Appendix A: SIP Sponsor Supporting Documentation

COLORADO
Department of Health Care Policy & Financing

1570 Grant Street
Denver, CO 80203

October 12, 2022

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: 1570 Grant Street, Denver, Colorado 80203

Responsible Individuals:

Name	Contact Information
Lauren Reveley, Drug Importation Program Manager	Lauren.Reveley@state.co.us, 303-866-2718
Kelly Swartzendruber, Drug Importation Pharmacist	Kelly.Swartzendruber@state.co.us, 303-866-3632

Sincerely,

Lauren Reveley
Drug Importation Program Manager
Pharmacy Office

COLORADO
Department of Health Care Policy & Financing

1570 Grant Street
Denver, CO 80203

October 12, 2022

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

RE: Attestation

I, Lauren Reveley, attest that I have no past criminal convictions or violations of State, Federal, or Canadian laws regarding drugs or devices against me. Further, I attest that I have not been involved in, or convicted of, any such violations and there have been no disciplinary actions against me.

Sincerely,

Lauren Reveley
Drug Importation Program Manager
Pharmacy Office

COLORADO
Department of Health Care Policy & Financing

1570 Grant Street
Denver, CO 80203

October 12, 2022

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

RE: Attestation

I, Kelly Swartzendruber, attest that I have no past criminal convictions or violations of State, Federal, or Canadian laws regarding drugs or devices against me. Further, I attest that I have not been involved in, or convicted of, any such violations and there have been no disciplinary actions against me.

Sincerely,

Kelly Swartzendruber

Kelly Swartzendruber
Drug Importation Pharmacist
Pharmacy Office

Appendix B: Foreign Seller Supporting Documentation

AdiraMedica Inc.

Suite #302, Unit #306
2233 Argentia Rd,
Mississauga, Ontario, L5N 2X7
Canada
Tel: +1 289 499 4569 Ext. 4569
www.adiramedica.com

October 25, 2022

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 Foreign Seller, Contact Information for Responsible Individuals

Name of Foreign Seller: AdiraMedica Inc
Address of Foreign Seller: 2233 Argentia Rd, Suite # 302, Unit # 306,
Mississauga, Ontario, L5N 2X7 Canada

Responsible Individuals:

Name	Contact Information
Arvind Bhandari President & CEO	[redacted]
Cal Bains Director Business Development	[redacted]

Sincerely,

Arvind Bhandari
President & CEO

AdiraMedica Inc.

Suite #302, Unit #306
2233 Argentia Rd,
Mississauga, Ontario, L5N 2X7
Canada
Tel: +1 289 499 4569 Ext. 4569
www.adiramedica.com

October 25, 2022

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

RE: Attestation

I, Arvind Bhandari, attest that I have no past criminal convictions or violations of State, Federal, or Canadian laws regarding drugs or devices against me. Further, I attest that I have not been involved in, or convicted of, any such violations and there have been no disciplinary actions against me.

Sincerely,

Arvind Bhandari
President & CEO

AdiraMedica Inc.

Suite #302, Unit #306
2233 Argentia Rd,
Mississauga, Ontario, L5N 2X7
Canada
Tel: +1 289 499 4569 Ext. 4569
www.adiramedica.com

October 25, 2022

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

RE: Attestation

I, Martin L. Jeiven, attest that I have no past criminal convictions or violations of State, Federal, or Canadian laws regarding drugs or devices against me. Further, I attest that I have not been involved in, or convicted of, any such violations and there have been no disciplinary actions against me.

Sincerely,

Martin L. Jeiven
Secretary

AdiraMedica Inc.

Suite #302, Unit #306
2233 Argentia Rd,
Mississauga, Ontario, L5N 2X7
Canada
Tel: +1 289 499 4569 Ext. 4569
www.adiramedica.com

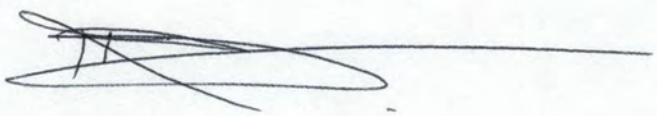
October 25, 2022

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

RE: Attestation

I, Cal Bains, attest that I have no past criminal convictions or violations of State, Federal, or Canadian laws regarding drugs or devices against me. Further, I attest that I have not been involved in, or convicted of, any such violations and there have been no disciplinary actions against me.

Sincerely,



Cal Bains
Director Business Development

Health Canada / Santé Canada

Establishment Licence | **Licence d'établissement**

Licence No. / No. de la licence
3-002515-A

AdiraMedica Inc.

2233 Argentia Road, Suite 302, Unit 306
Mississauga ON L5N 2X7

This licence is issued in accordance with the *Food and Drugs Act and Regulations* (Division 1A) for the following activities /
Cette licence est délivrée conformément à la *Loi et au Règlement sur les aliments et drogues* (titre 1A) pour les activités et les catégories de drogues suivants :

Category / Catégorie	Activity / Activité	Non-Sterile / Non-Stérile	Sterile / Stérile
Biological / Biologique	Wholesale / Vendre en gros	X	
Prescription Drug List, Schedule G, and/or Narcotics / Liste des drogues sur ordonnance, l'Annexe G, et/ou Stupéfiants	Wholesale / Vendre en gros	X	X
Vaccine / Vaccin	Wholesale / Vendre en gros	X	X

1 - if applicable / s'il y a lieu
«Biological» includes drugs listed in Schedule D to the Act, other than vaccines or whole blood and its components / « Biologique » inclut les drogues visée à l'annexe D de la Loi, autre que les vaccins ou le sang total et ses composants
«Radiopharmaceutical» includes drugs listed in Schedule C to the Act / « Radiopharmaceutique » inclut les drogues visée à l'annexe C de la Loi

2 - if applicable / s'il y a lieu
«Distribute» as set out in paragraph C.01 A.003 (a) and/or (b) / « Distribuer » à titre de distribuer au sens de l'alinéa C 01A 003 (a) et/ou (b)
«Test» includes any tests and examinations required under Division 2 / « Analyser » conformement au titre 2

This licence contains the following additional annex(es) / Cette licence contient les annexes suivantes :

Warehouse Annex / Annexe des entrepôts

Date of last GMP inspection / Date de la dernière inspection BPF : 2018-05-15

MINISTER OF HEALTH / MINISTRE DE LA SANTÉ	Countersigned Director General, Regulatory Operations and Regions Branch or designated official Contresigné par Directeur général, Direction générale des opérations réglementaires et des régions ou responsable désigné
Establishment Licence Licence d'établissement Health Canada / Santé Canada Canada	Kimby N. Barton Kimby Barton Issued on / Émise le : 2018-06-01

This licence is the property of the Regulatory Operations and Regions Branch and must be returned upon demand.
Cette licence appartient à la Direction générale des opérations réglementaires et des régions et doit être retournée sur demande.

Canada

Health Canada Santé Canada

Establishment Licence **Licence d'établissement**

Licence No. / No. de la licence
3-002515-A

Warehouse Annex / Annexe des entrepôts

Pursuant to C.01A.008(2)(b) of the *Food and Drug Regulations*, the holder of this establishment licence is authorized to store the category(ies) of drugs, as approved on the first page of this licence, at the following Canadian building(s).

En vertu de l'article C.01A.008(2)(b) du *Règlement sur les aliments et drogues*, le détenteur de cette licence est autorisé d'entreposer les catégories de drogues, tel qu'approuvé à la première page de cette licence, dans les bâtiments canadiens suivants.

Warehouse Name / Nom d'entrepôt	Address / Adresse
Bioscript Logistics Inc.	3330 Ridgeway Drive, Unit 12, Mississauga, ON, L5L 5Z9
Kuehne + Nagel Ltd.	2300 Hogan Drive, Mississauga, ON, L5N 0C8

Canada

Government of Canada / Gouvernement du Canada

Drug & health product inspections

Licensing information

Establishment name: AdiraMedica Inc.

Address: 2233 Argentia Road, Suite 302, Unit 306
Mississauga, Ontario
Canada
L5N 2X7

Reference number: 509997

Site: A

Licence number: 3-002515

Currently licensed: Yes

Activities(categories):

- Wholesale (Prescription Drug List, Schedule G, and/or Narcotics or a drug containing cannabis as defined in subsection 2(1) of the Cannabis Act.)
- Wholesale (Vaccine)
- Wholesale (Biological)

Terms and conditions: No

Inspection information

Inspection:

Inspection start date	Rating	Type of inspection
2019-05-06	Compliant	GMP Domestic - Regular Inspection
2018-05-15	Compliant	GMP Domestic - Initial Inspection

Date modified: 2016-11-08

Government of Canada Gouvernement du Canada

Drug & health product inspections

Inspection report card summary

Initial inspection deficiencies report

Establishment name	Reference number	Inspection start date	Type of inspection	Inspection rating
AdiraMedica Inc.	509997	2018-05-15	GMP Domestic - Initial Inspection	Compliant

Summary of observations

Filter items

Showing 1 to 1 of 1 entries Show 10 entries

Observation number	Regulation	Summary of observation
1	C.02.015 - Quality control department	• The handling of standard operating procedures for good manufacturing practices was inadequate.

Inspection outcome

Inspection resulted in a Compliant rating. The site has been determined to be in Compliance with Part C, Division 2 of the Food and Drug Regulations. Ratings are the result of observations made by Health Canada based on a reasonable belief at a particular point in time during the course of an inspection that the company was conducting the regulated activity / activities in compliance with the Food and Drugs Act or its Regulations.

Measures taken by Health Canada

- Initial inspection in relation to a Drug Establishment Licence (DEL) application. A DEL was issued.

Date modified: 2016-11-08

Government of Canada / Gouvernement du Canada

Drug & health product inspections

Inspection report card summary

Initial inspection deficiencies report

Establishment name	Reference number	Inspection start date	Type of inspection	Inspection rating
AdiraMedica Inc.	509997	2019-05-06	GMP Domestic - Regular Inspection	Compliant

Summary of observations

Filter items

Showing 1 to 3 of 3 entries **Show** 10 **entries**

Observation number	Regulation	Summary of observation
1	C.02.011 - Manufacturing control	• Investigations into deviations, reports, and/or follow-up actions were inadequate.
2	C.02.014 - Quality control department	• The assessment, documentation, and/or procedures for considering the resale of returned drugs were inadequate.
3	C.02.015 - Quality control department	• The guidelines and/or procedures were inadequate in ensuring storage and/or transportation conditions would maintain the quality and safe distribution of the drug.

Inspection outcome

Inspection resulted in a Compliant rating. The site has been determined to be in Compliance with Part C, Division 2 of the Food and Drug Regulations. Ratings are the result of observations made by Health Canada based on a reasonable belief at a particular point in time during the course of an inspection that the company was conducting the regulated activity / activities in compliance with the Food and Drugs Act or its Regulations.

Measures taken by Health Canada

- Drug Establishment Licence (DEL) was maintained.

Date modified: 2016-11-08

Appendix C: Importer Supporting Documentation

Premier Pharmaceuticals

Title: Colorado's Drug Importation Program

10/25/2022

Premier Pharmaceuticals
7259 W Franklin Road,
Boise, Idaho 83709
Phone: (208) 639-0241

Responsible Individuals for the Colorado's Importation Program are:

Name	Title	Contact Information
Jacob Fuchs	President	[redacted]
Adrian Constance	Executive Vice President	[redacted]
Tanner Wollan	Vice President of Strategy	[redacted]
Ericka Valdez	Manager, Marketing and People	[redacted]

I, Jacob Fuchs, attest that there are no past criminal convictions or violations of State, Federal, or Canadian laws regarding drugs or devices against or by the responsible individual(s), or Importer. Further, Premier Pharmaceuticals attests that the responsible individual(s), or Importer have not been involved in, or convicted of, any such violations. Premier Pharmaceuticals principal owners (owning 10 percent or greater) are Jacob Fuchs and K2Red LLC.

Lastly, there have been no disciplinary actions against the responsible individual(s), or Importer by State, Federal, or Canadian regulatory bodies, including any such actions against the principals, owners, directors, officers, quality unit, or any such facility manager or designated representative of such manager for the previous 7 years prior to submission of the SIP Proposal.

Warm regards,

Jacob Fuchs

Jacob Fuchs
President

IDAHO STATE BOARD OF PHARMACY
P.O. Box 83720 Boise, Idaho 83720-0067
Telephone: (208) 334-2356 FAX: (208) 334-3536

The person, firm, or corporation whose name appears on this certificate has complied with the provisions of the Idaho State Board of Pharmacy statutes and/or rules and regulations and is hereby authorized to engage in the activity as indicated below.

Premier Pharmaceuticals LLC dba Premier Pharmaceuticals LLC

Wholesale Distributor License
License No: W57324

ISSUED: 02/21/2020 EXPIRES: 12/31/2022

The official status and business address of this license must be verified at Idaho Board of Pharmacy License Verification.
http://bop.idaho.gov

Physical Address:
7259 W Franklin Rd
Boise, ID 83709

0
Printed: 12/30/2021

NICKI CHOPSKI PHARMD
EXECUTIVE DIRECTOR

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RP0563874	03-31-2023	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4, 5	DISTRIBUTOR	02-18-2022

PREMIER PHARMACEUTICALS LLC
7259 W FRANKLIN RD
BOISE, ID 83709

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RP0563874	03-31-2023	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4, 5	DISTRIBUTOR	02-18-2022

PREMIER PHARMACEUTICALS LLC
7259 W FRANKLIN RD
BOISE, ID 83709

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

IDAHO

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

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

LICENSE
License No: W57324
License Type: Wholesale Distributor

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

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

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

24.36.01.500.05.d. Controlled substance distribution invoices, in the form and including the requirements of federal law. (4-11-19)	Compliant
24.36.01.103.03. Inspection Deficiencies.	
Question	**Answer**
24.36.01.103.03. Inspection Deficiencies. Deficiencies noted must be promptly remedied, and if requested, the Board office notified of corrective measures. One (1) follow-up inspection may be performed by the Board at no cost. For additional follow-up inspections, the drug outlet will be charged actual travel and personnel costs incurred in the inspection to be paid within ninety (90) days of inspection. (7-1-18)	submit response to CS storage security
24.36.01.103.04. Inspection Reports. Inspection reports must be reviewed with the Board inspector and signed by an agent of the drug outlet upon completion of the exit interview. (7-1-18) [Discussed with]	Jacob
Deficiencies- Education of Code and Rule provided?	Yes
Deficiencies- Issued Warning to Drug Oulet -Possible Discipline?	No
Disclaimer - Any items not discussed specifically by compliance officer on this inspection does not constitute compliance nor approval.	True

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

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

Compliance Officer

3/22/2022

Date/Time

Signature of Owner/Representative

IDAHO

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

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

LICENSE
License No:
License Type: Wholesale Distributor

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

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

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

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

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

---------- Forwarded message ---------
From: **Amy Hickerson** [redacted]
Date: Thu, Aug 18, 2022 at 5:31 PM
Subject: follow up inspection
To: Jacob Fuchs [redacted]

Jacob,

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

Amy Hickerson

Drug Compliance Officer

Division of Occupational and Professional Licenses

Health Professions - Board of Pharmacy

[redacted]

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

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

LICENSE
License No:
License Type: Wholesale Distributor

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

Notes:
Remarks: No Controls.

Checklist Results

27.01.01.022.02 BOARD INSPECTIONS

Question	Answer
27.01.01.022.02.. - Inspections. Prior to the commencement of business, as applicable, and thereafter at regular intervals, upon presentation of appropriate identification, registrants and licensees must permit the Board or its compliance officers to enter and inspect the premises and to audit the records of each drug outlet for compliance with laws enforced by or under the Board's jurisdiction.	reviewed

27.01.06.041 - FACILITY REQUIREMENTS

Question	Answer
27.01.06.041 - Facilities where drugs are stored, warehoused, handled, held, offered, marketed, or displayed for wholesale distribution must:	True
27.01.06.041.01 - Minimum Physical Standards. Be of suitable size, construction, and location to accommodate cleaning, maintenance, and proper operations;	Compliant
27.01.06.041.02 - Minimum Environmental Standards. Have adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;	Compliant
27.01.06.041.03 - Quarantine. Have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, or adulterated or that are in immediate or sealed secondary containers that have been opened;	Compliant
27.01.06.041.04 - Maintenance Requirements. Be maintained in a clean and orderly condition	Compliant
27.01.06.041.05 - Pest Controls. Be free from infestation by insects, rodents, birds, or vermin of any kind	Compliant

27.01.06.042 - FACILITY SECURITY REQUIREMENTS

Question	Answer
27.01.06.042 - Facilities used for wholesale drug distribution must be secure from unauthorized entry, as follows:	Not Answered
27.01.06.042.01 - Access from Outside. Access from outside the premises must be kept to a minimum and well controlled;	Compliant
27.01.06.042.02 - Perimeter Lighting. The outside perimeter of the premises must be well lighted;	Compliant
27.01.06.042.03 - Authorized Entry. Entry into areas where drugs are held must be limited to authorized personnel;	Compliant
27.01.06.042.04 - Alarm Systems. Facilities must be equipped with an alarm system to detect entry after hours	Compliant
27.01.06.042.05 - Security Systems. Facilities must be equipped with security systems sufficient to protect against theft, diversion, and record tampering	Compliant

27.01.06.043 / 044 - DRUG STORAGE & SHIPMENT RQMTS

Question	Answer
27.01.06.043 - Drugs must be stored at temperatures and under conditions required by the labeling of the drugs, if any, or by current requirements of the USP-NF, to preserve product identity, strength, quality, and purity. Temperature and humidity recording equipment, devices, or logs must document proper storage of drugs.	Compliant
27.01.06.044.01 - Examination on Receipt. Each shipping container must be visually examined on receipt for identity and to avoid acceptance of drugs that are contaminated or otherwise unfit for distribution.	Compliant
27.01.06.044.02 - Outgoing Shipment Inspections. Outgoing shipments must be inspected to verify the accuracy and product integrity of the shipment contents.	Compliant

27.01.06.045 - QUARANTINE

Question	Answer

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

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

3/27/2019

Compliance Officer	Date/Time	Signature of Owner/Representative

Search Results for **Q Labs, LLC**

CSV Excel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Q Labs, LLC	1527260	080737501	ANALYSIS;	1930 Radcliff Dr, Cincinnati, Ohio (OH) 45204, United States (USA)	12/31/2022

Showing 1 to 1 of 1 entries

Previous 1 Next

Data Current through: Monday, Mar 21, 2022

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

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

BIOLOGICAL

Valid To: July 31, 2024 Certificate Number: 3026.02

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

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

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

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

Accredited Laboratory

A2LA has accredited

Q LABS LLC.

Cincinnati, OH

for technical competence in the field of

Biological Testing

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

Presented this 9th day of September 2022.

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

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

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

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

CHEMICAL

Valid To: July 31, 2024 Certificate Number: 3026.01

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

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

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

Accredited Laboratory

A2LA has accredited

Q LABS LLC.

Cincinnati, OH

for technical competence in the field of

Chemical Testing

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

Presented this 9th day of September 2022.

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

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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

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

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

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

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

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

Specifically,

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

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

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

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

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*DATES OF INSPECTION

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

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

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

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

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

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

November 22nd, 2019

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

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

Mr. Czabaniuk,

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

Observation 1

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

Specifically,

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

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

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

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

Response:

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

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

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

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

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

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

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

Best regards,

X

Jeffrey Rowe
President & CEO, Q Labs LLC

Site Master File

Table of Contents

1. Scope

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

2. Purpose

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

3. Corporate Authorizations

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

4. Product Services

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

5. Facility Location Description

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

Q Labs currently operates at the following locations:

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

6. Company History

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

7. Site Description

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

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

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

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

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

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

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

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

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

8. Organization Charts & Department Staffing

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

9. Management Responsibilities

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

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

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

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

10. USP Purified Water System

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

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

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

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

11. Quality Management System

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

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

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

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

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

12. Resource Training

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

13. Quality Control & Assurance

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

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

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

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

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

14. Stability

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

15. Third-Party Contracts

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

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

16. Document Control Procedures

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

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

17. **Data Integrity Program**

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

Approved By: _____ 3-31-2022

August Smithmeyer, Director of Microbiology Operations — Date

Approved By: _____ 3-30-22

Jeff Knowles, VP Quality — Date

Approved By: _____ 3-30-22

Jeff Rowe, President and Chief Executive Officer — Date

REVISION HISTORY:

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

Q LABS SOP TOC

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

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

Drug Establishments Current Registration Site

New Search (default.cfm)

Search Results for **omega tech labs**

CSVExcel
Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Omega Tech Labs Inc	3005274476	019313817	MANUFACTURE;	5858 W Franklin Rd., Boise, Idaho (ID) 83709, United States (USA)	12/31/2022

Showing 1 to 1 of 1 entries
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Data Current through: Friday, Oct 28, 2022

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

Appendix D: Drug List with Required Data Elements

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Active Ingredient	Canadian Proprietary Name	Canadian Generic Name	DIN	Company Name	Address	CAN Strength	Dosage Form	# of active Ingred.	Canadian Ingredients	US Proprietary Name	US Generic Name	US Strength	NDC	NDA or ANDA	Number	Applicant Holder Name	Applicant Holder Address	US Ingredients	Comment for FDA
abiraterone	Zytiga	abiraterone acetate	02457113	Janssen Inc.	19 Green Belt Drive Toronto Ontario Canada M3C 1L9	500mg	tablet	1	500 mg abiraterone acetate non-medicinal ingredients: colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, silicified microcrystalline cellulose, and sodium lauryl sulfate. Tablet Core: colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, silicified microcrystalline cellulose, and sodium lauryl sulfate. The tablet film coating contains iron oxide black, iron oxide red, macrogol 3350, polyvinyl alcohol, talc, and titanium dioxide.	Zytiga	abiraterone	500mg	57894-0195-06	NDA	202379	Janssen Biotech, Inc.	800 Ridgeview Road Horsham, PA 19044	500 mg abiraterone acetate; microcrystalline cellulose, croscarmellose sodium, hypromellose 2910, lactose monohydrate, magnesium stearate, silicon dioxide, sodium lauryl sulfate, polyvinyl alcohol (unspecified), titanium dioxide, polyethylene glycol 335, talc, ferric oxide red, ferrosoferric oxide, Water	
albuterol	Airomir	salbutamol	02232570	Bausch Health Canada, Inc.	2150 Boul. St-Elzear Ouest Laval, Quebec CAN, H7L 4A8	100mcg	metered dose inhaler	1	100 mcg salbutamol (albuterol), as Salbutamol Sulfate, per actuation, equivalent to 90mcg salbutamol (albuterol) per spray non-medicinal ingredients: 1,1,1,2-Tetrafluoroethane (HFA-134a, norflurane), Ethanol, and Oleic Acid	Proventil HFA	albuterol	90mcg	66758-0959-85	NDA	020503	Kindeva Drug Delivery LP	11200 Hudson Road, Woodbury, Minnesota (MN) 55129, United States (USA)	Active ingredient: albuterol sulfate Inactive ingredient: Inactive ingredients: 1, 1, 1,2-tetrafluoroethane (HFA-134a, norflurane); alcohol, oleic acid	This is an authorized brand name marketed by Sandoz, Inc. Princeton, NJ 08540
albuterol	Airomir	salbutamol	02232570	Bausch Health Canada, Inc.	2150 Boul. St-Elzear Ouest Laval, Quebec CAN, H7L 4A8	100mcg	metered dose inhaler	1	100 mcg salbutamol (albuterol), as Salbutamol Sulfate, per actuation, equivalent to 90mcg salbutamol (albuterol) per spray non-medicinal ingredients: 1,1,1,2-Tetrafluoroethane (HFA-134a, norflurane), Ethanol, and Oleic Acid	Albuterol Sulfate	albuterol	90mcg	00781-7296-85	NDA Authorized Generic	020503	Kindeva Drug Delivery LP	11200 Hudson Road, Woodbury, Minnesota (MN) 55129, United States (USA)	Active ingredient: albuterol sulfate Inactive ingredient: Inactive ingredients: 1, 1, 1,2-tetrafluoroethane (HFA-134a, norflurane); alcohol, oleic acid	This is an authorized generic marketed by Sandoz Inc. Princeton, NJ, 08540
albuterol	Airomir	salbutamol	02232570	Bausch Health Canada, Inc.	2150 Boul. St-Elzear Ouest Laval, Quebec CAN, H7L 4A8	100mcg	metered dose inhaler	1	100 mcg salbutamol (albuterol), as Salbutamol Sulfate, per actuation, equivalent to 90mcg salbutamol (albuterol) per spray non-medicinal ingredients: 1,1,1,2-Tetrafluoroethane (HFA-134a, norflurane), Ethanol, and Oleic Acid	Ventolin HFA	albuterol	90mcg	00173-0682-20	NDA	020983	GlaxoSmithKline LLC	5 Moore Drive Mailstop 5.5B Research Triangle Park, NC 27709	Active ingredient: albuterol sulfate Inactive ingredient: 1, 1, 1,2-tetrafluoroethane (HFA-134a, norflurane)	
albuterol	Airomir	salbutamol	02232570	Bausch Health Canada, Inc.	2150 Boul. St-Elzear Ouest Laval, Quebec CAN, H7L 4A8	100mcg	metered dose inhaler	1	100 mcg salbutamol (albuterol), as Salbutamol Sulfate, per actuation, equivalent to 90mcg salbutamol (albuterol) per spray non-medicinal ingredients: 1,1,1,2-Tetrafluoroethane (HFA-134a, norflurane), Ethanol, and Oleic Acid	ProAir HFA	albuterol	90mcg	59310-0579-22	NDA	021457	Teva Pharmaceuticals USA	400 Interpace Pkwy #3, Parsippany, NJ 07054	Active ingredient: albuterol sulfate Inactive ingredient: 1, 1, 1,2-tetrafluoroethane (HFA-134a) & alcohol	
albuterol	Airomir	salbutamol	02232570	Bausch Health Canada, Inc.	2150 Boul. St-Elzear Ouest Laval, Quebec CAN, H7L 4A8	100mcg	metered dose inhaler	1	100 mcg salbutamol (albuterol), as Salbutamol Sulfate, per actuation, equivalent to 90mcg salbutamol (albuterol) per spray non-medicinal ingredients: 1,1,1,2-Tetrafluoroethane (HFA-134a, norflurane), Ethanol, and Oleic Acid	Albuterol Sulfate HFA -	albuterol	90mcg	00093-3174-31	NDA	021457	Teva Pharmaceuticals, USA, Inc.	400 Interpace Pkwy #3, Parsippany-Troy Hills, NJ 07054	Active ingredient: albuterol sulfate Inactive ingredient: 1, 1, 1,2-tetrafluoroethane (HFA-134a, norflurane) & alcohol	
albuterol	Apo-Salbutamol HFA	salbutamol	02245669	Apotex Inc.	150 Signet Drive Toronto, Ontario, CAnada M9L 1T9	100mcg	metered dose inhaler	1	100 mcg salbutamol (albuterol), as Salbutamol Sulfate, per actuation, equivalent to 90mcg salbutamol (albuterol) per spray non-medicinal ingredients: 1,1,1,2-Tetrafluoroethane (HFA-134a, norflurane)	Proventil HFA	albuterol	90mcg	66758-0959-85	NDA	020503	Kindeva Drug Delivery LP	11200 Hudson Road, Woodbury, Minnesota (MN) 55129, United States (USA)	Active ingredient: albuterol sulfate Inactive ingredient: Inactive ingredients: 1, 1, 1,2-tetrafluoroethane (HFA-134a, norflurane); alcohol, oleic acid	This is an authorized brand name marketed by Sandoz, Inc. Princeton, NJ 08540
albuterol	Apo-Salbutamol HFA	salbutamol	02245669	Apotex Inc.	150 Signet Drive Toronto, Ontario, CAnada M9L 1T9	100mcg	metered dose inhaler	1	100 mcg salbutamol (albuterol), as Salbutamol Sulfate, per actuation, equivalent to 90mcg salbutamol (albuterol) per spray non-medicinal ingredients: 1,1,1,2-Tetrafluoroethane (HFA-134a, norflurane)	Albuterol Sulfate	albuterol	90mcg	00781-7296-85	NDA Authorized Generic	020503	Kindeva Drug Delivery LP	11200 Hudson Road, Woodbury, Minnesota (MN) 55129, United States (USA)	Active ingredient: albuterol sulfate Inactive ingredient: Inactive ingredients: 1, 1, 1,2-tetrafluoroethane (HFA-134a, norflurane); alcohol, oleic acid	This is an authorized generic marketed by Sandoz Inc. Princeton, NJ, 08540
albuterol	Apo-Salbutamol HFA	salbutamol	02245669	Apotex Inc.	150 Signet Drive Toronto, Ontario, CAnada M9L 1T9	100mcg	metered dose inhaler	1	100 mcg salbutamol (albuterol), as Salbutamol Sulfate, per actuation, equivalent to 90mcg salbutamol (albuterol) per spray non-medicinal ingredients: 1,1,1,2-Tetrafluoroethane (HFA-134a, norflurane)	Ventolin HFA	albuterol	90mcg	00173-0682-20	NDA	020983	GlaxoSmithKline LLC	5 Moore Drive Mailstop 5.5B Research Triangle Park, NC 27709	Active ingredient: albuterol sulfate Inactive ingredient: 1, 1, 1,2-tetrafluoroethane (HFA-134a, norflurane)	
albuterol	Apo-Salbutamol HFA	salbutamol	02245669	Apotex Inc.	150 Signet Drive Toronto, Ontario, Canada M9L 1T9	100mcg	metered dose inhaler	1	100 mcg salbutamol (albuterol), as Salbutamol Sulfate, per actuation, equivalent to 90mcg salbutamol (albuterol) per spray non-medicinal ingredients: 1,1,1,2-Tetrafluoroethane (HFA-134a, norflurane)	ProAir HFA	albuterol	90mcg	59310-0579-22	NDA	021457	Teva Pharmaceuticals USA, Inc.	400 Interpace Pkwy #3, Parsippany, NJ 07054	Active ingredient: albuterol sulfate Inactive ingredient: 1, 1, 1,2-tetrafluoroethane (HFA-134a, norflurane) & alcohol	
albuterol	Apo-Salbutamol HFA	salbutamol	02245669	Apotex Inc.	150 Signet Drive Toronto, Ontario, Canada M9L 1T9	100mcg	metered dose inhaler	1	100 mcg salbutamol (albuterol), as Salbutamol Sulfate, per actuation, equivalent to 90mcg salbutamol (albuterol) per spray non-medicinal ingredients: 1,1,1,2-Tetrafluoroethane (HFA-134a, norflurane)	Albuterol Sulfate HFA -	albuterol	90mcg	00093-3174-31	NDA	021457	Teva Pharmaceuticals USA, Inc.	400 Interpace Pkwy #3, Parsippany-Troy Hills, NJ 07054	Active ingredient: albuterol sulfate Inactive ingredient: 1, 1, 1,2-tetrafluoroethane (HFA-134a, norflurane) & alcohol	
albuterol	Salbutamol HFA	salbutamol	02419858	Sanis Health Inc.	1 Presidents Choice Circle Brampton, Ontario, CAN L67 5S5	100mcg	metered dose inhaler	1	100 mcg salbutamol (albuterol), as Salbutamol Sulfate, per actuation, equivalent to 90mcg salbutamol (albuterol) per spray non-medicinal ingredients: 1,1,1,2-Tetrafluoroethane (HFA-134a, norflurane)	Proventil HFA	albuterol	90mcg	66758-0959-85	NDA	020503	Kindeva Drug Delivery LP	11200 Hudson Road, Woodbury, Minnesota (MN) 55129, United States (USA)	Active ingredient: albuterol sulfate Inactive ingredient: Inactive ingredients: 1, 1, 1,2-tetrafluoroethane (HFA-134a, norflurane); alcohol, oleic acid	This is an authorized brand name marketed by Sandoz, Inc. Princeton, NJ 08540
albuterol	Salbutamol HFA	salbutamol	02419858	Sanis Health Inc.	1 Presidents Choice Circle Brampton, Ontario, CAN L67 5S5	100mcg	metered dose inhaler	1	100 mcg salbutamol (albuterol), as Salbutamol Sulfate, per actuation, equivalent to 90mcg salbutamol (albuterol) per spray non-medicinal ingredients: 1,1,1,2-Tetrafluoroethane (HFA-134a, norflurane)	Albuterol Sulfate	albuterol	90mcg	00781-7296-85	NDA Authorized Generic	020503	Kindeva Drug Delivery LP	11200 Hudson Road, Woodbury, Minnesota (MN) 55129, United States (USA)	Active ingredient: albuterol sulfate Inactive ingredient: Inactive ingredients: 1, 1, 1,2-tetrafluoroethane (HFA-134a, norflurane); alcohol, oleic acid	This is an authorized generic marketed by Sandoz Inc. Princeton, NJ, 08540

Appendix D: Drug List with Required Data Elements

Active Ingredient	Canadian Proprietary Name	Canadian Generic Name	DIN	Company Name	Address	CAN Strength	Dosage Form	# of active Ingred.	Canadian Ingredients	US Proprietary Name	US Generic Name	US Strength	NDC	NDA or ANDA	Number	Applicant Holder Name	Applicant Holder Address	US Ingredients	Comment for FDA
albuterol	Salbutamol HFA	salbutamol	02419858	Sanis Health Inc.	1 Presidents Choice Circle Brampton, Ontario, CAN L67 5S5	100mcg	metered dose inhaler	1	100 mcg salbutamol (albuterol), as Salbutamol Sulfate, per actuation, equivalent to 90mcg salbutamol (albuterol) per spray non-medicinal ingredients: 1,1,1,2-Tetrafluoroethane (HFA-134a, norflurane)	Ventolin HFA	albuterol	90mcg	00173-0682-20	NDA	020983	GlaxoSmithKline LLC	5 Moore Drive Mailstop 5.5B Research Triangle Park, NC 27709	Active ingredient: albuterol sulfate Inactive ingredient: 1, 1, 1,2-tetrafluoroethane (HFA-134a, norflurane)	
albuterol	Salbutamol HFA	salbutamol	02419858	Sanis Health Inc.	1 Presidents Choice Circle Brampton, Ontario, CAN L67 5S5	100mcg	metered dose inhaler	1	100 mcg salbutamol (albuterol), as Salbutamol Sulfate, per actuation, equivalent to 90mcg salbutamol (albuterol) per spray non-medicinal ingredients: 1,1,1,2-Tetrafluoroethane (HFA-134a, norflurane)	ProAir HFA	albuterol	90mcg	59310-0579-22	NDA	021457	Teva Pharmaceuticals USA, Inc.	400 Interpace Pkwy #3, Parsippany, NJ 07054	Active ingredient: albuterol sulfate Inactive ingredient: 1, 1, 1,2-tetrafluoroethane (HFA-134a, norflurane) & alcohol	
albuterol	Salbutamol HFA	salbutamol	02419858	Sanis Health Inc.	1 Presidents Choice Circle Brampton, Ontario, CAN L67 5S5	100mcg	metered dose inhaler	1	100 mcg salbutamol (albuterol), as Salbutamol Sulfate, per actuation, equivalent to 90mcg salbutamol (albuterol) per spray non-medicinal ingredients: 1,1,1,2-Tetrafluoroethane (HFA-134a, norflurane)	Albuterol Sulfate HFA	albuterol	90mcg	00093-3174-31	NDA	021457	Teva Pharmaceuticals USA, Inc.	400 Interpace Pkwy #3, Parsippany-Troy Hills, NJ 07054	Active ingredient: albuterol sulfate Inactive ingredient: 1, 1, 1,2-tetrafluoroethane (HFA-134a, norflurane) & alcohol	
albuterol	Teva-Salbutamol HFA	salbutamol	02326450	Teva Canada Ltd.	30 Novopharm Court, Toronto, Ontario, CAN M1B 2K9	100mcg	metered dose inhaler	1	100 mcg salbutamol (albuterol), as Salbutamol Sulfate, per actuation, equivalent to 90mcg salbutamol (albuterol) per spray non-medicinal ingredients: 1,1,1,2-tetrafluoroethane (HFA-134a, norflurane) and Ethanol	Proventil HFA	albuterol	90mcg	66758-0959-85	NDA	020503	Kindeva Drug Delivery LP	11200 Hudson Road, Woodbury, Minnesota (MN) 55129, United States (USA)	Active ingredient: albuterol sulfate Inactive ingredient: Inactive ingredients: 1, 1, 1,2-tetrafluoroethane (HFA-134a, norflurane); alcohol, oleic acid	This is an authorized brand name marketed by Sandoz, Inc. Princeton, NJ 08540
albuterol	Teva-Salbutamol HFA	salbutamol	02326450	Teva Canada Ltd.	30 Novopharm Court, Toronto, Ontario, CAN M1B 2K9	100mcg	metered dose inhaler	1	100 mcg salbutamol (albuterol), as Salbutamol Sulfate, per actuation, equivalent to 90mcg salbutamol (albuterol) per spray non-medicinal ingredients: 1,1,1,2-tetrafluoroethane (HFA-134a, norflurane) and Ethanol	Albuterol Sulfate	albuterol	90mcg	00781-7296-85	NDA Authorized Generic	020503	Kindeva Drug Delivery LP	11200 Hudson Road, Woodbury, Minnesota (MN) 55129, United States (USA)	Active ingredient: albuterol sulfate Inactive ingredient: Inactive ingredients: 1, 1, 1,2-tetrafluoroethane (HFA-134a, norflurane); alcohol, oleic acid	This is an authorized generic marketed by Sandoz Inc. Princeton, NJ, 08540
albuterol	Teva-Salbutamol HFA	salbutamol	02326450	Teva Canada Ltd.	30 Novopharm Court, Toronto, Ontario, CAN M1B 2K9	100mcg	metered dose inhaler	1	100 mcg salbutamol (albuterol), as Salbutamol Sulfate, per actuation, equivalent to 90mcg salbutamol (albuterol) per spray non-medicinal ingredients: 1,1,1,2-tetrafluoroethane (HFA-134a, norflurane) and Ethanol	Ventolin HFA	albuterol	90mcg	00173-0682-20	NDA	020983	GlaxoSmithKline LLC	5 Moore Drive Mailstop 5.5B Research Triangle Park, NC 27709	Active ingredient: albuterol sulfate Inactive ingredient: 1, 1, 1,2-tetrafluoroethane (HFA-134a, norflurane)	
albuterol	Teva-Salbutamol HFA	salbutamol	02326450	Teva Canada Ltd.	30 Novopharm Court, Toronto, Ontario, CAN M1B 2K9	100mcg	metered dose inhaler	1	100 mcg salbutamol (albuterol), as Salbutamol Sulfate, per actuation, equivalent to 90mcg salbutamol (albuterol) per spray non-medicinal ingredients: 1,1,1,2-tetrafluoroethane (HFA-134a, norflurane) and Ethanol	ProAir HFA	albuterol	90mcg	59310-0579-22	NDA	021457	Teva Pharmaceuticals USA, Inc.	400 Interpace Pkwy #3, Parsippany, NJ 07054	Active ingredient: albuterol sulfate Inactive ingredient: 1, 1, 1,2-tetrafluoroethane (HFA-134a, norflurane) & alcohol	
albuterol	Teva-Salbutamol HFA	salbutamol	02326450	Teva Canada Ltd.	30 Novopharm Court, Toronto, Ontario, CAN M1B 2K9	100mcg	metered dose inhaler	1	100 mcg salbutamol (albuterol), as Salbutamol Sulfate, per actuation, equivalent to 90mcg salbutamol (albuterol) per spray non-medicinal ingredients: 1,1,1,2-tetrafluoroethane (HFA-134a, norflurane) and Ethanol	Albuterol Sulfate HFA	albuterol	90mcg	00093-3174-31	NDA	021457	Teva Pharmaceuticals USA, Inc.	400 Interpace Pkwy #3, Parsippany-Troy Hills, NJ 07054	Active ingredient: albuterol sulfate Inactive ingredient: 1, 1, 1,2-tetrafluoroethane (HFA-134a, norflurane) & alcohol	
albuterol	Ventolin HFA	Salbutamol	02241497	GlaxoSmithKline Inc.	7333 Mississauga Road Mississauga Ontario Canada L5N 6L4	100mcg	metered dose inhaler	1	100 mcg salbutamol (albuterol), as Salbutamol Sulfate, per actuation, equivalent to 90mcg salbutamol (albuterol) per spray non-medicinal ingredients: 1, 1, 1, 2-tetrafluoroethane (HFA-134a, norflurane)	Proventil HFA	albuterol	90mcg	66758-0959-85	NDA	020503	Kindeva Drug Delivery LP	11200 Hudson Road, Woodbury, Minnesota (MN) 55129, United States (USA)	Active ingredient: albuterol sulfate Inactive ingredient: Inactive ingredients: 1, 1, 1,2-tetrafluoroethane (HFA-134a, norflurane); alcohol, oleic acid	This is an authorized brand name marketed by Sandoz, Inc. Princeton, NJ 08540
albuterol	Ventolin HFA	Salbutamol	02241497	GlaxoSmithKline Inc.	7333 Mississauga Road Mississauga Ontario Canada L5N 6L4	100mcg	metered dose inhaler	1	100 mcg salbutamol (albuterol), as Salbutamol Sulfate, per actuation, equivalent to 90mcg salbutamol (albuterol) per spray non-medicinal ingredients: 1, 1, 1, 2-tetrafluoroethane (HFA-134a, norflurane)	Albuterol Sulfate	albuterol	90mcg	00781-7296-85	NDA Authorized Generic	020503	Kindeva Drug Delivery LP	11200 Hudson Road, Woodbury, Minnesota (MN) 55129, United States (USA)	Active ingredient: albuterol sulfate Inactive ingredient: Inactive ingredients: 1, 1, 1,2-tetrafluoroethane (HFA-134a, norflurane); alcohol, oleic acid	This is an authorized generic marketed by Sandoz Inc. Princeton, NJ, 08540
albuterol	Ventolin HFA	Salbutamol	02241497	GlaxoSmithKline Inc.	7333 Mississauga Road Mississauga Ontario Canada L5N 6L4	100mcg	metered dose inhaler	1	100 mcg salbutamol (albuterol), as Salbutamol Sulfate, per actuation, equivalent to 90mcg salbutamol (albuterol) per spray non-medicinal ingredients: 1, 1, 1, 2-tetrafluoroethane (HFA-134a, norflurane)	Ventolin HFA	albuterol	90mcg	00173-0682-20	NDA	020983	GlaxoSmithKline LLC	5 Moore Drive Mailstop 5.5B Research Triangle Park, NC 27709	Active ingredient: albuterol sulfate Inactive ingredient: 1, 1, 1,2-tetrafluoroethane (HFA-134a, norflurane)	
albuterol	Ventolin HFA	Salbutamol	02241497	GlaxoSmithKline Inc.	7333 Mississauga Road Mississauga Ontario Canada L5N 6L4	100mcg	metered dose inhaler	1	100 mcg salbutamol (albuterol), as Salbutamol Sulfate, per actuation, equivalent to 90mcg salbutamol (albuterol) per spray non-medicinal ingredients: 1, 1, 1, 2-tetrafluoroethane (HFA-134a, norflurane)	ProAir HFA	albuterol	90mcg	59310-0579-22	NDA	021457	Teva Pharmaceuticals USA, Inc.	400 Interpace Pkwy #3, Parsippany, NJ 07054	Active ingredient: albuterol sulfate Inactive ingredient: 1, 1, 1,2-tetrafluoroethane (HFA-134a, norflurane) & alcohol	
albuterol	Ventolin HFA	Salbutamol	02241497	GlaxoSmithKline Inc.	7333 Mississauga Road Mississauga Ontario Canada L5N 6L4	100mcg	metered dose inhaler	1	100 mcg salbutamol (albuterol), as Salbutamol Sulfate, per actuation, equivalent to 90mcg salbutamol (albuterol) per spray non-medicinal ingredients: 1, 1, 1, 2-tetrafluoroethane (HFA-134a, norflurane)	Albuterol Sulfate HFA	albuterol	90mcg	00093-3174-31	NDA	021457	Teva Pharmaceuticals USA, Inc.	400 Interpace Pkwy #3, Parsippany-Troy Hills, NJ 07054	Active ingredient: albuterol sulfate Inactive ingredient: 1, 1, 1,2-tetrafluoroethane (HFA-134a, norflurane) & alcohol	
apalutamide	Erleada	apalutamide	02478374	Janssen Inc.	19 Green Belt Drive Toronto Ontario Canada M3C 1L9	60mg	tablet	1	apalutamide, 60 mg oral tablet nonmedicinal ingredients: Tablet Core: colloidal anhydrous silica, croscarmellose sodium, hydroxypropyl methylcellulose-acetate succinate (HPMC-AS), magnesium stearate, microcrystalline cellulose, and silicified microcrystalline cellulose. Tablet Coating: iron oxide black (E172), iron oxide yellow (E172), polyethylene glycol, polyvinyl alcohol, talc, and titanium dioxide.	Erleada	apalutamide	60mg	59676-0600-12	NDA	210951	Janssen Ortho LLC	State Road 933 KM 0.1,Mamey Ward, Gurabo, Puerto Rico (PR) 00778, United States (USA)	apalutamide silicon dioxide, croscarmellose sodium, hypromellose acetate succinate, magnesium stearate, microcrystalline cellulose, ferrosoferric oxide, ferric oxide yellow, polyethylene glycol unspecified, polyvinyl alcohol unspecificed, talc, titanium dioxide	

Appendix D: Drug List with Required Data Elements

Active Ingredient	Canadian Proprietary Name	Canadian Generic Name	DIN	Company Name	Address	CAN Strength	Dosage Form	# of active Ingred.	Canadian Ingredients	US Proprietary Name	US Generic Name	US Strength	NDC	NDA or ANDA	Number	Applicant Holder Name	Applicant Holder Address	US Ingredients	Comment for FDA
apixiban	Eliquis	apixaban	02377233	Bristol-Myers Squibb Canada	2344 Boul. Alfred-Nobel, Suite 300 Montréal (St-Laurent) Quebec Canada H4S 0A4	2.5mg	tablet	1	Active Ingredient: Apixaban non-medicinal ingredients: Anhydrous lactose, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium lauryl sulphate, titanium dioxide, triacetin, and yellow iron oxide	Eliquis	Apixaban	2.5mg	00003-0893-21	NDA	202155	Bristol-Myers Squibb	P.O. Box 4000 Princeton, NJ 08543-4000	Active ingredient: apixaban. Inactive ingredients: anhydrous lactose, microcrystalline cellulose, croscarmellose sodium, sodium lauryl sulfate, and magnesium stearate. The film coating contains lactose monohydrate, hypromellose, titanium dioxide, triacetin, and ferric oxide yellow	
apixiban	Eliquis	apixaban	02397714	Bristol-Myers Squibb Canada	2344 Boul. Alfred-Nobel, Suite 300 Montréal (St-Laurent) Quebec Canada H4S 0A4	5mg	tablet	1	Active Ingredient: Apixaban non-medicinal ingredients: Anhydrous lactose, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium lauryl sulphate, titanium dioxide, triacetin, and red iron oxide	Eliquis	Apixaban	5mg	0003-0894-21	NDA	202155	Bristol-Myers Squibb	P.O. Box 4000 Princeton, NJ 08543-4000	Active ingredient: apixaban. Inactive ingredients: anhydrous lactose, microcrystalline cellulose, croscarmellose sodium, sodium lauryl sulfate, and magnesium stearate. The film coating contains lactose monohydrate, hypromellose, titanium dioxide, triacetin, and ferric oxide red	
bictegravir, emtricitabine, and tenofovir alafenamide	Biktarvy	Bictegravir, emtricitabine, and tenofovir alafenamide	2478579	Gilead Sciences Canada Inc.	600 6711 Mississauga Road Mississauga Ontario Canada L5N 2W3	50-200-25 mg	tablet	3	50mg of BIC (equivalent to 52.5mg of bictegravir sodium), 200mg of FTC (emtricitabine), and 25mg of of TAF (equivalent to 28.0mg of tenofovir alafenamide humifumarate) non-medicinal: croscarmellose sodium, iron oxide black, iron oxide red, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talc, and titanium-dioxide	Biktarvy	Bictegravir, emtricitabine, and tenofovir alafenamide	50-200-25 mg	61958-2501-01	NDA	210251	Gilead Sciences, Inc.	333 Lakeside Drive Foster City, CA 94404	bictegravir sodium), emtricitabine tenofovir alafenamide fumarate inactive: microcrystalline cellulose, croscarmellose sodium, magnesium stearate,, water, polyvinyl alcohol (unspecified), titanium dioxide, polyethylene glycol (unspecified), talc, ferrosoferric oxide, ferric oxide red	
budesonide	Pulmicort Turbuhaler	Budesonide	00852074	AstraZeneca Canada Inc.	1004 Middlegate Road, Suite 5000 Mississauga Ontario Canada L4Y 1M4	100mcg	metered powder inhaler	1	Turbuhaler® is a breath-activated dry powder inhaler. It contains only the active ingredient budesonide – no propellants or preservatives. Non-medicinal ingredients: None	Pulmicort Flexhaler	budesonide	90mcg	00186-0917-06	NDA	021949	AstraZeneca Pharmaceuticals LP	4601 Highway 62 East, Mount Vernon, Indiana (IN) 47620, United States (USA)	budesonide inactive: lactose (unspecified form)	
budesonide	Pulmicort Turbuhaler	Budesonide	00857152	AstraZeneca Canada Inc.	1004 Middlegate Road, Suite 5000 Mississauga Ontario Canada L4Y 1M4	200mcg	metered powder inhaler	1	Turbuhaler® is a breath-activated dry powder inhaler. It contains only the active ingredient budesonide – no propellants or preservatives. Non-medicinal ingredients: None	Pulmicort Flexhaler	budesonide	180mcg	00186-0916-12	NDA	021949	AstraZeneca Pharmaceuticals LP	4601 Highway 62 East, Mount Vernon, Indiana (IN) 47620, United States (USA)	budesonide inactive: lactose (unspecified form)	
cabotegravir/ rilpivirine	Cabenuva	Cabotegravir/ rilpivirine	02497247	Viiv Healthcare Ulc.	77 Rue Queen, Suite 1400 Montreal, Quebec Canada H3C 2N6	200 mg cabotegravir/mL (600mg/3mL) & 300 mg rilpivirine/mL (900mg/3mL)	Suspension (extended release), kit	2	Active ingredients: Extended Release Injectable Suspension/ 600 mg cabotegravir / 3 mL Extended Release Injectable Suspension/ 900 mg rilpivirine / 3 mL non-medicinal ingredients: Cabotegravir: mannitol, polysorbate 20, polyethylene glycol (PEG) 3350, water for injection Rilpivirine: citric acid monohydrate, glucose monohydrate, poloxamer 338, sodium dihydrogen phosphate monohydrate, sodium hydroxide, water for injection	Cabenuva 3mL	cabotegravir and rilpivirine	600 mg cabotegravir / 3 mL Extended Release Injectable Suspension/ 900 mg rilpivirine / 3 mL	49702-0240-15	NDA	212888	ViiV Healthcare Company	Company 42 Moore Dr, Research Triangle, NC 27709	cabotegravir inactive: mannitol, polysorbate 20, polyethylene glycol 3350, water rilpivirine inactive: polyxamer 338, citric acid monohydrate, dextrose monohydrate, sodium phoshate (monobasic monohydrate), sodium hydroxide, water	
cabotegravir/ rilpivirine	Cabenuva	Cabotegravir/ rilpivirine	02497220	Viiv Healthcare Ulc.	75 Rue Queen, Suite 1400 Montreal, Quebec Canada H3C 2N6	200 mg cabotegravir/mL (400mg/2mL) & 300 mg rilpivirine/mL (600mg/2mL)	Suspension (extended release), kit	2	Active ingredients: Extended Release Injectable Suspension/ 400 mg cabotegravir / 2 mL Extended Release Injectable Suspension/ 600 mg rilpivirine / 2 mL non-medicinal ingredients: Cabotegravir: mannitol, polysorbate 20, polyethylene glycol (PEG) 3350, water for injection Rilpivirine: citric acid monohydrate, glucose monohydrate, poloxamer 338, sodium dihydrogen phosphate monohydrate, sodium hydroxide, water for injection	Cabenuva 2mL	cabotegravir and rilpivirine	400 mg cabotegravir / 2 mL Extended Release Injectable Suspension/ 600 mg rilpivirine / 2 mL	49702-0253-15	NDA	212888	ViiV Healthcare Company	Company 42 Moore Dr, Research Triangle, NC 27709	cabotegravir inactive: mannitol, polysorbate 20, polyethylene glycol 3350, water rilpivirine inactive: polyxamer 338, citric acid monohydrate, dextrose monohydrate, sodium phoshate (monobasic monohydrate), sodium hydroxide, water	
cabozantinib	Cabometyx	Cabozantinib	02480824	Ipsen Biopharmaceuticals Canda Inc.	SUITE 500 5050 Satellite Drive Mississauga Ontario Canada L4W 0G1	20mg	tablet	1	cabozantinib as cabozantinib (S)-malate non-medicinal ingredients: colloidal Silicon Dioxide, Croscarmellose Sodium, Hydroxypropyl Cellulose, Hypromellose 2910, Iron Oxide Yellow, Lactose Anhydrous, Magnesium Stearate, Microcrystalline Cellulose, Titanium Dioxide and Triacetin.	Cabometyx	Cabozantinib	20mg	42388-024-26	NDA	208692	Exelixis, Inc.	1851 Harbor Bay Parkway Alameda, CA 94502	cabozantinib s-malate inactive ingredients: microcrystalline cellulose, lactose anhydrous, hydroxypropyl cellulose, croscarmellose sodium, silicon dioxide, magnesium stearate, hypromelloses, titanium dioxide, triacetin, ferroc oxide yellow	
cabozantinib	Cabometyx	Cabozantinib	02480832	Ipsen Biopharmaceuticals Canda Inc.	SUITE 500 5050 Satellite Drive Mississauga Ontario Canada L4W 0G2	40mg	tablet	1	cabozantinib as cabozantinib (S)-malate non-medicinal ingredients: colloidal Silicon Dioxide, Croscarmellose Sodium, Hydroxypropyl Cellulose, Hypromellose 2910, Iron Oxide Yellow, Lactose Anhydrous, Magnesium Stearate, Microcrystalline Cellulose, Titanium Dioxide and Triacetin.	Cabometyx	Cabozantinib	40mg	42388-025-26	NDA	208692	Exelixis, Inc.	1851 Harbor Bay Parkway Alameda, CA 94502	cabozantinib s-malate inactive ingredients: microcrystalline cellulose, lactose anhydrous, hydroxypropyl cellulose, croscarmellose sodium, silicon dioxide, magnesium stearate, hypromelloses, titanium dioxide, triacetin, ferroc oxide yellow	
cabozantinib	Cabometyx	Cabozantinib	02480840	Ipsen Biopharmaceuticals Canda Inc.	SUITE 500 5050 Satellite Drive Mississauga Ontario Canada L4W 0G3	60mg	tablet	1	cabozantinib as cabozantinib (S)-malate non-medicinal ingredients: colloidal Silicon Dioxide, Croscarmellose Sodium, Hydroxypropyl Cellulose, Hypromellose 2910, Iron Oxide Yellow, Lactose Anhydrous, Magnesium Stearate, Microcrystalline Cellulose, Titanium Dioxide and Triacetin.	Cabometyx	Cabozantinib	60mg	42388-023-26	NDA	208692	Exelixis, Inc.	1851 Harbor Bay Parkway Alameda, CA 94502	cabozantinib s-malate inactive ingredients: microcrystalline cellulose, lactose anhydrous, hydroxypropyl cellulose, croscarmellose sodium, silicon dioxide, magnesium stearate, hypromelloses, titanium dioxide, triacetin, ferroc oxide yellow	

Appendix D: Drug List with Required Data Elements

Active Ingredient	Canadian Proprietary Name	Canadian Generic Name	DIN	Company Name	Address	CAN Strength	Dosage Form	# of active Ingred.	Canadian Ingredients	US Proprietary Name	US Generic Name	US Strength	NDC	NDA or ANDA	Number	Applicant Holder Name	Applicant Holder Address	US Ingredients	Comment for FDA
canagiflozin	Invokana	Canagliflozin	02425483	Janssen Inc.	19 Green Belt Drive Toronto Ontario Canada M3C 1L9	100mg	tablet	1	canagliflozin non-medicinal ingredients: Core Tablet: croscarmellose sodium, hydroxypropyl cellulose, lactose anhydrous, magnesium stearate, and microcrystalline cellulose. Film Coat: iron oxide yellow, Macrogol (polyethylene glycol), polyvinyl alcohol, talc, and titanium dioxide.	Invokana	Canagliflozin	100mg	50458-0140-30	NDA	204042	Janssen Pharmaceuticals, Inc.	1125 Trenton-Harbourton Road PO Box 200 Titusville, Nj 08560-1504	100mg of canagliflozin inactive: croscarmellose sodium, hydroxypropyl cellulose, lactose anhydrous, magnesium stearate, and microcrystalline cellulose. In addition, the tablet coating contains iron oxide yellow E172 (100 mg tablet only), macrogol/PEG, polyvinyl alcohol, talc, and titanium dioxide.	
canagiflozin	Invokana	Canagliflozin	02425491	Janssen Inc.	19 Green Belt Drive Toronto Ontario Canada M3C 1L9	300mg	tablet	1	canagliflozin non-medicinal ingredients: Core Tablet: croscarmellose sodium, hydroxypropyl cellulose, lactose anhydrous, magnesium stearate, and microcrystalline cellulose. Film Coat: Macrogol (polyethylene glycol), polyvinyl alcohol, talc, and titanium dioxide.	Invokana	Canagliflozin	300mg	50458-0141-30	NDA	204042	Janssen Pharmaceuticals, Inc.	1125 Trenton-Harbourton Road PO Box 200 Titusville, Nj 08560-1504	300mg of canagliflozin inactive: croscarmellose sodium, hydroxypropyl cellulose, lactose anhydrous, magnesium stearate, and microcrystalline cellulose, iron oxide, macrogol/PEG, polyvinyl alcohol, talc, and titanium dioxide.	
cyclosporine	Restasis	Cyclosporine	02355655	Abbvie Corporation	8401 Trans-Canada Highway Saint-Laurent Quebec Canada H4S 1Z1	0.05%	emulsion	1	cyclosporine emulsion, 0.05% w/v non-medicinal ingredients: Carbomer Copolymer Type A, castor oil, glycerin, polysorbate 80, purified water and sodium hydroxide	Restasis	Cyclosporine	0.05%	00023-9163-30	NDA	050790	Allergan Sales, LLC.	2525 Dupont Drive, Irvine, California (CA) 92612, United States (USA)	Active: cyclosporinee 0.05%. Inactives: glycerin; castor oil; polysorbate 80; carbomer copolymer type A; purified water; and sodium hydroxide to adjust pH.	
cyclosporine	Restasis Multi-Dose	Cyclosporine	02476835	Allergan, Inc.	500-85 Enterprise Blvd. Markham, ON L6G 0B5	0.05%	emulsion	1	cyclosporine emulsion, 0.05% w/v non-medicinal ingredients: Carbomer Copolymer Type A, castor oil, glycerin, polysorbate 80, purified water and sodium hydroxide	Restasis Multi-Dose	Cyclosporine	0.05%	00023-5301-05	NDA	050790	Allergan Sales, LLC.	2525 Dupont Drive, Irvine, California (CA) 92612, United States (USA)	Active: cyclosporinee 0.05%. Inactives: glycerin; castor oil; polysorbate 80; carbomer copolymer type A; purified water; and sodium hydroxide to adjust pH.	
cyclosporine	Teva-Cyclosporine	Cyclosporine	02462486	Teva Canada Ltd.	30 Novopharm Court Toronto Ontario Canada M1B 2K9	0.05%	emulsion	1	cyclosporine emulsion, 0.05% w/v non-medicinal ingredients: Carbomer Copolymer Type A, castor oil, glycerin, polysorbate 80, purified water and sodium hydroxide	Cyclosporine	Cyclosporine	0.05%	60505-6202-02	NDA Authorized Generic	050790	Allergan Sales, LLC.	Waco, Texas (TX) 76712-6578, United States (USA)	cyclosporine 0.05% inactive: glycerin, castor oil, polysorbate 80, carbomer copolymer type A, purified water, sodium hydroxide to adjust PH.	This is an authorized generic marketed by Apotex Corp., 2400 N Commerce Pkwy, Weston, FL 33326
cyclosporine	Teva-Cyclosporine	Cyclosporine	02462486	Teva Canada Ltd.	30 Novopharm Court Toronto Ontario Canada M1B 2K9	0.05%	emulsion	1	cyclosporine emulsion, 0.05% w/v non-medicinal ingredients: Carbomer Copolymer Type A, castor oil, glycerin, polysorbate 80, purified water and sodium hydroxide	Cyclosporine	Cyclosporine	0.05%	00378-8760-58	ANDA	205894	Mylan Pharmaceuticals Inc.	5005 Greenbag Road, Morgantown, West Virginia (WV) 26508, United States (USA)	cyclosporine 0.05% inactive: glycerin, castor oil, polysorbate 80, carbomer copolymer type A (allyl pentaerythritol crosslinked), purified water, sodium hydroxide to adjust PH.	
cyclosporine	Teva-Cyclosporine	Cyclosporine	02462486	Teva Canada Ltd.	30 Novopharm Court Toronto Ontario Canada M1B 2K9	0.05%	emulsion	1	cyclosporine emulsion, 0.05% w/v non-medicinal ingredients: Carbomer Copolymer Type A, castor oil, glycerin, polysorbate 80, purified water and sodium hydroxide	Cyclosporine	Cyclosporine	0.05%	68180-0214-30	NDA Authorized Generic	050790	Allergan Sales, LLC.	Waco, Texas (TX) 76712-6578, United States (USA)	cyclosporine 0.05% inactive: glycerin, castor oil, polysorbate 80, carbomer copolymer type A, purified water, sodium hydroxide to adjust PH.	This is an authorized generic marketed by Lupin Pharmaceuticals, Inc. Baltimore MD, 21202, USA
cyclosporine	Teva-Cyclosporine	Cyclosporine	02462486	Teva Canada Ltd.	30 Novopharm Court Toronto Ontario Canada M1B 2K9	0.05%	emulsion	1	cyclosporine emulsion, 0.05% w/v non-medicinal ingredients: Carbomer Copolymer Type A, castor oil, glycerin, polysorbate 80, purified water and sodium hydroxide	Cyclosporine	Cyclosporine	0.05%	10702-0808-03	NDA Authorized Generic	050790	Allergan Sales, LLC.	Waco, Texas (TX) 76712-6578, United States (USA)	cyclosporine 0.05% inactive: glycerin, castor oil, polysorbate 80, carbomer copolymer type A, purified water, sodium hydroxide to adjust PH.	This is an authorized generic marketed by KVK-Tech, Inc. 110 Terry Dr. Newtown, PA, 18940, United States (USA)
dapaglifozin	Forxiga	Dapagliflozin	02435462	AstraZeneca Canada Inc.	1004 Middlegate Road, Suite 5000 Mississauga Ontario Canada L4Y 1M4	5mg	tablet	1	5 mg dapagliflozin as dapagliflozin propanediol monohydrate, anhydrous lactose, crospovidone, magnesium stearate, microcrystalline cellulose, silicon dioxide. The film coating contains the following inactive ingredients: polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc and yellow iron oxide.	Farxiga	Dapagliflozin	5mg	00310-6205-30	NDA	202293	AstraZeneca Pharmaceuticals LP	1800 Concord Pike, Wilmington, DE 19803	5 mg dapagliflozin as dapagliflozin propanediol inactive: microcrystalline cellulose, anhydrous lactose, crospovidone, silicon dioxide, and magnesium stearate. The film coating contains: polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc, and yellow iron oxide.	
dapaglifozin	Forxiga	Dapagliflozin	02435470	AstraZeneca Canada Inc.	1004 Middlegate Road, Suite 5000 Mississauga Ontario Canada L4Y 1M4	10mg	tablet	1	10 mg dapagliflozin as dapagliflozin propanediol monohydrate, anhydrous lactose, crospovidone, magnesium stearate, microcrystalline cellulose, silicon dioxide. The film coating contains the following non-medicinal ingredients: polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc and yellow iron oxide.	Farxiga	Dapagliflozin	10mg	00310-6210-30	NDA	202293	AstraZeneca Pharmaceuticals LP	1800 Concord Pike, Wilmington, DE 19803	10 mg dapagliflozin as dapagliflozin propanediol inactive: microcrystalline cellulose, anhydrous lactose, crospovidone, silicon dioxide, and magnesium stearate. The film coating contains: polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc, and yellow iron oxide.	
darunavir/ cobicistat/ emtricitabine/ tenofovir alafenamide	Symtuza	darunavir/ cobicistat/ emtricitabine/ tenofovir alafenamide	02473720	Janssen Inc.	19 Green Belt Drive Toronto Ontario Canada M3C 1L9	800/150/ 200/10mg	tablet	4	800 mg darunavir(as 867mg darunavir ethanolate)/ 150 mg cobicistat/ 200 mg emtricitabine/ 10 mg tenofovir alafenamide (as 11.2 mg tenofovir alafenamide hemifumarate) non-medicinal: Tablet core: colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, microcrystalline cellulose. Film-coating: polyethylene glycol (macrogol), polyvinyl alcohol (partially hydrolyzed), talc, titanium dioxide, yellow ferric oxide.	Symtuza	darunavir/ cobicistat/ emtricitabine/ tenofovir alafenamide	800/150/ 200/10mg	59676-0800-30	NDA	210455	Janssen Pharmaceuticals, Inc.	PO Box 200 1125 Trenton Harbourton Rd, Titusville, New Jersey (NJ) 08560-1504, United States (USA)	darunavir/ cobicistat/ emtricitabine/ tenofovir alafenamide silicon dioxide, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, polyethylene glycol (unspecified), talc, titanium dioxide, ferric oxide yellow	
dasatinib	Sprycel	Dasatinib (Dasitinib Monohydrate)	02293137	Bristol-Myers Squibb Canada	2344 Boul. Alfred-Nobel Suite 300 Montreal (St-Laurent) Quebec Canada H4A 0A4	50mg	tablet	1	50 mg dasatinib (as monohydrate) non-medicinal ingredients for the tablet core: croscarmellose sodium, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate and microcrystalline cellulose. The film-coating contain the following non-medicinal ingredients: hypromellose, polyethylene glycol and titanium dioxide.	Sprycel	Dasatinib (Dasitinib Monohydrate)	50mg	00003-0528-11	NDA	021986	Bristol-Myers Squibb	100 Nassau Park Blvd #300, Princeton, NJ 08540	dasatinib, with the following inactive ingredients: lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, hydroxypropyl cellulose, and magnesium stearate. The tablet coating consists of hypromellose, titanium dioxide, and polyethylene glycol unspecified	

Appendix D: Drug List with Required Data Elements

Active Ingredient	Canadian Proprietary Name	Canadian Generic Name	DIN	Company Name	Address	CAN Strength	Dosage Form	# of active Ingred.	Canadian Ingredients	US Proprietary Name	US Generic Name	US Strength	NDC	NDA or ANDA	Number	Applicant Holder Name	Applicant Holder Address	US Ingredients	Comment for FDA
dasatinib	Sprycel	Dasatinib (Dasitinib Monohydrate)	02320193	Bristol-Myers Squibb Canada	2344 Boul. Alfred-Nobel Suite 300 Montreal (St-Laurent) Quebec Canada H4A 0A4	100mg	tablet	1	100 mg dasatinib (as monohydrate) non-medicinal ingredients for the tablet core: croscarmellose sodium, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate and microcrystalline cellulose. The film-coating contain the following inactive ingredients: hypromellose, polyethylene glycol and titanium dioxide.	Sprycel	Dasatinib (Dasitinib Monohydrate)	100mg	00003-0852-22	NDA	021986	Bristol-Myers Squibb	100 Nassau Park Blvd #300, Princeton, NJ 08540	dasatinib, with the following inactive ingredients: lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, hydroxypropyl cellulose, and magnesium stearate. The tablet coating consists of hypromellose, titanium dioxide, and polyethylene glycol unspecified	
dolutegravir	Tivicay	Dolutegravir (dolutegravir sodium)	02414945	Viiv Healthcare Ulc.	1400 75 Rue Queen Montreal Quebec Canada H3C 2N6	50mg	tablet	1	52.6 mg of dolutegravir sodium, which is equivalent to 50 mg dolutegravir free acid non-medicinal: D-mannitol, microcrystalline cellulose, povidone K29/32, sodium starch glycolate, and sodium stearyl fumarate. The tablet film-coating contains the inactive ingredients iron oxide yellow (25 mg and 50 mg tablets only), macrogol/PEG, polyvinyl alcohol – part hydrolyzed, talc, and titanium dioxide	Tivicay	Dolutegravir	50mg	49702-0228-13	NDA	204790	ViiV Healthcare Company	Five Moore Drive, P.O. Box 13398 Research Triangle Park, NC 27709	52.6 mg of dolutegravir sodium, which is equivalent to 50 mg dolutegravir inactive. D-mannitol, microcrystalline cellulose, povidone K29/32, sodium starch glycolate, and sodium stearyl fumarate. The tablet film-coating contains the inactive ingredients iron oxide yellow (for the 25-mg and 50-mg tablets only), macrogol/PEG, polyvinyl alcohol-part hydrolyzed, talc, and titanium dioxide.	
dolutegravir, abacavir, and lamivudine	Triumeq	dolutegravir, abacavir, and lamivudine	02430932	Viiv Healthcare Ulc.	1400 75 Rue Queen Montreal Quebec Canada H3C 2N6	600-50-300mg	tablet	3	50 mg dolutegravir (as dolutegravir sodium), 600 mg abacavir (as abacavir sulfate) and 300 mg lamivudine non-medicinal: D-mannitol, magnesium stearate, microcrystalline cellulose, povidone K29/32, and sodium starch glycolate. The tablet film-coating (OPADRY II Purple 85F90057) contains the inactive ingredients iron oxide black, iron oxide red, macrogol/PEG, polyvinyl alcohol-part hydrolyzed, talc, and titanium dioxide.	Triumeq	dolutegravir, abacavir, and lamivudine	600-50-300mg	49702-231-13	NDA	205551	ViiV Healthcare Company	Five Moore Drive, P.O. Box 13398 Research Triangle Park, NC 27710	abacavir sulfate, dolutegravir sodium, lamivudine inactive: mannitol, magnesium stearate, microcrystalline cellulose, povidone (unspecified), sodium starch glycolate type a corn, ferrosoferric oxide, ferric oxide red, polyethylene glycol (unspecified), polyvinyl alcohol (unspecified), talc, titanium dioxide	
eltrombopag	Revolade	Eltrombopag (Elotrombopag olamine)	02361825	Novartis Pharmaceuticals Canada Inc.	385 Bouchard Blvd Dorval Quebec Canada, H9S 1A9	25mg	tablet	1	25 mg eltrombopag as eltrombopag olamine. non-medicinal ingredients: magnesium stearate, mannitol, microcrystalline cellulose, povidone, sodium starch glycolate, hypromellose, macrogol and titanium dioxide, polysorbate.	Promacta	Eltrombopag (Elotrombopag olamine)	25mg	00078-0685-15	NDA	022291	Novartis Pharmaceuticals Corporation	220 E Hanover Ave, Morris Plains, NJ, 07950	eltrombopag olamine 25 mg. inactive: Tablet Core: magnesium stearate, mannitol, microcrystalline cellulose, povidone, and sodium starch glycolate, hypromelloses, polyethylene glycol 400, titanium dioxide, ferric oxide red, ferrosoferric oxide.	
eltrombopag	Revolade	Eltrombopag (Elotrombopag olamine)	02361833	Novartis Pharmaceuticals Canada Inc.	385 Bouchard Blvd Dorval Quebec Canada, H9S 1A9	50mg	tablet	1	50 mg of eltrombopag as eltrombopag olamine. non-medicinal ingredients: magnesium stearate, mannitol, microcrystalline cellulose, povidone, sodium starch glycolate, hypromellose, macrogol and titanium dioxide, iron oxide yellow and iron oxide red.	Promacta	Eltrombopag (Elotrombopag olamine)	50mg	00078-0686-15	NDA	022291	Novartis Pharmaceuticals Corporation	220 E Hanover Ave, Morris Plains, NJ, 07950	eltrombopag olamine 50 mg. inactive: Tablet Core: magnesium stearate, mannitol, microcrystalline cellulose, povidone, and sodium starch glycolate, hypromelloses, polyethylene glycol 400, titanium dioxide, FD&C Blue number 2	
elvitegravir, cobicistat, emtricitabine, tenofovir alafenamide	Genvoya	elvitegravir, cobicistat, emtricitabine, tenofovir alafenamide	02449498	Gilead Sciences Canada Inc.	600 6711 Mississauga Road Mississauga Ontario Canada L5N 2W3	150-150-200-10mg	tablet	4	Each tablet contains 150 mg of elvitegravir, 150 mg of cobicistat, 200 mg of emtricitabine, and 10 mg of tenofovir alafenamide (as 11.2 mg of tenofovir alafenamide hemifumarate). non-medicinal: croscarmellose sodium, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, silicon dioxide, and sodium lauryl sulfate. The tablets are coated with a coating material containing polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc, indigo carmine aluminum lake, and iron oxide yellow.	Genvoya	elvitegravir, cobicistat, emtricitabine, tenofovir alafenamide	150-150-200-10mg	61958-1901-1	NDA	207561	Gilead Sciences, Inc.	333 Lakeside Drive Foster City, CA 94404	elvitegravir, cobicistat, emtricitabine, tenofovir alafenamide fumarate inactive ingredients: lactose monohydrate, microcrystalline cellulose, hydroxypropyl cellulose , sodium lauryl sulfate, croscarmellose sodium, water, magnesium stearate, polyvinyl alcohol (unspecified), titanium dioxide, polyethylene glycol (unspecified), talc, FD&C blue no. 2, ferric oxide yellow.	
empagliflozin	Jardiance	empagliflozin	02443937	Boehringer Ingelheim (Canada), LTD LTEE	5180 South Service Road Burlington Ontario Canada L7L 5H4	10mg	tablet	1	10mg mg of empagliflozin non-medicinal ingredients: colloidal silicon dioxide, croscarmellose sodium, hydroxypropyl cellulose, hypromellose, lactose monohydrate, magnesium stearate, macrogol, microcrystalline cellulose, titanium dioxide, talc, and yellow ferric oxide.	Jardiance	empagliflozin	10mg	0597-0152-30	NDA	204629	Boehringer Ingelheim Pharmaceuticals, Inc.	900 Ridgebury Road P.O. Box 368 Ridgefield, CT 06877	10 mg or empagliflozin (free base) and the following inactive ingredients: lactose monohydrate, microcrystalline cellulose, hydroxypropyl cellulose, croscarmellose sodium, colloidal silicon dioxide and magnesium stearate. In addition, the film coating contains the following inactive ingredients: hypromellose, titanium dioxide, talc, polyethylene glycol, and yellow ferric oxide.	
empagliflozin	Jardiance	empagliflozin	02443945	Boehringer Ingelheim (Canada), LTD LTEE	5180 South Service Road Burlington Ontario Canada L7L 5H4	25mg	tablet	1	25 mg of empagliflozin non-medicinal ingredients: colloidal silicon dioxide, croscarmellose sodium, hydroxypropyl cellulose, hypromellose, lactose monohydrate, magnesium stearate, macrogol, microcrystalline cellulose, titanium dioxide, talc, and yellow ferric oxide.	Jardiance	empagliflozin	25mg	0597-0153-30	NDA	204629	Boehringer Ingelheim Pharmaceuticals, Inc.	900 Ridgebury Road P.O. Box 368 Ridgefield, CT 06877	25 mg or empagliflozin (free base) and the following inactive ingredients: lactose monohydrate, microcrystalline cellulose, hydroxypropyl cellulose, croscarmellose sodium, colloidal silicon dioxide and magnesium stearate. In addition, the film coating contains the following inactive ingredients: hypromellose, titanium dioxide, talc, polyethylene glycol, and yellow ferric oxide.	
emtricitabine, rilpivirine, tenofovir alafenamide	Odefsey	emtricitabine, rilpivirine, tenofovir alafenamide	02461463	Gilead Sciences Canada Inc.	600 6711 Mississauga Road Mississauga Ontario Canada L5N 2W3	200-25-25mg	tablet	3	Each tablet contains 200 mg of emtricitabine, 25 mg of rilpivirine, (as 27.5 mg of rilpivirine hydrochloride) and 25 mg of tenofovir alafenamide (as 28.0 mg of tenofovir alafenamide hemifumarate). non-medicinal: croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polysorbate 20 and povidone. The tablets are film-coated with a coating material containing polyvinyl alcohol, titanium dioxide, macrogol/polyethylene glycol, talc, and iron oxide black.	Odefsey	emtricitabine, rilpivirine, tenofovir alafenamide	200-25-25mg	61958-2101- 1	NDA	208351	Gilead Sciences, Inc.	333 Lakeside Drive Foster City, CA 94404	Each tablet contains 200 mg of FTC, 25 mg of RPV (equivalent to 27.5 of rilpivirine hydrochloride) and 25 mg of TAF (equivalent to 28 mg of tenofovir alafenamide fumarate) and the following inactive ingredients: croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polysorbate 20, and povidone. The tablets are film-coated with a coating material containing iron oxide black, polyethylene glycol, polyvinyl alcohol, talc, and titanium dioxide.	

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Active Ingredient	Canadian Proprietary Name	Canadian Generic Name	DIN	Company Name	Address	CAN Strength	Dosage Form	# of active Ingred.	Canadian Ingredients	US Proprietary Name	US Generic Name	US Strength	NDC	NDA or ANDA	Number	Applicant Holder Name	Applicant Holder Address	US Ingredients	Comment for FDA
emtricitabine/ tenofovir alafenamide	Descovy	emtricitabine/ tenofovir alafenamide	02454424	Gilead Sciences Canada Inc.	600 6711 Mississauga Road Mississauga Ontario Canada L5N 2W3	200-25mg	tablet	2	200 mg emtricitabine, 25 mg tenofovir alafenamide non-medicinal: microcrystalline cellulose, croscarmellose sodium, and magnesium stearate. The grey tablets are film-coated with a coating material containing polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc, and iron oxide black. The blue tablets are film coated with a coating material containing polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc, and indigo carmine aluminum lake.	Descovy	emtricitabine/ tenofovir alafenamide	200-25mg	61958-2002-1	NDA	208215	Gilead Sciences, Inc.	333 Lakeside Drive Foster City, CA 94404	emtricitabine (FTC) , tenofovir alafenamide fumarate (TAF) inactive ingredients: microcrystalline cellulose, croscarmellose sodium, magnesium stearate, water, polyvinyl alcohol, titanium dioxide, polyethylene glycol 3350, talc, FD&C blue	
emtricitabine/ tenofovir alafenamide	Descovy	emtricitabine/ tenofovir alafenamide	02454416	Gilead Sciences Canada Inc.	600 6711 Mississauga Road Mississauga Ontario Canada L5N 2W3	200-25mg	tablet	2	200 mg emtricitabine, 25 mg tenofovir alafenamide non-medicinal: microcrystalline cellulose, croscarmellose sodium, and magnesium stearate. The grey tablets are film-coated with a coating material containing polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc, and iron oxide black. The blue tablets are film coated with a coating material containing polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc, and indigo carmine aluminum lake.	Descovy	emtricitabine/ tenofovir alafenamide	200-25mg	61958-2002-1	NDA	208215	Gilead Sciences, Inc.	333 Lakeside Drive Foster City, CA 94404	emtricitabine (FTC) , tenofovir alafenamide fumarate (TAF) inactive ingredients: microcrystalline cellulose, croscarmellose sodium, magnesium stearate, water, polyvinyl alcohol, titanium dioxide, polyethylene glycol 3350, talc, FD&C blue	
enzalutamide	Xtandi	Enzalutamide	02407329	Astellas Pharma Canada Inc.	675 Cochrane Drive, West Tower Suite 500 Markham Ontario Canada, L3R 0B8	40mg	capsule	1	40 mg of enzalutamide non-medicinal ingredients: caprylocaproyl macrogolglycerides, butylhydroxyanisole and butylhydroxytoluene. The ingredients of the capsule shell are gelatin, sorbitol sorbitan solution, glycerol, titanium dioxide (E171), and purified water. The ingredients of the ink are: ethanol, ethyl acetate, propylene glycol, iron oxide black (E172), polyvinyl acetate phthalate, purified water, isopropyl alcohol, macrogol 400, and ammonia solution concentrated.	Xtandi	Enzalutamide	40mg	00469-0125-99	NDA	203415	Astellas Pharma US, Inc.	One Astellas Way Northbrook, IL 60062	40 mg of enzalutamide as a solution in caprylocaproyl polyoxylglycerides. The inactive ingredients are caprylocaproyl polyoxylglycerides, butylated hydroxyanisole, butylated hydroxytoluene, gelatin, sorbitol sorbitan solution, glycerin, purified water, titanium dioxide, and black iron oxide	
epinephrine	Allerject	epinephrine	02382067	Kaleo Inc.	111 Virginia Street, Suite 300 Richmond Virginia United States 23219	0.3mg	autoinjector	1	epinephrine auto-injector non-medicinal: hydrochloric acid, sodium chloride, sodium metabisulfite, water for injection	Epinephrine	epinephrine	0.3mg	0093-5986-27	ANDA	090589	Teva Pharmaceuticals USA, Inc.	North Wales, PA 19454	Each 0.3 mL in the Auto-Injector contains 0.3 mg epinephrine, sodium chloride, sodium metabisulfite, sodium tartrate dihydrate, hydrochloric acid, and water.	
epinephrine	Allerject	epinephrine	02382067	Kaleo Inc.	111 Virginia Street, Suite 300 Richmond Virginia United States 23219	0.3mg	autoinjector	1	epinephrine auto-injector non-medicinal: hydrochloric acid, sodium chloride, sodium metabisulfite, water for injection	EpiPen	epinephrine	0.3mg	49502-0500-02	NDA	019430	Mylan Specialty LP	781 Chestnut Ridge Rd, Morgantown, WV 26505	Each 0.3 mL in the EpiPen Auto-Injector contains 0.3 mg epinephrine, sodium chloride, sodium metabisulfite, hydrochloric acid, and Water.	
epinephrine	Allerject	epinephrine	2382059	Kaleo Inc.	111 Virginia Street, Suite 300 Richmond Virginia United States 23219	0.15mg	autoinjector	1	epinephrine auto-injector non-medicinal: hydrochloric acid, sodium chloride, sodium metabisulfite, water for injection	Epinephrine	epinephrine	0.15mg	0093-5985-27	ANDA	090589	Teva Pharmaceuticals USA, Inc.	North Wales, PA 19454	Each 0.3 mL in the Auto-Injector contains 0.15 mg epinephrine, sodium chloride, sodium metabisulfite, sodium tartrate dihydrate, hydrochloric acid, and water.	
epinephrine	Allerject	epinephrine	2382059	Kaleo Inc.	111 Virginia Street, Suite 300 Richmond Virginia United States 23219	0.15mg	autoinjector	1	epinephrine auto-injector non-medicinal: hydrochloric acid, sodium chloride, sodium metabisulfite, water for injection	EpiPen Jr.	epinephrine	0.15mg	49502-0501-02	NDA	019430	Mylan Specialty LP	781 Chestnut Ridge Rd, Morgantown, WV 26505	Each 0.3 mL in the EpiPen Auto-Injector contains 0.3 mg epinephrine, sodium chloride, sodium metabisulfite, hydrochloric acid, and Water.	
epinephrine	Emerade	epinephrine	02458446	Bausch Health Canada, Inc.	2150 Boul. St-Elzear Ouest Laval Quebec Canada H7L 4A8	0.3mg	pre-filled pen	1	0.3 mg of epinephrine (as hydrogen tartrate). Non-medicinal ingredients: Sodium chloride, Sodium metabisulfite, Disodium edetate, Hydrochloric acid (for adjustment of pH), Water for injection	Epinephrine	epinephrine	0.3mg	0093-5986-27	ANDA	090589	Teva Pharmaceuticals USA, Inc.	North Wales, PA 19454	Each 0.3 mL in the Auto-Injector contains 0.3 mg epinephrine, sodium chloride, sodium metabisulfite, sodium tartrate dihydrate, hydrochloric acid, and water.	
epinephrine	Emerade	epinephrine	02458446	Bausch Health Canada, Inc.	2150 Boul. St-Elzear Ouest Laval Quebec Canada H7L 4A8	0.3mg	pre-filled pen	1	0.3mg of epinephrine (as hydrogen tartrate). Non-medicinal ingredients: Sodium chloride, Sodium metabisulfite, Disodium edetate, Hydrochloric acid (for adjustment of pH), Water for injection	EpiPen	epinephrine	0.3mg	49502-0500-02	NDA	019430	Mylan Specialty LP	781 Chestnut Ridge Rd, Morgantown, WV 26505	Each 0.3 mL in the EpiPen Auto-Injector contains 0.3 mg epinephrine, sodium chloride, sodium metabisulfite, hydrochloric acid, and Water.	
epinephrine	Emerade	epinephrine	02458438	Bausch Health Canada, Inc.	2150 Boul. St-Elzear Ouest Laval Quebec Canada H7L 4A8	0.15mg	pre-filled pen	1	0.15 mg of epinephrine (as hydrogen tartrate). Non-medicinal ingredients: Sodium chloride, Sodium metabisulfite, Disodium edetate, Hydrochloric acid (for adjustment of pH), Water for injection	Epinephrine	epinephrine	0.15mg	0093-5985-27	ANDA	090589	Teva Pharmaceuticals USA, Inc.	North Wales, PA 19454	Each 0.3 mL in the Auto-Injector contains 0.15 mg epinephrine, sodium chloride, sodium metabisulfite, sodium tartrate dihydrate, hydrochloric acid, and water.	
epinephrine	Emerade	epinephrine	02458438	Bausch Health Canada, Inc.	2150 Boul. St-Elzear Ouest Laval Quebec Canada H7L 4A8	0.15mg	pre-filled pen	1	0.15 mg of epinephrine (as hydrogen tartrate). Non-medicinal ingredients: Sodium chloride, Sodium metabisulfite, Disodium edetate, Hydrochloric acid (for adjustment of pH), Water for injection	EpiPen Jr.	epinephrine	0.15mg	49502-0501-02	NDA	019430	Mylan Specialty LP	781 Chestnut Ridge Rd, Morgantown, WV 26505	Each 0.3 mL in the EpiPen Auto-Injector contains 0.3 mg epinephrine, sodium chloride, sodium metabisulfite, hydrochloric acid, and Water.	

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Active Ingredient	Canadian Proprietary Name	Canadian Generic Name	DIN	Company Name	Address	CAN Strength	Dosage Form	# of active Ingred.	Canadian Ingredients	US Proprietary Name	US Generic Name	US Strength	NDC	NDA or ANDA	Number	Applicant Holder Name	Applicant Holder Address	US Ingredients	Comment for FDA
epinephrine	EpiPen	epinephrine	00509558	Mylan Specialty, LP	3711 Collins Ferry Road Morgantown West Virginia United States 26505	0.3mg	autoinjector	1	epinephrine auto-injector non-medicinal: hydrochloric acid, sodium chloride, sodium metabisulfite, water for injection	Epinephrine	epinephrine	0.3mg	0093-5986-27	ANDA	090589	Teva Pharmaceuticals USA, Inc.	North Wales, PA 19454	Each 0.3 mL in the Auto-Injector contains 0.3 mg epinephrine, sodium chloride, sodium metabisulfite, sodium tartrate dihydrate, hydrochloric acid, and water.	
epinephrine	EpiPen	epinephrine	00509558	Mylan Specialty, LP	3711 Collins Ferry Road Morgantown West Virginia United States 26505	0.3mg	autoinjector	1	epinephrine auto-injector non-medicinal: hydrochloric acid, sodium chloride, sodium metabisulfite, water for injection	EpiPen	epinephrine	0.3mg	49502-0500-02	NDA	019430	Mylan Specialty LP	781 Chestnut Ridge Rd, Morgantown, WV 26505	Each 0.3 mL in the EpiPen Auto-Injector contains 0.3 mg epinephrine, sodium chloride, sodium metabisulfite, hydrochloric acid, and Water.	
epinephrine	EpiPen Jr	epinephrine	00578657	Mylan Specialty, LP	3711 Collins Ferry Road Morgantown West Virginia United States 26505	0.15mg	autoinjector	1	epinephrine auto-injector non-medicinal: hydrochloric acid, sodium chloride, sodium metabisulfite, water for injection	Epinephrine	epinephrine	0.15mg	0093-5985-27	ANDA	090589	Teva Pharmaceuticals USA, Inc.	North Wales, PA 19454	Each 0.3 mL in the Auto-Injector contains 0.15 mg epinephrine, sodium chloride, sodium metabisulfite, sodium tartrate dihydrate, hydrochloric acid, and water.	
epinephrine	EpiPen Jr	epinephrine	00578657	Mylan Specialty, LP	3711 Collins Ferry Road Morgantown West Virginia United States 26505	0.15mg	autoinjector	1	epinephrine auto-injector non-medicinal: hydrochloric acid, sodium chloride, sodium metabisulfite, water for injection	EpiPen Jr.	epinephrine	0.15mg	49502-0501-02	NDA	019430	Mylan Specialty LP	781 Chestnut Ridge Rd, Morgantown, WV 26505	Each 0.3 mL in the EpiPen Auto-Injector contains 0.3 mg epinephrine, sodium chloride, sodium metabisulfite, hydrochloric acid, and Water.	
estradiol	Estring	estradiol	02168898	Pfizer Canada Ulc.	17300 Trans-Canada Highway Kirkland Quebec Canada H9J 2M5	2mg	vaginal ring	1	estradiol non-medicinal ingredients: Silicone elastomer. Barium sulphate, Silicone fluid	Estring	estradiol	2mg	00013-2150-36	NDA	020472	Pfizer Laboratories Div. Pfizer Inc.	257 Eastern Point Road, Groton, CT 06340 USA	estradiol, barium sulfate	
estradiol	Imvexxy	estradiol	02503689	Knight Therapeutics, Inc.	3400 De Maisonneuve W., Suite 1055 Montreal, Quebec, Canada H3Z 3B8	4mcg	vaginal insert	1	estradiol - Small, light pink, tearshaped, softgel inserts of 4mcg estradiol. non-medicinal ingredients: Ethylene glycol palmitostearate, FD&C Red #40, gelatin, glycerin, hydrolyzed gelatin, lecithin, mannitol, medium chain triglycerides, pharmaceutical ink, polyethylene glycol stearates, purified water, sorbitan, sorbitol, titanium dioxide.	Imvexxy	estradiol	4mcg/insert	50261-104-18	NDA	208564	TherapeuticsMD, Inc.	951 Yamato Rd #220, Boca Raton, FL 33431	estradiol 4mcg inactive: medium-chain triglycerides, PEG-6 stearate, PEG-32 stearate, glycol stearate, gelatin (unspecified), sorbitol, sorbitan, mannitol, glycerin, FD&C red #40, titanium dioxide, water, ethyl acetate, propylene glycol, polyvinyl acetate phthalate, isopropyl alcohol, polyethylene glycol (unspecified), ammonia, alcohol, lechitan (soybean)	
estradiol	Imvexxy	estradiol	02503697	Knight Therapeutics, Inc.	3400 De Maisonneuve W., Suite 1055 Montreal, Quebec, Canada H3Z 3B8	10mcg	vaginal insert	1	estradiol - Small, light pink, tearshaped, softgel inserts of 10 mcg estradiol. non-medicinal ingredients: Ethylene glycol palmitostearate, FD&C Red #40, gelatin, glycerin, hydrolyzed gelatin, lecithin, mannitol, medium chain triglycerides, pharmaceutical ink, polyethylene glycol stearates, purified water, sorbitan, sorbitol, titanium dioxide.	Imvexxy	estradiol	10mcg/insert	50261-110-08	NDA	208564	TherapeuticsMD, Inc.	951 Yamato Rd #220, Boca Raton, FL 33431	estradiol 10mcg inactive: medium-chain triglycerides, PEG-6 stearate, PEG-32 stearate, glycol stearate, gelatin (unspecified), sorbitol, sorbitan, mannitol, glycerin, FD&C red #40, titanium dioxide, water, ethyl acetate, propylene glycol, polyvinyl acetate phthalate, isopropyl alcohol, polyethylene glycol (unspecified), ammonia, alcohol, lechitan (soybean)	
ethinyl estradiol/ etonogestrel	Haloette	ethinyl estradiol/ etonogestrel	02520028	Searchlight Pharma, Inc.	1600 Rue Notre Dame Ouest, Suite 312 Montreal, Quebec Canada H3J 1M1	2.6mg - 11.4 mg	vaginal ring	2	Active Ingredients: Slow release vaginal ring, 11.7 mg etonogestrel / 2.7 mg ethinyl estradiol (120 mcg etonogestrel / 15 mcg ethinyl estradiol per day) non-medicinal: Ethylene vinylacetate copolymers	EluRyng	ethinyl estradiol/ etonogestrel	2.6mg - 11.4 mg	65162-0469-35	ANDA	210830	Amneal Pharmaceuticals, LLC	995 US Hwy 202/206, Bridgewater, New Jersey (NJ) 08807, United States (USA)	each ring releases on average 0.120 mg/day of etonogestrel and 0.015 mg/day of ethinyl estradiol from 11.7 mg etonogestrel and 2.7 mg ethinyl estradiol, USP Inactive: ethylene vinylacetate copolymers & magnesium stearate	
ethinyl estradiol/ etonogestrel	Haloette	ethinyl estradiol/ etonogestrel	02520028	Searchlight Pharma, Inc.	1600 Rue Notre Dame Ouest, Suite 312 Montreal, Quebec Canada H3J 1M1	2.6mg - 11.4 mg	vaginal ring	2	Active Ingredients: Slow release vaginal ring, 11.7 mg etonogestrel / 2.7 mg ethinyl estradiol (120 mcg etonogestrel / 15 mcg ethinyl estradiol per day) non-medicinal: Ethylene vinylacetate copolymers	Nuvaring	ethinyl estradiol/ etonogestrel	2.6mg - 11.4 mg	78206-0146-03	NDA	021187	Organon USA,LLC	Organon USA,LLC, a subsidiary of Organon & CO Jersey City, NJ 07302	each ring releases on average 0.120 mg/day of etonogestrel and 0.015 mg/day of ethinyl estradiol over a three-week period of use. NuvaRing is made of ethylene vinylacetate copolymers (28% and 9% vinylacetate) and magnesium stearate and contains 11.7 mg etonogestrel and 2.7 mg ethinyl estradiol.	
ethinyl estradiol/ etonogestrel	Haloette	ethinyl estradiol/ etonogestrel	02520028	Searchlight Pharma, Inc.	1600 Rue Notre Dame Ouest, Suite 312 Montreal, Quebec Canada H3J 1M1	2.6mg - 11.4 mg	vaginal ring	2	Active Ingredients: Slow release vaginal ring, 11.7 mg etonogestrel / 2.7 mg ethinyl estradiol (120 mcg etonogestrel / 15 mcg ethinyl estradiol per day) non-medicinal: Ethylene vinylacetate copolymers	etonogestrel - ethinyl estradiol	ethinyl estradiol/ etonogestrel	2.6mg - 11.4 mg	66993-0605-36	NDA Authorized Generic	021187	Organon USA,LLC	Organon USA,LLC, a subsidiary of Organon & CO Jersey City, NJ 07302	etonogestrel & ethinyl estradiol inactive: ethylene-vinyl acetate copolymer (28% vinyl acetate), ethylene-vinyl acetate copolymer (9% vinyl acetate), magnesium stearate	This is an authorized generic marketed by Prasco Laboratories, Mason, OH 45040 USA
ethinyl estradiol/ etonogestrel	Haloette	ethinyl estradiol/ etonogestrel	02520028	Searchlight Pharma, Inc.	1600 Rue Notre Dame Ouest, Suite 312 Montreal, Quebec Canada H3J 1M1	2.6mg - 11.4 mg	vaginal ring	2	Active Ingredients: Slow release vaginal ring, 11.7 mg etonogestrel / 2.7 mg ethinyl estradiol (120 mcg etonogestrel / 15 mcg ethinyl estradiol per day) non-medicinal: Ethylene vinylacetate copolymers	etonogestrel - ethinyl estradiol	ethinyl estradiol/ etonogestrel	2.6mg - 11.4 mg	00093-7679-02	ANDA	204305	Teva Pharmaceuticals, USA, Inc.	North Wales, PA 19454	etonogestrel & ethinyl estradiol inactive: ethylene-vinyl acetate copolymer (28% vinyl acetate), ethylene-vinyl acetate copolymer (9% vinyl acetate), magnesium stearate	
ethinyl estradiol/ etonogestrel	Nuvaring	ethinyl estradiol/ etonogestrel	02253186	Organon Canada Inc.	300 16766 Route Transcanadienne Kirkland Quebec Canada H9H 4M7	2.6mg - 11.4 mg	vaginal ring	2	Slow release vaginal ring / 11.4 mg etonogestrel / 2.6 mg ethinyl estradiol (120 mcg etonogestrel/15 mcg ethinyl estradiol per day) non-medicinal ingredients: Ethylene vinylacetate copolymers (28% and 9% vinylacetate) and magnesium stearate.	Nuvaring	ethinyl estradiol/ etonogestrel	2.6mg - 11.4 mg	78206-0146-03	NDA	021187	Organon USA,LLC	Organon USA,LLC, a subsidiary of Organon & CO Jersey City, NJ 07302	each ring releases on average 0.120 mg/day of etonogestrel and 0.015 mg/day of ethinyl estradiol over a three-week period of use. NuvaRing is made of ethylene vinylacetate copolymers (28% and 9% vinylacetate) and magnesium stearate and contains 11.7 mg etonogestrel and 2.7 mg ethinyl estradiol.	

Appendix D: Drug List with Required Data Elements

Active Ingredient	Canadian Proprietary Name	Canadian Generic Name	DIN	Company Name	Address	CAN Strength	Dosage Form	# of active Ingred.	Canadian Ingredients	US Proprietary Name	US Generic Name	US Strength	NDC	NDA or ANDA	Number	Applicant Holder Name	Applicant Holder Address	US Ingredients	Comment for FDA
ethinyl estradiol/ etonogestrel	Nuvaring	ethinyl estradiol/ etonogestrel	02253186	Organon Canada Inc.	300 16766 Route Transcanadienne Kirkland Quebec Canada H9H 4M7	2.6mg - 11.4 mg	vaginal ring	2	Slow release vaginal ring / 11.4 mg etonogestrel / 2.6 mg ethinyl estradiol (120 mcg etonogestrel/15 mcg ethinyl estradiol per day) non-medicinal ingredients: Ethylene vinylacetate copolymers (28% and 9% vinylacetate) and magnesium stearate.	EluRyng	ethinyl estradiol/ etonogestrel	2.6mg - 11.4 mg	65162-0469-35	ANDA	210830	Amneal Pharmaceuticals, LLC	995 US Hwy 202/206, Bridgewater, New Jersey (NJ) 08807, United States (USA)	each ring releases on average 0.120 mg/day of etonogestrel and 0.015 mg/day of ethinyl estradiol from 11.7 mg etonogestrel and 2.7 mg ethinyl estradiol, USP Inactive: ethylene vinylacetate copolymers & magnesium stearate	
ethinyl estradiol/ etonogestrel	Nuvaring	ethinyl estradiol/ etonogestrel	02253186	Organon Canada Inc.	300 16766 Route Transcanadienne Kirkland Quebec Canada H9H 4M7	2.6mg - 11.4 mg	vaginal ring	2	Slow release vaginal ring / 11.4 mg etonogestrel / 2.6 mg ethinyl estradiol (120 mcg etonogestrel/15 mcg ethinyl estradiol per day) non-medicinal ingredients: Ethylene vinylacetate copolymers (28% and 9% vinylacetate) and magnesium stearate.	etonogestrel - ethinyl estradiol	ethinyl estradiol/ etonogestrel	2.6mg - 11.4 mg	66993-0605-36	NDA Authorized Generic	021187	Organon USA,LLC	Organon USA,LLC, a subsidiary of Organon & CO Jersey City, NJ 07302	etonogestrel & ethinyl estradiol inactive: ethylene-vinyl acetate copolymer (28% vinyl acetate), ethylene-vinyl acetate copolymer (9% vinyl acetate), magnesium stearate	This is an authorized generic marketed by Prasco Laboratories, Mason, OH 45040 USA
ethinyl estradiol/ etonogestrel	Nuvaring	ethinyl estradiol/ etonogestrel	02253186	Organon Canada Inc.	300 16766 Route Transcanadienne Kirkland Quebec Canada H9H 4M7	2.6mg - 11.4 mg	vaginal ring	2	Slow release vaginal ring / 11.4 mg etonogestrel / 2.6 mg ethinyl estradiol (120 mcg etonogestrel/15 mcg ethinyl estradiol per day) non-medicinal ingredients: Ethylene vinylacetate copolymers (28% and 9% vinylacetate) and magnesium stearate.	etonogestrel - ethinyl estradiol	ethinyl estradiol/ etonogestrel	2.6mg - 11.4 mg	00093-7679-02	ANDA	204305	Teva Pharmaceuticals, USA, Inc.	North Wales, PA 19454	etonogestrel & ethinyl estradiol inactive: ethylene-vinyl acetate copolymer (28% vinyl acetate), ethylene-vinyl acetate copolymer (9% vinyl acetate), magnesium stearate	
everolimus	Afinitor	Everolimus	02339501	Novartis Pharmaceuticals Canada Inc.	385 Bouchard Blvd Dorval Quebec Canada, H9S 1A9	5mg	tablet	1	5mg everolimus non-medicinal ingredients: Butylated hydroxytoluene (E321), crospovidone, hypromellose, lactose anhydrous, lactose monohydrate, magnesium stearate.	Afinitor	everolimus	5mg	00078-0566-51	NDA	022334	Novartis Pharmaceuticals Corporation	One Health Plaza, East Hanover, New Jersey (NJ) 07936, United States (USA)	5mg of everolimus and the following inactive ingredients: butylated hydroxytoluene, crospividone, hypromellose, anhydroous lactose, lactose monohydrate, magnesium stearate	
everolimus	Afinitor Disperz	Everolimus	02425645	Novartis Pharmaceuticals Canada Inc.	385 Bouchard Blvd Dorval Quebec Canada, H9S 1A9	2mg	Tablet for suspension	1	2mg everolimus non-medicinal ingredients: butylated hydroxytoluene (E321), cellulose microcrystalline, crospovidone, hypromellose, lactose monohydrate, magnesium stearate, mannitol, silica colloidal anhydrous.	Afinitor Disperz	Everolimus	2mg	00078-0626-51	NDA	203985	Novartis Pharmaceuticals Corporation	One Health Plaza East Hanover, NJ 07936	2 mg of everolimus and the following inactive ingredients: butylated hydroxytoluene,magnesium stearate, lactose monohydrate, hypromelloses, crospividone, mannitol, microcrystalline cellulose, silicon dioxide	
everolimus	Afinitor Disperz	Everolimus	02425653	Novartis Pharmaceuticals Canada Inc.	385 Bouchard Blvd Dorval Quebec Canada, H9S 1A9	3mg	Tablet for suspension	1	3mg everolimus non-medicinal: butylated hydroxytoluene (E321), cellulose microcrystalline, crospovidone, hypromellose, lactose monohydrate, magnesium stearate, mannitol, silica colloidal anhydrous.	Afinitor Disperz	Everolimus	3mg	00078-0627-51	NDA	203985	Novartis Pharmaceuticals Corporation	One Health Plaza East Hanover, NJ 07936	3 mg of everolimus and the following inactive ingredients: butylated hydroxytoluene,magnesium stearate, lactose monohydrate, hypromelloses, crospividone, mannitol, microcrystalline cellulose, silicon dioxide	
everolimus	Afinitor Disperz	Everolimus	02425661	Novartis Pharmaceuticals Canada Inc.	385 Bouchard Blvd Dorval Quebec Canada, H9S 1A9	5mg	Tablet for suspension	1	5mg everolimus non-medicinal: butylated hydroxytoluene (E321), cellulose microcrystalline, crospovidone, hypromellose, lactose monohydrate, magnesium stearate, mannitol, silica colloidal anhydrous.	Afinitor Disperz	Everolimus	5mg	00078-0628-51	NDA	203985	Novartis Pharmaceuticals Corporation	One Health Plaza East Hanover, NJ 07936	5 mg of everolimus and the following inactive ingredients: butylated hydroxytoluene,magnesium stearate, lactose monohydrate, hypromelloses, crospividone, mannitol, microcrystalline cellulose, silicon dioxide	
everolimus	PMS-Everolimus	everolimus	02504685	Pharmascience Inc.	100 6111 Royalmount Ave Montreal Quebec Canada H4P 2T4	5mg	tablet	1	everolimus non-medicinal: Butylhydroxytoluene, Crospovidone, Hypromellose, Lactose Anhydrous, Lactose Monohydrate and Magnesium Stearate.	Everolimus	everolimus	5mg	00054-0481-13	ANDA	207486	Hikma Pharmaceuticals, USA Inc.	1809 Wilson Road, Columbus, Ohio (OH) 43228, United States (USA)	5mg of everolimus and the following inactive ingredients: butylated hydroxytoluene, crospividone, hypromellose, anhydroous lactose, lactose monohydrate, magnesium stearate	
everolimus	Sandoz Everolimus	everolimus	02492938	Sandoz Canada Incorporated	110 Rue De Lauzon Boucherville Quebec Canada J4B 1E6	5mg	tablet	1	everolimus non-medicinal: Butylhydroxytoluene (E321), Crospovidone, Hypromellose, Lactose Anhydrous, Lactose Monohydrate and Magnesium Stearate.	Everolimus	everolimus	5mg	00054-0481-13	ANDA	207486	Hikma Pharmaceuticals, USA Inc.	1809 Wilson Road, Columbus, Ohio (OH) 43228, United States (USA)	5mg of everolimus and the following inactive ingredients: butylated hydroxytoluene, crospividone, hypromellose, anhydroous lactose, lactose monohydrate, magnesium stearate	
everolimus	Teva-Everolimus	everolimus	02463237	Teva Canada Ltd.	30 Novopharm Court Toronto Ontario Canada M1B 2K9	5mg	tablet	1	everolimus non-medicinal: Butylhydroxytoluene, Crospovidone, Hypromellose, Lactose Anhydrous, Lactose Monohydrate and Magnesium Stearate.	Everolimus	everolimus	5mg	00054-0481-13	ANDA	207486	Hikma Pharmaceuticals, USA Inc.	1809 Wilson Road, Columbus, Ohio (OH) 43228, United States (USA)	5mg of everolimus and the following inactive ingredients: butylated hydroxytoluene, crospividone, hypromellose, anhydroous lactose, lactose monohydrate, magnesium stearate	
fingolimod	Gilenya	Fingolimod	02365480	Novartis Pharmaceuticals Canada Inc.	385 Bouchard Blvd Dorval Quebec Canada, H9S 1A9	0.5mg	capsule	1	0.5 mg fingolimod (as fingolimod hydrochloride) non-medicinal: gelatin, magnesium stearate, mannitol, titanium dioxide, yellow iron oxide	Gilenya	fingolimod	0.5mg	00078-0607-15	NDA	22527	Novortis Pharmaceuticals Corporation	One Health Plaza East Hanover, NJ 07936	fingolimod hydrochloride, inactive: gelatin, magnesium stearate, mannitol, titanium dioxide,ferric oxide yellow.	
fluticasone	Flovent HFA	fluticasone	02244291	GlaxoSmithKline Inc.	800 100 Milverton Drive Mississauga Ontario Canada L5R 4H1	50mcg	metered dose inhaler	1	fluticasone propionate inhalation aerosol 50 mcg/metered dose non-medicinal ingredient: 1,1,1,2-tetrafluoroethane (HFA-134a, norflurane)	Flovent HFA	fluticasone	44mcg	00173-0718-20	NDA	021433	GlaxoSmithKline LLC	5 Moore Drive Research Triangle Park, NC 27709	fluticasone propionate inactive: norflurane (1, 1, 1,2-tetrafluoroethane (HFA-134a))	
fluticasone	Flovent HFA	fluticasone	02244291	GlaxoSmithKline Inc.	800 100 Milverton Drive Mississauga Ontario Canada L5R 4H1	50mcg	metered dose inhaler	1	fluticasone propionate inhalation aerosol 50 mcg/metered dose non-medicinal ingredient: 1,1,1,2-tetrafluoroethane (HFA-134a, norflurane)	Fluticasone HFA	fluticasone	44mcg	66993-0078-96	NDA Authorized Generic	021433	GlaxoSmithKline LLC	5 Moore Drive Research Triangle Park, NC 27709	fluticasone propionate inactive: norflurane (1, 1, 1,2-tetrafluoroethane (HFA-134a))	This is an authorized generic marketed by Prasco Laboratories, Mason, OH 45040 USA
fluticasone	Flovent HFA	fluticasone	02244292	GlaxoSmithKline Inc.	800 100 Milverton Drive Mississauga Ontario Canada L5R 4H1	125mcg	metered dose inhaler	1	125 mcg fluticasone propionate metered dose non-medicinal: 1,1,1,2-tetrafluoroethane (HFA-134a, norflurane)	Flovent HFA	fluticasone	110mcg	00173-0719-20	NDA	021433	GlaxoSmithKline LLC	5 Moore Drive Research Triangle Park, NC 27709	fluticasone propionate inactive: norflurane (1, 1, 1,2-tetrafluoroethane (HFA-134a))	
fluticasone	Flovent HFA	fluticasone	02244292	GlaxoSmithKline Inc.	800 100 Milverton Drive Mississauga Ontario Canada L5R 4H1	125mcg	metered dose inhaler	1	125 mcg fluticasone propionate metered dose non-medicinal: 1,1,1,2-tetrafluoroethane (HFA-134a, norflurane)	Fluticasone HFA	fluticasone	110mcg	66693-0079-96	NDA Authorized Generic	021433	GlaxoSmithKline LLC	5 Moore Drive Research Triangle Park, NC 27709	fluticasone propionate inactive: norflurane (1, 1, 1,2-tetrafluoroethane (HFA-134a))	This is an authorized generic marketed by Prasco Laboratories, Mason, OH 45040 USA

Appendix D: Drug List with Required Data Elements

Active Ingredient	Canadian Proprietary Name	Canadian Generic Name	DIN	Company Name	Address	CAN Strength	Dosage Form	# of active Ingred.	Canadian Ingredients	US Proprietary Name	US Generic Name	US Strength	NDC	NDA or ANDA	Number	Applicant Holder Name	Applicant Holder Address	US Ingredients	Comment for FDA
fluticasone	Flovent HFA	fluticasone	02244293	GlaxoSmithKline Inc.	800 100 Milverton Drive Mississauga Ontario Canada L5R 4H1	250mcg	Aerosole	1	250mcg fluticasone propionate metered dose non-medicinal: 1,1,1,2-tetrafluoroethane (HFA-134a, norflurane)	Flovent HFA	fluticasone	220mcg	00173-0720-20	NDA	021433	GlaxoSmithKline LLC	5 Moore Drive Research Triangle Park, NC 27709	fluticasone propionate inactive: norflurane (1, 1, 1,2-tetrafluoroethane (HFA-134a))	
fluticasone	Flovent HFA	fluticasone	02244293	GlaxoSmithKline Inc.	800 100 Milverton Drive Mississauga Ontario Canada L5R 4H1	250mcg	Aerosole	1	250mcg fluticasone propionate metered dose non-medicinal: 1,1,1,2-tetrafluoroethane (HFA-134a, norflurane)	Fluticasone HFA	fluticasone	220mcg	66693-0080-96	NDA Authorized Generic	021433	GlaxoSmithKline LLC	5 Moore Drive Research Triangle Park, NC 27709	fluticasone propionate inactive: norflurane (1, 1, 1,2-tetrafluoroethane (HFA-134a))	This is an authorized generic marketed by Prasco Laboratories, Mason, OH 45040 USA
fluticasone	PMS Fluticasone HFA	fluticasone	02503115	PharmaScience Inc.	100 6111 Royalmount Ave Montreal Quebec Canada H4P 2T4	50mcg	metered dose inhaler	1	Inhalation Aerosol 50mcg/metered dose non-medicinal ingredient: 1,1,1,2-tetrafluoroethane (HFA-134a, norflurane)	Fluticasone HFA	fluticasone	44mcg	66993-0078-96	NDA Authorized Generic	021433	GlaxoSmithKline LLC	5 Moore Drive Research Triangle Park, NC 27709	fluticasone propionate inactive: norflurane (1, 1, 1,2-tetrafluoroethane (HFA-134a))	This is an authorized generic marketed by Prasco Laboratories, Mason, OH 45040 USA
fluticasone	PMS Fluticasone HFA	fluticasone	02503115	Pharmascience Inc.	100 6111 Royalmount Ave Montreal Quebec Canada H4P 2T4	50mcg	metered dose inhaler	1	Inhalation Aerosol 50mcg/metered dose non-medicinal ingredient: 1,1,1,2-tetrafluoroethane (HFA-134a, norflurane)	Flovent HFA	fluticasone	44mcg	00173-0718-20	NDA	021433	GlaxoSmithKline LLC	5 Moore Drive Research Triangle Park, NC 27709	fluticasone propionate inactive: norflurane (1, 1, 1,2-tetrafluoroethane (HFA-134a))	
fluticasone	PMS Fluticasone HFA	fluticasone	02503123	Pharmascience Inc.	100 6111 Royalmount Ave Montreal Quebec Canada H4P 2T4	125mcg	metered dose inhaler	1	125 mcg fluticasone propionate metered dose non-medicinal ingredient: 1,1,1,2-tetrafluoroethane (HFA-134a, norflurane)	Fluticasone HFA	fluticasone	110mcg	66693-0079-96	NDA Authorized Generic	021433	GlaxoSmithKline LLC	5 Moore Drive Research Triangle Park, NC 27709	fluticasone propionate inactive: norflurane (1, 1, 1,2-tetrafluoroethane (HFA-134a))	This is an authorized generic marketed by Prasco Laboratories, Mason, OH 45040 USA
fluticasone	PMS Fluticasone HFA	fluticasone	02503123	Pharmascience Inc.	100 6111 Royalmount Ave Montreal Quebec Canada H4P 2T4	125mcg	metered dose inhaler	1	125 mcg fluticasone propionate metered dose non-medicinal ingredient: 1,1,1,2-tetrafluoroethane (HFA-134a, norflurane)	Flovent HFA	fluticasone	110mcg	00173-0719-20	NDA	021433	GlaxoSmithKline LLC	5 Moore Drive Research Triangle Park, NC 27709	fluticasone propionate inactive: norflurane (1, 1, 1,2-tetrafluoroethane (HFA-134a))	
fluticasone	PMS Fluticasone HFA	fluticasone	02503131	PharmaScience Inc.	100 6111 Royalmount Ave Montreal Quebec Canada H4P 2T4	250mcg	metered dose inhaler	1	250 mcg fluticasone propionate metered dose non-medicinal: 1,1,1,2-tetrafluoroethane (HFA-134a, norflurane)	Fluticasone HFA	fluticasone	220mcg	66693-0080-96	NDA Authorized Generic	021433	GlaxoSmithKline LLC	5 Moore Drive Research Triangle Park, NC 27709	fluticasone propionate inactive: norflurane (1, 1, 1,2-tetrafluoroethane (HFA-134a))	This is an authorized generic marketed by Prasco Laboratories, Mason, OH 45040 USA
fluticasone	PMS Fluticasone HFA	fluticasone	02503131	PharmaScience Inc.	100 6111 Royalmount Ave Montreal Quebec Canada H4P 2T4	250mcg	metered dose inhaler	1	250 mcg fluticasone propionate metered dose non-medicinal: 1,1,1,2-tetrafluoroethane (HFA-134a, norflurane)	Flovent HFA	fluticasone	220mcg	00173-0720-20	NDA	021433	GlaxoSmithKline LLC	5 Moore Drive Research Triangle Park, NC 27709	fluticasone propionate inactive: norflurane (1, 1, 1,2-tetrafluoroethane (HFA-134a))	
fluticasone & salmeterol	pms-fluticasone propionate/ salmeterol DPI	fluticasone & salmeterol	02494507	Pharmascience Inc.	100 6111 Royalmount Ave Montreal Quebec Canada H4P 2T4	100mcg/ 50mcg	powder	2	100 mcg Fluticasone Propionate and 50 mcg Salmeterol non-medicinal ngredients: lactose and milk protein	Fluticasone Propionate And Salmeterol Diskus	fluticasone & salmeterol	100mcg/ 50mcg	66993-0584-97	NDA Authorized Generic	021077	GlaxoSmithKline LLC	5 Moore Drive Research Triangle Park, NC 27709	fluticasone propionate & salmeterol xinafoate inactive: lactose, unspecified form	This is an authorized generic marketed by Prasco Laboratories, Mason, OH 45040 USA
fluticasone & salmeterol	pms-fluticasone propionate/ salmeterol DPI	fluticasone & salmeterol	02494507	Pharmascience Inc.	100 6111 Royalmount Ave Montreal Quebec Canada H4P 2T4	100mcg/ 50mcg	powder	2	100 mcg Fluticasone Propionate and 50 mcg Salmeterol non-medicinal ngredients: lactose and milk protein	Advair Diskus	fluticasone & salmeterol	100mcg/ 50mcg	00173-0695-00	NDA	021077	GlaxoSmithKline LLC	5 Moore Drive Research Triangle Park, NC 27709	Active ingredients: fluticasone propionate, salmeterol xinafoate Inactive ingredient: lactose, unspecified form	
fluticasone & salmeterol	pms-fluticasone propionate/ salmeterol DPI	fluticasone & salmeterol	02494507	Pharmascience Inc.	100 6111 Royalmount Ave Montreal Quebec Canada H4P 2T4	100mcg/ 50mcg	powder	2	100 mcg Fluticasone Propionate and 50 mcg Salmeterol non-medicinal ngredients: lactose and milk protein	Wixela Inhub	fluticasone & salmeterol	100mcg/ 50mcg	0378-9320-32	ANDA	208891	Mylan Pharmaceuticals Inc.	3711 Collins Ferry Road, Morgantown, West Virginia (WV) 26505, United States (USA)	Active ingredients: fluticasone propionate, salmeterol xinafoate Inactive ingredient: lactose monohydrate	
fluticasone & salmeterol	pms-fluticasone propionate/ salmeterol DPI	fluticasone & salmeterol	02494515	Pharmascience Inc.	100 6111 Royalmount Ave Montreal Quebec Canada H4P 2T4	250mcg/ 50mcg	powder	2	250 mcg Fluticasone Propionate and 50 mcg Salmeterol non-medcinal ingredients: lactose and milk protein	Fluticasone Propionate And Salmeterol Diskus	fluticasone & salmeterol	250mcg/ 50mcg	66993-0585-97	NDA Authorized Generic	021077	GlaxoSmithKline LLC	5 Moore Drive Research Triangle Park, NC 27709	fluticasone propionate & salmeterol xinafoate inactive: lactose, unspecified form	This is an authorized generic marketed by Prasco Laboratories, Mason, OH 45040 USA
fluticasone & salmeterol	pms-fluticasone propionate/ salmeterol DPI	fluticasone & salmeterol	02494515	Pharmascience Inc.	100 6111 Royalmount Ave Montreal Quebec Canada H4P 2T4	250mcg/ 50mcg	powder	2	250 mcg Fluticasone Propionate and 50 mcg Salmeterol non-medcinal ingredients: lactose and milk protein	Advair Diskus	fluticasone & salmeterol	250mcg/ 50mcg	0173-0696-00	NDA	021077	GlaxoSmithKline LLC	5 Moore Drive Research Triangle Park, NC 27709	Active ingredients: fluticasone propionate, salmeterol xinafoate Inactive ingredient: lactose, unspecified form	
fluticasone & salmeterol	pms-fluticasone propionate/ salmeterol DPI	fluticasone & salmeterol	02494515	Pharmascience Inc.	100 6111 Royalmount Ave Montreal Quebec Canada H4P 2T4	250mcg/ 50mcg	powder	2	250 mcg Fluticasone Propionate and 50 mcg Salmeterol non-medcinal ingredients: lactose and milk protein	Wixela Inhub	fluticasone & salmeterol	250mcg/ 50mcg	0378-9321-32	ANDA	208891	Mylan Pharmaceuticals Inc.	3711 Collins Ferry Road, Morgantown, West Virginia (WV) 26505, United States (USA)	Active ingredients: fluticasone propionate, salmeterol xinafoate Inactive ingredient: lactose monohydrate	
fluticasone & salmeterol	pms-fluticasone propionate/ salmeterol DPI	fluticasone & salmeterol	02494523	Pharmascience Inc.	100 6111 Royalmount Ave Montreal Quebec Canada H4P 2T4	500mcg/ 50mcg	powder	2	500 mcg Fluticasone Propionate and 50 mcg Salmeterol non-medcinal ingredients: lactose and milk protein	Fluticasone Propionate And Salmeterol Diskus	fluticasone & salmeterol	500mcg/ 50mcg	66993-0586-97	NDA Authorized Generic	021077	GlaxoSmithKline LLC	5 Moore Drive Research Triangle Park, NC 27709	fluticasone propionate & salmeterol xinafoate inactive: lactose, unspecified form	This is an authorized generic marketed by Prasco Laboratories, Mason, OH 45040 USA

Appendix D: Drug List with Required Data Elements

Active Ingredient	Canadian Proprietary Name	Canadian Generic Name	DIN	Company Name	Address	CAN Strength	Dosage Form	# of active Ingred.	Canadian Ingredients	US Proprietary Name	US Generic Name	US Strength	NDC	NDA or ANDA	Number	Applicant Holder Name	Applicant Holder Address	US Ingredients	Comment for FDA
fluticasone & salmeterol	pms-fluticasone propionate/ salmeterol DPI	fluticasone & salmeterol	02494523	Pharmascience Inc.	100 6111 Royalmount Ave Montreal Quebec Canada H4P 2T4	500mcg/ 50mcg	powder	2	500 mcg Fluticasone Propionate and 50 mcg Salmeterol non-medicinal ingredients: lactose and milk protein	Advair Diskus	fluticasone & salmeterol	500mcg/ 50mcg	00173-0697-00	NDA	021077	GlaxoSmithKline LLC	5 Moore Drive Research Triangle Park, NC 27709	Active ingredients: fluticasone propionate, salmeterol xinafoate Inactive ingredient: lactose, unspecified form	
fluticasone & salmeterol	pms-fluticasone propionate/ salmeterol DPI	fluticasone & salmeterol	02494523	Pharmascience Inc.	100 6111 Royalmount Ave Montreal Quebec Canada H4P 2T4	500mcg/ 50mcg	powder	2	500 mcg Fluticasone Propionate and 50 mcg Salmeterol non-medicinal ingredients: lactose and milk protein	Wixela Inhub	fluticasone & salmeterol	500mcg/ 50mcg	0378-9322-32	ANDA	208891	Mylan Pharmaceuticals Inc.	3711 Collins Ferry Road, Morgantown, West Virginia (WV) 26505, United States (USA)	Active ingredients: fluticasone propionate, salmeterol xinafoate Inactive ingredient: lactose monohydrate	
fluticasone & salmeterol	Advair 100 Diskus	fluticasone & salmeterol	02240835	GlaxoSmithKline Inc.	800 100 Milverton Drive Mississauga Ontario Canada L5R 4H1	100mcg/ 50mcg	powder	2	100 mcg fluticasone propionate and 50 mcg salmeterol non-medicinal: lactose and milk protein	Advair Diskus	fluticasone & salmeterol	100mcg/ 50mcg	00173-0695-00	NDA	021077	GlaxoSmithKline LLC	5 Moore Drive Research Triangle Park, NC 27709	Active ingredients: fluticasone propionate, salmeterol xinafoate Inactive ingredient: lactose, unspecified form	
fluticasone & salmeterol	Advair 100 Diskus	fluticasone & salmeterol	02240835	GlaxoSmithKline Inc.	800 100 Milverton Drive Mississauga Ontario Canada L5R 4H1	100mcg/ 50mcg	powder	2	100 mcg fluticasone propionate and 50 mcg salmeterol non-medicinal: lactose and milk protein	Fluticasone Propionate And Salmeterol Diskus	fluticasone & salmeterol	100mcg/ 50mcg	66993-0584-97	NDA Authorized Generic	021077	GlaxoSmithKline LLC	5 Moore Drive Research Triangle Park, NC 27709	fluticasone propionate & salmeterol xinafoate inactive: lactose, unspecified form	This is an authorized generic marketed by Prasco Laboratories, Mason, OH 45040 USA
fluticasone & salmeterol	Advair 100 Diskus	fluticasone & salmeterol	02240835	GlaxoSmithKline Inc.	800 100 Milverton Drive Mississauga Ontario Canada L5R 4H1	100mcg/ 50mcg	powder	2	100 mcg fluticasone propionate and 50 mcg salmeterol non-medicinal: lactose and milk protein	Wixela Inhub	fluticasone & salmeterol	100mcg/ 50mcg	0378-9320-32	ANDA	208891	Mylan Pharmaceuticals Inc.	3711 Collins Ferry Road, Morgantown, West Virginia (WV) 26505, United States (USA)	Active ingredients: fluticasone propionate, salmeterol xinafoate Inactive ingredient: lactose monohydrate	
fluticasone & salmeterol	Advair 125	fluticasone & salmeterol	02245126	GlaxoSmithKline Inc.	800 100 Milverton Drive Mississauga Ontario Canada L5R 4H1	125mcg/ 25mcg	inhaler	2	125mcg fluticasone propionate/ 25 mcg salmeterol/ metered dose ; non-medicinal: 1,1,1,2-tetrafluoroethane (HFA-134a, norflurane)	Advair HFA	fluticasone & salmeterol	115mcg/ 21mcg	00173-0716-20	NDA	021254	GlaxoSmithKline	GlaxoSmithKline, Research Triangle Park, NC 27709	fluticasone propionate & salmeterol xinafoate inactive: norflurane (1, 1, 1,2-tetrafluoroethane (HFA-134a))	
fluticasone & salmeterol	Advair 250	fluticasone & salmeterol	02245127	GlaxoSmithKline Inc.	800 100 Milverton Drive Mississauga Ontario Canada L5R 4H1	250mcg/ 25mcg	inhaler	2	250 mcg fluticasone propionate/ 25 mcg salmeterol/ metered dose ; non-medicinal: 1,1,1,2-tetrafluoroethane (HFA-134a, norflurane)	Advair HFA	fluticasone & salmeterol	230mcg/ 21mcg	0173-0717-20	NDA	021254	GlaxoSmithKline LLC	GlaxoSmithKline, Research Triangle Park, NC 27709	fluticasone propionate & salmeterol xinafoate inactive: norflurane (1, 1, 1,2-tetrafluoroethane (HFA-134a))	
fluticasone & salmeterol	Advair 250 Diskus	fluticasone & salmeterol	02240836	GlaxoSmithKline Inc.	800 100 Milverton Drive Mississauga Ontario Canada L5R 4H1	250mcg/ 50mcg	powder	2	250 mcg fluticasone propionate and 50 mcg salmeterol non-medicinal: lactose and milk protein	Advair Diskus	fluticasone & salmeterol	250mcg/ 50mcg	0173-0696-00	NDA	021077	GlaxoSmithKline LLC	5 Moore Drive Research Triangle Park, NC 27709	Active ingredients: fluticasone propionate, salmeterol xinafoate Inactive ingredient: lactose, unspecified form	
fluticasone & salmeterol	Advair 250 Diskus	fluticasone & salmeterol	02240836	GlaxoSmithKline Inc.	800 100 Milverton Drive Mississauga Ontario Canada L5R 4H1	250mcg/ 50mcg	powder	2	250 mcg fluticasone propionate and 50 mcg salmeterol non-medicinal: lactose and milk protein	Fluticasone Propionate And Salmeterol Diskus	fluticasone & salmeterol	250mcg/ 50mcg	66993-0585-97	NDA Authorized Generic	021077	GlaxoSmithKline LLC	5 Moore Drive Research Triangle Park, NC 27709	fluticasone propionate & salmeterol xinafoate inactive: lactose, unspecified form	This is an authorized generic marketed by Prasco Laboratories, Mason, OH 45040 USA
fluticasone & salmeterol	Advair 250 Diskus	fluticasone & salmeterol	02240836	GlaxoSmithKline Inc.	800 100 Milverton Drive Mississauga Ontario Canada L5R 4H1	250mcg/ 50mcg	powder	2	250 mcg fluticasone propionate and 50 mcg salmeterol non-medicinal: lactose and milk protein	Wixela Inhub	fluticasone & salmeterol	250mcg/ 50mcg	0378-9321-32	ANDA	208891	Mylan Pharmaceuticals Inc.	3711 Collins Ferry Road, Morgantown, West Virginia (WV) 26505, United States (USA)	Active ingredients: fluticasone propionate, salmeterol xinafoate Inactive ingredient: lactose monohydrate	
fluticasone & salmeterol	Advair 500 Diskus	fluticasone & salmeterol	0224837	GlaxoSmithKline Inc.	800 100 Milverton Drive Mississauga Ontario Canada L5R 4H1	500mcg/ 50mcg	powder	2	500 mcg fluticasone propionate and 50 mcg salmeterol non-medicinal: lactose and milk protein	Advair Diskus	fluticasone & salmeterol	500mcg/ 50mcg	00173-0697-00	NDA	021077	GlaxoSmithKline LLC	5 Moore Drive Research Triangle Park, NC 27709	Active ingredients: fluticasone propionate, salmeterol xinafoate Inactive ingredient: lactose, unspecified form	
fluticasone & salmeterol	Advair 500 Diskus	fluticasone & salmeterol	0224837	GlaxoSmithKline Inc.	800 100 Milverton Drive Mississauga Ontario Canada L5R 4H1	500mcg/ 50mcg	powder	2	500 mcg fluticasone propionate and 50 mcg salmeterol non-medicinal: lactose and milk protein	Fluticasone Propionate And Salmeterol Diskus	fluticasone & salmeterol	500mcg/ 50mcg	66993-0586-97	NDA Authorized Generic	021077	GlaxoSmithKline LLC	5 Moore Drive Research Triangle Park, NC 27709	fluticasone propionate & salmeterol xinafoate inactive: lactose, unspecified form	This is an authorized generic marketed by Prasco Laboratories, Mason, OH 45040 USA
fluticasone & salmeterol	Advair 500 Diskus	fluticasone & salmeterol	0224837	GlaxoSmithKline Inc.	800 100 Milverton Drive Mississauga Ontario Canada L5R 4H1	500mcg/ 50mcg	powder	2	500 mcg fluticasone propionate and 50 mcg salmeterol non-medicinal: lactose and milk protein	Wixela Inhub	fluticasone & salmeterol	500mcg/ 50mcg	0378-9322-32	ANDA	208891	Mylan Pharmaceuticals Inc.	3711 Collins Ferry Road, Morgantown, West Virginia (WV) 26505, United States (USA)	Active ingredients: fluticasone propionate, salmeterol xinafoate Inactive ingredient: lactose monohydrate	
fluticasone & salmeterol	Wixela Inhub	fluticasone & salmeterol	02495597	Mylan Pharmaceuticals Ulc.	85 Advance Road Etobicoke Ontario Canada M8Z 2S6	100mcg/ 50mcg	powder	2	100 mcg Fluticasone Propionate and 50 mcg Salmeterol non-medicinal: lactose monohydrate	Wixela Inhub	fluticasone & salmeterol	100mcg/ 50mcg	0378-9320-32	ANDA	208891	Mylan Pharmaceuticals Inc.	3711 Collins Ferry Road, Morgantown, West Virginia (WV) 26505, United States (USA)	Active ingredients: fluticasone propionate, salmeterol xinafoate Inactive ingredient: lactose monohydrate	
fluticasone & salmeterol	Wixela Inhub	fluticasone & salmeterol	02495597	Mylan Pharmaceuticals Ulc.	85 Advance Road Etobicoke Ontario Canada M8Z 2S6	100mcg/ 50mcg	powder	2	100 mcg Fluticasone Propionate and 50 mcg Salmeterol non-medicinal: lactose monohydrate	Advair Diskus	fluticasone & salmeterol	100mcg/ 50mcg	00173-0695-00	NDA	021077	GlaxoSmithKline LLC	5 Moore Drive Research Triangle Park, NC 27709	Active ingredients: fluticasone propionate, salmeterol xinafoate Inactive ingredient: lactose, unspecified form	

Appendix D: Drug List with Required Data Elements

Active Ingredient	Canadian Proprietary Name	Canadian Generic Name	DIN	Company Name	Address	CAN Strength	Dosage Form	# of active Ingred.	Canadian Ingredients	US Proprietary Name	US Generic Name	US Strength	NDC	NDA or ANDA	Number	Applicant Holder Name	Applicant Holder Address	US Ingredients	Comment for FDA
fluticasone & salmeterol	Wixela Inhub	fluticasone & salmeterol	02495597	Mylan Pharmaceuticals Ulc.	85 Advance Road Etobicoke Ontario Canada M8Z 2S6	100mcg/ 50mcg	powder	2	100 mcg Fluticasone Propionate and 50 mcg Salmeterol non-medicinal: lactose monohydrate	Fluticasone Propionate And Salmeterol Diskus	fluticasone & salmeterol	100mcg/ 50mcg	66993-0584-97	NDA Authorized Generic	021077	GlaxoSmithKline LLC	5 Moore Drive Research Triangle Park, NC 27709	fluticasone propionate & salmeterol xinafoate inactive: lactose, unspecified form	This is an authorized generic marketed by Prasco Laboratories, Mason, OH 45040 USA
fluticasone & salmeterol	Wixela Inhub	fluticasone & salmeterol	02495600	Mylan Pharmaceuticals Ulc.	85 Advance Road Etobicoke Ontario Canada M8Z 2S6	250mcg/ 50mcg	powder	2	250 mcg Fluticasone Propionate and 50 mcg Salmeterol on-medicinal: lactose monohydrate	Wixela Inhub	fluticasone & salmeterol	250mcg/ 50mcg	0378-9321-32	ANDA	208891	Mylan Pharmaceuticals Inc.	3711 Collins Ferry Road, Morgantown, West Virginia (WV) 26505, United States (USA)	Active ingredients: fluticasone propionate, salmeterol xinafoate Inactive ingredient: lactose monohydrate	
fluticasone & salmeterol	Wixela Inhub	fluticasone & salmeterol	02495600	Mylan Pharmaceuticals Ulc.	85 Advance Road Etobicoke Ontario Canada M8Z 2S6	250mcg/ 50mcg	powder	2	250 mcg Fluticasone Propionate and 50 mcg Salmeterol on-medicinal: lactose monohydrate	Advair Diskus	fluticasone & salmeterol	250mcg/ 50mcg	0173-0696-00	NDA	021077	GlaxoSmithKline LLC	5 Moore Drive Research Triangle Park, NC 27709	Active ingredients: fluticasone propionate, salmeterol xinafoate Inactive ingredient: lactose, unspecified form	
fluticasone & salmeterol	Wixela Inhub	fluticasone & salmeterol	02495600	Mylan Pharmaceuticals Ulc.	85 Advance Road Etobicoke Ontario Canada M8Z 2S6	250mcg/ 50mcg	powder	2	250 mcg Fluticasone Propionate and 50 mcg Salmeterol on-medicinal: lactose monohydrate	Fluticasone Propionate And Salmeterol Diskus	fluticasone & salmeterol	250mcg/ 50mcg	66993-0585-97	NDA Authorized Generic	021077	GlaxoSmithKline LLC	5 Moore Drive Research Triangle Park, NC 27709	fluticasone propionate & salmeterol xinafoate inactive: lactose, unspecified form	This is an authorized generic marketed by Prasco Laboratories, Mason, OH 45040 USA
fluticasone & salmeterol	Wixela Inhub	fluticasone & salmeterol	02495619	Mylan Pharmaceuticals Ulc.	85 Advance Road Etobicoke Ontario Canada M8Z 2S6	500mcg/ 50mcg	powder	2	500 mcg Fluticasone Propionate and 50 mcg Salmeterol non-medicinal: lactose monohydrate	Wixela Inhub	fluticasone & salmeterol	500mcg/ 50mcg	0378-9322-32	ANDA	208891	Mylan Pharmaceuticals Inc.	3711 Collins Ferry Road, Morgantown, West Virginia (WV) 26505, United States (USA)	Active ingredients: fluticasone propionate, salmeterol xinafoate Inactive ingredient: lactose monohydrate	
fluticasone & salmeterol	Wixela Inhub	fluticasone & salmeterol	02495619	Mylan Pharmaceuticals Ulc.	85 Advance Road Etobicoke Ontario Canada M8Z 2S6	500mcg/ 50mcg	powder	2	500 mcg Fluticasone Propionate and 50 mcg Salmeterol non-medicinal: lactose monohydrate	Advair Diskus	fluticasone & salmeterol	500mcg/ 50mcg	00173-0697-00	NDA	021077	GlaxoSmithKline LLC	5 Moore Drive Research Triangle Park, NC 27709	Active ingredients: fluticasone propionate, salmeterol xinafoate Inactive ingredient: lactose, unspecified form	
fluticasone & salmeterol	Wixela Inhub	fluticasone & salmeterol	02495619	Mylan Pharmaceuticals Ulc.	85 Advance Road Etobicoke Ontario Canada M8Z 2S6	500mcg/ 50mcg	powder	2	500 mcg Fluticasone Propionate and 50 mcg Salmeterol non-medicinal: lactose monohydrate	Fluticasone Propionate And Salmeterol Diskus	fluticasone & salmeterol	500mcg/ 50mcg	66993-0586-97	NDA Authorized Generic	021077	GlaxoSmithKline LLC	5 Moore Drive Research Triangle Park, NC 27709	fluticasone propionate & salmeterol xinafoate inactive: lactose, unspecified form	This is an authorized generic marketed by Prasco Laboratories, Mason, OH 45040 USA
glatiramer	Copaxone	Glatiramer acetate	02245619	Teva Canada Ltd.	31 Novopharm Court Toronto Ontario Canada M1B 2K9	20mg	solution	1	glatiramer acetate non-medicinal: mannitol and sterile water for injection.	Copaxone	Glatiramer acetate	20mg	68456-0317-30	NDA	020622	Teva Neuroscience, Inc.	Parsippany, NJ 07054	glatiramer acetate inactive: mannitol	
glatiramer	Copaxone	Glatiramer acetate	02245619	Teva Canada Ltd.	31 Novopharm Court Toronto Ontario Canada M1B 2K9	20mg	solution	1	glatiramer acetate non-medicinal: mannitol and sterile water for injection.	Glatopa	Glatiramer acetate	20mg	00781-3234-34	ANDA	090218	Sandoz Inc.	100 College Rd W Princeton, NJ, 08540	glatiramer acetate inactive: mannitol	
glatiramer	Copaxone	Glatiramer acetate	02245619	Teva Canada Ltd.	31 Novopharm Court Toronto Ontario Canada M1B 2K9	20mg	solution	1	glatiramer acetate non-medicinal: mannitol and sterile water for injection.	Glatiramer acetate	Glatiramer acetate	20mg	00378-6960-93	ANDA	091646	Mylan Pharmaceuticals Inc.	Morgantown, WV 26508, United States	glatiramer acetate inactive: mannitol & water	
glatiramer	Copaxone	Glatiramer acetate	02456915	Teva Canada Ltd.	30 Novopharm Court Toronto Ontario Canada M1B 2K9	40mg	solution	1	glatiramer acetate non-medicinal: mannitol and sterile water for injection.	Copaxone	Glatiramer acetate	40mg	68456-0325-12	NDA	020622	Teva Neuroscience, Inc.	Parsippany, NJ 07054	glatiramer acetate inactive: mannitol	
glatiramer	Copaxone	Glatiramer acetate	02456915	Teva Canada Ltd.	30 Novopharm Court Toronto Ontario Canada M1B 2K9	40mg	solution	1	glatiramer acetate non-medicinal: mannitol and sterile water for injection.	Glatopa	Glatiramer acetate	40mg	00781-3250-34	ANDA	206921	Sandoz Inc.	100 College Rd W Princeton, NJ, 08540	glatiramer acetate inactive: mannitol	
glatiramer	Copaxone	Glatiramer acetate	02456915	Teva Canada Ltd.	30 Novopharm Court Toronto Ontario Canada M1B 2K9	40mg	solution	1	glatiramer acetate non-medicinal: mannitol and sterile water for injection.	Glatiramer Acetate	Glatiramer acetate	40mg	00378-6961-12	ANDA	206936	Mylan Pharmaceuticals Inc.	Morgantown, WV 26508, United States	glatiramer acetate inactive: mannitol	
glatiramer	Glatect	Glatiramer acetate	02460661	Pharmascience Inc.	100 6111 Royalmount Ave Montreal Quebec Canada H4P 2T4	20mg	solution	1	Solution for injection 20 mg/mL glatiramer acetate 1 mL prefilled syringes non-medicinal: 40mg mannitol in water for injection	Glatiramer acetate	Glatiramer acetate	20mg	00378-6960-93	ANDA	091646	Mylan Pharmaceuticals Inc.	Morgantown, WV 26508, United States	glatiramer acetate inactive: mannitol & water	
glatiramer	Glatect	Glatiramer acetate	02460661	Pharmascience Inc.	100 6111 Royalmount Ave Montreal Quebec Canada H4P 2T4	20mg	solution	1	Solution for injection 20 mg/mL glatiramer acetate 1 mL prefilled syringes non-medicinal: 40mg mannitol in water for injection	Copaxone	Glatiramer acetate	20mg	68456-0317-30	NDA	020622	Teva Neuroscience, Inc.	Parsippany, NJ 07054	glatiramer acetate inactive: mannitol	
glatiramer	Glatect	Glatiramer acetate	02460661	Pharmascience Inc.	100 6111 Royalmount Ave Montreal Quebec Canada H4P 2T4	20mg	solution	1	Solution for injection 20 mg/mL glatiramer acetate 1 mL prefilled syringes non-medicinal: 40mg mannitol in water for injection	Glatopa	Glatiramer acetate	20mg	00781-3234-34	ANDA	090218	Sandoz Inc.	100 College Rd W Princeton, NJ, 08540	glatiramer acetate inactive: mannitol	
glucagon	Baqsimi	glucagon	02492415	Eli Lilly Canada Inc.	Exchange Tower, 130 King Street, Suite 900 West Toronto Ontario Canada M5X 1B1	3mg/ container	powder	1	Powder / 3 mg glucagon per device non-medicinal: Betadex and dodecylphosphocholine (DPC)	Baqsimi	glucagon	3mg/ container	00002-6145-11	NDA	210134	Eli Lilly and Company	Lilly Corporate Center, Indianapolis, Indiana (IN) 46285, United States (USA)	glucagon inactive: betadex, dodecylphosphocholine, water, acetic acid	

Appendix D: Drug List with Required Data Elements

Active Ingredient	Canadian Proprietary Name	Canadian Generic Name	DIN	Company Name	Address	CAN Strength	Dosage Form	# of active Ingred.	Canadian Ingredients	US Proprietary Name	US Generic Name	US Strength	NDC	NDA or ANDA	Number	Applicant Holder Name	Applicant Holder Address	US Ingredients	Comment for FDA
glucagon	GlucaGen	glucagon	02333619	Novo Nordisk Canada Inc.	101-2476 Argentia Road Mississauga Ontario Canada L5N 6M1	1mg/vial	kit/powder for solution	1	Lyophilized glucagon powder for injection/1 mg non-medicinal: Hydrochloric acid and/or sodium hydroxide (pH adjusters), lactose monohydrate, and water for injection	GlucaGen	glucagon	1mg/vial	00597-0053-01	NDA	020918	Boehringer Ingelheim Pharmaceuticals, Inc.	900 Ridgebury Road P.O. Box 368 Ridgefield, CT 06877	glucagon hydrochloride inactive: lactose monohydrate vial of water (2nd ingredient)	
glucagon	GlucaGen HypoKit	glucagon	02333627	Novo Nordisk Canada Inc.	101-2476 Argentia Road Mississauga Ontario Canada L5N 6M1	1mg/vial	kit/powder for solution	1	Lyophilized glucagon powder for injection/1 mg non-medicinal: Hydrochloric acid and/or sodium hydroxide (pH adjusters), lactose monohydrate, and water for injection	GlucaGen Hypokit	glucagon	1mg/vial	00169-7065-15	NDA	020918	Novo Nordisk	3612 Powhatan Road, Clayton, North Carolina (NC) 27527, United States (USA)	glucagon hydrochloride inactive: lactose monohydrate vial of water (2nd ingredient)	
glucagon	Glucagon	glucagon	02243297	Eli Lilly Canada Inc.	SUITE 900 Exchange Tower, 130 King Street West Toronto Ontario Canada M5X 1B1	1mg/vial	kit/powder for solution	1	Lyophilized glucagon powder for injection/1 mg non-medicinal: Each vial of glucagon contains 49.0 mg of lactose. The diluent syringe contains 1 mL of 1.2% glycerin.	Glucagon	glucagon	1mg/vial	00002-8031-01	NDA	020928	Eli Lilly and Company	Lilly Corporate Center, Indianapolis, Indiana (IN) 46285, United States (USA)	glucagon inactive: lactose monohydrate, hydrochloric acid dilution vial: glycerin, water hydrochloric acid	
ibrutinib	Ibrance	Palbociclib	02493535	Pfizer Canada Ulc.	17300 Trans-Canada Highway Kirkland Quebec Canada H9J 2M5	75mg	tablet	1	palbociclib non-medicinal: Colloidal silicon dioxide, crospovidone, FD&C Blue #2 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, red iron oxide, succinic acid, titanium dioxide, triacetin	Ibrance	Palbociclib	75mg	00069-0284-07	NDA	212436	Pfizer Inc.	New York, NY 10017	Palbociclib inactive ingredients: microcrystalline cellulose, silicon dioxide, magnesium stearate, ferric oxide red, titanium dioxide, crospovidone, succinic acid, hypromellose 2910 (6MPA.S), Triacetin, FD&C Blue No. 2	
ipratropium/ albuterol	Combivent Respimat	Ipratropium Bromide/ Salbutamol sulfate	02419106	Boehringer Ingelheim (Canada), LTD LTEE	5180 South Service Road Burlington Ontario Canada L7L 5H4	20mcg/ 100mcg	solution	2	Inhalation Solution / Each actuation delivers 20 mcg ipratropium bromide (monohydrate) and 100 mcg salbutamol (as salbutamol sulfate) from the mouth piece. Non-medicinal: benzalkonium chloride, edetate disodium, hydrochloric acid and purified water	Combivent Respimat	Ipratropium Bromide/ Albuterol sulfate	20mcg/ 100mcg	00597-0024-02	NDA	021747	Boehringer Ingelheim International, GmbH	Binger Strasse 173, Ingelheim am Rhein, Rhineland-Palatinate 55216, Germany (DEU)	ipratropium bromide, albuterol sulfate	
levonorgestrel	Kyleena	Levonorgestrel	02459523	Bayer Inc.	2920 Matheson Blvd East Mississauga, Ontario L4W 5R6	19.5mg	IUD	1	Intrauterine system / 19.5 mg levonorgestrel (LNG); Inactive Ingredients: Barium sulphate, copper phthalocyanine, polydimethylsiloxane elastomer, polyethylene, polypropylene, silica colloidal anhydrous, silver	Kyleena	levonorgestrel	19.5mg	50419-0424-01	NDA	208224	Bayer HealthCare Pharmaceuticals Inc.	100 Bayer Blvd, Whippany, NJ 07981	Active ingredient: levonorgestrel Inactive ingredients: silicone, polyethylene, silver, silica, barium sulfate, polypropylene, copper phthalocyanine	
levonorgestrel	Mirena	Levonorgestrel	02243005	Bayer Inc.	2920 Matheson Blvd East Mississauga Ontario Canada L4W 5R6	52 mg	intrauterine device	1	Intrauterine system / 52 mg levonorgestrel (LNG) clinically relevant inactive ingredients: barium sulphate, iron oxide, polydimethylsiloxane, polyethylene, silica	Mirena	levonorgestrel	52 mg	50419-423-01	NDA	21225	Bayer HealthCare Pharmaceuticals Inc.	100 Bayer Blvd, Whippany, NJ 07981	Active ingredient: levonorgestrel Inactive ingredients: silicone, polyethylene, silica, barium sulfate, iron oxide	
levothyroxine	Synthroid	levothyroxine	02172100	BGP Pharma Ulc.	85 Advance Road Etobicoke Ontario Canada M8Z 2S6	100mcg	tablet	1	levothyroxine non-medicinal: Acacia, confectioner's sugar, lactose, magnesium stearate, povidone, and talc. Color additives: D&C Yellow No. & 10 FD&C Yellow No. 6	Synthroid	levothyroxine	100mcg	00074-6624-11	NDA	021402	Abbvie Inc.	1 N Waukegan Rd, North Chicago, Illinois (IL) 60064, United States (USA)	100mcg (0.1mg) levothyroxine sodium inactive ingredients: acacia, lactose monohydrate, magnesium stearate, talc, D&C yellow #10, FD&C yellow #6, sucrose, povidone (unspecified)	
liraglutide	Victoza	Liraglutide	02351064	Novo Nordisk Canada Inc.	101-2476 Argentia Road Mississauga Ontario Canada L5N 6M1	18mg/3mL	Solution	1	6 mg/mL Liraglutide non-medicinal: Disodium phosphate dihydrate, propylene glycol, phenol and water for injections	Victoza	Liraglutide	18mg/3mL	00169-4060-13	NDA	022341	Novo Nordisk	3612 Powhatan Road, Clayton, North Carolina (NC) 27527, United States (USA)	Liraglutide inactive: phenol, propylene glycol, water, sodium phosphate (dibasic, dihydrate)	
lurasidone	Latuda	Lurasidone	02422050	Sunovion Pharmaceuticals Canada Inc.	7025 Langer Drive, Suite 301 Mississauga Ontario Canada L5N 0E8	20mg	tablet	1	lurasidone hydrochloride non-medicinal: carnauba wax, croscarmellose sodium, hypromellose, magnesium stearate, mannitol, Opadry® (hypromellose, polyethylene glycol, and titanium dioxide), pregelatinized starch	Latuda	Lurasidone	20mg	63402-302-30	NDA	200603	Sunovion Pharmaceuticals, Inc.	One Bridge Plaza, Suite 510 Fort Lee, NJ 07024	Each tablet contains 20 mg of lurasidone hydrochloride. Inactive ingredients: mannitol, corn starch, croscarmellose sodium, hypromellose 2910 (6MPA.S), magnesium stearate, carnauba wax.	
lurasidone	Latuda	Lurasidone	02387751	Sunovion Pharmaceuticals Canada Inc.	7025 Langer Drive, Suite 301 Mississauga Ontario Canada L5N 0E8	40mg	tablet	1	lurasidone hydrochloride non-medicinal: carnauba wax, croscarmellose sodium, hypromellose, magnesium stearate, mannitol, Opadry® (hypromellose, polyethylene glycol, and titanium dioxide), pregelatinized starch	Latuda	Lurasidone	40mg	63402-304-30	NDA	200603	Sunovion Pharmaceuticals, Inc.	One Bridge Plaza, Suite 510 Fort Lee, NJ 07024	Each tablet contains 40 mg of lurasidone hydrochloride. Inactive ingredients: mannitol, corn starch, croscarmellose sodium, hypromellose 2910 (6MPA.S), magnesium stearate, carnauba wax.	
lurasidone	Latuda	Lurasidone	02413361	Sunovion Pharmaceuticals Canada Inc.	7025 Langer Drive, Suite 301 Mississauga Ontario Canada L5N 0E8	60mg	tablet	1	lurasidone hydrochloride non-medicinal: carnauba wax, croscarmellose sodium, hypromellose, magnesium stearate, mannitol, Opadry® (hypromellose, polyethylene glycol, and titanium dioxide), pregelatinized starch	Latuda	Lurasidone	60mg	63402-306-30	NDA	200603	Sunovion Pharmaceuticals, Inc.	One Bridge Plaza, Suite 510 Fort Lee, NJ 07024	Each tablet contains 60 mg of lurasidone hydrochloride. Inactive ingredients: mannitol, corn starch, croscarmellose sodium, hypromellose 2910 (6MPA.S), magnesium stearate, carnauba wax.	
lurasidone	Latuda	Lurasidone	02387778	Sunovion Pharmaceuticals Canada Inc.	7025 Langer Drive, Suite 301 Mississauga Ontario Canada L5N 0E8	80mg	tablet	1	lurasidone hydrochloride non-medicinal: carnauba wax, croscarmellose sodium, hypromellose, magnesium stearate, mannitol, Opadry® (hypromellose, polyethylene glycol, and titanium dioxide), pregelatinized starch; 80 mg tablet also contains: FD&C Blue No.2 Aluminum Lake and yellow ferric oxide.	Latuda	Lurasidone	80mg	63402-308-30	NDA	200603	Sunovion Pharmaceuticals, Inc.	One Bridge Plaza, Suite 510 Fort Lee, NJ 07024	Each tablet contains 80 mg of lurasidone hydrochloride. Inactive ingredients: mannitol, corn starch, croscarmellose sodium, hypromellose 2910 (6MPA.S), magnesium stearate, carnauba wax.	
mometasone/ formoterol	Zenhale	mometasone/ formoterol	02361752	Organon Canada Inc.	300 16766 Route Transcanadienne Kirkland Quebec Canada H9H 4M7	100mcg/ 5mcg	metered dose aerosole	2	Inhalation aerosol 100mcg mometasone furoate & 5 mcg formoterol fumarate dihydrate per actuation non-medicinal: Ethanol, HFA (propellant), oleic acid	Dulera	mometasone/ fomoterol	100mcg/5mcg	78206-0127-01	NDA	022518	Organon LLC	30 Hudson St, Jersey City, NJ 07302	mometasone furoate & formoterol fumarate inactive: alcohol & oleic acid	
mometasone/ formoterol	Zenhale	mometasone/ formoterol	02361760	Organon Canada Inc.	300 16766 Route Transcanadienne Kirkland Quebec Canada H9H 4M7	200mcg/ 5mcg	metered dose aerosole	2	Inhalation aerosol 200mcg mometasone furoate & 5 mcg formoterol fumarate dihydrate per actuation non-medicinal: Ethanol, HFA (propellant), oleic acid	Dulera	mometasone/ fomoterol	200mcg/5mcg	78206-0126-01	NDA	022518	Organon LLC	30 Hudson St, Jersey City, NJ 07302	mometasone furoate & formoterol fumarate inactive: alcohol & oleic acid	

Appendix D: Drug List with Required Data Elements

Active Ingredient	Canadian Proprietary Name	Canadian Generic Name	DIN	Company Name	Address	CAN Strength	Dosage Form	# of active Ingred.	Canadian Ingredients	US Proprietary Name	US Generic Name	US Strength	NDC	NDA or ANDA	Number	Applicant Holder Name	Applicant Holder Address	US Ingredients	Comment for FDA
niltinib	Tasigna	Nilotinib (nilotinib hydrochloride monohydrate)	02315874	Novartis Pharmaceuticals Canada Inc.	385 Bouchard Blvd Dorval Quebec Canada, H9S 1A9	200mg	capsule	1	200 mg nilotinib base (as hydrochloride monohydrate), non-medicinal: Capsule content: Colloidal silicon anhydrous; Crospovidone; Lactose monohydrate; Poloxamer 188; Magnesium stearate. Capsule shell: Gelatin; Titanium dioxide; Iron oxide, yellow.	Tasigna	Nilotinib	200mg	00078-0526-87	NDA	022068	Novartis Pharmaceuticals Corporation	One Health Plaza East Hanover, NJ 07936	200 mg nilotinib inactive ingredients: silicon dioxide, crospovidone, lactose monohydrate, magnesium stearate and poloxamer 188, gelatin, ferric oxide red, ferric oxide yellow, and titanium dioxide.	
nintedanib	Ofev	Nintedanib (nintedanib esilate)	02443066	Boehringer Ingelheim (Canada), LTD LTEE	5180 South Service Road Burlington Ontario Canada L7L 5H4	100mg	capsule	1	100 corresponding to 120.40 mg of nintedanib ethanesulfonate (esilate) non-medicinal: black ink (Opacode®), gelatin, glycerol, hard fat, iron oxide black (E172), iron oxide red (E172), iron oxide yellow (E172), medium chain triglycerides, propylene glycol (E1520), shellac glaze, soya lecithin (E322), titanium dioxide (E171)	Ofev	nintedanib esilate	100mg	00597-0143-60	NDA	205832	Boehringer Ingelheim Pharmaceuticals, Inc.	900 Ridgebury Road P.O. Box 368 Ridgefield, CT 06877	100 mg equivalent to 120.40 mg inactive ingredients: triglycerides, hard fat, lecithin, gelatin, glycerol, titanium dioxide, red ferric oxide, yellow ferric oxide, black ink.	
nintedanib	Ofev	Nintedanib (nintedanib esilate)	02443074	Boehringer Ingelheim (Canada), LTD LTEE	5180 South Service Road Burlington Ontario Canada L7L 5H4	150mg	capsule	1	150 mg of nintedanib (as a free base) corresponding to 180.60 mg of nintedanib ethanesulfonate (esilate) non-medicinal: non-medicinal: black ink (Opacode®), gelatin, glycerol, hard fat, iron oxide black (E172), iron oxide red (E172), iron oxide yellow (E172), medium chain triglycerides, propylene glycol (E1520), shellac glaze, soya lecithin (E322), titanium dioxide (E171)	Ofev	nintedanib esilate	150mg	00597-0145-60	NDA	205832	Boehringer Ingelheim Pharmaceuticals, Inc.	900 Ridgebury Road P.O. Box 368 Ridgefield, CT 06877	150 mg of nintedanib equivalent to 180.60 mg nintedanib ethanesulfonate inactive ingredients: triglycerides, hard fat, lecithin, gelatin, glycerol, titanium dioxide, red ferric oxide, yellow ferric oxide, black ink.	
palbociclib	Ibrance	Palbociclib	02493543	Pfizer Canada Ulc.	17300 Trans-Canada Highway Kirkland Quebec Canada H9J 2M5	100mg	tablet	1	palbociclib non-medicinal: Colloidal silicon dioxide, crospovidone, FD&C Blue #2 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, succinic acid , titanium dioxide, triacetin and yellow iron oxide	Ibrance	Palbociclib	100mg	00069-0486-03	NDA	212436	Pfizer Inc.	New York, NY 10017	Palbociclib inactive ingredients: microcrystalline cellulose, silicon dioxide, magnesium stearate, titanium dioxide, crospovidone, succinic acid, hypromellose 2910 (6MPA.S), Triacetin, FD&C Blue No. 2), ferric oxide yellow	
palbociclib	Ibrance	Palbociclib	02493551	Pfizer Canada Ulc.	17300 Trans-Canada Highway Kirkland Quebec Canada H9J 2M5	125mg	tablet	1	palbociclib non-medicinal: Colloidal silicon dioxide, crospovidone, FD&C Blue #2 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, red iron oxide, succinic acid, titanium dioxide, triacetin	Ibrance	Palbociclib	125mg	00069-0688-07	NDA	212436	Pfizer Inc.	New York, NY 10017	Palbociclib inactive ingredients: microcrystalline cellulose, silicon dioxide, magnesium stearate, ferric oxide red, titanium dioxide, crospovidone, succinic acid, hypromellose 2910 (6MPA.S), Triacetin, FD&C Blue No. 2	
pazopanib	Votrient	Pazopanib (pazopanib hydrochloride)	02352303	Novartis Pharmaceuticals Canada Inc.	385 Bouchard Blvd Dorval Quebec Canada, H9S 1A9	200mg	tablet	1	pazopanib as pazopanib hydrochloride non-medicinal: hypromellose, iron oxide black (E172), macrogol, magnesium stearate, microcrystalline cellulose, polysorbate 80, povidone (K30), sodium starch glycollate and titanium dioxide (E171)	Votrient	pazopanib	200mg	00078-0670-66	NDA	022465	Novartis Pharmaceuticals Corporation	One Health Plaza, East Hanover, New Jersey (NJ) 07936, United States (USA)	200 mg of pazopanib equivalent to 216.7 mg of pazopanib hydrochloride inactive ingredients: Magnesium stearate, microcrystalline cellulose, povidone, and sodium starch glycolate type A potato, hypromelloses, ferrosoferric oxide, polyethylene glycol 400 (PEG 400), polysorbate 80, and titanium dioxide	
rifaximin	Zaxine	Rifamixin	02410702	Salix Pharmaceuticals Inc.	400 Somerset Corporate Boulevard Bridgewater, NJ 08807	550mg	tablet	1	Rifaximin 550mg non-medicinal: colloidal silicon dioxide, glyceryl distearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, red iron oxide, gluten-free sodium starch glycolate, talc, and titanium dioxide.	Xifaxan	Rifaximin	550mg	65649-0303-02	NDA	021361	Salix Pharmaceuticals, a division of Bauch Healht, US, LLC	Bridgewater, NJ, 08807, USA	Rifaximin 550mg inactive: silicon dioxide, glycerol palmitostearate, microcrystalline cellulose, propylene glycol, polyvinyl alcohol (unspecified), ferric oxide red, sodium starch glycolate type a potato, talc, titanium dioxide	
rilpivirine	Edurant	Rilpivirine	02370603	Janssen Inc.	19 Green Belt Drive Toronto Ontario Canada M3C 1L9	25mg	tablet	1	active ingredient: rilpivirine hydrochloride non-medicinal ingredients: croscarmellose sodium, hypromellose 2910 6 mPa.s, lactose monohydrate, magnesium stearate, polyethylene glycol 3000, polysorbate 20, povidone K30, silicified microcrystalline cellulose, titanium dioxide and triacetin.	Edurant	rilpivirine	25mg	59676-278-01	NDA	202022	Janssen Products, LP	PO Box 200 1125 Trenton Harbourton Rd, Titusville, New Jersey (NJ) 08560-1504, United States (USA)	25mg of rilpivirine hydrochloride inactive: croscarmellose sodium, magnesium stearate, lactose monohydrate, povidone K30, polysorbate 20, silicon dioxide, microcrystalline cellulose, hypromellose 2010 (6MPA.S), polyethylene glycol 3000, titanium dioxide, triacetin	
rivaroxaban	Xarelto	Rivaroxaban	02480808	Bayer Inc.	2920 Matheson Blvd East Mississauga Ontario Canada L4W 5R6	2.5mg	tablet	1	Rivaroxaban non-medicinal: cellulose microcrystalline, croscarmellose sodium, hypromellose 5 cP, lactose monohydrate, magnesium stearate, sodium lauryl sulphate, ferric oxide yellow, hypromellose 15 cP, polyethylene glycol, titanium dioxide	Xarelto	rivaroxaban	2.5mg	50458-0577-60	NDA	022406	Janssen Pharmaceuticals, Inc.	1125 Trenton-Harbourton Road PO Box 200 Titusville, Nj 08560-1504	rivaroxaban inactive: croscarmellose sodium, hypromellose (unspecified), lactose monohydrate, magnesium stearate, microcrystalline cellulose, and sodium lauryl sulfate, ferric oxide yellow, polyethylene glycol 3350, and titanium dioxide.	
rivaroxaban	Xarelto	Rivaroxaban	02316986	Bayer Inc.	2920 Matheson Blvd East Mississauga Ontario Canada L4W 5R6	10mg	tablet	1	Rivaroxaban non-medicinal: cellulose microcrystalline, croscarmellose sodium, hypromellose 5 cP, lactose monohydrate, magnesium stearate, sodium lauryl sulphate,ferric oxide red, hypromellose 15 cP, polyethylene glycol, titanium dioxide	Xarelto	rivaroxaban	10mg	50458-0580-30	NDA	022406	Janssen Pharmaceuticals, Inc.	1125 Trenton-Harbourton Road PO Box 200 Titusville, Nj 08560-1504	rivaroxaban inactive: microcrystalline cellulose, croscarmellose sodium, hypromellose (unspecified), lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium lauryl sulfate, polyethylene glycol 3350, titanium dioxide, ferric oxide red.	
rivaroxaban	Xarelto	Rivaroxaban	02378604	Bayer Inc.	2920 Matheson Blvd East Mississauga Ontario Canada L4W 5R6	15mg	tablet	1	Rivaroxaban non-medicinal: cellulose microcrystalline, croscarmellose sodium, hypromellose 5 cP, lactose monohydrate, magnesium stearate, sodium lauryl sulphate,ferric oxide red, hypromellose 15 cP, polyethylene glycol, titanium dioxide	Xarelto	rivaroxaban	15mg	50458-0578-90	NDA	022406	Janssen Pharmaceuticals, Inc.	1125 Trenton-Harbourton Road PO Box 200 Titusville, Nj 08560-1504	rivaroxaban inactive: microcrystalline cellulose, croscarmellose sodium, hypromellose (unspecified), lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium lauryl sulfate, polyethylene glycol 3350, titanium dioxide, ferric oxide red.	
rivaroxaban	Xarelto	Rivaroxaban	02378612	Bayer Inc.	2920 Matheson Blvd East Mississauga Ontario Canada L4W 5R6	20mg	tablet	1	Rivaroxaban non-medicinal: cellulose microcrystalline, croscarmellose sodium, hypromellose 5 cP, lactose monohydrate, magnesium stearate, sodium lauryl sulphate,ferric oxide red, hypromellose 15 cP, polyethylene glycol, titanium dioxide	Xarelto	rivaroxaban	20mg	50458-0579-30	NDA	022406 202439	Janssen Pharmaceuticals, Inc.	1125 Trenton-Harbourton Road PO Box 200 Titusville, Nj 08560-1504	rivaroxaban inactive: microcrystalline cellulose, croscarmellose sodium, hypromellose (unspecified), lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium lauryl sulfate, polyethylene glycol 3350, titanium dioxide, ferric oxide red.	

Appendix D: Drug List with Required Data Elements

Active Ingredient	Canadian Proprietary Name	Canadian Generic Name	DIN	Company Name	Address	CAN Strength	Dosage Form	# of active Ingred.	Canadian Ingredients	US Proprietary Name	US Generic Name	US Strength	NDC	NDA or ANDA	Number	Applicant Holder Name	Applicant Holder Address	US Ingredients	Comment for FDA
selexipag	Uptravi	Selexipag	02451212	Janssen Inc.	19 Green Belt Drive Toronto Ontario Canada M3C 1L9	1400mcg	tablet	1	Selexipag 1400mg non-medicinal: carnauba wax, corn starch, D- mannitol, hydroxypropyl cellulose, hypromellose, iron oxide yellow (E172), low substituted hydroxypropyl cellulose, magnesium stearate, propylene glycol, titanium dioxide (E171)	Uptravi	Selexipag	1400 mcg	66215-0614-06	NDA	207947	Actelion Pharmaceuticals US, Inc.	5000 Shoreline Court, Ste. 200 South San Francisco, CA 94080, USA	selexipag 1400mg Inactive ingredients: mannitol, corn starch, low substituted hydroxypropylcellulose (unspecified), hydroxypropylcellulose (1200000 WAMW), and magnesium stearate, hypromellose (unspecified), propylene glycol, titanium dioxide, ferric oxide yellow, carnauba wax	
sitagliptin	Januvia	Sitagliptin (Sitagliptin phosphate monohydrate)	02388839	Merck Canada Inc.	16750 Route Transcanadienne Kirkland Quebec Canada H9H 4M7	25mg	tablet	1	sitagliptin phosphate monohydrate 32.13mg (25mg sitagliptin) Anhydrous dibasic calcium phosphate (calcium hydrogen phosphate, anhydrous), croscarmellose sodium, magnesium stearate, microcrystalline cellulose, polyethylene glycol (macrogol), polyvinyl alcohol, red iron oxide, sodium stearyl fumarate, talc, titanium dioxide, and yellow iron oxide.	Januvia	Sitagliptin phosphate	25mg	00006-0221-31	NDA	021995	Merck Sharp & Dohme Corp.	Whitehouse Station, NJ 08889	sitagliptin phosphate inactive: anhydrous dibasic calcium phosphate, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, polyethylene glycol (unspecified), polyvinyl alcohol (unspecified), ferric oxide red, sodium steryl fumarate, talc, titanium dioxide, ferric oxide yellow.	
sitagliptin	Januvia	Sitagliptin (Sitagliptin phosphate monohydrate)	02388847	Merck Canada Inc.	16750 Route Transcanadienne Kirkland Quebec Canada H9H 4M7	50mg	tablet	1	sitagliptin phosphate monohydrate 64.25mg (50mg sitagliptin) Anhydrous dibasic calcium phosphate (calcium hydrogen phosphate, anhydrous), croscarmellose sodium, magnesium stearate, microcrystalline cellulose, polyethylene glycol (macrogol), polyvinyl alcohol, red iron oxide, sodium stearyl fumarate, talc, titanium dioxide, and yellow iron oxide.	Januvia	Sitagliptin phosphate	50mg	00006-0112-31	NDA	021995	Merck Sharp & Dohme Corp.	Whitehouse Station, NJ 08889	sitagliptin phosphate inactive: anhydrous dibasic calcium phosphate, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, polyethylene glycol (unspecified), polyvinyl alcohol (unspecified), ferric oxide red, sodium steryl fumarate, talc, titanium dioxide, ferric oxide yellow.	
sitagliptin	Januvia	Sitagliptin (Sitagliptin phosphate monohydrate)	02303922	Merck Canada Inc.	16750 Route Transcanadienne Kirkland Quebec Canada H9H 4M7	100mg	tablet	1	sitagliptin phosphate monohydrate 128.5mg (100mg sitagliptin) Anhydrous dibasic calcium phosphate (calcium hydrogen phosphate, anhydrous), croscarmellose sodium, magnesium stearate, microcrystalline cellulose, polyethylene glycol (macrogol), polyvinyl alcohol, red iron oxide, sodium stearyl fumarate, talc, titanium dioxide, and yellow iron oxide.	Januvia	Sitagliptin phosphate	100mg	00006-0277-31	NDA	021995	Merck Sharp & Dohme Corp.	Whitehouse Station, NJ 08889	sitagliptin phosphate inactive: anhydrous dibasic calcium phosphate, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, polyethylene glycol (unspecified), polyvinyl alcohol (unspecified), ferric oxide red, sodium steryl fumarate, talc, titanium dioxide, ferric oxide yellow.	
sitagliptin/ metformin	Janumet	Sitagliptin phosphate monohydrate/ metformin hydrochloride	02333856	Merck Canada Inc.	16750 Route Transcanadienne Kirkland Quebec Canada H9H 4M7	50-500mg	tablet	2	sitagliptin phosphate monohydrate and metformin hydrochloride non-medicinal: Black iron oxide, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, polyvinylpyrrolidone, red iron oxide, sodium lauryl sulfate, sodium stearyl fumarate, talc and titanium dioxide.	Janumet	Sitagliptin phosphate monohydrate/ metformin hydrochloride	50-500mg	00006-0575-61	NDA	022044	Merck Sharp & Dohme Corp.	Whitehouse Station, NJ 08890	sitagliptin phosphate, metformin hydrochloride inactive: ferrosoferric oxide, microcrystalline cellulose, polyethylene glycol (unspecified), polyvinyl alcohol (unspecified), povidone K30, ferric oxide red, sodium lauryl sulfate, sodium stearyl fumarate, talc, titanium dioxide	
sitagliptin/ metformin	Janumet	Sitagliptin phosphate monohydrate/ metformin hydrochloride	02333872	Merck Canada Inc.	16750 Route Transcanadienne Kirkland Quebec Canada H9H 4M7	50-1000mg	tablet	2	sitagliptin phosphate monohydrate and metformin hydrochloride non-medicinal: Black iron oxide, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, polyvinylpyrrolidone, red iron oxide, sodium lauryl sulfate, sodium stearyl fumarate, talc and titanium dioxide.	Janumet	Sitagliptin phosphate monohydrate/ metformin hydrochloride	50-1000mg	00006-0577-61	NDA	022044	Merck Sharp & Dohme Corp.	Whitehouse Station, NJ 08891	sitagliptin phosphate, metformin hydrochloride inactive: ferrosoferric oxide, microcrystalline cellulose, polyethylene glycol (unspecified), polyvinyl alcohol (unspecified), povidone K30, ferric oxide red, sodium lauryl sulfate, sodium stearyl fumarate, talc, titanium dioxide	
tiotropium	Spiriva	Tiotropium (tiotropium bromide monohydrate)	02246793	Boehringer Ingelheim (Canada), LTD LTEE	5180 South Service Road Burlington Ontario Canada L7L 5H4	18mcg	capsule (inhalation)	1	capsule / 18 mcg / equivalent to 22.5 mcg tiotropium bromide monohydrate non-medicinal: gelatin, lactose monohydrate (which contains milk protein)	Spiriva Handihaler	tiotropium bromide	18mcg	00597-0075-41	NDA	021395	Boehringer Ingelheim Pharmaceuticals, Inc.	Ridgefield, CT 06877 USA	tiotropium bromide monohydrate inactive: lactose monohydrate	
tiotropium	Spiriva Respimat	Tiotropium (tiotropium bromide monohydrate)	02435381	Boehringer Ingelheim (Canada), LTD LTEE	5180 South Service Road Burlington Ontario Canada L7L 5H4	2.5mcg	Solution (inhalation)	1	Solution for Inhalation mcg / 2 .5 per actuation non-medicinal: Benzalkonium chloride, disodium edetate, hydrochloric acid and purified water	Spiriva Respimat	tiotropium bromide	2.5mcg	00597-0100-61	NDA	021936	Boehringer Ingelheim Pharmaceuticals, Inc.	Ridgefield, CT 06877 USA	tiotropium bromide anhydrous inactive/excipients: water for injection, edetate disodium, benzalkonium chloride and hydrochloric acid	
tofacitinib	Xeljanz XR	Tofacitinib (Tofacitinib citrate)	02470608	Pfizer Canada Ulc.	17300 Trans-Canada Highway Kirkland Quebec Canada H9J 2M5	11mg	tablet	1	11 mg tofacitinib (as tofacitinib citrate) non-medicinal: ammonium hydroxide, cellulose acetate, copovidone, ferrosoferric oxide/black iron oxide, hydroxyethyl cellulose, hydroxypropyl cellulose, HPMC 2910/hypromellose, magnesium stearate, propylene glycol, red iron oxide, shellac glaze, sorbitol, titanium dioxide, triacetin.	Xeljanz XR	Tofacitinib citrate	11mg	00069-0501-30	NDA	208246	Pfizer Laboratories Div. Pfizer Inc.	235 East 42nd Street New York, NY 10017	11 mg tofacitinib citrate inactive ingredients: sorbitol, hydroxyyethyl cellulose (140 MPA.S at 5%), copividone K25-31, magnesium stearate, cellulose acetate, hydroxypropyl Cellulose (1600000 WAMW), titanium dioxide, hypromellose 2910 (6 MPA.S), Triacetin, ferric oxide red, shellac, ammonia, propylene glycol, ferrosoferric oxide	
varenicline	Apo-Varenicline	Varenicline (varenicline tartrate)	02419882	Apotex Inc.	150 Signet Drive Toronto Ontario Canada M9L 1T9	0.5mg	tablet	1	varenicline tartrate non-medicinal: Anhydrous dibasic calcium phosphate, croscarmellose sodium, sodium stearyl fumarate. The film-coating contains hydroxypropyl cellulose, hydroxypropyl methylcellulose, titanium dioxide and triacetin.	Varenicline	Varenicline	0.5mg	49884-0155-76	ANDA	201785	Par Pharmaceutical Inc.	Chesnut Ridge NY, 10977, USA	varenicline tartrate inactive: croscarmellose sodium, maltodextrin, microcrystalline cellulose, stearic acid, hydroxypropyl cellulose (unspecified), hypromellose 2910 (6 MPA.S), talc, titanium dioxide	
varenicline	Apo-Varenicline	Varenicline (varenicline tartrate)	02419882	Apotex Inc.	150 Signet Drive Toronto Ontario Canada M9L 1T9	0.5mg	tablet	1	varenicline tartrate non-medicinal: Anhydrous dibasic calcium phosphate, croscarmellose sodium, sodium stearyl fumarate. The film-coating contains hydroxypropyl cellulose, hydroxypropyl methylcellulose, titanium dioxide and triacetin.	Varenicline	Varenicline	0.5mg	60505-4765-	N/A	N/A	Apotex Corp.	2400 N Commerce Pkwy Ste 400 Weston, FL, 33326-3253 United States	varenicline tartrate inactive: microystalline cellulose, anhydrous dibasic calcium phosphate, magnesium stearate, hypromellose 2910 (5 MPA.S), hydroxypropyl cellulose (110000 WAMW), triacetin, titanium dioxide	
varenicline	Apo-Varenicline	Varenicline (varenicline tartrate)	02419890	Apotex Inc.	150 Signet Drive Toronto Ontario Canada M9L 1T9	1mg	tablet	1	varenicline tartrate non-medicinal: Anhydrous dibasic calcium phosphate, croscarmellose sodium, sodium stearyl fumarate. The film-coating contains hydroxypropyl cellulose, hydroxypropyl methylcellulose, titanium dioxide and triacetin. The 1 mg tablet also contains indigotine aluminum lake 12% to 14% as a colouring agent.	Varenicline	Varenicline	1mg	60505-4766-6	N/A	N/A	Apotex Corp.	2400 N Commerce Pkwy Ste 400 Weston, FL, 33326-3253 United States	varenicline tartrate inactive: microystalling cellulose, anhydrous dibasic calcium phosphate, magnesium stearate, hypromellose 2910 (5 MPA.S), hydroxypropyl cellulose (110000 WAMW), triacetin, titanium dioxide, FD&C Blue #2	

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varenicline	Apo-Varenicline	Varenicline (varenicline tartrate)	02419890	Apotex Inc.	150 Signet Drive Toronto Ontario Canada M9L 1T9	1mg	tablet	1	varenicline tartrate non-medicinal: Anhydrous dibasic calcium phosphate, croscarmellose sodium, sodium stearyl fumarate. The film-coating contains hydroxypropyl cellulose, hydroxypropyl methylcellulose, titanium dioxide and triacetin. The 1 mg tablet also contains indigotine aluminum lake 12% to 14% as a colouring agent.	Varenicline	Varenicline	1mg	49884-0156-76	ANDA	201785	Par Pharmaceutical Inc.	Chesnut Ridge NY, 10977, USA	verenicline tartrate inactive: croscarmellose sodium, maltodextrin, microcrystalline cellulose, stearic acid, hydroxypropyl cellulose (unspecified), hypromellose 2910 (6 MPA.S), talc, titanium dioxide, FD&C blue #2, ferric oxide yellow	
varenicline	Champix	Varenicline (varenicline tartrate)	02291177	Pfizer Canada Ulc.	17300 Trans-Canada Highway Kirkland Quebec Canada H9J 2M5	0.5mg	tablet	1	varenicline tartrate non-medicinal: anhydrous dibasic calcium phosphate, colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, and microcrystalline cellulose. The film-coating contains hypromellose, polyethylene glycol, titanium dioxide and triacetin.	Chantix	Varenicline	0.5mg	0069-0468-56	NDA	021928	Pfizer Laboratories Div. Pfizer Inc.	235 East 42nd Street New York, NY 10017	varenicline tartrate inactive: microystalline cellulose, anhydrous dibasic calcium phosphate, croscarmellose sodium, silicon dioxide, magnesium stearate, hypromellose (unspecified), titanium dioxide, polyethylene glycol (unspecified), triacetin, FD&C Blue No 2.	
varenicline	Champix	Varenicline (varenicline tartrate)	02291185	Pfizer Canada Ulc.	17300 Trans-Canada Highway Kirkland Quebec Canada H9J 2M5	1mg	tablet	1	varenicline tartrate non-medicinal: anhydrous dibasic calcium phosphate, colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, and microcrystalline cellulose. The film-coating contains hypromellose, polyethylene glycol, titanium dioxide and triacetin. The 1.0 mg tablet also contains FD&C Blue #2/Indigo Carmine Aluminum Lake as a colouring agent.	Chantix	Varenicline	1mg	0069-0469-56	NDA	021928	Pfizer Laboratories Div. Pfizer Inc.	235 East 42nd Street New York, NY 10017	varenicline tartrate inactive: microystalline cellulose, anhydrous dibasic calcium phosphate, croscarmellose sodium, silicon dioxide, magnesium stearate, hypromellose (unspecified), titanium dioxide, polyethylene glycol (unspecified), triacetin, FD&C Blue No 2.	
varenicline	Teva-Varenicline	Varenicline (varenicline tartrate)	02426226	Teva Canada Ltd.	30 Novopharm Court Toronto Ontario Canada M1B 2K9	0.5mg	tablet	1	Varenicline tartrate non-medicinal: Dibasic calcium phosphate dihydrate, microcrystalline cellulose, croscarmellose sodium, povidone, colloidal silicon dioxide and magnesium stearate. The film-coating contains hypromellose, titanium dioxide and triacetin.	Varenicline	Varenicline	0.5mg	49884-0155-76	ANDA	201785	Par Pharmaceutical Inc.	Chesnut Ridge NY, 10977, USA	varenicline tartrate inactive: croscarmellose sodium, maltodextrin, microcrystalline cellulose, stearic acid, hydroxypropyl cellulose (unspecified), hypromellose 2910 (6 MPA.S), talc, titanium dioxide	
varenicline	Teva-Varenicline	Varenicline (varenicline tartrate)	02426226	Teva Canada Ltd.	30 Novopharm Court Toronto Ontario Canada M1B 2K9	0.5mg	tablet	1	Varenicline tartrate non-medicinal: Dibasic calcium phosphate dihydrate, microcrystalline cellulose, croscarmellose sodium, povidone, colloidal silicon dioxide and magnesium stearate. The film-coating contains hypromellose, titanium dioxide and triacetin.	Varenicline	Varenicline	0.5mg	60505-4765-	N/A	N/A	Apotex Corp.	2400 N Commerce Pkwy Ste 400 Weston, FL, 33326-3253 United States	varenicline tartrate inactive: microystalline cellulose, anhydrous dibasic calcium phosphate, magnesium stearate, hypromellose 2910 (5 MPA.S), hydroxypropyl cellulose (110000 WAMW), triacetin, titanium dioxide	
varenicline	Teva-Varenicline	Varenicline (varenicline tartrate)	02426226	Teva Canada Ltd.	30 Novopharm Court Toronto Ontario Canada M1B 2K9	1mg	tablet	1	Varenicline tartrate non-medicinal: Dibasic calcium phosphate dihydrate, microcrystalline cellulose, croscarmellose sodium, povidone, colloidal silicon dioxide and magnesium stearate. The film-coating contains hypromellose, titanium dioxide and triacetin. The 1 mg tablet also contains FD&C Blue #1 / brilliant blue FCF aluminum lake and iron oxide black as colouring agents.	Varenicline	Varenicline	1mg	60505-4766-6	N/A	N/A	Apotex Corp.	2400 N Commerce Pkwy Ste 400 Weston, FL, 33326-3253 United States	varenicline tartrate inactive: microystalling cellulose, anhydrous dibasic calcium phosphate, magnesium stearate, hypromellose 2910 (5 MPA.S), hydroxypropyl cellulose (110000 WAMW), triacetin, titanium dioxide, FD&C Blue #2	
varenicline	Teva-Varenicline	Varenicline (varenicline tartrate)	02426226	Teva Canada Ltd.	30 Novopharm Court Toronto Ontario Canada M1B 2K9	1mg	tablet	1	Varenicline tartrate non-medicinal: Dibasic calcium phosphate dihydrate, microcrystalline cellulose, croscarmellose sodium, povidone, colloidal silicon dioxide and magnesium stearate. The film-coating contains hypromellose, titanium dioxide and triacetin. The 1 mg tablet also contains FD&C Blue #1 / brilliant blue FCF aluminum lake and iron oxide black as colouring agents.	Varenicline	Varenicline	1mg	49884-0156-76	ANDA	201785	Par Pharmaceutical Inc.	Chesnut Ridge NY, 10977, USA	verenicline tartrate inactive: croscarmellose sodium, maltodextrin, microcrystalline cellulose, stearic acid, hydroxypropyl cellulose (unspecified), hypromellose 2910 (6 MPA.S), talc, titanium dioxide, FD&C blue #2, ferric oxide yellow	
vilanterol trifenate, fluticasone furoate, umeclidinium bromide	Trelegy Ellipta	Vilanterol trifenate, lfuticasone furoate, umeclidinium bromide	02474522	GlaxoSmithKline Inc.	800 100 Milverton Drive Mississauga Ontario Canada L5R 4H1	vilanterol 25mcg, fluticasone 100mcg, umeclidinium 62.5mcg	Powder (inhaler)	3	Dry powder for oral inhalation 100 mcg fluticasone furoate 62.5 mcg umeclidinium (as bromide) 25 mcg vilanterol (as trifenatate) non-medicinal: lactose monohydrate (which contains milk protein) and magnesium stearate	Trelegy Ellipta	Vilanterol trifenate, fluticasone furoate, umeclidinium bromide	vilanterol 25mcg, fluticasone 100mcg, umeclidinium 62.5mcg	0173-0887-10	NDA	209482	GlaxoSmithKline LLC	5 Moore Drive Research Triangle Park, NC 27709	vilanterol 25mcg, fluticasone 100mcg, umeclidinium 62.5mcg inactive: magnesium stearate, lactose monohydrate	
vilanterol trifenate, fluticasone furoate, umeclidinium bromide	Trelegy Ellipta	Vilanterol trifenate, lfuticasone furoate, umeclidinium bromide	02515776	GlaxoSmithKline Inc.	800 100 Milverton Drive Mississauga Ontario Canada L5R 4H1	vilanterol 25mcg, fluticasone 200mcg, umeclidinium 62.5mcg	Powder (inhaler)	3	Dry powder for oral inhalation 200 mcg fluticasone furoate 62.5 mcg umeclidinium (as bromide) 25 mcg vilanterol (as trifenatate) non-medicinal: lactose monohydrate (which contains milk protein) and magnesium stearate	Trelegy Ellipta	Vilanterol trifenate, fluticasone furoate, umeclidinium bromide	vilanterol 25mcg, fluticasone 200mcg, umeclidinium 62.5mcg	00173-0893-10	NDA	209482	GlaxoSmithKline LLC	5 Moore Drive Research Triangle Park, NC 27709	vilanterol 25mcg, fluticasone 200mcg, umeclidinium 62.5mcg inactive: magnesium stearate, lactose monohydrate	

Appendix E: Drug List with Cost Savings Analysis

Appendix E: Drug List with Cost Savings Analysis

Drug Name	Strength	Brand or Generic	Drug Category	Colorado Unit Price	Canadian Unit Price with 50% Markup[9]	APDC Units	Self Funded Units[8]	Total Units	Annual Colorado Commercial Cost	Annual Importation Cost	Total Annual Savings	Percent Savings
Advair Diskus	100-50mcg	Brand	respiratory	$252.95	$85.26	9300	4916	14216	$3,595,914.21	$1,212,089.45	$2,383,824.76	66%
fluticasone & salmeterol diskus	100-50mcg	Generic	respiratory	$153.34	$47.71	2310	1221	3531	$541,458.10	$168,468.42	$372,989.68	69%
Wixela Inhub	100-50mcg	Generic	respiratory	$94.47	$47.71	7102	3754	10856	$1,025,584.53	$517,951.67	$507,632.86	49%
Advair Diskus	250-50mcg	Brand	respiratory	$314.88	$102.03	22425	11853	34278	$10,793,576.56	$3,497,290.66	$7,296,285.91	68%
fluticasone & salmeterol diskus	250-50mcg	Generic	respiratory	$186.75	$57.11	5504	2909	8412	$1,571,065.72	$480,395.40	$1,090,670.31	69%
Wixela Inhub	250-50mcg	Generic	respiratory	$103.63	$57.11	24894	13158	38052	$3,943,393.76	$2,172,931.95	$1,770,461.81	45%
Advair Diskus	500-50mcg	Brand	respiratory	$408.84	$102.03	7291	3854	11145	$4,556,527.94	$1,137,071.41	$3,419,456.53	75%
fluticasone & salmeterol diskus	500-50mcg	Generic	respiratory	$209.21	$81.07	1419	750	2169	$453,783.46	$175,838.88	$277,944.58	61%
Wixela Inhub	500-50mcg	Generic	respiratory	$124.72	$81.07	13974	7386	21360	$2,664,111.27	$1,731,624.71	$932,486.56	35%
Advair HFA	115-21mcg	Brand	respiratory	$350.92	$144.83	7330	3874	11204	$3,931,727.36	$1,622,690.13	$2,309,037.23	59%
Advair HFA	230/21mcg	Brand	respiratory	$442.56	$144.83	6480	3425	9905	$4,383,654.49	$1,434,586.60	$2,949,067.89	67%
Afinitor	5mg	Brand	cancer	$496.46	$209.25	712	376	1088	$540,322.72	$227,735.74	$312,586.97	58%
Afinitor Disperz	2mg	Brand	cancer	$534.05	$238.32	84	44	128	$68,571.52	$30,600.29	$37,971.23	55%
Afinitor Disperz	3mg	Brand	cancer	$487.99	$238.32	56	30	86	$41,772.13	$20,400.19	$21,371.94	51%
Afinitor Disperz	5mg	Brand	cancer	$432.91	$238.32	22	291	841	$363,951.65	$200,359.03	$163,592.62	45%
Baqsimi	3mg	Brand	low blood sugar	$276.04	$148.05	2371	1253	3624	$1,000,418.92	$536,569.16	$463,849.77	46%
Biktarvy[1]	50-200-25mg	Brand	HIV	$105.24	$44.12	275883	145824	421707	$44,380,917.92	$18,606,774.92	$25,774,143.00	58%
Cabenuva (2mL)[2]	400-200mg	Brand	HIV	$4,160.48	$1,537.08	42	22	65	$268,869.37	$99,332.94	$169,536.43	63%
Cabenuva (3mL)[2]	600-300mg	Brand	HIV	$6,240.71	$3,074.14	8	4	13	$80,660.68	$39,733.03	$40,927.65	51%
Cabometyx	20mg	Brand	cancer	$586.42	$330.00	1215	642	1857	$1,089,107.60	$612,873.75	$476,233.85	44%
Cabometyx	40mg	Brand	cancer	$736.78	$330.00	3050	1612	4662	$3,434,973.61	$1,538,489.66	$1,896,483.95	55%
Cabometyx	60mg	Brand	cancer	$719.57	$330.00	894	473	1367	$983,323.24	$450,954.02	$532,369.23	54%
Chantix	0.5mg	Brand	smoking cessation	$7.88	$1.93	4921	2601	7522	$59,295.41	$14,529.88	$44,765.54	75%
varenicline	0.5mg	Generic	smoking cessation	$7.69	$1.04	5154	2724	7878	$60,578.50	$8,154.00	$52,424.50	87%
Chantix	1mg	Brand	smoking cessation	$8.35	$1.93	136090	71933	208023	$1,736,117.20	$401,846.38	$1,334,270.82	77%
varenicline	1mg	Generic	smoking cessation	$7.50	$1.04	73917	39070	112987	$847,182.00	$116,941.97	$730,240.03	86%
Combivent Respimat	20-100mcg	Brand	respiratory	$373.87	$34.14	4053	2142	6195	$2,316,229.09	$211,530.77	$2,104,698.32	91%
Copaxone	20mg	Brand	multiple sclerosis	$209.45	$48.60	5922	3130	9052	$1,895,944.74	$439,936.92	$1,456,007.82	77%
glatiramer	20mg	Generic	multiple sclerosis	$127.40	$36.45	540	285	825	$105,160.61	$30,086.87	$75,073.74	71%
Glatopa	20mg	Generic	multiple sclerosis	$72.88	$36.45	5355	2831	8186	$596,528.36	$298,361.48	$298,166.89	50%
Copaxone	40mg	Brand	multiple sclerosis	$424.64	$138.22	14136	7472	21608	$9,175,503.90	$2,986,587.94	$6,188,915.95	67%
glatiramer	40mg	Generic	multiple sclerosis	$213.28	$138.22	11544	6102	17646	$3,763,446.75	$2,438,962.31	$1,324,484.44	35%
Descovy	200 -25mg	Brand	HIV	$54.36	$32.30	196344	103782	300126	$16,313,567.51	$9,693,689.11	$6,619,878.40	41%
Dulera	100-5mcg	Brand	respiratory	$298.87	$87.75	1024	541	1566	$467,982.61	$137,402.90	$330,579.71	71%
Dulera	200-5mcg	Brand	respiratory	$322.78	$108.00	2198	1162	3360	$1,084,463.18	$362,858.40	$721,604.78	67%
Edurant	25mg	Brand	HIV	$41.83	$15.53	2940	1554	4494	$187,990.37	$69,769.35	$118,221.02	63%
Eliquis	2.5mg	Brand	blood thinner	$5.75	$1.80	1078985	570321	1649306	$9,485,689.48	$2,968,750.16	$6,516,939.32	69%
Eliquis	5mg	Brand	blood thinner	$6.22	$1.80	5076184	2683126	7759310	$48,242,562.22	$13,966,757.69	$34,275,804.53	71%
EpiPen	0.3mg	Brand	anaphylaxis	$264.89	$91.13	193	102	295	$78,146.75	$26,883.18	$51,263.57	66%
Epinephrine	0.3mg	Generic	anaphylaxis	$116.97	$91.13	30293	16012	46305	$5,416,038.90	$4,219,521.30	$1,196,517.60	22%
EpiPen Jr	0.15mg	Brand	anaphylaxis	$224.94	$91.13	106	56	162	$36,446.86	$14,764.85	$21,682.01	59%
Epinephrine	0.15mg	Generic	anaphylaxis	$124.50	$91.13	7518	3974	11492	$1,430,731.56	$1,047,190.28	$383,541.29	27%
Erleada	60mg	Brand	cancer	$92.97	$31.88	52350	27671	80021	$7,439,525.81	$2,551,260.42	$4,888,265.38	66%
Estring	2mg	Brand	women's health	$415.69	$70.62	2379	1257	3636	$1,511,630.20	$256,793.98	$1,254,836.22	83%
everolimus	5mg	Generic	cancer	$260.92	$57.00	4380	2315	6695	$1,746,864.87	$381,600.80	$1,365,264.07	78%
Farxiga	10mg	Brand	type 2 diabetes	$14.59	$2.76	351383	185731	537114	$7,835,819.39	$1,480,420.50	$6,355,398.89	81%
Farxiga	5mg	Brand	type 2 diabetes	$14.09	$2.76	147779	78112	225891	$3,182,621.75	$622,611.40	$2,560,010.35	80%
Flovent HFA[3]	44mcg	Brand	respiratory	$179.06	$25.44	5241	2770	8011	$1,434,457.04	$203,775.61	$1,230,681.43	86%

Appendix E: Drug List with Cost Savings Analysis

Drug Name	Strength	Brand or Generic	Drug Category	Colorado Unit Price	Canadian Unit Price with 50% Markup[9]	APDC Units	Self Funded Units[8]	Total Units	Annual Colorado Commercial Cost	Annual Importation Cost	Total Annual Savings	Percent Savings
Fluticasone HFA[3][7]	44mcg	Generic	respiratory	$132.95	$39.51	5241	2770	8011	$1,065,094.74	$316,524.21	$748,570.53	70%
Flovent HFA[3]	110mcg	Brand	respiratory	$235.61	$42.81	6728	3556	10283	$2,422,856.58	$440,196.54	$1,982,660.04	82%
Fluticasone HFA[3][7]	110mcg	Generic	respiratory	$177.99	$39.50	6728	3556	10283	$1,830,353.81	$406,183.98	$1,424,169.82	78%
Flovent HFA[3]	220mcg	Generic	respiratory	$353.25	$85.62	2680	1416	4096	$1,446,853.36	$350,698.37	$1,096,154.99	76%
Fluticasone HFA[3][7]	220mcg	Generic	respiratory	$276.46	$50.65	2680	1416	4096	$1,132,326.84	$207,442.39	$924,884.45	82%
Genvoya	150-150-200-10mg	Brand	HIV	$101.78	$49.28	136220	72002	208222	$21,193,696.37	$10,260,209.32	$10,933,487.04	52%
Gilenya	0.5mg	Brand	multiple sclerosis	$287.33	$95.81	45578	24091	69669	$20,017,740.92	$6,674,660.44	$13,343,080.47	67%
GlucaGen HypoKit	1mg	Brand	low blood sugar	$284.88	$128.90	132	70	202	$57,481.04	$26,008.84	$31,472.20	55%
Glucagon	1mg	Brand	low blood sugar	$241.27	$86.74	2299	1215	3514	$847,869.88	$304,811.68	$543,058.20	64%
Ibrance[4]	75mg	Brand	cancer	$524.56	$285.65	4867	2573	7440	$3,902,491.45	$2,125,120.29	$1,777,371.16	46%
Ibrance[4]	100mg	Brand	cancer	$516.16	$285.65	10171	5376	15547	$8,024,807.43	$4,441,051.66	$3,583,755.77	45%
Ibrance[4]	125mg	Brand	cancer	$547.51	$285.65	14364	7592	21956	$12,021,452.22	$6,271,877.50	$5,749,574.72	48%
Invokana	100mg	Brand	type 2 diabetes	$15.89	$2.94	6614+14811	11325	32750	$520,391.83	$96,444.83	$423,946.99	81%
Invokana	300mg	Brand	type 2 diabetes	$15.78	$2.94	7110+25477	17225	49812	$786,076.18	$146,690.68	$639,385.51	81%
Janumet	50/500mg	Brand	type 2 diabetes	$6.29	$1.54	49768	26306	76074	$478,207.91	$117,248.96	$360,958.95	75%
Janumet	50/1000mg	Brand	type 2 diabetes	$6.18	$1.54	217956	115205	333161	$2,057,871.40	$513,484.88	$1,544,386.52	75%
Januvia	25mg	Brand	type 2 diabetes	$12.87	$2.94	37911	20039	57950	$745,892.74	$170,656.71	$575,236.03	77%
Januvia	50mg	Brand	type 2 diabetes	$12.38	$2.94	128510	67927	196437	$2,432,621.65	$578,488.94	$1,854,132.71	76%
Januvia	100mg	Brand	type 2 diabetes	$12.90	$2.94	489048	258497	747545	$9,645,708.33	$2,201,454.03	$7,444,254.30	77%
Jardiance	10mg	Brand	type 2 diabetes	$15.78	$2.94	459406	242829	702235	$11,078,246.89	$2,068,020.29	$9,010,226.59	81%
Jardiance	25mg	Brand	type 2 diabetes	$15.47	$2.94	768580	406249	1174829	$18,173,436.43	$3,459,769.87	$14,713,666.56	81%
Kyleena[6]	19.5mg	Brand	women's health	$888.16	$403.50	1016	537	1553	$1,379,337.86	$626,652.85	$752,685.00	55%
Latuda	20mg	Brand	mental health	$42.07	$4.02	47368	25037	72405	$3,046,105.25	$290,798.07	$2,755,307.18	90%
Latuda	40mg	Brand	mental health	$42.73	$4.02	69687	36835	106522	$4,551,275.52	$427,817.20	$4,123,458.32	91%
Latuda	60mg	Brand	mental health	$42.74	$4.02	47921	25330	73251	$3,130,837.42	$294,193.01	$2,836,644.41	91%
Latuda	80mg	Brand	mental health	$43.44	$4.02	68495	36205	104700	$4,548,178.74	$420,499.37	$4,127,679.37	91%
Mirena[6]	52 mg	Brand	women's health	$547.62	$431.21	5934	3137	9071	$4,967,242.99	$3,911,331.46	$1,055,911.53	21%
Nuvaring	2.6mg - 11.4 mg	Brand	women's health	$142.71	$14.11	13890	7342	21232	$3,030,018.69	$299,528.42	$2,730,490.27	90%
EluRyng	2.6mg - 11.4 mg	Generic	women's health	$84.63	$14.11	17337	9164	26501	$2,242,791.27	$373,860.64	$1,868,930.63	83%
ethinyl estradiol/etonogestrel	2.6mg - 11.4 mg	Generic	women's health	$92.01	$14.11	15232	8051	23283	$2,142,397.59	$328,467.74	$1,813,929.84	85%
Odefsey	200-25-25mg	Brand	HIV	$92.40	$44.13	44354	23444	67798	$6,264,664.39	$2,991,634.54	$3,273,029.85	52%
Ofev	100mg	Brand	idiopathic pulmonary fibrosis	$151.57	$31.28	12000	6343	18343	$2,780,162.69	$573,672.86	$2,206,489.84	79%
Ofev	150mg	Brand	idiopathic pulmonary fibrosis	$156.52	$61.16	16770	8864	25634	$4,012,161.07	$1,567,656.01	$2,444,505.06	61%
Pulmicort	90mcg	Brand	respiratory	$170.01	$34.76	1280	677	1957	$332,636.71	$68,015.31	$264,621.39	80%
Pulmicort	180mcg	Brand	respiratory	$233.01	$71.06	1884	996	2880	$671,028.86	$204,626.22	$466,402.64	70%
Restasis[5]	0.05%	Brand	dry eye	$8.28	$4.53	350205	185108	535313	$4,434,161.13	$2,426,976.93	$2,007,184.20	45%
cyclosporin[5][7]	0.05%	Generic	dry eye	$6.63	$1.54	350205	185108	535313	$3,550,911.94	$825,051.71	$2,725,860.22	77%
Restasis Multi-Dose	0.05%	Brand	dry eye	$87.79	$41.32	2219	1173	3392	$297,774.90	$140,140.20	$157,634.70	53%
Revolade	25mg	Brand	blood	$167.85	$59.06	4805	2540	7345	$1,232,822.28	$433,801.41	$799,020.88	65%
Revolade	50mg	Brand	blood	$295.36	$118.13	5684	3004	8688	$2,566,199.62	$1,026,317.25	$1,539,882.37	60%

Appendix E: Drug List with Cost Savings Analysis

Drug Name	Strength	Brand or Generic	Drug Category	Colorado Unit Price	Canadian Unit Price with 50% Markup[9]	APDC Units	Self Funded Units[8]	Total Units	Annual Colorado Commercial Cost	Annual Importation Cost	Total Annual Savings	Percent Savings
Spiriva Handihaler	18mcg	Brand	respiratory	$377.35	$58.39	4777	2525	7302	$2,755,428.98	$426,353.62	$2,329,075.37	85%
Spiriva Respimat	2.5mcg	Brand	respiratory	$324.04	$58.39	10289	5438	15727	$5,096,394.95	$918,287.74	$4,178,107.22	82%
Sprycel	50mg	Brand	cancer	$262.22	$82.31	3008	1590	4598	$1,205,677.96	$378,479.21	$827,198.75	69%
Sprycel	100mg	Brand	cancer	$476.49	$164.63	13276	7017	20293	$9,669,510.75	$3,340,886.56	$6,328,624.20	65%
Symtuza	800-150-200-10mg	Brand	HIV	$128.70	$63.24	10034	5304	15338	$1,974,031.61	$969,897.73	$1,004,133.88	51%
Synthroid	100mcg	Brand	thyroid deficiency	$0.95	$0.07	457658	241905	699563	$665,106.67	$48,794.52	$616,312.15	93%
Tasigna	200mg	Brand	cancer	$144.33	$39.65	7504	3966	11470	$1,655,494.71	$454,777.56	$1,200,717.15	73%
Tivicay	50mg	Brand	HIV	$50.73	$20.81	100093	52906	152999	$7,761,239.55	$3,184,297.93	$4,576,941.62	59%
Trelegy	100-62.5-25mcg	Brand	respiratory	$237.37	$148.73	18416	9734	28150	$6,681,829.86	$4,186,603.94	$2,495,225.91	37%
Trelegy	200-62.5-25mcg	Brand	respiratory	$255.26	$186.67	5971	3156	9126	$2,329,581.15	$1,703,634.01	$625,947.14	27%
Triumeq	600-50-300mg	Brand	HIV	$93.68	$45.64	75063	39676	114739	$10,748,920.75	$5,236,360.95	$5,512,559.79	51%
Uptravi	1400 mcg	Brand	pulmonary arterial hypertension	$215.31	$72.19	1560	825	2385	$513,412.52	$172,136.34	$341,276.18	66%
Ventolin	90mcg	Brand	respiratory	$54.00	$6.75	17802	9409	27211	$1,469,288.75	$183,675.05	$1,285,613.70	87%
Albuterol Inhaler	90mcg	Generic	respiratory	$25.97	$5.63	206061	108918	314979	$8,180,823.07	$1,771,759.27	$6,409,063.80	78%
Victoza	18mg/3mL	Brand	type 2 diabetes	$266.97	$77.05	29249	15460	44709	$11,936,126.26	$3,444,898.65	$8,491,227.61	71%
Votrient	200mg	Brand	cancer	$125.05	$38.71	6775	3581	10356	$1,295,062.40	$400,896.47	$894,165.93	69%
Xarelto	2.5mg	Brand	blood thinner	$7.06	$1.60	45947	24286	70233	$495,654.95	$112,197.65	$383,457.29	77%
Xarelto	10mg	Brand	blood thinner	$13.73	$3.20	227155	120068	347223	$4,767,952.65	$1,109,376.34	$3,658,576.31	77%
Xarelto	15mg	Brand	blood thinner	$12.58	$3.20	156837	82900	239737	$3,016,642.02	$765,958.30	$2,250,683.72	75%
Xarelto	20mg	Brand	blood thinner	$12.99	$3.20	1387544	733416	2120960	$27,544,913.67	$6,776,467.57	$20,768,446.11	75%
Xeljanz XR	11mg	Brand	chronic inflammatory disorder	$145.43	$51.97	69832	36911	106743	$15,523,766.26	$5,547,137.22	$9,976,629.05	64%
Xifaxan	550mg	Brand	irritable bowel syndrome	$41.01	$8.64	175177	92594	267771	$10,979,962.22	$2,312,784.51	$8,667,177.71	79%
Xtandi	40mg	Brand	cancer	$74.40	$31.88	95790	50632	146422	$10,893,698.57	$4,668,294.86	$6,225,403.71	57%
Zytiga	500mg	Brand	cancer	$178.91	$63.75	630	333	963	$172,290.33	$61,391.25	$110,899.08	64%
							Totals		**$538,559,209.30**	**$188,049,183.33**	**$350,510,025.97**	**65%**

Biktarvy[1] volume was reduced by 20% to estimate savings for Cabenuva.

Cabenuva[2] volume was estimated using 20% of the Biktarvy volume to show potential annual savings. Treatment begins with single 2mL injection, followed by 3mL every 2 months (6 injections per year).

Flovent HFA[3] brand name units were reduced by 50% to estimate volume and savings for the equivalent generic fluticasone HFA.

Ibrance[4] capsules are being discontinued. 2021 capsule & tablet volumes were combined to provide accurate replacement estimates.

Restasis[5] brand name units were reduced by 50% to show estimated volume and savings for the equivalent generic cyclosporine.

Kyleena[6] & Mirena[6] volume and Colorado Unit cost estimates were obtained from aggregated commercial plan Physician Administered Drug (PAD) data from the CIVHC APDC for calendar year (CY) 2020.

Generic Flovent (fluticasone)[7] & generic Restasis (cyclosporine)[7] - To identify the Colorado Unit cost, we used the wholesale acquisition cost (WAC), accessed September 2022, as listed in the Department's contracted access to First Databank (FDB) pricing data which is received and updated weekly from FDB.

[8]CIVHC data includes 100 percent of fully insured and 63 percent of self-funded lives (according to CIVHC and other sources). In order to derive a cost savings estimate for the self-funded lives ont included in CIVHC data, we assumed similar utilization rates to CIVHC claims but a lower cost per claim of 10% to account for the stronger negotiating power of larger self-funded employers.

[9]Canadian pricing was sourced primarily from the July 2022 Quebec Province's "List of Medications." The prices reflected on the Quebec list are the "guaranteed selling price," which is defined as the price at which it is sold by an accredited manufacturer or wholesaler to pharmacies. When Quebec data was unavailable, the Department used Ontario pricing or wholesale prices supplied by our Foreign Seller. All Canadian prices were then converted to U.S. dollars and a 50% markup was applied to each unit price to cover estimated costs of the supply chain.

Appendix F: Certification Reports

RC Kennedy Consulting
208 Holmard St
Gaithersburg, MD 20878
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AdiraMedica Visit
4/11/22
Observations and Comments

General

A team representing the Colorado Importation Program visited AdiraMedica and Bioscript Logistics on 4/11/22 for a review of their business and operations in consideration of their participation as an importer for the program. The visit included a visit to the Adira offices in Toronto and to Adira's 3PL partner, Bioscript.

Adira is a pharmaceutical sourcing firm touting a global reach for the sourcing of drugs. The firm is based in Clark, NJ, with offices in Toronto. Their primary business is sourcing active pharmaceutical ingredients, finished dosage forms, raw materials, intermediates and excipients. A core part of their business is in support of clinical trials.

As this review is primarily focused on the storage and distribution of drugs, the focus is on the visit to Bioscript. Bioscript Logistics is a Toronto based 3PL that specializes in the distribution of pharmaceuticals in Canada. We ensure products are imported, stored and delivered securely, on time and with quality assured. Bioscript touts their GMP-compliant facility with cold chain capabilities from ambient to refrigerated and frozen inventory, ensuring that the integrity of your product is maintained. Bioscript focuses their business on importation and distribution of pharmaceuticals and medical devices in Canada. They hold a Drug Establishment License (DEL) for wholesale and packaging.

System

The WMS and inventory management system used by Bioscript is proprietary. The system was built by a Bioscript partner specifically around the needs of their business model. The system is quite capable regarding the ability to manage a pharma distribution center with strict system controls on the movement of inventory and rules for storage. Mobile devices equipped with scanners are deployed both on the inbound and outbound process to verify the accuracy and timeliness of receiving and picking.

Though the system is supportive of good practices for lot-controlled items, it is maintained by a single individual who is a Bioscript contractor. There does not appear to be a back-up plan for support, nor does there appear to be sufficient documentation of code for knowledge transfer. This puts Bioscript at risk of a single point of failure. Steps should be taken with urgency to transfer knowledge and create documentation for the system.

Process

Bioscript management clearly understands the requirements of managing pharmaceuticals, particularly regarding the management of lots and expiration dates. As a 3PL, Bioscript has multiple pharma customers and so has been through rigorous past reviews and validation of their processes. The facility appeared to be quite full of inventory, and we were informed that there is an expansion planned to accommodate growth that is already expected aside from the Colorado process.

Training and SOP's

Though the visit did not provide time for a detailed review, management claimed that the users have been formally trained on their tasks and responsibilities. As a GMP compliant facility and as a 3PL with multiple pharma clients, it is likely true that both a training program and set of SOPs is in place.

Summary

Adira, partnered with Bioscript, present Colorado with a capable and experienced partner for sourcing and managing drugs for the Importation program. Related specifically to drug storage and distribution, as an existing third-party logistics provider in the pharmaceutical space, and with multiple other pharma companies as customers, Bioscript is a competent and experienced company capable for the Colorado Importation program.

Client
Lauren Reveley, Drug Importation Program Manager
Kelly Swartzendruber, Pharm.D. – Drug Importation Pharmacist
State of Colorado Department of Health Care Policy & Financing
1570 Grant Street
Denver CO 80203

Performer, Document Author:
Tyler Foley
Principal Consultant

Project Scope:
Assist State of Colorado Dept. of HCPF in auditing Premier Pharmaceuticals for their drug reimportation program by conducting a site visit of the Premier Pharmaceuticals to verify facility meets compliance to appropriately warehouse and distribute pharmaceutical products.

Project number:
WO-1002663

Körber Pharma Inc. – a Körber group company
2243 Energy Drive Apex, NC 27502, USA
Tyler.Foley@Koerber.com

Koerber-Pharma.com

Confidential
June 29th, 2022

Introduction

Korber Pharma Inc. (KPI) specializes in pharmaceutical product inspection, secondary packaging, and storage of finished drug products. Our consultants are industry experts with decades of training and actual pharmaceutical industry experience doing the respective work. Korber Pharma Inc has been engaged to provide consulting services to the State of Colorado Dept. HCPF to assist in the evaluation of Premier Pharmaceuticals' ability to adhere to cGMP principles and compliance with appropriate regulations and industry best practices.

Trip Report

The below regulations and industry guidance documentation were utilized by KPI to facilitate its final determination of regulatory compliance:

- 21 CFR 211 part C
- 21 CFR 1301.71-7
- 21 CFR 205.50
- USP 1079
- USP 659
- Canada GUI-0069

The characterizations and conditions of the Premier warehouse were made by direct observation during facility walkthrough and observations of personnel performing their actual assigned work tasks, along with review of the following documentation provided by the facility's management:

- The complete set of company SOPs
- Employee training forms
- Maintenance, Cleaning, and Pest Control logs
- Recent internal audits
- Facility floor plans
- Environmental monitoring logs

The Premier warehouse facility is of suitable size, construction, and location to facilitate cleaning, maintenance, and proper operations. Work processes are segregated into specifically designated areas with physical and procedural control systems in place to prevent mix-ups during the course of normal operations. Lighting is adequately provided in all areas both inside and outside the building for required work processes and illumination of spaces for security observations. Appropriate facilities and utilities exist for the cleaning and sanitation required for the areas used to store drug products. Building maintenance, pest control, and cleaning is performed and logged on a routine schedule.

All documentation including SOPs and work instructions, and logs are properly maintained and secure. Documentation control is currently maintained via a paper-based system with plans to convert to an electronic-based document management system in the near future. Employees are trained to the appropriate SOPs for their job functions. The Quality Management System shows an appropriate level of control for the operations. Security, document control, version control and accountability are under the scrutiny of both the quality unit and the C-suite management.

All areas designated to store drug products are temperature and humidity controlled and monitored. The storage area is separated from external environment factors by 3 secured doors that are procedurally not allowed to be open at the same time. All temperature and humidity recorded are well within USP specifications and show only an impressive insignificant variance of under one degree centigrade. The HVAC system and electric required for refrigerated storage are backed up with a natural gas generator.

Temperature, humidity, and security footage are available in real time and accessible via the internet at any location. Monitoring systems are set to alarm and notify management and select users through email, text, and phone call outs. The alarms are set at levels still within specification so that corrections can be made before going out of specification. The local environmental conditions and potential natural disasters have been considered in risk analysis and disaster recovery plan.

Premier has recently invested in the expansion and improvement of its existing facilities to better meet existing business and be able to support anticipated expansion more easily. Plans also exist to further expand existing warehousing into adjacent spaces already controlled by Premier.

Recommendations

Premier Pharmaceuticals has demonstrated sufficient capacity, knowledge and expertise to provide the warehousing and distribution services required in support of the Colorado HCPF drug re-importation project. The distributor is already a known and active member of the industry providing drug products and devices to pharmacies across the United States. Korber Pharma Inc. is confident that they can adequately provide the services necessary to make this program successful. We would endorse the Colorado Dept. of HCPF selection of this distributor.

Sincerely,

Tyler Foley

Principal Consultant

RC Kennedy Consulting
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Premier Pharmaceuticals Visit
6/30/22
Observations and Comments

General Assessment

The Premier site in Boise, ID was visited by a team representing the Colorado Importation program. The purpose of the visit was to conduct a follow-up review from a visit last year to review the Premier operations. In that first visit, a series of recommendations were made to Premier to advance them toward compliance with generally good practices for pharmaceutical operations.

As a general statement, Premier has made significant improvements in every area discussed, regarding facilities, procedures, and systems. Specifically, with respect to systems, Premier has deployed NetSuite as their ERP platform giving them an industry leading system that has functionality and controls to properly manage pharmaceuticals.

The following report details observations of the operation from the visit of 6/27/22.

System

Premier has implemented the NetSuite ERP system with the native WMS as a replacement for Fishbowl. The new system has been in use since mid-January of 2022. NetSuite is used for financial management, CRM, inventory management and document management. The system is also used for customer order management where Premier sales staff can directly create orders, or, customers can use the Premier portal and those orders will arrive in NetSuite through a Premier built interface.

NetSuite is a highly popular ERP system owned by Oracle that is exclusively cloud based. NetSuite is one of the leading ERP systems in the market. The company has a strong support organization, is highly innovative with a strong R&D capability. NetSuite is also supported by a large partner solution community that provide additional partner solutions and services to augment the NetSuite core software.

As a cloud-based system, NetSuite deploys their software in a true SaaS, or multi-tenant scheme. The company houses the software in NetSuite data centers that are structured for security and redundancy. Currently NetSuite has 12 data centers in locations around the globe. For more information on the NetSuite data centers use this link: https://www.netsuite.com/portal/assets/pdf/ds-netsuite-data-center.pdf.

Standard Operating Procedures (SOP's)

Premier has invested in an effort to create and document SOP's that detail how processes are conducted. The SOP's are available in hard copy and will also be electronically kept in NetSuite. Premier has built a full collection of SOPs to direct each specific task being conducted in the operation. Each SOP is version controlled and employs signature verification for changes.

Training program

Premier originally purchased training from NetSuite for the lead staff users. The intent is to use those users to transfer their training knowledge to additional staff as needed based on job roles. A core group of Premier staff have been trained in their specific use of the system.

Security

As mentioned above, NetSuite provides the facility to restrict access to the system based on user roles, and the assignment of individual users to those roles. In this manner, Premier has created a security hierarchy that restricts access to only those screens that are defined for a particular role. Further, access has been restricted by transaction by role so that certain user roles are restricted in what they can transact. For example, some fields can be updated, others can only be viewed.

Disaster Recovery

There are several components of a master disaster recovery plan, such of which Premier have implemented, or are in the process of implementing:

1. System reliability. Because the business system is NetSuite, and is therefore hosted in NetSuite datacenters, the system is secure against extended downtime. Oracle data centers are architected for failover and redundancy, assuring 99% plus uptime. As long as Premier has internet access, they will have access to their system.
2. Premier has purchased a high-end backup generator that will enable continuous operations in the event of a power outage, ensuring continuous internet access.
3. Facility access. Premier has only the Boise facility to house the drugs that will be included in the Colorado import program. Plans for distribution of drugs to additional facilities are in process. Until then, in any event where the facility is put out of commission, either through natural events, fire or flooding, plans need to be developed for quick response recovery.
4. Communication. Premier is developing a formal, structured communication plan for quick response to a disaster which will define the communication chain and designate who is responsible and what is the order of communication.

Inventory Management

The NetSuite system is the primary record of inventory, including the physical management of inventory. NetSuite includes essential capabilities for the management of pharmaceuticals, including:

1. management of lots and expiration dates for each drug. Users can apply transactions to inventory that make it available or not for processing. Lots can be restricted to alternative storage based on availability status. Lots can be applied to orders automatically by NetSuite in the order creation process based on FEFO.
2. Inventory is managed by location, that is, each item is assigned to a specific location, visible in the system. One item only is assigned to a location. Multiple lots of that item can be stored in the same location. There is an overflow area where inventory can be temporarily assigned when space is not available in the primary location. That inventory can be transferred to the primary through a Bin Transfer transaction in the system.
3. Premier conducts full physical inventories twice annually. Discrepancies are handled through NetSuite using inventory adjustments, which update the inventory records and include the ability to attach a reason code. Access to inventory adjustments can be restricted, so that the persons handling inventory through normal operational processes are not also adjusting inventory.

Process Flow inbound

Purchase orders are created by Premier staff in NetSuite. As inventory arrives, product is checked in by physically opening cartons and inspecting/verifying accuracy by first comparing the actual receipt against the vendor

packing list. The product is then also verified against the PO using the appropriate NetSuite screens. Best practices suggest that the electronic status of inventory in the system should always reflect the physical status. In the short term, this can be somewhat addressed manually. In the longer term, Premier is investigate inserting a putaway transaction between receipt check in and storage. This transaction will be enhanced in accuracy with the future use of mobile terminals to scan products to confirm location putaway.

Premier does process a small amount of returns, using NetSuite to create a return authorization to accompany the shipment back to Premier. Returned items are then inspected and returned to inventory or disposed.

Process Flow Outbound

Once a customer order is added to NetSuite, it holds a status of Pending Fulfillment, and is visible to the user for completion. Lots can be assigned by the system, or in relevant cases, can be manually assigned. Typically, orders are processed in the sequence of when they were created, though Premier can choose to process any order in any sequence. Larger orders may be assigned and completed individually through a pass through the warehouse. Smaller orders may be "clustered" together and picked simultaneously. Several steps are involved in processing the completion of an order through NetSuite:

1. Assign and Fulfill

   When this transaction is completed, a packlist is printed and inventory is allocated to the order. The packlist is also used as a pick sheet. With the completion the system also decrements inventory of the item and the lot and the product is physically decremented from the shelf for packing.

2. Inspection and Packing

   As items are picked and then physically packed, the system is updated to reflect that. Premier uses a double inspection of picked/packed items to ensure accuracy.

3. Ship and Bill

   Once packed and inspected, the FEDEX label is printed, which accords the shipment a status of shipped. Then the order is moved to a status of billed so that the invoice can be printed and inserted into the carton. For future growth, Premier is investigating the possibility of inserting a status of "staged" for those orders that are completed and awaiting pickup.

Future Considerations

1. Mobile Terminals and Scanning

   Premier has plans to eventually introduce the use of mobile terminals into the process. These units will be equipped with scanners. The introduction of these units will be critical for future growth as they are a means of closing the receiving and picking gaps mentioned above by enabling more real time transactions, and, the scanning will introduce better accuracy into the putaway process and pick confirmation process.

2. Cycle Counting

   As the business grows, Premier should investigate the availability of cycle counting with the NetSuite system. A system managed cycle count capability will better ensure the verification counting of inventory locations and do so much more efficiently than manual physical inventory counts.

3. Cluster or Batch Picking

   As mentioned, Premier will sometimes group multiple smaller orders together to be picked simultaneously. For future consideration, Premier should investigate whether NetSuite carries the logic to manage this process. Most WMS software has a batch picking capability.

4. Weights and Measures

   Premier is in the process of collecting dimension and weight data primarily for shipping use. That process may be able to be facilitated by the use of a Cubiscan device, or through an effort to collect the data from manufacturers. As the business grows, that data could become useful for other purposes such as picking containerization, putaway allocated and storage zoning.

Summary

Since the first visit to the Premier site, the company has made substantial improvements that address original comments regarding security, systems, and facility. This investment in their business indicates that the Importation program is an important strategic direction for Premier. These improvements, coupled with an experienced and capable management team, position Premier to be a capable partner for the Importation program

LDT Health Solutions, Inc.
38 Cedar Place
Wayne, NJ 07470
862. 221.9575
www.LDTRx.com

5.5.22

Report to:

Colorado Dept. of Health Care Policy & Financing / Pharmacy Office **(the "Client")**
1570 Grant Street, [State Relay – 711]
Denver, CO 80203
Attn: Dr. Kelly Swartzendruber, Pharm.D. – Drug Importation Pharmacist

Re:

Q Laboratories
1930 Radcliff Drive
Cincinnati, OH 45204-1823
(513) 471-1300
www.qlaboratories.com

DUNS # 0807377501
FEIN # 1527260

Overview

LDT Health Solutions Inc. ("LDT") is a medication safety & quality management consulting firm specializing in compliance programs and independent review activities related to the production of compounded preparations, regulatory compliance, including FDA matters, and other specialty areas of pharmacy practice. Our principals have over 70 years of experience in multiple healthcare settings. Our current consulting work includes FDA approved manufacturers, 503B Outsourcing Facilities, and hospitals.

LDT Health Solutions, Inc. was engaged to provide consulting services to the Client to facilitate the Client's contract decision regarding the importation wholesaler / distributor model by verifying the activities related to that project by the contract laboratory named above. LDT inspected visit to this laboratory to assist in evaluating the quality, scope, and regulatory compliance, of the laboratory. As well as to assist in analyzing the contracted services required by any importation partner or contractor engaged in this drug importation program to access their operations and related compliance issues in connection with the State importation system.

Observations & Findings

The following characterizations of the operations and physical plant conditions currently at Q Laboratory LLC were made by direct observation, and document review provided by the lab's quality staff and were used as a basis for this report.

General Scope-

The following LDT intellectual properties, Federal regulations and other guidance documents were utilized by LDT to facilitate its final determination of regulatory compliance:

1. LDT's document (12-01A.01) **ISO/IEC 17025**[1] General Accreditation Requirements Compliance Crosswalk -
    a. Covering the following required areas-
        i. General
        ii. Confidentiality
        iii. Structural
        iv. Personnel
        v. Record retention
        vi. Facilities and Environmental Conditions
        vii. Equipment
            1. Metrological Traceability
            2. Traceability of Results
            3. Externally Provided products & services
        viii. Process (controlled)
            1. Requests, tenders, and contracts
            2. Selection, Verification, and validations of Methods
            3. Validation of Methods & record retention
            4. Sampling plans
            5. Handling of tests and calibration of items
        ix. Technical Records
        x. Reporting of results
            1. Conformity statements
            2. Amendments to reports
        xi. Complaints
        xii. Non-conforming work
        xiii. Data control and Information Management
        xiv. Control of Management System Documents
            1. Internal audits & findings
            2. Management reviews & reporting

2. Compliance to applicable federal statues, rules, and regulations governing analytical laboratories, as described by the Drug Quality & Security Act (DQSA)[2] and the applicable sections of the USP/NF and the Federal Food Drug & Cosmetic Act (FDCA).
    a. **Colorado Senate Bill 19-005**, passed in 2019, the Department of HealthCare Policy & Financing (Department) / Canadian Prescription Drug importation program.
    b. Compliance to relevant FDA Guidance documents for Reference Laboratory Establishments.

[1] ISO 17025 - https://www.iso.org/ISO-IEC-17025-testing-and-calibration-laboratories.html
[2] https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa

c. Compliance to Local Department of Health Regulation in the jurisdiction the laboratory is registered (Ohio).
d. Review of policies and procedures relating to receiving, processing, storage, security, holding, and processing of drug inventory samples (as applicable).
e. Review of compliance with relevant recordkeeping requirements, including sampling of current operation files.

Findings & General Impressions of Current Q-Labs Operations –

Utilizing the provided documents listed below, in advance of the visit and additional documents which were requested by LDT on-site to complete the assessment of compliance required by the statement-of-work agreed to by LDT and the Colorado Dept. of Health Care Policy & Financing / Pharmacy Office.

These documents were, in part:

1. A copy of the complete table-of-contents of the policy manual for the lab.
2. A copy of a new employee orientation/training checklist (new hire)
3. A copy of an annual employee training checklist
4. A copy of the firm's table of organization.
5. A floor plan of the entire space including the processing area(s)
6. Two (2) lab technician training files
    a. The newest employee
    b. A tenured employee
7. Temperature, Humidity, & Pressure Logs for the last 30 days.
8. Cleaning Logs for the last 30 days.
9. A copy of any open correspondence with any state, federal or local licensing authority.

The laboratory was most cooperative, and all records requested were made available in short order and those documents were in good order and complete. LDT did request the following documents as representative of the scope, quality and completeness of the information provided:

1. A summary of Q Labs LLC quality operations, services, and a description of the organization, structure & scope of business. (Site Master File)[3]
2. A current table of Organization of Q-labs LLC[4]
3. A complete table of contents of standard operating procedures (Policy & Procedures)[5]
4. Current floor plans of Q-labs production building (levels I & II) for reference. [6]

The documents revealed an FDA registered establishment in good standing holding an ISO 17025 accreditation *(most recently conducted November 12-14, 2019).* They have no open or unresolved issues with FDA. Their applicable state registration (OH) is in good standing and current.

The site is of suitable size and construction to accommodate current operations and appears to have sufficient unutilized space to accommodate some increased production volume. Discussion with

[3] ATTACHMENT ONE - Q-Labs site master file
[4] ATTACHMENT TWO – Q-Labs TOO
[5] ATTACHMENT THREE – Q-Labs SOP TOC
[6] ATTACHMENT FOUR – Q-Labs Floor plans (level I & II) 1911 Radcliffe Drive, Cincinnati, OH 452204

ownership revealed a future expansion plan that includes development of adjoining real estate which is already owned and controlled by Q Labs LLC.

The lab maintains its major equipment in good repair and all requisite independent calibrations and certifications were evident. Evidence of regular cleaning, maintenance, and calibration of equipment in-use was apparent.

Q-labs only sub-contracts lab work outside its organization if a customer requests it, or if the lab is temporarily unable to perform the necessary work, and only after specific approval by the customer.

Critical documents, including policy & procedure, and master work instructions are properly maintained, and secure. Document control is all maintained electronically. Quality Management System shows a high level of control, sophistication, and is well developed for the operations. Security, documents control, version control and accountability are maintained electronically and under the scrutiny of both the Quality Unit and C-suite management.

It is apparent that the company invested in physical plant construction, continues to invest in the maintenance, upkeep, and expansion of the business. Along with that investment in capital equipment, Q-labs continues to invest and provide an orientation, training & development program for employees which is broad and on-going and appears to be sufficient to support current operations.

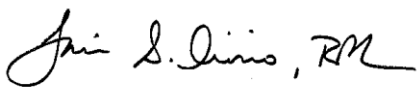
FINAL DETERMINATION OF COMPLAINCE & SUITABLITY OF SERVICES-

Q-Labs LLC appears to have sufficient capacity, knowledge, and expertise to provide the technical services required to support this drug importation project. The laboratory is currently providing these services to numerous other customers in the Pharma & healthcare sectors without incident. LDT is confident that they can deliver the services to make this program successful.

We would endorse the CO Dept. of Health Care Policy & Financing / Pharmacy Office's selection/approval of this service provider.

Thank you for the opportunity to serve you, your staff, and patients.

Very truly yours,



Louis S. Diorio, RPh, FAPhA

Principal

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Background

On October 18th, members of the Colorado Drug Importation program, including RC Kennedy Consulting, conducted meeting and a tour of the Omega Tech Labs manufacturing site in Boise, ID. The purpose of the visit was to review Omega as a source for relabeling of Canadian products to be compliant with federal regulations governing the importation initiative. Below is a summary of those findings.

Current Business Operations

Omega Tech Labs was founded by the current CEO in the 1980's. Omega is a contract manufacturer producing, packaging, and labeling personal and hygiene care products. In total, Omega produces approximately 100 distinct items for their customers. Omega is somewhat unique in their business model as they will formulate products based on customer requirements, as opposed to traditional contract manufacturers who more commonly produce products with exact specifications provided by the customer.

The management of Omega shows deep experience in both contract manufacturing including pharmaceutical manufacturing. Omega management has made clear their desire to participate in the importation program. Their strategic goal is to move into the pharmaceutical manufacturing business and the Colorado program is seen as an entre into doing so.

Labeling

As a CMO, Omega is well versed in labeling operations for their current product line. Their current labeling operations include automatic labeling equipment to rapidly apply labels to a variety of containers. Currently, label production is outsourced to Action Quality Printers where labels artwork is designed, and labels are produced for Omega products.

Relabeling Operations

As discussed with both Omega and Premier management, the scope of participation for Omega in the importation program will be to produce and relabel Canadian containers. The plan is to tightly manage the relabeling operation under the following scenario:

1. Omega will cordon off an appropriate area of their current facility to be reserved for the relabeling operation which will be compliant with regulatory requirements for manufacturing of pharmaceuticals. The area will be secured by an access limited steel cage and will include a separate entrance and exit to the building which will be secured. The relabeling operation will be self-contained within the area, that is, all components (label stock etc.), product, equipment, will be kept in this area only. Inventory will be stored and managed separately from the rest of the Omega operations. In effect, Omega will be creating a facility within a facility.
2. All inventory will be stored and managed by Premier, except for work-in-process inventory that is actively being relabeled by Omega.
3. Work orders will be created by Premier and transmitted directly to Omega. Premier will deliver the inventory to Omega from their facility (less than 1 mile away). All product will be received into Omega inventory using the current DBA system. Premier will manage the workflow so that only a single workorder will be active at a time. Each workorder will also consist of a single product and lot.
4. Omega will provide for quality assurance of the relabeled product, including management of inventory and component inventory, damaged or destroyed items.

5. When work is completed, Premier will issue an order for Omega to ship the finished product. Premier will then pickup the product for receipt back into their facility.

Under this arrangement, Omega's relabeling operation for the Importation program will be separate from its current business operations. The operation will act as a manufacturing and storage site. That is, inventory coming from Premier will be received into Omega, and finished product leaving Omega will be shipped out of inventory against a Premier order. In this manner, a change of custody will occur on the product each time it moves in and out of the two facilities.

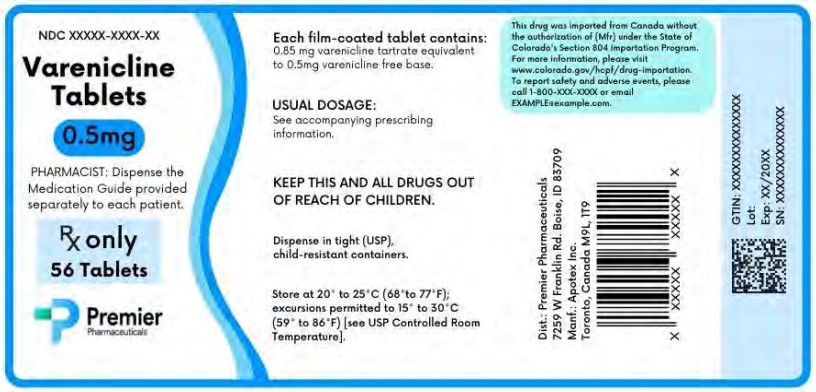
By cordoning off the relabeling area and making it self-contained, Omega will be able to avoid having to bring the rest of their operation into more strict regulatory requirements for facility and inventory management.

Summary

Omega Tech Labs, in partnership with Premier, is easily qualified to manage the relabeling of Canadian drugs for the Colorado Importation Program. Labeling is a routine part of their current manufacturing processes, and the Omega team includes people who are well-versed and experienced in regulations regarding manufacturing and distribution. The plan described above will make compliance, quality assurance, and delivery of drugs easily achievable for the program.

Appendix G: Proposed Relabeling Figures

Label Comparisons and Annotation for varenicline 0.5 mg

Canadian Product Label DIN 02419882		**Label Comparison:** - Canadian label contains both English and French languages. - ANDA label and proposed label specify temperature controls that are narrower than Canadian, although allow excursions outside of the temperature range. - Proposed label specifies all current approved ANDA labeling statements and storage conditions. - Proposed label includes Final Rule specific statement specifying that it is an imported drug under Colorado's Section 804 Importation Program. Colorado disagrees with this statement, as all drugs imported through the program will have the express authorization of drug manufacturers. - Proposed rule has all additional requirements as specified in part 251.13.
ANDA 49884-155-76 Approved Bottle Label		
Proposed Label for Imported Eligible Drug		

	US Product ANDA	Equivalent Canadian Import
Product Name	Varenicline	Apo-Varenicline
Route of Administration	Oral	Oral
Active Ingredients	varenicline tartrate API Manufacturer: Unknown Currently	varenicline tartrate API Manufacturer: Unknown Currently
Inactive Ingredients	croscarmellose sodium, maltodextrin, microcrystalline cellulose, stearic acid, hydroxypropyl cellulose (unspecified), hypromellose 2910 (6 MPA.S), talc, titanium dioxide	Anhydrous dibasic calcium phosphate, croscarmellose sodium, sodium stearyl fumarate. The film-coating contains hydroxypropyl cellulose, hydroxypropyl methylcellulose, titanium dioxide and triacetin.
Manufacturer/Labeler	Par Pharmaceutical, Inc. Manufactured by Par Formulations Private Limited, 9/215, Pudupakkam, Kelambakkam-603103.	Apotex, Inc. 150 Signet Drive Toronto, Ontario, Canada M9L 1T9
Tablet Characteristics	Circular, biconvex tablets: 0.5 mg (white to off-white film-coated tablets, debossed with “P” on one side and “155” on other side)	White, modified capsule shape, biconvex, coated tablet, engraved “APO” on one side and “VAR” over “0.5” on the other side. Each tablet contains 0.5 mg of varenicline (as tartrate).
Storage Conditions	Store at 20° to 25° C (68°-77° F); excursions permitted to 15°-30° C (59°-86° F) [see USP Controlled Room Temperature].	Store at room temperature (15ºC to 30ºC) Difference: Storage considerations have a wider specification range. However, the Colorado product will require 20° to 25° C

Appendix H: Enlarged Figure Library

Detailed Movement of Prescription Drugs - Colorado Canadian Drug Importation Program

Step 1

Eligible Prescription Drug Purchased directly from FDA approved manufacturer

Step 2

Drug is shipped from the manufacturer to AdiraMedica in Canada
(Foreign Seller)

Step 3

Drug enters US via Customs & Border Protection (C.B.P.) Port of Entry in Buffalo, NY

Step 4

Drug shipped to Designated Secure Warehouse (Premier Pharmaceuticals, Idaho)
(Importer)

Step 5

After test results are approved by FDA, drugs are relabeled by Omega Tech Labs, Idaho
(Relabeler)

Step 6

Drugs are sent back to Premier and are ready to sell to participating pharmacies

Step 7

Drugs sent to participating pharmacies in Colorado

Drug samples are sent for testing to Q Laboratories
(Qualified Lab)

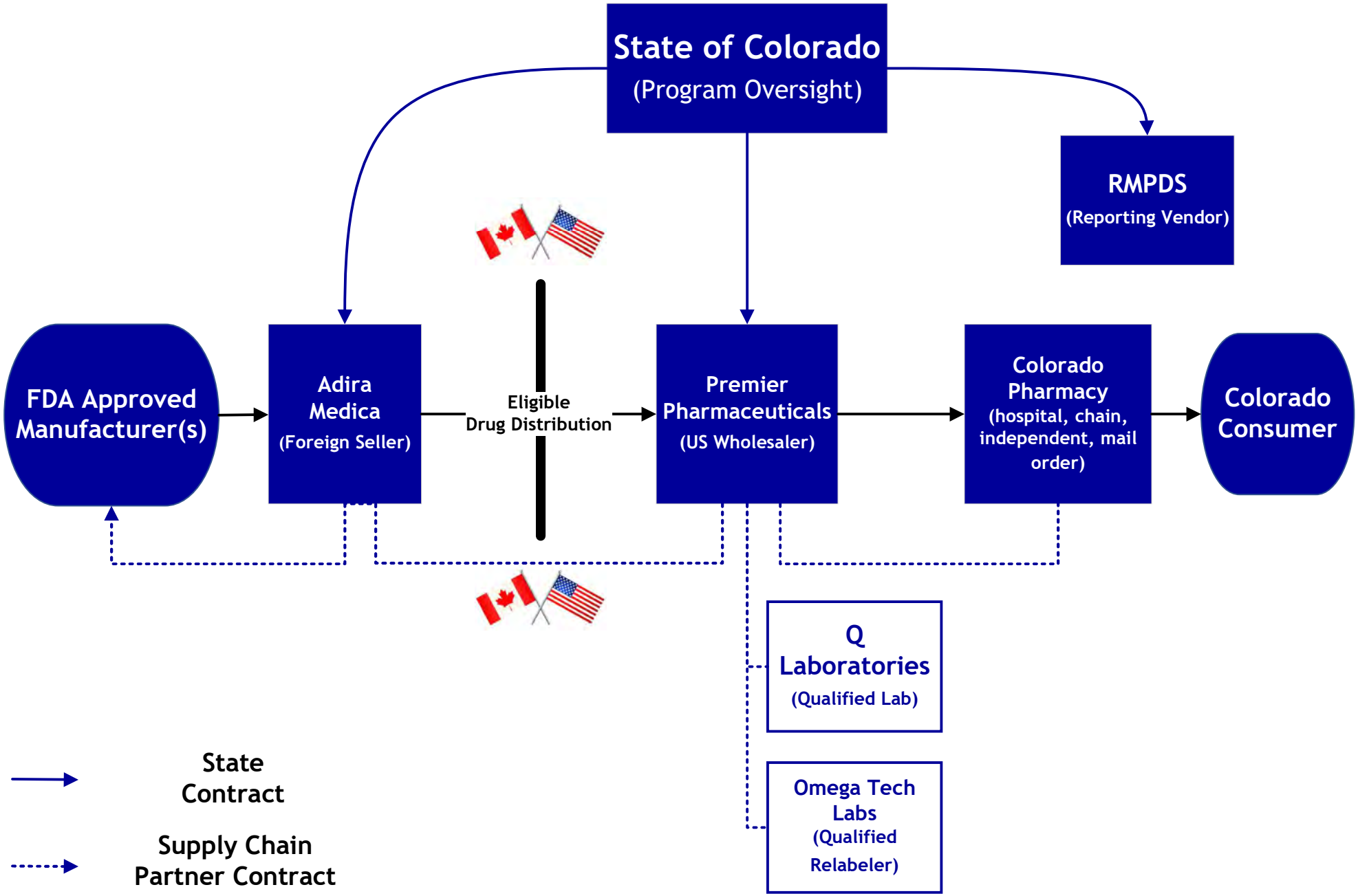
Step 4a

Q Laboratories sends Test results to FDA

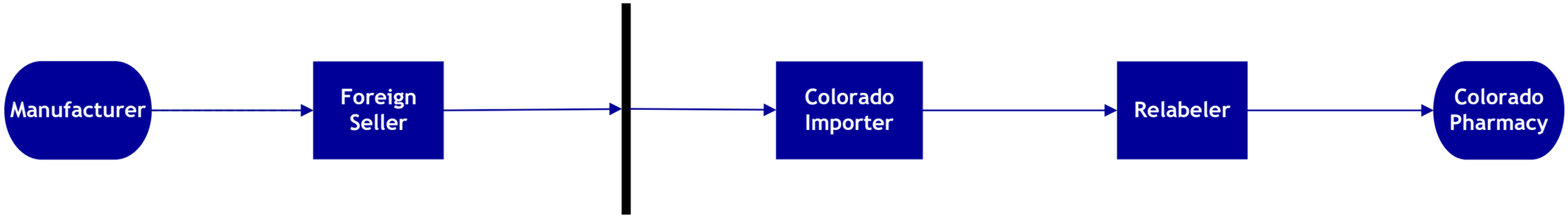
Step 4b

Colorado Drug Importation Program

Contracts & Program Participants



Imported Eligible Drug Movement through an Importation Program with DSCSA Compliance



- FDA Registered
- Manufactures Drug in accordance with the requirements of the FDA approval and the FDCA (excluding U.S. labeling requirements)
- Provides comprehensive documentation to the foreign seller about the sale of the specific drug from the manufacturer to the foreign seller, which third parties can use to verify the sale

- Licensed through Canadian federal and provincial laws
- New registration with the FDA
- Assigns and affixes unique SSI associated with Canadian DIN
- Provides comparable T3 data as described by DSCSA sections 581(25-27) (with SSI instead of DSCSA product identifier)

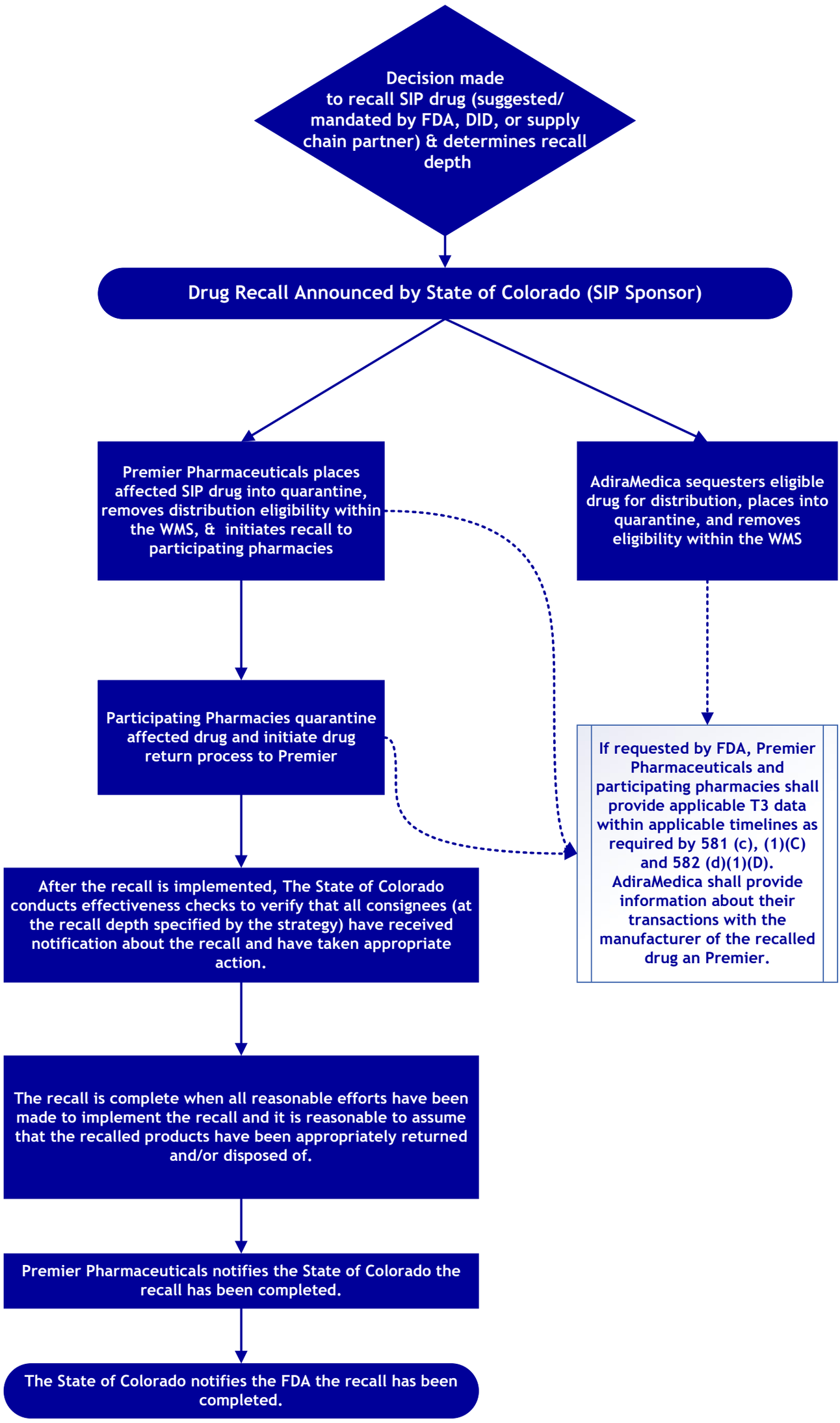
- State Registered*
- Authorized Trading Partner
- Maintains records linking SSI and PI for the drug
- Responsible for testing for authenticity and degradation as required by FDCA 804 (a requirement that applies only to drugs imported under a SIP)

- FDA Registered
- Authorized Trading Partner
- Relabels with FDA required/US labeling standards on behalf of the Colorado Importer
- Places DSCSA-required product identifier (PI)
- Places NDC unique to imported drug
- Returns eligible drug to Importer for distribution

- State Registered
- Authorized Trading Partner
- Confirmation of registration of manufacturers & relabelers
- Contracted with licensed wholesaler
- Receive, store & provide tracing documentation (T3 data)
- Investigate & properly handle suspect & illegitimate drugs

***Federal Licensure pending based on FDA Final Guidance regarding licensure of Wholesale Drug Distributors & Third-Party Logistics Providers**
(https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/fda-announces-proposed-rule-national-standards-licensure-wholesale-drug-distributors-and-third-party)

Overview of Drug Recall Process - Colorado Drug Importation



Appendix I: Guidance Request and Stakeholder Engagement

COLORADO
Department of Health Care Policy & Financing

Request for Information - Pharmacy Questions

Drug importation is one of many potential strategies to bring down the cost of prescriptions for the American consumer. Colorado Senate Bill 19-005 was signed into law in 2019. For additional background about the Colorado bill, please see the bill in its entirety here:

The Federal Food Drug and Cosmetic Act (FDCA) Section 804, Congress permits importation and reimportation of prescription drugs from Canada by a pharmacist or wholesaler, provided the drugs meet certain minimum standards and the Secretary of Health and Human Services (HHS) certifies to Congress that implementation of such a program will (A) pose no additional risk to the public's health and safety; and (B) result in a significant reduction in the cost of covered products to the American consumer. *See* 21 U.S.C. 384. For additional information, click here. This provision is specifically designed to promote importation of drugs to make them available at lower cost to American citizens while not increasing the risks to health and safety that do not already exist within the current drug supply.

For additional background about importation, please see the FDA's Safe Importation Action Plan released 7.31.19:

Purpose:
The primary goal of this Request for Information (RFI) is for Colorado to assess interest among pharmacies whether they would consider participation in a prescription drug importation program from Canada. Colorado will use this feedback to design the operational details of a future state program. We encourage answering all questions. However, feel free to skip questions you prefer not to answer.

Pharmacy compensation:
The current price differential between US and Canadian wholesale acquisition costs for drugs that are likely to be favored for importation is large. For pharmacies considering pursuing this importation opportunity, savings were achieved including the assumption of a mark-up on the Canadian wholesale acquisition costs. Though it will be up to Colorado to determine allowable profit margins during contracting, the significant price differential allows for consumers to capture substantial savings while the pharmacies capture positive margins.

1. What are your general thoughts on importing drugs from Canada or another country?

2. What positive outcomes could result from foreign drug importation?
    a. For consumers?

    b. For businesses?

3. What factors would prohibit your participation or decrease your interest in participating?

4. What drugs would you like to see included in Canadian importation? (Excluded drugs include controlled substances, biological products, infused drugs, intravenously injected drugs, drugs inhaled during surgery, and certain parenteral drugs). Please explain your reasoning for each drug/drug class

5. What specific recommendations do you have to ensure safety as required by federal law?

6. What payment models would work for you?

7. How would the following potential requirements influence your decision to sign up for a state program? (Please state why you are supportive or opposed to each idea)
    a. Separate shelf space for Canadian drug stock
    b. Separate file for Canadian drug invoices
    c. Separate file for Canadian drug hard copies
    d. Additional inspections by the state and potentially federal level
    e. Obtaining a separate license for importation
    f. Using a separate wholesaler just for Canadian drugs
    g. What other potential requirements would influence your decision?

8. What are your thoughts on limiting distribution of Canadian imported drugs to a defined set of pharmacies or a single pharmacy, for example, a mail order only option?

9. What other support would you need from the State of Colorado?

10. What other information do you want to share with the State of Colorado?

COLORADO
Department of Health Care Policy & Financing

Request for information
Wholesaler Questions

Drug importation is one of many potential strategies to bring down the cost of prescriptions for the American consumer. Colorado Senate Bill 19-005 was signed into law in 2019. For additional background about the Colorado bill, please see the bill in its entirety here:

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For additional background about importation, please see the FDA's Safe Importation Action Plan released 7.31.19:

Purpose:
The primary goal of this Request for Information (RFI) is for Colorado to assess interest among prescription drug wholesalers, distributors, repackers, relabelers, logistics providers, and importers (collectively, wholesalers) for participation in a wholesale prescription drug importation program from Canada. Colorado will use this feedback to design the operational details of a future state program. Such wholesalers may be in the U.S. or in Canada. We encourage answering all questions. However, feel free to skip questions you prefer not to answer.

Wholesaler role:
The exact role may vary but could entail the following:

- Establishing a relationship with a Canadian wholesaler
- Performing or subcontracting for repacking and relabeling
- Performing or subcontracting for batch testing
- Record keeping, including pedigree and track and trace obligations
- Recall management
- Responsiveness to state audits

Wholesaler compensation:
The current price differential between US and Canadian wholesale acquisition costs for drugs that are likely to be favored for importation is large. For wholesalers considering pursuing this importation opportunity, savings were achieved including the assumption of a mark-up on the Canadian wholesale acquisition costs. Though it will be up to Colorado to determine allowable profit margins during contracting, the significant price differential allows for consumers to capture substantial savings while the wholesalers capture positive margins.

Questions:

1. Would you be interested in contracting with Colorado to provide wholesale importation services from Canada? Why or why not?

2. What factors would encourage your participation?

3. What factors would prohibit your participation or decrease your interest in participating?

4. Do you have locations in Canada?

5. What is the breakdown by percent of your existing volume of maintenance vs specialty medications over the past 12 months?

6. Do you already purchase medications from Canadian or other foreign sources?

7. What parts of electronic track and trace requirements in the DSCSA to be required in the future have you already implemented?

8. Do you have direct relationships with manufacturers?
    a. All manufacturers
    b. No manufacturers
    c. Mix of some manufactures and other wholesalers

9. How would the following potential requirements influence your decision to sign up for a state program? (Please state why you are supportive or opposed to each idea)
    a. Separate warehouse space for Canadian stock?
    b. Creating a separate invoice/file for Canadian drugs?
    c. Requirement to obtain a separate license from the state for importation?
    d. Audit of financial records to ensure “substantial cost savings” to the consumer
    e. Additional inspections by the state and potentially federal level
    f. What other requirements not listed above could be a barrier?

10. What payment models would work for you?

11. Would you be reluctant to participate in a wholesale importation program from Canada out of concern that it could impact your existing contracts with drug manufacturers or expose you to risks of retaliation from opposing market actors?

12. What other support would you need from the State of Colorado?

13. What other information do you want to share with the State of Colorado?

COLORADO
Department of Health Care Policy & Financing

Drug **Consumer** Importation Survey

Responses Question 1: Please select all that apply:

	Number of Response(s)	Response Ratio
I purchase prescription drugs for myself or someone else.	25	64.1%
I am a physician, nurse, or other health care provider who has direct contact with patients.	5	12.8%
I am a pharmacist.	6	15.3%
I work in health care in an administrative capacity.	7	17.9%
I am a stakeholder.	7	17.9%
I am a lobbyist, lawmaker, or policy maker.	4	10.2%
Other	8	20.5%
Total	39	100%

"Other" responses include:

Healthcare policy consultant
Consumer advocate
I am a former pharmaceutical industry analyst
Family member used Canadian pharmacy
Insurance Broker
I am a volunteer lobbyist
Insurance Broker
Consultant

Question 2: Please explain your interest in a Canadian drug importation program.

reduce costs for high-cost diseases such as certain cancers, to avoid the health effects of "financial toxicity." High drug costs result in patient noncompliance or dropout from therapeutic regimens, resulting in unnecessary morbidity and mortality.

The National MS Society is committed to stopping MS in its tracks, restoring what's been lost, and ending MS forever. Until that happens, we help people living with MS live their best lives. Evidence shows that early and ongoing treatment of MS with a disease modifying therapy is the best way to prevent disability in the brain and body. However, these MS drugs are exorbitantly expensive. The first drug came to market at approx. $10,000 a year- that same drug, no changes to formula, is now over $80,000 a year. People with MS struggle to afford these life changing drugs, which can literally be the difference between walking and using a wheelchair. The National MS Society has no position on Canadian Importation and neither supported nor opposed SB19-005. However, we are interested in seeing how this program can bring relief to people living with MS in terms of lowering drug costs.

cheaper prices, less finagling with insurance copays and coinsurance

We should not pay more for same drugs than Canada or any country in the world, due to various price-fixing, negotiating that pharma is engaging in to monopolize their market share, prevent generics from coming on the market, or basically preventing good health in their profit motivation.
Competition from Canada, like any threat to the market, should bring down prices for all consumers as well as for public programs paid for by the taxpayer.
Lowering premiums.
would like to see any program that would help reduce cost
It feels like the Pharma charges prices that aren't justified and beyond the scope of doing business.
Worried about drug re-labeling and FDA's ability to oversee in cases of drug adverse effects.
I would like to understand what is possible from a legal and logistics point of view, the savings a program would be expected to achieve (both for the State and for consumers), and what response the State anticipates will come from the Federal government, industry and the domestic supply chain. I hope to be helping develop policy for Colorado, and this is information germane to my interests.
Anything we can do to keep medicine affordable is a good thing. Also with the large profits pharmaceutical companies make it doesn't seem fair to the people, these companies do have the ability to do research and provide medicines at affordable rates, they choose not to. Maybe more competition will help even out our market. Plus I'm also in support of price transparency so consumers can make educated choices
i have concerns with quality control issues that may arise from importing medications. i do not believe it is possible to have qualified oversight necessary to ensure safety and ingredients
Our health-system is currently opposed to general importation of drugs from Canada due to concerns with logistics, costs of importation, safety, and overall feasibility given the limited supply of drugs in Canada. In addition, these drugs may not comply with NDC standards and will not be available in drug databases (FDB, Medispan, etc.) to allow for appropriate charging & drug interaction checking.
In cases where US approved product is not available, we would support importation. However, we do not support importation based solely on cost and strongly recommend that cost/contracting issues be addressed with a cost/contracting strategy."
Not interested
I like the lower cost option.
I'm skeptical as to whether or not this will work. The pharmaceutical companies will just reduce the supply into Canada to drove prices back up.
My regular birth control (Seasonique) is incredibly expensive in Colorado, and I cannot take generic (it messes up my body too much).
When living in Boston, MA, I belonged to a community health center which participated in the Federal 340B drug pricing program. The difference in price (cash pay) - $50 in Boston, $450 in Colorado for the same drug. This is a huge cost savings due to negotiation, so I can only assume what the price would be for the Rx if imported from Canada.

My interest is both professional and personal. I have several medical conditions that require me to be on medications to maintain my health and quality of life. Recently I was prescribed a medication that is still hundreds of dollars a month even with my private insurance. This is not an option for me so I have to go with out. I'm not sure how sustainable this decision is. But I have no choice. That is one example of how prescription drug prices impact my life and health. I also am a psychotherapist and work with clients that have to choose to pay rent, buy food, pay utilities, pay medical bills etc. over getting a prescription they need. Unfortunately having to forego taking a medication keeps my clients sick. Both physically and mentally. We need help. We need a better way.

Families, and individuals, across Colorado are cost-burdened with the high cost of medication... especially for diabetes, stroke prevention, and cancer treatment.

Recommend Canada to some of my Medicare clients and they have found Canada a viable option.

None I do not want to Canadian drugs. If industry and the Goverment can not come t some agreement then would should not go to other countries for supplies

Most of the cost of medicine is paid for through our taxes several of the drugs were developed at NIH A lot of the cost of the drugs we buy goes to pay for advertising, lobbying in DC and local government. So many people as they get older have to choose between their medicine or food. There is just to much greed and waste in this country

I need for life lengthening and life saving drugs to be available, safe and within the payment ability of all of those who need them.

Some of these drugs are manufactured in the US and shipped to Canada. To solve the problem by then purchasing from Canada and shipping back to US seems a very convoluted way to solve a problem that resides here in the US.

Seems like a way for politicians to avoid solving this directly here at home in an attempt to avoid lose of donations by big pharma"

I am actively involved in all matters related to bringing down the cost of care.

Put pressure on Big Pharma to behave in consumer interest.

People are having difficulty purchasing prescription drugs because of cost. Canadian drugs are more reasonable. People living on Social Security cannot afford needed drugs in the U.S. where pharmaceutical companies are out of control. We need to find a solution, and importation would be a first important step.

I want to purchase cheaper drugs

It is important to lower the increasingly high cost of prescription medications so everyone can afford the treatments they need. Most of the US pharmaceutical manufacturers have plants in Canada. FDA inspects these plants as the US pharma imports from Canada and sells here or labels for export. Thus I believe Canadian drugs are safe. The current problem with carcinogens in some products are not from Canadian sourced prescription drugs. If this action encourages the US HHS to formulate regulations for direct importation, we could broaden the scope and use any FDA approved product source in our effort to lower prices.

Well...I need a prescription for Xifaxin and it costs 1600 for a 2nweek treatment...300 from Canada. My daughters epi pen was over 300. I have patients everyday that without.

If it can be safe and efficient, it would disrupt the current system that gives drug companies too much power. That could have both positive and negative impacts, but would change the dynamics of policy and negotiations.

Drug prices are a huge burden on our communities. It's unfair that we are mandated to bear such a burden when our neighbor to the North has better options.

why reimport meds that are already available in America. I struggle to understand why drug companies sell to other nations at such reduced prices and charge extremely high prices to Americans...?

If market share is what these companies seek, sell at the same AWP worldwide.

At this point Americans are subsidizing other nation's health care costs as well as our own which is completely unfair.

The result is people are not compliant with their medication regimens and health care costs accelerate as a result.

It would certainly drive the cost of prescriptions downward a little bit and help to reduce the cost of health insurance including the federal government's cost of Medicare and Medicaid insurance which would help us all in the long run.

Save my patients money on certain prescription drugs and possibly make a profit for a change.

I do not understand the point of the entire industry jumping through the hoops to comply with the DSCSA track and trace laws just to allow people to get their drugs from another country outside of the US supply chain.

I am interested in a short term project centering around a pharmaceutical issue. I am very interested in the Canadian Prescription Drug Importation legislation. I am a pharmacist with experience as Director of Pharmacy for BCBS of Wyoming, Vice President of Sales for Prime Therapeutics (PBM), Perform Cost Management (PBM). Vice President of Sales for ComCoTec (Prescription Processing software). Owner of Haraseks Pharmacy in Berwyn Illinois. Pharmacy Manager Banner Health Greeley Colorado. I would like to focus on a single project like Canadian Drug Importation. A project of one year or less would be ideal. I can work as a contract employee. Can you direct me to the appropriate person or agency?

As a matter of public health, access to prescription drugs is very important to the population. Not all individuals are able to afford the prescriptions that they need, therefore they place not only themselves, but others around them at risk for increased illness. Many individuals are forced to choose between putting food on their tables or taking necessary medications, thus the high costs of prescription drugs contributes to nutritional deficits that can lead to increased illnesses. Reducing prescription drug costs will help increase access and ultimately lead to a healthier population.

I am curious to see if it will actually help patients. The drug industry has been aggressively raising prices and entering into exotic lobbying arrangements for years in order to unethically extort patients and public entities. I am hopeful this will present an actual threat to these practices.

The current state of the prescription marketplace in Colorado is oligopolistic and profit-driven. The exorbitant prices paid for prescription drugs in this country is an outrage. This needs to change. We need additional sources of supply, and we need actors who are not driven by profit. This law is a good step in that direction.

Question 3: I think the quality and safety of drugs imported from Canada would be:

	Number of Response(s)	Response Ratio
More safe	2	5.1%
Less safe	5	12.8%
The same	25	64.1%
I'm not sure	7	17.9%
No responses	0	0.0%
Total	39	100%

Question 4: Tell us what you would expect from a Canadian prescription drug importation program.

Lower prices.

The ability to acquire therapeutically equivalent drugs at a significantly lower cost.

cheaper prices, less finagling with insurance copays and coinsurance

Have every belief that Canada exercises the same oversight over pharmaceuticals as the U.S. does through the FDA. Quality would remain the same. US residents would not be prompted to go across the border and purchase expensive medications and bring them back to the U.S. as is happening now, even though technically against the law.

I would expect more open market in Canada to have an effect on US drug prices by bringing them down.

assurance that the medications were equal want to was available domestically.

An easy process for patients to obtain medications via mail

Lower costs

Tampering

For cash pay customers, the cost of drugs obtained in Canada ought to be lower. If Colorado is the only state (or one of just a few) to engage in a formal importation program, it's possible supply/access would be reliable. However, I believe manufacturers would respond by restricting supply to Canada as well as upping the paperwork quotient for persons obtaining pharmaceutical products (especially those in the "specialty" category) while covered by health insurance. I worry that important customer service functions will be impacted adversely as well. If there's a side effect and the lot is Canadian, how will the manufacturer work with the patient, physician and FDA to remedy the situation?

I would expect a third choice at the pharmacy: name brand, generic or imported or something similar to that.

COLORADO
Department of Health Care Policy & Financing

Request for Information - Pharmacy Questions

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1. What are your general thoughts on importing drugs from Canada or another country?

2. What positive outcomes could result from foreign drug importation?
    a. For consumers?

    b. For businesses?

3. What factors would prohibit your participation or decrease your interest in participating?

4. What drugs would you like to see included in Canadian importation? (Excluded drugs include controlled substances, biological products, infused drugs, intravenously injected drugs, drugs inhaled during surgery, and certain parenteral drugs). Please explain your reasoning for each drug/drug class

5. What specific recommendations do you have to ensure safety as required by federal law?

6. What payment models would work for you?

7. How would the following potential requirements influence your decision to sign up for a state program? (Please state why you are supportive or opposed to each idea)
    a. Separate shelf space for Canadian drug stock
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    d. Additional inspections by the state and potentially federal level
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    f. Using a separate wholesaler just for Canadian drugs
    g. What other potential requirements would influence your decision?

8. What are your thoughts on limiting distribution of Canadian imported drugs to a defined set of pharmacies or a single pharmacy, for example, a mail order only option?

9. What other support would you need from the State of Colorado?

10. What other information do you want to share with the State of Colorado?

COLORADO
Department of Health Care Policy & Financing

Request for information
Wholesaler Questions

Drug importation is one of many potential strategies to bring down the cost of prescriptions for the American consumer. Colorado Senate Bill 19-005 was signed into law in 2019. For additional background about the Colorado bill, please see the bill in its entirety here:

The Federal Food Drug and Cosmetic Act (FDCA) Section 804, Congress permits importation and reimportation of prescription drugs from Canada by a pharmacist or wholesaler, provided the drugs meet certain minimum standards and the Secretary of Health and Human Services (HHS) certifies to Congress that implementation of such a program will (A) pose no additional risk to the public's health and safety; and (B) result in a significant reduction in the cost of covered products to the American consumer. *See* 21 U.S.C. 384. For additional information, click here. This provision is specifically designed to promote importation of drugs to make them available at lower cost to American citizens while not increasing the risks to health and safety that do not already exist within the current drug supply.

For additional background about importation, please see the FDA's Safe Importation Action Plan released 7.31.19:

Purpose:
The primary goal of this Request for Information (RFI) is for Colorado to assess interest among prescription drug wholesalers, distributors, repackers, relabelers, logistics providers, and importers (collectively, wholesalers) for participation in a wholesale prescription drug importation program from Canada. Colorado will use this feedback to design the operational details of a future state program. Such wholesalers may be in the U.S. or in Canada. We encourage answering all questions. However, feel free to skip questions you prefer not to answer.

Wholesaler role:
The exact role may vary but could entail the following:

- Establishing a relationship with a Canadian wholesaler
- Performing or subcontracting for repacking and relabeling
- Performing or subcontracting for batch testing
- Record keeping, including pedigree and track and trace obligations
- Recall management
- Responsiveness to state audits

Wholesaler compensation:
The current price differential between US and Canadian wholesale acquisition costs for drugs that are likely to be favored for importation is large. For wholesalers considering pursuing this importation opportunity, savings were achieved including the assumption of a mark-up on the Canadian wholesale acquisition costs. Though it will be up to Colorado to determine allowable profit margins during contracting, the significant price differential allows for consumers to capture substantial savings while the wholesalers capture positive margins.

Questions:

1. Would you be interested in contracting with Colorado to provide wholesale importation services from Canada? Why or why not?

2. What factors would encourage your participation?

3. What factors would prohibit your participation or decrease your interest in participating?

4. Do you have locations in Canada?

5. What is the breakdown by percent of your existing volume of maintenance vs specialty medications over the past 12 months?

6. Do you already purchase medications from Canadian or other foreign sources?

7. What parts of electronic track and trace requirements in the DSCSA to be required in the future have you already implemented?

8. Do you have direct relationships with manufacturers?
    a. All manufacturers
    b. No manufacturers
    c. Mix of some manufactures and other wholesalers

9. How would the following potential requirements influence your decision to sign up for a state program? (Please state why you are supportive or opposed to each idea)
    a. Separate warehouse space for Canadian stock?
    b. Creating a separate invoice/file for Canadian drugs?
    c. Requirement to obtain a separate license from the state for importation?
    d. Audit of financial records to ensure “substantial cost savings” to the consumer
    e. Additional inspections by the state and potentially federal level
    f. What other requirements not listed above could be a barrier?

10. What payment models would work for you?

11. Would you be reluctant to participate in a wholesale importation program from Canada out of concern that it could impact your existing contracts with drug manufacturers or expose you to risks of retaliation from opposing market actors?

12. What other support would you need from the State of Colorado?

13. What other information do you want to share with the State of Colorado?

COLORADO
Department of Health Care Policy & Financing

Drug **Consumer** Importation Survey

Responses Question 1: Please select all that apply:

	Number of Response(s)	Response Ratio
I purchase prescription drugs for myself or someone else.	25	64.1%
I am a physician, nurse, or other health care provider who has direct contact with patients.	5	12.8%
I am a pharmacist.	6	15.3%
I work in health care in an administrative capacity.	7	17.9%
I am a stakeholder.	7	17.9%
I am a lobbyist, lawmaker, or policy maker.	4	10.2%
Other	8	20.5%
Total	39	100%

"Other" responses include:

Healthcare policy consultant
Consumer advocate
I am a former pharmaceutical industry analyst
Family member used Canadian pharmacy
Insurance Broker
I am a volunteer lobbyist
Insurance Broker
Consultant

Question 2: Please explain your interest in a Canadian drug importation program.

reduce costs for high-cost diseases such as certain cancers, to avoid the health effects of "financial toxicity." High drug costs result in patient noncompliance or dropout from therapeutic regimens, resulting in unnecessary morbidity and mortality.

The National MS Society is committed to stopping MS in its tracks, restoring what's been lost, and ending MS forever. Until that happens, we help people living with MS live their best lives. Evidence shows that early and ongoing treatment of MS with a disease modifying therapy is the best way to prevent disability in the brain and body. However, these MS drugs are exorbitantly expensive. The first drug came to market at approx. $10,000 a year- that same drug, no changes to formula, is now over $80,000 a year. People with MS struggle to afford these life changing drugs, which can literally be the difference between walking and using a wheelchair. The National MS Society has no position on Canadian Importation and neither supported nor opposed SB19-005. However, we are interested in seeing how this program can bring relief to people living with MS in terms of lowering drug costs.

cheaper prices, less finagling with insurance copays and coinsurance

We should not pay more for same drugs than Canada or any country in the world, due to various price-fixing, negotiating that pharma is engaging in to monopolize their market share, prevent generics from coming on the market, or basically preventing good health in their profit motivation.
Competition from Canada, like any threat to the market, should bring down prices for all consumers as well as for public programs paid for by the taxpayer.
Lowering premiums.
would like to see any program that would help reduce cost
It feels like the Pharma charges prices that aren't justified and beyond the scope of doing business.
Worried about drug re-labeling and FDA's ability to oversee in cases of drug adverse effects.
I would like to understand what is possible from a legal and logistics point of view, the savings a program would be expected to achieve (both for the State and for consumers), and what response the State anticipates will come from the Federal government, industry and the domestic supply chain. I hope to be helping develop policy for Colorado, and this is information germane to my interests.
Anything we can do to keep medicine affordable is a good thing. Also with the large profits pharmaceutical companies make it doesn't seem fair to the people, these companies do have the ability to do research and provide medicines at affordable rates, they choose not to. Maybe more competition will help even out our market. Plus I'm also in support of price transparency so consumers can make educated choices
i have concerns with quality control issues that may arise from importing medications. i do not believe it is possible to have qualified oversight necessary to ensure safety and ingredients
Our health-system is currently opposed to general importation of drugs from Canada due to concerns with logistics, costs of importation, safety, and overall feasibility given the limited supply of drugs in Canada. In addition, these drugs may not comply with NDC standards and will not be available in drug databases (FDB, Medispan, etc.) to allow for appropriate charging & drug interaction checking.
In cases where US approved product is not available, we would support importation. However, we do not support importation based solely on cost and strongly recommend that cost/contracting issues be addressed with a cost/contracting strategy."
Not interested
I like the lower cost option.
I'm skeptical as to whether or not this will work. The pharmaceutical companies will just reduce the supply into Canada to drove prices back up.
My regular birth control (Seasonique) is incredibly expensive in Colorado, and I cannot take generic (it messes up my body too much).
When living in Boston, MA, I belonged to a community health center which participated in the Federal 340B drug pricing program. The difference in price (cash pay) - $50 in Boston, $450 in Colorado for the same drug. This is a huge cost savings due to negotiation, so I can only assume what the price would be for the Rx if imported from Canada.

My interest is both professional and personal. I have several medical conditions that require me to be on medications to maintain my health and quality of life. Recently I was prescribed a medication that is still hundreds of dollars a month even with my private insurance. This is not an option for me so I have to go with out. I'm not sure how sustainable this decision is. But I have no choice. That is one example of how prescription drug prices impact my life and health. I also am a psychotherapist and work with clients that have to choose to pay rent, buy food, pay utilities, pay medical bills etc. over getting a prescription they need. Unfortunately having to forego taking a medication keeps my clients sick. Both physically and mentally. We need help. We need a better way.

Families, and individuals, across Colorado are cost-burdened with the high cost of medication... especially for diabetes, stroke prevention, and cancer treatment.

Recommend Canada to some of my Medicare clients and they have found Canada a viable option.

None I do not want to Canadian drugs. If industry and the Goverment can not come t some agreement then would should not go to other countries for supplies

Most of the cost of medicine is paid for through our taxes several of the drugs were developed at NIH A lot of the cost of the drugs we buy goes to pay for advertising, lobbying in DC and local government. So many people as they get older have to choose between their medicine or food. There is just to much greed and waste in this country

I need for life lengthening and life saving drugs to be available, safe and within the payment ability of all of those who need them.

Some of these drugs are manufactured in the US and shipped to Canada. To solve the problem by then purchasing from Canada and shipping back to US seems a very convoluted way to solve a problem that resides here in the US.

Seems like a way for politicians to avoid solving this directly here at home in an attempt to avoid lose of donations by big pharma"

I am actively involved in all matters related to bringing down the cost of care.

Put pressure on Big Pharma to behave in consumer interest.

People are having difficulty purchasing prescription drugs because of cost. Canadian drugs are more reasonable. People living on Social Security cannot afford needed drugs in the U.S. where pharmaceutical companies are out of control. We need to find a solution, and importation would be a first important step.

I want to purchase cheaper drugs

It is important to lower the increasingly high cost of prescription medications so everyone can afford the treatments they need. Most of the US pharmaceutical manufacturers have plants in Canada. FDA inspects these plants as the US pharma imports from Canada and sells here or labels for export. Thus I believe Canadian drugs are safe. The current problem with carcinogens in some products are not from Canadian sourced prescription drugs. If this action encourages the US HHS to formulate regulations for direct importation, we could broaden the scope and use any FDA approved product source in our effort to lower prices.

Well...I need a prescription for Xifaxin and it costs 1600 for a 2nweek treatment...300 from Canada. My daughters epi pen was over 300. I have patients everyday that without.

If it can be safe and efficient, it would disrupt the current system that gives drug companies too much power. That could have both positive and negative impacts, but would change the dynamics of policy and negotiations.

Drug prices are a huge burden on our communities. It's unfair that we are mandated to bear such a burden when our neighbor to the North has better options.

why reimport meds that are already available in America. I struggle to understand why drug companies sell to other nations at such reduced prices and charge extremely high prices to Americans...?

If market share is what these companies seek, sell at the same AWP worldwide.

At this point Americans are subsidizing other nation's health care costs as well as our own which is completely unfair.

The result is people are not compliant with their medication regimens and health care costs accelerate as a result.

It would certainly drive the cost of prescriptions downward a little bit and help to reduce the cost of health insurance including the federal government's cost of Medicare and Medicaid insurance which would help us all in the long run.

Save my patients money on certain prescription drugs and possibly make a profit for a change.

I do not understand the point of the entire industry jumping through the hoops to comply with the DSCSA track and trace laws just to allow people to get their drugs from another country outside of the US supply chain.

I am interested in a short term project centering around a pharmaceutical issue. I am very interested in the Canadian Prescription Drug Importation legislation. I am a pharmacist with experience as Director of Pharmacy for BCBS of Wyoming, Vice President of Sales for Prime Therapeutics (PBM), Perform Cost Management (PBM). Vice President of Sales for ComCoTec (Prescription Processing software). Owner of Haraseks Pharmacy in Berwyn Illinois. Pharmacy Manager Banner Health Greeley Colorado. I would like to focus on a single project like Canadian Drug Importation. A project of one year or less would be ideal. I can work as a contract employee. Can you direct me to the appropriate person or agency?

As a matter of public health, access to prescription drugs is very important to the population. Not all individuals are able to afford the prescriptions that they need, therefore they place not only themselves, but others around them at risk for increased illness. Many individuals are forced to choose between putting food on their tables or taking necessary medications, thus the high costs of prescription drugs contributes to nutritional deficits that can lead to increased illnesses. Reducing prescription drug costs will help increase access and ultimately lead to a healthier population.

I am curious to see if it will actually help patients. The drug industry has been aggressively raising prices and entering into exotic lobbying arrangements for years in order to unethically extort patients and public entities. I am hopeful this will present an actual threat to these practices.

The current state of the prescription marketplace in Colorado is oligopolistic and profit-driven. The exorbitant prices paid for prescription drugs in this country is an outrage. This needs to change. We need additional sources of supply, and we need actors who are not driven by profit. This law is a good step in that direction.

Question 3: I think the quality and safety of drugs imported from Canada would be:

	Number of Response(s)	Response Ratio
More safe	2	5.1%
Less safe	5	12.8%
The same	25	64.1%
I'm not sure	7	17.9%
No responses	0	0.0%
Total	39	100%

Question 4: Tell us what you would expect from a Canadian prescription drug importation program.

Lower prices.

The ability to acquire therapeutically equivalent drugs at a significantly lower cost.

cheaper prices, less finagling with insurance copays and coinsurance

Have every belief that Canada exercises the same oversight over pharmaceuticals as the U.S. does through the FDA. Quality would remain the same. US residents would not be prompted to go across the border and purchase expensive medications and bring them back to the U.S. as is happening now, even though technically against the law.

I would expect more open market in Canada to have an effect on US drug prices by bringing them down.

assurance that the medications were equal want to was available domestically.

An easy process for patients to obtain medications via mail

Lower costs

Tampering

For cash pay customers, the cost of drugs obtained in Canada ought to be lower. If Colorado is the only state (or one of just a few) to engage in a formal importation program, it's possible supply/access would be reliable. However, I believe manufacturers would respond by restricting supply to Canada as well as upping the paperwork quotient for persons obtaining pharmaceutical products (especially those in the "specialty" category) while covered by health insurance. I worry that important customer service functions will be impacted adversely as well. If there's a side effect and the lot is Canadian, how will the manufacturer work with the patient, physician and FDA to remedy the situation?

I would expect a third choice at the pharmacy: name brand, generic or imported or something similar to that.

the same scrutiny as medications allowed within US
We are generally opposed to importation due to the complex logistics. I would support a program when drugs are on shortage in the US. Ideally, these drugs would be available through our standard wholesalers and distribution channels to minimize the potential for diversion and adulteration.
Not interested
Monitored.
I would expect it to bring additional competition to the market, more reasonably priced prescription drugs and a safe option to Colorado.
To begin, Timeliness and education.
Lower cost and potentially increased selection.
There are companies in Canada that people can currently use to fill their prescriptions. Expanding the education of state side clients could prove to a cost savings for everyone and PBM's companies would have to learn to accept they need to become competitive to stay in business.
No I am not in favor
I would expect the program to start with some of the most prescribed drugs high blood pressure, simvastatins, depression medicine, if all goes well then slowly expand the program to include more medications
Please see #2 above. I would expect that we proceed in full agreement with Canada. I don't think it is wise to move forward without Canadian (policy makers and general population) agreement.
The program should provide protections to physicians and other clinicians from lawsuits that could stem from supply chain, quality, and safety issues.
The buyer of the medications should have a choice and be well informed from where the medications originate. Once the information obligation has been met then responsibility is transferred to the buyer/patient since they are making an informed choice.
Hopefully lower prices without sacrificing quality and safety.
Lower costs directly from Canada and pressure on Big Pharma.
Lower costs for people of all ages. Relief for parents of children who have diabetes and other life-threatening diseases.
cheaper drugs
Colorado would be able to offer considerable savings to patients for some medications that are 40-60% cheaper in Canada than in the US. I would expect a Board, a State office and a contractor to ensure that the products are FDA approved, purchased from a reliable source and that state-wide pharmacies could provide savings to their pockets as well as to consumers.
Cheaper prices
Lower costs
No impacts on access
Equivalent or better safety than current system
Flexibility for policy discussions

Consideration of impacts on US pharmacies, especially in small, rural,or underserved communities
Cheaper prescriptions that sent to my home
Nothing. Keep the products here so that the consumer can be confident in pedigree, no tampering or storing meds in poor conditions - either in actual storage (climate control) or transporting.
Most of it would be run through mail order programs of course.
Be able to buy and dispense band name medication below current wholesale costs.
It's going to complicate things more in the US. I do not understand how Canada would be able to sustain all the extra products being shipped out of their country to the US. How will DEA regulate for controlled substances?
Competition for U.S. pharmaceutical companies and lower costs to the consumer.
I hope the state will choose the classes of drugs that have seen the greatest increases in price without new innovation, such as insulins, doxycycline or other ancient drugs that have seen absurd price increased. Then purchase vast quantities, return those to retail in the state and depress the price of similar medications. Drug companies function as cabals and hide behind claims of innovation and caring for patients, by targeting older drugs with inflated prices the state can both save lives and lay bare industry lies.
Lower prices for the identical or chemically identical product.

Question 5: How many prescriptions does your household purchase each month?

8 - 10
People living with MS may use upwards of 10 symptom management drugs in addition to a disease modifying therapy.
6
8
1
2
2
8
2-3
2-3
11
2
5
2
0
I purchase one. I have cut back on others due to the cost.
6 approx
5
None
4

Eight per month
5
2
3
2
Seven.
6
one
2
6
4
none due to the cost
4
N/A
2
12
2
It's around 7 different products.

Question 6: How much does your household pay each month for prescription medicine?

$100 more or less
People living with MS pay anywhere from $200-$3000 per month for their prescriptions.
$100
approx $70
$8
100
$100+
$80
$100
Not a huge amount but I have paid over $100 for antibiotics in the past and that is a terrible burden when you are already sick and choice would help.
$200
$5 - Our drugs are very cheap - $1-2 per prescription typically....
$100
$25.00
O
I am currently lucky that after 4 months of appeals, phone calls, and paperwork, my insurance company now covers part of the cost of my RX, so $20/month.
$100 aprox
369
Nothing
Insurance and co pays

I am Medicare so I have reached catastrophic cost by March
About $80
100
Under $30
$15
We are very fortunate because my husband who is disabled vet gets his medications from the VA. We pay about $80 a month on average.
$400
$15
200
usually about $50, but one drug (intermittently filled) can cost upwards of $100 per month alone
$180
we would pay over $2,500 in unreimbursable cost or pay exorbitant premiums to cover these meds.
450
Business purchases $150,000 per month for resale.
20
$75-$100 as co-pays to medical insurance. We are among the lucky ones that can afford good health insurance coverage.
$8
After insurance coverage, somewhere in the range of $400.

Question 7: How much does your most expensive prescription cost?

During my spouse's bouts with cancer, we often faced COPAYS of $600 / week
Some people living with MS have a 40% coinsurance, meaning their therapy can cost $2500 a month.
$27
$20 for 90 days
$8
60
$100/month
$10 (with insurance.)
$100/mo.
The cozy fluctuates with insurance and that is a separate and equally problematic issue. If not for chp I would not be able to afford my sons asthma medicine
"cost to me: $35
actual cost $1,200"
$3
$25
$35.00
O

$450 for 3 months at full retail price in Colorado (which I would be paying if I didn't convince Anthem to cover it).
$250
280
50.00
The most expensive drug cost is 7246 dollars.Per month.
New prescription is $50 out of pocket. Retail price is $600, at least that is what is printed on the packaging.
50
$15
$15
$60 copay
$350/month
Epipen for $148/year OOP, after deductible or $370 if deductible not met.
The antibiotic I need is $1600
when filled, $80-100/month, per above, but routinely $20-25/month.
$180
$1,800 for biologicals
200
N/A
Not sure due to my copay costs
Without insurance coverage, the most expensive prescription would cost just over $600 per month.
$4
Several thousand dollars before insurance, for a three-month supply.

Question 8: What's the most you have ever had to pay out of pocket for a prescription drug?

$600 per dose for Neupogen
$2500/month on the extreme end.
$189
$45
$70
200
none of our prescriptions are covered in our drug plan, so we plan full price
$90
$100/mo.
Something around $100
$50
$40
$80
Over $100.00.
500

$450
I cant remember
480
Can't recall
Yes
$2578 dollars, I am still paying on that charge card for this years first months co pay for it. I will have to add 2020 first months on to the same charge card it charges me 28% interest.
As far as I remember, this new drug at $40 is the most expensive one that I paid for. I did not fill the one with a co-pay of $200.
1000
A couple hundred.
$100
$60
$350
$370
Trying not to pay the above. Epi pens 430
$100
$675
$1,800
600
N/A
125.00
$435.
$50-60
One time I had to pay full retail for one of these extremely expensive drugs, something like $30 or more per DAILY DOSAGE.

Question 9: What type of pharmacy do you use today? Please select all that apply.

	Number of Response(s)	Response Ratio
Chain drug store (Walgreens, CVS, Rite Aid, etc.)	21	53.8%
Independently owned pharmacy	7	17.9%
Grocery store pharmacy (King Soopers, City Market, Safeway, etc.)	13	33.3%
Kaiser Permanente (outpatient or mail order)	6	15.3%
Mail order	11	28.2%
Hospital outpatient (Denver Health, UCHealth, Children's Hospital, etc.)	3	7.6%
I get samples from my doctor	3	7.6%
Other	3	7.6%

Total	39	100%

Question 10: How important is it for you to be able to continue using the pharmacy you use today for all of your prescriptions?

Top number is the count of respondents selecting the option. Bottom % is percent of the total respondents selecting the option.	I Don't Care	Not Important	Neutral	Important	Very Important
	5	7	12	9	5
	13%	18%	32%	24%	13%

Question 11: Would you be willing to change where you get your prescriptions if it meant you could purchase cheaper Canadian drugs?

	Number of Response(s)	Response Ratio
Yes	22	56.4%
No	9	23.0%
I'm not sure	7	17.9%
No Responses	1	2.5%
Total	39	100%

Question 12: Would having a choice of pharmacy influence your decision whether to purchase Canadian imported drugs? Please explain your answer.

	Number of Response(s)	Response Ratio
I want to be able to choose my pharmacy	10	25.6%
I don't care what pharmacy I use	16	41.0%
I'm not sure	12	30.7%
No Responses	1	2.5%
Total	39	100%

17 Comment(s)

Comments include:

I don't understand the question.

Pharmacies are irrelevant to me. I use goodrx.com as drug/price vetting comparison site to see who is charging what for a drug. Apps and online access to information is what is now key to drug purchases, not pharmacies.

Ours are only oral meds. For brand, the pharmacy is just a distribution node. For generics, the manufacturer can be important, but we monitor that.
I'd be willing to change my pharmacy but I don't want to go to a pharmacy that I feel takes advantage of people like Walgreens or to king Soopers who has the worst customer ser Also what would systems like kaiser do? They don't give their members a choice and I would hope if it saved the people money they would have to participate.
not likely to purchase Canadian imported drugs
I may avoid pharmacies that preferably import Canadian drugs due to cost only.
Choice is always good.
With different insurance plans over my lifetime, I have been bounced around among many different pharmacies/mail order options. If you wanted your Rx, you did what the insurance company says.
Would US pharmacy's control the use of Canadian pharmacy's, if so then the process could become a very cumbersome mess. Clients could become confused, frustrated and discouraged, not wanting to use the program.
As I ride the bus, it needs to be somewhere I can get to easlily
My concern is that the drugs be quality drugs, safe, affordable and available.
Just as long as the drugs are as safe as US drugs.
Since we live in a rural area, the choices are limited. However, we could drive which is fine now, but question is will it always be okay.
I would be willing to use mail order for a 90 day supply of my current medication, assuming the source is reliable and considers shipment time for keeping me stocked.
For acute care needs, I'd like to go to the closest and cheapest location that I can purchase my prescription.
There is some value to convenience. We don't pay huge amounts, so the savings may not be worth the hassle of less convenient access.
Some medications laying in the mailbox can be frozen or become damaged
Choice of pharmacy is not my first concern. Affordability and quality are primary, area proximity to pharmacy is secondary.

Question 13: If Canadian imported drugs were only available through a mail order pharmacy, would you be willing to switch if it meant those drugs were less expensive?

	Number of Response(s)	Response Ratio
Yes	21	53.8%
No	9	23.0%
I'm not sure	8	20.5%
No Responses	1	2.5%

Total	39	100%

Question 14: Do you have anything else you would like to share with us regarding a Canadian prescription drug importation program?

Canadian drug importation should look for the most bang for the buck. Vermont made a list of the most expensive drugs to the consumer, to employers (in self-insured health plans) and to the taxpayer (for Medicaid and other public programs).

Clearly there needs to be some reason/advantage for Canadian wholesalers to sell to the U.S., in the way of expansion of their markets as well.

Drugs become more of a commodity sale, like generics are, than a branded drug.

Absolutely the ludicrousness of on TV ads from drug companies, spending huge amounts of our precious health care dollars on marketing, needs to be stopped. And let's stop it by importing from Canada.

Interestingly, the Consumer is not very influenced by brands, as they most undoubtedly will be by their premium and out of pocket costs.

Do it

thanks for all you are doing to try to bring down the cost of health care in colorado

Really hope this doesn't happen.

Personally, I believe that there are far more sustainable programs Colorado could consider to alleviate the cost pressures we face v/v Rx.

I think we need to be careful to be respectful of Canada and their health system and I would like to know why their drugs are so much cheaper, maybe we need to look into some significant system changes.

While there may be a limited role for importation during shortages, I generally feel importation is a work around that is not solving the key issue which is primarily a cost and contracting problem. Canada has limited resources and interested in participating in importation programs due to the concerns with supply, cost, and logistics. I strongly suggest that government agencies pursue expansion of 340B and other discount/contracting programs to address the issue of cost. Please refer to the ASHP statement on drug importation for additional concerns related to importation.

After my mother passed, it was very hard to discontinue services from Canadian pharmacy. It seemed at though we were put on unnecessary holds on the phone, lasting for over an hour.

Hell Yes please go for this!

As a health insurance agent I listen to client express their concerns of the cost of prescription medication. This becomes more of a concern for those clients on Medicare, as doctors continue to prescribe more new expensive medication and the client is making some very interesting decisions regarding their medications.

Just get it done,please.

I have used a mail order pharmacy before. For me it was not convenient and felt less reliable than going to my corner pharmacy.

mail order pharmacies have been problematic for some of my patients due to delayed delivery and disagreement between insurance and pharmacy as to # of months supplied.

Safety and quality are very important. If Canadian drugs are not as safe or have the same quality, I would not put safety and quality over cost.
let all pharmacies do this! don't limit it.
I would like to see transparency on costs and the process. I am concerned that politics might interfere with successful execution of the program once HHS Sec approval and regulations are achieved. I would like visible accounting of the drugs selected and the average cost savings.
Get on it!
Only allow independent pharmacies to dispense them.
How can we be sure that the medications are not going to be counterfeit?
My spouse and I have both good and bad experiences with mail-order pharmaceuticals. The answer to question #13 would have to depend upon the mail-order pharmacy policies and procedures, and comparative local pharmacy choices.
My particular prescriptions are inexpensive. I am more concerned for my patients, and society in general.
Mail order pharmacies are problematic, as there is no real connection between the pharmacist and the customer.

COLORADO
Department of Health Care Policy & Financing

NMDOH
NEW MEXICO DEPARTMENT OF HEALTH

STATE OF NEW HAMPSHIRE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

VERMONT
AGENCY OF HUMAN SERVICES

March 29, 2022

S. Leigh Verbois, Director
Office of Drug Security, Integrity & Response
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Ms. Verbois,

As states leading the way in the development of State Importation Programs (SIPs), we thank you and FDA leadership for your efforts to support us in this process, including establishing a team dedicated to the implementation of SIPs. We are looking forward to our upcoming meeting with you to discuss our progress in implementing Section 804 and hope to have a collaborative discussion around opportunities for further FDA guidance to advance state efforts.

As you know, escalating prescription drug costs continue to be a challenge across the country. Our States are dedicated to advancing importation programs to bring needed prescription drug cost relief to residents and we have been collaborating on this topic for several years— analyzing regulation, evaluating program challenges, and sharing best practices. We have been bolstered by recent federal engagement and the creation of a regulatory structure for implementation and see great opportunities to further enhance the state-federal partnership on Section 804.

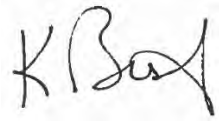
States have identified several areas of regulation in which states would benefit from additional clarity and guidance. These guidance requests focus on two main areas: SIP Application Policy and Operational Policy. Please see the attached guidance requests, including detailed explanations and citations to the specific areas of regulation. We look forward to an opportunity to explore these guidance

recommendations during our upcoming meeting, as well as discuss best practices and other key FDA priorities.

We appreciate your continued partnership.

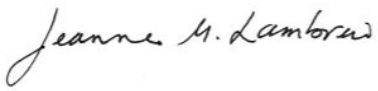
Sincerely,

Kim Bimestefer



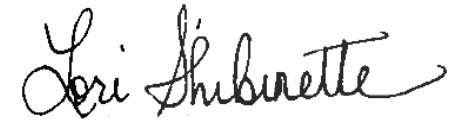
Executive Director
Colorado Department of Health Care Policy & Financing

Jeanne M. Lambrew, PhD



Commissioner
Maine Department of Health and Human Services

Lori A. Shibinette



Commissioner, New Hampshire Department of Health and Human Services

David R. Scrase, MD, MHSA

Acting Cabinet Secretary, New Mexico Department of Health

Ena Backus

Director of Health Care Reform, Vermont Agency of Human Services

FDA Guidance Request
Importation of Prescription Drugs, 21 CFR 1 and 21 CFR 251

SIP Application Policy Issue	Proposed Questions & Answers	Related Final Rule Sections
Demonstrating SIP Cost Savings - As states break new ground establishing new prescription drug marketplaces, it is assumed that initial SIPs will "pilot" Section 804 with narrow drug lists. Early programs will be focused on demonstrating proof of concept. This requires a flexible interpretation of demonstrating cost savings in SIP applications.	Question: The Final Rule provides only a high level explanation of how a SIP Sponsor must justify that their SIP will result in a significant reduction in the cost to the consumer for eligible prescription drugs. Can the FDA clarify that proving cost savings will be assessed with the greatest flexibility given that SIP sponsors are piloting new marketplaces which will take time to establish and yield such savings? Suggested Response: Given state SIP sponsors are establishing new and innovative marketplaces that require time, resources, and a shift in market dynamics to drive cost savings, the FDA will consider demonstration of initial modest savings with the potential for greater savings over time as sufficient in meeting the statutory and regulatory requirements outlined in § 251.3. FDA recognizes that for many states initial SIPs will be piloting the Canadian drug importation program concept and therefore, our assessment of meeting cost savings requirements will take this into account.	§ 251.3 SIP proposal submission requirements.(11) A summary of how the SIP Sponsor will ensure that: (v)The SIP will result in a significant reduction in the cost to the American consumer of the eligible prescription drugs that the SIP Sponsor seeks to import. § 251.3 SIP proposal submission requirements.(e)The SIP Sponsor's importation plan must: (9) Explain how the SIP Sponsor will ensure that the SIP will result in a significant reduction in the cost to the American consumer of the eligible prescription drugs that the SIP Sponsor seeks to import. The explanation must include any assumptions and uncertainty, and it must be sufficiently detailed to allow for a meaningful evaluation.

SIP Review Process and Phased Approval - As states pursue partnerships with manufacturers, insurance carriers and supply chain partners, it is critical that SIP applicants are able to demonstrate progress towards application approval to support the development of such partnerships. FDA communication to a SIP applicant demonstrating progress towards a successful outcome would assist states in such efforts.	Question: The Final Rule indicates that the FDA will make reasonable efforts to communicate about information that is lacking in a SIP application. State SIP applicants would benefit from additional communication regarding FDA's review process, including information regarding meeting certain benchmarks towards a final approval. This will support state efforts to secure partners. Can FDA provide guidance that it intends to share such details during its application review process? Suggested Response: In addition to communications regarding application details that are lacking, FDA will also provide SIP Sponsors with a letter of completeness once all required elements of an application have been received. FDA will also provide applicants with a letter stating that the application review process has been completed and that a final determination is imminent.	251.4 (c) Review and authorization of importation program proposals. "... FDA will make a reasonable effort to promptly communicate to a SIP Sponsor about any information required by § 251.3 that was not submitted in a SIP Proposal.…"
Drug List in SIP - The process to confirm access to Canadian drug supply is an ongoing and evolving process. The Drug list included in the SIP should be an aspirational list and may not necessarily represent the universe of drugs a SIP Sponsor may be able to import. Market forces in Canada may present opportunities to acquire drugs outside of the original submitted list. States seek flexibility in what they may ultimately submit for each pre-import request.	Question: While the Final Rule requires submission of a drug list with a SIP application, nowhere in the Rule does it state that this list must represent the universe of drugs that may be submitted in pre-import requests. Can the FDA clarify that pre-import requests may include prescription drugs beyond those included in the original SIP application, as long as all statutory and regulatory requirements are met? Suggested Response: As long as FDA approves drugs included in a pre-import request, the SIP Sponsor and their Importer may import such drugs.	§ 251.3 SIP proposal submission requirements.(e)The SIP Sponsor's importation plan must:(5) Include the proprietary name (if any), the established name, the approved application numbers, and the DIN and National Drug Code (NDC) for each eligible prescription drug that the SIP Sponsor seeks to import from Canada and for its FDA-approved counterpart. § 251.5 Pre-Import Request. (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. § 251.8 Modification or extension of authorized importation programs.
Clarifying SIP Application Safety Requirements - States share FDA's view that safety must be the first priority in establishing importation programs. The Final Rule provides FDA with broad discretion to not authorize a SIP proposal due to "potential safety concerns" which gives SIP sponsors little guidance regarding how to address such concerns in its application.	Question: The Final Rule does not provide details on what the FDA may consider "potential safety concerns" as outlined in § 251.4 that may compel FDA to reject an application. Can FDA release detailed guidance that outlines any anticipated safety concerns that SIP applicants must consider when applying for an approval? Such guidance will help states clarify specific safety measures that align with FDA safety priorities above and beyond what is outlined in the Final Rule. Suggested Response: The FDA appreciates state interest in additional clarifications regarding safety requirements under the Final Rule and intends to release a detailed FAQ that will provide additional guidance to states regarding this aspect of regulation.	§ 251.4 Review and authorization of importation program proposals. (a)...FDA may decide not to authorize a SIP Proposal or supplemental proposal because of potential safety concerns with the SIP.
Operational Policy Issues	Proposed Questions & Answers	Related Final Rule Sections
Pre-Import Requests, Testing Approval Timelines and Communication Plans - Required approvals for pre-import requests and testing of imported products, add significant time to the distribution timeline for imported products. Such approvals will	Question: The Final Rule does not provide any detail on the timing for FDA's review of pre-import requests and testing results which will have negative downstream impacts on the supply chain and related distribution. As states invest in implementation of SIPs once approved, some assurances are needed regarding review timelines. Can FDA provide written guidance including a formalized timeline that prioritizes the shortest possible approval times and clear	§ 251.5 Pre-Import Request. (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.

require wholesalers to purchase drugs up to an estimated 6 months in advance of distribution which will present a significant financial burden in the supply chain. Creating efficiencies in the review process will be critical to addressing this.	communication strategies (ie. CMS's process for review and approval of Medicaid State Plan Amendments). Additionally, states request a template for a pre-import request. Suggested Response: The FDA appreciates state interest in additional clarifications regarding timelines for approvals of pre-import requests and testing results under the Final Rule and intends to release a detailed FAQ that will provide additional guidance to states regarding this aspect of regulation.	§ 251.16 Laboratory testing requirements. Note: This section does not include any details regarding FDA's review and approval process for laboratory testing results.
US Agent - It is unclear from the Final Rule whether or not this must be an agent employed by the Foreign Seller. This could be a barrier to partnering with such an entity in Canada and therefore, flexibility is requested.	Question: The Final Rule does not specify whether the Foreign Seller's US Agent must be an employee of the Foreign Seller. State's request flexibility in interpretation of this part to allow for individuals other than an employee of the Foreign Seller to act as their US Agent. Suggested Response: The FDA appreciates this question regarding the Foreign Seller's US Agent. This individual does not need to be an employee of the Foreign Seller, rather a contractual, or otherwise, legal relationship will suffice.	§ 251.11 Official contact and U.S. agent for Foreign Sellers.(b) U.S. agent. (1) 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.