Any entity** with which the Importer contracts to accomplish such labeling **must**, even if not engaged in a repackaging operation with respect to the eligible prescription drug, **have systems and processes in place to meet applicable requirements of a "repackager" under section 582(e)** of the Federal Food, Drug, and Cosmetic Act for **any transaction involving the eligible prescription drug**.
251.14(d)(3)	The **repackager** that **affixes** or **imprints** the **product identifier** on **each package** and **homogenous case** of an eligible prescription drug in accordance with section 582 of the Federal Food, Drug, and Cosmetic Act, which may be the **Importer** or the **Importer's authorized repackager** -
251.14(d)(3)(i)	**May affix** or **imprint** a **product identifier only on a package of an eligible prescription drug** that has a **serial number** that was **assigned** and **affixed** by the **Foreign Seller**;
251.14(d)(3)(ii)	**Must maintain the product identifier information** for such drug for not less than **6 years**; and

251.14(d)(3)(iii)	**Must maintain records** for not less than **6 years** that **associate the product identifier** the repackager affixes or imprints with the **serial number** assigned by the Foreign Seller and the **Canadian DIN**.
251.14(d)(4)	An **Importer must retain records**, for not less than **6 years**, that allow the **Importer** to **associate** the **product identifier** affixed or imprinted on each package or homogenous case of product it received from the **Foreign Seller**, with the **SSI** that had been assigned by the **Foreign Seller**, and the **Canadian DIN** that was on the package when the Foreign Seller received the product from the manufacturer.
251.14(d)(5)	An **Importer must**, upon **receipt of an eligible prescription drug** and **records** from a **Foreign Seller**, **compare** such information with **information** the **Importer received** from the **manufacturer**, including **relevant documentation about the transaction** that the **manufacturer** provided to the **Foreign Seller** upon its transfer of ownership of the product for the Canadian market.
251.14(d)(6)	An **Importer must comply with all applicable requirements of section 582** of the Federal Food, Drug, and Cosmetic Act, including requirements that apply to **subsequent transactions with trading partners**, unless a **waiver**, **exception**, or **exemption applies**.
251.14(d)(7)	For **transactions of eligible prescription drugs** between **Importers** and **Foreign Sellers** under a SIP, an **Importer** is **exempt** from the following specific supply chain security requirements that are otherwise applicable:
251.14(d)(7)(i)	An **Importer is exempt** from the **prohibition on receiving a product** for which the **previous owner did not provide the transaction history, transaction information, and transaction statement**, under sections 582(c)(1)(A) or (d)(1)(A) of the Federal Food, Drug, and Cosmetic Act, as applicable, **provided that the Importer receives from the Foreign Seller the information required under paragraph (c) of this section**
251.14(d)(7)(ii)	An **Importer is exempt** from the **prohibition on receiving a product** that **is not encoded with a product identifier**, under sections 582(c)(2) or (d)(2) of the Federal Food, Drug, and Cosmetic Act, as applicable, **provided that the product the Importer received from the Foreign Seller has an SSI**.
251.14(d)(7)(iii)	An **Importer is exempt from the prohibition on conducting a transaction** with an **entity** that is not an **"authorized trading partner,"** under sections 582(c)(3) or (d)(3) of the Federal Food, Drug, and Cosmetic Act, as applicable.
251.14(d)(7)(iv)	An **Importer is exempt from the requirement to verify that a product in the Importer's possession or control contains a "standardized numerical identifier" at the package level**, under sections 582(c)(4)(A)(i)(II) or (d)(4)(A)(ii)(II) of the Federal Food, Drug, and Cosmetic Act as applicable, **provided that the Importer verifies that each package and**

	homogenous case of the product includes the SSI affixed or imprinted by the Foreign Seller.
251.16(a)	The **manufacturer** or the **Importer must arrange** for drugs imported under an authorized SIP to be **tested by a qualifying laboratory**.
251.16(b)	Unless the **manufacturer** conducts the **Statutory Testing**, in accordance with this part, the **manufacturer** of the drugs imported under an authorized SIP **must supply to the Importer**, within **30 calendar days of receiving the Importer's request, all information needed to conduct the Statutory Testing**, including any **testing protocols, Certificate of Analysis**, and **samples of analytical reference standards** that the manufacturer has developed. The **manufacturer must also provide the Importer**, within **30 calendar days** of receiving the **Importer's request**, with **formulation information** about the **HPFB-approved drug**, a **stability-indicating assay**, and the **FDA-approved drug** to facilitate authentication.
251.16(c)	Testing done on a **statistically valid sample** of the **batch** or **shipment**, as applicable, must be **sufficiently thorough to establish**, in conjunction with data and information from the manufacturer, that the batch or shipment is eligible for importation under a SIP. The **size of the sample must be large enough to enable a statistically valid statement to be made regarding the authenticity and stability of the quantity of the batch in the shipment or the entire shipment**, as applicable.
251.16(f)	Regardless of whether testing under this section is performed by the manufacturer or Importer, the **sample of a batch** or **shipment** of drugs must be **randomly selected for testing** or, in the alternative, the **sample must be selected to be representative of the quantity of the batch** in a shipment or of a shipment, as applicable.
251.16(g)	Information supplied by the **manufacturer** to **authenticate** the prescription drug being tested and confirm that the labeling of the prescription drug complies with labeling requirements under the Federal Food, Drug, and Cosmetic Act, and any trade secrets or commercial or financial information that is privileged or confidential that the manufacturer supplies for the purposes of testing or otherwise complying with the Federal Food, Drug, and Cosmetic Act and this part, **must be kept in strict confidence and used only for the purposes of testing** or otherwise complying with the Federal Food, Drug, and Cosmetic Act and this part.
251.16(h)(1)	The **information** that the **manufacturer** supplies about a prescription drug **must not be disseminated except for the purpose of testing or otherwise complying** with the Federal Food, Drug, and Cosmetic Act and this part; and

251.17(a)	**Importers must ensure** that **each shipment** of eligible prescription drugs imported or offered for import pursuant to this part **is accompanied by an import entry for consumption filed electronically** as a formal entry in ACE, or another CBP-authorized electronic data interchange system, and designated in such a system as a **drug imported** pursuant to this part.
251.17(b)	The **Importer may make entry for consumption and arrival of shipments containing eligible prescription drugs only at the CBP port of entry authorized by FDA to import eligible prescription drugs** under section 804 of the Federal Food, Drug, and Cosmetic Act. The **Importer must keep the product at a secured warehouse**, location within a **specific foreign trade zone**, or **other secure distribution facility** controlled by or under contract with the Importer, and under **appropriate environmental conditions to maintain the integrity of the products**, until FDA issues an **admissibility decision**. The **secured warehouse** or **other secure distribution facility** must be within **30 miles** of the **authorized Port of Entry for examination**.
251.17(c)	If the **entry for consumption** is filed in ACE **before** the **testing** and **relabeling** of the eligible prescription drug, the **Importer must submit an application to bring the drug into compliance and must relabel and test the drug in accordance with the plan approved by FDA** pursuant to §§ 1.95 and 1.96 of this chapter.
251.17(d)	Upon **arrival** in the United States of an **initial shipment** that contains a batch of an eligible prescription drug **identified in a Pre-Import Request** that has been **granted by FDA**, the **Importer must select a statistically valid sample of that batch to send to a qualifying laboratory for Statutory Testing**, unless the **manufacturer** conducts the Statutory Testing at a qualifying laboratory.
251.17(d)(1)	In the case of any subsequent shipment composed entirely of a batch of an eligible prescription drug that has already been tested in accordance with this part, the **Importer must select a statistically valid sample of the shipment** to send to a **qualifying laboratory** for **Statutory Testing**.
251.17(d)(2)	The **Importer must send three sets of the samples** sent to the qualifying laboratory in accordance with § 251.16 to the **FDA field lab identified by FDA** when the Agency granted the **Pre-Import Request**.
251.17(d)(3)	The **Importer must submit to FDA a complete set of laboratory records**, a detailed description of the sampling method used to select the sample of the eligible prescription drug sent to the qualifying laboratory, the testing protocols used, complete data derived from all tests necessary to ensure that the eligible prescription drug meets the specifications of the FDA-approved drug that are established in the NDA or ANDA, a Certificate of Analysis, and all relevant documentation demonstrating that the testing meets the requirements under section 804(e)(1) of the Federal Food, Drug, and Cosmetic

	Act, as well as any additional information FDA deems necessary to evaluate whether the drug meets **manufacturing**, **quality**, and **safety standards**.
251.17(e)	If the **manufacturer** conducts the **Statutory Testing**, **upon arrival in the United States of an initial shipment** that contains a batch of an eligible prescription drug **identified in a Pre-Import Request** that has been **granted by FDA**, a **statistically valid sample of that batch must be selected** to send to a qualifying laboratory for the Statutory Testing.
251.17(e)(1)	In the case of any subsequent shipment composed entirely of a batch or batches of an eligible prescription drug that has already been tested in accordance with this part, the **manufacturer must select a statistically valid sample of that shipment** to send to a **qualifying laboratory** for that **Statutory Testing**.
251.17(e)(2)	The **manufacturer must send three sets of the samples** the manufacturer sent to the qualifying laboratory in accordance with § 251.16 to the **FDA field lab identified by FDA** when the Agency granted the **Pre-Import Request**.
251.17(e)(3)	The **manufacturer must submit to FDA, directly in electronic form to the ESG** or to an alternative transmission point identified by FDA, **a complete set of laboratory records**, a detailed description of the selection method for the sample of the eligible prescription drug sent to the qualifying laboratory, the testing methods used, complete data derived from all tests necessary to ensure that the eligible prescription drug meets the conditions in the FDA-approved drug's NDA or ANDA, a Certificate of Analysis, and all relevant documentation demonstrating that the testing meets the requirements under section 804(e)(1) of the Federal Food, Drug, and Cosmetic Act, as well as any additional information FDA deems necessary to evaluate whether the drug meets **manufacturing**, **quality**, and **safety standards**.
251.17(f)	After **FDA** has **reviewed** the **testing results** provided by the **Importer** or **manufacturer** and determined that they are **acceptable**, **FDA will notify the Importer** and then the **Importer must cause the eligible prescription drug to be relabeled with the required U.S. labeling**.
251.17(g)	After the eligible prescription drug has been shown by **testing** and **relabeling** to meet the requirements of section 804 of the Federal Food, Drug, and Cosmetic Act and this part, the **Importer** or the **manufacturer must provide to FDA the written certification** described in section 804(d)(1)(K) of the Federal Food, Drug, and Cosmetic Act in electronic format via the ESG or to an alternative transmission point identified by FDA.

251.18(b)	**Field alert reports. Importers must submit NDA and ANDA field alert reports**, as described in §§ 314.81(b)(1) and 314.98 of this chapter, to the **manufacturer** and to **FDA**.
251.18(c)	**Additional reporting requirements for combination products**. For combination products containing a device constituent part, **Importers must submit the reports to the manufacturer and to FDA** described in § 4.102(c)(1) of this chapter and maintain the records described in §§ 4.102(c)(1) and 4.105(b) of this chapter.
251.18(d)	**Adverse event reports -**
251.18(d)(1)	Scope. An Importer must establish and maintain records and submit to FDA and the manufacturer reports of all adverse events associated with the use of its drug products imported under this part.
251.18(d)(2)	Review of safety information. The Importer must promptly review all domestic safety information for the eligible prescription drugs obtained or otherwise received by the Importer.
251.18(d)(3)	Expedited ICSRs. The Importer must submit expedited ICSRs for each domestic adverse event to FDA and the manufacturer as soon as possible but no later than 15 calendar days from the date when the Importer has both met the reporting criteria described in this paragraph (d) and acquired a minimum data set for that adverse event.
251.18(d)(3)(i)	Serious, unexpected adverse events. The Importer must submit expedited ICSRs for domestic adverse events reported to the Importer spontaneously (such as reports initiated by a patient, consumer, or healthcare professional) that are both serious and unexpected, whether or not the Importer believes the events are related to the product.
251.18(d)(3)(ii)	Other adverse event reports to be expedited upon notification by FDA. Upon notification by FDA, the Importer must submit as expedited ICSRs any adverse event reports that do not qualify for expedited reporting under paragraph (d)(3)(i) of this section. The notice will specify the adverse events to be reported and the reason for requiring the expedited reports.
251.18(d)(4)	Followup reports for expedited ICSRs. The Importer must actively seek any missing data elements under paragraph (d)(7) of this section or updated information for any previously submitted expedited ICSR under paragraph (d)(3) of this section. The Importer must also investigate any new information it obtains or otherwise receives about previously submitted expedited ICSRs. The Importer must submit followup reports for expedited ICSRs to FDA and the manufacturer as soon as possible but no later than 15 calendar days after obtaining the new information. The Importer must document and maintain records of its efforts to obtain missing or incomplete information.

251.18(d)(5)	Nonexpedited ICSRs. The Importer must submit to FDA and the manufacturer an ICSR for each domestic adverse event not reported under paragraph (d)(3)(i) of this section (all serious, expected adverse events and nonserious adverse events) within 90 calendar days from the date when the Importer has both met the reporting criteria described in this paragraph (d) and acquired a minimum data set for that adverse event.
251.18(d)(6)	Completing and submitting safety reports. This paragraph (d)(6) describes how to complete and submit ICSRs required under this section. Additionally, upon written notice, FDA may require the Importer to submit any of this section's adverse event reports at a different time period than identified in paragraphs (d)(1) through (5) and (7) through (11) of this section.
251.18(d)(6)(i)	Electronic format for submissions.
251.18(d)(6)(i)(A)	ICSR and ICSR attachments must be submitted in an electronic format that FDA can process, review, and archive, as described in § 314.80(g)(1) of this chapter.
251.18(d)(6)(i)(B)	The Importer may request, in writing, a temporary waiver of the requirements in paragraph (d)(6)(i)(A) of this section, as described in § 314.80(g)(2) of this chapter. These waivers will be granted on a limited basis for good cause shown.
251.18(d)(6)(ii)	Completing and submitting ICSRs -
251.18(d)(6)(ii)(A)	Single submission. Submit each ICSR only once.
251.18(d)(6)(ii)(B)	Separate ICSR. The Importer must submit a separate ICSR for each patient who experiences an adverse event reportable under paragraph (d)(3)(i) or (ii) or (d)(4) or (5) of this section.
251.18(d)(6)(ii)(C)	Coding terms. The adverse event terms described in the ICSR must be coded using standardized medical terminology.
251.18(d)(6)(ii)(D)	Minimum data set. All ICSRs submitted under this section must contain at least the minimum data set for an adverse event. The Importer must actively seek the minimum data set in a manner consistent with its written procedures under paragraph (d)(9) of this section. The Importer must document and maintain records of its efforts to obtain the minimum data set.
251.18(d)(6)(ii)(E)	ICSR elements. The Importer must complete all available elements of an ICSR as specified in paragraph (d)(7) of this section.
251.18(d)(6)(ii)(E)(1)	The Importer must actively seek any information needed to complete all applicable elements, consistent with its written procedures under paragraph (d)(9) of this section.

251.18(d)(6)(ii)(E)(2)	The Importer must document and maintain records of its efforts to obtain the missing information.
251.18(d)(6)(ii)(F)	Supporting documentation. When submitting supporting documentation for expedited ICSRs of adverse events, the Importer must:
251.18(d)(6)(ii)(F)(1)	Submit for each ICSR for a domestic adverse event, if available, a copy of the autopsy report if the patient died, or a copy of the hospital discharge summary if the patient was hospitalized. The Importer must submit each document as an ICSR attachment. The ICSR attachment must be submitted either with the initial ICSR or no later than 15 calendar days after obtaining the document.
251.18(d)(6)(ii)(F)(2)	Include in the ICSR a list of available, relevant documents (such as medical records, laboratory results, death certificates) that are held in its drug product safety files. Upon written notice from FDA, the Importer must submit a copy of these documents within 5 calendar days of the FDA notice.
251.18(d)(7)ff	Information reported on ICSRs. ICSRs must include the following information:
251.18(d)(8)	Recordkeeping.
251.18(d)(8)(i)	For a period of 10 years from the initial receipt of information, the Importer must maintain records of information relating to adverse event reports under this section, whether or not submitted to FDA.
251.18(d)(8)(ii)	These records must include raw data, correspondence, and any other information relating to the evaluation and reporting of adverse event information that is obtained by the Importer.
251.18(d)(8)(iii)	Upon written notice by FDA, the Importer must submit any or all of these records to FDA within 5 calendar days after receipt of the notice. The Importer must permit any authorized FDA employee, at reasonable times, to access, copy, and verify its established and maintained records described in this section.
251.18(d)(9)	Written procedures. The Importer must develop written procedures needed to fulfill the requirements in this section for the surveillance, receipt, evaluation, and reporting to FDA and the manufacturer of adverse event information, including procedures for employee training, and for obtaining and processing safety information from the Foreign Seller.

251.18(d)(10)	Patient privacy. The Importer must not include in reports under this section the names and addresses of individual patients; instead, the Importer must assign a unique code for identification of the patient. The Importer must include the name of the reporter from whom the information was received as part of the initial reporter information, even when the reporter is the patient. As set forth in FDA's public information regulations in part 20 of this chapter, FDA generally may not disclose the names of patients, individual reporters, healthcare professionals, hospitals, and geographical identifiers submitted to FDA in adverse event reports.
251.18(d)(11)	Safety reporting disclaimer.
251.18(d)(11)(i)	A report or information submitted by the Importer under this section (and any release by FDA of that report or information) does not necessarily reflect a conclusion by the Importer or by FDA that the report or information constitutes an admission that the eligible prescription drug imported under section 804 of the Federal Food, Drug, and Cosmetic Act caused or contributed to an adverse event.
251.18(d)(11)(ii)	The Importer need not admit, and may deny, that the report or information submitted as described in this section constitutes an admission that the drug product caused or contributed to an adverse event.
251.18(e)(2)	If **FDA**, the **SIP Sponsor**, the **Foreign Seller**, the **Importer**, or the **manufacturer** determines that a recall is warranted, the **SIP Sponsor must effectuate the recall in accordance with its written recall plan** under paragraph (e)(3) of this section.
251.18(e)(3)ff	A **SIP must have a written recall plan** that **describes the procedures to perform a recall** of the product and **specifies** who will be responsible for performing the procedures. The recall plan must cover **recalls mandated or requested by FDA** and **recalls initiated by the SIP Sponsor, the Foreign Seller, the Importer, or the manufacturer**. The **recall plan must include sufficient procedures** for the SIP Sponsor to:
251.18(e)(4)	In the event of a recall, the **Importer must, upon request by FDA, provide transaction history, information, and statement** (as these terms are defined in sections 581(25), 581(26), and 581(27) of the Federal Food, Drug, and Cosmetic Act), in accordance with applicable requirements under sections 582(c)(1)(C) and 582(d)(1)(D).
251.18(e)(4)(i)	The **Importer must also provide to FDA**, upon request, information given by the **manufacturer** under § 251.14(a)(6), including **transaction documents** that were provided from the **manufacturer** to the **Foreign Seller**.
251.18(e)(5)	The **Foreign Seller** and **Importer must cooperate with any recalls, including recalls initiated by the SIP Sponsor, FDA, the Foreign Seller, the Importer, or the drug's manufacturer**.

251.19(c)	The **Importer must** also **confirm** as part of the report in paragraph (a) of this section that the **eligible prescription drug(s) were bought directly from the manufacturer by the Foreign Seller** and that the **Foreign Seller sold the eligible prescription drug(s) directly to the Importer**.
251.19(d)(2)	Documentation **demonstrating** that the eligible prescription drug **was received by the Foreign Seller** from the **manufacturer** and subsequently **shipped** by the **Foreign Seller** to the **Importer**;
251.19(d)(4)	Documentation demonstrating that the **sampling** and **testing requirements** described in section 804(d)(1)(J)(i)(III) of the Federal Food, Drug, and Cosmetic Act **were met for each shipment** of each eligible prescription drug.
251.19(e)ff	The report in paragraph (a) of this section **must include certifications** from the **Importer for each shipment** of each eligible prescription drug that the **drug is approved for marketing in the United States** and is not **adulterated** or **misbranded** and **meets all labeling requirements** under the Federal Food, Drug, and Cosmetic Act. This certification must include:
251.19(f)	The report in paragraph (a) of this section **must include laboratory records**, including complete data derived from all tests necessary to ensure that each eligible prescription drug is in compliance with established specifications and standards, and documentation demonstrating that the **Statutory Testing was conducted at a qualifying laboratory**, unless the **manufacturer** conducted the testing and submitted this information directly to FDA.
251.19(h)	A **SIP Sponsor must submit a report to FDA** within **10 calendar days**, in electronic format via the ESG or to an alternative transmission point identified by FDA, **regarding any applicable criminal conviction, violation of law, or disciplinary action** as described in § 251.3(e)(2) and (3).

COLORADO
Department of Health Care Policy & Financing

DCN: HCPF FORM 5196.1
Effective Date: 23Feb2024

Qualified Lab Compliance Checklist

General Information					
Qualified Laboratory Name:					
Business Type:					
Phone:		Website:			
Qualified Laboratory Address:					
Primary Contact Name and Title:		Email:		Phone:	
Completed By:		Date:			
Title:					

INSTRUCTIONS:

Please attach a copy of any relevant documents to support the questions in this assessment such as SOPs, Quality Manual etc. to the *last page* of this document.

Qualified Laboratory Quality Self-Assessment

Question	Yes	No	N/A	Comments / Explanation
1. Does your company maintain a documented quality management system? *251.3(e)(15)(iii)*	☐	☐	☐	
2. Do you have a Quality Manual? *251.3(e)(15)(iii)*	☐	☐	☐	
3. Do you have formal, documented policies, procedures and work instructions or other documentation for managing quality related issues? *251.3(e)(15)(iii)*	☐	☐	☐	
4. Do you have a system to control quality related documents in regard to their creation, revision, approval and implementation? Is a documented procedure available? Briefly describe relevant processes. *251.3(e)(15)(iii)*	☐	☐	☐	
5. Is there a policy or procedure to identify training needs of employees? *251.3(e)(15)(iv)*	☐	☐	☐	

Qualified Lab Compliance Checklist

6. Are employee training records maintained? *251.3(e)(15)(iv)*	☐	☐	☐	
7. Do you have a system to evaluate your suppliers? *251.3(e)(15)(iii)*	☐	☐	☐	
8. How do you measure the quality performance of your suppliers? *251.3(e)(15)(iii)*	☐	☐	☐	
9. Do you have processes/procedures in place for raising deviations and management of corrective and preventive actions? *251.3(e)(15)(iii)*	☐	☐	☐	
10. Do you have a process to identify/control nonconformances? *251.3(e)(15)(iii)*	☐	☐	☐	
11. Do you have adequate and documented procedures to address nonconformance? *251.3(e)(15)(iii)*	☐	☐	☐	
12. Do you have processes/procedures in place for raising deviations and management of corrective and preventive actions? *251.3(e)(15)(iii)*	☐	☐	☐	
13. Do you have an internal audit program? *251.3(e)(15)(iii), 251.7(b)*	☐	☐	☐	
14. Do you have an audit schedule? *251.3(e)(15)(iii), 251.7(b)*	☐	☐	☐	
15. Do you report on audit outcomes? *251.3(e)(15)(iii), 251.7(b)*	☐	☐	☐	
16. Is there follow-up to ensure acceptable corrective action for audit findings? *251.3(e)(15)(iii), 251.7(b)*	☐	☐	☐	
17. Do you have a Business Continuity/Disaster Recovery Plan to ensure your company is able to operate and fulfill contractual obligations? Briefly describe your key actions for business continuity and disaster planning. *251.3(e)(15)(iii)*	☐	☐	☐	
Confirm that the following requirements are available for review	Yes	No	N/A	Comments / Explanation
1. ISO 17025 accreditation *251.15(a)*	☐	☐	☐	
2. FDA Inspection History and records that any findings or comments have been addressed *251.15(b)*	☐	☐	☐	
3. Laboratory records as indicated by § 211.194	☐	☐	☐	

Reference	Section 804 Requirement	List SOP(s) that meet Requirement or provide comments / explanation

Qualified Lab Compliance Checklist

251.15(c)	Provide documentation of laboratory controls in place to demonstrate that all procedures comply with applicable current good manufacturing practice requirements.	
251.15(c)	Discuss how laboratory records are documented and maintained in accordance to § 211.194 and applicable current good manufacturing practices requirements	
251.15(c)	Are there any additional items outside of laboratory controls and records that demonstrate compliance to current good manufacturing practice requirements? How are requirement updates monitored for and updated internally?	
251.16(c), 251.16(d), 251.16(f), 251.16(g)	Explain how samples are received from the Importer. How are the sample sizes confirmed and what information is received with the samples.	
251.16(c), 251.16(d), 251.16(f), 251.16(g)	How are the testing procedures determined and what processes are followed to ensure testing is done accurately?	
251.16(g), 251.16(h)(1-2)	How is proprietary information including testing procedures ensured to be kept confidential?	
251.16(e), 251.16(f)	Discuss how all communication to and from the FDA about the Section 804	

Qualified Lab Compliance Checklist

	Importation Plan will be performed. How will test results be communicated to the FDA? How will samples be sent to the FDA?	

Please list the attachments being provided here, as applicable:	
Certifications:	
Quality Manual:	
List any documents/certifications relevant to Section 804 not otherwise listed:	

References from Section 804 of the FD&C Act Final Rule:

251.15(a)	To be considered a qualifying laboratory for purposes of section 804 of the Federal Food, Drug, and Cosmetic Act and this part, a laboratory must have ISO 17025 accreditation.
251.15(b)	To be considered a qualifying laboratory for purposes of section 804 of the Federal Food, Drug, and Cosmetic Act and this part, a laboratory must have an FDA inspection history and it must have satisfactorily addressed any objectionable conditions or practices identified during its most recent FDA inspection, if applicable.
251.15(c)	To be considered a qualifying laboratory for purposes of section 804 of the Federal Food, Drug, and Cosmetic Act and this part, a laboratory must comply with the applicable current good manufacturing practice requirements, including provisions regarding laboratory controls in § 211.160 of this chapter and laboratory records in § 211.194 of this chapter.
251.16(a)	The manufacturer or the Importer must arrange for drugs imported under an authorized SIP to be tested by a qualifying laboratory.

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251.16(b)	Unless the manufacturer conducts the Statutory Testing, in accordance with this part, the manufacturer of the drugs imported under an authorized SIP must supply to the Importer, within 30 calendar days of receiving the Importer's request, all information needed to conduct the Statutory Testing, including any testing protocols, Certificate of Analysis, and samples of analytical reference standards that the manufacturer has developed. The manufacturer must also provide the Importer, within 30 calendar days of receiving the Importer's request, with formulation information about the HPFB-approved drug, a stability-indicating assay, and the FDA-approved drug to facilitate authentication.
251.16(c)	Testing done on a statistically valid sample of the batch or shipment, as applicable, must be sufficiently thorough to establish, in conjunction with data and information from the manufacturer, that the batch or shipment is eligible for importation under a SIP. The size of the sample must be large enough to enable a statistically valid statement to be made regarding the authenticity and stability of the quantity of the batch in the shipment or the entire shipment, as applicable.
251.16(d)	The statistically valid sample of the HPFB-approved drug must be subjected to testing to confirm that the HPFB-approved drug meets the FDA-approved drug's specifications and standards, which include the analytical procedures and methods and the acceptance criteria. In addition, to test for degradation, a stability-indicating assay provided by the manufacturer must be conducted on the sample of the drug that is proposed for import.
251.16(e)	If the manufacturer performs the Statutory Testing at a qualifying laboratory, the testing results, a complete set of laboratory records, a detailed description of the selection method for the samples, the testing methods used, complete data derived from all tests necessary to ensure that the eligible prescription drug meets the specifications and standards of the FDA-approved drug that are established in the NDA or ANDA, a Certificate of Analysis, and any other documentation demonstrating that the testing meets the requirements under section 804 must be submitted in electronic format directly to FDA via the ESG or to an alternative transmission point identified by FDA. The manufacturer must notify the Importer and FDA of the manufacturer's intent to perform the Statutory Testing, and identify the qualifying laboratory for FDA review and approval pursuant to section 804 of the Federal Food, Drug, and Cosmetic Act, within 30 calendar days of receipt of the request from the Importer described in paragraph (b).
251.16(f)	Regardless of whether testing under this section is performed by the manufacturer or Importer, the sample of a batch or shipment of drugs must be randomly selected for testing or, in the alternative, the sample must be selected to be representative of the quantity of the batch in a shipment or of a shipment, as applicable.

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251.16(g)	Information supplied by the manufacturer to authenticate the prescription drug being tested and confirm that the labeling of the prescription drug complies with labeling requirements under the Federal Food, Drug, and Cosmetic Act, and any trade secrets or commercial or financial information that is privileged or confidential that the manufacturer supplies for the purposes of testing or otherwise complying with the Federal Food, Drug, and Cosmetic Act and this part, must be kept in strict confidence and used only for the purposes of testing or otherwise complying with the Federal Food, Drug, and Cosmetic Act and this part.
251.16(h)	To ensure that the information described in paragraph (g) is protected:
251.16(h)(1)	The information that the manufacturer supplies about a prescription drug must not be disseminated except for the purpose of testing or otherwise complying with the Federal Food, Drug, and Cosmetic Act and this part; and
251.16(h)(2)	The SIP Sponsor must take all of the steps set out in the authorized SIP Proposal to ensure that the information is kept in strict confidence and used only for the purpose of testing or otherwise complying with the Federal Food, Drug, and Cosmetic Act and this part.