

Prescription Drugs States Seek to Import from Canada

Purpose

This is a living document maintained by the Partnership for Safe Medicines (PSM). Within it, you will find a collection of all the drug lists from known drug importation applications (SIPs), including previous versions superseded by subsequent filings.

In 2003, the Medicare Modernization Act included a provision to allow states to import prescription drugs from Canada as long as doing so would not endanger patients and that it would give significant savings to the American consumer. A federal rule was not finalized until 2020. That finalized rule can be seen here and it governs the requirements of any state's application to the FDA to operate a program to import medicine from Canada. As part of a Section 804 program application, a state needs to provide a list of drugs they seek to import.

Methods

The drug lists were collected in one of three ways:

- 1. A state publicly published the SIP application containing the drug list
- 2. PSM obtained the information through a Freedom of Information Act (FOIA) request
- 3. The information was obtained from public evidence from ongoing litigation.

Notes

As of January 29, 2024, legislators in Colorado, Connecticut, Florida, Maine, New Hampshire, New Mexico, Texas, and Vermont have drafted applications though not all to the same level of detail. To the best of PSM's knowledge, **Connecticut, Maine, Texas, and Vermont** have not submitted drug lists. If/when a state does, that information will be included in this document.

SIP applications included in this document are:

Colorado: February 2024¹, December 2022, and March 2020

Florida: October 2023, April 2023, November 2021, September 2021, April 2021, and November 2020. At this time, PSM does not have a copy of FL's final, approved SIP from November 2023.

New Hampshire: April 2021

New Mexico: December 2020 and October 2020

This is a living document that PSM will maintain that collects all drug lists from all known importation applications, including previous versions superseded by subsequent filings

¹ Information from this SIP application was added as part of the February 27, 2024 update

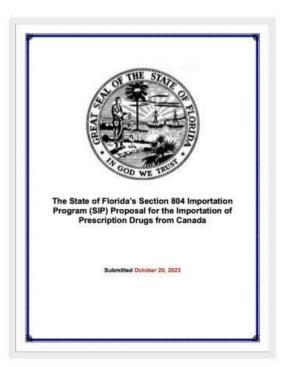


FOIA Responsive Document

Source: Nov 2024 FL SIP Application to FDA: Not Yet Available

A FOIA request has been submitted





Source: FOIA Responsive Document October 20, 2023 FL SIP Application to FDA

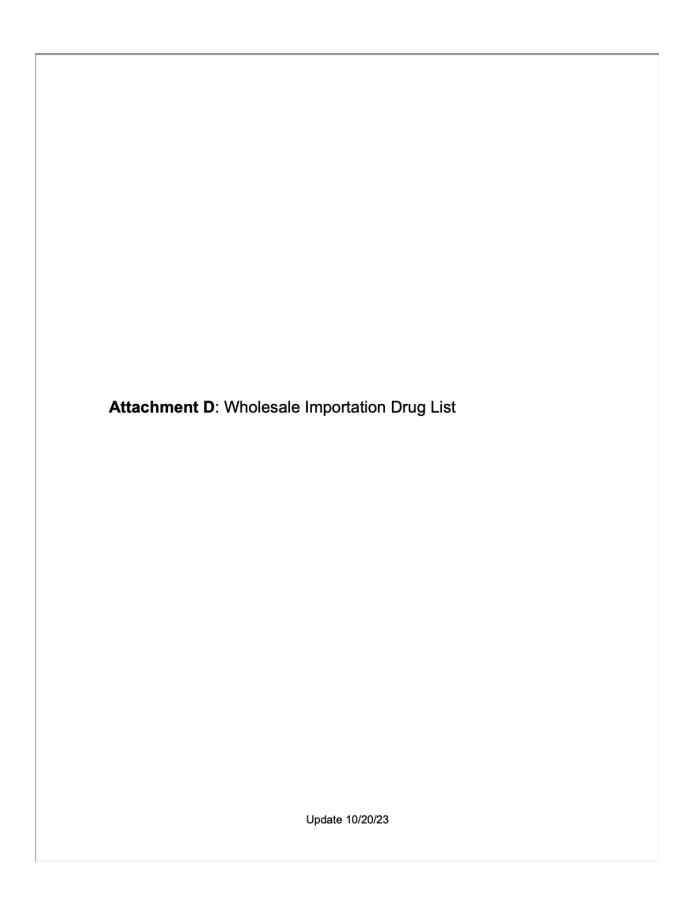
Find the entire application online at our website: www.safemedicines.org

Source: document can be found on PSM's website

The following drugs were submitted as part of Florida's SIP application dated October 20, 2023.

Biktarvy	Descovy	Dovato	Genvoya
Juluca	Odefsey	Prezcobix	Prezista
Ravicti	Rexulti	Symtuza	Tivicay
Vraylar	Xtandi		

On the next 3 pages, we have included the original 3 page PDF (Attachment D) from Florida's October 20, 2023 application. Please note: the state of Florida indicated revisions or additions to the text of its SIP by displaying those words in red.



This attachment incorporates by file a document for each drug identified below. For each drug, the Agency intends to import all strengths and dosage forms listed on the cover sheet. The Agency does not intend to import any approved dosage form or strength combination not listed on the cover sheets. Each file contains:

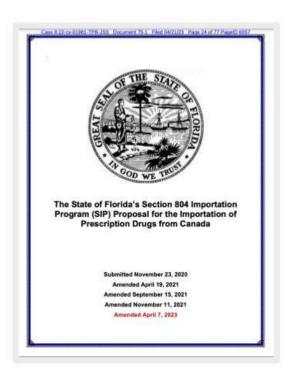
- A drug label cover sheet providing each eligible prescription drug's FDA-approved counterpart, the manufacturer(s) of the finished dosage form and the active ingredient or ingredients of each eligible prescription drug that the SIP Sponsor seeks to import, the legal relationship of these entities to the SIP Sponsor, and information about the HPFB-approved product and its FDA-approved counterpart. Unless otherwise specified, information on each of the cover sheets, including proprietary/brand names, active ingredients, inactive ingredients, and dosage forms, are identical for both HPFB- and FDA-approved products and will not be listed separately. Ingredient names referring to the same chemical entity may be different between HPFB-approved monographs and FDA-approved labels. A list of such entities will be provided at the end of this document.
- The proposed label and side-by-side comparison of proposed label to FDA-approved drug label, including the Prescribing Information, carton and container labeling, and patient labeling (e.g., Medication Guide, Instructions for Use, patient package inserts), with all differences annotated and explained.
- The proposed package insert.
- The FDA-approved package insert.
- The HPFB-approved package insert.
- Marketing Status in the United States.

Drug Name

Biktarvy	Descovy	Dovato
Genvoya	Juluca	Odefsey
Prezcobix	Prezista	Ravicti
Rexulti	Symtuza	Tivicay
Vraylar	Xtandi	

Interchangeable chemical names: Each row represents all listed names for the same chemical entity separated by semicolon. • Tenofovir alafenamide fumarate; Tenofovir alafenamide hemifumarate • Macrogol, PEG; Polyethylene glycol • Sunset yellow FCF aluminum lake; FD&C Yellow No. 6 • Ferric oxide; Iron oxide HCI; Hydrochloride Caprylocaproyl macrogolglycerides, Caprylocaproyl polyoxylglycerides Glycerol; Glycerin





Source: PACER document April 7, 2023 FL SIP Application to FDA

Find the entire application online at our website: www.safemedicines.org

Source: document can be found on PSM's website.

The following drugs were submitted as part of Florida's SIP application dated April 7, 2023.

Biktarvy	Descovy	Dovato	Eliquis
Entresto	Eucrisa	Genoya	Juluca
Odefsey	Prezcobix	Prezista	Ravicti
Rexulti	Symtuza	Tivicay	Vraylar
Xtandi			

On the next two pages, we have included the original two-page PDF from Florida's April 7, 2023 application. Please note: the state of Florida indicated revisions or additions to the text of its SIP from previously submitted versions by displaying those words in red.

Florida's List of Prescription Drugs to Import

The FDA rule requires the SIP to include the following information related to the prescription drugs that will be imported:

- · Names and Drug Identification Numbers (DIN) of selected drugs to import.
- Information of the applicant that holds the New Drug Applications (NDA) or Abbreviated New Drug Applications (ANDA).
- · Name and address of the manufacturer of the finished dosage form.
- Names and addresses of manufacturers of the prescription drugs and active ingredients.

As part of this proposal, the State is providing the list of prescription drugs it will initially attempt to import under the SIP. The final list of imported prescription drugs is subject to change and can be addressed in an amended SIP or through the pre-import request, based on the FDA's preference. At the time of this submission, the State does not know the addresses of the manufacturers' facilities that produce the finished dosage forms or active ingredients.

Florida has chosen a limited set of drugs that will yield the highest potential savings. Also, these specific medications allow Florida the best opportunity to maximize the importation program's benefits while remaining compliant with federal law. After the program has proven to be a success, the State intends to amend its SIP to expand the list of medications that will be imported.

The list of proposed drugs for this SIP is in **Table 2**, Proposed Drug List, below. Full information regarding each drug as listed in the above bullets and the proposed labels can be found in **Attachment D**, Wholesale Importation Drug List. The State will import only the strengths and dosage forms that are listed in the SIP Proposal.

TABLE 2 PROPOSED DRUG LIST						
Brand Name (active ingredients)	Dose / Dosage Form					
Biktarvy (bictegravir-emtricitabine-tenofovir alafenamide)	50-200-25 mg tablet					
Descovy (emtricitabine-tenofovir alafenamide)	200-25 mg tablet					
Dovato (dolutegravir-lamivudine)	50-300 mg tablet					
Eliquis (apixaban)	2.5 mg tablet					
	5 mg tablet					
Entresto (sacubitril-valsartan)	24-26 mg tablet					
	49-51 mg tablet					
	97-103 mg tablet					
Eucrisa (crisaborole)	0.02 topical ointment					
Genvoya (elvitegravir-cobicistat-emtricitabine-tenofovir alafenamide)	150-150-200-10 mg tablet					
Juluca (dolutegravir-rilpivirine)	50-25 mg tablet					
Odefsey (emtricitabine-rilpivirine-tenofovir alafenamide)	200-25-25 mg tablet					
Prezcobix (darunavir-cobicistat)	150-800 mg tablet					
Prezista (darunavir)	150 mg tablet					
	600 mg tablet					
	800 mg tablet					
Ravicti (glycerol phenylbutyrate)	1.1 g/mL oral liquid					

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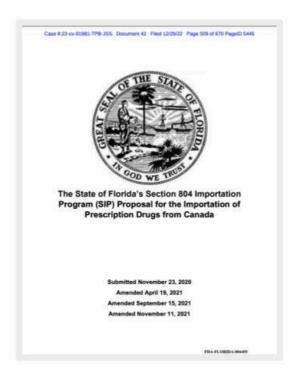
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Rexulti (brexpiprazole)	0.25 mg tablet
	0.5 mg tablet
	1 mg tablet
	2 mg tablet
	3 mg tablet
	4 mg tablet
Symtuza (darunavir-cobicistat-emtricitabine-tenofovir	150-800-200-10 mg tablet
alafenamide)	
Tivicay (dolutegravir)	50 mg tablet
Vraylar (cariprazine)	1.5 mg capsule
	3 mg capsule
	4.5 mg capsule
	6 mg capsule
Xtandi (enzalutamide)	40 mg capsule

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Source: PACER document November 11, 2021 FL SIP Application to FDA

Find the entire application online at our website: www.safemedicines.org

Source: document can be found on PSM's website.

The following drugs were submitted as part of Florida's SIP application dated November 11, 2021.

Harvoni	Epclusa	Mavyret	Zepatier
Latuda	Farxiga	Tradjenta	Januvia
Spiriva Respimat	Combivent Respimat	Wixela	Incruse Ellipta
Kaletra	Genvoya	Complera	Stribild
Emtricitabine Tenofovir DF	Odefsey	Edurant	Intelence
Triumeq	Biktarvy	Isentress	Descovy
Juluca			

On the next four pages, we have included the original four-page listing from Florida's November 11, 2021 application. Please note: the state of Florida indicated revisions or additions to the text of its SIP by displaying those words highlighted in yellow.

Florida's List of Prescription Drugs to Import

The FDA rule requires the SIP to include the following information related to the prescription drugs that will be imported:

- · Names and Drug Identification Numbers (DIN) of selected drugs to import
- Information of the applicant that holds the New Drug Applications or Abbreviated New Drug Applications
- · Name and address of the manufacturer of the finished dosage form
- · Names and addresses of manufacturers of the prescription drugs and active ingredients

As part of this proposal, the State is providing the list of prescription drugs it will initially attempt to import under the SIP. The final list of imported prescription drugs is subject to change and can be addressed in an amended SIP or through the pre-import request, based on the FDA's preference. The State will also update the list of prescription drugs with the manufacturer information once that is confirmed (known).

Florida has chosen a more limited set of eligible prescription drug classes for which to initiate its importation program, focusing on medications that are used to treat certain conditions (e.g., HIV/AIDS, asthma, chronic obstructive pulmonary disease, diabetes, etc.) and that will yield the highest potential savings. Also, these specific medications allow Florida the best opportunity to maximize the importation program's benefits while remaining compliant with federal law. After the program has proven to be a success, the State intends to amend its SIP to expand the list of medications that will be imported.

The list of proposed drugs for this SIP is given below. Full information regarding each drug, including the proposed labels, can be found in Attachment D.

Hepatitis C Prescription Drugs

Drug Name	Active Ingredient	NDC	U.S. Price	NDA/ ANDA	DIN	Canadian Name	Sold in
							U.S.
Harvoni 90-	Ledipasvir,	61958-	\$1,098.94	NDA205834	02432226	Harvoni	Yes
400mg	Sofosbuvir	1801-01					
Epclusa 400-	Sofosbuvir,	61958-	\$869.05	NDA208341	02456370	Epclusa	Yes
100mg	Velpatavir	2201-01					
Mavyret 100-	Glecaprevir,	00074-	\$153.11	NDA209394	02467550	Maviret	Yes
40mg	Pibrentasvir	2625-80					
Zepatier 50-	Elbasvir,	00006-	\$260.00	NDA208261	02451131	Zepatier	Yes
100mg	Grazoprevir	3074-01					

Psychiatric Prescription Drugs

Drug Name	Active Ingredient	NDC	U.S. Price	NDA/ ANDA	DIN	Canadian Name	Sold in U.S.
Latuda 20mg tab	Lurasidone HCL	63402- 0302-30	\$40.99	NDA200603	02422050	Latuda	Yes

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Drug Name	Active Ingredient	NDC	U.S. Price	NDA/ ANDA	DIN	Canadian Name	Sold in U.S.
Latuda 40mg	Lurasidone HCL	63402- 0304-10	\$41.00	NDA200603	02387751	Latuda	Yes
Latuda 60mg	Lurasidone HCL	63402- 0306-30	\$41.04	NDA200603	02413361	Latuda	Yes
Latuda 80mg	Lurasidone HCL	63402- 0308-30	\$41.03	NDA200603	02387778	Latuda	Yes
Latuda 120mg	Lurasidone HCL	63402- 0312-30	\$61.13	NDA200603	02387786	Latuda	Yes

Diabetes Prescription Drugs

Drug Name	Active Ingredient	NDC	U.S. Price	NDA/ ANDA	DIN	Canadian Name	Sold in U.S.
Farxiga 5mg tabs	Dapagliflozin Propanediol	00310- 6205-30	\$16.55	NDA202293	02435462	Farxiga	Yes
Farxiga 10mg tabs	Dapagliflozin Propanediol	00310- 6210-30	\$16.54	NDA202293	02435470	Farxiga	Yes
Tradjenta 5mg tabs	Linagliptin	00597- 0140-30	\$14.79	NDA201280	02370921	Tradjenta	Yes
Januvia 50mg tabs	Sitagliptin Phosphate	00006- 0112-31	\$15.13	NDA021995	02388847	Januvia	Yes
Januvia 25mg tabs	Sitagliptin Phosphate	00006- 0221-31	\$15.13	NDA021995	02388839	Januvia	Yes
Januvia 100mg tabs	Sitagliptin Phosphate	00006- 0277-31	\$15.14	NDA021995	02303922	Januvia	Yes

Asthma and Chronic Obstructive Pulmonary Disease Prescription Drugs

Drug Name	Active Ingredient	NDC	U.S. Price	NDA/ ANDA	DIN	Canadian Name	Sold in U.S.
Spiriva 30 caps, 18mcg	Tiotropium Bromide	00597- 0075-41	\$436.80	NDA021395	02246793	Spiriva	Yes
Spiriva Respimat 2.5 mcg	Tiotropium Bromide	00597- 0100-61	\$461.62	NDA021936	02435381	Spiriva .	Yes
Combivent Respimat 20- 100 mcg	Ipatroprium Bromide, Albuterol Sulfate (aka salbutamol sulfate)	00597- 0024-02	\$408.76	NDA021747	02419106	Combivent Respimat	Yes
Wixela Inhub 100-50 mcg	Fluticasone Propion, Salmeterol	00378- 9320-32	\$123.00	ANDA208891	02495597	Wixela Inhub	Yes

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Drug Name	Active	NDC	U.S.	NDA/ ANDA	DIN	Canadian	Sold in
	Ingredient		Price			Name	U.S.
Wixela Inhub	Fluticasone	00378-	\$150.00	ANDA208891	02495600	Wixela Inhub	Yes
250-50 mcg	Propion,	9321-32					
	Salmeterol						
Wixela Inhub	Fluticasone	00378-	\$199.20	ANDA208891	02495619	Wixela Inhub	Yes
500-50 mcg	Propion,	9322-32					
	Salmeterol						
Incruse Ellipta	Umeclidinium	00173-	\$329.40	NDA205382	02423596	Incruse	Yes
62.5 mcg		0873-10				Ellipta	

HIV/AIDS Prescription Drugs

Drug Name	Active	NDC	U.S.	NDA/ ANDA	DIN	Canadian	Sold in
	Ingredient		Price			Name	U.S.
Kaletra 200- 50mg	Lopinovir, Ritonovir	00074- 2605-21	\$8.53	NDA021906	02285533	Kaletra	Yes
Kaletra 100- 25mg	Lopinovir, Ritonovir	00074- 0522-60	\$4.27	NDA021906	02312301	Kaletra	Yes
Genvoya 150- 150-200-10 mg tabs	Elviteg, COB, Emtri, Tenof, Alafen	61958- 1901-01	\$104.93	ANDA207561	02449498	Genvoya	Yes
Complera 200- 25-300 mg tabs	Emtricit, Rilpivirine, Tenofovir DF	61958- 1101-01	\$95.52	NDA202123	02374129	Complera	Yes
Stribild 150-150- 200-300 mg	Elviteg, COB, Emtricit, Tenofovir Disop	61958- 1201-01	\$109.51	NDA203100	02397137	Stribild	Yes
Emtricitabine, Tenofovir DF 200-300mg	Emtricitabine, Tenofovir DF	00093- 7607-56	\$45.69	ANDA090894	02399059	TEVA- Emtricitabin e, Tenofovir	Yes
Odefsey 200-25- 25 mg	Emtricit, Rilpivirine, Tenofovir Ala	61958- 2101-01	\$95.77	NDA208351	02461463	Odefsey	Yes
Edurant 25 mg	Rilpivirine HCL	59676- 0278-01	\$37.58	NDA202022	02370603	Edurant	Yes
Intelence 100mg	Etravirine	59676- 0570-01	\$10.92	NDA022187	02306778	Intelence	Yes
Intelence 200mg	Etravirine	59676- 0571-01	\$22.41	NDA022187	02375931	Intelence	Yes
Triumeq 50- 600-300 mg	Abacavir, Dolutegravir, Lamivudine	49702- 0231-13	\$98.19	NDA205551	02430932	Triumeq	Yes
Biktarvy	Bictegravir, Emtricit, Tenofovir Ala	61958- 2501-01	\$104.52	NDA210251	02478579	Biktarvy	Yes

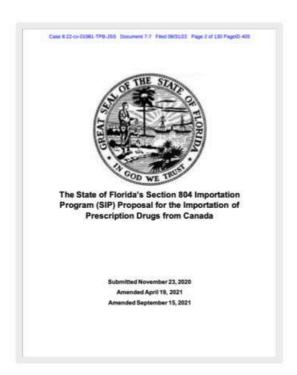
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Drug Name	Active	NDC	U.S.	NDA/ ANDA	DIN	Canadian	Sold in
	Ingredient		Price			Name	U.S.
Isentress 400mg	Raltegravir	00006- 0277-61	\$26.74	NDA022145	02301881	Isentress	Yes
Descovy	Emtricitabine, Tenofovir 200mg-25mg	61958- 2002-01	\$59.67	NDA208215	02454424	Descovy	Yes
Juluca	Dolutegravir, Rilpivirine	49702- 0242-13	\$91.75	NDA210192	02475774	Juluca	Yes

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Source: PACER document September 15, 2021 FL SIP Application to FDA

Find the entire application online at our website: www.safemedicines.org

Source: document can be found on PSM's website.

The following drugs were submitted as part of Florida's SIP application dated September 15, 2021.

Harvoni	Epclusa	Mavyret	Zepatier
Latuda	Zyprexa	Olanzapine	Seroquel
Quetiapine Fumarate	Clozaril	Clozapine	Abilify
Aripiprazole	Risperidone	Chlorpromazine	Fluphenazine
Metformin	Farxiga	Tradjenta	Januvia
Spiriva	Combivent Respimat	Advair Diskus	Fluticasone Propion, Salmeterol
Wikela	Atrovent HFA	Incruse Ellipta	Kaletra
Emtricitabine Tenofovir	Sustiva	Efavirenz	Genvoya
Atripla	Efavirenz, Emtricit, Tenofovir DF	Complera	Stribild
Truvada	Emtricitabine Tenofovir DF	Odefsey	Invirase
Edurant	Intelence	Triumeq	Juluca
Biktarvy	Isentress	Descovy	

On the next seven pages, we have included the original seven-page listing from Florida's September 15, 2021 application.

Florida's List of Prescription Drugs to Import

The FDA rule requires the SIP to include the following information related to the prescription drugs that will be imported:

- Names and Drug Identification Numbers (DIN) of selected drugs to import
- Information of the applicant that holds the New Drug Applications or Abbreviated New Drug Applications
- Name and address of the manufacturer of the finished dosage form
- · Names and addresses of manufacturers of the prescription drugs and active ingredients

As part of this proposal, the State is providing the list of prescription drugs it will initially attempt to import under the SIP. Since the State has not finalized an agreement with a foreign seller and has not secured agreements from manufacturers, the final list of imported prescription drugs is subject to change and can be addressed in an amended SIP or through the pre-import request, based on the FDA's preference. The State will also update the list of prescription drugs with the manufacturer information once that is confirmed (known).

Florida has chosen a more limited set of eligible prescription drug classes for which to initiate its importation program, focusing on medications that are used to treat certain conditions (e.g., HIV/AIDS, asthma, chronic obstructive pulmonary disease, diabetes, etc.) and that will yield the highest potential savings. Also, these specific medications allow Florida the best opportunity to maximize the importation program's benefits while remaining compliant with federal law. After the program has proven to be a success, the State intends to amend its SIP to expand the list of medications that will be imported.

The below chart outlines preliminary information necessary for these prescription drugs as it applies in both the U.S. and Canada.

Hepatitis C Prescription Drugs

Drug Name	Active Ingredient	NDC	U.S. Price	NDA/ANDA	DIN	Canadian Name	Sold in U.S.
Harvoni 90-	Ledipasvir,	61958-	\$1,098.94	NDA205834	02432226	Harvoni	Yes
400mg	Sofosbuvir	1801-01					
Epclusa 400-	Sofosbuvir,	61958-	\$869.05	NDA208341	02456370	Epclusa	Yes
100mg	Velpatavir	2201-01					
Mavyret 100-	Glecaprevir,	00074-	\$153.11	NDA209394	02467550	Maviret	Yes
40mg	Pibrentasvir	2625-80					
Zepatier 50-	Elbasvir,	00006-	\$260.00	NDA208261	02451131	Zepatier	Yes
100mg	Grazoprevir	3074-01					

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Psychiatric Prescription Drugs

Drug Name	Active	NDC	U.S.	NDA/ANDA	DIN	Canadian	Sold
	Ingredient		Price			Name	in U.S.
Latuda 20mg tab	Lurasidone HCL	63402- 0302-30	\$40.99	NDA200603	02422050	Latuda	Yes
Latuda 40mg	Lurasidone HCL	63402- 0304-10	\$41.00	NDA200603	02387751	Latuda	Yes
Latuda 60mg	Lurasidone HCL	63402- 0306-30	\$41.04	NDA200603	02413361	Latuda	Yes
Latuda 80mg	Lurasidone HCL	63402- 0308-30	\$41.03	NDA200603	02387778	Latuda	Yes
Latuda 120mg	Lurasidone HCL	63402- 0312-30	\$61.13	NDA200603	02387786	Latuda	Yes
Zyprexa 2.5mg tabs	Olanzapine	00002- 4112-30	\$10.06	NDA020592	02229250	Zyprexa	Yes
Olanzapine 2.5mg	Olanzapine	65862- 0561-30	\$0.11	ANDA202050	02276712	Teva- Olanzapine	Yes
Zyprexa 5mg tabs	Olanzapine	00002- 4115-30	\$11.87	NDA020592	02243086	Zyprexa Zydis	Yes
Olanzapine 5mg	Olanzapine	65862- 0562-30	\$0.12	ANDA202050	02276720	Teva- Olanzapine	Yes
Zyprexa 7.5mg	Olanzapine	00002- 4116-30	\$14.38	NDA020592	02229277	Zyprexa	Yes
Olanzapine 7.5mg	Olanzapine	65862- 0563-30	\$0.13	ANDA202050	02276739	Teva- Olanzapine	Yes
Zyprexa 10mg tabs	Olanzapine	00002- 4117-30	\$20.79	NDA020592	02243087	Zyprexa Zydis	Yes
Olanzapine 10mg	Olanzapine	65862- 0564-30	\$0.15	ANDA202050	02276747	Teva- Olanzapine	Yes
Zyprexa 15mg tabs	Olanzapine	00002- 4415-30	\$31.26	NDA020592	02238850	Zyprexa 15mg	Yes
Olanzapine 15mg	Olanzapine	65862- 0565-30	\$0.18	ANDA202050	02276755	Teva- Olanzapine	Yes
Seroquel 100mg	Quetiapine Fumarate	00310- 0271-10	\$6.42	NDA020639	02236952	Seroquel	Yes
Quetiapine Fumarate 100mg	Quetiapine Fumarate	46708- 0136-31	\$0.05	ANDA203390	02316099	ACT Quetiapine	Yes
Seroquel 25mg	Quetiapine Fumarate	003100275- 10	\$3.79	NDA020639	02236951	Seroquel	Yes
Quetiapine Fumarate 25mg	Quetiapine Fumarate	46708- 0134-31	\$0.04	ANDA203390	02316080	ACT Quetiapine	Yes

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Seroquel 200mg	Quetiapine Fumarate	00310- 0272-10	\$12.07	NDA020639	02236953	Seroquel	Yes
Quetiapine	Quetiapine	46708-	\$0.11	ANDA203390	02316110	ACT Quetiapine	Yes
Fumarate	Fumarate	0137-31	30.11	ANDAZUSSSU	02310110	ACT Quetiapine	163
200mg	Tulliarate	0137-31					
	0	00240	Ć45 05	ND ACCCCC	00044407	C	V
Seroquel	Quetiapine	00310-	\$15.95	NDA020639	02244107	Seroquel	Yes
300mg	Fumarate	0274-60					
Quetiapine	Quetiapine	46708-	\$0.17	ANDA203390	02316129	ACT Quetiapine	Yes
Fumarate	Fumarate	0138-60					
300mg							
Clozaril 25mg	Clozapine	69809-	\$4.79	NDA019758	00894737	Clozaril	Yes
tabs		0126-05					
Clozapine 25mg	Clozapine	0093-4359-	\$0.83	ANDA074949	02247243	GEN-Clozapine	Yes
		01					
Clozaril 100mg	Clozapine	69809-	12.06	NDA019758	00894745	Clozaril	Yes
		0127-05					
Clozapine	Clozapine	0093-7772-	1.38	ANDA074949	02247244	GEN-Clozapine	Yes
100mg		01				,	
Clozaril 50mg	Clozapine	69809-	10.15	NDA019758	02490668	Clozaril	Yes
tabs		0130-05					
Clozapine 50mg	Clozapine	0093-4404-	1.68	ANDA074949	02305003	GEN-Clozapine	Yes
Clozapine Joing	Clozapine	01	1.00	ANDA074343	02303003	GEN-Clozapine	163
Clozaril 200mg	Clozapine	69809-	29.29	NDA019758	02490676	Clozaril	Yes
Clozarii Zooriig	Clozapine	0135-05	25.25	NDA019736	02490070	Clozarii	163
Clozapine	Clozapine	0093-4405-	2.19	ANDA074949	02305011	GEN-Clozapine	Yes
	Ciozapine	l	2.19	ANDAU74343	02303011	GEN-Clozapine	163
200mg	Auininganala	01	20.64	ND 402142C	02222202	A L:I:E.	Vaa
Abilify 5mg	Aripiprazole	59148-	28.64	NDA021436	02322382	Abilify	Yes
tabs		0007-13	0.47	4415 4202424	00474004	400	.,
Aripiprazole	Aripiprazole	62332-	0.17	ANDA202101	02471094	APO-	Yes
5mg		0098-30				Aripiprazole	
Abilify 10mg	Aripiprazole	59148-	28.22	NDA021436	02322390	Abilify	Yes
tabs		0008-13					
Aripiprazole	Aripiprazole	62332-	0.15	ANDA202101	02471108	APO-	Yes
10mg		0099-30				Aripiprazole	
Abilify 15mg	Aripiprazole	59148-	28.55	NDA021436	02322404	Abilify	Yes
tabs		0009-13					
Aripiprazole	Aripiprazole	62332-	0.16	ANDA202101	02471116	APO-	Yes
15mg		0100-30				Aripiprazole	
Abilify 20mg	Aripiprazole	59148-	40.56	NDA021436	02322412	Abilify	Yes
tabs		0010-13					
Aripiprazole	Aripiprazole	62332-	0.2	ANDA202101	02471124	APO-	Yes
20mg	' '	0101-30				Aripiprazole	
Abilify 30mg	Aripiprazole	59148-	40.69	NDA021436	02322455	Abilify	Yes
tabs		0011-13					
Aripiprazole	Aripiprazole	62332-	0.26	ANDA202101	02471132	APO-	Yes
30mg	7. Ipipi uzoic	0102-30	0.20	7.107202101	024/1132	Aripiprazole	'``
Johns		0102-30				Alibibiazoie	

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Risperidone	Risperidone	27241-003-	0.06	ANDA201003	02282127	APO-	Yes
0.5mg		06				Risperidone	
Risperidone	Risperidone	27241-001-	0.06	ANDA201003	02282135	APO-	Yes
1mg		06				Risperidone	
Risperidone	Risperidone	27241-004-	0.07	ANDA201003	02282143	APO-	Yes
2mg		06				Risperidone	
Risperidone	Risperidone	27241-005-	0.08	ANDA201003	02282151	APO-	Yes
3mg		06				Risperidone	
Risperidone	Risperidone	27241-006-	0.14	ANDA201003	02282178	APO-	Yes
4mg		06				Risperidone	
Chlorpromazine	Chlorpromazine	0781-5914-	2.25	ANDA084112	00232823	TEVA-	Yes
25mg tabs		01				Chlorpromazine	
Chlorpromazine	Chlorpromazine	0781-5915-	3.17	ANDA084113	00232807	TEVA-	Yes
50mg tabs		01				Chlorpromazine	
Chlorpromazine	Chlorpromazine	0781-5916-	4.78	ANDA084114	00232831	TEVA-	Yes
100mg tabs		01				Chlorpromazine	
Fluphenazine	Fluphenazine	60219-	2.31	ANDA213647	00405345	Fluphenazine	Yes
1mg tabs		1678-01					
Fluphenazine	Fluphenazine	60219-	5.61	ANDA213647	00405361	Fluphenazine	Yes
5mg tabs		1680-01					

Diabetes Prescription Drugs

Drug Name	Active Ingredient	NDC	U.S. Price	NDA/ANDA	DIN	Canadian Name	Sold in U.S.
Metformin	Metformin	67877-	\$0.02	ANDA090564	02257726	ACT-	Yes
500mg tabs	Hydrochloride	0561-01				Metformin	
Metformin	Metformin	67877-	\$0.03	ANDA090564	02257734	ACT-	Yes
850mg tabs	Hydrochloride	0562-01				Metformin	
Metformin 1,000mg tabs	Metformin Hydrochloride	67877- 0563-01	\$0.03	ANDA090564	02460653	APO- Metformin ER	Yes
Farxiga 5mg tabs	Dapagliflozin Propanediol	00310- 6205-30	\$16.55	NDA202293	02435462	Farxiga	Yes
Farxiga 10mg tabs	Dapagliflozin Propanediol	00310- 6210-30	\$16.54	NDA202293	02435470	Farxiga	Yes
Tradjenta 5mg tabs	Linagliptin	00597- 0140-30	\$14.79	NDA201280	02370921	Tradjenta	Yes
Januvia 50mg tabs	Sitagliptin Phosphate	00006- 0112-31	\$15.13	NDA021995	02388847	Januvia	Yes
Januvia 25mg tabs	Sitagliptin Phosphate	00006- 0221-31	\$15.13	NDA021995	02388839	Januvia	Yes
Januvia 100mg tabs	Sitagliptin Phosphate	00006- 0277-31	\$15.14	NDA021995	02303922	Januvia	Yes

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Asthma and Chronic Obstructive Pulmonary Disease Prescription Drugs

Drug Name	Active Ingredient	NDC	U.S. Price	NDA/ANDA	DIN	Canadian Name	Sold in U.S.
Spiriva 30 caps, 18mcg / handihaler	Tiotropium Bromide	00597- 0075-41	\$436.80	NDA021395	02246793	Spiriva	Yes
Combivent Respimat	Ipatroprium Bromide, Albuterol Sulfate (aka salbutamol sulfate)	00597- 0024-02	\$408.76	NDA021747	02419106	Combivent Respimat	Yes
Advair Diskus 100-50mcg	Fluticasone Propion, Salmeterol	00173- 0695-00	\$303.60	NDA021077	02240835	Advair 100 Diskus	Yes
Fluticasone Propion, Salmeterol 100- 50	Fluticasone Propion, Salmeterol	66993- 0584-97	\$123.00	NDA021077	02494507	PMS- Fluticasone Propion, Salmeterol DPI	Yes
Wikela 100-50	Fluticasone Propion, Salmeterol	00378- 9320-32	\$123.00	ANDA208891	02495597	Wixela Inhub	Yes
Advair Diskus 250-50mcg	Fluticasone Propion, Salmeterol	00173- 0696-00	\$377.40	NDA021077	02240836	Advair 250 Diskus	Yes
Fluticasone Propion, Salmeterol 250-50	Fluticasone Propion, Salmeterol	66993- 0585-97	\$127.20	NDA021077	02494515	PMS- Fluticasone Propion, Salmeterol DPI	Yes
Wikela 250-50 mcg	Fluticasone Propion, Salmeterol	00378- 9321-32	\$150.00	ANDA208891	02495600	Wixela Inhub	Yes
Advair Diskus 500-50mcg	Fluticasone Propion, Salmeterol	00173- 0697-00	\$496.80	NDA021077	02240837	Advair 500 Diskus	Yes
Fluticasone Propion, Salmeterol 500-50	Fluticasone Propion, Salmeterol	66993- 0586-97	\$155.40	NDA021077	02494523	PMS- Fluticasone Propion, Salmeterol DPI	Yes
Wikela 500-50	Fluticasone Propion, Salmeterol	00378- 9322-32	\$199.20	ANDA208891	02495619	Wixela Inhub	Yes

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Atrovent HFA	Ipratropium	00597-	\$396.50	NDA021527	02247686	Atrovent HFA	Yes
17mcg	Bromide	0087-17					
Incruse Ellipta	Umeclidinium	00173-	\$329.40	NDA205382	02423596	Incruse	Yes
62.5 mcg #30		0873-10				Ellipta	

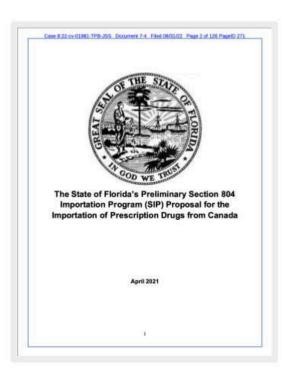
HIV/AIDS Prescription Drugs

Drug Name	Active	NDC	U.S.	NDA/ANDA	DIN	Canadian	Sold in
	Ingredient		Price			Name	U.S.
Kaletra 200-	Lopinovir,	00074-	\$8.53	NDA021906	02285533	Kaletra	Yes
50mg	Ritonovir	2605-21					
Kaletra 100-	Lopinovir,	00074-	\$4.27	NDA021906	02312301	Kaletra	Yes
25mg	Ritonovir	0522-60					
Emtricitabine,	Emtricitabine,	00093-	\$45.69	ANDA090894	02461110	PMS-	Yes
Tenofovir (TDF)	Tenofovir	7607-56				Emtricitabin	
	(TDF)					e, Tenofovir	
						(TDF)	
Sustiva 600mg	Efavirenz	00056-	\$8.57	NDA021360	02246045	Sustiva	Yes
tabs		0510-30				Tablets	
Efavirenz 600mg	Efavirenz	00378-	\$8.57	ANDA091471	02389762	TEVA-	Yes
tabs		2233-93				Efavirenz	
Sustiva 50mg	Efavirenz	00056-	\$3.50	NDA020972	02239886	Sustiva	Yes
caps.		0470-30				50MG	
Sustiva 200mg	Efavirenz	00056-	\$10.50	NDA020972	02239888	Sustiva	Yes
caps		0474-92				200MG	
Genvoya tabs	Elviteg, COB,	61958-	\$104.93	ANDA207561	02449498	Genvoya	Yes
	Emtri, Tenof,	1901-01					
	Alafen						
Atripla tab	Efavirenz,	15584-	\$96.91	ANDA021937	02300699	Atripla	Yes
	Emtricit,	0101-01					
	Tenofovir DF						
Efavirenz,	Efavirenz,	00093-	\$73.31	ANDA091215	02393549	TEVA-	Yes
Emtricit,	Emtricit,	5234-56				Efavirenz,	
Tenofovir DF	Tenofovir DF					Emtricitabin	
						e, tenofovir	
Complera tabs	Emtricit,	61958-	\$95.52	NDA202123	02374129	Complera	Yes
	Rilpivirine,	1101-01					
	Tenofovir DF						
Stribild	Elviteg, COB,	61958-	\$109.51	NDA203100	02397137	Stribild	Yes
	Emtricit,	1201-01					
	Tenofovir						
	Disop						
Truvada 200-	Emtricitabine,	61958-	\$59.70	NDA021752	02274906	Truvada	Yes
300mg	Tenofovir DF	0701-01					
Emtricitabine,	Emtricitabine,	00093-	\$45.69	ANDA090894	02399059	TEVA-	Yes
Tenofovir DF	Tenofovir DF	7607-56				Emtricitabin	
200-300mg						e, Tenofovir	

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Odefsey	Emtricit,	61958-	\$95.77	NDA208351	02461463	Odefsey	Yes
	Rilpivirine,	2101-01					
	Tenofovir Ala						
Invirase	Squinavir	00004-	\$9.76	NDA020628	02279320	Invirase	Yes
	Mesylate	0244-51					
Edurant	Rilpivirine HCL	59676-	\$37.58	NDA202022	02370603	Edurant	Yes
	·	0278-01					
Intelence	Etravirine	59676-	\$10.92	NDA022187	02306778	Intelence	Yes
100mg		0570-01					
Intelence	Etravirine	59676-	\$22.41	NDA022187	02375931	Intelence	Yes
200mg		0571-01					
Intelence 25mg	Etravirine	59676-	\$2.88	NDA022187	02396750	Intelence	Yes
		0572-01					
Triumeq	Abacavir,	49702-	\$98.19	NDA205551	02430932	Triumeq	Yes
	Dolutegravir,	0231-13					
	Lamivudi						
Juluca	Dolutegravir,	49702-	\$91.75	NDA210192	02475774	Juluca	Yes
	Rilpivirine	0242-13					
Biktarvy	Bictegravir,	61958-	\$104.52	NDA210251	02478579	Biktarvy	Yes
	Emtricit,	2501-01					
	Tenofovir Ala						
Isentress 400mg	Raltegravir	00006-	\$26.74	NDA022145	02301881	Isentress	Yes
		0277-61					
Descovy	Emtricitabine,	61958-	\$59.67	NDA208215	02454424	Descovy	Yes
	Tenofovir	2002-01					
	200mg-25mg						





Source: PACER document April 19, 2021 FL SIP Application to FDA

Find the entire application online at our website: www.safemedicines.org Source: document can be found on PSM's website.

The following drugs were submitted as part of Florida's SIP application dated April 19, 2021.

Harvoni	Epclusa	Mavyret	Zepatier
Latuda	Zyprexa	Olanzapine	Seroquel
Quetiapine Fumarate	Clozaril	Clozapine	Abilify
Aripiprazole	Risperidone	Chlorpromazine	Fluphenazine
Metformin	Farxiga	Tradjenta	Januvia
Spiriva	Combivent Respimat	Advair Diskus	Fluticasone Propion, Salmeterol
Wikela	Atrovent HFA	Incruse Ellipta	Kaletra
Emtricitabine Tenofovir	Sustiva	Efavirenz	Genvoya
Atripla	Efavirenz, Emtricit, Tenofovir DF	Complera	Stribild
Truvada	Emtricitabine Tenofovir DF	Odefsey	Invirase
Edurant	Intelence	Triumeq	Juluca
Biktarvy	Isentress	Descovy	

On the next seven pages, we have included the original seven-page listing from Florida's April 19, 2021 application.

Florida's List of Prescription Drugs to Import

The FDA rule requires the SIP to include the following information related to the prescription drugs that will be imported:

- Names and Drug Identification Numbers (DIN) of selected drugs to import
- Information of the applicant that holds the New Drug Applications or Abbreviated New Drug Applications
- Name and address of the manufacturer of the finished dosage form
- Names and addresses of manufacturers of the prescription drugs and active ingredients

As part of this proposal, the State is providing the list of prescription drugs it will initially attempt to import under the SIP. Since the State has not finalized an agreement with a foreign seller and has not secured agreements from manufacturers, the final list of imported prescription drugs is subject to change and can be addressed in an amended SIP or through the pre-import request, based on the FDA's preference. The State will also update the list of prescription drugs with the manufacturer information once that is confirmed (known).

Florida has chosen a more limited set of eligible prescription drug classes for which to initiate its importation program, focusing on medications that are used to treat certain conditions (e.g., HIV/AIDS, asthma, chronic obstructive pulmonary disease, diabetes, etc.) and that will yield the highest potential savings. Also, these specific medications allow Florida the best opportunity to maximize the importation program's benefits while remaining compliant with federal law. After the program has proven to be a success, the State intends to amend its SIP to expand the list of medications that will be imported.

The below chart outlines preliminary information necessary for these prescription drugs as it applies in both the U.S. and Canada.

Hepatitis C Prescription Drugs

Drug Name	Active Ingredient	NDC	U.S. Price	NDA/ANDA	DIN	Canadian Name	Sold in U.S.
Harvoni 90- 400mg	Ledipasvir, Sofosbuvir	61958- 1801-01	\$1,098.94	NDA205834	02432226	Harvoni	Yes
Epclusa 400- 100mg	Sofosbuvir, Velpatavir	61958- 2201-01	\$869.05	NDA208341	02456370	Epclusa	Yes
Mavyret 100- 40mg	Glecaprevir, Pibrentasvir	00074- 2625-80	\$153.11	NDA209394	02467550	Maviret	Yes
Zepatier 50- 100mg	Elbasvir, Grazoprevir	00006- 3074-01	\$260.00	NDA208261	02451131	Zepatier	Yes

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Psychiatric Prescription Drugs

Drug Name	Active	NDC	U.S.	NDA/ANDA	DIN	Canadian	Sold
	Ingredient		Price			Name	in
			4.0.00				U.S.
Latuda 20mg	Lurasidone HCL	63402-	\$40.99	NDA200603	02422050	Latuda	Yes
tab	Luna sidan a UCI	0302-30	Ć41 00	ND A 200CO2	02207754	Lakuda	V
Latuda 40mg	Lurasidone HCL	63402- 0304-10	\$41.00	NDA200603	02387751	Latuda	Yes
Latuda 60mg	Lurasidone HCL	63402-	\$41.04	NDA200603	02413361	Latuda	Yes
Latuda borrig	Lurasidone nct	0306-30	341.04	NDAZOOOOS	02415501	Latuua	163
Latuda 80mg	Lurasidone HCL	63402-	\$41.03	NDA200603	02387778	Latuda	Yes
		0308-30	7				
Latuda 120mg	Lurasidone HCL	63402-	\$61.13	NDA200603	02387786	Latuda	Yes
		0312-30					
Zyprexa 2.5mg	Olanzapine	00002-	\$10.06	NDA020592	02229250	Zyprexa	Yes
tabs		4112-30					
Olanzapine	Olanzapine	65862-	\$0.11	ANDA202050	02276712	Teva-	Yes
2.5mg		0561-30				Olanzapine	
Zyprexa 5mg	Olanzapine	00002-	\$11.87	NDA020592	02243086	Zyprexa Zydis	Yes
tabs		4115-30					
Olanzapine	Olanzapine	65862-	\$0.12	ANDA202050	02276720	Teva-	Yes
5mg		0562-30	4			Olanzapine	
Zyprexa 7.5mg	Olanzapine	00002-	\$14.38	NDA020592	02229277	Zyprexa	Yes
Olanzanina	Olonzanina	4116-30 65862-	\$0.13	ANDA202050	02276739	Teva-	Yes
Olanzapine	Olanzapine	0563-30	\$0.13	ANDAZUZUSU	022/0/39	Olanzapine	res
7.5mg Zyprexa 10mg	Olanzapine	00002-	\$20.79	NDA020592	02243087	Zyprexa Zydis	Yes
tabs	Olatizapine	4117-30	\$20.79	NDAU20392	02243067	Zyprexa Zyuis	165
Olanzapine	Olanzapine	65862-	\$0.15	ANDA202050	02276747	Teva-	Yes
10mg	Cianzapine	0564-30	70.13	/	02270747	Olanzapine	
Zyprexa 15mg	Olanzapine	00002-	\$31.26	NDA020592	02238850	Zyprexa 15mg	Yes
tabs		4415-30					
Olanzapine	Olanzapine	65862-	\$0.18	ANDA202050	02276755	Teva-	Yes
15mg		0565-30				Olanzapine	
Seroquel	Quetiapine	00310-	\$6.42	NDA020639	02236952	Seroquel	Yes
100mg	Fumarate	0271-10					
Quetiapine	Quetiapine	46708-	\$0.05	ANDA203390	02316099	ACT Quetiapine	Yes
Fumarate	Fumarate	0136-31					
100mg							
Seroquel 25mg	Quetiapine	003100275-	\$3.79	NDA020639	02236951	Seroquel	Yes
	Fumarate	10					
Quetiapine	Quetiapine	46708-	\$0.04	ANDA203390	02316080	ACT Quetiapine	Yes
Fumarate	Fumarate	0134-31				,	
25mg							

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Seroquel 200mg	Quetiapine Fumarate	00310- 0272-10	\$12.07	NDA020639	02236953	Seroquel	Yes
Quetiapine Fumarate 200mg	Quetiapine Fumarate	46708- 0137-31	\$0.11	ANDA203390	02316110	ACT Quetiapine	Yes
Seroquel 300mg	Quetiapine Fumarate	00310- 0274-60	\$15.95	NDA020639	02244107	Seroquel	Yes
Quetiapine Fumarate 300mg	Quetiapine Fumarate	46708- 0138-60	\$0.17	ANDA203390	02316129	ACT Quetiapine	Yes
Clozaril 25mg tabs	Clozapine	69809- 0126-05	\$4.79	NDA019758	00894737	Clozaril	Yes
Clozapine 25mg	Clozapine	0093-4359- 01	\$0.83	ANDA074949	02247243	GEN-Clozapine	Yes
Clozaril 100mg	Clozapine	69809- 0127-05	12.06	NDA019758	00894745	Clozaril	Yes
Clozapine 100mg	Clozapine	0093-7772- 01	1.38	ANDA074949	02247244	GEN-Clozapine	Yes
Clozaril 50mg tabs	Clozapine	69809- 0130-05	10.15	NDA019758	02490668	Clozaril	Yes
Clozapine 50mg	Clozapine	0093-4404- 01	1.68	ANDA074949	02305003	GEN-Clozapine	Yes
Clozaril 200mg	Clozapine	69809- 0135-05	29.29	NDA019758	02490676	Clozaril	Yes
Clozapine 200mg	Clozapine	0093-4405- 01	2.19	ANDA074949	02305011	GEN-Clozapine	Yes
Abilify 5mg tabs	Aripiprazole	59148- 0007-13	28.64	NDA021436	02322382	Abilify	Yes
Aripiprazole 5mg	Aripiprazole	62332- 0098-30	0.17	ANDA202101	02471094	APO- Aripiprazole	Yes
Abilify 10mg tabs	Aripiprazole	59148- 0008-13	28.22	NDA021436	02322390	Abilify	Yes
Aripiprazole 10mg	Aripiprazole	62332- 0099-30	0.15	ANDA202101	02471108	APO- Aripiprazole	Yes
Abilify 15mg tabs	Aripiprazole	59148- 0009-13	28.55	NDA021436	02322404	Abilify	Yes
Aripiprazole 15mg	Aripiprazole	62332- 0100-30	0.16	ANDA202101	02471116	APO- Aripiprazole	Yes
Abilify 20mg tabs	Aripiprazole	59148- 0010-13	40.56	NDA021436	02322412	Abilify	Yes
Aripiprazole 20mg	Aripiprazole	62332- 0101-30	0.2	ANDA202101	02471124	APO- Aripiprazole	Yes
Abilify 30mg	Aripiprazole	59148- 0011-13	40.69	NDA021436	02322455	Abilify	Yes
Aripiprazole 30mg	Aripiprazole	62332- 0102-30	0.26	ANDA202101	02471132	APO- Aripiprazole	Yes

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Risperidone 0.5mg	Risperidone	27241-003- 06	0.06	ANDA201003	02282127	APO- Risperidone	Yes
Risperidone 1mg	Risperidone	27241-001- 06	0.06	ANDA201003	02282135	APO- Risperidone	Yes
Risperidone 2mg	Risperidone	27241-004- 06	0.07	ANDA201003	02282143	APO- Risperidone	Yes
Risperidone 3mg	Risperidone	27241-005- 06	0.08	ANDA201003	02282151	APO- Risperidone	Yes
Risperidone 4mg	Risperidone	27241-006- 06	0.14	ANDA201003	02282178	APO- Risperidone	Yes
Chlorpromazine 25mg tabs	Chlorpromazine	0781-5914- 01	2.25	ANDA084112	00232823	TEVA- Chlorpromazine	Yes
Chlorpromazine 50mg tabs	Chlorpromazine	0781-5915- 01	3.17	ANDA084113	00232807	TEVA- Chlorpromazine	Yes
Chlorpromazine 100mg tabs	Chlorpromazine	0781-5916- 01	4.78	ANDA084114	00232831	TEVA- Chlorpromazine	Yes
Fluphenazine 1mg tabs	Fluphenazine	60219- 1678-01	2.31	ANDA213647	00405345	Fluphenazine	Yes
Fluphenazine 5mg tabs	Fluphenazine	60219- 1680-01	5.61	ANDA213647	00405361	Fluphenazine	Yes

Diabetes Prescription Drugs

Drug Name	Active	NDC	U.S.	NDA/ANDA	DIN	Canadian	Sold in
	Ingredient		Price			Name	U.S.
Metformin	Metformin	67877-	\$0.02	ANDA090564	02257726	ACT-	Yes
500mg tabs	Hydrochloride	0561-01				Metformin	
Metformin	Metformin	67877-	\$0.03	ANDA090564	02257734	ACT-	Yes
850mg tabs	Hydrochloride	0562-01				Metformin	
Metformin	Metformin	67877-	\$0.03	ANDA090564	02460653	APO-	Yes
1,000mg tabs	Hydrochloride	0563-01				Metformin ER	
Farxiga 5mg	Dapagliflozin	00310-	\$16.55	NDA202293	02435462	Farxiga	Yes
tabs	Propanediol	6205-30					
Farxiga 10mg	Dapagliflozin	00310-	\$16.54	NDA202293	02435470	Farxiga	Yes
tabs	Propanediol	6210-30					
Tradjenta 5mg	Linagliptin	00597-	\$14.79	NDA201280	02370921	Tradjenta	Yes
tabs		0140-30					
Januvia 50mg	Sitagliptin	00006-	\$15.13	NDA021995	02388847	Januvia	Yes
tabs	Phosphate	0112-31					
Januvia 25mg	Sitagliptin	00006-	\$15.13	NDA021995	02388839	Januvia	Yes
tabs	Phosphate	0221-31					
Januvia 100mg	Sitagliptin	00006-	\$15.14	NDA021995	02303922	Januvia	Yes
tabs	Phosphate	0277-31					

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Asthma and Chronic Obstructive Pulmonary Disease Prescription Drugs

Drug Name	Active	NDC	U.S.	NDA/ANDA	DIN	Canadian	Sold in
	Ingredient		Price			Name	U.S.
Spiriva 30 caps, 18mcg/ handihaler	Tiotropium Bromide	00597- 0075-41	\$436.80	NDA021395	02246793	Spiriva	Yes
Combivent Respimat	Ipatroprium Bromide, Albuterol Sulfate (aka salbutamol sulfate)	00597- 0024-02	\$408.76	NDA021747	02419106	Combivent Respimat	Yes
Advair Diskus 100-50mcg	Fluticasone Propion, Salmeterol	00173- 0695-00	\$303.60	NDA021077	02240835	Advair 100 Diskus	Yes
Fluticasone Propion, Salmeterol 100- 50	Fluticasone Propion, Salmeterol	66993- 0584-97	\$123.00	NDA021077	02494507	PMS- Fluticasone Propion, Salmeterol DPI	Yes
Wikela 100-50	Fluticasone Propion, Salmeterol	00378- 9320-32	\$123.00	ANDA208891	02495597	Wixela Inhub	Yes
Advair Diskus 250-50mcg	Fluticasone Propion, Salmeterol	00173- 0696-00	\$377.40	NDA021077	02240836	Advair 250 Diskus	Yes
Fluticasone Propion, Salmeterol 250-50	Fluticasone Propion, Salmeterol	66993- 0585-97	\$127.20	NDA021077	02494515	PMS- Fluticasone Propion, Salmeterol DPI	Yes
Wikela 250-50 mcg	Fluticasone Propion, Salmeterol	00378- 9321-32	\$150.00	ANDA208891	02495600	Wixela Inhub	Yes
Advair Diskus 500-50mcg	Fluticasone Propion, Salmeterol	00173- 0697-00	\$496.80	NDA021077	02240837	Advair 500 Diskus	Yes
Fluticasone Propion, Salmeterol 500-50	Fluticasone Propion, Salmeterol	66993- 0586-97	\$155.40	NDA021077	02494523	PMS- Fluticasone Propion, Salmeterol DPI	Yes
Wikela 500-50	Fluticasone Propion, Salmeterol	00378- 9322-32	\$199.20	ANDA208891	02495619	Wixela Inhub	Yes

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Atrovent HFA 17mcg	Ipratropium Bromide	00597- 0087-17	\$396.50	NDA021527	02247686	Atrovent HFA	Yes
Incruse Ellipta 62.5 mcg #30	Umeclidinium	00173- 0873-10	\$329.40	NDA205382	02423596	Incruse Ellipta	Yes

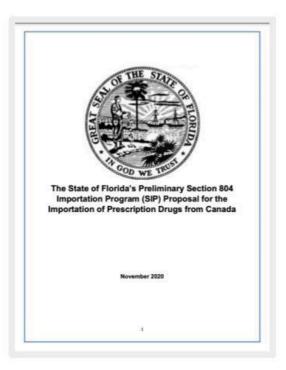
HIV/AIDS Prescription Drugs

Drug Name	Active	NDC	U.S.	NDA/ANDA	DIN	Canadian	Sold in
	Ingredient		Price			Name	U.S.
Kaletra 200-	Lopinovir,	00074-	\$8.53	NDA021906	02285533	Kaletra	Yes
50mg	Ritonovir	2605-21					
Kaletra 100-	Lopinovir,	00074-	\$4.27	NDA021906	02312301	Kaletra	Yes
25mg	Ritonovir	0522-60					
Emtricitabine,	Emtricitabine,	00093-	\$45.69	ANDA090894	02461110	PMS-	Yes
Tenofovir (TDF)	Tenofovir	7607-56				Emtricitabin	
	(TDF)					e, Tenofovir	
	_					(TDF)	
Sustiva 600mg	Efavirenz	00056-	\$8.57	NDA021360	02246045	Sustiva	Yes
tabs	-c ·	0510-30	40.57	4410 4004 474	00000760	Tablets	
Efavirenz 600mg	Efavirenz	00378-	\$8.57	ANDA091471	02389762	TEVA-	Yes
tabs	Efavirenz	2233-93 00056-	ć2 F0	NDA020972	02239886	Efavirenz	Yes
Sustiva 50mg	Etavirenz		\$3.50	NDA020972	02239886	Sustiva	Yes
caps.	Efavirenz	0470-30 00056-	\$10.50	NDA020972	02239888	50MG Sustiva	Yes
Sustiva 200mg	Eravirenz	0474-92	\$10.50	NDA020972	02239888	200MG	res
Caps Genvoya tabs	Elviteg, COB,	61958-	\$104.93	ANDA207561	02449498	Genvoya	Yes
Genvoya tabs	Emtri, Tenof,	1901-01	\$104.93	ANDAZU/361	02449498	Genvoya	res
	Alafen	1301-01					
Atripla tab	Efavirenz,	15584-	\$96.91	ANDA021937	02300699	Atripla	Yes
/ templa tab	Emtricit,	0101-01	750.51	7111071021337	02300033	/ teripia	103
	Tenofovir DF						
Efavirenz,	Efavirenz,	00093-	\$73.31	ANDA091215	02393549	TEVA-	Yes
Emtricit,	Emtricit,	5234-56				Efavirenz,	
Tenofovir DF	Tenofovir DF					Emtricitabin	
						e, tenofovir	
Complera tabs	Emtricit,	61958-	\$95.52	NDA202123	02374129	Complera	Yes
	Rilpivirine,	1101-01					
	Tenofovir DF						
Stribild	Elviteg, COB,	61958-	\$109.51	NDA203100	02397137	Stribild	Yes
	Emtricit,	1201-01					
	Tenofovir						
	Disop						
Truvada 200-	Emtricitabine,	61958-	\$59.70	NDA021752	02274906	Truvada	Yes
300mg	Tenofovir DF	0701-01	A 4 = - = -				.,
Emtricitabine,	Emtricitabine,	00093-	\$45.69	ANDA090894	02399059	TEVA-	Yes
Tenofovir DF	Tenofovir DF	7607-56				Emtricitabin	
200-300mg						e, Tenofovir	

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Odefsey	Emtricit,	61958-	\$95.77	NDA208351	02461463	Odefsey	Yes
	Rilpivirine,	2101-01					
	Tenofovir Ala						
Invirase	Squinavir	00004-	\$9.76	NDA020628	02279320	Invirase	Yes
	Mesylate	0244-51					
Edurant	Rilpivirine HCL	59676-	\$37.58	NDA202022	02370603	Edurant	Yes
		0278-01					
Intelence	Etravirine	59676-	\$10.92	NDA022187	02306778	Intelence	Yes
100mg		0570-01					
Intelence	Etravirine	59676-	\$22.41	NDA022187	02375931	Intelence	Yes
200mg		0571-01					
Intelence 25mg	Etravirine	59676-	\$2.88	NDA022187	02396750	Intelence	Yes
		0572-01					
Triumeq	Abacavir,	49702-	\$98.19	NDA205551	02430932	Triumeq	Yes
	Dolutegravir,	0231-13					
	Lamivudi						
Juluca	Dolutegravir,	49702-	\$91.75	NDA210192	02475774	Juluca	Yes
	Rilpivirine	0242-13					
Biktarvy	Bictegravir,	61958-	\$104.52	NDA210251	02478579	Biktarvy	Yes
	Emtricit,	2501-01					
	Tenofovir Ala						
Isentress 400mg	Raltegravir	00006-	\$26.74	NDA022145	02301881	Isentress	Yes
		0277-61					
Descovy	Emtricitabine,	61958-	\$59.67	NDA208215	02454424	Descovy	Yes
	Tenofovir	2002-01					
	200mg-25mg						





Source: Publicly available document November 23, 2020 FL SIP Application to FDA

Find the entire application online at our website: www.safemedicines.org

Source: document can be found on PSM's website.

The following drugs were submitted as part of Florida's SIP application dated November 23, 2020.

Harvoni	Epclusa	Mavyret	Zepatier
Latuda	Zyprexa	Olanzapine	Seroquel
Quetiapine Fumarate	Clozaril	Clozapine	Abilify
Aripiprazole	Risperidone	Chlorpromazine	Fluphenazine
Metformin	Farxiga	Tradjenta	Januvia
Spiriva	Combivent Respimat	Advair Diskus	Fluticasone Propion, Salmeterol
Wikela	Atrovent HFA	Incruse Ellipta	Kaletra
Emtricitabine Tenofovir	Sustiva	Efavirenz	Genvoya
Atripla	Efavirenz, Emtricit, Tenofovir DF	Complera	Stribild
Truvada	Emtricitabine Tenofovir DF	Odefsey	Invirase
Edurant	Intelence	Triumeq	Juluca
Biktarvy	Isentress	Descovy	

On the next seven pages, we have included the original seven-page listing from Florida's November 23, 2020 application.

Florida's List of Prescription Drugs to Import

The FDA rule requires the SIP to include the following information related to the prescription drugs that will be imported:

- Names and Drug Identification Numbers (DIN) of selected drugs to import
- Information of the applicant that holds the New Drug Applications or Abbreviated New Drug Applications
- · Name and address of the manufacturer of the finished dosage form
- · Names and addresses of manufacturers of the prescription drugs and active ingredients

As part of this proposal, the State is providing the list of prescription drugs it will initially attempt to import under the SIP. Since the State has not finalized an agreement with a foreign seller and has not secured agreements from manufacturers, the final list of imported prescription drugs is subject to change and can be addressed in an amended SIP or through the pre-import request, based on the FDA's preference. The State will also update the list of prescription drugs with the manufacturer information once that is confirmed (known).

Florida has chosen a more limited set of eligible prescription drug classes for which to initiate its importation program, focusing on medications that are used to treat certain conditions (e.g., HIV/AIDS, asthma, chronic obstructive pulmonary disease, diabetes, etc.) and that will yield the highest potential savings. Also, these specific medications allow Florida the best opportunity to maximize the importation program's benefits while remaining compliant with federal law. After the program has proven to be a success, the State intends to amend its SIP to expand the list of medications that will be imported.

The below chart outlines preliminary information necessary for these prescription drugs as it applies in both the U.S. and Canada.

Hepatitis C Prescription Drugs

Drug Name	Active Ingredient	NDC	U.S. Price	NDA/ ANDA	DIN	Canadian Name	Sold in U.S.
Harvoni 90-	Ledipasvir,	61958-	\$1,098.94	NDA205834	02432226	Harvoni	Yes
400mg	Sofosbuvir	1801-01					
Epclusa 400-	Sofosbuvir,	61958-	\$869.05	NDA208341	02456370	Epclusa	Yes
100mg	Velpatavir	2201-01					
Mavyret 100-	Glecaprevir,	00074-	\$153.11	NDA209394	02467550	Maviret	Yes
40mg	Pibrentasvir	2625-80					
Zepatier 50-	Elbasvir,	00006-	\$260.00	NDA208261	02451131	Zepatier	Yes
100mg	Grazoprevir	3074-01					

Psychiatric Prescription Drugs

Drug Name	Active Ingredient	NDC	U.S. Price	NDA/ ANDA	DIN	Canadian Name	Sold in
	ingredient		Price			Ivame	U.S.
Latuda 20mg tab	Lurasidone HCL	63402- 0302-30	\$40.99	NDA200603	02422050	Latuda	Yes
Latuda 40mg	Lurasidone HCL	63402- 0304-10	\$41.00	NDA200603	02387751	Latuda	Yes
Latuda 60mg	Lurasidone HCL	63402- 0306-30	\$41.04	NDA200603	02413361	Latuda	Yes
Latuda 80mg	Lurasidone HCL	63402- 0308-30	\$41.03	NDA200603	02387778	Latuda	Yes
Latuda 120mg	Lurasidone HCL	63402- 0312-30	\$61.13	NDA200603	02387786	Latuda	Yes
Zyprexa 2.5mg tabs	Olanzapine	00002- 4112-30	\$10.06	NDA020592	02229250	Zyprexa	Yes
Olanzapine 2.5mg	Olanzapine	65862- 0561-30	\$0.11	ANDA202050	02276712	Teva- Olanzapine	Yes
Zyprexa 5mg tabs	Olanzapine	00002- 4115-30	\$11.87	NDA020592	02243086	Zyprexa Zydis	Yes
Olanzapine 5mg	Olanzapine	65862- 0562-30	\$0.12	ANDA202050	02276720	Teva- Olanzapine	Yes
Zyprexa 7.5mg	Olanzapine	00002- 4116-30	\$14.38	NDA020592	02229277	Zyprexa	Yes
Olanzapine 7.5mg	Olanzapine	65862- 0563-30	\$0.13	ANDA202050	02276739	Teva- Olanzapine	Yes
Zyprexa 10mg tabs	Olanzapine	00002- 4117-30	\$20.79	NDA020592	02243087	Zyprexa Zydis	Yes
Olanzapine 10mg	Olanzapine	65862- 0564-30	\$0.15	ANDA202050	02276747	Teva- Olanzapine	Yes
Zyprexa 15mg tabs	Olanzapine	00002- 4415-30	\$31.26	NDA020592	02238850	Zyprexa 15mg	Yes
Olanzapine 15mg	Olanzapine	65862- 0565-30	\$0.18	ANDA202050	02276755	Teva- Olanzapine	Yes
Seroquel 100mg	Quetiapine Fumarate	00310- 0271-10	\$6.42	NDA020639	02236952	Seroquel	Yes
Quetiapine Fumarate 100mg	Quetiapine Fumarate	46708- 0136-31	\$0.05	ANDA203390	02316099	ACT Quetiapine	Yes
Seroquel 25mg	Quetiapine Fumarate	003100275- 10	\$3.79	NDA020639	02236951	Seroquel	Yes
Quetiapine Fumarate 25mg	Quetiapine Fumarate	46708- 0134-31	\$0.04	ANDA203390	02316080	ACT Quetiapine	Yes

Seroque Quetiapine O0310- O0310			I			I	I	
Quetiapine Fumarate Zuomg Quetiapine Fumarate 46708- 0137-31 \$0.11 ANDA203390 02316110 ACT Quetiapine Yes Seroquel 300mg Quetiapine Fumarate 00310- 0274-60 \$15.95 NDA0206399 02244107 Seroquel Yes Quetiapine Fumarate 300mg Quetiapine Fumarate Bumarate 46708- 0138-60 \$0.17 ANDA203390 02316129 ACT Quetiapine Yes Glozaril 25mg tabs Clozapine Ge9809- 0126-05 \$4.79 NDA019758 00894737 Clozaril Yes Clozaril 100mg Clozapine Ge9809- 0127-05 \$0.83 ANDA074949 02247243 GEN-Clozapine Yes Clozapine Clozapine Ge9809- 0127-05 \$1.38 ANDA074949 02247244 GEN-Clozapine Yes Clozapine Clozapine Ge9809- 0130-05 \$1.138 ANDA074949 02247244 GEN-Clozapine Yes Clozapine Somg Clozapine Ge9809- 0130-05 \$10.15 NDA019758 02490668 Clozaril Yes Clozapine Somg Clozapine Ge9809- 0135-05 \$10.15 NDA019758 02490666 Clozaril Yes Clozapine Glozapine Ge9809- 0135-05 \$10.15 NDA019758 02490676	Seroquel	Quetiapine	00310-	\$12.07	NDA020639	02236953	Seroquel	Yes
Fumarate 200mg Fumarate 200mg Fumarate 200mg Coloration 200mg Colorapine 200mg Quetiapine 200mg Colorapine 200mg S15.95 NDA020639 02244107 Seroquel 200mg Yes Quetiapine Fumarate 3000mg Quetiapine Fumarate 3000mg 46708-1038-60 \$0.17 ANDA203390 02316129 ACT Quetiapine Promarate 200mg Yes Glozaril 25mg tabs Clozapine 25mg Clozapine 25mg Clozapine 25mg \$0.83 ANDA074949 02247243 GEN-Clozapine Promarate 200mg Yes Clozaril 100mg Clozapine 25mg Clozapine 25mg 12.06 NDA019758 00894745 Clozaril Promarate 200mg Yes Clozapine 25mg tabs Clozapine 25mg 12.06 NDA019758 00894745 Clozaril Promarate 200mg Yes Clozapine 25mg tabs Clozapine 25mg tabs Clozapine 25mg 25mg 10.15 NDA019758 02490668 Clozaril Promarate 25mg Yes Clozapine 25mg tabs Clozapine 25mg 25mg 25mg 10.15 NDA019758 02490668 Clozaril Promarate 25mg Yes Clozaril 200mg tabs Clozapine 25mg 25mg 25mg 25mg 25mg 25mg								
200mg Quetiapine 00310- 515.95 NDA020639 02244107 Seroquel Yes Ves Ves				\$0.11	ANDA203390	02316110	ACT Quetiapine	Yes
Seroquel 300mg		Fumarate	0137-31					
Quetiapine				4			_	
Quetiapine Fumarate Soomg 46708- 0138-60 o138-60 o136-05 o136-05 o160 o1626-05 o160 o1626-05 o160 o1626-05 o160 o1626-05 o160 o1626-05 o160 o1626-05 o16266-05 o16266-05 o1626-05 o1626-05 o1626-05 o1626-05 o1626-05 o1626-05 o1626-05 o1626-05 o1				\$15.95	NDA020639	02244107	Seroquel	Yes
Fumarate 300mg	300mg	Fumarate	0274-60					
Fumarate 300mg				4				
300mg				\$0.17	ANDA203390	02316129	ACT Quetiapine	Yes
Clozaril 25mg tabs		Fumarate	0138-60					
tabs Clozapine 25mg Clozapine 0034-34359-01 \$0.83 ANDA074949 02247243 GEN-Clozapine Yes Clozaril 100mg Clozapine 69809-0127-05 12.06 NDA019758 00894745 Clozaril Yes Clozapine 0093-7772-01 1.38 ANDA074949 02247244 GEN-Clozapine Yes Clozaril 50mg Clozapine 69809-0130-05 10.15 NDA019758 02490668 Clozaril Yes Clozaril 200mg Clozapine 093-4404-01 1.68 ANDA074949 02305003 GEN-Clozapine Yes Clozaril 200mg Clozapine 69809-0135-05 29.29 NDA019758 02490676 Clozaril Yes Clozapine 0093-4405-01 2.19 ANDA074949 02305011 GEN-Clozapine Yes Clozapine Clozapine 29.29 NDA019758 02490676 Clozaril Yes Aripiprazole Aripiprazole 59148-0007-13 ANDA021436 02322328 Abilify Yes Aripiprazole								
Clozapine 25mg Clozapine 0093-4359-01 \$0.83 ANDAO74949 02247243 GEN-Clozapine Yes Clozapine 100mg Clozapine 0127-05 12.06 NDA019758 00894745 Clozaril Yes Clozapine 100mg Clozapine 093-7772-01 1.38 ANDA074949 02247244 GEN-Clozapine Yes Clozapine 50mg tabs Clozapine 093-4404-01 1.68 ANDA074949 02305003 GEN-Clozapine Yes Clozapine 50mg Clozapine 093-4404-01 69809-0135-05 29.29 NDA019758 02490676 Clozaril Yes Clozapine 200mg 79148-0909-14 28.64 NDA021436 02322382 Abilify Yes Aripiprazole 3mg Aripiprazole 40009-13 28.22 NDA021436		Clozapine		\$4.79	NDA019758	00894737	Clozaril	Yes
Clozaril 100mg								
Clozaril 100mg Clozapine 69809-0127-05 12.06 NDA019758 00894745 Clozaril Yes Clozapine 100mg Clozapine 0093-7772-01 1.38 ANDA074949 02247244 GEN-Clozapine Yes Clozaril 50mg tabs Clozapine 69809-0130-05 10.15 NDA019758 02490668 Clozaril Yes Clozapine 50mg Clozapine 0093-4404-01 1.68 ANDA074949 02305003 GEN-Clozapine Yes Clozapine 200mg Clozapine 69809-0135-05 29.29 NDA019758 02490676 Clozaril Yes Clozapine 200mg Clozapine 093-4405-01 2.19 ANDA074949 02305011 GEN-Clozapine Yes 200mg Aripiprazole 59148-0007-13 28.64 NDA021436 02322382 Abilify Yes 5mg Aripiprazole 62332-0098-30 0.17 ANDA021436 02322390 Abilify Yes Abilify 10mg tabs Aripiprazole 62332-00098-30 0.15 ANDA021436 02322404	Clozapine 25mg	Clozapine		\$0.83	ANDA074949	02247243	GEN-Clozapine	Yes
Clozapine Cloz								
Clozapine	Clozaril 100mg	Clozapine		12.06	NDA019758	00894745	Clozaril	Yes
100mg								
Clozaril 50mg tabs Clozapine 69809-0130-05 10.15 NDA019758 02490668 Clozaril Yes Clozapine 50mg tabs Clozapine 0093-4404-01 1.68 ANDA074949 02305003 GEN-Clozapine Yes Clozaril 200mg Clozapine 69809-0135-05 29.29 NDA019758 02490676 Clozaril Yes Clozapine 200mg Clozapine 0093-4405-01 2.19 ANDA074949 02305011 GEN-Clozapine Yes Abilify 5mg tabs Aripiprazole 59148-0007-13 28.64 NDA021436 02322382 Abilify Yes 5mg Aripiprazole 62332-0098-30 0.17 ANDA202101 02471094 APO-Aripiprazole Yes Abilify 10mg tabs Aripiprazole 62332-008-13 0.15 ANDA202101 02471108 APO-Aripiprazole Yes 10mg Aripiprazole 59148-009-13 28.55 NDA021436 02322404 Abilify Yes Aripiprazole 62332-0100-30 ARIPIPIPRADE 40.56 NDA021436		Clozapine		1.38	ANDA074949	02247244	GEN-Clozapine	Yes
tabs 0130-05 Modern Program Clozapine 50mg Clozapine 0093-4404-01 1.68 ANDA074949 02305003 GEN-Clozapine Yes Clozaril 200mg Clozapine 69809-0135-05 29.29 NDA019758 02490676 Clozaril Yes Clozapine 200mg Clozapine 0093-4405-01 2.19 ANDA074949 02305011 GEN-Clozapine Yes 200mg Aripiprazole 59148-0007-13 28.64 NDA021436 02322382 Abilify Yes Aripiprazole 3hilify 10mg Aripiprazole 62332-0098-30 0.17 ANDA202101 02471094 APO-Aripiprazole Aripiprazole Aripiprazole Abilify Yes Abilify 10mg 4abs Aripiprazole 59148-0008-13 28.22 NDA021436 02322390 Abilify Yes Aripiprazole 10mg Aripiprazole 62332-0099-30 0.15 ANDA202101 02471108 APO-Aripiprazole Yes Abilify 15mg 4bs Aripiprazole 62332-0099-30 0.16 ANDA202101 02471116 APO-Aripiprazole Yes Abilify 20mg 4bs Aripiprazole 59148-0010-13								
Clozapine 50mg Clozapine 0093-4404-01 1.68 ANDA074949 02305003 GEN-Clozapine Yes Clozaril 200mg Clozapine 69809-0135-05 29.29 NDA019758 02490676 Clozaril Yes Clozapine 200mg Clozapine 0093-4405-01 2.19 ANDA074949 02305011 GEN-Clozapine Yes Abilify 5mg tabs Aripiprazole 59148-0007-13 28.64 NDA021436 02322382 Abilify Yes 5mg Aripiprazole 62332-0998-30 0.17 ANDA202101 02471094 APO-Aripiprazole Yes Abilify 10mg tabs Aripiprazole 59148-0008-13 28.22 NDA021436 02322390 Abilify Yes Abilify 15mg tabs Aripiprazole 62332-0099-30 ANDA202101 02471108 APO-Aripiprazole Yes Abilify 15mg tabs Aripiprazole 62332-010-30 ANDA202101 02471116 APO-Aripiprazole Yes Abilify 20mg tabs Aripiprazole 59148-010-30 ANDA202101 02471116 APO-Aripiprazole<		Clozapine		10.15	NDA019758	02490668	Clozaril	Yes
Clozaril 200mg								
Clozaril 200mg Clozapine 69809-0135-05 29.29 NDA019758 02490676 Clozaril Yes Clozapine 200mg Clozapine 0093-4405-01 2.19 ANDA074949 02305011 GEN-Clozapine Yes Abilify 5mg tabs Aripiprazole 59148-0007-13 28.64 NDA021436 02322382 Abilify Yes 5mg Aripiprazole 62332-098-30 0.17 ANDA202101 02471094 APO-Aripiprazole Yes Abilify 10mg tabs Aripiprazole 59148-099-30 0008-13 ANDA202101 02471108 APO-Aripiprazole Yes Abilify 15mg tabs Aripiprazole 62332-099-30 0.15 ANDA202101 02471108 APO-Aripiprazole Yes Abilify 25mg tabs Aripiprazole 62332-010-30 0.16 ANDA202101 02471116 APO-Aripiprazole Yes Abilify 20mg tabs Aripiprazole 59148-0100-30 40.56 NDA021436 02322412 Abilify Yes Abilify 30mg tabs Aripiprazole 62332-0101-30 0.2	Clozapine 50mg	Clozapine	0093-4404-	1.68	ANDA074949	02305003	GEN-Clozapine	Yes
Clozapine								
Clozapine 200mg Clozapine 01 2.19 ANDA074949 02305011 GEN-Clozapine Yes Abilify 5mg tabs Aripiprazole 59148-0007-13 28.64 NDA021436 02322382 Abilify Yes Aripiprazole 5mg Aripiprazole 62332-0098-30 0.17 ANDA202101 02471094 APO-Aripiprazole Yes Abilify 10mg tabs Aripiprazole 59148-0008-13 28.22 NDA021436 02322390 Abilify Yes Aripiprazole 10mg Aripiprazole 62332-0099-30 0.15 ANDA202101 02471108 APO-Aripiprazole Yes Abilify 15mg tabs Aripiprazole 59148-0009-13 28.55 NDA021436 02322404 Abilify Yes Aripiprazole Aripiprazole 62332-0100-30 0.16 ANDA202101 02471116 APO-Aripiprazole Yes Abilify 20mg tabs Aripiprazole 59148-0100-30 40.56 NDA021436 02322412 Abilify Yes Aripiprazole 62332-0101-30 ANDA020101 02471124 APO-Aripiprazole Aripiprazole	Clozaril 200mg	Clozapine	69809-	29.29	NDA019758	02490676	Clozaril	Yes
200mg 01 28.64 NDA021436 02322382 Abilify Yes Abilify 5mg tabs Aripiprazole 59148- 0007-13 28.64 NDA021436 02322382 Abilify Yes Aripiprazole Aripiprazole 62332- 0008-13 0.17 ANDA202101 02471094 APO- Aripiprazole Yes Abilify 10mg tabs Aripiprazole 62332- 0009-30 0.15 ANDA202101 02471108 APO- Aripiprazole Yes Abilify 15mg tabs Aripiprazole 59148- 0009-13 28.55 NDA021436 02322404 Abilify Yes Aripiprazole Aripiprazole 62332- 0100-30 0.16 ANDA202101 02471116 APO- Aripiprazole Yes Abilify 20mg tabs Aripiprazole 59148- 0010-13 40.56 NDA021436 02322412 Abilify Yes Aripiprazole Aripiprazole 62332- 0101-30 0.2 ANDA202101 02471124 APO- Aripiprazole Yes Abilify 30mg tabs Aripiprazole 59148- 0011-13 40.69 NDA021436 023			0135-05					
Abilify 5mg tabs	Clozapine	Clozapine	0093-4405-	2.19	ANDA074949	02305011	GEN-Clozapine	Yes
tabs 0007-13 Aripiprazole Aripiprazole 62332-0098-30 0.17 ANDA202101 02471094 APO-Aripiprazole Yes Abilify 10mg tabs Aripiprazole 59148-0008-13 28.22 NDA021436 02322390 Abilify Yes Aripiprazole Aripiprazole 62332-0099-30 0.15 ANDA202101 02471108 APO-Aripiprazole Yes Abilify 15mg tabs Aripiprazole 59148-0099-30 28.55 NDA021436 02322404 Abilify Yes Aripiprazole Aripiprazole 62332-0100-30 0.16 ANDA202101 02471116 APO-Aripiprazole Yes Abilify 20mg tabs Aripiprazole 59148-0100-30 40.56 NDA021436 02322412 Abilify Yes Aripiprazole 62332-0101-30 0.2 ANDA202101 02471124 APO-Aripiprazole Yes Abilify 30mg tabs Aripiprazole 59148-0101-30 40.69 NDA021436 02322455 Abilify Yes Aripiprazole Aripiprazole 59148-0101-30	200mg		01					
Aripiprazole Aripiprazole 62332- 0098-30 0.17 ANDA202101 02471094 APO- Aripiprazole Yes Abilify 10mg tabs Aripiprazole 59148- 0008-13 28.22 NDA021436 02322390 Abilify Yes Aripiprazole 10mg Aripiprazole 62332- 0099-30 0.15 ANDA202101 02471108 APO- Aripiprazole Yes Abilify 15mg tabs Aripiprazole 59148- 0009-13 28.55 NDA021436 02322404 Abilify Yes Aripiprazole 62332- 0100-30 0.16 ANDA202101 02471116 APO- Aripiprazole Yes Abilify 20mg tabs Aripiprazole 59148- 0010-13 40.56 NDA021436 02322412 Abilify Yes Aripiprazole 62332- 0101-30 0.2 ANDA202101 02471124 APO- Aripiprazole Yes Abilify 30mg tabs Aripiprazole 59148- 0011-13 40.69 NDA021436 02322455 Abilify Yes Aripiprazole 59148- 0011-13 40.69 NDA021436 02322455 Abilify	Abilify 5mg	Aripiprazole	59148-	28.64	NDA021436	02322382	Abilify	Yes
5mg 0098-30 Aripiprazole Aripiprazole Abilify 10mg tabs Aripiprazole 59148- 0008-13 28.22 NDA021436 02322390 Abilify Yes Aripiprazole Aripiprazole 62332- 0099-30 0.15 ANDA202101 02471108 APO- Aripiprazole Yes Abilify 15mg tabs Aripiprazole 59148- 0009-13 28.55 NDA021436 02322404 Abilify Yes Aripiprazole 62332- 0100-30 0.16 ANDA202101 02471116 APO- Aripiprazole Yes Abilify 20mg tabs Aripiprazole 59148- 0010-13 40.56 NDA021436 02322412 Abilify Yes Abilify 30mg tabs Aripiprazole 59148- 0101-30 0.2 ANDA202101 02471124 APO- Aripiprazole Yes Abilify 30mg tabs Aripiprazole 59148- 0011-13 40.69 NDA021436 02322455 Abilify Yes Aripiprazole 59148- 0011-13 40.69 NDA021436 02322455 Abilify Yes	tabs		0007-13					
Abilify 10mg tabs	Aripiprazole	Aripiprazole	62332-	0.17	ANDA202101	02471094	APO-	Yes
tabs 0008-13 Aripiprazole Aripiprazole 62332-0099-30 0.15 ANDA202101 02471108 APO-Aripiprazole Yes Abilify 15mg Aripiprazole 59148-0009-13 28.55 NDA021436 02322404 Abilify Yes Aripiprazole Aripiprazole 62332-0100-30 0.16 ANDA202101 02471116 APO-Aripiprazole Yes Abilify 20mg Aripiprazole 59148-010-13 40.56 NDA021436 02322412 Abilify Yes Aripiprazole Aripiprazole 62332-0101-30 0.2 ANDA202101 02471124 APO-Aripiprazole Yes Abilify 30mg Aripiprazole 59148-0101-30 40.69 NDA021436 02322455 Abilify Yes Aripiprazole Aripiprazole 59148-0101-30 40.69 NDA021436 02322455 Abilify Yes Aripiprazole Aripiprazole 62332-026 0.26 ANDA202101 02471132 APO-Yes			0098-30				Aripiprazole	
Aripiprazole 10mg Aripiprazole 2099-30 62332- 0099-30 0.15 ANDA202101 02471108 APO- Aripiprazole Aripiprazole Yes Abilify 15mg tabs Aripiprazole Aripiprazole 59148- 0009-13 28.55 NDA021436 02322404 Abilify Yes Aripiprazole 15mg Aripiprazole 0100-30 62332- 0100-30 0.16 ANDA202101 02471116 APO- Aripiprazole Aripiprazole Yes Abilify 20mg tabs Aripiprazole 20mg 62332- 0101-30 0.2 ANDA202101 02471124 APO- Aripiprazole Aripiprazole Yes Abilify 30mg tabs Aripiprazole 2011-13 59148- 0011-13 40.69 NDA021436 02322455 Abilify Yes Aripiprazole Aripiprazole 59148- 0011-13 40.69 NDA021436 02322455 Abilify Yes	Abilify 10mg	Aripiprazole	59148-	28.22	NDA021436	02322390	Abilify	Yes
10mg 0099-30 Aripiprazole Aripiprazole Abilify 15mg tabs Aripiprazole 59148- 0009-13 28.55 NDA021436 02322404 Abilify Yes Aripiprazole Aripiprazole 62332- 0100-30 0.16 ANDA202101 02471116 APO- Aripiprazole Yes Abilify 20mg tabs Aripiprazole 59148- 0100-13 40.56 NDA021436 02322412 Abilify Yes Aripiprazole Aripiprazole 62332- 0101-30 0.2 ANDA202101 02471124 APO- Aripiprazole Yes Abilify 30mg tabs Aripiprazole 59148- 0101-13 40.69 NDA021436 02322455 Abilify Yes Aripiprazole Aripiprazole 62332- 0.26 ANDA202101 02471132 APO- Yes	tabs		0008-13					
Abilify 15mg tabs Aripiprazole 59148- 0009-13 28.55 NDA021436 02322404 Abilify Yes Aripiprazole 15mg Aripiprazole 0100-30 62332- 0100-30 0.16 ANDA202101 02471116 APO- Aripiprazole Aripiprazole Yes Abilify 20mg tabs Aripiprazole 20mg Aripiprazole 2332- 0101-30 ANDA021436 02322412 Abilify Yes Abilify 30mg tabs Aripiprazole 20mg 62332- 0101-30 ANDA021436 02322455 Abilify Yes Aripiprazole Aripiprazole 59148- 0011-13 40.69 NDA021436 02322455 Abilify Yes Aripiprazole Aripiprazole 62332- 0.26 ANDA202101 02471132 APO- Yes	Aripiprazole	Aripiprazole	62332-	0.15	ANDA202101	02471108	APO-	Yes
tabs 0009-13 Aripiprazole Aripiprazole 62332-0100-30 0.16 ANDA202101 02471116 APO-Aripiprazole Yes Abilify 20mg Aripiprazole 59148-0100-13 40.56 NDA021436 02322412 Abilify Yes Aripiprazole Aripiprazole 62332-0101-30 0.2 ANDA202101 02471124 APO-Aripiprazole Yes Abilify 30mg Aripiprazole 59148-011-30 40.69 NDA021436 02322455 Abilify Yes Aripiprazole Aripiprazole 62332-0.26 ANDA202101 02471132 APO-Yes	10mg		0099-30				Aripiprazole	
Aripiprazole 15mg Aripiprazole 0100-30 62332- 0100-30 0.16 0100-30 ANDA202101 02471116 02471116 APO- Aripiprazole Yes Aripiprazole Abilify 20mg tabs Aripiprazole 0010-13 40.56 0010-13 NDA021436 02322412 Abilify Yes Abilify Aripiprazole 20mg Aripiprazole 0101-30 62332- 0101-30 0.2 40.69 ANDA202101 02471124 02322455 APO- Aripiprazole Abilify Yes Abilify Aripiprazole Aripiprazole 62332- 0.26 ANDA202101 02471132 APO- APO- APO- APO- Yes	Abilify 15mg	Aripiprazole	59148-	28.55	NDA021436	02322404	Abilify	Yes
15mg 0100-30 Aripiprazole Aripiprazole Abilify 20mg tabs Aripiprazole 59148- 0010-13 40.56 NDA021436 02322412 Abilify Yes Aripiprazole 20mg Aripiprazole 62332- 0101-30 ANDA202101 02471124 APO- Aripiprazole Yes Abilify 30mg tabs Aripiprazole 59148- 0011-13 40.69 NDA021436 02322455 Abilify Yes Aripiprazole Aripiprazole 62332- 0.26 ANDA202101 02471132 APO- Yes	tabs		0009-13					
Abilify 20mg tabs Aripiprazole 59148- 0010-13 40.56 NDA021436 02322412 Abilify Yes Aripiprazole 20mg Aripiprazole 62332- 0101-30 0.2 ANDA202101 02471124 APO- Aripiprazole Yes Abilify 30mg tabs Aripiprazole 59148- 0011-13 40.69 NDA021436 02322455 Abilify Yes Aripiprazole Aripiprazole 62332- 0.26 ANDA202101 02471132 APO- Yes	Aripiprazole	Aripiprazole	62332-	0.16	ANDA202101	02471116	APO-	Yes
tabs 0010-13 0010-13 0010-13 0010-13 0010-13 0010-13 0010-13 0010-13 0010-13 0010-13 0010-13 0010-13 0010-13 0010-13 0010-13 0010-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0011-13 0	15mg		0100-30				Aripiprazole	
Aripiprazole 20mg Aripiprazole 20mg 62332- 0101-30 0.2 ANDA202101 02471124 APO- Aripiprazole Yes Aripiprazole Abilify 30mg tabs Aripiprazole 59148- 0011-13 40.69 NDA021436 02322455 Abilify Yes Abilify Aripiprazole Aripiprazole 62332- 0.26 ANDA202101 02471132 APO- Yes	Abilify 20mg	Aripiprazole	59148-	40.56	NDA021436	02322412	Abilify	Yes
20mg 0101-30 Aripiprazole Aripiprazole Abilify 30mg tabs Aripiprazole 59148- 0011-13 40.69 NDA021436 02322455 O2322455 Abilify Yes Aripiprazole Aripiprazole 62332- 0.26 ANDA202101 02471132 APO- Yes Yes	tabs		0010-13					
Abilify 30mg tabs Aripiprazole 59148- 0011-13 40.69 MDA021436 02322455 Abilify Yes Aripiprazole Aripiprazole 62332- 0.26 ANDA202101 02471132 APO- Yes	Aripiprazole	Aripiprazole	62332-	0.2	ANDA202101	02471124	APO-	Yes
tabs 0011-13	20mg		0101-30				Aripiprazole	
Aripiprazole Aripiprazole 62332- 0.26 ANDA202101 02471132 APO- Yes	Abilify 30mg	Aripiprazole	59148-	40.69	NDA021436	02322455	Abilify	Yes
	tabs		0011-13					
	Aripiprazole	Aripiprazole	62332-	0.26	ANDA202101	02471132	APO-	Yes
	30mg		0102-30				Aripiprazole	

Risperidone	Risperidone	27241-003-	0.06	ANDA201003	02282127	APO-	Yes
0.5mg	•	06				Risperidone	
Risperidone	Risperidone	27241-001-	0.06	ANDA201003	02282135	APO-	Yes
1mg		06				Risperidone	
Risperidone	Risperidone	27241-004-	0.07	ANDA201003	02282143	APO-	Yes
2mg		06				Risperidone	
Risperidone	Risperidone	27241-005-	0.08	ANDA201003	02282151	APO-	Yes
3mg		06				Risperidone	
Risperidone	Risperidone	27241-006-	0.14	ANDA201003	02282178	APO-	Yes
4mg		06				Risperidone	
Chlorpromazine	Chlorpromazine	0781-5914-	2.25	ANDA084112	00232823	TEVA-	Yes
25mg tabs		01				Chlorpromazine	
Chlorpromazine	Chlorpromazine	0781-5915-	3.17	ANDA084113	00232807	TEVA-	Yes
50mg tabs		01				Chlorpromazine	
Chlorpromazine	Chlorpromazine	0781-5916-	4.78	ANDA084114	00232831	TEVA-	Yes
100mg tabs		01				Chlorpromazine	
Fluphenazine	Fluphenazine	60219-	2.31	ANDA213647	00405345	Fluphenazine	Yes
1mg tabs		1678-01					
Fluphenazine	Fluphenazine	60219-	5.61	ANDA213647	00405361	Fluphenazine	Yes
5mg tabs		1680-01					

Diabetes Prescription Drugs

Drug Name	Active	NDC	U.S.	NDA/ ANDA	DIN	Canadian	Sold in
	Ingredient		Price			Name	U.S.
Metformin	Metformin	67877-	\$0.02	ANDA090564	02257726	ACT-	Yes
500mg tabs	Hydrochloride	0561-01				Metformin	
Metformin	Metformin	67877-	\$0.03	ANDA090564	02257734	ACT-	Yes
850mg tabs	Hydrochloride	0562-01				Metformin	
Metformin	Metformin	67877-	\$0.03	ANDA090564	02460653	APO-	Yes
1,000mg tabs	Hydrochloride	0563-01				Metformin ER	
Farxiga 5mg	Dapagliflozin	00310-	\$16.55	NDA202293	02435462	Farxiga	Yes
tabs	Propanediol	6205-30					
Farxiga 10mg	Dapagliflozin	00310-	\$16.54	NDA202293	02435470	Farxiga	Yes
tabs	Propanediol	6210-30					
Tradjenta 5mg	Linagliptin	00597-	\$14.79	NDA201280	02370921	Tradjenta	Yes
tabs		0140-30					
Januvia 50mg	Sitagliptin	00006-	\$15.13	NDA021995	02388847	Januvia	Yes
tabs	Phosphate	0112-31					
Januvia 25mg	Sitagliptin	00006-	\$15.13	NDA021995	02388839	Januvia	Yes
tabs	Phosphate	0221-31					
Januvia 100mg	Sitagliptin	00006-	\$15.14	NDA021995	02303922	Januvia	Yes
tabs	Phosphate	0277-31					

Asthma and Chronic Obstructive Pulmonary Disease Prescription Drugs

Drug Name	Active Ingredient	NDC	U.S. Price	NDA/ ANDA	DIN	Canadian Name	Sold in U.S.
Spiriva 30 caps, 18mcg / handihaler	Tiotropium Bromide	00597- 0075-41	\$436.80	NDA021395	02246793	Spiriva	Yes
Combivent Respimat	Ipatroprium Bromide, Albuterol Sulfate (aka salbutamol sulfate)	00597- 0024-02	\$408.76	NDA021747	02419106	Combivent Respimat	Yes
Advair Diskus 100-50mcg	Fluticasone Propion, Salmeterol	00173- 0695-00	\$303.60	NDA021077	02240835	Advair 100 Diskus	Yes
Fluticasone Propion, Salmeterol 100- 50	Fluticasone Propion, Salmeterol	66993- 0584-97	\$123.00	NDA021077	02494507	PMS- Fluticasone Propion, Salmeterol DPI	Yes
Wikela 100-50	Fluticasone Propion, Salmeterol	00378- 9320-32	\$123.00	ANDA208891	02495597	Wixela Inhub	Yes
Advair Diskus 250-50mcg	Fluticasone Propion, Salmeterol	00173- 0696-00	\$377.40	NDA021077	02240836	Advair 250 Diskus	Yes
Fluticasone Propion, Salmeterol 250-50	Fluticasone Propion, Salmeterol	66993- 0585-97	\$127.20	NDA021077	02494515	PMS- Fluticasone Propion, Salmeterol DPI	Yes
Wikela 250-50 mcg	Fluticasone Propion, Salmeterol	00378- 9321-32	\$150.00	ANDA208891	02495600	Wixela Inhub	Yes
Advair Diskus 500-50mcg	Fluticasone Propion, Salmeterol	00173- 0697-00	\$496.80	NDA021077	02240837	Advair 500 Diskus	Yes
Fluticasone Propion, Salmeterol 500-50	Fluticasone Propion, Salmeterol	66993- 0586-97	\$155.40	NDA021077	02494523	PMS- Fluticasone Propion, Salmeterol DPI	Yes
Wikela 500-50	Fluticasone Propion, Salmeterol	00378- 9322-32	\$199.20	ANDA208891	02495619	Wixela Inhub	Yes

Atrovent HFA	Ipratropium	00597-	\$396.50	NDA021527	02247686	Atrovent HFA	Yes
17mcg	Bromide	0087-17					
Incruse Ellipta	Umeclidinium	00173-	\$329.40	NDA205382	02423596	Incruse	Yes
62.5 mcg #30		0873-10				Ellipta	

HIV/AIDS Prescription Drugs

Drug Name	Active	NDC	U.S.	NDA/ ANDA	DIN	Canadian	Sold in
	Ingredient		Price			Name	U.S.
Kaletra 200-	Lopinovir,	00074-	\$8.53	NDA021906	02285533	Kaletra	Yes
50mg	Ritonovir	2605-21					
Kaletra 100-	Lopinovir,	00074-	\$4.27	NDA021906	02312301	Kaletra	Yes
25mg	Ritonovir	0522-60					
Emtricitabine,	Emtricitabine,	00093-	\$45.69	ANDA090894	02461110	PMS-	Yes
Tenofovir (TDF)	Tenofovir	7607-56				Emtricitabin	
	(TDF)					e, Tenofovir	
						(TDF)	
Sustiva 600mg	Efavirenz	00056-	\$8.57	NDA021360	02246045	Sustiva	Yes
tabs		0510-30				Tablets	
Efavirenz 600mg	Efavirenz	00378-	\$8.57	ANDA091471	02389762	TEVA-	Yes
tabs		2233-93				Efavirenz	
Sustiva 50mg	Efavirenz	00056-	\$3.50	NDA020972	02239886	Sustiva	Yes
caps.		0470-30				50MG	
Sustiva 200mg	Efavirenz	00056-	\$10.50	NDA020972	02239888	Sustiva	Yes
caps		0474-92				200MG	
Genvoya tabs	Elviteg, COB,	61958-	\$104.93	ANDA207561	02449498	Genvoya	Yes
	Emtri, Tenof,	1901-01					
	Alafen						
Atripla tab	Efavirenz,	15584-	\$96.91	ANDA021937	02300699	Atripla	Yes
	Emtricit,	0101-01					
	Tenofovir DF						
Efavirenz,	Efavirenz,	00093-	\$73.31	ANDA091215	02393549	TEVA-	Yes
Emtricit,	Emtricit,	5234-56				Efavirenz,	
Tenofovir DF	Tenofovir DF					Emtricitabin	
						e, tenofovir	
Complera tabs	Emtricit,	61958-	\$95.52	NDA202123	02374129	Complera	Yes
	Rilpivirine,	1101-01					
	Tenofovir DF		4				
Stribild	Elviteg, COB,	61958-	\$109.51	NDA203100	02397137	Stribild	Yes
	Emtricit,	1201-01					
	Tenofovir						
	Disop		4				.,
Truvada 200-	Emtricitabine,	61958-	\$59.70	NDA021752	02274906	Truvada	Yes
300mg	Tenofovir DF	0701-01	44				.,
Emtricitabine,	Emtricitabine,	00093-	\$45.69	ANDA090894	02399059	TEVA-	Yes
Tenofovir DF	Tenofovir DF	7607-56				Emtricitabin	
200-300mg						e, Tenofovir	

Odefsey	Emtricit,	61958-	\$95.77	NDA208351	02461463	Odefsey	Yes
,	Rilpivirine,	2101-01	,				
	Tenofovir Ala						
Invirase	Squinavir	00004-	\$9.76	NDA020628	02279320	Invirase	Yes
	Mesylate	0244-51					
Edurant	Rilpivirine HCL	59676-	\$37.58	NDA202022	02370603	Edurant	Yes
		0278-01					
Intelence	Etravirine	59676-	\$10.92	NDA022187	02306778	Intelence	Yes
100mg		0570-01					
Intelence	Etravirine	59676-	\$22.41	NDA022187	02375931	Intelence	Yes
200mg		0571-01					
Intelence 25mg	Etravirine	59676-	\$2.88	NDA022187	02396750	Intelence	Yes
		0572-01					
Triumeq	Abacavir,	49702-	\$98.19	NDA205551	02430932	Triumeq	Yes
	Dolutegravir,	0231-13					
	Lamivudi						
Juluca	Dolutegravir,	49702-	\$91.75	NDA210192	02475774	Juluca	Yes
	Rilpivirine	0242-13					
Biktarvy	Bictegravir,	61958-	\$104.52	NDA210251	02478579	Biktarvy	Yes
	Emtricit,	2501-01					
	Tenofovir Ala						
Isentress 400mg	Raltegravir	00006-	\$26.74	NDA022145	02301881	Isentress	Yes
		0277-61					
Descovy	Emtricitabine,	61958-	\$59.67	NDA208215	02454424	Descovy	Yes
	Tenofovir	2002-01					
	200mg-25mg						



Section 804 Importation Program

Colorado's Drug Importation Program February 27, 2024

Original Submission: December 5, 2022

Amended February 27, 2024

Source: Publicly available document February 27, 2024 CO SIP Application to FDA

Find the entire application online at our website: $\underline{www.safemedicines.org}$

Source: document can be found on PSM's website.

The following drugs were submitted as part of Colorado's SIP application dated February 27, 2024.

Bkitarvy	Eliquis	Erleada	Ibrance
Janumet	Januvia	Odefsey	Otezla
Ozempic	Prezcobix	Rinvoq	Spiriva Respimat
Sprycel	Symtuza	Tivicay	Trikafta
Triumeq	Victoza 3 PAK		

On the next page, we have included the original one-page listing from Colorado's February 27, 2024 application.

Figure 3: Final Drug List

Fi	gure 3: Fina	l Drug List				
Drug Index	Drug Name	Strength	Category	2027 Baseline Scenario Price per Unit	2027 Plan Scenario Importation Price per Unit	Savings Percentage
1	Biktarvy	50/200/25 mg 30/120/15 mg tablets will not be imported.	Specialty	\$118.28	\$55.81	53%
2	Eliquis	2.5 mg 5 mg tablets will not be imported.	Brand	\$7.20	\$3.74	48%
3	Erleada	60 mg 240 mg tablets will not be imported.	Brand	\$117.81	\$42.90	64%
4	Ibrance	75 mg	Specialty	\$521.99	\$258.54	50%
5	Ibrance	100 mg	Specialty	\$523.65	\$246.82	53%
6	Ibrance	125 mg	Specialty	\$498.41	\$235.09	53%
7	Janumet	50/500 mg	Brand	\$4.88	\$3.93	19%
8	Janumet	50/1000 mg	Brand	\$4.86	\$3.25	33%
9	Januvia	25 mg	Brand	\$9.97	\$8.17	18%
10	Januvia	50 mg	Brand	\$9.56	\$6.99	27%
11	Januvia	100 mg	Brand	\$10.15	\$6.17	39%
12	Odefsey	200/25/25 mg	Brand	\$95.94	\$64.41	33%
	Otezla	30 mg 10 mg and 20 mg tablets will not be imported.	Brand	\$64.76	\$35.39	45%
14	Ozempic	0.25/0.5 mg 2.68 mg/mL injections will not be imported.	Brand	\$502.59	\$275.13	45%
15	Ozempic	1 mg 2.68 mg/mL injections will not be imported.	Brand	\$268.00	\$137.57	49%
16	Prezcobix	800/150 mg	Brand	\$60.80	\$49.12	1 9 %
17	Rinvoq	15 mg 30 mg and 45 mg tablets will not be imported.	Brand	\$176.55	\$76.73	57%
18	Spiriva Respimat	2.5 mcg 1.25 mcg inhalation spray will not be imported.	Brand	\$53.25	\$20.51	61%
19	Sprycel	100 mg 20 mg, 50 mg, 70 mg, 80 mg, and 140 mg tablets will not be imported.	Brand	\$397.35	\$127.36	68%
20	Symtuza	800/150/200/10 mg	Brand & Specialty	\$133.63	\$98.49	26%
21	Tivicay	50 mg 10 mg and 25 mg tablets will not be imported.	Brand & Specialty	\$50.40	\$36.02	29%
22	Trikafta	100/50/75 mg co-packaged with 150 mg 50/25/37.5 mg tablets co-packaged with 75 mg tablets will not be imported.	Brand & Specialty	\$325.91	\$268.37	18%
23	Triumeq	600/50/300 mg 60/5/30 mg tablets for oral suspension will not be imported.	Brand & Specialty	\$71.86	\$55.79	22%
24	Victoza 3 PAK	18 mg/3 mL	Brand & Specialty	\$59.03	\$48.68	18%

^{18 |} Colorado's Drug Importation Program





Section 804 Importation Program

Colorado's Drug Importation Program

December 5, 2022



Source: Publicly available document December 5, 2022 CO SIP Application to FDA

Find the entire application online at our website: www.safemedicines.org

Source: document can be found on PSM's website.

The following drugs were submitted as part of Colorado's SIP application dated December 5, 2022.

EpiPen Jr	epinephrine	EpiPen	Eliquis
Xarelto	Afinitor	everolimus	Afinitor Disperz
Cabometyx	Erleada	Ibrance	Sprycel
Tasigna	Votrient	Xtandi	Zytiga
Xeljanz XR	Restasis	cyclosporin	Restasis Multidose
Biktarvy	Cabenuva	Descovy	Edurant
Genvoya	Odefsey	Symtuza	Tivicay
Triumeq	Xifaxan	Baqsimi	GlucaGen Hypo Kit
Glucagon	Latuda	Copaxone	Glatopa
glatiramer	Gilenya	Revolade	Uptravi
Ofev	Advair Diskus	Fluticasone & salmeterol diskus	Wixela Inhub
Advair HFA	Combivent Respimat	Dulera	Flovent HFA
Fluticasone HFA	Pulmicort	Spiriva Handihaler	Trelegy
Ventolin	Albuterol Inhaler	Chantix	varenicline
Synthroid	Farxiga	Invokana	Janumet
Januvia	Jardiance	Victoza	Nuvaring
EluRyng	Ethinyl estradiol/ etonogestrel	Estring	Kyleena
Mirena			

On the next six pages, we have included the original six-page listing from Colorado's December 5, 2022 application.

Figure 2. Final Drug List

Drug Name	Strength	Broad Category	Brand/ Generic	U.S. Price	Importation Price	Percent Savings
EpiPen Jr	0.15mg	Anaphylaxis	Brand	\$224.94	\$91.13	59%
epinephrine	0.15mg	Anaphylaxis	Generic	\$124.50	\$91.13	27%
EpiPen	0.3mg	Anaphylaxis	Brand	\$264.89	\$91.13	66%
epinephrine	0.3mg	Anaphylaxis	Generic	\$116.97	\$91.13	22%
Eliquis	2.5mg	Blood Thinner	Brand	\$5.75	\$1.80	69%
Eliquis	5mg	Blood Thinner	Brand	\$6.22	\$1.80	71%
Xarelto	2.5mg	Blood Thinner	Brand	\$7.06	\$1.60	77%
Xarelto	10mg	Blood Thinner	Brand	\$13.73	\$3.20	77%
Xarelto	15mg	Blood Thinner	Brand	\$12.58	\$3.20	75%
Xarelto	20mg	Blood Thinner	Brand	\$12.99	\$3.20	75%
Afinitor	5mg	Cancer	Brand	\$496.46	\$209.25	58%
everolimus	5mg	Cancer	Generic	\$260.92	\$57.00	78%
Afinitor Disperz	2mg	Cancer	Brand	\$534.05	\$238.32	55%
Afinitor Disperz	3mg	Cancer	Brand	\$487.99	\$238.32	51%
Afinitor Disperz	5mg	Cancer	Brand	\$432.91	\$238.32	45%
Cabometyx	20mg	Cancer	Brand	\$586.42	\$330.00	44%
Cabometyx	40mg	Cancer	Brand	\$736.78	\$330.00	55%
Cabometyx	60mg	Cancer	Brand	\$719.57	\$330.00	54%
Erleada	60mg	Cancer	Brand	\$92.97	\$31.88	66%
Ibrance**	100mg	Cancer	Brand	\$516.16	\$285.65	45%
Ibrance**	125mg	Cancer	Brand	\$547.51	\$285.65	48%



Ibrance**	75mg	Cancer	Brand	\$524.56	\$285.65	46%
Sprycel	50mg	Cancer	Brand	\$262.22	\$82.31	69%
Sprycel	100mg	Cancer	Brand	\$476.49	\$164.63	65%
Tasigna	200mg	Cancer	Brand	\$144.33	\$39.65	73%
Votrient	200mg	Cancer	Brand	\$125.05	\$38.71	69%
Xtandi	40mg	Cancer	Brand	\$74.40	\$31.88	57%
Zytiga	500mg	Cancer	Brand	\$178.91	\$63.75	64%
Xeljanz XR	11mg	Chronic Inflammatory Diseases	Brand	\$145.43	\$51.97	64%
Restasis	0.05%	Dry Eye	Brand	\$8.28	\$4.53	45%
cyclosporin*	0.05%	Dry Eye	Generic	\$6.63	\$1.54	77%
Restasis Multidose	0.05%	Dry Eye	Brand	\$87.79	\$41.32	53%
Biktarvy*	50-200-25mg	HIV	Brand	\$105.24	\$44.12	58%
Cabenuva* (2mL)*	400-200mg	HIV	Brand	\$4,160.48	\$1,537.08	63%
Cabenuva* (3mL)*	600-300mg	HIV	Brand	\$6,240.71	\$3,074.14	51%
Descovy	200 -25mg	HIV	Brand	\$54.36	\$32.30	41%
Edurant	25mg	HIV	Brand	\$41.83	\$15.53	63%
Genvoya	150-150-200- 10mg	HIV	Brand	\$101.78	\$49.28	52%
Odefsey	200-25-25mg	HIV	Brand	\$92.40	\$44.13	52%
Symtuza	800-150-200- 10mg	HIV	Brand	\$128.70	\$63.24	51%
Tivicay	50mg	HIV	Brand	\$50.73	\$20.81	59%



Triumeq	600-50- 300mg	HIV	Brand	\$93.68	\$45.64	51%
Xifaxan	550mg	Irritable Bowel Syndrome	Brand	\$41.01	\$8.64	79%
Baqsimi	3mg	Low Blood Sugar	Brand	\$276.04	\$148.05	46%
GlucaGen HypoKit	1mg	Low Blood Sugar	Brand	\$284.88	\$128.90	55%
Glucagon	1mg	Low Blood Sugar	Brand	\$241.27	\$86.74	64%
Latuda	20mg	Mental Health	Brand	\$42.07	\$4.02	90%
Latuda	40mg	Mental Health	Brand	\$42.73	\$4.02	91%
Latuda	60mg	Mental Health	Brand	\$42.74	\$4.02	91%
Latuda	80mg	Mental Health	Brand	\$43.44	\$4.02	91%
Copaxone	20mg	Multiple Sclerosis	Brand	\$209.45	\$48.60	77%
Glatopa	20mg	Multiple Sclerosis	Generic	\$72.88	\$36.45	50%
glatiramer	20mg	Multiple Sclerosis	Generic	\$127.40	\$36.45	71%
Copaxone	40mg	Multiple Sclerosis	Brand	\$424.64	\$138.22	67%
glatiramer	40mg	Multiple Sclerosis	Generic	\$213.28	\$138.22	35%
Gilenya	0.5mg	Multiple Sclerosis	Brand	\$287.33	\$95.81	67%
Revolade	25mg	Primary Immune Thrombocytopenia	Brand	\$167.85	\$59.06	65%
Revolade	50mg	Primary Immune Thrombocytopenia	Brand	\$295.36	\$118.13	60%
Uptravi	1400 mcg	Pulmonary Arterial Hypertension	Brand	\$215.31	\$72.19	66%



Ofev	100mg	Pulmonary Fibrosis	Brand	\$151.57	\$31.28	79%
Ofev	150mg	Pulmonary Fibrosis	Brand	\$156.52	\$61.16	61%
Advair Diskus	100-50mcg	Respiratory	Brand	\$252.95	\$85.26	66%
fluticasone & salmeterol diskus	100-50mcg	Respiratory	Generic	\$153.34	\$47.71	69%
Wixela Inhub	100-50mcg	Respiratory	Generic	\$94.47	\$47.71	49%
Advair Diskus	250-50mcg	Respiratory	Brand	\$314.88	\$102.03	68%
fluticasone & salmeterol diskus	250-50mcg	Respiratory	Generic	\$186.75	\$57.11	69%
Wixela Inhub	250-50mcg	Respiratory	Generic	\$103.63	\$57.11	45%
Advair Diskus	500-50mcg	Respiratory	Brand	\$408.84	\$102.03	75%
fluticasone & salmeterol	500-50mcg	Respiratory	Generic	\$209.21	\$81.07	61%
Wixela Inhub	500-50mcg	Respiratory	Generic	\$124.72	\$81.07	35%
Advair HFA	115-21mcg	Respiratory	Brand	\$350.92	\$144.83	59%
Advair HFA	230-21mcg	Respiratory	Brand	\$442.56	\$144.83	67%
Combivent Respimat	20-100mcg	Respiratory	Brand	\$373.87	\$34.14	91%
Dulera	100-5mcg	Respiratory	Brand	\$298.87	\$87.75	71%
Dulera	200-5mcg	Respiratory	Brand	\$322.78	\$108.00	67%
Flovent HFA	44mcg	Respiratory	Brand	\$179.06	\$25.44	86%
Fluticasone HFA*	44mcg	Respiratory	Generic	\$132.95	\$39.51	70%
Flovent HFA	110mcg	Respiratory	Brand	\$235.61	\$42.81	82%



Fluticasone HFA* 110mcg Respiratory Generic \$177.99 \$39.50 Flovent HFA 220mcg Respiratory Brand \$353.25 \$85.62 Fluticasone HFA* 220mcg Respiratory Generic \$276.46 \$50.65 Pulmicort 90mcg Respiratory Brand \$170.01 \$34.76 Pulmicort 180mcg Respiratory Brand \$233.01 \$71.06 Spiriva Handihaler 18mcg Respiratory Brand \$377.35 \$58.39 Spiriva Respimat 2.5mcg Respiratory Brand \$324.04 \$58.39 Trelegy 100-62.5-25mcg Respiratory Brand \$237.37 \$148.73 Trelegy 200-62.5-25mcg Respiratory Brand \$255.26 \$186.67 Ventolin 90mcg Respiratory Brand \$54.00 \$6.75 Albuterol Inhaler 90mcg Respiratory Generic \$25.97 \$5.63 Varenicline 0.5mg Smoking Cessation Bran							
Fluticasone HFA* 220mcg Respiratory Generic \$276.46 \$50.65 Pulmicort 90mcg Respiratory Brand \$170.01 \$34.76 Pulmicort 180mcg Respiratory Brand \$233.01 \$71.06 Spiriva Handihaler 18mcg Respiratory Brand \$377.35 \$58.39 Spiriva Respimat 2.5mcg Respiratory Brand \$324.04 \$58.39 Trelegy 100-62.5-25mcg Respiratory Brand \$237.37 \$148.73 Trelegy 200-62.5-25mcg Respiratory Brand \$255.26 \$186.67 Ventolin 90mcg Respiratory Brand \$54.00 \$6.75 Albuterol Inhaler 90mcg Respiratory Generic \$25.97 \$5.63 Chantix 0.5mg Smoking Cessation Brand \$7.88 \$1.93 varenicline 0.5mg Smoking Cessation Brand \$8.35 \$1.04 Chantix 1mg Smoking Cessation Brand	Fluticasone HFA*	110mcg	Respiratory	Generic	\$177.99	\$39.50	78%
Pulmicort 90mcg Respiratory Brand \$170.01 \$34.76 Pulmicort 180mcg Respiratory Brand \$233.01 \$71.06 Spiriva Handihaler 18mcg Respiratory Brand \$377.35 \$58.39 Spiriva Respimat 2.5mcg Respiratory Brand \$324.04 \$58.39 Trelegy 100-62.5-25mcg Respiratory Brand \$237.37 \$148.73 Trelegy 200-62.5-25mcg Respiratory Brand \$255.26 \$186.67 Ventolin 90mcg Respiratory Brand \$54.00 \$6.75 Albuterol Inhaler 90mcg Respiratory Generic \$25.97 \$5.63 Chantix 0.5mg Smoking Cessation Brand \$7.88 \$1.93 varenicline 0.5mg Smoking Cessation Brand \$8.35 \$1.04 Chantix 1mg Smoking Cessation Brand \$8.35 \$1.04 Synthroid 100mcg Thyroid Deficiency Brand <td< td=""><td>Flovent HFA</td><td>220mcg</td><td>Respiratory</td><td>Brand</td><td>\$353.25</td><td>\$85.62</td><td>76%</td></td<>	Flovent HFA	220mcg	Respiratory	Brand	\$353.25	\$85.62	76%
Pulmicort 180mcg Respiratory Brand \$233.01 \$71.06 Spiriva Handihaler 18mcg Respiratory Brand \$377.35 \$58.39 Spiriva Respimat 2.5mcg Respiratory Brand \$324.04 \$58.39 Trelegy 100-62.5-25mcg Respiratory Brand \$237.37 \$148.73 Trelegy 200-62.5-25mcg Respiratory Brand \$255.26 \$186.67 Ventolin 90mcg Respiratory Brand \$54.00 \$6.75 Albuterol Inhaler 90mcg Respiratory Generic \$25.97 \$5.63 Chantix 0.5mg Smoking Cessation Brand \$7.88 \$1.93 varenicline 0.5mg Smoking Cessation Brand \$8.35 \$1.04 Chantix 1mg Smoking Cessation Brand \$8.35 \$1.93 varenicline 1mg Smoking Cessation Generic \$7.50 \$1.04 Synthroid 100mcg Thyroid Deficiency Brand	Fluticasone HFA*	220mcg	Respiratory	Generic	\$276.46	\$50.65	82%
Spiriva Handihaler 18mcg Respiratory Brand \$377.35 \$58.39 Spiriva Respimat 2.5mcg Respiratory Brand \$324.04 \$58.39 Trelegy 100-62.5-25mcg Respiratory Brand \$237.37 \$148.73 Trelegy 200-62.5-25mcg Respiratory Brand \$255.26 \$186.67 Ventolin 90mcg Respiratory Brand \$54.00 \$6.75 Albuterol Inhaler 90mcg Respiratory Generic \$25.97 \$5.63 Chantix 0.5mg Smoking Cessation Brand \$7.88 \$1.93 varenicline 0.5mg Smoking Cessation Generic \$7.69 \$1.04 Chantix 1mg Smoking Cessation Brand \$8.35 \$1.93 varenicline 1mg Smoking Cessation Generic \$7.50 \$1.04 Synthroid 100mcg Thyroid Deficiency Brand \$14.09 \$2.76	Pulmicort	90mcg	Respiratory	Brand	\$170.01	\$34.76	80%
Spiriva Respimat 2.5mcg Respiratory Brand \$324.04 \$58.39 Trelegy 100-62.5-25mcg Respiratory Brand \$237.37 \$148.73 Trelegy 200-62.5-25mcg Respiratory Brand \$255.26 \$186.67 Ventolin 90mcg Respiratory Brand \$54.00 \$6.75 Albuterol Inhaler 90mcg Respiratory Generic \$25.97 \$5.63 Chantix 0.5mg Smoking Cessation Brand \$7.88 \$1.93 varenicline 0.5mg Smoking Cessation Generic \$7.69 \$1.04 Chantix 1mg Smoking Cessation Brand \$8.35 \$1.93 varenicline 1mg Smoking Cessation Generic \$7.50 \$1.04 Synthroid 100mcg Thyroid Deficiency Brand \$0.95 \$0.07 Farxiga 5mg Type 2 Diabetes Brand \$14.09 \$2.76	Pulmicort	180mcg	Respiratory	Brand	\$233.01	\$71.06	70%
Trelegy 100-62.5-25mcg Respiratory Brand \$237.37 \$148.73 Trelegy 200-62.5-25mcg Respiratory Brand \$255.26 \$186.67 Ventolin 90mcg Respiratory Brand \$54.00 \$6.75 Albuterol Inhaler 90mcg Respiratory Generic \$25.97 \$5.63 Chantix 0.5mg Smoking Cessation Brand \$7.88 \$1.93 varenicline 0.5mg Smoking Cessation Generic \$7.69 \$1.04 Chantix 1mg Smoking Cessation Brand \$8.35 \$1.93 varenicline 1mg Smoking Cessation Generic \$7.50 \$1.04 Synthroid 100mcg Thyroid Deficiency Brand \$0.95 \$0.07 Farxiga 5mg Type 2 Diabetes Brand \$14.09 \$2.76	Spiriva Handihaler	18mcg	Respiratory	Brand	\$377.35	\$58.39	85%
Trelegy 200-62.5-25mcg Respiratory Brand \$255.26 \$186.67 Ventolin 90mcg Respiratory Brand \$54.00 \$6.75 Albuterol Inhaler 90mcg Respiratory Generic \$25.97 \$5.63 Chantix 0.5mg Smoking Cessation Brand \$7.88 \$1.93 varenicline 0.5mg Smoking Cessation Generic \$7.69 \$1.04 Chantix 1mg Smoking Cessation Brand \$8.35 \$1.93 varenicline 1mg Smoking Cessation Generic \$7.50 \$1.04 Synthroid 100mcg Thyroid Deficiency Brand \$0.95 \$0.07 Farxiga 5mg Type 2 Diabetes Brand \$14.09 \$2.76	Spiriva Respimat	2.5mcg	Respiratory	Brand	\$324.04	\$58.39	82%
Ventolin90mcgRespiratoryBrand\$54.00\$6.75Albuterol Inhaler90mcgRespiratoryGeneric\$25.97\$5.63Chantix0.5mgSmoking CessationBrand\$7.88\$1.93varenicline0.5mgSmoking CessationGeneric\$7.69\$1.04Chantix1mgSmoking CessationBrand\$8.35\$1.93varenicline1mgSmoking CessationGeneric\$7.50\$1.04Synthroid100mcgThyroid DeficiencyBrand\$0.95\$0.07Farxiga5mgType 2 DiabetesBrand\$14.09\$2.76	Trelegy	100-62.5-25mcg	Respiratory	Brand	\$237.37	\$148.73	37%
Albuterol Inhaler 90mcg Respiratory Generic \$25.97 \$5.63 Chantix 0.5mg Smoking Cessation Brand \$7.88 \$1.93 varenicline 0.5mg Smoking Cessation Generic \$7.69 \$1.04 Chantix 1mg Smoking Cessation Brand \$8.35 \$1.93 varenicline 1mg Smoking Cessation Generic \$7.50 \$1.04 Synthroid 100mcg Thyroid Deficiency Brand \$0.95 \$0.07 Farxiga 5mg Type 2 Diabetes Brand \$14.09 \$2.76	Trelegy	200-62.5-25mcg	Respiratory	Brand	\$255.26	\$186.67	27%
Chantix 0.5mg Smoking Cessation Brand \$7.88 \$1.93 varenicline 0.5mg Smoking Cessation Generic \$7.69 \$1.04 Chantix 1mg Smoking Cessation Brand \$8.35 \$1.93 varenicline 1mg Smoking Cessation Generic \$7.50 \$1.04 Synthroid 100mcg Thyroid Deficiency Brand \$0.95 \$0.07 Farxiga 5mg Type 2 Diabetes Brand \$14.09 \$2.76	Ventolin	90mcg	Respiratory	Brand	\$54.00	\$6.75	87%
varenicline0.5mgSmoking CessationGeneric\$7.69\$1.04Chantix1mgSmoking CessationBrand\$8.35\$1.93varenicline1mgSmoking CessationGeneric\$7.50\$1.04Synthroid100mcgThyroid DeficiencyBrand\$0.95\$0.07Farxiga5mgType 2 DiabetesBrand\$14.09\$2.76	Albuterol Inhaler	90mcg	Respiratory	Generic	\$25.97	\$5.63	78%
Chantix 1mg Smoking Cessation Brand \$8.35 \$1.93 varenicline 1mg Smoking Cessation Generic \$7.50 \$1.04 Synthroid 100mcg Thyroid Deficiency Brand \$0.95 \$0.07 Farxiga 5mg Type 2 Diabetes Brand \$14.09 \$2.76	Chantix	0.5mg	Smoking Cessation	Brand	\$7.88	\$1.93	75%
varenicline1mgSmoking CessationGeneric\$7.50\$1.04Synthroid100mcgThyroid DeficiencyBrand\$0.95\$0.07Farxiga5mgType 2 DiabetesBrand\$14.09\$2.76	varenicline	0.5mg	Smoking Cessation	Generic	\$7.69	\$1.04	87%
Synthroid 100mcg Thyroid Deficiency Brand \$0.95 \$0.07 Farxiga 5mg Type 2 Diabetes Brand \$14.09 \$2.76	Chantix	1mg	Smoking Cessation	Brand	\$8.35	\$1.93	77%
Farxiga 5mg Type 2 Diabetes Brand \$14.09 \$2.76	varenicline	1mg	Smoking Cessation	Generic	\$7.50	\$1.04	86%
	Synthroid	100mcg	Thyroid Deficiency	Brand	\$0.95	\$0.07	93%
Farxiga 10mg Type 2 Diabetes Brand \$14.59 \$2.76	Farxiga	5mg	Type 2 Diabetes	Brand	\$14.09	\$2.76	80%
	Farxiga	10mg	Type 2 Diabetes	Brand	\$14.59	\$2.76	81%
Invokana 100mg Type 2 Diabetes Brand \$15.89 \$2.94	Invokana	100mg	Type 2 Diabetes	Brand	\$15.89	\$2.94	81%



Invokana	300mg	Type 2 Diabetes	Brand	\$15.78	\$2.94	81%
Janumet	50/500mg	Type 2 Diabetes	Brand	\$6.29	\$1.54	75%
Janumet	50/1000mg	Type 2 Diabetes	Brand	\$6.18	\$1.54	75%
Januvia	25mg	Type 2 Diabetes	Brand	\$12.87	\$2.94	77%
Januvia	50mg	Type 2 Diabetes	Brand	\$12.38	\$2.94	76%
Januvia	100mg	Type 2 Diabetes	Brand	\$12.90	\$2.94	77%
Jardiance	10mg	Type 2 Diabetes	Brand	\$15.78	\$2.94	81%
Jardiance	25mg	Type 2 Diabetes	Brand	\$15.47	\$2.94	81%
Victoza	18mg/3mL	Type 2 Diabetes	Brand	\$266.97	\$77.05	71%
Nuvaring	2.6mg - 11.4 mg	Women's Health	Brand	\$142.71	\$14.11	90%
EluRyng	2.6mg - 11.4 mg	Women's Health	Generic	\$84.63	\$14.11	83%
ethinyl estradiol/ etonogestrel	2.6mg - 11.4 mg	Women's Health	Generic	\$92.01	\$14.11	85%
Estring	2mg	Women's Health	Brand	\$415.69	\$70.62	83%
Kyleena	19.5mg	Women's Health	Brand	\$888.16	\$403.50	55%
Mirena	52 mg	Women's Health	Brand	\$547.62	\$431.21	21%

Department of Health Care Policy & Financing, 2022.

Significant Savings

This SIP meets Final Rule requirements to demonstrate significant cost savings, providing details on uncertainties that may influence our success. Colorado has requested flexibility from the FDA in the interpretation of significant savings given the need for state-led programs to begin with narrower lists of drugs and expand over time.







Source: Publicly available document March 9, 2020 CO SIP Application to FDA

Find the entire application online at our website: www.safemedicines.org

Source: documents (<u>draft proposal</u> and <u>appendices</u>) can be found on PSM's website.

The following drugs were submitted as part of Colorado's SIP application dated March 9, 2020.

Adcirca	Advair Diskus	Afinitor	Alecensa
Anoro Ellipta	Apri 28 Day	Aptiom	Atripla
Aubagio	Banzel	Breo Ellipta	Brilinta
Cayston	Climara	Combivent Respimat	Complera
Cuprimine	Dexilant	Diclegis Dr	Dificid
Dulera	Eliquis	Elmiron	Enstilar
Entresto	EpiPen	EpiPen Jr	Erivedge
Estring	Farxiga	Finacea	Firazyr
Forteo	Genvoya	Gilenya	Gleevec
Glucagon Kit	Ibrance	Imbruvica	Incruse Ellipta
Inlyta	Intelence	Invokana	Isentress
Jadenu	Jakafi	Janumet	Janumet XR
Januvia	Jardiance	Jentadueto	Keppra
Kombiglyze XR	Kuvan	Lamictal	Latuda
Lonsurk	Lumigan	Myrbetriq ER	Nexavar
Noxafil	Nuvaring	Ofev	Onglyza
Otezla	Portia 28	Premarin	Premarin Cream
Prezcobix	Prezista	Prograf	Relpax
Retin-A	Revatio	Rexulti	Sabril
Sensipar	Serevent Diskus	Spiriva Handihaler	Sprycel
Stivarge	Stribild	Sutent	Synthroid
Tagrisso	Tarceva	Tasigna	Tecfidera

Tivicay	Tracleer	Tradjenta	Triumeq
Truvada	Uloric	Uptravi	Vesicare
Victoza	Vimovo DR	Vimpat Vivelle-Dot	Wellbutrin XL
Xalkori	Xarelto	Xeljanz	Xeloda
Xifaxan	Xigduo	Xtandi	Yasmin 28
Yax 28	Zelboraf	Zomig	Zytiga

On the next five pages, we have included the original five-page listing from Colorado's March 9, 2020 application.



Drug Name	Strength	Indication	Candian Unit Cost with 45% Markup adjusted units	Colorado Unit Cost	APCD Units	Self Funded Units*	Total Utilization by Unit	Current CO Price (per total Utilization by Unit)	Importation Price	Total Annual Savings	Percent Savings
Entresto	49/51mg	Heart Failure	\$3.94	\$8.00	19769	10645	30413	\$234,657.68	\$119,729.31	\$114,928.37	49%
Entresto	97/103mg	Heart Failure	\$3.94	\$7.88	18628	10030	28658	\$218,038.77	\$112,820.74	\$105,218.03	48%
Epi Pen	0.3mg/0.3mL	Anaphylaxis	\$88.09	\$267.30	829	446	1275	\$328,919.36	\$112,324.09	\$216,595.27	%99
Epi Pen Jr	0.15mg/0.3mL	Anaphylaxis	\$88.09	\$259.19	642	346	886	\$247,029.00	\$86,998.86	\$160,030.14	%59
Erivedge	150mg	Cancer	\$319.97	\$402.01	702	378	1080	\$418,977.54	\$345,565.62	\$73,411.92	18%
Estring		Menopause	\$68.26	\$439.16	2643	1423	4066	\$1,723,072.29	\$277,546.88	\$1,445,525.41	84%
Farxiga	10mg	Diabetes	\$2.66	\$15.18	98295	52928	151223	\$2,215,380.43	\$402,914.28	\$1,812,466.15	82%
Farxiga	5mg	Diabetes	\$2.66	\$15.24	34596	18629	53225	\$782,657.67	\$141,812.15	\$640,845.52	82%
Finacea	15%	Inflammation	\$0.65	\$6.83	24312	13091	37403	\$246,372.15	\$24,405.33	\$221,966.82	%06
Firazyr	10mg/1mL / 30mg/3mL	Hereditary Angioedema	\$2,936.25	\$3,699.59	1074	578	1652	\$5,898,916.36	\$4,851,588.46	\$1,047,327.90	18%
Forteo	250 mcg/mL	Osteoporosis	\$80.58	\$1,526.19	2405	1295	3700	\$5,449,943.89	\$3,258,561.51	\$2,191,382.38	40%
Genvoya	150, 150, 200, 10mg	ΛIH	\$47.63	\$92.79	234760	126409	361169	\$32,340,301.82	\$17,203,517.07	\$15,136,784.75	47%
Gilenya	0.5mg	Multiple Sclerosis	\$92.62	\$256.06	61793	33273	99056	\$23,490,701.76	\$8,804,699.25	\$14,686,002.51	63%
Gleevec	400mg	Cancer	\$115.36	\$334.84	2301	1239	3539	\$1,143,658.53	\$408,290.08	\$735,368.45	64%
Gleevec	100mg	Cancer	\$28.84	\$94.13	1050	565	1615	\$146,727.02	\$46,585.69	\$100,141.33	%89
Glucagon Kit	1mg	Hypoglycemia	\$93.17	\$284.48	3032	1632	4664	\$1,280,440.46	\$434,541.38	\$845,899.09	%99
Ibrance	125mg	Cancer	\$276.13	\$591.34	7890	4249	12139	\$6,926,988.85	\$3,351,901.30	\$3,575,087.55	52%
Ibrance	100mg	Cancer	\$276.13	\$570.00	5571	3000	8571	\$4,714,677.28	\$2,366,823.26	\$2,347,854.02	20%
Ibrance	75mg	Cancer	\$276.13	\$592.79	1743	939	2682	\$1,534,276.14	\$740,613.19	\$793,662.95	52%
Imbruvica	140mg	Cancer	\$98.58	\$137.05	11063	5957	17020	\$2,250,951.81	\$1,677,864.75	\$573,087.06	25%
Incruse Ellipta	62.5mcg	Respiratory	\$1.81	\$10.57	41754	22483	64237	\$655,225.42	\$116,430.28	\$538,795.15	82%
Inlyta	5mg	Cancer	\$101.14	\$251.37	450	242	692	\$167,934.50	\$70,020.00	\$97,914.50	28%
Intelence	200mg	HIV	\$11.85	\$22.02	11129	5993	17122	\$363,781.19	\$202,961.99	\$160,819.19	44%
Invokana	300mg	Diabetes	\$2.85	\$15.39	94019	50626	144645	\$2,148,185.56	\$411,768.41	\$1,736,417.16	81%
Invokana	100mg	Diabetes	\$2.85	\$15.47	51992	27995	79987	\$1,194,268.93	\$227,703.11	\$966,565.82	81%
Isentress	400mg	HIV	\$12.51	\$25.14	61537	33136	94673	\$2,296,911.68	\$1,184,003.54	\$1,112,908.13	48%
Jadenu	360mg	Iron Overload	\$47.39	\$167.95	4241	2284	6525	\$1,057,440.17	\$309,173.06	\$748,267.11	71%
Jakafi	10mg	Myelofibrosis	\$89.38	\$211.63	4581	2467	7048	\$1,439,267.02	\$629,947.99	\$809,319.03	26%
Jakafi	20mg	Myelofibrosis	\$89.38	\$221.06	4080	2197	6277	\$1,338,998.10	\$561,053.87	\$777,944.23	28%
Jakafi	5mg	Myelofibrosis	\$89.38	\$224.02	3590	1933	5523	\$1,193,950.73	\$493,672.40	\$700,278.33	26%
Jakafi	15mg	Myelofibrosis	\$89.38	\$222.29	2960	1594	4554	\$976,854.89	\$407,039.08	\$569,815.81	28%
Janumet	50/1000mg	Diabetes	\$1.49	\$6.90	112081	60351	172432	\$1,148,420.18	\$256,902.41	\$891,517.76	78%
Janumet	50/500mg	Diabetes	\$1.49	\$7.01	21164	11396	32560	\$220,312.47	\$48,509.80	\$171,802.67	78%
Janumet XR	50/1000mg	Diabetes	\$1.49	\$7.07	38908	20950	59858	\$408,219.82	\$89,181.06	\$319,038.76	78%

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Drug Name	Strength	Indication	Candian Unit Cost with 45% Markup adjusted units	Colorado Unit Cost	APCD Units	Self Funded Units*	Total Utilization by Unit	Current CO Price (per total Utilization by Unit)	Importation Price	Total Annual Savings	Percent Savings
Adcirca	20mg	Pulmonary Hypertension	\$13.23	\$61.09	14450	7781	22231	\$1,310,544.97	\$294,221.45	\$1,016,323.52	78%
Advair Diskus	250/50	Respiratory	\$1.64	\$4.54	1848883	995552	2844435	\$12,461,754.45	\$4,675,557.91	\$7,786,196.54	62%
Advair Diskus	500/50	Respiratory	\$2.33	\$5.12	946340	509568	1455908	\$7,193,348.08	\$3,397,232.90	\$3,796,115.18	53%
Advair Diskus	100/50	Respiratory	\$1.37	\$4.67	567013	305315	872328	\$3,931,190.04	\$1,198,311.61	\$2,732,878.43	70%
Afinitor	10mg	Cancer	\$202.28	\$543.12	3097	1668	4765	\$2,497,186.38	\$963,762.58	\$1,533,423.80	61%
Afinitor	5mg	Cancer	\$202.28	\$556.65	938	202	1443	\$775,173.66	\$291,898.38	\$483,275.28	62%
Alecensa	150mg	Cancer	\$45.86	\$65.32	27862	15003	42865	\$2,702,089.48	\$1,965,607.41	\$736,482.07	27%
Anoro Ellipta	62.5-25 mcg	Respiratory	\$2.28	\$6.64	123670	66591	190261	\$1,218,915.82	\$434,509.22	\$784,406.59	64%
Apri 28 Day	.15mg	Contraceptive	\$0.30	\$0.41	683365	367966	1051330	\$416,437.27	\$317,271.78	\$99,165.49	24%
Aptiom	800mg	Anticonvulsant	\$10.40	\$30.59	3859	2078	5937	\$175,252.94	\$61,720.81	\$113,532.13	859
Atripla	600, 200, 300mg	NIH	\$42.25	\$83.93	18161	6226	27940	\$2,262,853.44	\$1,180,343.76	\$1,082,509.68	48%
Aubagio	14mg	Multiple Sclerosis	\$55.42	\$238.86	26292	14319	40910	\$9,429,588.46	\$2,267,101.46	\$7,162,487.00	292
Banzel	400mg	Anticonvulsant	\$3.40	\$23.77	19129	10300	29430	\$675,060.08	\$100,168.19	\$574,891.88	85%
Breo Ellipta	100/25	Respiratory	\$2.98	\$5.65	362505	195195	557700	\$3,041,962.54	\$1,661,807.92	\$1,380,154.62	45%
Breo Ellipta	200/25	Respiratory	\$4.24	\$5.63	338917	182494	521410	\$2,835,285.24	\$2,209,541.34	\$625,743.89	22%
Brilinta	90mg	Anticoagulant	\$1.61	\$6.01	146243	78746	224989	\$1,304,488.99	\$362,120.54	\$942,368.45	72%
Cayston	75mg	Antibiotic	\$46.11	\$103.15	7151	3851	11002	\$1,095,105.71	\$507,298.69	\$587,807.02	54%
Climara	0.05mg/day	Menopause	\$5.71	\$12.93	17342	9338	26680	\$332,810.12	\$152,398.66	\$180,411.46	54%
Climara	0.025mg/day	Menopause	\$5.35	\$12.79	8974	4832	13806	\$170,394.76	\$73,832.29	\$96,562.47	57%
Combivent Respimat	20mcg/20mcg	Respiratory	\$32.63	\$95.98	7151	3850	11001	\$1,018,931.27	\$358,900.35	\$660,030.92	%59
Complera	200/25/300mg	HIV	\$42.65	\$72.66	3148	1695	4843	\$339,596.85	\$206,586.30	\$133,010.55	39%
Copaxone	20mg	Multiple Sclerosis	\$46.98	\$238.08	3057	1646	4703	\$1,080,602.09	\$220,966.43	\$859,635.66	80%
Cuprimine	250mg	Wilson's Disease	\$0.92	\$262.15	1260	678	1938	\$490,376.98	\$1,791.87	\$488,585.12	100%
Dexilant	60mg	GERD	\$0.39	\$8.97	204298	110006	314304	\$2,720,294.99	\$124,007.05	\$2,596,287.94	82%
Dexilant	30mg	GERD	\$0.39	\$9.07	26816	14440	41256	\$361,264.41	\$16,277.26	\$344,987.15	85%
Diclegis Dr	10/10mg	Morning Sickness	\$1.38	\$6.80	29019	15625	44644	\$292,812.44	\$61,755.85	\$231,056.59	79%
Difficid	200mg	C.diff	\$86.13	\$185.64	1710	921	2631	\$471,240.97	\$226,573.69	\$244,667.28	52%
Dulera	200/5mg	Respiratory	\$8.03	\$29.90	36123	19451	55574	\$1,603,521.97	\$446,302.09	\$1,157,219.88	72%
Dulera	100/5mg	Respiratory	\$6.53	\$26.91	23714	12769	36484	\$947,433.36	\$238,057.00	\$709,376.36	75%
Eliquis	5mg	Anticoagulant	\$1.74	\$6.93	825823	444674	1270496	\$8,495,548.60	\$2,210,663.66	\$6,284,884.94	74%
Eliquis	2.5mg	Anticoagulant	\$1.74	\$6.87	104820	56442	161262	\$1,069,174.13	\$280,595.05	\$788,579.08	74%
Elmiron	100mg	Bladder pain	\$1.43	\$8.92	129504	69733	199236	\$1,714,586.48	\$284,703.88	\$1,429,882.60	83%
Enstilar	0.005/0.064%	Psoriasis	\$1.53	\$16.71	22337	12028	34365	\$554,157.54	\$52,458.00	\$501,699.55	91%
Entresto	24/26mg	Heart Failure	\$3.94	\$7.93	34162	18395	52557	\$401,980.00	\$206,902.86	\$195,077.14	49%

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Janumet XR	100/1000mg	Diabetes	\$2.98	\$14.55	11030	5939	16969	\$238,267.29	\$50,563.04	\$187,704.25	%62
Januvia	100mg	Diabetes	\$2.85	\$14.08	217062	116879	333941	\$4,538,628.93	\$950,646.53	\$3,587,982.40	79%
Januvia	50mg	Diabetes	\$2.85	\$14.11	22948	12356	35304	\$480,559.33	\$100,502.12	\$380,057.20	%62
Jardiance	25mg	Diabetes	\$2.85	\$15.06	216910	116798	333708	\$4,850,621.89	\$949,982.22	\$3,900,639.67	80%
Jardiance	10mg	Diabetes	\$2.85	\$14.99	119360	64271	183631	\$2,655,868.31	\$522,752.46	\$2,133,115.85	80%
Jentadueto	2.5/1000mg	Diabetes	\$1.29	\$6.76	30906	16642	47548	\$310,383.10	\$61,206.90	\$249,176.21	80%
Keppra	500mg	Epilepsy	\$1.06	\$7.50	16469	8988	25337	\$183,368.65	\$26,865.40	\$156,503.25	85%
Kombiglyze XR	2.5/1000mg	Diabetes	\$1.38	\$6.61	21410	11528	32938	\$209,953.68	\$45,492.13	\$164,461.55	78%
Kuvan	100mg	Hyperphenylalaninemia	\$35.89	\$38.67	19623	10566	30190	\$1,126,674.29	\$1,083,441.10	\$43,233.19	4%
Lamictal	100mg	Epilepsy	\$1.56	\$11.94	40022	21550	61573	\$709,377.23	\$95,820.21	\$613,557.02	%98
Lamictal	150mg	Epilepsy	\$2.28	\$11.95	19355	10422	7777	\$343,325.24	\$67,911.76	\$275,413.48	80%
Latuda	40mg	Schizophrenia, bipolar	\$3.88	\$40.21	44226	23814	68040	\$2,639,821.10	\$264,156.70	\$2,375,664.40	%06
Latuda	20mg	Schizophrenia, bipolar	\$3.88	\$39.74	33722	18158	51880	\$1,989,392.25	\$201,418.83	\$1,787,973.41	%06
Latuda	80mg	Schizophrenia, bipolar	\$3.88	\$40.14	31826	17137	48964	\$1,896,691.51	\$190,094.72	\$1,706,596.79	%06
Latuda	gm09	Schizophrenia, bipolar	\$3.88	\$40.82	30964	16673	47638	\$1,876,699.96	\$184,947.05	\$1,691,752.91	%06
Latuda	120mg	Schizophrenia, bipolar	\$3.88	\$60.64	15747	8479	24226	\$1,417,753.19	\$94,055.51	\$1,323,697.69	93%
Lonsurf	20/8.19mg	Cancer	\$82.92	\$218.94	2683	1444	4127	\$871,960.46	\$342,222.64	\$529,737.82	61%
Lumigan	0.01%	Inflammation	\$58.78	\$71.16	6280	3381	1996	\$663,446.01	\$567,859.57	\$95,586.43	14%
Myrbetriq ER	50mg	Overactive Bladder	\$1.59	\$11.96	28554	15375	43929	\$506,989.28	\$69,748.06	\$437,241.22	898
Myrbetriq ER	25mg	Overactive Bladder	\$1.59	\$11.39	22219	11964	34183	\$375,881.07	\$54,274.03	\$321,607.04	%98
Nexavar	200mg	Cancer	\$50.03	\$160.64	3350	1804	5154	\$798,946.10	\$257,870.48	\$541,075.62	%89
Noxafil	100mg	Antifungal	\$50.81	\$67.96	26453	14244	40697	\$2,668,974.67	\$2,067,884.61	\$601,090.06	23%
Nuvaring		Contraceptive	\$16.01	\$154.70	44576	24002	88578	\$10,237,567.86	\$1,097,798.68	\$9,139,769.18	86%
Ofev	100mg	Pulmonary Fibrosis	\$29.56	\$155.99	1920	1034	2954	\$444,635.88	\$87,310.52	\$357,325.36	80%
Onglyza	5mg	Diabetes	\$2.50	\$13.06	36178	19480	55658	\$701,705.69	\$139,215.73	\$562,489.96	80%
Otezla	30mg	Psoriasis	\$20.56	\$53.07	107499	57884	165383	\$8,469,045.72	\$3,399,986.47	\$5,069,059.25	%09
Otezla	10, 20, 30mg kit	Psoriasis	\$20.56	\$26.85	2425	1306	3731	\$204,680.84	\$76,695.04	\$127,985.80	63%
Portia 28	0.03/0.15mg	Contraceptive	\$0.28	\$0.91	1015631	546878	1562510	\$1,364,918.77	\$441,799.60	\$923,119.17	%89
Premarin	0.625mg	Menopause	\$0.38	\$5.25	22741	12245	34986	\$177,405.91	\$13,438.16	\$163,967.75	92%
Premarin Cream	0.625mg/g	Menopause	\$0.68	\$10.82	95396	51367	146763	\$1,531,806.36	\$100,231.46	\$1,431,574.90	93%
Prezcobix	800/150mg	HIV	\$27.39	\$53.88	20084	10814	30898	\$1,606,514.04	\$846,322.52	\$760,191.51	47%
Prezista	800mg	HIV	\$21.30	\$48.21	21270	11453	32723	\$1,522,258.07	\$697,083.64	\$825,174.43	54%
Prezista	600mg	HIV	\$18.69	\$23.11	10376	5587	15963	\$355,975.73	\$298,382.13	\$57,593.60	16%
Prograf	1mg	Transplant	\$2.72	\$6.16	55208	29728	84936	\$505,199.29	\$230,873.17	\$274,326.13	54%

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Relpax	40mg	Migraines	\$14.35	\$52.36	2380	1282	3662	\$185,034.52	\$52,552.74	\$132,481.77	72%
Retin-A	0.025%	Acne	\$0.39	\$1.71	212957	114669	327626	\$541,409.40	\$126,840.23	\$414,569.18	77%
Retin-A	0.05%	Acne	\$0.38	\$1.96	121900	65638	187538	\$353,932.77	\$70,423.27	\$283,509.50	80%
Revatio	20mg	Pulmonary Hypertension	\$11.63	\$48.29	3960	2132	6092	\$283,925.45	\$70,873.06	\$213,052.38	75%
Rexulti	3mg	Schizophrenia, MDD	\$3.81	\$38.82	2835	1527	4362	\$163,388.90	\$16,617.46	\$146,771.44	%06
Rexulti	2mg	Schizophrenia, MDD	\$3.81	\$35.66	17034	9172	26206	\$901,733.43	\$99,744.83	\$801,988.60	868
Rexulti	1mg	Schizophrenia, MDD	\$3.81	\$36.75	13503	7271	20774	\$736,624.93	76.690,67\$	\$657,554.96	%68
Rexulti	0.5mg	Schizophrenia, MDD	\$3.81	\$37.18	4648	2503	7150	\$256,523.92	\$27,215.54	\$229,308.38	868
Sabril	500mg	Epilepsy	\$0.96	\$140.15	1170	930	1800	\$243,433.36	\$1,736.30	\$241,697.06	%66
Sensipar	30mg	Hyperparathyroidism	\$11.73	\$24.75	5493	2958	8450	\$201,859.69	\$99,103.14	\$102,756.55	51%
Sensipar	gm09	Hyperparathyroidism	\$21.38	\$51.94	1989	1071	3060	\$153,385.53	\$65,424.56	\$87,960.97	22%
Serevent diskus	50mcg	Respiratory	\$0.95	\$6.16	18617	10024	28641	\$170,169.41	\$27,326.52	\$142,842.89	84%
Spiriva Handihaler	18mcg	Respiratory	\$1.88	\$12.84	95562	51457	147019	\$1,822,025.20	\$276,598.02	\$1,545,427.18	85%
Sprycel	100mg	Cancer	\$159.14	\$442.91	9733	5241	14974	\$6,400,114.97	\$2,383,038.23	\$4,017,076.74	%89
Sprycel	50mg	Cancer	\$79.57	\$253.52	947	510	1457	\$356,425.62	\$115,928.93	\$240,496.69	%29
Sprycel	70mg	Cancer	\$87.75	\$251.66	069	372	1062	\$257,796.42	\$93,151.32	\$164,645.10	64%
Stivarga	40mg	Cancer	\$78.97	\$208.51	3304	1779	5083	\$1,022,791.86	\$401,432.19	\$621,359.67	61%
Stribild	150/150/200/3 00mg	ΛIH	\$47.85	\$102.92	5994	3228	9222	\$915,865.10	\$441,251.14	\$474,613.95	25%
Sutent	50mg	Cancer	\$274.71	\$633.58	448	241	689	\$421,397.73	\$189,340.09	\$232,057.64	25%
Sutent	25mg	Cancer	\$137.36	\$367.26	623	335	826	\$339,506.92	\$131,581.77	\$207,925.15	819
Synthroid	100mcg	Hypothyroidism	\$0.07	\$1.18	263066	141651	404717	\$459,902.57	\$27,288.07	\$432,614.50	94%
Synthroid	75mcg	Hypothyroidism	\$0.09	\$1.17	245550	132219	377769	\$425,850.79	\$34,344.89	\$391,505.90	92%
Synthroid	50mcg	Hypothyroidism	\$0.05	\$1.18	221186	119100	340286	\$386,852.91	\$17,318.87	\$369,534.04	%96
Synthroid	112mcg	Hypothyroidism	\$0.10	\$1.19	221658	119354	341012	\$390,846.51	\$32,783.16	\$358,063.35	92%
Synthroid	125mcg	Hypothyroidism	\$0.10	\$1.19	216372	116508	332880	\$382,517.94	\$32,544.40	\$349,973.54	91%
Synthroid	88mcg	Hypothyroidism	\$0.09	\$1.19	208644	112347	320991	\$370,033.79	\$29,182.93	\$340,850.87	92%
Tagrisso	80mg	Cancer	\$320.46	\$509.47	7305	3933	11238	\$5,525,245.94	\$3,601,470.31	\$1,923,775.63	35%
Tagrisso	40mg	Cancer	\$320.46	\$511.02	390	210	009	\$295,879.88	\$192,276.35	\$103,603.53	35%
Tarceva	150mg	Cancer	\$87.00	\$281.56	1605	864	2469	\$670,897.14	\$214,823.08	\$456,074.07	%89
Tarceva	100mg	Cancer	\$58.00	\$264.81	999	358	1023	\$261,441.35	\$59,338.42	\$202,102.92	77%
Tasigna	150mg	Cancer	\$29.66	\$118.49	14338	7720	22058	\$2,522,076.66	\$654,257.81	\$1,867,818.85	74%
Tasigna	200mg	Cancer	\$38.33	\$119.15	8598	4630	13227	\$1,520,862.14	\$506,948.12	\$1,013,914.01	%29
Tecfidera	240mg	Multiple Sclerosis	\$27.71	\$125.49	106817	57517	164334	\$19,900,768.63	\$4,553,528.12	\$15,347,240.52	77%
Tivicay	50mg	HIV	\$20.12	\$48.07	127927	68884	196811	\$9,128,830.10	\$3,959,596.04	\$5,169,234.06	27%
Tracleer	125mg	Pulmonary Hypertension	\$69.79	\$189.04	2705	1456	4161	\$759,089.43	\$290,428.66	\$468,660.77	62%

*CIVHC data includes 100 percent of fully-insured and 65 percent of self-funded lives (according to CIVHC and other sources). In order to derive a cost savings estimate for the self-funded lives not 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.





Drug Name	Strength	Indication	Candian Unit Cost with 45% Markup adjusted units	Colorado Unit Cost	APCD Units	Self Funded Units*	Total Utilization by Unit	Current CO Price (per total Utilization by Unit)	Importation Price	Total Annual Savings	Percent Savings
Tradjenta	5mg	Diabetes	\$2.45	\$13.24	114441	61622	176064	\$2,249,715.16	\$430,805.69	\$1,818,909.47	81%
Triumeq	600/50/300mg	AIN	\$44.12	\$87.50	98177	52865	151042	\$12,752,982.07	\$6,663,347.29	\$6,089,634.78	48%
Truvada	200/300mg	HIV (PrEP)	\$28.39	\$53.87	378909	204028	582937	\$30,304,085.00	\$16,547,200.25	\$13,756,884.75	45%
Uloric	80mg	Gout	\$1.73	\$10.89	24202	13032	37234	\$391,254.07	\$64,381.93	\$326,872.14	84%
Uptravi	1200mcg	Pulmonary Hypertension	\$69.78	\$292.34	1260	879	1938	\$546,850.76	\$135,268.34	\$411,582.42	75%
Uptravi	400mcg	Pulmonary Hypertension	\$69.78	\$288.49	540	291	831	\$231,278.97	\$57,972.15	\$173,306.82	75%
Uptravi	200mcg	Pulmonary Hypertension	\$69.78	\$185.10	938	202	1443	\$257,761.25	\$100,699.76	\$157,061.49	61%
Vesicare	10mg	Overactive Bladder	\$1.63	\$11.42	17903	9640	27543	\$303,631.42	\$44,929.90	\$258,701.51	85%
Victoza	6mg/mL	Diabetes	\$74.48	\$94.31	59460	32017	91477	\$8,325,466.89	\$6,813,488.14	\$1,511,978.76	18%
Vimovo DR	500/20mg	Arthritis Pain	\$1.00	\$41.80	3360	1809	5169	\$208,535.30	\$5,171.82	\$203,363.48	%86
Vimpat	100mg	Epilepsy	\$3.61	\$14.06	79711	42922	122633	\$1,664,330.42	\$442,766.31	\$1,221,564.11	73%
Vivelle-Dot	0.05mg	Menopause	\$2.91	\$16.05	18256	9830	28086	\$434,890.82	\$81,857.10	\$353,033.72	81%
Vivelle-Dot	0.1mg	Menopause	\$3.25	\$16.08	15779	8496	24275	\$376,669.13	\$78,802.45	\$297,866.68	262
Vivelle-Dot	0.0375mg	Menopause	\$2.72	\$16.01	10680	5751	16431	\$253,778.57	\$44,760.50	\$209,018.07	82%
Vivelle-Dot	0.075mg	Menopause	\$3.13	\$16.10	9592	5165	14757	\$229,257.81	\$46,138.44	\$183,119.37	80%
Wellbutrin XL	300mg	Depression	\$1.15	\$14.47	33221	17888	51109	\$713,493.80	\$58,615.79	\$654,878.01	92%
Wellbutrin XL	150mg	Depression	\$0.57	\$13.83	12225	6583	18807	\$251,064.84	\$10,782.78	\$240,282.06	%96
Xalkori	250mg	Cancer	\$141.38	\$300.42	1730	932	7997	\$771,599.97	\$376,275.00	\$395,324.97	51%
Xarelto	20mg	DVT Treatment	\$3.09	\$13.79	564085	303738	867823	\$11,546,088.45	\$2,680,271.61	\$8,865,816.84	77%
Xarelto	10mg	DVT Treatment	\$3.09	\$14.02	63897	34406	80286	\$1,329,602.09	\$303,609.35	\$1,025,992.74	77%
Xarelto	15mg	DVT Treatment	\$3.09	\$13.98	53674	28901	82576	\$1,114,222.63	\$255,034.75	\$859,187.87	77%
Xeljanz	5mg	Arthritis	\$25.12	\$65.81	46696	25144	71840	\$4,562,549.99	\$1,804,449.28	\$2,758,100.71	%09
Xeloda	500mg	Cancer	\$6.63	\$45.63	11543	6215	17758	\$782,024.14	\$117,805.19	\$664,218.94	82%
Xifaxan	550mg	Hepatic Encephalopathy	\$8.35	\$37.13	95911	51644	147555	\$5,286,320.12	\$1,231,981.45	\$4,054,338.67	77%
Xigduo	5/1000mg	Diabetes	\$1.33	\$8.20	12654	6814	19468	\$154,047.85	\$25,892.03	\$128,155.82	83%
Xtandi	40mg	Cancer	\$30.83	\$87.86	37699	20300	66629	\$4,917,630.83	\$1,787,829.09	\$3,129,801.73	64%
Yasmin 28	3/0.03mg	Contraceptive	\$0.46	\$3.96	92665	32295	1,2271	\$352,188.73	\$42,431.37	\$309,757.36	88%
Yaz 28	3/0.02mg	Contraceptive	\$0.46	\$4.80	114128	61454	175582	\$814,013.37	\$80,742.42	\$733,270.94	%06
Zelboraf	240mg	Cancer	\$37.12	\$47.97	7073	3809	10882	\$503,732.49	\$403,948.35	\$99,784.15	20%
Zomig	5mg	Migraines	\$15.06	\$73.99	3802	2047	5849	\$417,576.74	\$88,092.51	\$329,484.23	79%
Zytiga	250mg	Cancer	\$30.81	\$86.22	33078	17811	68809	\$4,234,059.97	\$1,568,022.58	\$2,666,037.39	%89
								\$395,077,866.22	\$153,876,323.80	\$241,201,542.41	61%

*CIVHC data includes 100 percent of fully-insured and 65 percent of self-funded lives (according to CIVHC data included in order to derive a cost savings estimate for the self-funded lives not 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.

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Application for Section 804 Importation Program

New Hampshire Department of Health and Human Services

April 21, 2021

Source: Publicly available document April 21, 2021 NH SIP Application to FDA

Find the entire application online at our website: www.safemedicines.org

Source: document can be found on PSM's website.

The following drugs were submitted as part of New Hampshire's SIP application dated April 21, 2021.

Abilify Maintena	Advair Diskus	Aubagio	Biktarvy
Breo Ellipta	Chantix	Eliquis	Epclusa
genvoya	Gilenya	Harvoi	Ibrance
Imbruvica	Ingrezza	Jakafi	Januvia
Jardiance	Kuvan	Latuda	Lupron
Mavyret	Myrbetiq	Odefsey	Otezla
Ozempic	Procysbi	Ravicti	Sabril
Spiriva Respimat	Sprycel	Tecfidera	Tradjenta
Triumeq	Truvada	Victoza	Vosevi
Wellbutrin XL	Wixela Inhub	Xarelto	Xifaxan
Xtandi			

On the next five pages, we have included the original five-page listing from New Hampshire's April 21, 2021 application. You can find a complete copy of this application's <u>SIPs documents here</u>.

including purchasers and payers.

At any level in the supply chain where there is no market competition, the state can establish a limit on mark-up or fees for each stage of the supply chain. The allowed mark-up will account for the routine and exceptional costs of importing and distributing product throughout the state. The mark-up limits for the non-competitive parts of the supply chain will be enforced by payers and purchasers who will know the import price and the state margin limits. In order to ensure the significant savings from importing certain prescription drugs wholesale from Canada would be passed on to consumers, New Hampshire could amend its annual rate review filing requirements for health plans doing business in the state and require health plans to document savings from importation as well as how those saving were passed on to consumers.

Options for passing savings to consumers may include:

- · Lowering premiums.
- · Lowering deductibles, and
- Reducing or eliminating co-pays.

In addition to the rate review process described above, the New Hampshire would establish a transparent, public price list of the imported drugs in order to ensure that mark-up along the supply chain was not exceeding the allowed amount at the expense of consumer savings.

Conclusion

Now more than ever, one of the biggest pressures on New Hampshire families' pocketbooks is the high cost of health care in the Granite State and prescription drugs are a driver of these health care costs. We look forward to the Administration's continued action to create a formal pathway for prescription drug importation from Canada and to its partnership with states on this important initiative.

Proposed Drug List

Drug Name	Active Ingredient	NDC	US Price	NDA/ANDA	Canadian Name	Sold in US
Abilify Maintena	Aripiprazole	59148-0019-71	\$2,179.10	NDA202971	Abilify Maintena	Yes

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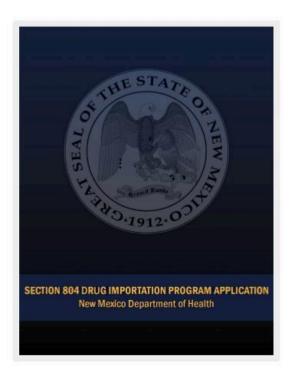
Drug Name	Active Ingredient	NDC	US Price	NDA/ANDA	Canadian Name	Sold in US
Advair Diskus 100- 50mcg	Fluticasone Propion / Salmeterol	00173-0695-00	\$303.60	NDA021077	Advair 100 Diskus	Yes
Advair Diskus 250- 50mcg	Fluticasone Propion / Salmeterol	00173-0696-00	\$377.40	NDA021077	Advair 250 Diskus	Yes
Advair Diskus 500- 50mcg	Fluticasone Propion / Salmeterol	00173-0697-00	\$496.80	NDA021077	Advair 500 Diskus	Yes
Aubagio 14mg	Teriflunomide	58468-0210-02	\$268.64	NDA202992	Aubagio	Yes
Bikyarvy 50- 200-25	Bictegrav / Emtricit / Tenofov Ala	61958-2501-01	\$104.52	NDA210251	Biktarvy	Yes
BREO ELLIPTA 100- 25mcg	FLUTICASONE / VILANTEROL	00173-0859-10	\$5.96	NDA204275	Breo Ellipta	Yes
BREO ELLIPTA 200- 25mcg	FLUTICASONE / VILANTEROL	00173-0882-10	\$5.96	NDA204275	Breo Ellipta	Yes
Chantix 0.5 (11)-1 (Champix in Canada)	Varenicline Tartrate	00069-0471-03	\$8.00	NDA021928	Champix	Yes
Chantix 0.5mg	Varenicline Tartrate	00069-0468-56	\$7.62	NDA021928	Champix	Yes
Chantix 1mg	Varenicline Tartrate	00069-0469-56	\$8.00	NDA021928	Champix	Yes
Eliquis 2.5mg	Apixaban	00003-0893-21	\$7.52	NDA202155	Elequis	Yes
Eliquis 5mg	Apixaban	00003-0894-21	\$7.53	NDA202155	Elequis	Yes
Epclusa 400- 100mg	Sofosbuvir, Velpatavir	61958-2210-01	\$869.05	NDA208341	Epclusa	Yes
Genvoya 150-200-10	Elviteg / Cob / Emtri / Tenof Alafen	61958-1901-01	\$104.93	ANDA207561	Genvoya	Yes
Gilenya 0.5mg	Fingolimod HCL	00078-0607-15	\$280.83	NDA022527	Gilenya	Yes
Harvoni 90- 400mg	Ledipasvir, Sofosbuvir	61958-1801-01	\$1,098.94	NDA205834	Harvoni	Yes
Ibrance 75 mg	Palbociclib	00069-0284-21	\$592.83	NDA207103	Ibrance	Yes
Ibrance 100mg	Palbociclib	00069-0188-21	\$592.83	NDA207103	Ibrance	Yes

Drug Name	Active Ingredient	NDC	US Price	NDA/ANDA	Canadian Name	Sold in US
	Palbociclib		0011100	it Dry rate r	- Tunine	00
Ibrance 125mg	Talboticilb	00069-0189-21	\$592.83	NDA207103	Ibrance	Yes
Imbruvica 140mg	Ibrutinib	57962-0140-09	\$154.36	NDA205552	Imbruvica	Yes
Ingrezza 80mg	Valbenazine Tosylate	70370-1080-01	\$234.77	NDA209241	Ingrezza	Yes
Jakafi 5mg	Ruxolitinib Phosphate	50881-0005-60	\$236.45	NDA202192	Jakavi	Yes
Jakafi 10mg	Ruxolitinib Phosphate	50881-0010-60	\$236.45	NDA202192	Jakavi	Yes
Jakafi 15mg	Ruxolitinib Phosphate	50881-0015-60	\$236.45	NDA202192	Jakavi	Yes
Jakafi 20mg	Ruxolitinib Phosphate	50881-0020-60	\$236.45	NDA202192	Jakavi	Yes
Januvia 100mg Tab	Sitagliptin Phosphate	00006-0277-31	\$15.14	NDA021995	Januvia	Yes
Januvia 25mg Tab	Sitagliptin Phosphate	00006-0221-31	\$15.13	NDA021995	Januvia	Yes
Januvia 50mg Tab	Sitagliptin Phosphate	00006-0112-31	\$15.13	NDA021995	Januvia	Yes
Jardiance 10mg	Empagliflozin	00597-0152-30	\$17.41	NDA204629	Jardiance	Yes
Jardiance 25mg	Empagliflozin	00597-0153-30	\$17.41	NDA204629	Jardiance	Yes
Kuvan 100 mg	Sapropterin Dihydrochloride	68135-0301-22	\$40.30	NDA205065	Kuvan	Yes
Latuda 120mg Tab	Lurasidone HCL	63402-0312-30	\$61.13	NDA200603	Latuda	Yes
Latuda 20mg Tab	Lurasidone HCL	63402-0302-30	\$40.99	NDA200603	Latuda	Yes
Latuda 40mg Tab	Lurasidone HCL	63402-0304-30	\$41.00	NDA200603	Latuda	Yes
Latuda 60mg Tab	Lurasidone HCL	63402-0306-30	\$41.04	NDA200603	Latuda	Yes
Latuda 80mg Tab	Lurasidone HCL	63402-0308-30	\$41.03	NDA200603	Latuda	Yes
Lupron Deopt-Ped 30mg	Leuprolide Acetate	00074-9694-03	\$10,078.5 6	NDA020263	Lupron Deop	Yes
Mavyret 100-40mg	Glecaprevir, Pibrentasvir	00074-2625-80	\$153.11	NDA209394	Maviret	Yes

Drug Name	Active Ingredient	NDC	US Price	NDA/ANDA	Canadian Name	Sold in US
Myrbetriq 25mg	Mirabegron	00469-2601-30	\$13.50	NDA202611	Myrbetriq	Yes
Myrbetriq 50mg	Mirabegron	00469-2602-30	\$13.50	NDA202611	Myrbetriq	Yes
Odefsey 200- 25-25	Emtricitab / Rilpiviri / Tenof Ala	61958-2101-01	\$95.77	NDA208351	Odefsey	Yes
Otezla 10- 20-30mg	Apremilast	55513-0369-55	\$65.30	NDA205437	Otezla	Yes
Otezla 30mg	Apremilast	55513-0137-28	\$59.86	NDA205437	Otezla	Yes
Ozempic 1mg/0.75ml	Semaglutide	00169-4136-02	\$270.35	NDA209637	Ozempic	Yes
Procysbi 75mg	Cysteamine Bitartrate	75987-0101-08	\$101.32	NDA203389	Procysbi	Yes
Ravicti 1.1Gm/ml	Glycerol Phenylbutyrate	75987-0050-06	\$201.24	NDA203284	Ravicti	Yes
Sabril 500mg	Vigabatrin	67386-0111-01	\$175.20	NDA020427	Sabril	Yes
Spiriva Respimat 2.5mcg	Tiotropium Bromide	00597-0100-28	\$18.75	NDA021936	Spiriva	Yes
Spiriva 18mcg Handihaler	Tiotropium Bromide	00597-0075-41	\$15.75	NDA021395	Spiriva	Yes
Sprycel 20mg	Dasatinib	00003-0527-11	\$140.20	NDA021986	Sprycel	Yes
Sprycel 50mg	Dasatinib	00003-0528-11	\$244.57	NDA021986	Sprycel	Yes
Sprycel 70mg	Dasatinib	00003-0524-11	\$280.39	NDA021986	Sprycel	Yes
Sprycel 100mg	Dasatinib	00003-0852-22	\$466.07	NDA021986	Sprycel	Yes
Tecfidera 240mg	Dimethyl Fumerate	64406-0006-02	\$137.93	NDA204063	Tecfidera	Yes
Tradjenta 5mg Tab	Linagliptin	00579-0140-30	\$14.79	NDA201280	Tradjenta	Yes
Triumeq 600-50-300	Abacavir / Dolutegravir / Lamivudi	49702-0231-13	\$98.19	NDA205551	Triumeq	Yes
Truvada 200- 300	Emtricitabine / Tenofovir (TDF)	61958-0701-01	\$59.70	NDA021752	Truvada	Yes

Drug Name	Active Ingredient	NDC	US Price	NDA/ANDA	Canadian Name	Sold in US
Victoza 0.6 MG/0.1ml (2-Pak)	Liraglutide	00169-4060-12	\$107.57	NDA022341	Victoza	Yes
Victoza 0.6 MG/0.1ml (3-Pak)	Liraglutide	00169-4060-13	\$107.57	NDA022341	Victoza	Yes
Vosevi	Sofosbuvir / Velpatas Voxilaprev	61958-2401-01	\$890.00	NDA209195	Vosevi	Yes
Wellbutrin XL 150mg	Bupropion HCL	00187-0730-30	\$46.97	NDA021515	Wellbutrin XL	Yes
Wellbutrin XL 300mg	Bupropion HCL	00187-0731-30	\$62.03	NDA021515	Wellbutrin XL	Yes
Wixela Inhub 100-50mcg	Fluticasone Propion, Salmeterol	00378-9320-32	\$123.00	ANDA208891	Wixela Inhub	Yes
Wixela Inhub 250-50mcg	Fluticasone Propion, Salmeterol	00378-9321-32	\$150.00	ANDA208891	Wixela Inhub	Yes
Wikela Inhub 500-50mcg	Fluticasone Propion, Salmeterol	00378-9322-32	\$153.10	ANDA208891	Wixela Inhub	Yes
Xarelto 2.5mg	Rivaroxaban	50458-0577-10	\$8.21	NDA202439	Xarelto	Yes
Xarelto 10mg	Rivaroxaban	50458-0580-10	\$16.42	NDA022406	Xarelto	Yes
Xarelto 15mg	Rivaroxaban	50458-0578-10	\$16.42	NDA202439	Xarelto	Yes
Xarelto 20mg	Rivaroxaban	50458-0579-10	\$15.03	NDA202439	Xarelto	Yes
Xifaxan 550mg	Rifaximin	65649-0303-02	\$44.06	NDA022554	Xifaxan	Yes
Xtandi 40mg	Enzalutamide	00469-0125-99	\$102.30	NDA203415	Xtandi	Yes





Source: Publicly available document December 2020 NM SIP Application to FDA

Find the entire application online at our website: www.safemedicines.org

Source: document can be found on PSM's website.

The following drugs were submitted as part of New Mexico's SIP application dated December 2020.

Latuda	Ventolin HFA	Advair Diskus	Chantix
Descovy	Jardiance	Invokana	Farxiga
Uptravi	Tecfidera	Xifaxan	Janumet
Januvia	Ravicti	Xarelto	Tivicay
Copaxone	Imbruvica	Victoza	Tasigna
Sprycel	Zytiga	Xtandi	Ofev
Promacta	Afinitor Disperz	Gilenya	Xeljanz XR
Votrient	Bydureon Bcise	Restasis	Biktarvy
Cabometyx	Genvoya	Triumeq	Odefsey
Korlym	Truvada	Eliquis	

On the next seven pages, we have included the original seven-page listing from New Mexico's December 2020 application.

LATUDA

LATUDA

LATUDA

CHANTIK

CHANTIK

U.S. INGREDIENTS	2 mg of mospillosin (free besal and the kilosine) elective hypoteests; biscope moshelphates, microsypalities eleliosa. hydromyprosyle calibosa, crossameliose adeim, collidada ilicos disolde and magnetim states had seed in the film constitute contains the following in.	100mg of caugatinon or 200mg of canagillionin, crocarmelions 100mg of caugatinon or 200mg of canagillionin, crocarmelions 100mg of canagillionin canagillion	100mg of campillions in 200mg of campillionin, concurrentions nooth. The contract in the contract and process and contract and	5 mg dapaglitions as dapaglitions proposed of the equivalent of 12 mg dapaglitions in dapaglitions. 12 mg dapaglitions in dapaglitions, proposed data controlled microscription databases, and reduces an effect of controlled, and superior mesself. The filter consisting contents polytriol school, listensia disorder, polytriol school, and polytriol school sc	5 ng dapaglitons is dapaglitons propuedid or the equivater of 10 ng dapaglitons is dapaglitons and dapaglitons can be compared to the compared of the compared	science 4-200mg handles improduents. Drausmood, corn naturb, low understand sproperspectualized, story suppressibilized, and magnetical streams. The tables are film coated with a coating material containing hyporoselizes, propriete gibed, italiating disorder, carried as was along with recordered, from outder edit or outder gibed, italiating disorder, and coated as the coated as well as the coated as the c	Singer dismetts intercorpatine endulars, inferited intercorpatine endulars, inferited intercorpatine endulars, inferited endulars endulars, endulars endular	Maturini SSImg, collodia ilitco dioxide, disodium refeate, givceel palmtocaseante, hypomelisse, microcrystalline cellulore, prospinese givou, ted iros eside, sodium steric pyrodise, tale, and stanium dioxide,	stagigion and methoms, morcoptation colution, proceedings of polystation and reference, morcoptations obtained to polystation that beater the consecuent that debugging questions regardents application and polystations about polystation and polystations that black into make
NDA APPLICANT HOLDER NAME AND ADDRESS	Bookninger ingelheim Pharmaceuticals, Inc. 900 Ridgebury Road P.O. Box 108 Ridgefield, CT 06877	Jansen Pharmaceuticals, Inc. 1125 Trenten Harbourten Road Transville, NJ 08560-1504	Jansen Pharmaceuticis, Inc. 1125 Trenten Herbourten Road Thauville, NJ 08560-150A	ASTRAZENECA LP PO BOX 13437 WILMINGTON, DE 13850	ASTRAZBNECA LP PO BOX 15437 WILMINGTON, DE 19850	Actelion Pharmaceuticals US, Inc. 5000 Shoreline Court, Sec. 200 South San Francisco, CA 94089, USA	Biogen 10EC Inc 222 Binney Street Cambridge, MA 02142	SALIX PHARMACEUTICALS 1700 Perimeter Park Drive Merrisville, NC 27560	MERC SULPE DOME 2000 Geograph Will Road Kenliworth, N 088889
NDA	204629	204042	204042	202293	202293	207947	204063	022554	022044
NDC	0597-0152-30	50458-0140-30	50458-0141-30	08310-6205-30	08310-6210-30	66215-0614-06	64406-0006-02	65649-0303-02	00006-0575-61
U.S. GENERIC NAME	EMPAGLIFLOZIN	CAGUFLOZIN	CAGLIFLOZIN	DAPAGLIGOZIN	DAPAGLIFOZIN	9valx3135	DIMETHYL FUMARATE	RIFAXUMIN	19 -4:09 5000) THI MONITORNIN LES.
U.S. PROPRIETARY NAME	JARDIANCE	INVOKANA	INVOIGNA	FABRIGA	FARMGA	UPTRAVI	TECFIDERA	XIFAXAN	JANUAET
CANADAIAN INGREDIENTS	25 mg of empagificien free bare, colloidal sillicon distile. Constraindos alloida colloida full confusion free bare, colloida full confusion	Otogo of canagilocio OR Bioma of canagilocio. Cere Talest custamentias solution. Cere Talest custamentias solution. Pedrony organizacione antividoro, steazete, and motoroptaline organizacione antividoro, steazete, and motoroptaline organizacione organizacione Macrosopi Opportunizacione organizacione Macrosopi Opportunizacione Recordo Carlo con organizacione (100 mp. state costy). Macrosopi Opportunizacione spicolo, polyviny alcohol, tale, and stanium doxode.	DOTINg of canagillosin Oi BiOmy of canagillosin of Cary Tablest reasonations sodium for Tablest reasonations sodium hydrosproyo calusos, bactors and reasonation and reasonation and reasonation and reasonation of Cary Cary Cary Cary Cary Cary Cary Cary	5 mg er 10 mg dasaglitoun na dasaglitoun propression consciplination in textus composition in textus crospowidous, manginatus nasente, crospowidous, illend edicide, in addition, allend edicide, in addition, allend edicide, in addition, the film costing contains the following inscribe impreference polyvisy lactorial, transmitter of doubless decided, to polyvishing the polyvishing polyvis, tak and yellow iron doubless polyvishing mg polyvis, tak and yellow iron	5 mg or 10 mg daeagifficain as daeagifficain perspecies (or monthes, anhytious battor, crospoolidos, magestum starette, montropstalling excludes, allond decide, in addition, the film coating contains the following lacktor ingredients polyienty alcohol, titamium dioxidio, polyhethere gylvini, alcohol, titamium	Deletiong 1400mg, cannaba wax, conn starch, D- namitel, hydroxyprospt reliulora, hypometicse, iron culture by few (1917) by on substituted hydroxyprospt relutions materialm steares, prosphere glycol, itanium dioxide (\$177).	280 mg of deneity funezet, caledad allow deneity, creamment an ampetent measure, membrand and appearance membrand membrand membrand and appearance mem	ifanimin 550mg, colloidal silicon dioxide, gherryl diseazate, microcrystalline cellulose, polyethylene glycol, polyhura dachidi, red ilen oxide, glaten-free sodium starch alpoiate, izle,	of 3 mg stageton prospector reconsistent as and angiging and a size and 500 mg mentioners. When the stage and 500 mg mentioners are been and 500 mg mentioners and productioning patients are supported to a size and 500 mg mentioners between the production and pr
NUMBER OF ACTIVE INGREDIENTS		п	-	r,	1	1	1	1	7
DOSAGE FORM	TABLET	TABLET	TABLET	TABLET	TABLET	TABLET	CAPSULE (DELAYE) RELEASE)	TABLET	TABLET
STRENGTH	25 MG	100 MG	300 MG	S MG	10 MG	1400 MCG	240 MG	550 MG	50-500 MG
ADDRESS	5180 South Service Road Burlington Ontario Canada 171, 5944	19 Green Belt Drive Toronto Ontario Canada M3C 119	19 Green Belt Drive Toronto Ontario Canada MSC 119	1004 Middlegate Road, Suite 5000 Mississanga Ontario Canada LAY 1M4	1004 Middlegate Road, Suite 5000 Missisauga Ontario Canada LAY 1M4	19 Green Belt Drive Torostbo Ontario Canada MSC 11.9	99 Burnhamthorpe Road West, Suite 1100 Mississanga Ontario Carsula LSB 3C3	400 Somerset Corporate Baulevard Bridgewater, NJ 08807	16720 Beinte Træncz andelene Grétand Grétand Cretand Grétand Caneda Hélét 4M7
COMPANY	BOEHRINGER INGELHEIM (CANNDA) I'TD LTEE	JANSSEN INC	JANSSEN INC	ASTRAZINECA CANADA INC	ASTRAZBNECA CANADA INC	JANSSEN INC	BIOGEN CANADA INC	SALIK PHARMACEUTICALS INC	МЕКС СМАТОА ИКС
NIIQ	02443945	02425483	02425491	02435462	02435470	02451212	02420201	02410702 5	02333856
CANADIAN GENERIC NAME	EMPAGLIFLOZIN	CANAGLIFLOZIN	CANAGLIFLOZIN	DAPAGLIFOZIN	DAPAGLIFOZIN	SELEXIPAG	DIMETHYL EUMMRATE	RIFAXIMIN	METFORMWSITAGLFIT
CANADIAN PROPRIETARY NAME	JARDIANCE	INVOCANA	INVOIGANA	PORNGA	FORMGA	UPTRAVI	TECFIDERA	ZAXINE	JANUART

	g, and r) with r) with r,	ium, oasting sycol.	ium, oasting glycol.	ellose arate, The e red,	pho nullified	BBD 60 offer, wide,	e e e e e e e e e e e e e e e e e e e
U.S. WOREDIENTS	200 rapidiciali bara, sebejotas lipsabetta 185 rap. 186 rap. 204 rap. 186 rap. 204 rap. 186 rap. 204 rap. 186 rap. 204 r	deacinits, with the following leature regredients licitates monochine in circumpating and confidence or committed consideration stellars. The label confidence controlled collidars, and analysts and polyethylene glycol control of hyprometism, tannium deades, and polyethylene glycol.	deacinits, with the following instain engredient listates monopolities in expression to the control of the cont	900 mg bleverenes scettit, colidad villen dieuks, crossmellen stellen versieren er schrijken in negerin in sterke, stellen versieren erdiens, ach dool in herby stellen in sterke stelle gebryk in private ach dool in herby stellen in stelle stellen gebryk in private in stelle back in en des frei, polyterijene groti, polyterij denkst, ste, ach teamin diedes.	On go de constitute as a soution to capitalistic de la soution de la sou	TOO mg or 150 mg of ministens beganware to 130 km mg or 186 so mg ministens to flatesterforsite, respectively. The success in proceedings of 50 km are following in flatesteric influences in properties. The following is flatesteric influences in the following in flatesteric influences in the following in the success in the following in the success in the following influences in the following influences in the following in the fo	110 mg or 50 mg of encedamb lequivalent to 110.00 mg or 180.00 mg or 1
NDA APPLICANT HOLDER NAME AND ADDRESS	MOVARTIS One Health Plaza East Hanover, NJ 07936	BRISTOL MYERS SQUIBB 4206 278h Street 14th Floor New York, NY 10016	BRISTOL MYTRS SQUIBB 4206 ZPSh Street 14th Floor New York, NY 10016	JANSSEN BIOTECH, INC. 800 Ridgeriew Road Horsham, PA 19044	ASTILLAS One Abesilos Way Northbross, I. 60002	Beebringer Ingelbein Pharmacentrals, Inc. 900 Riegebury Road P. O. Box 3-88 Rodgefield, CT 06877	Bedvirger Tugelseim Phremasoriala, inc. 900 Rigelseim Anne 200 Rigelseim Phremasoriala P. O. Inc. 166 Ridgelfield, CT 06877
NDA	022068	021986	021986	202379	203415	205832	205832
NDC	00078-0526-87	00003-0528-11	00003-0852-22	57894-0195-06	66-STD-69RD0	09:87-0143-60	09-5-10-05-60
U.S. GENERIC NAME	NILOTINIB HYDROCHLORIDE	DASATINB	DASATINIB	ABBATERONE ACTATE	BRZAUTAMOE	NINTEDANIB ESYLATE	NNTEDANB ESTATE
U.S. PROPRIETARY NAME	TASIGNA	TIDANASS	TECHNOS	ZYTIĞA	хтлави	OFEV	A340
CANADALAN INGREDIENTS	200 ng niletrich base jan kydrochieride monodychesi. Goliede silecon anhydrous, Console silecon anhydrous, Console silecon anhydrous, Chropson and Magnesium noterbrich serieste. Polasser et chapter anhie Gestern, Transum dexode; Iron code, yellow. Printing silet, includes red inco noide	So me and storing the slowing its monohydrate) containing the Soloving non-noticitial illustration for the subtraction containing the subtraction concurrent and monohydrate mysterian is state and microcytatine colloca. The first contain the following lastive ingredients: hypromelion, poyerhydrae gives and elaminating hypromelion, poyerhydrae gives and elaminating hypromelion, poyerhydrae gives and elaminating disorder.	So mg and store of detaction to reconciverably constraining the following nor medicinal ingredients for the tablet our consumelture soldient, hydroxypropi celuloso, iactors soldient, hydroxypropi celuloso, iactors microsyptatem resultations. The film coaling contains the following lactive ingredients: hydromelious, polyentylesse gives and stanions of dioxides.	SOOMs abstratores actain, colloids illinon diousle, crossmelloss oblim, hypomelloss, lactore monitolydist, magnetium issuaria, lactore monitolydist, magnetium issuaria, launy suffers. The tablet l'im condité gordans ren oude back, toro coide red, marcrego 3350, polyviny alceloi, talk, and ttanium dioodes.	40 ag di establismite in oli te nozive importanti su di establismite in oli te nozive importanti su di establismite in oli te nozive di establismi su di suprimento in altra suprimenta suprimenta in altra suprimenta in altra suprimenta in altra su	TO and 150 mg of introducible is a fee based corresponding to 130.0 mg and a 130.0 mg of ministration is clearly in uncertained in the control of 123, in the control of 1	(EXTR) paid majded (LATE) property (LATE) prop
NUMBER OF ACTIVE INGREDIBATS	1	1	1	ч		4	
DOSAGE FORM	CAPSULE	TABLET	TABLET	TABLET	CAPSUE	CAPSULE	CAPSUE
STRENGTH	200 MG	SOMG	100 MG	500 MG	db MG	100 MG	150 MG
ADDRESS	385 Bouchard Bivd Dorval Quebec Canada, H95 1A9	2344 Boul, Mfred-Nobel Suite 300 Montreal (Sr.Laurent) Queboc Canada H45 0A4	2344 Boul, Affred-Nobel Suite 300 Montreal (5'-Laurent) Quebec Canada H45 0A4	19 Green Belt Drive Treonto Ontario Canada MSC 119	SUITE 500 673 Cochuse Dine, West Tower Markham Oceario Canada, LINSSS	5.180 South Service Road Burlington Ontario Canada 171.5944	5180 South Service Road Burlington Ortano Canada 171 SH4
COMPANY	NOVARTIS PHARMACE UTICALS CANADA INC	BRSTOL-MYERS SQUIBB CANADA	BRSTOL-MYERS SQUIBB CANADA	JANSSEN INC	ASTELLS PHENA CONDO.	BODHRNGS INCLHEM	ELI (CAMON) LID LTE (CAMON) LID LTE
NIG	02315874	02293137	02320193	02457113	02407329	02443066	02443074
CANADIAN GENERIC NAME	NILTINIB (NILOTINIB HYDROCHLORDE MONOHYDRATE)	DASATIVIB (DASATIVIB MONOHTDRATE)	DASATINIB (DASATINIB MONOHPDRATE)	ABRATERONE ACETATE 02457113	ENZALUTAMIDE	NINTEDANIB (PINTEDANIB ESLATE)	FLORESCO (LIVER) BRACITIVING (LIVER) BRACITIVI
CANADIAN PROPRIETARY NAME	TASIGNA	SPRYCIL	SPRYCE,	ZYTIGA	хланоі	OFEV	ASSO

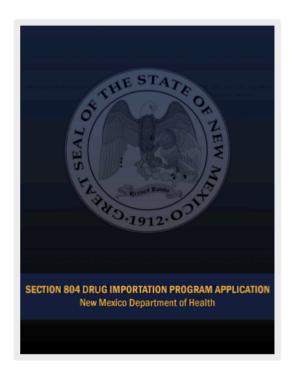
		# E w		-	9 4		6	n a d E = .
U.S. INGREDIENTS	design and methors in contrast to color the color of the	131.5 s g of suggions possphera monohybrate, which is equivalent to 100 mp, respectively, of free base and the following Lectric Representation for free base and the following Lectric Representation for screentarilities settlent, suggestent sectors and sections and sectors are settlent and sectors and sectors are settlent for following the sectors and sectors are settlent for fine to the sectors and pellow into static. Extra for month, and pellow into static.	1.1 g/m, of gyrearol phem/butyrate (delivers 1.02 g/m, of phem/butyrate).	ineroushin, crisciameliose colum, hypereoloos, luttine menohylette, magnesium streatte, microsynalines edilukos, and sodium laury sallists, ferrit cude red, polyetnynes glycol 3350, polyetny skohol (paralla) hydrolyredi, sub, and stansium dioxide.	193, \$13, or \$2 any of oblinggree roodinn, which is equivalent to go of oblinggree roodinn, which is equivalent to go of oblinger to the supplement of the s	40 mg of gatiramer scetate, 40 mg of mannitol mannitol	COPRISE to their power special and the desired grants imposed and the desired grants in special control power special respectation states. An encourage and the special respectation states and the special respectation of the special special respectation of the special respectation of the special respectation of the special states of the special respectation states are the special and the respectation in the special respectation of the special respectation of the special respectation in the special resp	Each I not of VCTOX subther contains for agricultural and the allowance in the friendings and the allowance in the analysis of the allowance in the allowance i
NDA APPLICANT HOLDER NAME AND ADDRESS	MERCE SAME DOWN. 2000 Galegie ein bad renkwent, in Obless	MEICH SAMP DONAL 2000 Galogne sei Band Kenkwath, IN 088899	Horizon Therapeutics, LLC. 520 Lake Cook Rd Surie S20 Deerfield, IL 60015	lansan Pharmaceuteals, Inc. 1125 Trenten Harbourton Road PD Box 200 Thusville, Nj OBS60-1504	WP HEALTHCARE For More Drive Recently Irlangie Park, NC 277709	TEVA PHARMACEUTICALS USA 400 Interpace Parkway #3 Parilippany, NII 07054	SERVE CATACONS OF SERVER O	NOVO NORDSK INC 800 Soudeers Mill Road Plaintborn, NJ 08536
NDA	022044	021995	203284	022406	204790	020622	205552	022341
NDC	00006-0577-61	00006 0277-31	76325-0100-04	50458-0579-30	49702-0228-13	68456-0325-12	57362-0140-09	00169-4060-13
U.S. GENERIC NAME	19-4750-90000 INTELLORINGHIET 000000 STATE	11/0445004 МІЛП'ЯТІ	GLYCEROL PHENYLBUTYRATE	RIVAROXABAN	DOLITEGRAVIE	GLATIRAMER ACETATE	extintee	LIRAGIUNDE
U.S. PROPRIETARY NAME	Tawnwet	WALLEN	RAVICTI	XARELTO	TWICAY	COPANONE	IMBRUFICA	WETOJA
CANADAIAN INGELDIENTS	The control of the co	13.5 or of staggless propplate monohydrate, which is questionly, and it is expectively, and it is the same investional explanes, surphrous disase calcium plotogeness (actions plotogeness (actions plotogeness propplates) and appropriate plotogeness (actions plotogeness and appropriate plotogeness (actions plotogeness and explaness and explanesses, and explanesses and expla	1.1 g/mi glycerol phenylbutyate (delihers 1.02 g/ml of PBA). There are no excipients.	Rivarozaban, cellulose microcrystaline, crossermentiles sociali apprometores 5 ¢? bactose monolyvitate, magnesium sasarate, sodium itanyi sulphate, ferme coside yellow (2.3 mg), fermi coode red (10 mg, 53 mg, 20 mg). hyprometises 15 ¢? polytebylere glycol, titanium dicoode.	S. J. mg of destroppine codom, which is republished to 30 of geologische free acid, which is republished to 30 of geologische free acid, and a second production of acid, and a second production of acid, and a second production acid, and a second many features. The table filter contribution from the market periodes, and acid many features and the market periodes and acid for the contribution of acid, and the second part hydrolyses, talk, and tables so filter.	glatiramer acetate, marnitol and sterile water for injection.	140 mg of benefith, collided allocan disolate, and colline disolated and colline disolat	6 mg/Mi Legytete, Doedum phoupkate dhydrate, popplere glycol, phenol and water for lightetton
NUMBER OF ACTIVE INGREDIENTS	Ν	4	1		-	1	-	a a
DOSAGE FORM	ТАВЕТ	7ABLET	ORAL LIQUID	TABLET	TABLET	NOILTHON	CAPSUE	SOLUTION
STRENGTH	50-1000 MG	300 MG	1.1 G/ML	20 MG	SOMG	40 MG	140 MG	JWG/JWIT
ADDRESS	16790 foute Transcrudierre Kritian Chelec Cunda Hist AM7	16750 Route Transcandiente Kirklan Guebec Canada Heid AM7	1st Floor, Connaught House 1 Burlington Road Dublin 4	2920 Matheson Blvd East Mississaya Ontario Canada L4W SR6	245 Booleward Armand- Frappier Lavel Quebe Canada HFV 4A7	30 Novopharm Court Toronto Ontario Canada M18 2X9	19 Green less Drive Tocosto Ontario Canada MSC11.9	101-2476 Argentia Road Misutisanga Ontario Canada LSN 6M1
COMPANY	MERCE CANADA INC	MERCY CANADA INC	HORIZON THERAPEUTICS IRELAND DAC	BAYER INC	OND HEALTHCARE ULC.	TEVA CANADA LIMITED	JANSEN INC	NOVO NORDISK CANADA INC
NIG	02333872	02303922	02453304	02378612	02414945	02456915	02434407	02351064 1
CANADIAN GENERIC NAME	METGRINIUSTIAGLIPTE	STAGLPTIN (SITAGLIPTIN PHOSHDATE) MONOHIDBATE)	GLYCEROL PHENYLBUTYRATE	RIVAROXABAN	DOLUTGRAVIR (DOLUTGRAVIR SCOLUM)	GLATIRAMER ACETATE		LIRAGLUTIDE
CANADIAN PROPRIETARY NAME	THEOREM	ANUTAN	RAVICTI	XARELTO	TIMCAN	COPAXONE	IMMBUVICA	VICTOZA

U.S. MOREDIENTS	eferoming claims 2 mg or 20 mg of demonstrate from each The matter are greaters of Throught Tables are Tables Core. The control of the Core of the C	detecteding states 2 mg of long of detecteding the soil The engine and a good man of the control of the control and the control of the control of the control of the and soil man by Special Control of the control of the and soil man by Special Control of the control of the hyperenties in Chelle has a control of the first billion polyectrique gives due to control to the control of the control of the control of the control of the control of the control polyectrique gives due to control to the control of the control of the control of the control of the control of the control of the control of the control of the contro	2 mg of everolimus and the following iteactive ingredients: but/steed hydrocal manuscalidada allona doodke, rospondone, hydrocardone, betroe encodyledrate magnesium stearest, mannish, and microcystalline cellulose.	0.56 mg of fingolimod hydrochoride, equivalent to 8.5 mg of fingolimod, gestain, magnetism steature, mawrito, titanium dioutde, and yellow iron ende.	11 m at thoron because to 327 mg talkatin intens) and the following nature greatest calcles settler, coordions, and present calcles settler, coordions. The present of solid, in proceed collisions of the coordinates of the	300 rs. of incursols excionent is 350.5 mg of excepted proportioning. The control registration of 100 Mg of the Con- Magnitudina states. Interpretating existing, and subsequence, and solution that is pleased according collection, income solution and an administration of the control of the con- sistence and a subsequence of the control of the control properties to the Control of the control	Mrt meastile, polyecides on juricides and sucrose Common of legal (Sucress), immore appreciants, median chain supported to the common	Lea ht of MEX ROS gehelmin emulation creature states of preservant and states of preservant and states of preservant and states and states and states the states and states help and states between the state of states and states in high states and states in high states and states in high states and	Of mag of becapes (BIC) lost instead to \$2.5 mg the designation should be a great of the control
NDA APPLICANT HOLDER NAME AND ADDRESS	NOVARTS One feelih flua East Hanover, NI 07396	NOVARITS One feelith Fluxa East Harrover, NI 07336	NOVARTIS One Health Flaza East Hanover, NJ 07936	NOVARTIS One Health Flaza East Hanover, NJ 07936	PRIER 235 fast 42nd Street New York, NY 10017	NOVARTS One Health Flaza East Harrower, NI 07936	ASTRAZENICA, LP PO BOX 15437 WILAMNGTON, DE 19850	ALLERGAN 5 Giraba Famo Madison, NJ 09740	Gliead Sciences, Inc. 333 Lakeside Drive Foster Chy, CA 94404
NDA	022291	022291	203985	022527	208246	022465	209210	05030	210251
NDC	03078 0685-15	03078-0686-15	15-979-0002	00078-0607-15	00069-0501-30	00078-0670-66	00310-6540-04	00023-9163-30	61958-2501-01
U.S. GENESIC NAME	В ГРОМНОРАС О САМИНЕ	ELTROMIDONG CLAMINE	SURIDIANUS	FINGOLIMOD HYDROCHLDRIDE	TOFACITMIS CITRATE	PAZOPANIB IN'DROCHLORIDE	EXEMIDE	JNIBO4SOTUJ	BICTEGRAVIR SODLIMI; EMPRICTABINE; TROCFOVE ALAFENAMIDE FUMMBATE
U.S. PROPRIETARY NAME	PROMACTA	PROMACTA	AFINITOR DISPERZ	GILENYA	SK TANT 3X	VOTREENT	SCD4 WORNERA	RESTASIS	BIKTARVY
CANADAJAN INGREDIENTS	Is mg or 50 mg of demondopag as demondopag delmen. The tablest also constant the following contronded that general seasons are more assets. mannels, microsytaline soldering, psychologica, psychologica dozden setzie plickine, hipomologica, morange and standam dozdes. RVDUAR 25 mg backet and standam forder, RVDUAR 25 mg backet tablest table contain from deep region and non- tablest also constant from deep region and non- codes rest.	25 mg or 50 mg of detrombogs as eftermbogs of coloning. The salest also contains the following controlled the salest also contains the following controlled the salest all salest and statement amongst and statement educates. RAVIOLAGIS for galactic and statement educates. RAVIOLAGIS for galactic contains projectivels.	Zng everolimus, barylated hydrosytoluene (E321), cellulose microcrystalline, crospoudone, hypromeliose, lactose monohydrate, magnesium stearste, mannitod, silica colloidal anhydrous.	0.5 mg fingolimod (as fingolimod hydrothoide) For the 0.5 mg. Magessium stearsts, mannitol, geistin, sitanium diodide, yellow iron oxide.	It me tortentine las indicacións convente, sorbisol, hydrosyethy cidados, coposidos con magnerium steasane. The first out control existence relates. First out control existence relates, hydrosypcosidos, trebut. ZEDANIENTE perior allos, trebut transmissiones procesanes procesanes hydrosypcosidos, trebut, not ben outile. The hydrosypcosidos, trebuth, not ben outile. Hydrosypcosidos, trebuth, not ben outile. Hydrosypcosidos, trebuth, not ben outile. Hydrosypcosidos, trebuth, not outile hydrosypcosidos.	200M (passare) is passared by decidentical, magnetia in season, miscopratifies estimate, magnetia in season, miscopratifies estimate, poly a leason to passared in the processor (EG) and a miscopratifies are not be used to processor to the passared processor (EG) and the miscopratical passared (EG).	2 mg exenatide jas white to off white microspheres suspended in a MAT vahilol) Sufficient suspended in a MAT vahilol Sufficient suspended eleters 2 mg deleter 2 mg of exenatide extended eleters in 6.85 mf, vahide extended eleters in 6.85 mf, vahide extended eleters in 6.85 mf, vahide eleters in 6.85 mf, vahide eleters off eleters of eleter	(LOSW, w/v is available as a statifie preservative free mission application to the density popularities reposted in the density of the state of the	Young of biotogravi (equalment to 3.3 mg of biotogravi (equalment to 3.3 mg of biotogravi codes). John mg of emerications, and 1.2 mg of the control of the
NUMBER OF ACTIVE INGREDIENTS	et	ed.	1	1	1	,	1	1	м
DOSAGE FORM	TABLET	TABLET	TABLET FOR SUSPENSION	CAPSULE	TABLET	TABLET	SUSPENSION (EXTENDED RELEASE)	EMULSION	TABLET
STRENGTH	25 MG	SOMG	2 MG	0.5 MG	11 MG	200 MG	2 MG/0.85 MIL	0.05%	SO-200-25 MG
ADORESS	385 Bouchard Blvd Dornol Quebec Canada, 195 1A9	385 Bouchard Blvd Dorval Quebec Canada, H95 1A9	385 Bouchard Blvd Dorval Quebec Canada, H95 1A9	385 Bouchard Blvd Derval Quebec Canada, H95 1A9	17300 Trans-Canada Hebway Kirkland Quebec Canada H9J 2MS	385 Bouchard Blvd Dorval Queboc Canada, H95 1A9	1004 Middlegate Road, Suite 5000 Mississuiga Ontario Canada LdY 1M4	S00 85 Enterprice Blvd Markham Ontazio Canada L6G 085	600 6711 Missisauga Road Missisauga Omanio Canada LSN 2W3
CONFANY	NOVARTS PHABMACEUTICALS	NOVARTIS PHARMAGEUTICALS	NOVARTIS PHABINACEUTICALS CANADA INC	NOVARTIS PHABMACEUTICALS CANADA INC	PFIZER CANADA ULC	NOVARTS PHABMACEUTICALS CANADA INC	ASTRAZENECA CANADA INC	ALENGAN INC	GILEAD SCIENCES CANADA INC
NIQ	02361825	02361833	02425645	02365480	02470608	02352303	02483203	02355655	02478579
CANADIAN GENERIC NAME	ELTROMBOPAG OLAMINE)	ELTROMBOPAG (ELTROMBOPAG OLAMINE)	EVEROLIMUS	FINGOLIMOD (FINGOLIMOD HYDROCHLORIDE)	TOFACTINIS CTRATT) 03470608	PAZOPANIB (PAZOPANIB HYDROCHLORIDE)	EXENATIDE	CYCLOSPORIN	EMPRCTABNE, TEMOSOVIR AMFINANDI AND BICTEGRAVIR
CANADIAN PROPRIETARY NAME	RIVOLADE	RIVOLADE	AFINITOR DISPERZ	GILENYA	XELANZ XR	VOTRIENT	BYDUREON BCISE	RESTASIS	BISTARVY

U.S. INGREDIENTS	20 mg. 40 mg. et din ng ef ecksonsteins, which is equivalent to 50 mg. 51 mg. et 24 mg. et chansamely in hande respectively. 52 Mg. et 24 mg. et chansamely chanse respectively. GADGATT via contain the fellowing instein general preference, microsynthism entitions, latena servidence, heleosynemy changes, cross-preference, colored size of entities, and changes of the colored services and colored services.	20 mg, 40 mg, or 60 mg of cubosanteinb), wisch is equivalent to 25 mg, 25 mg, or 50 mg of cubosanteinb), wisch is equivalently. CalloMATY has contain the following instance represents inferior captured may be expected in the following instance agreement inferior-prairies for capture, better as Preferent, inferior-propriet callulate, cross-marking exident allowing instances and management of capital silicon dioxide, and management management management management management and management of capital silicon dioxide, and	mg. 40 mg. or 60 mg of caboursticitis, which is equivalent to 25 mg. or 80 mg. or 60 mg or 60 mg. or 60 mg	Lex habite contino 135 mg of obtagaio, 155 mg of obtatos, 200 mg of obtatos, 200 mg of all members of all members of all members of processing the processing of the state of the obtatos of the state of the obtatos of the state included an extrametton soldino, in processing of the obtatos of	Lea filte-constat shall contains abstore unline equivalence to GO mg of abstorer, death for the contains abstorer unline equivalent to Simple debotegers, and SiD mg all seasonables. This MGC shalles are purple, bloomer, and shot mg all seasonables. This MGC shalles are purple, bloomer, and shot mg all seasonables are set also and contain the little with the seasonable seasonable seasonable seasonable properties and seasonable seasonable seasonable properties are seasonable seasonable properties are seasonable seasonable properties are seasonable seasonable properties and seasonable seasonable properties are seasonable properties are seasonable seasonable properties are seasonable properties properties properties properties properties properties properties properties properties properties properties properties properties properties properties properties properties properties properties properties properties properties properties properties properties properties properties properties properties properties properties properties properties properties properties properties properties properties properties prop	Let baker some 20 gr. (F.C.) my El (F) (quickee; 2.75) function a particulation (p. 17) for all the presents of the formation of the formatio	Active lapredient, mitigations has the ingredent; slicited microcytallier cellulate, actival pycasia; microcytallier cellulate, actival material pycasia; pyconelloc; it anima dioxid; interact, Dick cyclics; to hamman lake, polyacitate Bil, and FOMC, yellow of aluminum lake.
NDA APPLICANT HOLDER NAME AND ADDRESS	20 mg, Exellets, Inc. 1853 Harbor Bay Parkway Mameda, CA 94502	20 mg, 1851 Harbor Bay Parkway Alameda, CA 94502 cel	Exelitis, Inc. 1353 Hardrot Bay Parkway ma. Alameda, CA 94502	Edents (diesd Science, Inc.) (1) Illustrict Deve. (2) The Control of Contr	WW Healthcare Company debath of Gascon MW Healthcare Company bottom of Gascon MW Healthcare Dr. Box 11358 micros Christophe Park, NC 27709 data mi	Each to fingle state of the fingle state of the fingle state of the final state of the fi	Ac Corcept Therapeutics 146 Commonwealth Drive Menio Park, CA 94025 hydrox
NDA	208692	208692	208692	207561	205551 R	20835.1	202107
	42388-024-26	42388-025-26	42388-023-26		49702-231-13		76346-073-01
U.S. GENERIC NAME	CABOZANTINIB 4:	CABOZANTINIB 4:	CABOZANTINIB 4.	R. BATFOCTABRIL, TROPCTORM. 6:2086-2000-1	ABACAWR SUIGATE, DOUTTGRAWN SODUM; 44	BATRICTABRI; BLAVIENE HEROCICLORIC TRANSONS AUFENMENT FUNDONS S1989 2101-1	MIFFPRISTONE
PROPRIETARY NAME	САВОМЕТУХ	CABOMETYX	CABOMETYX	GINOTA	TRUMEQ	J353900	KORLYM
CHARLES INCOME IN	cabosantinib IS malate, cotolodal Silcon Dioxide, Croscantiniolos Solium, Horoxypcoy (Cotolates, Haptometios 25 III, 100 Odde Villoue, Lactae Anhydrous, Magnesium Stearate, Microcystalline Celisiose, Titanium Dioxide and Triacetin.	cabosantini (s) matse, colocial Silcon Dioxido, Consaminelos Solium, Monospoory (challone, Heypromolices Solium, Solio Proder Veledus, Latone Anthydrous, Magnesium Stearste, Microcystalline Cellulose, Thanism Dioxide and Trisectin.	cabouantinib (5) malata, coloidal Silicon Dioxide, Consumilento Sodium, Historyperpy (Gellaten, Hydrorellora 2501, Inn Odde Yellow, Latcue Arthydrous, Magnesiam Stearate, Microrystalline Celulose, Tranlum Dioxide and Triscetin.	bach shart contains 150 mg of entergence, 150 mg of entergence, and 150 mg of entergence and 150 mg of entergonic particular sensitives and entergone deficient de meliteraturals have a legislation of adjustment and the application of adjustment and the regislation of the contramentary entergonic meliterior, lactors are entergorist ent	pdienti. D maenito, magenium stearete, microcr	Cach basis contain 20 mg of TIC, 25 mg of BMV (in 27 mg of BMV whoshboiled had 25 mg of TIV TIV is as 28 mg of TIV sendemants). The tablest also include the following examts tablest also include the following examts reporting an experient assets and monohiphorise, magnetism season. TIV is as the season of the tip of TIV professor. The shader as the most who also the chart as the most polypowing should thank of the tip of TIV thank of the tip of TIV thank of	UNABLE TO LOCATE
	1			q	m	m	UNABLE TO LOCATE
DOSAGE FORM	TABLET	TABLET	TABLET	TABLET	TABLET	TABLET	UNABLE TO LOCATE
STRENGTH	20 MG	40 MG	60 MG	259-159-200-10 MG	DW 00E-05-009	200-25-25 MG	UNABLE TO LOCATE
ADDRESS	SUITE 505 5060 Spectrum Way Mississauga Ontario Canada L4W 5NS	SUITE 505 5060 Spectrum Way Misissauga Ontario Canada LAW SN6	Surtr 565 5060 Spectrum Way Mississauga Ontario Canada LAW SN7	600 6711 Missisauga Fload Missisauga Missisuga Onanto Canada LSN 2793	245 Bouleard Amand- Frappler Laval Quebec Canada H7v 4A7	600 6711 Mitrisrauga Read Mississauga Omario Canada LSN 2W3	UNABLE TO LOCATE
COMPANY	IPSEN BIOPHARMACEUTICALS CANADA INC	IPSEN BIOPHARMACEUTICALS CANADA INC	IPSEN BIOPHARMACEUTICALS CANADA INC	GIEMO SCEINCES CANDA INC	VIIV HEALTHCARE LIC	GIEAD SCIBVCES CANADA INC	UNABLE TO LOCATE
NIG	02480824	02480832	02480840	02449498	02430932	208351	UNABLETO
CANADIAN GENERIC NAME	CABOZANTINIB	CABOZANTINIB	CABOZANTINIB	EMTRICTABNE, TRIODO VER AASTEMANDE, EVITTGEMAN AND COBIGSTAT	AMPUDINE, ABACAVIR AND DOLUTIGRAVIR	EMTROTIABNU; RILPINGRINE HYBRIO CHURRIE TENGEVIR ALAFENANIDE FUMMANTE	UNABLE TO LOCATE
CANADIAN PROPRIETARY NAME	CABOMETYX	CABOMETYX	CABOMETYX	AYOWAYA.	TRUMEQ	A35.900	UNABLE TO LOCATE
4							,

STANDSCHOOL ALL	Each lin-coased tablet contains 200 mg of emiriciables and 300 mg of mericiables and 300 mg of mericiables and 300 mg of mericiables and 400 mg of mericiables and 400 mg of mericial and excellent and index and excellent and ex	Active ingredient apicabace, heache ingredients anhydrous income, microstyniaerie endolous, comessione seden, andeloim insul- tablic, and regulation incomessione seden, andeloim insul- tablic, and regulation incomessione sedential incomessione in monthylation. In generalizes, traversion discolor, traverse, and relates from order (2.5 mg stabled) or ned from other (5.5 mg stabled).	
SECURITY OF THE SECURITY OF TH	Glaed Science, Inc. 333 Laberice Grove Fronter City, CA \$44404	Britos Myers Squibb P.O. Box 4000 Princeton, NJ 08543-4000	
KDA.	21:752	202155	
DON	61958-0701.1	0003-0894-21	
New Symmils and Table 1970.	DOTECTIANE, ENCYCOR.	APIXABAN	
ANN DEPENDEN	TRIVAGA	ELQUIS	
ELEGICIANO INVESTMONO	Leth sakes centure 120 mg of emiscitation and all structure 120 mg of emiscitation and all structure 120 km and an all structure 120 km and as a structure 120 km and a structure 120 km and as structure 120 km and as a structure 120 km and as structure 120 km and as a structure 120 km and as structure 120 km and as a structure 120 km and as structure 120	Azine legeolent. Apisaban Eucipiente. Tabet cores. Administrations, microsyntaline desidose, creamentos sodium. rodalin hary datas and sagressimi tesaran. contain hary datas and sagressimi tesaran. tesaran administrativa, and pieno intro cele ta migrativa or med son societi from guibies).	
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NOON TO THE TOTAL THE TOTAL TO THE TOTAL TOT	TABLET	TABLET	
d HOMMAS	ZOD-300 M/G	5 MG	
ACONESS	CO 571 Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melensep Melen	2344 Boul, Affred-Nobel, Suite 300 Montrée (Straurent) Queboc Canada H45 0A4	
ANYEMOD	ORTO SCIENCE COMPAN NC	BRISTOL-AVYERS SQUIBB CANADA	
ă	90687.220	02397714	
BANGLINAD	TRIGOVID DEOPRORL AND EATHEFT ARM	APUABAN	
AWY, LYCHISCHA WECCHYO	TRUVADA	ELQUIS	





Source: Publicly available document October 8, 2020 NM SIP Application to FDA

Find the entire application online at our website: $\underline{www.safemedicines.org}$

Source: document can be found on PSM's website.

The following drugs were submitted as part of New Mexico's SIP application dated October 8, 2020.

Latuda	Ventolin HFA	Advair Diskus	Chantix
Descovy	Jardiance	Invokana	Farxiga
Uptravi	Tecfidera	Xifaxan	Janumet
Januvia	Ravicti	Xarelto	Tivicay
Copaxone	Imbruvica	Victoza	Tasigna
Sprycel	Zytiga	Xtandi	Ofev
Promacta	Afinitor Disperz	Gilenya	Jakafi
Xeljanz XR	Votrient	Bydureon Bcise	Restasis
Biktarvy	Cabometyx	Genvoya	Triumeq
Odefsey	Truvada	Eliquis	

On the next ten pages, we have included the original ten-page listing from New Mexico's October 8, 2020 application.

Each tablet contains 40 mg of lurasidone hydrochloride, inactive ingredients are amonitol, preglatnized starch, croscamellose somin, hydromellose, magnesium stearate, Opadry* and camauba wax. Additi Each tablet contains 80 mg of lurasidone hydrochloride, inactive ingredients are mannitol, pregiathrized stark, croscamellose sondin, hypromellose, magnesium stearate, Opadry® and camauba wax. Additi Each tablet contains 20 mg of lurasidone hydrochloride, inactive ingredients are mannitol, pregelatinized starch, roscarmellose sodium, hypromellose, magnesium stearte, Opadry* and carnauba wax. Additi Each tablet contains 60 mg of lurasidone
Mytorchloride. Inactive ingredients are
mannitol, pregelatinized starch, croscarmellose
sodium, hypromellose, magnesium stearate,
Opadny* and carnauba wax. Additi Active ingredient: albuterol sulfate Inactive ingredient: propellant HFA-134a salmeterol xinafoate Inactive ingredient: lactose monohydrate (contains milk protein U.S. INGREDIENTS croscarmello dioxide, magne (for 0.5 mg), (Sunovion Pharmaceuticals, Inc. One Bridge Plaza, Suite 510 Fort Lee, NJ 07024 Sunovion Pharmaceuticals, Inc. One Bridge Plaza, Suite 510 Fort Lee, NJ 07025 Sunovion Pharmaceuticals, Inc. One Bridge Plaza, Suite 510 Fort Lee, NJ 07026 Sunovion Pharmaceuticals, Inc. One Bridge Plaza, Suite 510 Fort Lee, NJ 07027 GlaxoSmithKline Five Moore Drive P. O. Box 13398 Research Triangle Park, NC 27709 PF Prism C V c/o Pfizer, Inc 235 East 42nd Street New York, NY 10017-5755 GlaxoSmithKline 5 Moore Drive Mailstop 5.58 arch Triangle Park, t. 27709 NDA APPLICANT HOLDER NAME AND ADDRESS NDA 63402-304-30 63402-308-30 0173-0696-00 NDC U.S. U.S. PROPRIETARY NAME GENERIC NAME SALMETEROL AND FLUTICASONE LURASIDONE LURASIDONE VENTOLIN HFA ADVAIR DISKUS LATUDA LATUDA LATUDA LATUDA CHANTIX lurasidone hydrochloride, carnauba wax, cocarmellose, adum, hypomollose, magnesium, stearate, mannio, Opadry, propromollose, postkylviene glv.col, and ttanium dioudel, pregelatines starch; 80 mg tabet also cornains; FDAC Blue No.2 Aluminum, the and ystilow ferric oxide. magnesium stearate, mannitol, Opadry*
(hypromeliose, polyekhrene givol, and titanium dioxide), pregelatinized starch;
80 mg tablet also contains: FD&C Blue No.2 Alumium Lake and yellow ferric oxide. magnesium stearate, and microsystaline cellulose. The film-coating contains hypromeliose, polyethylene glycol, thankna disode and triacetin. The 1.0 mg tablet also contains TOBX Elbu et Alfundigo Camine Aluminum Jake as a colouring agent. 250 mcg fluticasone propionate and 50 mcg salmeterol (as the xinafoate salt) CANADAIAN INGREDIENTS NUMBER OF ACTIVE INGREDIENTS METERED-DOSE AEROSOL STRENGTH FORM TABLET TABLET TABLET POWDER TABLET 250/50 0.5 MG 20 MG 40 MG 9W 09 80 MG ACT 17300 Trans-Canada Highway Kirkland Quebec Canada H9J 2M5 7025 Langer Drive, Suite 301 Mississauga Ontario Canada LSN 0E8 7026 Langer Drive, Suite 301 Mississauga Ontario Canada LSN 0E8 7027 Langer Drive, Suite 301 Mississauga Ontario Canada LSN 0E8 7028 Langer Drive, Sulte 301 Mississauga Ontario Canada LSN 0E8 Road Mississauga Ontario Canada LSN 6L4 7333 Mississauga Road Mississauga Ontario Canada LSN 6L4 ADDRESS SUNOVION PHARMACEUTICALS CANADA INC SUNOVION PHARMACEUTICALS CANADA INC SUNOVION PHARMACEUTICALS CANADA INC SUNOVION PHARMACEUTICALS CANADA INC SMITHKLINE INC 02387751 02413361 02387778 02241497 02240836 02291177 NIQ CANADIAN CANADIAN PROPRIETARY NAME GENERIC NAME SALMETEROL AND FLUTICASONE LURASIDONE HFA ADVAIR DISKUS LATUDA LATUDA LATUDA LATUDA CHANTIX

DRUG LIST WITH REQUIRED HPFB AND FDA DATA ELEMENTS Page 1 of 10

U.S. INGREDIENTS	Each 0.5 mg CHANTX tablet contains 0.85 mg of varendien Eartate squoident to 0.5 mg of varendien Fareta sepas, each 1 mg CHANTX tablet contains 1.71 mg varendien teatrate eguwhent to 1 mg of varendien teatrate elguwhent to 1 mg of varendien teatrate elguwhent to 1 mg of varendien teatrate elguwhent to 2 mg of varendien teatrate elguwhent in contropretaline cellulose, anhydrous clabaci cellulose, anhydrous clabaci cellulom phosphate, crossarmellose sedum; colledal sillicon diocide, magnesium stearate, Opadry* White (for 0.5 mg, Opadry* Clear; n mg, and	Each 200/25 mg tablet contains 200 mg of emtricitabine (FTC) and 25 mg of tendiorid allatenamide (TAF) and the following inactive imagenetism scarses, and microcrystaline collutions. The tables are film costed with a couling material containing indigo carmine aluminum lake, polyethylene glycol, polywiny alcohol, tale, and transium dioxide.	25 mg of empaglificatin (free base) and the following hacther ingredients: lactore monabydrate, marcorystilline cellulose, mydrasypropy feellulose, crossammeliose sodium, colleda laticand disolder and magnesium stearate in addition, the film coating contains the following in	100mg of canagillosin or 300mg of canagillosin, crostameliose sodium, hydroxypopy losillosis, bactose anhydrous, magnesium stearate, and microcrystalline cellulose, in addition, the tablet casaling contains from oxide yellow ET22 (100 mg tablet combis, macrogio/PES, polywary) alcohol, talc, and Itanium dioxide.	JOOmg of canagillionin or 300mg of canagillionin, croscamellose sodium, hydroxypoty cellulose, bactose anhydrous, magnesium stearate, and microcrystalline cellulose, in addition, the tablet casaling contains and experience on the state of the contains from oxide yellow ET22 (100 mg tablet only), macrogol/PES, polywary alcohol, talc, and thenlum disoide.	5 mg dapagilflotin as dapagilflotin propanediol or the equivelent of 10 mg dapagilflotins and dapagilflotins and propanediod, imcorystalline cellulose, anhydrous lactose, crospovidone, silicon dioxide, and magrelant stearer. The film costing contains; polyvnyl alcohol, tranium dioxide, polyvthylene gyrot, tanium dioxide, polyvthylene gyrot, tani, and yellow
NDA APPLICANT HOLDER NAME AND ADDRESS	PF Prizn C V c/o Pfiter, inc 235 Est 42nd Street New York, NY 10017-5756	Glied Sciences, Inc. 333 Lakeside Drive Foster Chy, CA 94404	Boehringer Ingelheim Pharmaceuticals, Inc. 900 Ridgebury Road P.O. Box 368 Ridgefield, CT 06877	Janssen Pharmaceuticals, 1125 Trentor-Harbourton Road PO Box 200 Titusville, NJ 08560-1504	Janssen Pharmaceuticals, 1125 Trenton-Harbourton Road PO Box 200 Titusville, NJ 08560-1504	ASTRAZENECA LP PO BOX 15437 WILMINGTON, DE 19850
NDA	021928	208215	204629	204042	204042	202293
NDC	0069-0469-56	61958-2002-1) 208215	0597-0152-30	50458-0140-30 204042	50458-0141-30 204042	00310-6205-30
U.S. GENERIC NAME	VARENICLINE	EMTRICITABINE; TENGFOVR ALAFENAMIDE FUMARATE	EMPAGLELOZIN 0597-0152-30 204629	CAGLIFLOZIN	CAGLIFLOZIN	DAPAGLIFICZIN (0310-6205-30 202293
U.S. PROPRIETARY NAME	СНАИТІХ	MOSSIG	JARDIANCE	INVOKANA	INVOKANA	FARXIGA
CANADA!AN INGREDIENTS	oxidum phosphate, colloidas illicom diodes, corcamellore sodium, diodes, corcamellore sodium, magnetium stearete, and microcystalier edulious. The film coarries contains hypomeellose, polychythere gold, til states take and tricetin. The 1.0 mg taket stok contains FD&C Blue Z./Indige Camine Aluminum Lake as a colouring agent.	200 mg emtrictabine, 25 mg tendrovir adalenande, incroorstamterostilosos, consamellos socialm, and magnetim stearate. The gret tablets are film-coated with a coating material containing polywing alcohol, tetanium foode, posychiyeme grotosi, tetanium foode, posychiyeme grotosi, tetanium foode, posychiyeme grotosi and the acoated with a coating material containing polywing alcohol, tetanium dioxide, posychiyeme glycol, tanium dioxide, posychiyeme glycol, tanic, and carmine aluminum lake.	25 mg of empagliflozin free base, coloida is illom dioxide, croscarmelione sodium, hydroxypropyl cellulose, prypromellose, bascos emonohydrate, magnesium stearte, macrogol, microcrystalline cellulose, titanium dioxide, tale, and yellow ferric oxide.	100mg of canagillocin OR 300mg of canagillocin. Core Table: croscarrellose acidum, hydrospopog relutices, lattose anhydrosy, magresium sestante, and microsynaline cellulose. Film Cost, iron oxide velove, (100 mg phosb), polywith alcohol, bolywith alcohol, takc, and ttanium dioxide.	100mg of canagilitorin OR 300mg of canagilitorin Core Takes canagilitorin Core Takes Canagilitorin Core Takes Callose, Batchose anhydroxy magnesium searant e, and mucosynaline cellulose. Film Cast: ten noide velove (100 mg. takes can't), knorzogo (topoketywne głycol), polywny alcohol, take, and ttannium dioxide.	5 mg or 10 mg dapagiflotin as dapagiflotin as dapagiflotin propared in monthyldrate, anhydrate, anhydrate, anhydrate, anhydrate, anhydrate, angareate, microcystallim, angareate, microcystallim coates comiant be following film coates comiant be following innative ingredients; polywiny alchool, thantium dioxide, polyethyldren glyrol, trantium dioxide, polyethyldren glyrol, talanium dioxide, polyethyldren glyrol.
NUMBER OF ACTIVE INGREDIENTS	r d	N	1	н	स	ц
DOSAGE FORM	TABLET	TABLET	TABLET	TABLET	TABLET	TABLET
STRENGTH	1 MG	200-25 MG	25 MG	100 MG	300 MG	S W S
ADDRESS	17301 Trans- Canada Highway Kirkland Quebec Canada H9J 2MS	600 6711 Mississauga Road Mississauga Ontario Ontario Canada LSN 2W3	5180 South Service Road Burlington Ontario Canada L7L 5H4	19 Green Belt Drive Toronto Ontario Canada M3C 119	19 Green Belt Drive Toronto Ontario Canada M3C 119	1004 Middlegate Road, Suite 5000 Mississauga Ontario Canada L4Y 1M4
COMPANY	PFIZER CANADA ULC	GILEND SCIENCES CANADA INC	BOEHRINGER INGELHEIM (CANADA) LTD LTEE	JANSSEN INC	JANSSEN INC	ASTRAZENECA CANADA INC
NIG	02291185	02454424	02443945	02425483	02425491	02435462
CANADIAN GENERIC NAME	VARENICLINE	EMTRICITABINE AND TENOFOVIR ALAFENAMIDE	EMPAGLIFLOZIN	CANAGLIFLOZIN	CANAGLIFLOZIN	DAPAGLIFOZIN
CANADIAN PROPRIETARY NAME	CHANTIX	DESCOVY	JARDIANCE	INVOKANA	INVOKANA	FORXIGA

	J	e	a di I E di I E M	p	. 5 2
U.S. INGREDIENTS	5 mg dapagilitorin as dapagilitorin propanediol or the equivalent of 10 mg dapagilitorin as dapagilitorin as propamediold, microcrystalline cellulose, andydrous baccar, cropporlone, allicon decode, and magnesium steared. The film costing contains polyviny alcohol, transium dioxide, polytetylene glocol, tilanium dioxide, polytetylene glocol, talc, and yellow	selecipag 1400mg inactive ingredients: D- manifol, corn starte, low substituted hydroxyportyletalizose, and magnesium approxypcatelizose, and magnesium starte. The labelians are film consider with a coating material containing hyprometicos, work along with those oxide red, for containing wax along with those code red, for containing yellow, or fron oxide black.	240mg dimethyl fumarate, microcrystalline cellulose, sillefied microcrystalline cellulose, sillefied microcrystalline cellulose, sillefied microcrystalline cellulose, sillefied microcrystalline, the sillefied colloidal sillefied magnetism steep stress the stretch sillefied cald copolymer city of methatory's cald copolymer dispersion, methatory's disclosion, method of sillefied sillef	Rifaximin 550mg, colloidal silicon dioxide, disodund dioxidum dioxidum deletate, glycerol palministearate, hypromeliose, microcrystaline celluiose, propyleme glycol, red moxide, sodium starch glycolate, talc, and ttalmum dioxide, coldium starch glycolate, talc, and ttalmum dioxide.	stbajlotin and metformin, microcrystalline subjects, polyvinghoden, sodium Buryl sulfate, and sodium steay / Immare. The subject film cardie of contains the following inactive ingerdents polyving alcohol, polystbylene glyco, late, transium diodde, red fron odde, and black fron odde
NDA APPLICANT HOLDER NAME AND ADDRESS	ASTRAZENECA LP PO BOX 15437 WILMINGTON, DE 19850	Actelion Pharmaceuticals US, S000 Shoreline Court, Ste. South San Francisco, CA 94080, USA	Biogen IDEC Inc 225 Binney Street Cambridge, MA 02142	SALIX PHARMACEUTICALS 1700 Perimeter Park Drive Morrisville, NC 27560	MERCE SHARP DOHME 2000 Galloping HII Road Kenilworth, NI 088889
NDA	202293		204063		022044
NDC	00310-6210-30	66215-0614-06 207947	64406-0006-02 204063	65649-0303-02 022554	00006-0575-61 022044
U.S. GENERIC NAME	DAPAGLIFLOZIN	SELEXIPAG	DIMETHYL FUMARATE	RIFAXIMIN	SITAGLIPTIN/ME TFORMIN HCL
U.S. PROPRIETARY NAME	FARXIGA	UPTRAVI	TECFIDERA	XIFAXAN	JANUMET
CANADAIAN INGREDIENTS	5 mg or 10 mg dapagificini as dapagificino proportioni opportioni any dapagificino a mayorou sicrosa, crospordioni, any divorus sicrosa, crospordioni, magnesium stearte, nicrocystalline cellulose, siloni obolido, in discolario di film cauding contains the following film cauding contains the following interferenties: polyvenity-lene givoci, transim daudde, polykehylene givoci, talariam daudde, polykehylene givoci, talariam daudde, polykehylene givoci,	Selezing 1400mg, carnaba wax, con starch, Drnannich, Jindongong cellulose, hypomellose, cellulose, hypomellose, hydroxypropyl cellulose, nagmesium stearate, propylene glycol, itanium stearate,	240 mg of dimethy lumante, colloidal alligiond deode, accordantellos es odium magnesium stearste, methacnýtic acid copolymet (kipe A), methacnýtic acid copolymet (kipe A), methacnýtic acid sinchtelom, postulna lavy slatifat, bac sinchtelom, acidno lavy slatifat, bac and triethy (citrat. The opsule shell and triethy (citrat. The opsule shell contains back from oxide, PSAC Blee 1, gelastin, titanium dioxide and yellow from oxide	Rifaximin 550mg, colloidai silicon dioxide, glycenyl distearate, microcrystalline cellulose, polyethylene glycol, polyivinyl alcoudy, red iron oxide, gluten-free sodium starch glycolate, lac, and titanium dioxide, and titanium dioxide.	64.25 mg stragilatin phosphate monohydrate and meteromin hydrochoide equivalent to 50 mg stragilatin are base and 500 mg stragilatin are base and 500 mg meteromin hydrochoide (AMUNINET'S 500 mg meteromin hydrochoide (LAMUNINET'S 50 mg 1000 mg motorhoide (LAMUNINET'S 50 mg 1000 mg motorhoide (LAMUNINET'S 50 mg 1000 mg, motorhoide (LAMUNINET'S 50 mg 1000 mg, motorhoide, sodium ban'y sulfate, and sodium stean'y furmanet in addiction, bed inmoorhoide incidence to polymylpytrolicing polymylpytrolicing contains the following incidence interedients polymylpytrolicing sodium; alcohol polymylpytrol goot lack standard clouds, red into sodie, and sidnohol polymylpytro glocol lack standard clouds, red into sodie, and standard sidnohol sodie, red into
NUMBER OF ACTIVE INGREDIENTS	1	£		1	2
DOSAGE	TABLET	TABLET	CAPSULE (DELAYED- RELEASE)	TABLET	TABLET
STRENGTH	10 MG	1400 MCG	240 MG ((550 MG	S0-500 MG
ADDRESS	1004 Middlegate Road, Suite 5000 Mississauga Ontario Canada L4Y 1M4	19 Green Belt Drive Toronto Ontario Canada M3C 119	90 Burnhamthorpe Road West, Suite 1100 Mississauga Ontario Canada LSB 3C3	400 Somerset Corporate Boulevard Bridgewater, NJ 08807	16750 Route Transcandlenne Kirkland Cuebec Canada H9H 4M7
COMPANY	ASTRAZENECA CANADA INC	JANSSEN INC	BIOGEN CANADA INC	SALIX PHARMACEUTICALS INC	MERCK CANADA INC
NIQ	02435470	02451212	02420201 B	02410702	02333856 N
CANADIAN GENERIC NAME	DAPAGLIFOZIN	SELEXIPAG	DIMETHYL	RIFAXIMIN	METFORMIN/SIT AGLPITN
CANADIAN CANADIAN PROPRIETARY NAME GENERIC NAME	FORXIGA	UPTRAVI	TECFIDERA	ZAXINE	JANUMET

U.S. INGREDIENTS	stagistics and hetforms, microcystilline cellulosis, solid market misses and metforms, and metros elicitors, solid market misses in polytics, and existing metros from the fill morals in misses from misses and polytics, polytics polytics, and consider metros from the misses of misses and pack from order and back from order.	128.5 mg of stagilprin phosphate monohydrate, who have been of the page and the following heart with the medical monohydrate, which is equivalent to 100 mg. Invastry of the base and the following history being the medical monohydrate, crocarmeliose codium, magnesium research, crocarmeliose codium, magnesium research film coasing contains the following nactive ingredients, polyvicular, it framium dioxide, not following matrix in glidycol, talk; I trainium dioxide, not for no orde. and yellow iron code.	 1.1 g/ml of glycerol phenylbutyrate (delivers 1.02 g/ml of phenylbutyrate). 	rivorcadan, crocamelices codium, hyporentices, bacos monohydrate, magnetium stearte, microsystaline cellotos, and codium landy staffer, left crooker et, polyethylene glocal 3350, polyviniy alcohol (partially hydrolyted), bit., and titanium dioxide.	105, 26.3 or \$2.6 mg of delutegrani sodium, half his equivalent to \$20 mg delutegrani regerint in equivalent to \$20 mg delutegrani respectively. Dramantol, microcrystaline abudicas, provident \$29.823, sodium starch glycolate, and sodium steavi furmate. The tablef film-costing ordaniar the match was deluted to so code eyelow (for the \$5.0 mg of the starch sound some starch sound some sound some starch sound some suit of some stakes only, mancapolified, polyviny) alcohol-spart hydrolyted, tale, and some suit sound of some suit sound suit suit suit suit sound suit suit suit suit suit suit suit suit	ng of glatiramer acetate, 40 mg of mannitol man
NDA APPLICANT HOLDER NAME AND ADDRESS	MERCK SHARP DOHNE 2000 Galloping Hill Road Kenilworth, NJ 088889	MERCK SHARP DOHNE 2006 calioping HII Road Kenilworth, NJ 088889	Horizon Therapeutics, LLC. 520 Lake Cook Rd Suite 520 Deerfield, IL 60015	Janssen Pharmaceuticals, inc. 1125 Trenton-Harbourton Road PO Box 200 Titusville, NJ 08560-1504	VIIV HEALTHCARE Five Moore Drive Recent'Th Triangle Park, NC 27709	TEVA PHARMACEUTICALS USA 400 Interpace Parkway #3 Parsippany, NJ 07054
NDA	022044	021995	203284	022406	204790	020622
NDC	00006-0577-61 022044	00006-0277-31 021995	76325-0100-04 203284	50458-0579-30	49702-0228-13	68456-0325-12 020622
U.S. GENERIC NAME	SITAGLIPTIN/ME TFORMIN HCL	SITAGLPTIN PHOSPHATE	GLYCEROL PHENYLBUTYRA TE	RIVAROXABAN 50458-0579-30 022406	DOULTGRAVIR 49702-0228-13 204790	GLATIRAMER ACETATE
U.S. PROPRIETARY NAME	LEWINERT	JANUVIA	RAVICTI	XARELTO	TIVICAY	COPAXONE
CANADAIAN INGREDIENTS	64.25 mg siteglicini phosphate monohydrate and meteromin hydrochioride squivalent to: 50 mg siteglicin is fee base and 50 ng meteromin hydrochioride (pulkUME* 50 ng mg/500 mg. 500 ng meteromin hydrochioride (pulkUME* 50 mg/500 mg. mg/ indrocynorg meteromin hydrochioride (pulkUME* 50 mg/500 mg.) hydrochioride (pulkUME* 50 mg/500 mg.) hydrochioride (pulkUME* 50 mg/500 mg.) mg/, mdrocynorgalime edilose, polyvivlyperrolidom, sodium bany udfas, and sodium stany udfas, and sodium stany ingredients; polyvini ingredients; polyvini hydrochioride (pulkume glocol, tac, taniam dioder, nd fore oode, and taniam dioder, nd fore oode, and taniam dioder, nd fore oode, and taniam dioder, nd fore oode, and	128.5 mg of slaaglipin phosphate monohydrate, which is equulvient to 100 mg, expectively, of the abuse, microrystaline reliuloos, amhdrous dissist calcium phosphate (calcium bloss) calcium prosphate (calcium anhydrous), coccamentoses coldium saphrous), coccamentoses coldium stearite, and coldium stearite ingereletics; polyviny alcohol, finantive ingereletics; polyviny alcohol, finantive ingereletics; polyviny alcohol, finantive ingereletics; tolyviny alcohol, finantive ingereletics; tolyviny alcohol, finantive ingereletics; tolyviny alcohol, finantive ingereletics; tolyviny alcohol, finantive indexide, and yellow from coldie.	1.1 g/mL glycerol phenylbutyrate (delivers 1.02 g/mL of PBA). There are no excipients.	Rivaroxban, cellulose microcrystalline, croscarmellose sodium, hipromellose 5 od by Latose monohydrate, magnesium stearate, sodium launy suphaste, ferric dele wilow (2, 5 mg.) ferric oxide red (10 mg. 15 mg. 20 mg.) kmy composible sub- P, polyethylene glycol, titanium dioxide	\$2.6 for gold dolutegravic sodium, which is equivalent to 50 mg dolutegravir free and, respectively, and the following inactive ingredients: Demantiol, microsystalise cellulose, provident (2292), acidium starto pilocolae, and coolium starto pilocolae, and cooling contains the inactive ingredients from code yellow (23 mg and 50 mg tablets only), marcogol/PSC, polyvinyi alcohol—past Myndoxod, lack, and confident coolium starto pilocolum starto p	glatiramer acetate, mannitol and sterile water for injection.
NUMBER OF ACTIVE INGREDIENTS	N	ч	1	н	ч	п
DOSAGE	TABLET	TABLET	ORAL	TABLET	TABLET	SOLUTION
STRENGTH	50-1000 MG	100 MG	1.1 G/ML	20 MG	50 MG	40 MG S
ADDRESS	16750 Route Transcandemen Kirkland Guebec Canada H9H 4MP	16750 Route Transcanademe Krikand Guebec Canada H9H 4M7	1st Floor, Connaught House 1 Burlington Road Dublin 4 Ireland D04 C5Y6	2920 Matheson Blvd East Mississauga Ontario Canada L4W 5R6	245 Boulevard Armand-Frappier Laval Quebec Canada H7V 4A7	30 Novopharm Court Toronto Ontario Canada M1B 2K9
COMPANY	MERCK CANADA INC	MERCK CAUADA INC	HORIZON THERAPEUTICS IRELAND DAC	BAYER INC	VIIV HEALTHCARE ULC	TEVA CANADA LIMITED
NIQ	02333872	02303922	02453304	02378612	02414945	02456915
CANADIAN GENERIC NAME	METFORMIN/SIT AGUPITN	SITAGLIPTIN (SITAGLIPTIN PHOSPHAITE MONOHYDRATE	GLYCEROL PHENYLBUTYRA TE	RIVAROXABAN	DOLUTEGRAVIR (DOLUTEGRAVIR SODIUM)	GLATIRAMER ACETATE
CANADIAN CANADIAN PROPRIETARY NAME GENERIC NAME	дамплечт	JANUVIA	RAVICTI	XAREITO	TIVICAY	COPAXONE

DRUG LIST WITH REQUIRED HPFB AND FDA DATA ELEMENTS Page 4 of 10

DRUG LIST WITH REQUIRED HPFB AND FDA DATA ELEMENTS Page 5 of 10

U.S. INGREDIENTS	desatinb, with the following inactive ingredients: alocalents: accommonyarian monocyprates, consistent and moreorystalline cellulose, cross-armelose sodium, hydroxypropy reliulose, and magnesium stearter in be tablet coating consists of hypomeliose, thanking dioxide, and polyeethylene giycol.	500 mg abiraterone acetate, coiloidai silicon dioxide, croscammeliose sodium, hypomeliose, latoce monohydrate, magnestium searate, allicified microcystaline cellulose, and sodium launy abilities. The coatain Coatain Puruje, contains fron oolde baled, fron oode red polyeethydene glycol, polywinyl alcohol, talc, and translum doode.	40 mg of enzalutamide as a solution in capyfocapuny polywydyterides. The inactive polywydyterides a prathricapuny in polywydyterides, burkete hydroxymaiola, burkjated hydroxymolaules, gedain, sonbiol sorbitan solution, gyfeerin, purfited water, titanium dioxide, and black iron oxide	100 mg or 150 mg of nintedanib (equivalent to 120 mg or 130 mg or 130 om ennedanib ethineseulfonate, respectively). The nactive ingredents of OFt verte following: Fill Material: tribycerides, hard fat, letthin. Capsule Shell: gelatin, glycerol, Itanium dioxide, red ferit coide, yellow ferric oxide, plack in black inc.	100 mg or 150 mg of nintedanib (equivalent to Lion) mg or 150 mg of sloop mendedanib ethanesulfonate, respectively. The nactive ingredients of OFV we the following: Fill Material: trip/cerdies, had fat, lecthin. Capsule Shell: geldanir, givereol, titanium dloxide, red ferric coide, gellow ferric coide, eldoxide, red ferric coide, eldoxide.
NDA APPLICANT HOLDER NAME AND ADDRESS	BRISTOL MYERS SQUIBB 430 E 29th Streat 14th Floor New York, NY 10016	JANSSEN BIOTECH, INC. 800 Ridgeview Road Horsham, PA 19044	ASTELAS One Astelias Way Northbrook, IL 60062	Boehringer Ingelheim Pharmaceuticals, Inc. 900 Riegeury Tood P.O. Box 368 Riegerfeid, CT 06877	Boehringer Ingelheim Pharmaceuticials Inc. 900 Bidgebury Acad P.O. Box 366 Ringerield, CT 06877
NDA	021986	202379	203415	205832	205832
NDC	00003-0852-22 021986	57894-0195-06 202379	00469-0125-99	00597-0143-60 205892	00597-0145-60 205832
U.S. GENERIC NAME	DASATINIB	ABIRATERONE ACETATE	ENZALUTAMIDE 00469-0125-99 203415	NINTEDANIB	NINTEDANIB ESYLATE
U.S. PROPRIETARY NAME	SPRYCEL	ZYTIGA	XTANDI	OFEV	OFEV
CANADA!AN INGREDIENTS	50 mg and 100 mg distatinin (as monohydrate) containing the following mon-medicinal ingredients for the tablet, or crostameliose sodium, hydroxyporaline, alexone monohydrate, magnesium steante and moricorystaline cellulose. The firm coating contain the following inactive coating contain the following inactive gedients: hypomeliose, polyethyleme glycol and translum dioode.	500MG abiraterone acetate, colloidal silicon dendude, crosarmellose, consarmellose dendum, hypomellose, lactose monohidrate, margersium steante, sileried microcrystaline, and roalium laury silante. The tablest life monohing contains from doeb lack, from coder est, marcogo 3350, polyvinyl acidool, lack, and thanium dioxides.	do mg of enzalutunide and the inactive ingredient caphricaryoristic appropriate caphricaryoristic and business. business caphricaryoristic and business. business capture shell are gletalen, softiol softiam solution. By gletalen, softial softiam solution in manifest softial softiam disolated EST, softial softi	100 and 150 mg of initedanib (as a free base) corresponding to 120.40 mg and 180.60 mg of initedanib (as of initedanic ethinicalization te (talista), respectively. Cappute fill, Medium chain trigheeride, hard fill and the cap technic (1522) capute shell; celatin, giverno 85 %, transium double (1217), into node red (1517), into mode red (1517), but chird (Opacode*) shell celating the capute (1517), but chird (1520) corporates the capute of the cap	100 and 150 mg of nintedamb (as a free base) corresponding to 120.040 mg and 138.05 mg of nintedamb (as of nintedamb (as of nintedam) capacities (challed). Fragacties (challed)
NUMBER OF ACTIVE INGREDIENTS	1	1	1	Ħ	rt
DOSAGE FORM	TABLET	TABLET	CAPSULE	CAPSULE	CAPSULE
STRENGTH	100 MG	500 MG	40 MG	100 MG CAPSULE	150 MG
ADDRESS	2344 Boul. Alfred- Nobel Suite 300 Montreal (St- Laurent) Quebec Canada H4S 0A4	19 Green Belt Drive Toronto Ontario Canada M3C 11.9	SUITE 500 675 Cochrane Drive, West Tower Markham Ontario Canada, I3R0B8	5180 South Service Road Burlingicon Ontario Canada L71,5H4	5180 South Service Road Burlington Ontario Canada IZL SHA
COMPANY	BRISTOL-MYERS SQUIBB CANADA	JANSSEN INC	ASTELLAS PHARMA CANADA INC	BOEHRINGER INGELHEIM (CANADA) LTD LTE	BOEHRINGER INGELIEIM (CANADA) LTD LTEE
DIN	02320193	02457113	02407329	02443066	02443074
CANADIAN GENERIC NAME	DASATINIB (DASATINIB MONOHYDRATE)	ABIRATERONE ACETATE	ENZALUTAMIDE	NINTEDANIB (MINTEDANIB ESILATE)	NINTEDANIB (NINTEDANIB ESILATE)
CANADIAN CANADIAN PROPRIETARY NAME GENERIC NAME	SPRYCEL	ZYTIGA	XTANDI	A340	OFEV

DRUG LIST WITH REQUIRED HPFB AND FDA DATA ELEMENTS Page 6 of 10

U.S. INGREDIENTS	eltrombopag olamine 25 mg or 50 mg of eltrombopag olamine 25 mg or 50 mg of eltrombopag free acid. The instache ingredients of PROMACTA tablets are Tablet Gree magnesiam teatrate, manned, microcytataline cellulose, povidorone, and osdam starch glycolate. Coaling: FDR. 5 llue. No. 2 aluminum late (25 mg ballet), PROSC reliaw. No. 6 aluminum late (25 mg ballet), propromeilose, front Gellulose, providoro Codo Red (25 mg ballet), polybethylene glycos 400, polybethylene 200 tolataliam dioxide.	ettromboeg clamine 25 mg or 50 mg of ettromboeg clamine 25 mg or 50 mg of ettromboeg free sicial, the incurbe ingredients of PROMACTA tablets are Tablet Gover magnesium stearate, and a odbum starch etchicuse, povidene and a odbum starch etchicuse, povidene and a odbum starch plouse, povidene and a odbum starch plouse in Plous Callen No. 2 aluminum lake (25 mg tablet), hypomeliosa, fronde Buck and fron Godde Red (37 mg tablet), polyterhylene glycol 400, odbug Red (37 mg tablet), polyterhylene glycol 400, polyterhylene (142 mg tablet), or titanium dioxides.	2 mg of everolimus and the following Inactive ingredents: Butylated hydroxytoluene, coloidal silicon dioxide, crospovidone, hypromeliose, lactose monohydrate, magresulam steartse manifol, and microcrystalline cellulose.	0.56 mg of fingolimod hydrochloride, equivalent to 0.5 mg of fingolimod, gelatin, magnesium stearate, mannitol, ttannum dioxide, and yellow fron oxide.	ruxolitinib phosphate equivalent to 10 mg of ruxolitinib free base together with mercack spatiens cellulose, lactose monodyldrate, magaine seated, colidical silicon doxide, sodium starch glycolate, povidone and hydroxypropyl cellulose.	11 mg to facilith (equivalent to 12/37 mg to facilith crare) and the following inactive ingredients: cellulose settles, copordione, ingredients: cellulose screates, copordione, hydroxyethy cellulose, hydroxyethy cellulose, hydroxyethy cellulose, compared to the compared to the magnetian stearate, red from oxide, softlot, translum dioxide and triscetin. Printing ink contains, ammonium hydroxide, ferrosofteric contains, ammonium hydroxide, ferrosofteric oxide/black from oxide, propyleme glycol, and shellac glaze.	200 mg of pazopanib equivalent to 216.7 mg of pazopanib hydrocholder. The narche pazopanib hydrocholder. The narche ingredents of VOTRENT aer. Tablet Core: Magnesiam teararts, microcrystalline celuloos, povidone, and sodium starch glycolate. Coating Gay filmoast typromelious, iron oxide black, marcogly(polyethyene glycol 400 (PEG 400), polyochate 80, and ttamium dioxide.
NDA APPLICANT HOLDER NAME AND ADDRESS	NOVARTIS One Health Plaza East Hanover, NI 07936	NOVARTIS One Health Plaza East Hanover, NJ 07936	NOVARTIS One Health Plaza East Hanover, NJ 07936	NOVARTIS One Health Plaza East Hanover, NJ 07936	INCYTE CORP 1801 Augustine Cut-off Wilmington, DE 19803	PFIZER 235 East 42nd Street New York, NY 10017	NOVARTIS One Health Plaza East Hanover, NI 07936
NDA	022291	022291	203985	022527	202192	208246	022465
NDC	00078-0685-15 022291	00078-0686-15 022291	00078-0626-51 203985	FINGOLIMOD HYDROCHLORID 00078-0607-15 022527	50881-0010-60 202192	00069-0501-30 208246	00078-0670-66
U.S. GENERIC NAME	ELTROMBOPAG OLAMINE	ELTROMBOPAG OLAMINE	EVEROLIMUS	FINGOLIMOD HYDROCHLORID E	RUXOLITINIB	TOFACITINIB	PAZOFANIB HYDROCHLORID (00078-0670-66) 022465
U.S. PROPRIETARY NAME	PROMACTA	PROMACTA	AFINITOR DISPERZ	GILENYA	JAKAFI	XELIANZ XR	VOTRIENT
CANADAIAN INGREDIENTS	25 mg or 50 mg of eltrombopag as eltrombopag inselfrompopag andertrompopag adminen. The tablest also contains the following nonmedicinal ingredients: ampresidant seasons, impresidants are and a mannfol microcrystaline cellulos, polydone, sodium starch glycolate, polydone, sodium starch glycolate, polydone, sodium starch glycolate, proprientelose, sodium starch glycolate, polydone, sodium starch states also contain polysociate. RivOLADE 55 mg tables so contain in sodio contain iron voldo E5 om grabes alond from oudde red.	25 mg or 50 mg of eltromboogs as eltromboog elemine. The tablet also contains the following nonmedicial ingredients: magnetium stearate, marniol, infrorsystelline cellulose, povidents, sodium starrit glycolate, propremients, est marcogal and transum florade. REVOLADE 55 mg tablets also contain polypostate, REVOLADE 55 mg tablets also contain polypostate. REVOLADE 55 mg tablets also tablets also contain from oxide red, tablets also contain from oxide red.	2mg everolimus, butylated hydroxytoluene (E321), cellulose microrystalline, crospovidone, hypromellose, lactose monohydrate, magnesium stearate, mannitol, silica colloidal anhydrous.	0.5 mg fingolimod (as fingolimod hydrochloride) For the 0.5 mg: Magnesium stearate, mannitol, gelatin, titanium dioxide, yellow iron oxide.	10 mg ruxolitinib free base (as ruxolitinib phosphate), Aydroxprosyletilulose, 142-90 mg lactose monohydrate, magnesium stearate, microcrystaline ellulose, colloidal sillicon diode, sodium starch glycolate (Type A), povidone.	It may tofactinib (as tofactinib circute), sorbitol, howeverby elializes, sorbitol, howeverby elializes, copolodone, magnesium stearet. The film cost contains cellulose acetate, hydrosprospic elializes, HPMC 3200 hyptomelesse, tratamin adoced, tratestin, tred from odde. The Printing ink contains shellice, ammonium hydrosde, prospiere gibco., Hercitoide prospiere gibco., ferrosoferric oxide/black fron oxide ferrosoferric oxide/black fron oxide	200MG (paropanib as paropanib hydrochlorid), magnesium stearste microcystaline cellulose, pooddone (KS) and sodium starch givosilate. The tablet castific activities the following excipients, hydromeliose, into oxide coopients, hydromeliose, into oxide black (E172 – 200mg tables), macrogol, polysorbate 80 antimum dioxide polysorbate 80 antimum dioxide (E171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 – 171 –
NUMBER OF ACTIVE INGREDIENTS	1	1	1	1	e e	1	н
DOSAGE FORM	TABLET	TABLET	TABLET FOR SUSPENSI ON	CAPSULE	TABLET	TABLET	TABLET
STRENGTH	25 MG	SO MG	2 MG	0.5 MG	10 MG	11 MG	200 MG
ADDRESS	385 Bouchard Blvd Dorval Quebec Canada, H95 1A9	385 Bouchard Blvd Dorval Quebec Canada, H95 1A9	385 Bouchard Blvd Dorval Quebec Canada, H9S 1A9	385 Bouchard Blvd Dorval Quebec Canada, H9S 1A9	385 Bouchard Blvd Dorval Quebec Canada, H9S 1A9	17300 Trans- Canada Highway Kirkland Quebec Canada H9J 2MS	385 Bouchard Blvd Dorval Quebec Canada, H9S 1A9
COMPANY	NOVARTIS PHARMACEUTICALS CANADA INC	NOVARTIS PHARMACEUTICALS CANADA INC	NOVARTIS PHARMACEUTICALS CANADA INC	NOVARTIS PHARMACEUTICALS CANADA INC	NOVARTIS PHARMACEUTICALS CANADA INC	PFIZER CANADA ULC	NOVARTIS PHARMACEUTICALS CANADA INC
DIN	02361825	02361833	02425645	02365480	02434814	02470608	02352303
CANADIAN GENERIC NAME	ELTROMBOPAG (ELTROMBOPAG OLAMINE)	ELTROMBOPAG (ELTROMBOPAG OLAMINE)	EVEROLIMUS	FINGOLIMOD (FINGOLIMOD HYDROCHLORID E)	RUXOLITINIB (RUXOLITINIB PHOSPHATE)	TOFACTINIB (TOFACTINIB CITRATE)	PAZOPANIB (PAZOPANIB HYDROCHLORID E)
CANADIAN CANADIAN PROPRIETARY NAME GENERIC NAME	REVOLADE	REVOLADE	AFINITOR DISPERZ	GILENYA	JAKAVI	XELIANZ XR	VOTRIENT

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U.S. INGREDIENTS	2MG exenatide, polylactide-co-glycolide and successive and successive contents of liquid (alluent): inactive lingredients: medium chain triglycerides:	Each mt. of RESTASS's optitalmic emulsion contains: Active cyclosporine to 165%, insertives: glycenin, castor oil, polyoriste 80, carboner copolymer type A; purifies water, and sodium hydroxide to adjust pH.	50 mg of bictegravir (BiC) (equivalent to 52.5 mg of bictegravir sodium), 200 mg of entricipabile (FC), and 52 mg of tendiovir alleframide (TAS) (equivalent to 25 mg of tendiovir alleframide fundate), accordantiles estimates, consciundiose sodium, magnesium sterante, and microcrystalline cellulose. The bables are film condex with a costing material containing florn oxide black, into oxide material containing and coule black, into oxide containing and coule black, into oxide and containing and coule black, and containing and coule black, and containing alcohol, tale, and transium dioxide.	20 mg, 40 mg, or 60 mg of cabozantinib, which is equivalent to 25 mg, 21 mg, or 76 mg of cabozantinib (5) malate, respectively. CABONETY xia so construct the following intactive ingerdents: microcrystaline cellulose, latera enhiploras, lytoxypropy cellulose, crostamellose sodium, collodal allicondiode, and magnetium stearate.	20 mg, 40 mg, or 60 mg of cabocanthinb, which is equivalent to 25 mg, 21 mg, or 76 mg of cabocanthin (5) maiste, respectively. CABONETY xa los constructs the following intractive ingredients: microcrystalline cellulose, latera enhipdross, horsypropy cellulose, crossramellose sodium, collodal allicon dioxide, and magnetium stearate.	20 mg, 40 mg or 60 mg of cabocantinib, which is equivalent to 25 mg, 21 mg, or 76 mg of cabocantinib (5)-mäsie, respectively. CABOMITTX also construct the following increase indrose any engeleters: microcrystalline calulose, latese anyidrous, phorosypopyl callidose, croscamellose sodium, colloida silicion dioude, and magnesium stearate.
NDA APPLICANT HOLDER NAME AND ADDRESS	ASTRAZENECA LP PO BOX 15437 WILMINGTON, DE 19850	ALERGAN 5 Ginida Farms Madison, NJ 09740	Glead Sciences, Inc. 333 Lakeade D'ive 334 Calences, Inc.	CABOZANTINIB 4238-024-26 208692 1851 Hurbor Bay Parkway Alameda, CA 94502	Exelixis, Inc. 1851 Harbor Bay Parkway Alameda, CA 94502	Exelixis, Inc. 1851 Harbor Bay Parkway Alameda, CA 94502
NDA	209210	050790	210251	208692	208692	208692
NDC	00310-6540-04 209210	00023-9163-30	61958-2501-01 210251	42388-024-26	42388-025-26	42388-023-26
U.S. GENERIC NAME	EXENATIDE	CYCLOSPORINE (00023-9165-3-01 056790)	BICTEGRAVIR SODIUM; EMTRICITABIUM; TENOFOVIR ALAFENAMIDE FUMARATE	CABOZANTINIB	CABOZANTINIB 42386-025-26 208692	CABOZANTINIB 42388-023-26 208692
U.S. PROPRIETARY NAME GENERIC NAME	BYDUREON BCISE	RESTASIS	BIKTARVY	CABOMETYX	CABOMETYX	САВОМЕТҮХ
CANADAIAN INGREDIENTS	Z mg exentide (is white to off-white microspheres supernded in a MCT white Sufficient supernded in a MCT white Sufficient supernder in a MCT deliver Z mg of exentides externded-referes in 08 Sm. I while Cognitional to 85 m. I while Microsphere formulation: Exentide, poly (I). Hatchle cor glycolide), sucrose Vehicle: Medium chain inglycerides. Which is the MCT in mglycerides.	0.005% w/v is available as a sterile proservative free remuision supplied in own density polyeethylene single tee visis containing 0.4 mL each remuision contains Each mLd of mention contains cyclosporine 0.5 mg with the following mercan medicial ingredients. Carborner Copolymer Type A. castor oil, gleerin, polyschotae 80, purified water and sodium hydroxide to adjust the pH.	50 mg of bictegravir (equivalent to 52.5 mg of bictegravir (equivalent to 52.5 mg of emotivative solidaril). Soon mg of emotivative solidarily additionally emotivative to 25 mg of tendovir additional emotivative to 25 mg of tendovir additional definitional emotivative to Crossimmeliose Solidarily. Migrociystalline Cellulose, Crossimmeliose Solidarily. Migrociyatiline Cellulose, Solidarili emotivative solidaril	cabozantinib as cabozantinib as cabozantinib (S)-malate, colloidaí Silicon Dioxide, forosamentibes Sodium, Hydroxypropy (Callulose, Hypromellore 2910, Iron Oxide Yallow, Lactose Anhýdrous, Magneslim Stearate, Microcrystaline Cellulose, Tranium Dioxide and Triacetin.	cabozantinib si cabozantinib as cabozantinib (S)-maite, colloida Silicon Dioxide, Grostamelloes Sodium, Hydroxypropy (Cellulose, Hypromellore 2910, Iron Oxide Yallow, Lactose Anbydrous, Magneslum Stearate, Microxystaline Cellulose, Titanium Dioxide and Triacetin.	cabozantnib as cabozantnib as cabozantnib as cabozantnib Symater, colloidus lilcon Dioxide, Croscarmellora Solodo Horizoporporpi Celiulose, hypomeliose 230, in colodo Yellow, Lactose Antydoxis, Magnesium Searate, Microcrystalline Cellulose, Titanium Dioxide and Triacetin.
NUMBER OF ACTIVE INGREDIENTS	1	1	m	1	1	E .
DOSAGE FORM	SUSPENSI ON (EXTENDE D D RELEASE)	EMULSION	TABLET	TABLET	TABLET	TABLET
STRENGTH	2 MG/0.85 (0.05%	50·200-25 MG	20 MG	40 MG	90 MG
ADDRESS	1004 Middlegate Road, Suite 5000 Mississauga Ontario Canada L4Y 1M4	500 85 Enterprise Blvd Markham Ontario Canada LGG 085	600 6711 Mississauga Road Mississauga Ontario Canada LSN 2W3	SUITE SOS SOGO Spectrum Way Mississauga Ontario Canada L4W SNS	SUITE 505 5060 Spectrum Way Mississauga Ontario Canada LAW 5N6	SUITE 505 5060 Spectrum Way Mississauga Ontario Canada LAW SN7
COMPANY	ASTRAZENECA CANADA INC	ALLERGAN INC	GILEAD SCIENCES CANADA INC	PESN CABOZANTINIB 02460824 BIOPHARNACEUTICA IS CANADA INC	IPSEN BIOPHARMACEUTICA LS CANADA INC	IPSEN BIOPHARMACEUTICA LS CANADA INC
NIG	02483203	02355655	02478579	02480824	02480832	02480840
CANADIAN GENERIC NAME	EXENATIDE	CYCLOSPORIN	EMTRICITABINE, TENGFOVIR ALAFENAMIDE AND BICTEGRAVIR	CABOZANTINIB	CABOZANTINIB	CABOZANTINIB
CANADIAN CANADIAN PROPRIETARY NAME GENERIC NAME	BYDURE ON BCISE	RESTASIS	BIKTARVY	САВОМЕТҮХ	САВОМЕТҮХ	CABOMETYX

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U.S. INGREDIENTS	Each film-coated tablet contains 200 mg of entricitable and 300 mg of tendrout disoproid flumarate, (who it is equivalent to 248 mg of tendrout disoproid), as active ingredients. The tables also include the following inactive ingredients: crossomelous sodium, lacose monohidrate, magnesium statem emicro-spainier calilloise, and present with Dealor II liber's 51,000, and which contains follood to 186,000 mg of 186,000 mg which contains follood to 186,000 mg of 186,000 mg which contains follood to 186,000 mg of 186,00	Active ingredient apixalan. Inactive ingredients anhydrous lactose, inicrorystalline cellulose, forostameliose adolin, sodim lauri coultie, and magnetium steartes. The film coultie gromains lactose monohydrate, phypomeliose, trainium dioxide, infacetin, and yellow irno noide (2.5 ng tablets) or red irno oxide (5 ng tablets).	
NDA APPLICANT HOLDER NAME AND ADDRESS	Gilasd Sciences, Inc. 333 Lakeside Drive Foster City, CA 54404	Bristol-Myers Squib P.O. Box 4000 Princeton, NJ 08543-4000	
NDA	21-752	202155	
NDC	61958 0701-1 21-752	0003-0894-21 202155	
U.S. GENERIC NAME	EMTRICITABINE; TENDOCOUR BUDGORATE FUMARATE	APIXABAN	
U.S. PROPRIETARY NAME	TRUVADA	ELIQUIS	
CANADAIAN INGREDIENTS	Each tablet contains 300 mg of emriticables and 300 mg of tendering reflection and 400 mg of tendering flexibilities and 300 mg of tendering flexibilities acqualent include the following incutive injections: Toriscumpliate collulous, across monohydrate, magnesiam stearer, monohydrate, magnesiam stearer, and microraphilities collulous, and toriscumpliated stard (lafforter free). The stablets are contained this Opport, which contains fable filled and the CADOTO, which contains fable filled and the CADOTO, which contains fable fable and accompanies the stablets are conceptions. The tablets are being with "GLEC on one sight and with" GLEC on one sight and with "Out on the other side. Each bottle and a describer of sabel dank is chosely with a childrenistant desure.	Active Ingredient: Apicaban Dacipients: Tablet care, Aninylaroa lateos, microcytalline cellulose, oroseaminelose sodium launyl sulfare and magnetium steamer film cost Lactore monohydrate, hypromeliose, trahmin dioxide, tritectin, and yellow fron coide (2.5 mg tablets) or red fron coide (5 mg tablets) or red fron coide (5 mg tablets) or red fron coide (5 mg tablets).	
NUMBER OF ACTIVE INGREDIENTS	2	1	
DOSAGE	TABLET	TABLET	
STRENGTH	200-300 MG	s MG	
ADDRESS	600 6711 Mississauga Mississauga Ontario Canada ISN 2W3	2344 Boul. Alfred- Nobel, Suite 300 Montréal (St- Laurent) Quebec Canada H4S 0A4	
COMPANY	GILEAD SCIENCES CANADA INC	BRISTOL-MYERS SQUIBB CANADA	
NIQ	02274906	02397714	
CANADIAN GENERIC NAME	TENOFOVIR DISOPROXIL AND EMTRICITABINE	APIXABAN	
CANADIAN CANADIAN PROPRIETARY NAME GENERIC NAME	тимда	ELIQUIS	

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