

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find a collection of all the drug lists from known drug importation applications (SIPs), including previous versions superseded by subsequent filings.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: 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PSM will maintain that collects all drug lists from all known importation applications, including previous versions superseded by subsequent filings

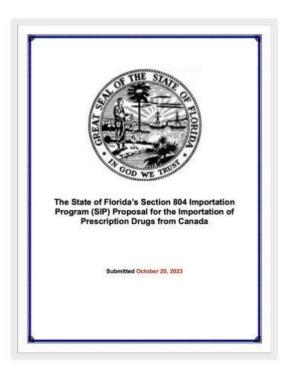


FOIA Responsive Document

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

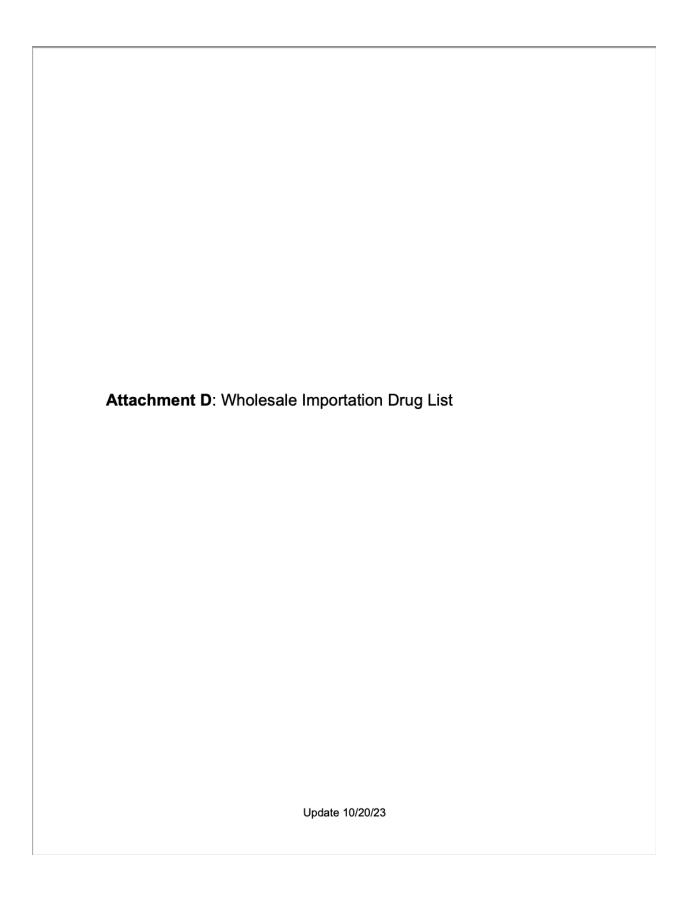
Find the entire application online at our website: www.safemedicines.org

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

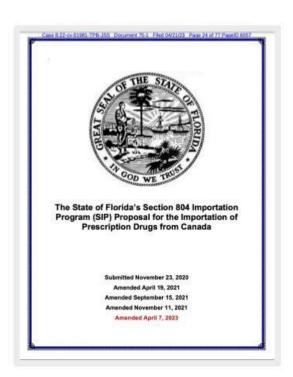
Biktarvy Descovy Dovato
Genvoya Juluca Odefsey
Prezcobix Prezista Ravicti
Rexulti Symtuza Tivicay
Vraylar Xtandi

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
- HCl; 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.

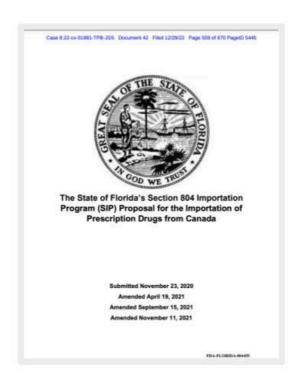
TABLE 2 PROPOSED DRUG LIST								
Brand Name (active ingredients)	Dose / Dosage Form							
Biktarvy (bictegravir-emtricitabine-tenofovir alafenamide)	50-200-25 mg tablet							
Descovy (emtricitabine-tenofovir alafenamide)	200-25 mg tablet							
Dovato (dolutegravir-lamivudine)	50-300 mg tablet							
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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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 alafenamide)	150-800-200-10 mg tablet
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	Sold
						Name	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	NDC	U.S.	NDA/ ANDA	DIN	Canadian	Sold in
	Ingredient		Price			Name	U.S.
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	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

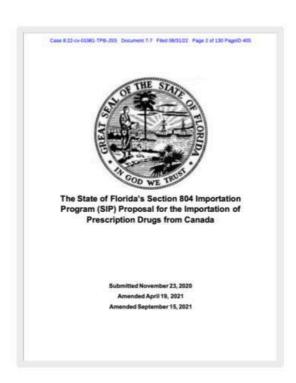
Drug Name	Active	NDC	U.S.	NDA/ ANDA	DIN	Canadian	Sold in
	Ingredient		Price			Name	U.S.
Kaletra 200-	Lopinovir,	00074-	\$8.53	NDA021906	02285533	Kaletra	Yes
50mg	Ritonovir	2605-21					
Kaletra 100-	Lopinovir,	00074-	\$4.27	NDA021906	02312301	Kaletra	Yes
25mg	Ritonovir	0522-60					
Genvoya 150-	Elviteg,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

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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





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	7.1107202101	024/1132	Aripiprazole	'``
Johns		0102-30				Alibibiazoie	

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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 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	NDC	U.S.	NDA/ANDA	DIN	Canadian	Sold in
Spiriva 30 caps, 18mcg/	Tiotropium Bromide	00597- 0075-41	Price \$436.80	NDA021395	02246793	Name Spiriva	Yes
handihaler			4				
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	

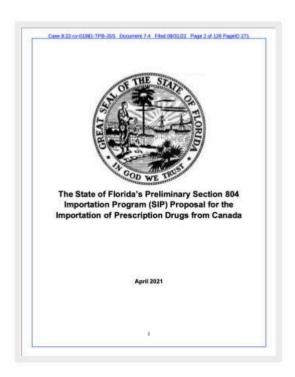
HIV/AIDS Prescription Drugs

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

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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	1	0302-30	Ć44 00	ND 4200C02	00007754	Laterda	
Latuda 40mg	Lurasidone HCL	63402-	\$41.00	NDA200603	02387751	Latuda	Yes
Latinda COma	Luma aidan a UCI	0304-10	C44 04	ND A 200CO2	02442264	Lakuda	V
Latuda 60mg	Lurasidone HCL	63402- 0306-30	\$41.04	NDA200603	02413361	Latuda	Yes
Latuda 80mg	Lurasidone HCL	63402-	\$41.03	NDA200603	02387778	Latuda	Yes
Latuda domg	Lui asidone rice	0308-30	341.03	NDAZOOOS	02307770	Latuua	163
Latuda 120mg	Lurasidone HCL	63402-	\$61.13	NDA200603	02387786	Latuda	Yes
Lutudu 1201116	Larasiaone rrez	0312-30	701.13	INDAZOOOS	02307700	Lutuuu	103
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				Olanzapine	
Zyprexa 7.5mg	Olanzapine	00002-	\$14.38	NDA020592	02229277	Zyprexa	Yes
		4116-30	4				
Olanzapine	Olanzapine	65862-	\$0.13	ANDA202050	02276739	Teva-	Yes
7.5mg		0563-30	4			Olanzapine	
Zyprexa 10mg	Olanzapine	00002-	\$20.79	NDA020592	02243087	Zyprexa Zydis	Yes
tabs	01	4117-30	60.45	AND 4202050	02276747	T	V
Olanzapine	Olanzapine	65862-	\$0.15	ANDA202050	02276747	Teva-	Yes
10mg Zyprexa 15mg	Olanzapine	0564-30 00002-	\$31.26	NDA020592	02238850	Olanzapine Zyprexa 15mg	Yes
tabs	Olarizapine	4415-30	\$51.20	NDAUZUS9Z	02236630	Zyprexa 15mg	162
Olanzapine	Olanzapine	65862-	\$0.18	ANDA202050	02276755	Teva-	Yes
15mg	Cianzapine	0565-30	70.10	/	02270733	Olanzapine	103
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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		00040	640.07	1101000000	00000000		
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 tabs	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 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	70.02	7	02237720	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	NDC	U.S.	NDA/ANDA	DIN	Canadian	Sold in
	Ingredient	20507	Price	ND 4004005	00046700	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
			ć220.40	ND 4205202	02422506	In an a	V
Incruse Ellipta	Umeclidinium	00173-	\$329.40	NDA205382	02423596	Incruse	Yes
62.5 mcg #30		0873-10				Ellipta	

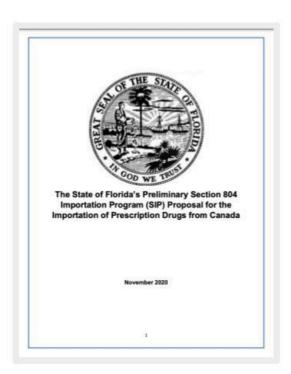
HIV/AIDS Prescription Drugs

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	
			4			(TDF)	
Sustiva 600mg	Efavirenz	00056-	\$8.57	NDA021360	02246045	Sustiva	Yes
tabs	Ef dans	0510-30	60.57	AND 4004 474	02200762	Tablets	V
Efavirenz 600mg	Efavirenz	00378-	\$8.57	ANDA091471	02389762	TEVA-	Yes
tabs Sustiva 50mg	Efavirenz	2233-93 00056-	\$3.50	NDA020972	02239886	Efavirenz Sustiva	Yes
caps.	Elavirenz	0470-30	\$3.50	NDA020972	02239886	50MG	res
Sustiva 200mg	Efavirenz	00056-	\$10.50	NDA020972	02239888	Sustiva	Yes
caps	Liaviieliz	0474-92	\$10.50	NDA020372	02233666	200MG	163
Genvoya tabs	Elviteg, COB,	61958-	\$104.93	ANDA207561	02449498	Genvoya	Yes
GCIIVOYa tabs	Emtri, Tenof,	1901-01	7104.55	ANDA207501	02443430	Genvoya	103
	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						
T	Disop	64050	¢50.70	ND 4024752	02274000	T	V
Truvada 200-	Emtricitabine,	61958-	\$59.70	NDA021752	02274906	Truvada	Yes
300mg	Tenofovir DF	0701-01	ĆAE CO	ANDA090894	02200050	TEVA-	Vaa
Emtricitabine,	Emtricitabine,	00093-	\$45.69	ANDA090894	02399059		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	NDC	U.S.	NDA/ ANDA	DIN	Canadian	Sold
	Ingredient		Price			Name	in
Latuda 20mg	Lurasidone HCL	63402-	\$40.99	NDA200603	02422050	Latuda	U.S. Yes
tab	Ediasidone free	0302-30	\$40.55	NUMEROOF	02422030	Lutudu	103
Latuda 40mg	Lurasidone HCL	63402-	\$41.00	NDA200603	02387751	Latuda	Yes
		0304-10	-				
Latuda 60mg	Lurasidone HCL	63402-	\$41.04	NDA200603	02413361	Latuda	Yes
		0306-30	A44.00	NDAGGGG	00007770		.,
Latuda 80mg	Lurasidone HCL	63402- 0308-30	\$41.03	NDA200603	02387778	Latuda	Yes
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	40.40	****		_	.,
Olanzapine	Olanzapine	65862-	\$0.12	ANDA202050	02276720	Teva-	Yes
5mg	Olamanina	0562-30	Ć14 20	NDAGGOEGG	02220277	Olanzapine	V
Zyprexa 7.5mg	Olanzapine	00002- 4116-30	\$14.38	NDA020592	02229277	Zyprexa	Yes
Olanzapine	Olanzapine	65862-	\$0.13	ANDA202050	02276739	Teva-	Yes
7.5mg	Olalizapille	0563-30	30.13	ANDAZOZOSO	022/0/33	Olanzapine	163
Zyprexa 10mg	Olanzapine	00002-	\$20.79	NDA020592	02243087	Zyprexa Zydis	Yes
tabs	- Chambaphine	4117-30	4 20.75	11071020002	022.0007	_, p. c, a	
Olanzapine	Olanzapine	65862-	\$0.15	ANDA202050	02276747	Teva-	Yes
10mg	·	0564-30				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	Overtioning	003100375	¢2.70	NDAGGGG	02226054	Canamual	Vac
Seroquel 25mg	Quetiapine Fumarate	003100275- 10	\$3.79	NDA020639	02236951	Seroquel	Yes
	rumarate	10					
Quetiapine	Quetiapine	46708-	\$0.04	ANDA203390	02316080	ACT Quetiapine	Yes
Fumarate	Fumarate	0134-31					
25mg							

			4				
Seroquel	Quetiapine	00310-	\$12.07	NDA020639	02236953	Seroquel	Yes
200mg	Fumarate	0272-10					
Quetiapine	Quetiapine	46708-	\$0.11	ANDA203390	02316110	ACT Quetiapine	Yes
Fumarate	Fumarate	0137-31					
200mg							
Seroquel	Quetiapine	00310-	\$15.95	NDA020639	02244107	Seroquel	Yes
300mg	Fumarate	0274-60	,				
5001116	T dilliarate	027100					
Quetiapine	Quetiapine	46708-	\$0.17	ANDA203390	02316129	ACT Quetiapine	Yes
			\$0.17	ANDAZUSSSU	02310129	ACT Quetiapine	162
Fumarate	Fumarate	0138-60					
300mg	-1 .		4				.,
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	G.GZGPG	01	2.00		022.72.7	ozii olozapiilo	
Clozaril 50mg	Clozapine	69809-	10.15	NDA019758	02490668	Clozaril	Yes
tabs	Clozapine	0130-05	10.13	NDA013738	02430008	Clozarii	163
	Cl		4.60	41104074040	00000000	CEN Classics	
Clozapine 50mg	Clozapine	0093-4404-	1.68	ANDA074949	02305003	GEN-Clozapine	Yes
		01					
Clozaril 200mg	Clozapine	69809-	29.29	NDA019758	02490676	Clozaril	Yes
		0135-05					
Clozapine	Clozapine	0093-4405-	2.19	ANDA074949	02305011	GEN-Clozapine	Yes
200mg		01					
Abilify 5mg	Aripiprazole	59148-	28.64	NDA021436	02322382	Abilify	Yes
tabs		0007-13					
Aripiprazole	Aripiprazole	62332-	0.17	ANDA202101	02471094	APO-	Yes
5mg	7 II I I I I I I I I I I I I I I I I I	0098-30	0.17	7111071202101	02171031	Aripiprazole	103
Abilify 10mg	Aripiprazole	59148-	28.22	NDA021436	02322390	Abilify	Yes
	Aripipiazoie		20.22	NDA021430	02322390	Ability	163
tabs		0008-13	0.45	****	00474400	100	.,
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	, ii pipi uzoie	0101-30	0.2	, ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	524,1124	Aripiprazole	103
	Aripiprazole	59148-	40.69	NDA021436	02322455		Yes
Abilify 30mg	Aripipiazole		40.09	NDAUZ1430	02322435	Abilify	162
tabs		0011-13		441D 455555	00471105	400	.,
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	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

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	4			Efavirenz	
Sustiva 50mg	Efavirenz	00056-	\$3.50	NDA020972	02239886	Sustiva	Yes
caps.		0470-30	4			50MG	
Sustiva 200mg	Efavirenz	00056-	\$10.50	NDA020972	02239888	Sustiva	Yes
caps	FI :: 00B	0474-92	440400	AND 1007564	00440400	200MG	
Genvoya tabs	Elviteg, COB,	61958-	\$104.93	ANDA207561	02449498	Genvoya	Yes
	Emtri, Tenof, Alafen	1901-01					
Atripla tab	Efavirenz,	15584-	\$96.91	ANDA021937	02300699	Atripla	Yes
Аспріа сар	Emtricit,	0101-01	\$96.91	ANDA021937	02300699	Atripia	res
	Tenofovir DF	0101-01					
Efavirenz,	Efavirenz,	00093-	\$73.31	ANDA091215	02393549	TEVA-	Yes
Emtricit,	Emtricit,	5234-56	7/3.31	ANDAOSIZIS	02333343	Efavirenz,	163
Tenofovir DF	Tenofovir DF	3234 30				Emtricitabin	
Tenoroviii Di	Telloroviii Bi					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	

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
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%
				1		1



Fluticasone HFA*	110mcg	Respiratory	Generic	\$177.99	\$39.50	78%
Flovent HFA	220mcg	Respiratory	Brand	\$353.25	\$85.62	76%
Fluticasone HFA*	220mcg	Respiratory	Generic	\$276.46	\$50.65	82%
Pulmicort	90mcg	Respiratory	Brand	\$170.01	\$34.76	80%
Pulmicort	180mcg	Respiratory	Brand	\$233.01	\$71.06	70%
Spiriva Handihaler	18mcg	Respiratory	Brand	\$377.35	\$58.39	85%
Spiriva Respimat	2.5mcg	Respiratory	Brand	\$324.04	\$58.39	82%
Trelegy	100-62.5-25mcg	Respiratory	Brand	\$237.37	\$148.73	37%
Trelegy	200-62.5-25mcg	Respiratory	Brand	\$255.26	\$186.67	27%
Ventolin	90mcg	Respiratory	Brand	\$54.00	\$6.75	87%
Albuterol Inhaler	90mcg	Respiratory	Generic	\$25.97	\$5.63	78%
Chantix	0.5mg	Smoking Cessation	Brand	\$7.88	\$1.93	75%
varenicline	0.5mg	Smoking Cessation	Generic	\$7.69	\$1.04	87%
Chantix	1mg	Smoking Cessation	Brand	\$8.35	\$1.93	77%
varenicline	1mg	Smoking Cessation	Generic	\$7.50	\$1.04	86%
Synthroid	100mcg	Thyroid Deficiency	Brand	\$0.95	\$0.07	93%
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	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	85%
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	AIH	\$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	292	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%

*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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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	505	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	190561	\$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	2665	\$175,252.94	\$61,720.81	\$113,532.13	%59
Atripla	600, 200, 300mg	AIH	\$42.25	\$83.93	18161	6776	27940	\$2,262,853.44	\$1,180,343.76	\$1,082,509.68	48%
Aubagio	14mg	Multiple Sclerosis	\$55.42	\$238.86	26592	14319	40910	\$9,429,588.46	\$2,267,101.46	\$7,162,487.00	26%
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	00225	\$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	826
Dexilant	30mg	GERD	\$0.39	\$9.07	26816	14440	41256	\$361,264.41	\$16,277.26	\$344,987.15	95%
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	79%
Januvia	100mg	Diabetes	\$2.85	\$14.08	217062	116879	333941	\$4,538,628.93	\$950,646.53	\$3,587,982.40	%62
Januvia	50mg	Diabetes	\$2.85	\$14.11	22948	12356	35304	\$480,559.33	\$100,502.12	\$380,057.20	79%
Jardiance	25mg	Diabetes	\$2.85	\$15.06	216910	116798	333708	\$4,850,621.89	\$949,982.22	\$3,900,639.67	%08
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	29777	\$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	60mg	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	88%
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	9661	\$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	%98
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	68578	\$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	\$56.85	2425	1306	3731	\$204,680.84	\$76,695.04	\$127,985.80	93%
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	Зтв	Schizophrenia, MDD	\$3.81	\$38.82	2835	1527	4362	\$163,388.90	\$16,617.46	\$146,771.44	%06
Rexulti	Zmg	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	\$79,069.97	\$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	%68
Sabril	500mg	Epilepsy	\$0.96	\$140.15	1170	630	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	60mg	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	93%
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	AH	\$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	928	\$339,506.92	\$131,581.77	\$207,925.15	61%
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	600	\$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	8298	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	829

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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	HIV	\$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	606828	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	829	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	505	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	29460	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	11167	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	%62
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	7656	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	26889	34406	98303	\$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	85%
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	57999	\$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	92271	\$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	2073	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	68805	\$4,234,059.97	\$1,568,022.58	\$2,666,037.39	93%
								\$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 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.



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

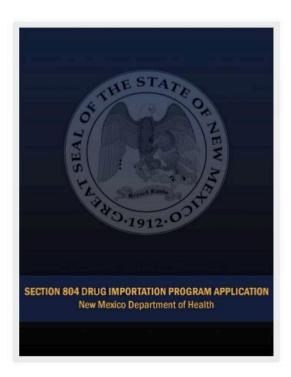
Drug Name	Active Ingredient	NDC	US Price	NDA/ANDA	Canadian Name	Sold in US
Advair Diskus 100- 50mcg	Fluticasone Propion / Salmeterol	00173-0695-00	\$303.60	NDA021077	Advair 100 Diskus	Yes
Advair Diskus 250- 50mcg		00173-0696-00	\$377.40	NDA021077	Advair 250 Diskus	Yes
Advair Diskus 500- 50mcg	Fluticasone 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)		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			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	Ibrance 75 Palbociclib		\$592.83	NDA207103	Ibrance	Yes
Ibrance 100mg	Palbociclib	00069-0284-21	\$592.83	NDA207103	Ibrance	Yes

	A	NDS	uc p.i	AUDA (ANIDA	Canadian	Sold
Drug Name	Active Ingredient	NDC	US Price	NDA/ANDA	Name	in US
Ibrance 125mg	Palbociclib	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		\$137.93	NDA204063	Tecfidera	Yes
Tradjenta 5mg Tab	Linagliptin	00579-0140-30	\$14.79	NDA201280	Tradjenta	Yes
Triumeq 600-50-300	riumeq Abacavir /		\$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	Rupropion HCI		\$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.

U.S. INGREDIENTS	Each shier construin 20 mg of locations hydrocholicies, hustive impredestrates are manned, progestioned starch, constructions, impression starch, Copady # and cannadas localies, hyporomilions, magnetium stream, Opady # and cannadas and the construction of the constr	Each stake contains on reg of locations hydrocholds, hustine ingredients are manned, pregistrational stack, concurrenties a codium, hypermelose, magnetium streets, Opsdyr's est cannolas and the contained of the	Each shelr consists of mg of lexistions hefrochistics, insolve ingrediests are manned, progestimest stack, consormitions of the construction inspection stream, Opsiehy* and exmusion soldiers, hyperentifore, magnetium stream, Opsiehy* and exmusions	Each stell constant Bring of lucations hydrocholicis, huston improducts are manned, pregistrational stack, constructions and constructions, magnetium stream, Opeshy' and cannot be seen way. Model in	Active ingredent, albano i suffee Inactive ingredent, propellant 16A, 18a	Active ingredients: fluktasone propinente, aufmetend sinaloate Inactive ingredient lactose monohydrate (contains milk proteind)	Les O. In Q. OMFIT bales contain O. S. mg of execution turning required to to S. mg of swelling the base and a 1-ge of QUITT and the contain 1.7 mg of swelling turning exploration to 1.5 mg of swelling the same. This discuss the profession to 1.5 mg of swelling the same has the following the profession are included in the balls turning the profession of the profession of the propulsar, concernments coulded, swhelen debate calculus in the profession of the pr	Let 0.1 mg CAMPIT to their contains 0.85 mg of eventricin strates required to 0.5 mg of workflow the backer on 1 mg op CAMPIT and the contains 1.7 mg of vormittee the trates equalwate 0.1 mg of vormittee the seals. The discharate high reductive a his close of the backer of the contains of the contains and the contains of the propulsar, excessmellers enables, and produced addisc caching in the backer of the contains of the contains of the contains of the contains of the contains of the contains of the contains of the magnetism recommenders and contains of the contains of the contains of 1 mg, and Opardy Cases.	Lead 2007 by taket centries 200 by of exercitables (FIC) and 25 by the control of
NDA APPLICANT HOLDER NAME AND ADDRESS	Surovice Pharmaceuticals, Inc. One Bridge Plaza, Suite S10 Fort Lee, NJ 07024	Surrovice Pharmaceuticile, Inc. One Bridge Plans, Suite S10 Fort Lee, NJ 07025	Surovice Pharmaceuticuls, Inc. One Bridge Plazs, Suite S10 Fort Lee, NJ 07026	Surovice Pharmaceuticus, Inc. Gre Bridge Plans, Suite S10 Fort Lee, NJ 07027	GlaxoSmithdline 5 Moore Drive Mailstep 5.58 Research Triangle Park, NC 27709	GlaxoSmithKline Five Moore Drive P. O. Box 13398 Research Triangle Park, NC 27709	PF Prion CV c/o Miles, linc 235 star Add Street New York, NY 10017-5755	PF Phism C V c/o Pistor, linc 235 Sast 47nd Street New York, NY 10017-5756	Gleed Sciences, Inc. 333 Lakeside Drive Foster Chy, CA 94404
NDA	200603	200604	200605	200606	020983	021077	021928	021928	208715
NDC	63402-302-30	63402-304-30	63402-306-30	63402-308-30	0173-0682-20	0173-0696-00	0069-0468-56	95-6910-6900	61958-2002-1]
U.S. GENERIC NAME	TURASIDONE	TURASIDONE	TURASIDONE	TURASIDONE	ALBUTEROL HFA	SALMETEROL AND FLUTICASONE	VARENICINE	VARENICINE	EMTRICINANG; TENGOVR AMFRANDE FUNABATE
U.S. Proprietary name	LATUDA	LATUDA	LATUDA	LATUDA	VENTOLIN HEA.	ADVAIR DISKUS	CHANTIX	CHANTE	DESCOVY
CANADAIAN INGREDIENTS	luzasidone hydrockocide, camadas was, croscamelioca sodium, hypromelioca, magnatum status, maminol, Josephangesam status, son quantimation objective regional such son quantimatica poderalise regional such son quantimatica poderalise last odos programmia such son quantimatica and yellow facritic codes.	lezasidore hydrochocke, camuska war, coscumiento andium, hypomelian, mognotim stace andium, hypomelian, (hypomelian, polyethylere gloria, ard thainm dioxele, pregletainine tarch, son gra baler and coordan; 1958 Elan No. 2 Alumium take and ydiow farrit solde.	lurasidone hydrockorde, camadas war, cocarmidiose acidum, hypromidiose, magnesalmis sarante, maninki, Opador, (Phypometica, polyethylere gizod, and thailum dioosia), pregestatinise artich, Son ge abele asio containe: Disk Bar No. 2 Aluminum take and ydioov facrii code.	luzabloce hydrochorde, camadas war, cocaramileas asolium, hystometica, magnesium staante, mantal, Opodry- (hypometica, polyethytes glyciu, and thaniom dioode), pregeteintes grout, and thaniom cootians: DSC liber hot. 2 Automium is the and ythore facrit codde.	lezatione hydrochoride, camuska war, cocammilera or ordium, hypomeliosa, magensalm starate, marintol, Opadry (hypomeliosa, poyethylera glycu, and thairm diosale, progetimina territ, Sin reg. and the cocamier. (Sin Marine di Ma	250 mcg fluticasone propienate and 50 mcg. salmeterol (as the xinafoste salt)	phosphate, colledia ilicon doode, phosphate, colledia ilicon doode, mercenfelse addin agestim straetite, and microcytalite calluce. The film costety carrier hypernelistic polyhetherse prod. Itaniam doode and tiscetii. The Ling Laber able contain 1064. Ilicu £2/Andigo Crimee Alumium Liake as a colouring agent.	propplate, collede allecon decided in propplate, collede allecon decide, mercentiles endium, genetim transite, and microcytalitie cellulose. The film-costney cacian hypernellose, polythelices glycol, the cellular properties polythelices glycol, them decide and tisectim. The Ling states abso contains TSAC Blace RV/Indigo Carmine Aluminum Lake as a colouring agent.	201 ng emitetable. Zi ng tendoloi addensalide moroprallise saladinas. In Egy saladinas and magazanin stenari. The gry saladinas are film contained and the second saladinas are saladinas and saladinas are saladina
NUMBER OF ACTIVE INGREDIENTS	1	1	1	1	1	2	;	1	2
DOSAGE FORM	TABLET	TABLET	TABLET	TABLET	METERED-DOSE AEROSOL	POWDER	TABLET	TABLET	ТАВІЕТ
STREWGTH	20 MG	40 MG	9W 09	BOMG	100 MCG/ ACT	250/50	O.5 MAG	1 MG	200-25 MG
ADDRESS	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, Suite 301 Mississauga Ontario Canada LSN 0E8	7333 Mississauga Road Mississauga Ontario Canada LSN 664	7333 Mississauga Road Mississauga Ontario Canada LSN 6L4	17300 Trans-Canada Highway Kirkland Quebec Canada H9) 2MS	17301 Trans-Canada Highway Kirkland Quebec Canada H91 2MS	600 6711 Microsuga Road Microsuga Orento Canada 154 2343
COMPANY	SUNCYION PHARMACEUTICALS CANADA INC	PHARMACEUTICALS CANADA INC	SUNOVIDN PHARMACEUTICALS CANADA INC	PHARMACEUTICALS CANADA INC	GLAXOSMITHKLINE INC	GLAXOSMITHICINE INC	PFIZER CANADA ULC	PFIZER CANADA ULC	GIEBO SCENCES CANADA INC
NIG	02422050	02387751	02413361	02387778	02241497	02240836	02291177	02291185	024524
CANADIAN GENERIC NAME	MODISVAITI	∌NOGISVEITI	∃NOGISVII IT	∌NOGISVIIIT	SALBUTAMOL HFA	SALMETEROL AND FLUTICASONE	VARENICLINE	VARENICLINE	EMTRICTABNE AND TENGEOVIR ALAFENAMIDE
CANADIAN PROPRIETARY NAME	LATUDA	LATUDA	LATUDA	LATUDA	VENTOLIN HFA	ADVAIR DISKUS	CHANTEX	CHANTER	DESCON

25 mg of empaglificatin five based and the following inextine ingrement. Negroteent, before monohysten, morroprystillner extitions, in yet may so other, collected and more defined and may be an extitute in the first contra	100 og d maglieten er 30m gel maglieten, creameliden som er, jedenspringer elektriken komen skrivens magenske maren, sen ersongstrager elektriken i sedlere blev skriven skrivens creame, som ersongstrager elektriken sedlere blev skrivenskelvens, creame, som er selver greden. Til 100 og sakke delij, samsgelyten,	100mg of caughtheir or 20mg of canadificatis, concarmellous nootin, hyperoper (closure) cancer and procur improving the control of the control of the control of the control of the control of the control of the control of the control of contain no make yellow (17) [10 mg state only, amongs/PM], contain no make yellow (17) [10 mg state only, amongs/PM].	5 mg depellitions as depellitions proposed or the opiniotes of 13 mg depellition is a depellition in a depellition in proposed depellition controlled information in depellition and before and before considerable allowed depelling and magnitum interests. The first coasting contents polytical batchels framewin soutide, polyticiphera plocal, this, and pellion into notide.	5 mg dapplitions a chapplition propared or the requisitor of 10 mg dapplition is observed or the requisitor of propared design infrared parties, and who can be propared to the companies of the companies of consideration polymer bands thanks manufacture, to price, that, and willow into order.	steeloog Liddong Institue ingrederett. D'manniol, con ratich, low unbefritted propergregication, proprespongeloog, proprespongeloog, and undergreging polition, and magnetium, and magnetium streats. The tables are film costed with a costing material containing hyperorelions, prospiene gibbol. Itanium dissident carried containing hyperorelions, prospiene gibbol. Itanium dissident carried to containing any above gibbol. The containing material containing hyperorelions, prospiene gibbol. Itanium dissident carried and carried to the containing t	Shang dimetry fearuran, microsystaline salukes, sitelined interceptables endology, concurrentions sodium, full, sitel collocial all not administrative endology, concurrentions sodium, full, sitel collocial all sodium, programmist and service and sodium and sodium programmist and sodium and sodium and sodium and the control of the concurrent and sodium and the pretent retained microsis, folk class it brittens bear FCS, yellow the pretent retained microsis, folk class it brittens bear FCS, yellow the pretent retained microsis, folk class it brittens bear fCS, yellow the pretent retained microsis and sodium and so	Ritaxinni SSOmg, collodal allicon dioxide, diacolum edetate, giycerel palmitestaerate, hypromeliose, microcrystalline cellolose, propylone gyrcol, red iron onide, sodium starch gycosle, taki, and stannium dioxide.	shapith and reform, incorptains oblicine, private the state of federal, incorptains oblicine, private the content the federal country for the state for country the debug federal polymer about polyme
Boehringer ingelheim Pharmacenticals, Inc. 900 Ridgebury Road P.O. Box Sd8 P.O. Box Sd8 Ridgefield, CT 06877	Jansen Pharmaceuticile, Inc. 1125 Trenten Habourinn Road PO Box 300 Thavville, NJ 08560-1504	Jansen Pharmaceuticils, inc. 1125 Trenten-Harbourinn Road Po Box 200 Tharville, NJ 08560-150A	ASTRAZENECA LP PO BOX 13437 WILMINGTON, DE 13850	ASTRAZENECA LP PO BOX 13437 WILMINGTON, DE 19850	Actelion Pharmaceuticals US, Inc. 5000 Shoreline Court, Sec. 200 South San Francisco, CA 94089, USA	Biogen 10EC Inc 222 Birmey Street Cambridge, MA 02142	SALIX PHARMACEUTICALS 1700 Perimeter Park Drive Morrisville, NC 27560	MRICC SULPE DOMA! ZODO Galogue juli facel Kanilworth, NI 088889
204629	204042	204042	202293	202293	207947	204063	022554	022044
0597-0152-30	50458-0140-30	50458-0141-30	08310-6205-30	00310-6210-30	66215-0614-06	64406-0006-02	65649-0303-02	00000 6575-61
EMPAGLIFLOZIN	CAGLIFLOZIN	OMBLIGZIN	DAPAGLFLOZIN	DAPAGLFLOZIN	9valx313S	DIMETHYL FUNABATE	RIFAXIMIN	19-4.09-9000) THI MAILLORING HET DOORS CO.S.
JARDIANCE	INVOIGNA	ANODONA	FARRIGA	FARMGA	UPTRAVI	TECFIDERA	NEADGAN	JANUARET
5 mg of empagifition free base, colloidal silicon distride, crossamellose sodium, hydrosypcopy, deliliose, pyperemiliose, pusches monethydrate, approxima testrate, macrogol, microcrystalline eluliose, titanism distride, and yellow ferric oxide.	Dong of canagillocin OR 300mg of canagillocin. Core Tablest canamistics solidari. Independent callabase better environmente solidari. Independent callabase so	Dong of canagillosis OR 300mg of canagillosis; Core Tablest consensitions of canagillosis; bydrosystropy clealuse, bictos environ- bydrosystropy clealuse, bictos environ- stearnes, and micropropalise ce adultor. According to the consensition of consensitions of con- tractions of consensitions of con- tractions of con- positions of con- tractions of con- positions of con- con- con- con- con- positions of con-	5 mg er 10 mg dasagilitosin an dasagilitosin compositiosis, an hidroni battos, crosposidosis, anhidroni battos, crosposidosis, anhidroni battosis, anticorpratilias escludos, alleno desides, in additios, ne film costing contrato les hollowing canciere legredente, polyviny alcohol, transium localde, polyvinhieres glycio, citic and yellow iron conder, polyvinhieres glycio, citic and yellow iron order.	5 mg or 10 mg dazagilitosin as dazagilitosin compositosis compositosis constitution in terrational intera- croppositosis magnatum starestes, monocratilism estidatosis, ilison discides, in addition, the film costing contrians the following nactive legradients polyviny alcohol, titamium ficialde, polyvinhienes polyvin, alcohol, titamium ficialde, polyvinhienes polyvin, alcohol, titamium onides.	elecipgs 1400mg, camadas wax, com starch, D- naminol, hydroxyprosyl reliulora, hypomeniese, inco relice elecipe (EST), low substituted hydroxyprosyl calulora magnetium steaures, propylene glycol, itamium dioxide (E373).	Set mg of dieselby finanzens, colloded sillon dieselbs, creatermières sodium, magnesium persents, metabolis ded cotopolime flope Al, metabolis del dieselbs dieselbs dieselbs propietate di pulidire interceptualistication and propietate di pulidire interceptualistication and propietate di pulidire interceptualistication discussion metabolis propietation di pulidire interceptualistication discussion and pulitication contributions or settle	frainin SSOME, colloidal silicon dioxide, glycery diseazate, microcrystalline celluiose, polyethylene glycol, polyethyl alcohol, red inon oxide, glaten-free socium starch glycolate, talc, and thankum dioxide.	LES net impleme production control care and implement in the second control care and implement in the second control care and implement in the second care and in the second care in patients product and care and implement in product and care and in the second care and in the second care in the second care and and care and in the second care and in the second car
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TABLET	TABLET	TABLET	TABLIT	TABLET	TABLET	CAPSULE (DELAYED- RELEASE)	TABLET	TABLET
25 MG	100 MG	300 MG	S MAG	10 MG	1400 MCG	240 MG	550 MG	SO-500 MG
5180 South Service Road Burlington Ontario Canada LPL 5H4	19 Green Belt Drive Toronto Ontario Canada M3C 11.9	19 Green Belt Drive Toronto Ontario Canada MSC 119	1004 Middlegate Road, Suite 5000 Mississaya Ontario Canada Liff 1M44	1004 Middingste Road, Suite 5000 Mississuga Ontario Canada L4Y 1M4	19 Green Belt Drive Toronto Ontario Canada M3C 119	99 Burnhamthorpe Road West, Suite 1100 Mississage Ontario Carada LSB 3C3	400 Somerset Corporate Boulevard Bridgewater, NJ 08807	16720 Route Transcandlene Gridden Quebec Canada H994 4M7
BOEHRINGER INGELHEIM (CANNDA) LTD LTEE	JANSSEN INC	JNI KISSSAMT	ASTRAZINICA CANADA INC	ASTRAZENECA CANADA INC	JANSSEN INC	BIOGEN CANADA INC	SALEK PHARMACEUTICALS INC	MERCIC CANADA INC.
02443945	02425483	02425491	02435462	02435470	02451212	02420201		02333856
EMPAGLIFLOZIN	CAMAGLIFLOZIN	CANAGLIFLOZIN	DAPAGUFOZIN	DAPAGLIFOZIN	SELEXIPAG	DIMETHYL FUMARATE	RIFAXIMIN	METORARVSTAGLIPIT
JARDIANCE	INVOICANA	INVOICANA	FORMGA	FORMICA	UPTRAVI	TEGFDERA	ZAXINE	JANUMIT
	SUPPLIES TO CHARGE WILD IN IN CHARGE WAS INCLUDING TO CHARGE WILD AND CHARGE WAS INCLUDING WAS INCLUDED WAS INCLUDING WAS INCLUDED WAS INCLUDING WAS INCLUDING WAS INCLUDING WAS INCLUDING WAS INCLUDING WAS INCLUDING WAS INCLUDE	THE CONNECTION CASES AND ACCOUNTS AND ACCOUN	EMPIRED COMMUNICATION COLUMN CO	EMPIRED COMMISSION COLORAD COL	Application	Particular Communication and Particular Communication an	The continue of the continue o	SECURIOR PROPERTY OF THE PROPE

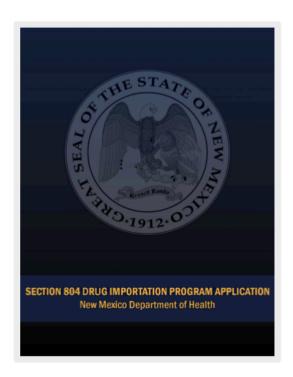
U.S. INGREDIÊNTS	opto sas persona per apera sua partigeoro, sur persona per persona per apera su persona del persona de	131.5 ng of suppless plaughete monohyters, which is equivalent to 2000 ms, respectively, of free base and the following lacetine ingestiment incorporation eligible, and these discharges and control of the control of	1.1 g/mL of glycerol phenybutyrate (delivers 1.02 g/mL of phenybutyrate).	rivaroushan, crostomelione sodium, hypermelione, lutcine monohydrate, megresium narente, microcrystaline celuloso, and sodium lawy usalite, ferrir code est, polyednýme gývod 3150, polyvený alcohol (partally hydrolyned), tač, and stanalum dioxide.	155, 383, or 3.28 mg of isolotogravir nodium, which is equivalent to the development of the segment of the segm	40 mg of glatinamer scetate, 40 mg of marnitol mannitol	COPPLICE straining borne special and straining according to the colorest according to the colore	Each in, of VCTOX satisfact contains fining of implication and the following that is, i.g. inflored particular, i.g. inflored particular, i.g. inflored particular, i.g. in propriet particular, i.g. inflored prior, i.g. ing. periors, i.g. ing. perior, i.g. ing. interfer inflored interfer propriets and a sign approach particular interfer inflored interfer in the state of an approach interfer in the state of the propriet in the particular interfer inte
NDA APPLICANT HOLDER NAME AND ADDRESS	MIRCE SAMP DOHAE Engineers, IS OBSESS Engineers, IS OBSESS	MIRCE SAAR DOHAE 2000 Galoging will bad Kenwarth, IN 088899	Horizon Therapeutics, LLC. 520 Lake Cook Rd Suite 520 Deerlield, IL 60015	Jansan Pharmaceuticals, Inc. 1125 Trenten Harbourton Road PO Box 200 Thurville, NJ 08560-1504	VWV HEALTHCARE Five Macer Of the Recearch Transple Facil, NC 27709	TEVA PHARMACEUTICALS USA 400 Interpace Parkway 83 Parsippany, NII 07054	Pokkakucricić Inć 998 sat Armer Ameri Somywale, CJ. 94855	NOVO NORDISK INC 800 Scudders MII Read Plaintbern, NJ 08536
NDA	022044	021995	203284	202439	204790	020622	205552	022341
NDC		00006-0277-31	76325-0100-04	50458-0579-30	49702-0228-13	68456-0325-12	57962-0140-09	00169-4060-13
U.S. GENERIC NAME	19 4/09 90000 TH WANDTHANTINGSTREE	згадити Риссенат	GLYCEROL PHENYLBUTYRATE	RIVAROXABAN	DOULTEGRAVIR	GLATIRAMER ACETATE	ewritwee	LIRAGLTIDE
U.S. PROPRIETARY NAME	Lawnwet	wunwer	RAVICTI	хаяе.то	TOLOGY	COPAXONE	MARKLIVICA	WITOZA
CANADALIAN INGREDIENTS	64.2 mg stappins monohina na manan m	Mark of singless people as month of the Mark equation is 100 mg, separately, of the base, marked as a properties of the car the base of the car can be possible as a properties of the car before calcium properties of the car marked car can properties of the car properties; people as a properties of the market and endom ready fremate in the film cashing contains the choicing extrains represent; people and properties of properties of properties; people as a properties of film of the car for the car of the car for the car for for the car for the car for for the car for for the car for for the car for for for for the car for	1.1 g/mL glycerol phenylbutyrate (deliners 1.02 g/mL of PBA). There are no excipients.	Rivaroaban, cellulose microcystaline, crosseramellose podini pypromellos 5 ct. bictose monolystas, magnesian starate, sodium lauryi sulphate, ferric coide yellow [2.5 mg, ferric coide red [10 mg, 15 mg, 20 mg, hypromellose 15 ct. polyethier glycol, titanium dioxide	2.5 mg of doubtagness motion, which is every entry of the Globerg problem, which recordingly and the Globerg problem in profession. To maniful intercorporation collector, profession 23/31, a doubt market profession from market funesses. The tablet film contrig contained the income profession from proposal problem and so that the contribution of the contribution of the ballet meltingly of the profession of the ballet meltingly of the profession of the profession from the proposal profession and the profession from the profession of the pro- posal representation of the pro- posal profession of the profession of the profession of the pro- posal profession of the profession of the profession of the pro- posal profession of the	glatiramer acetate, marmitol and sterile water for injection.	140 mg of borothic voltated floran deadels, and the processing of	6 mg/MI Unspiride, Doedium phosphate dhydrate, propylere glycol, phenol and water for lightness and water for
NUMBER OF ACTIVE INGREDIENTS	~	-	1	1		1	-	F F
DOSAGE FORM	TABLET	ТАВІЕТ	ORALLIQUID	TABLET	TABLET	NOLLUTION	CAPSULE	SOLUTION
STRENGTH	SØ 1000 MG	100 MG	1.1 G/ML	20 MG	SOMG	40 MG	140 M/G	38MG/3ML
ADDRESS	16750 foute Transcanderne Ordene Canada Hest AM7	16750 Route Transcandaerne Krithad Guebec Canada H964 AAF	1st Floor, Connaught House 1 Burlington Road Dubin 4	2920 Matheson Blvd East Mestissauga Ontario Canada L#W SR6	245 Boolevard Armand- Frappier Laval Quebec Canada HTV 4A7	30 Novopharm Court Toronto Ontario Canada M18 2K9	19 Green Belt Drive Toopido Ontario Canada M3C 119	101-2476 Argentia Road Mississanga Ontario Canada LSN 6M1
COMPANY	MERCY CHALDA INC	MERCY CANADA INC	HORIZON THERAPEUTICS IRELAND DAC	BAYER INC	VIEV HEALTHCARE ULC	TEVA CANADA LIMITED	JANSSEN INC	NOVD NORDISK CANADA INC
NIG	02333872	02303922	02453304	02378612	02414945	02456915	0243407	02351064
CANADIAN GENERIC NAME	METGRINBUST M	STAGLIPTN (STAGLIPTN PHOSPATE MONOHTORATE)	GLYCEROL PHENYLBUTYRATE	RIVAROXABAN	DOLITIGRAVIR (DOLITIGRAVIR SODIUM)	GLATIRAMER ACETATE	(выстине)	LIRAGIUTIDE
CANADIAN PROPRIETARY NAME	Läppennye	WAYAWF	RAVICTI	XAREITO	TIVICAN	COPAXONE	MABLUYICA	VICTOZA

U.S. WOREDIEWTS	efformedage claimes 23 mg or 50 mg of elementages (fine and the angles) and the angles of the angles	thereboyage closerus 23 mg or Din ng of demokrapig free acid. The magnetion or means, manache, controppidate or closure, produce and general manache, controppidate or closure, produce and software the produce of the produce of the produce and software prices of the produce of the produce by proposelloss, provided the produce of the produce proported by the produce of the produce of the produce produced produce prices of the produce of the produce produced produce produce produce produced produce produce produce produced produce produce produced produce produce produced produce produce produced produce produce produced produce produce produced prod	2 mg of everolimus and the following inactive ingradients: but/lated hydroxytoliume, calodista ilitono dioxide, crospovidore, protective dioxide ilitono dioxide, crospovidore, hypromeliose, battose monohydrate, magnesium stearste, mannibol, and microcystalline cellidose.	O 56 mg of fingolimod hydrochloride, equivalent to 0.5 mg of fingolimod, grazie, magnetam stearate, maneriol, itanium dioxide and yellow fron earle.	If my uslacens because is 37.7 my uslacines certain brown and the following persons broadeness calciuses sectors, coopsisions. The following incusts in grantering actions, broadeness calciuses actions to the following a following the following persons to the following the followin	200 mg of prosposite equivalent to 25.65 mg of passpowle bedrouderfor. The stacks we greatent or 4 VOTRING hare 1 based core bedrouderfor. This stacks was served in earliest explained, and propositions, and configuration of the configuratio	Mic sensities, polyarides no glycotile and success Comers of lead found the company of the comers of lead found the company of	Lich m. et MSTASS ophtheine envision condities Active organization (2005). So that the preference active of polysophere 90, so the profession of 2005, backers speak, particle sever; and code on independent of the profession of t	50 mg of betregave (BIC) (equalment to 23.3 mg of betregave (BIC) (equalment to 23.3 mg of betregave (BIC), and 51 mg of transferior abstraction (BIC), and 52 mg of transferior abstraction (BIC) (Proportion in the general medical abstraction in the general medical medical and transferior endings and transferior endines are sometiment and transferior endines are sometiment and transferior endines are deleted, hen one desired properties (BIC)
NDA APPLICANT HOLDER NAME AND ADDRESS	NOVARTS One feelith fluxa East Hanover, NI 07936	NOVARTS One feelith fran East Hanover, NI 07936	NOVARTIS One Health Flaza East Hanover, NJ 07936	NOVARTIS One Health Flaza East Hanover, NJ 07936	PHTER 235 East 42nd Street New York, NY 10017	MOVARITS One Health Plaza East Hanover, NI 07936	ASTRAZINICA LP PO BOX 15437 WILMINGTON, DE 19850	ALLENGANI S Girabla Farms Madison, NJ 09740	Gliead Sciences, Inc. 333 Lakeside Drive Foster Chy, CA, 94404
NDA	022291	022291	203985	022527	208246	022465	209210	05030	210251
NDC	00078-0685-15 022291	03078-0686-15	00078 0626-51		00069-0501-30		00310-6540-04	00023-9163-30	61958-2501-01
U.S. GENERIC NAME	ELTROMIOPAG OLAMINE	ELTNOMIROPAG OLAMINE	EVEROLIMIUS	FINGOLIMOD HYDROCHLONIDE 00078-0607-15	TOFACITIMIS CITRATE	PAZOPANIB WTDHOCHLORIDE 00078-0670-06	EXEMATIDE	CYCLOSPORINE	MCTGRANG SQUING. AAATHARANG UNABATE
U.S. Proprietary name	PROMACTA	PROMACTA	ASINITOR DISPERZ	GILENYA	XELIANZ XR	VOTRENT	BYDUREON BCISE	RESTASIS	BISTARVY
CANADALAN INGREDIENTS	Sing of Sing of eleconbopage a eleconbopage of an observation of the safet is in conteas the following controlled the safet is in conteas and the safet in conteas and the safet in conteas and the safet in conteas and part in conteas and conteas a	35 mg or 50 mg of elevendopag as elevendopag olemine. The salest side contains the following contains the following contains the following contains the signature, amproved in street, profession, and present and profession thereoffice contains the following the profession and stream of code; RVQLAGS 25 mg salest also contain professions the RVQLAGS 30 mg states also contain from outder profession and from tablests also contain from outder profession and from code profession and	Zag everolimus, burklated hydroxytoluene (EE21), celulous microsynallims, crospovidone, hypromellone, listrose monohydrate, magnerium stearate, mannitol, silica celloidal arehydrous.	mg fingolimod (as mg fingolimod kydenchloride) For the 0.5 mg Magnesium stearte, manneta, gelatin, titanium dioulde, yellow iron oxide.	It my bulestine la valucian ciranel, sorbiol, hydroxyethy elidade, coprodero, mapraism steaste. The Firm cots controls receive, eliver, Protopycopy celabor, eliver, 2000-protopycopy celabor, eliver, protopycopy celabor, eliver, protopycopy celabor, eliver, protopycopy celabor, eliver, protopycopy celabor, eliver, protopycopy celabor, eliver, protopycopy celabor, eliver, protopycopycopycopycopycopycopycopycopycopyc	200MG (purspanits as paragorate) indenotionided, may result as that as minor synaline retiliation, the content of 100 MeV and	2 mg exempled (as where no off-white morticabless supervised in a MCF whitely left-morticabless supervised in a MCF whitely left-method-evelope in 2.55 m, whitely exempled-evelope in 2.55 m, whitely Mcrosuperv formulation is benaute, poly (p.). Incide, whether formulation is benaute, poly (p.). Incide is whether whitely in the comprehension of the polycender (whitely in	(DOX W) is smalled as a satisfy preservative. The emotion applied in the description of populment and populment and other and command of the command and other and applied to the common and section in proceeds on adjoint the pit.	So my of belogyout (equivalent to \$2.5 mg of belogyout (equivalent to \$2.5 mg of the street of the s
NUMBER OF ACTIVE INGREDIENTS	1		1	1	1	1	1	,	m
DOSAGE FORM	TABLET	TABLET	TABLET FOR SUSPENSION	CAPSULE	TABLET	TABLET	SUSPENSION (EXTENDED RELEASE)	EMULSION	TABLET
STRENGTH	25 MG	SD MG	2 MG	0.5 MG	11 MG	200 MG	2 MG/0.85 ML	WS0.0	SO 200-25 MG
ADDRESS	385 Bouchard Bivd Darval Queber Canada, H95 1A9	385 Bouchard Bivd Donval Quebec Canada, H95 1A9	385 Bouchard Bivd Dorval Quebec Canada, H95 1A9	385 Bouchard Bivd Dorval Quebec Canada, H95 1A9	17300 Trans-Canada Highway Kirkland Quebec Canada H9J 2MS	385 Bouchard Blvd Dorwal Quebec Canada, H95 1A9	1004 Middlegate Road, Suite 5000 Mississauga Ontario Canada LAY 1M4	500 85 Enterprise Blvd Markham Ontario Canada LGG 085	600 6711 Missisrauga Mississauga Ontaxio Canada USY 2W3
COMPANY	NOVARTIS PHARMAGEUTICALS CANADA INC	NOVARTIS PHARMACEUTICALS CANADA INC	NOVARTIS PHABMACEUTICALS CANADA INC	NOVARTIS PHABIMACEUTICALS CANADA INC	PFIZER CANADA ULC	NOVARTIS PHABINACEUTICALS CANADA INC	ASTRAZENECA CANADA INC	ALENGAN INC	GIEAD SCIENCES CANADA INC
NIQ	02361825	02363833	02425645	02365480	02470608	02352303	02483203	02355655	02478579
CANADIAN GENERIC NAME	ELTROMBOPAG (ELTROMBOPAG OLAMINE)	ELTROMBOPAG (LLTROMBOPAG OLAMINE)	EVEROLIMUS	FINGOLIMOD (FINGOLIMOD HYDROCHLORIDE)	TOFACTINIB (TOFACTINIB CITRATE)	PAZOPANIB (PAZOPANIB HYDROCHLORIDE)	EXENATIDE	CYCLOSPORIN	EMPRCITABNE, TENGFONR AMENAMIDI AND BICTEGRAVER
CANADIAN PROPRIETARY NAME	REVOLADE	REVOLADE	AFINITOR DISPERZ	GILENYA	XELINZ XR	VOTRINT	BYDUREON BCISE	RESTASS	BIKTARYY

U.S. INGREDIENTS	20 mg, 40 mg, or 10 mg of calcustration, which is equivalent to 25 mg, 15 mg, or 10 mg of calcustration, which is equivalent to 25 mg, 21 mg, or 10 mg of calcustration [Paradace reportation]. CALGOORITY due contains the claimwag manore upgredents, meterorratisting redefines, uncertainstation, professions, thouse redevines, the containing redefines, crosscratisting redefines, concernations and containing and professions, collecting, and magnetisms steamers.	20 mg, 40 mg, or 60 mg of cabecarrieth, which is equivalent to 25 mg. S1 mg, or 74 mg of cabecarrieth, which is equivalent to 75 mg. CALGARIETH And CALGARIE	20 mg, 40 mg, or 60 mg of cabosanchia, which is equivalent to 25 mg. 81 mg, or 16 mg of cabosanchia (Jambier requirently, Callod/MTV also centains the following nucleon spredenter, microsystalism cabolaca, katosa sahiphosa, hydroxypospyl cellulosis, crossanshiphosa, hydroxypospyl cellulosis, crossanshiphosa, hydroxypospyl cellulosis, crossanshiphosa, mydanshim sabastas.	Les solici consino 130 m el chiangenio 130 m el chiancio 200 m el chiangenio 200 m el	Leab time cannot shales creations alamone unline equivalent to 600 me debatement, and for the control of the co	Les table contain 20 mg of T. 25 mg of 97 (squadest to 213 of the contain 20 mg of T. 25 mg of 97 (squadest to 213 of the contain 20 mg of the contain contain and contain and contain and contained as colors and colo	Active legeofers: Infeptitions incitive inguishment, slicited incorpulative delicate, ocidem active legiologicate. The properties of the p
NDA APPLICANT HOLDER NAME AND ADDRESS	Exelbis, Inc. 1851 Harbor Bay Parkway Alameda, CA 94502	Exelitis, Inc. 1851 Harbor Bay Parkway Alameda, CA 94502	Exelitis, Inc. 1851 Harbor Bay Parkway Alameda, CA 94502	Glied Siment, Inc. 33 Dates of the Folia Chi, Cl 9463	WiW Heathcare Company For Go Backordmithding Research Triangle Park, NC 27709	Gillead Sciences, Inc. 333 Lekeside Drue Foster Chy, CA 9440A	Corcept Therapeutics 149 Commonwealth Drive Menio Park, CA 94025
NDA	208692	208692	208692	207561	205551	208351	202107
NDC	42388-024-26	42388-025-26	42388-023-26	61958-1901-1	49702-231-13	61958-2101-1	76346-073-01
U.S. GENERIC NAME	CABOZANTINIB	CABOZANTINIB	CABOZANTINIB	Pt. DATROCTABRIQ; TENGETOR A. 6.1550-1001.1	ABACANIS SUISATE. DOLUTEGRANIS SODUME: LAMINUDINE	MATERIANS REPRESE HTMOCLORES TRADONS AUTHORISES TRADASTE	MIFPRSTONE
U.S. PROPRIETARY NAME	САВОМЕТУХ	CABOMETYX	CABOMETYX	CENOTA	ъзмпац	A35:300	KORLYM
CANADAIAN INGREDIENTS	caborantinib ss caborantinib ss caborantinib ss caborantinib (\$\sime\) malata, cotoloda Silicon Dioxide, Oroszontilez Sodium, Alforosypcop (Calladox, Alexandrion 29 31), fron Order Velloudox, Lucina Anhydroux, Magensiam Stearate, Microcrystalline Celulose, Tisanium Dioxide and Trisectin.	cabosantinib ts rabosantinib ts cabosantinib ts cabosantinib [5] matabase, coliodal Silicon Dioxide, Consumalious Sodium, Videoropyropy (Callulates, Phytometropy 12, inch Oxide Yellow, Latons Ahlydross, Angeresium Steesate, Microcrystalline Cellulate, Tranhum Dioxide and Trisectin.	caborantinib ss caborantinib as caborantinib ss caborantinib (5) matabar, cotoloda Silicon Dioxide, Constantinios Sodium, Videorogycopy (Collubra, Approvagions 2510, inco Dodie Yellow, Lactora Arbydrow, Magersalam Stearate, Microcrystalline Celulace, Translum Dioxide sand Tritectin.	Les sable contain. 150 mp d'elebrgoné, 150 de debelegra, 150 mp de recibiliste, and 151 mp describe de recibiliste, and 150 mp de recibiliste and 150 mp de recipio and 15	rdierti. D navritoi, magoreium steurie, mirosci	Each tables contained 200 mg of TIC, 25 mg of Boyy In a 275 mg of Brith Worksholdshield had 25 mg of TM for 150 mg of TVD beneficiarieshield and believe also on other the following exactly singulariest contamentalism scales. But only monohighest, magnetism scarests, monohighest, magnetism scarests, monohighest, magnetism scarests, monohighest, magnetism scarests, monohighest, magnetism scarests, monohighest, magnetism scarests and media monohighest or flow control of the monohighest or flow control of the the control of the control of the control of the the control of the control of the control of the the control of the control of the control of the the control of the control of the control of the the control of the control of the control of the control of the the control of the control of the control of the control of the the control of the con	UMMBLTOLOGATE
NUMBER OF ACTIVE INGREDIENTS	1	п	ı	4	· ·	m	UMABLE TO LOCATE
DOSAGE FORM	TABLET	TABLET	TABLET	TABLET	TABLET	TABLET	UNABLETO
STRENGTH	50 MG	€0 MG	эмоэ	159-150-10 MG	9W 08: 05: 009	200-25-25 MG	UNABLE TO LOCATE
ADDRESS	SUITE 505 5060 Spectrum Way Mississauga Ontanio Canada LAW 5NS	Surve 505 5060 Spectrum Way Mississauga Ontario Canada L4W SN6	SUTE 505 5060 Spectrum Way Mississauga Ontario Canada L4W SN7	600 6711 Missisauga Missisauga Onario Canda ISN 2W3	245 Boulevard Armand- Frappier Laval Quebec Canada H7V 4A7	600 6711 Mireinauga Mireinauga Ontario Canada LSN 2W3	UMABLE TO LOCATE
COMPANY	IPSEN BIOPHARMACEUTICALS CANADA INC	IPSEN BIOPHARMACEUTICALS CANADA INC	IPSEN BIOPHARMACEUTICALS	GIEAD SCIENCES CANADA INC	אות אנערוורטישב חוכ	GIEAD SCIENCES CANADA INC	UNABLE TO LOCATE
NIQ	02480824	02480832	02480840	02449498	02430932	208351	UNABLE TO
CANADIAN GENERIC NAME	CABOZANTINIB	CABOZANTINIB	CABOZANTINIB	EMTEGTABNE, TENOPO VIR AAASTAMBOE, CUNTICORANT AND COBICSTAT	LAMIVUDINE, ABACAVIR AND DOLLITEGRAVIR	EMFRICTABNE; BILPWINNE HYDROCHORD; TENGCOVRE ALAFEWANDE FUIMAGNIT	UNABLE TO LOCATE
CANADIAN PROPRIETARY NAME	CABOMETXX	CABOMETYX	CABOMETYX	иломае	TRUMEQ	A35.900	UNABLE TO LOCATE
CANADIAN PROPRIETARY NAME	CAROMETYX	САВОМЕТУХ	САВОМЕТУХ	GENOTA		A35:800	

U.S. INGREDIENTS	Cas differented ballet cassion 2000 and entrologies and 2000 red of throughout programme and common and an entrologies and an entrologies and extent impredient an entrologies and an entr	Active legistient apublish, hostov eignedents, anlydeus lations, intoropysallises eichkots, to consmisses soden, soden hary- aufte, and metalem nassest. It in coeffe contain better modifysie in yeproedent, and end in coeffe commission better from cade (2.3 mg blacks) or end no made (5 mg blacks).
NDA APPLICANT HOLDER NAME AND ADDRESS	Olman Somere, Inc. 1) The Somere, Inc. 1) Court City, CA 44404	Bristol Myers Squibb P.O. Box 4000 Princeton, NI 08543-4000
NDA	21:752	202155
NDC	61958-0701-1	0003-0894-21
U.S. GENERIC NAME	DATROCHANG, TRACKOVR DOOPROM, UMARATE	APIXABAN
U.S. PROPRIETARY NAME	TRUNKSA	ELIQUIS
CANADALAN INGREDIENTS	The thirt crudent DO my of exercitation we all exercised to the control of the co	Active lagredient Apisabas Excipents. Tablet core. Anythoris stress, microsyntalline colleges, controlysalline colleges, controlysalline colleges, controlysalline colleges, controlysalline section buyl, tablet and magnetium stearine. In the control buyl, tablet and magnetium stearine. The colleges of the colleges. The colleges of th
NUMBER OF ACTIVE INGREDIENTS	n.	1
DOSAGE FORM	TABLET	TABLET
STRENGTH	200-300 MG	s MG
ADDRESS	Consider LSH 2W)	2344 Boul Affred Nobel, Suite 300 Montréal (St-Laurent) Quebec Canada H45 0A4
COMPANY	פוקדס לכונובבו כאאיטיו אוכ	BRISTOL-AFFRS SQUIBB
NIG	02274906	02397714
CANADIAN GENERIC NAME	AND EMPICIABINE	АРШАВАН
CANADIAN PROPRIETARY NAME	TROOLDA	Enduis





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.

	a		u	e e			NO Va. 83 0
U.S. INGREDIENTS	Each tablet contains 20 mg of lutasidose hydrochloride, inactive ingredients are manniol, pregediented starch, cross-mediose sodium, hydromeliose, magnesium stearte, Opadry's and camauba was. Additi	Each tablet cominin do mg of lutraidone hydrochloride, Inactive logsdelents are manniol, pregedelented starch, crossammeloses sodium, hydromellose, magnesium stearte, Opadry's and camauba was. Additi	Each tablet contains 60 mg of lurasidone hydrochlorides Inactive Ingredients are manning, pregetalinized starch, cross-mellose sodium, hydromellose, magnesium stearte, Opadry's and camauba was Additi	Each tablet contains 80 mg of lurasione hydrochoride, has the is gredients are mannitol, pregedentiated startly, crossmelloss sodium, hydromellose, magnesium stearte, Opadry's and camanias was Additi	Active ingredient: albutarol sulfate Inactive ingredient: propelliant HFA-134a	Active ingredients: fluticasone propionate, salmeterol xinafoate inactive ingredient: lactose monohydrate (contains milk proteins)	Each 0.5 mg CHANTK tablet contains 0.85 mg Overacifier actives equalisation 0.5 mg off varietisms free base, sach 1. mg CHANTM, varietisms free base, sach 1. mg CHANTM, and contains 1.1 mg of varietisms tartized equalisation 1 mg of varietisms free base. The proposition of the properties of the proposition that tablets: microcrystaline cellulose, crossameliose sodium, coloida silicon diodode, magnesium steerate, Opathy White (for 0.5 mg) Opathy Elea.
NDA APPLICANT HOLDER NAME AND ADDRESS	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 5 Moore Drive Malistop 5.58 Research Triangle Park, NC 27709	GlaxoSmithKline Five Moore Drive P. O. Box 13398 Research Triangle Park, NC 27709	PF Prism C V do Pfizer, Inc 235 East 42nd Street New York, NY 10017-5755
NDA	200603	200604	200605	200606	020983	021077	021928
NDC	63402-302-30 200603	63402-304-30 200604	63402-306-30 200605	63402-308-30 200606	0173-0682-20	0173-0696-00 021077	0069-0468-56 021928
U.S. GENERIC NAME	LURASIDONE	LURASIDONE	LURASIDONE	LURASIDONE	ALBUTEROL HFA 0173-0682-20 020983	SALMETEROL AND FLUTICASONE	VARENICLINE
U.S. PROPRIETARY NAME	LATUDA	LATUDA	LATUDA	LATUDA	VENTOLIN HFA	ADVAIR DISKUS	СНАМТІХ
CANADAIAN INGREDIENTS	urasidone hydrochloride, carnauba wax, croscarmellose sodium, hypromellose magnesium steaster, manniol, podary (hypromellose, polyethylene gyleol, and titanium dioxide), pregelatinized starch; 80 mg tablet also contains: FD&C Blue No.2 Aluminum lake and yellow ferric oxide.	urasidone hydrochloride, carnauba wax, croscarmellose sodium, hydromellose, magnesium stearate, mannihol. Opadry (hypromellose, polyethylene gylvol, and titanium daoide), pregelatinized starch; 80 mg tablet also contains: FD&C Blue No.2 Aluminum Lake and yellow ferric oxide.	lurasidone hydrochloride, carnauba wax, croscarmellose sodium, hydromellose, magnesium stearem amanilo. Opadry (hypromellose, polyethylere gylool, and titanium diocide), pregelatinized starch; 80 mg tablet also connains: FD&C Blue No.2 Aluminum Lake and yellow ferric, oxide.	urasidone hydrochloride, carnauba wax, croscarmellose sodium, hydromellose, magnesium stearate, maminio, Opadry (hypromellose, polyethylene gybol, and titanium dioxide), pregelatinized starch; 80 mg tablet also contains: FD&C Blue No.2 Aluminum lake and yellow ferric oxide.	lurasidone hydrochloride, carnauba wax, croscarmellose sodium, hydromellose magnesium stearter mannilo. Opadry (hypromellose, polyethylene gylool, and titanium dioxide), pregelatinized starch; 80 mg tablet also conta	250 mcg fluticasone propionate and 50 mcg salmeterol (as the xinafoate salt)	varencilne tarrate, anhydrous dibasic calcium prosphate, colloida silicon disorde, crosmelose a sodium, magnetium stearies, and microcystalies celloice. The film-coating contains hypomelose, polychylwine polycy, illamini microcystalia disordenia silicon microcystalia disordenia proposalia su distributa silicon microcystalia su disordenia silicon disordenia se a si colouring agenti.
NUMBER OF ACTIVE INGREDIENTS	1	1	ı	1	1	2	н
DOSAGE FORM	TABLET	TABLET	TABLET	TABLET	METERED- DOSE AEROSOL	POWDER	ТАВLЕТ
STRENGTH	20 MG	40 MG	60 MG	80 MG	100 MCG/ ACT	250/50	0.5 MG
ADDRESS	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	7333 Mississauga Road Mississauga Ontario Canada LSN 6L4	7333 Mississauga Road Mississauga Ontario Canada LSN 6L4	17300 Trans- Canada Highway Kirkand Quebec Canada H9J 2MS
COMPANY	SUNOVION PHARMACEUTICALS CANADA INC	SUNOVION PHARMACEUTICALS CANADA INC	SUNOVION PHARMACEUTICALS CANADA INC	SUNDVION PHARMACEUTICALS CANADA INC	GLAXOSMITHKLINE INC	GLAXOSMITHKLINE INC	PFIZER CANADA ULC
NIG	02422050	02387751	02413361	02387778	02241497	02240836	02291177
CANADIAN GENERIC NAME	LURASIDONE	LURASIDONE	LURASIDONE	LURASIDONE	SALBUTAMOL HFA	SALMETEROL AND FLUTICASONE	VARENICLINE
CANADIAN PROPRIETARY NAME	LATUDA	LATUDA	LATUDA	LATUDA	VENTOLIN HFA	ADVAIR DISKUS	CHANTIX

	S mg g of IX	of wir tive n ne inyl	e e e	ous, ne g g ablet alc,	ous, ne g g g g g g ablet	ediol as n n lm low
U.S. INGREDIENTS	Each 0.5 mg CHANTX tablet contains 0.85 mg Verwelline that the equilment to 0.5 mg Of varietine that the equilment to 0.5 mg Of varietine the base, each 1 mg CHANTX mg CHANTX mg Of varietine that the equilment to 1 mg of varietine the tablet equilment to 1 mg of varietine free base. The tablets microcrystaline cellulose, and manylous delated called mg of varietine cellulose, coccarmellose acidim, cellulose, coccarmellose acidim, cellulose in apprentiment necessaria, Opadry White (for 0.5 mg) Opadry Blee (for 0.5 mg) Opadry Blee (for 0.5 mg) Opadry Blee (for 0.5 mg) Opadry Clear.	Each 20075 mg tablet contains 200 mg of entricitablene (FTC) and 2.5 mg of tenofrorir alleforamride (TAS) and 12 mg of tenofrorir impredients colocameloles cooldium, magnetium steared, and microcrystaline coalubos. The tables are film-coalubos. The tables coalubos. The tables are film-coalubos coalubos. The tables are film-coalubos coalubos. The tables are film-coalubos coalubos. The tables are coalubos. The tables of the coalubos. The tables of coalubos are tables of tables of tables of tables of tables tables of tables tables tables tables tables tables tables tables tables tables tables tables tables tables	25 mg of empagificioni (free base) and the following lanche ingredients: Lattose following lanche ingredients: Lattose monohydras, microcystalline cellulose, hydroxypropy cellulose, crossammelose acolum, collodial silicen dioade and magnesim stearate, institution, beliation, beliam coating contains the following in	100mg of canagilitatin or 300mg of canagilitatin, crocrameliose sodium, crocrameliose sodium, diversoproper (canagilitation), actors analyticus, magnesium searatu, and microcrystaline, the calcinocerystaline, the tablect coating contains from cade vellone, ETZ (100 mg table coating contains from cade vellone, ETZ (100 mg table coating contains from cade vellone, ETZ (100 mg table coating contains from cade vellone, ETZ (100 mg table coating coating from the coating coating coating coating canadia	100mg of campillrain or 300mg of campillrain or 300mg of campillrain, craceamelose sodium, deveryoney federose, lactose anheforus, magnesium searate, and microcrystalline cellidose, in addition, the tablet crashing contains from cade vellone, ETJS (100 mg pates only), macrogel/PES, polywiny alcohol, talc, and tranium dioxide.	5 mg dapagillotin as dapagillotin propamediol or the equivalent of 10 mg dapagillotin as propamediold, microcrystaline ceibilose, antifytos bacco-crospoldento, illom doode, and magnetium steature. The film costing contains polywith alcohol, itanium dioxide, polywithytes givos, till, and yellow iron oode.
NDA APPLICANT HOLDER NAME AND ADDRESS	PF Priem C V c/o Pflee, Inc 235 Est 42nd Street New York, NY 10017-5756	Gilead Sciences, Inc. 333 Lakeside Brive Foster City, CA 94404	Boehringer ingelheim Pharmaceuticals, Inc. 900 Ridgebury Road P.O. Box 368 Ridgefield, CT 06877	Janssen Pharmaceuticals, 1125 Trenton-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 021928	61958-2002-1) 208215	0597-0152-30	50458-0140-30 204042	50458-0141-30 204042	00310-6205-30
U.S. GENERIC NAME	VARENICLINE	EMTRICITABINE; TENGFOVIR ALAFENAMIDE FUMARATE	EMPAGLELOZIN 0597-0152-30 204629	CAGLIFLOZIN	CAGLIFLOZIN	DAPAGIFICZIN 00310 6205-30 202293
U.S. PROPRIETARY NAME GENERIC NAME	СНАМТІХ	MOSSA	JARDIANCE	INVOKANA	INVOKANA	FARXIGA
CANADAIAN INGREDIENTS	varencine tartrate, anhydrous dibasic calcium phosphate, collodes silicon dioxde, crossmellore sodium, magnetium stearets, and mircorystalme eculiose. The film-coaring contains hypomelose, polychythylere polycul traineum dioxde and tristent. The 1.0 mg tablet also contains FD&C Blue ZJ.Indigo Carnine Aluminum lates as a colouring agent.	200 mg emtrictabine, 25 mg tendrovir adalensamie, uncorportaline celliolos, conscentellos socialm, and magnetim stearet. The yet tablets are film-coarde with coarde with a couring material containing polyviny a couling material containing polyviny a couling material conditions to material containing polyviny alcohol, transming polyviny alcohol, transming polyviny alcohol, transmin dioxide, polyviny alcohol, transming dioxide, polyviny alcohol.	25 mg of empagliflozin free base, coloidai silicon dioxide, croscarmeliose sodium, hydroxypropyl celiulose, hypromeliose, locose emondylarie, magnesium stearte, macrogol, microcrystalline celiulose, titanium dioxide, taić, and yellow ferric coide.	100mg of canagilliotin OR 300mg of canagilliotin Core share conscarmellors action, hydroxypropy cellulose, lattose anhydroxy, magnesium sestante, and microsynaline cellulose. Film Cost: ten oxide velove, (100 mg table oxide, Narcogol (100 mg Bycol), polywith alcohol, lade, and ttannium dioxide.	100mg of canagillocin OR 300mg of canagillocin Core rabase consequency or canagillocin. Core rabase celluloce, lactose anhydroxy, magnesium search as minor orspanine celluloce. Film Cost: ten oxide velove, (100 mg table only, Marcogol Icohorhymen glycol), polywith allochol, ladic, and ttannium dioxide.	5 mg or 10 mg dapagificion as dapagificion promorbidates, ambydrous lactous, crospordiene, ambydrous lactous, crospordiene, magnetium stearate, microcrystaline, magnetium stearate, microcrystaline, magnetium stearate, polymyd aktorbol, film coulting contains the following lim coulting contains the following the promorbol of the promorbol of the promorbol transium dioxide, polyetiviene glycol, talic and yellow fron coide.
NUMBER OF ACTIVE INGREDIENTS	1	2	1	1	1	1
DOSAGE FORM	TABLET	TABLET	TABLET	TABLET	TABLET	TABLET
STRENGTH	1 MG	200-25 MG	25 MG	100 MG	300 MG	SMG
ADDRESS	17301 Trans- Canada Highway Kirkland Quebec Canada H9J 2MS	600 6711 Mississauga Road Mississauga 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 LAY 1M4
COMPANY	PFIZER CANADA ULC	GILEAD 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 CANADIAN PROPRIETARY NAME GENERIC NAME	CHANTIX	DESCONY	JARDIANCE	INVOKANA	INVOKANA	FORXIGA

U.S. INGREDIENTS	5 mg dapagillocin as dapagillocin propanediol or the equivalent of 10 mg dapagillocin as dapagillocin dapagillocin composition of propanediod, minterceptatiline celluloce, anhydros lactose, cropovidone, silicon dioxide, an magnesium stearate the limit costing contains: polywing alcohol, thanium dioxide, polyetylpine givos, tay wellow dioxide, polyetylpine givos, ta, and yellow dioxide, polyetylpine givos, ta, and yellow	selecipag 1400mg Inactive ingredients: D- mannifo, com service, los wabistituted hydroxyprospicellulose, and magnesium steparate. The ulbida service with a coating material containing hypomeliose, was along with into modele camalaba was along with into modele camalaba was along with into modele facili on codele yellow, or fron oxide back.	240mg dimethyl fumarab, microcystalline cellulose, silicited microcystalline cellulose, silicited microcystalline cellulose, silicited microcystalline cellulose, silicited microcystalline, tid., silicited cellulose, silicited missing magnetium steares, triterly methors of ecolophyme cellophyme (action choose), magnetium steares, presentions; policy silicited cell copolyme celluloses, celluloses, acid copolyme celloseston, methody, scalable said opsycrabet 80, getalin, transmin dioxide, PORC blac 1; brilliant blue FG; yellow form oxide and black forn oxide.	Rifaximin S50mg, colloidal silicon dioxide, disolution dioxidum debetace, glycerol paintinistosaras, hypomeliose, microcrystaline cellulace, propylene glycol, red oxide, sodium starch glycolate, talc, and ttalmum dioxide.	situalitate and metformin, microcrostalline callulane, polyvinlyprosidene, sodium tum sulfare, and codum tearyf furmanes. The base film consider consists the following incache in gendelmic, polyvinly diction), polyvethylene glytod, tud, filmsium dioxide, red pror codie, and bised fron codie.
NDA APPLICANT HOLDER NAME AND ADDRESS	ASTRAZENECA LP PO BOX 15437 WILMINGTON, DE 19850	Actelion Pharmaceuticals US, S000 Shoreline Court, Ste. 200 South San Francisco, CA 94080, USA	Biogen IDEC Inc 225 Binney Street Cambridge, MA 02142	SALIX PHARMACEUTICALS 1700 Perimeter Park Drive Morrisville, NC 27560	MECCSHAP DOHME 2006 Galborg Hill Road Kenikorth, N 088859
NDA	202293	207947	204063	022554	022044
NDC	00310-6210-30 202293	66215-0614-06 207947	64406-0006-02 204063	RIFAXIMIN 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 GENERIC NAME	FARXIGA	UPTRAVI	TEGFIDERA	XIFAXAN	JANUMET
CANADAIAN INGREDIENTS	5 mg or 10 mg dapagifilotin as dapagaliflant proparated inmontheritati, anhydrous lattosa, crosporateon, magnesium stearta, microcrystalline cellores, silicon doode in addition, the film coating certainsh the following inactive ingredients; polywith alcohol, thank mad doolde, polyetivine giroc, tale and yellow fron coide.	Selexing 1400mg, carnauba wax, com starch. D-manitol, inytoropropyl cellulose, hypomeliose, tripomeliose, tripomeliose, constitute of tripomeliose, hydroxypropyl cellulose, magnesium stearate, propylene Bytol, ttanlum stearate,	240 mg of dimethyl furmantae, colloidal allicrior dende, brocestemente endium, magnesium stearta, metharcylic acid copolymer (type A), methacrylic acid copolymer dispersion, polyonotae 80, silerfeld microcystaline cellulose, silerfeld microcystaline cellulose, silerfeld microcystaline cellulose, silerfeld microcystaline cellulose, silerfeld microcystaline cellulose, and triethyl dirtae. The appule shell contains black irno oxide, EP&C Blue 1, gelatin, transium dioxidos and yellow iron oxide.	Rifaximin 550mg, colloidal silicon dioxide, glyceryl distearate, microcrystaline cellulose, polyetylylene glycol, polyystyline cellulose, polyetylylene glytor, prolymy al colloi, red iron exide, gluten free sodium starch glycolate, laic, and titanium dioxide.	64.25 mg sitnglightin photosphate monocybrate and meterofromin hydrochloride equivalent tro. 50 mg situglights as fee base and 20.00 mg situglights as 16.00 mg situglights as 15.00 mg meteromin hydrochloride (LANUNIATE's 50 mg/200 mg meteromin hydrochloride (LANUNIATE's 50 mg/200 mg meteromin hydrochloride (LANUNIATE's 50 mg/200 mg meteromine (Lanuniate) mg/, microcyprilline edulloxes, polyvin/hydrocyloride (Lanuniate) and sodium launy suffers, and suffers, and suffers, and suffers, and suffers suffers, and suffers suffers suffers suffers, and suffers su
NUMBER OF ACTIVE INGREDIENTS	1	1	et.	1	N
DOSAGE FORM	TABLET	TABLET	CAPSULE (DELAYED- RELEASE)	TABLET	TABLET
STRENGTH	10 MG	1400 MCG	240 MG	550 MG	SO-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 1.100 Mississauga Ontario Canada LSB 3.C3	400 Somerset Corporate Boulevard Bridgewater, NJ 08807	16750 Route Transcanademe Kirkland Quebec Canada H9H 4M7
COMPANY	ASTRAZENECA CANADA INC	JANSSEN INC	BIOGEN CANADA INC	SALIX PHARMACEUTICALS INC	MERCK CANADA INC
NIG	02435470	02451212	02420201	02410702	0233856
CANADIAN GENERIC NAME	DAPAGLIFOZIN	SELEXIPAG	DIMETHYL FUMARATE	RIFAXIMIN	METFORMIN/SIT AGLIPITN
CANADIAN CANADIAN PROPRIETARY NAME GENERIC NAME	FORXIGA	UPTRAVI	TECFIDERA	ZAXINE	JANUMET

	illine The ving ving le, red	on mg, whing liulose, te, arate, arate, ar, the rive here wide,	livers	n, e, Ilulose, rred, ohol um	odium, Air free stalline sarch s. The ive 5-mg EG,	tol manı
U.S. INGREDIENTS	stagigts and marternin, microcytalline cellules, polymripprofilers, codum bust sulfate, and sodum steary fumerate. The state film conductor comman the following inactive impedients; polywaly alcohol, polyerbyene giyord, tak, translum disoide, ned polyerbyene giyord, tak, translum disoide, ned code, and black fron code.	1285 mg of straighten phosphate monophydrag, who properly equivalent to 100 mg respectively, of five base and the following interfer by gredients: microcrystalline cellulosa marydrous dialosa cellulosa, conscrimelos sodium, magnesia cellulosa adolam stearful marade in adollono, the film costing contains the following nactive ingredients: polyhoming active, polyment activo looper proposition of the proposition	1.1 g/mL of glycerol phenylbutyrate (delivers 1.02 g/mL of phenylbutyrate).	rivarcasban, croscarmellose sodium, hypromellose, lacrose monohydrate, magnesium stearast, microcystalline cellulose, and sodium lauvit sulfase, ferric code red, polytethylene glytol 3330, polytumi alcohol (partially hydrolyzed), lau, and titanium dioxide.	10.5, 26.5, or 52.6 mg of dolutegranir sodium, mind in Sequender 20 or mg dolutegranir free deficies, pouldour 20.732, adum starch efficies, pouldour S1292, adum starch glycale, and sodium steay furnates. The tablet firm-canning contains the instaction to make yellow (for the 25 mg and 50 mg tablets only, mercragol/PICE, polyvimy alcoinle part hydrotyreet, talk, and polyvimy alcoinle part hydrotyreet, talk, and	ng of glatiramer acetate, 40 mg of mannitol man
NDA APPLICANT HOLDER NAME AND ADDRESS	MERCY SHARP DOHME 2000 Galogner HII hoad Kenikorth, NJ 08889	MERCK SHARP DOHME 2000 Galoping HII Road Kenliworth, 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 FWe Moore Drive Researth Trangle Fark, NC 27799	TEVA PHARMACEUTICALS USA 400 Interpace Parkway #3 Parsippany, NJ 07054
NDA	022044	021995	203284	022406 202439	204790	020622
NDC	00006 0577 61 022044	00006-0277-31	76325-0100-04 203284	50458-0579-30	49702-0228-13	68456-0325-12 020622
U.S. GENERIC NAME	SITAGLIPTIN/ME TFORMIN HCL	SITAGLIPTIN PHOSPHATE	GLYCEROL PHENYLBUTYRA TE	RIVAROXABAN SO4S#-0579-30 022406	DOULTGRAVIR 49702-0228-13 204790	GLATIRAMER ACETATE
U.S. PROPRIETARY NAME	TANUMET	JANUNA	RAVICTI	XARELTO	WJWT	COPAXONE
CANADAIAN INGREDIENTS	64.25 me situalitation phosphate monosyleriate and meteromin hydrochioride equivalent us: 50 meteromin hydrochioride equivalent us: 50 meteromin hydrochioride (ANAUNET'S 50 meteroministic meteroministic hydrochioride (ANAUNET'S 50 meteroministic hydrochioride (ANAUNET'S 50 meteroministic meteroministic hydrochioride (ANAUNET'S 50 meteroministic hydrochioride hydrochi	128.5 mg of stagilishin phosphate monohydrate, which is equivalent to 100 mg, especially of the first phosphate of the control	1.1 g/mL glycerol phenylbutyrate (delivers 1.02 g/mL of PBA). There are no excipients.	Rivaroxaban, collulose microcrystalline, croscarmaliose socium, hyporonaliose 5 by Latose monohydrate, magnesium stearate, sodium launy suphate, ferric dele Weilow (12, 20 mg). Terric noode red (10 mg. 15 mg. 20 mg). Perporonaliose 15 P., polyethylene glycol, titanium dioxide.	\$2.6 mg of dolategravir sodium, which is equivalent to 50 mg dolategravir free and, respectively, and the following inactive ingredients: D-manitol. microcytalism cellulose, providone \$7.292, sodium starto picolate, and sodium starto picolate, and codium starto picolate, and codium starto picolate, and starto picolate, and starto picolate, and starto sondy, marze an 'free dieferitation odde yellow (25 mg and 50 mg tablets only, marzequi?f5c, polyvinyl allohological part yhdrolyzed, allo, and allohological provided allohological part yhdrolyzed, allo, and allohological part yhdrolyzed, allohological part yhdrolyzed, allo, and allohological part yhdrolyzed, allohological part yhdrolyzed allohological yhdrological part yhdrolyzed allohological part yhdrolyzed allohological yhdrological	glatiramer acetate, mannitol and sterile water for injection.
NUMBER OF ACTIVE INGREDIENTS	2	1	1	1	ч	1
DOSAGE FORM	TABLET	TABLET	ORAL LIQUID	TABLET	TABLET	SOLUTION
STRENGTH	50-1000 MG	100 MG	1.1 G/ML	20 MG	SO MG	40 MG
ADDRESS	16750 Route Transcandeme Kirkland Quebec Canada H9H 4M7	16750 Route Transcanadienne Kirkland 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 M18 2K9
COMPANY	MERCK CANADA INC	MERCK CANADA INC	HORIZON THERAPEUTICS IRELAND DAC	BAYER INC	VIIV HEALTHCARE ULC	TEVA CANADA LIMITED
NIG	02333872	02303922	02453304	02378612	02414945	02456915
CANADIAN GENERIC NAME	METORMIN/SIT AGLPITN	SITAGLIPTIN (SITAGLIPTIN PHOSPHATE MONOJYDRATE	GLYCEROL PHENYLBUTYRA TE	RIVAROXABAN 02378612	DOLUTEGRAVIR (DOLUTEGRAVIR SODIUM)	GLATIRAMER ACETATE
CANADIAN CANADIAN PROPRIETARY NAME GENERIC NAME	JANUMET	ANUMAL	RAVICTI	XARELTO	TVICAY	COPAXONE

CAFSUES: incutinib (active ingredient) and the following market eight in market incorpstalline cellulos, sodium, margines in states, microcystalline cellulos, sodium, market valuatise. The rappule shell contains gebian, tanium dioxide, yellow hell contains gebian, tanium dioxide, yellow from coade (70 mg capsule only), and black int. TARIETS: mutnib factive ingredients: colloids sillow following inactive ingredients: colloids sillow microcystalline sodium, actorise microcystalline solution, actorise microcystalline solution, actorise microcystalline solutions, povidone, and solution and and and and and and and and and an	linguides and the clowing instance of migorial ingredients debodium phosphate dihydrate. 1.42 mg, proplyme glyou, 1.4 mg, phonol, 5.5 mg, proplyme glyou, 1.4 mg, phonol, 5.5 mg, or injection. VICTOZA has a phonol of approximately 8.1. Widercholers and or column hydroide may be added to adjust plut. Each pre-filled pen contains 3.5 mt, solution of VICTOZA equivalent to 28 mg linguide (free-bases, pen added to make a pen added to adjust plut.)	200 mg milorini base, amhydrous (equivalent to S. Sm. Li fels mg. and 221 mg milorini concolydrochiodis monohydrate respectively) with the following inactive ingredients. collidas allorin diodice, recopolodious, lactose monohydrate, respection, steams et all plokamer 181. The capulates contain gleath, fron oxide (red), iron oxide (pallow), no oxide (black), and titanium dioxide.	dissatirib, with the following inactive ingredients: large-dients; large-dients; large-dients; large-dients, and microcyntaline cellulose, croscarnelose sodium, hydroxypropyl cellulose, and magnesium steaster. Het tablet coating consists of hypromeliose, thalmund doodde, and polylethylene glycol.
PHARMACYCLICS INC 999 Eat Aques Avenue Sumyvale, CA 94085	NOVO NORDISK INC 800 Scudders Mill Road Plainsboro, NJ 08536	NOVARTIS One Health Plaza East Hanover, NI 07936	BRISTOL MYERS SQUIBB 430 E 29th Street 14th Floor New York, NY 10016
205552	022341	022068	021986
57962-0140-09	00169-4060-13	00078-0526-87	00003-0528-11 021986
IBRUTINE	LIRAGLUTIDE	NILOTINIB HYDROCHLORID E	DASATINIB
IMBRUVICA	VICTOZA	TASIGNA	SPRYCEL
140 mg of ibrutinib, celloidal silicon dodout, crostamelloste sodium, lactose monohiritate, maperisium steares menority stalline cellulose, povidone, and sodium lauk, tien oxide III all sodium sodium suback iron oxide II.d. mg. Babletti, lipolettily leno oxide II.d. mg. Babletti, loolettily lene givod, mg. and soon mg.	6 mg/Mi Linglutide, Disodum phosphate dinyarate, propylene glycol, phenol and water for injections	200 mg nitorini base (as hydrochloride monohydrate), Collodad silcon anhydrous, Cospododone, Lactose monohydrate; Polosamer 188, Magessiam steamate. Capsule shell: Gestin; Trainand Goodeg, Frinting ink: includes red iron oxide.	50 mg and 100 mg disastinin (as monohydrate) containing the following mon-medicinal gredients for the tablet, core crost-ameliose solium, hydroxyporg fellolosi, abetoe monohydrate, magnesium issante and microcyptaline cellulose. The firm coaling contain the following inactive coaling contains thypomeliose, polyethylmin ingredients: hypomeliose, polyethylmin ingredients:
τ	1	1	1
CAPSULE	OLUTION	CAPSULE	TABLET
140 MG	18MG/3M L	200 MG	50 MG
19 Green Belt Driv Toronto Ontario Canada M3C 119	101-2476 Argenti Road Mississauga Ontario Canada LSN 6M1	385 Bouchard Blvv Dorval Quebec Canada, H95 1A9	2344 Boul. Alfred- Nobel Suite 300 Montreal (St- Laurent) Quebec Canada H4S 0A4
JANSSEN INC	NOVO NORDISK CANADA INC	NOVARTIS PHARMACEUTICALS CANADA INC	BRISTOL-MYERS SQUIBB CANADA
02434407	02351064	02315874	02293137
IBRUTINIB	LIRAGLUTIDE	NILTINIB (NILOTINIB HYDROCHLORID E MONOHYDRATE)	DASATINIB (DASATINIB MONOHYDRATE)
IMBRUVICA	VICTOZA	TASIGNA	SPRYCEL
	140 mg of Brutinib, colloidal silicon aldooda, vocatemmeliose and broad, vocatemmeliose sodium lactures monophydrate, magnetium stease monophydrate, magnet	HANDENING 02554477 HANSEN INC TOTALS Agentia 100 diodes, crossmellose and diodes	Standard Standard

U.S. INGREDIENTS	distainib, with the following inactive ingredients better monohydrate, microsystalline cellulose, crose-mellose sodium, hydroxypropy cellulose, and magnesium stease. The tablet costing consists of hypomeliose, tablishim dioxide, and polyethylene glycol.	SOOm gabriereone acetate, coloidal silicon dioude, crossemeliose, sodium, hypromeliose, dioude, crossemeliose sodium, hypromeliose, latente embodrose, magnesium stearate, silicifice microcystaline cellulose, and sodium valuatier. The consider, Osady-Pira Piraple, contains iron code back, iron code red, polyvethylene gircol, polyventy alcehol, tale, and timnium dioude.	4.0 mg of excalulamide as a solution in capyiouspoyl polycydyleceldes. The inactive polycydyleceldes, polycydyleceldes, polycydyleceldes	100 mg or 150 mg of nintedanib (equivalent to 210.40 mg or 150.00 mg nintedanib ethanasulkonata, respectively). The inactive my respectively of the set for following: Fill Materials trillycerides, had foll the lethih. Capsule Shell: gehelin, glycerot, titanium dioude, red ferric coxide, yellow ferric coide, black his.	100 mg or 150 mg of nintedenib (equivalent to 20.04 mg or 150.05 mg orderson ethnication ethnication between the 100 mg orderson orderson mg orderson orders
NDA APPLICANT HOLDER NAME AND ADDRESS	BRISTOL MYERS SQUIBB 430 E 29th Street 14th Floor New York, NY 10016	JANSSEN BIOTECH, INC. 800 Ridgeview Road Horsham, PA 19044	ASTELAS One Astelia: Way Northbrock, IL 60062	Boehringer Ingelheim Pharmaceurlas, Inc. 900 Magebury Aoad P.O. Box 388 Ridgefield, CT 06877	Boehringer Ingelheim Pharmaceuticisk, Inc. 900 feldgeburn Road P. O. Box 368 Rügerleid, CT 06877
NDA	021986	202379	203415	205832	205832
NDC	00003-0852-22 021986	57894-0195-06 202379	ENZALUTAMIDE DOGG-0125-99 209415	00597-0143-60 205892	00597-0145-60 205892
U.S. GENERIC NAME	DASATINIB	ABIRATERONE ACETATE	ENZALUTAMIDE	NINTEDANIB	NINTEDANIB ESYLATE
U.S. PROPRIETARY NAME	SPRYCEL	ZYTIGA	XTANDI	OFEV	OFEV
CANADAIAN INGREDIENTS	50 mg and 100 mg dasathinh (as monohydrata) containing the following non-medicinal progedents for the abbet core cross-melose sodium. Pudrospropor follotos, but actos monohydrate, magnesium steante and microcystaline cellulose. The film coaling contain the following hardyte mgedients: hypomeliose, polyethylene glycol and titanium dioode.	500MG abiraterone acetatic colloidal listion denduc roscarmellose acolum, histornellose, lactose monohidate, magnesiam steaante, silicífica microcysiam estalose, aná sodium laury silatier. The tables tim costine contains from doce black, ton coder est, marcogo 3330, polyviny lacitos, lack, and titanium diosides.	do mg of entalutamide and the inactive ingredient caphricaporal caphrica	100 and 150 mg of nintedanib (as a free base) corresponding to 120.40 mg and 180.60 mg of nintedanib and 180.60 mg of nintedanib ethanesillorate (stalles), respectively. Capoule (iii) Modium chain trighyeredde, had fit, sopa leither (1512), for godde (1517), for no sold end (1517), into mg odde ethan (1517), both (1517), both (1518), back int. Obsacode*) (Black int. Shellic glass, iron noide back (1517), son popplene glass, iron noide back (1518), son popplene glass, iron noide back (1519), propylene glycol (15120)	100 and 150 mg of intredants lies a free basel corresponding to 120.40 mg and 180.60 mg of intredants of intredants of intredant elabareal/locate (elabarea), respectively. Tappute IIII Madura chain trighyderodds, hard fit, sopa technic (1222). Capacia Shider, Galainn, Byecord SS %, ttanhum dioxide (1271), for oxide red (1272), for oxide red (1272), and (1272), but in (1272), but in (1272), but in (1273), propylere gives (1273).
NUMBER OF ACTIVE INGREDIENTS	1	1	н	et	r ·
DOSAGE FORM	TABLET	TABLET	CAPSULE	CAPSULE	CAPSULE
STRENGTH	100 MG	500 MG	40 MG	100 MG	150 MG
ADDRESS	2344 Boul, Alfred- Nobel Suite 300 Montreal (St- Laurent) Quebec Canada H4S 0A4	19 Green Belt Drive Toronto Ontario Canada M3C 119	SUITE 500 675 Codrane Drive West Tower Markham Ontario Canada, L3R0BB	5180 South Service Read Burlington Ontario Canada IZI SH4	5.180 South Service Read Builington Ontario Canada L7L SH4
COMPANY	BRISTOL-MYERS SQUIBE CANADA	JANSSEN INC	ASTELAS PHARMA CANADA INC	BOEHRINGER INGELHEIM (CANADA) LTD LTEE	BOEHRINGER INGELFEIM (CANADA) LTD LTEE
NIG	02320193	02457113		02443066	0243074
CANADIAN GENERIC NAME	DASATINIB (DASATINIB MONOHYDRATE)	ABIRATERONE ACETATE	ENZALUTAMIDE 02407329	NINTEDANIB (NINTEDANIB ESILATE)	NINTEDANIB (NINTEDANIB ESILATE)
CANADIAN PROPRIETARY NAME	SPRYCEL	ZYTIGA	XTANDI	OFEV	OFEV

CANADIAN CANADIAN PROPRIETARY NAME GENERIC NAME	CANADIAN GENERIC NAME	NIG	COMPANY	ADDRESS	STRENGTH	DOSAGE FORM	NUMBER OF ACTIVE INGREDIENTS	CANADAIAN INGREDIENTS	U.S. PROPRIETARY NAME GENERIC NAME	U.S. GENERIC NAME	NDC	NDA	NDA APPLICANT HOLDER NAME AND ADDRESS	U.S. INGREDIENTS
REVOLADE	ELTROMBOPAG (ELTROMBOPAG OLAMINE)	02361825	NOVARTIS PHARMACEUTICALS CANADA INC	38S Bouchard Blvd Dorval Quebec Canada, H9S 1A9	25 MG	TABLET	1	25 mg or 50 mg of eltrombopag as eletrombopag andeltrombopag andeltrombopag andeltrombopag andeltrombopag andeltrombopag andeltrombopag andeltrombopag andeltrombopagagagagagagagagagagagagagagagagagagag	PROMACTA	ELTROMBOPAG OLAMINE	00078-0685-15 022291	5 022291	NOVARTIS One Health Plaza East Hanover, NI 07936	ettrombogeg clamine 25 mg or 50 mg of ettrombogeg clamine 21 mg or 50 mg or of PROMACTA balets are Tabet core magnesiant seazate, manniola microcoptalline glycolate Coating FORC telle No. 2 aluminum lave 150 mg tabet, 105C vielow No. 6 aluminum lave 160 mg tabet, 105C vielow No. 6 aluminum lave 160 mg tabet, 105C vielow No. 6 aluminum lave 150 mg tabet, 105C vielow lave 105C vielow (11.5 mg tabet), or translum dioxide.
REVOLADE	ELTROMBOPAG (ELTROMBOPAG OLAMINE)	02361833	NOVARTIS PHARMACEUTICALS CANADA INC	38S Bouchard Blvd Dorval Quebec Canada, H9S 1A9	SO MG	TABLET	1	25 mg or 50 mg of eltrombopag as eltrombopag andeltrombopag andeltrombopag andeltrombopag andeltrombopag andeltrombopag andeltrombopag andeltrombopag andeltrombopagaline selutora-providence, sodium starta playodate, mypromelsora are orago and retainsium starta playodate, providence, sodium starta playodate, providence, sodium starta playodate, are organia polyacotate RivOLADE 25 mg tablets also cornali morphysorbate RivOLADE 50 mg and for order red.	PROMACTA	ELTROMBOPAG OLAMINE	00078-0686-15 022291	5 022291	NOVARTIS One Health Plaza East Hanover, NI 07936	ettromboage clamine 25 mg or 50 mg of ettromboage (et seid. 11) in nachtee intraelierts of PROMACTA balets are Tablet core: magnesium steazet, mannitol, microcoptalline glycolate Costing FO&C late No. 3 aluminum late (50 mg black). To RCS viction No. 6 aluminum late (50 mg black). To RCS viction No. 6 aluminum late (50 mg black). To RCS viction No. 6 aluminum late (50 mg black). To RCS viction No. 6 aluminum late (50 mg black). To RCS viction No. 6 aluminum late (50 mg black). To RCS viction No. 6 aluminum late (50 mg black). To RCS viction No. 6 aluminum late (50 mg black). To RCS viction (12 mg black). To RCS victi
AFINITOR DISPERZ	EVEROLIMUS	02425645	NOVARTIS PHARMACEUTICALS CANADA INC	385 Bouchard Blvd Dorval Quebec Canada, H9S 1A9	2 MG	TABLET FOR SUSPENSI ON	1	2mg everolimus, butylated hydroxytoluene (E321), cellulose microcystalline, crospovidone, hypromellose, lactose monohydrate, magnesium stearate, mannito, silica colloidal anhydrous.	AFINITOR DISPERZ	EVEROLIMUS	00078-0626-51 203985	1 203985	NOVARTIS One Health Plaza East Hanover, NJ 07936	2 mg of everolimus and the following inactive ingredients: buylated hydroxytoluene, coloidal allicon dioxide, crospowldone, hydromeliose, lactose monohydrate, magnesium steariet amenitol, and microcrystalline cellulose.
GILENYA	FINGOLIMOD (FINGOLIMOD HYDROCHLORID E)	02365480	NOVARTIS PHARMACEUTICALS CANADA INC	385 Bouchard Blvd Dorval Quebec Canada, H9S 1A9	0.5 MG	CAPSULE	1	0.5 mg fingolimod (as fingolimod hydrochloride) For the 0.5 mg. Magnesium stearate, mannitol, gelatin, titanium dioxide, yellow iron oxide.	GILENYA	FINGOLIMOD HYDROCHLORID 00078-0607-15 022527	00078-0607-15	5 022527	NOVARTIS One Health Plaza East Hanover, NJ 07936	0.56 mg of fingolimod hydrochloride, equivalent to 0.5 mg of fingolimod, gelatin, magnesium stearate, mannitol, tranium dioxide, and yellow iron oxide.
JAKAVI	RUXOLITINIB (RUXOLITINIB PHOSPHATE)	02434814	NOVARTIS PHARMACEUTICALS CANADA INC	385 Bouchard Blvd Dorval Quebec Canada, H9S 1A9	10 MG	TABLET	1	10 mg uxolitinib free base (as ruxolitinib phosphate), Mydroxpropytediuliose, 142 90 mg lextose monohydrae, marginesium stearate, microcystalinee elliones, colloidal silicon dioxide, sodium starch giyrolate (Type A), povidone.	JAKAFI	RUXOUTINIB PHOSPHATE	50881-0010-60 202192	0 202192	INCYTE CORP 1801 Augustine Cut-off Wilmington, DE 19803	rucolitini phosphate equivalent to 10 mg of rucolitini bree base together with microcrystalline fulloses, lactose monorohydrate, magnesium stearate, colloidal silicon dioxide, sodium starch glycolate, povidone and hydroxypropyl cellulose.
XELIANZXR	TOFACITINIB (TOFACITINIB CITRATE)	02470608	PHZER CANADA ULC	17300 Trans- Canada Highway Kirkland Quebec Canada H9J 2MS	11 MG	TABLET	н	11 mg urfactinib (as tofactinib citrate), sorbitol, hovorethy tellulose, copouldone, magnesim retarate. The film Cost continus cellulose acetate, film Cost continus cellulose acetate, film Cost continus cellulose acetate, pago propose general, 2910/hopromeliose, tetanium diodocie, bizacchir, cell ron galas, ammonium hydroxide, propylene glycol, ferrosoflerric culde/black fron oxide ferrosoflerric culde/black fron oxide	XELIANZ XR	TOFACITINIB	00069-0501:30_208246	0 208246	PFIZER 235 East 42nd Street New York, NY 10017	11 mg tofactinib (equivalent to 12.77 mg tofactinib citrate) and the following inactive impreferents: cellulose extents, copordione, hydroxyethy cellulose, hydroxyethycopid collulose, hydroxyethycopid collulose, collulose, hydroxyethycopid collulose in collulose collulo
VOTRIENT	PAZOPANIB (PAZOPANIB HYDROCHLORID E)	02352303	NOVARTIS PHARMACEUTICALS CANADA INC	385 Bouchard Blvd Dorval Quebec Canada, H95 1A9	200 MG	TABLET	Ħ	200MG (paropamile as paropamile hydrocholoride) impresent stearter microcystaline refullaces, povidone (2003) and solution stront pyloridiste. The tablet contrip contains the following excipients; hydrochients (E172 – 200mg tablet), macrogol, pholysophes e 200mg tablet), macrogol, polysophes e 200mg tablet), macrogol, polysophes e 200mg tablet), macrogol, polysophes e 200mg tablet).	VOTRIENT	PAZOFANIB HYDROCHLORID DODYS-0670-66 022465	00078-0670-66	6 022465	NOVARTIS One Health Plaza East Hanover, NJ 07936	200 mg of pazopanib equivalent to 216.7 mg of pazopanib hydrothole. The inactive ingredients of VOTRIMT are: Tables Coxe: Magnesiant stears are incropratelline cellulose, pooldone, and sodium starch pirocate. Costing: Gray filmost: Hyporonellose, iron oxide black, microgolf polybethylene glycal 400 (PEG 400), polyporobate 80, and thanium dioxide.

U.S. INGREDIENTS	2MG exenatide, polylactide-co-glycolide and successive formers of injent deliuent; mactive ingredients: medium chain triglycerides	Each mt. of RESTASIS* ophthalmic emidion contains. Active: cyclosporine to 60%, incatives: cyclosporine to 10%, incatives: cyclosporine to 10%, and the copolymer type A; purified water, and sodium hydroxide to adjust pit.	50 mg of bictegravii (BiC) (equivalent to 52.5 mg of bictegravii sodium), 200 mg of emicialable (FIC), and 55 mg of tenofosis allenamide (TAS) (equivalent to 28 mg of tenofosis and microcrystaline edilulose. The tables are film-coaded with a constitute form oxide black, fron oxide material containing from oxide black, fron oxide red, polycethydner glycol, polywind alcohol, talk, and tranium dioxide.	20 mg, 40 mg, or 60 mg of cabozantinib, which is equivalent to 25 mg, 25 mg, or 76 mg of cabozantinib (5) malate, respectively. CABOMETY also commit the following limathe highests: microcrystalline cellulose, lactose anilydrose, hacks anilydrose, battle anilydrose, battle cellulose, crosszmellose sodium, collopola silicio dioxide, and magnesium stearate.	20 mg, 40 mg, or 60 mg of cabozantinib, which is equivalent to 25 mg, 25 mg, or 76 mg of cabozantinib (5)-maiste, respectively. CABOMETY xia do commist the following ilmatche ingredients: microcrystaline cellulose, latoce anilytoris, hydroxyproxyl cellulose, crosszmellose sodlum, colloida silicon dioxide, and magnetium steam, colloida silicon dioxide, and magnetium steams.	20 mg, 40 mg, or 60 mg of cabozantinib, which is equivalent to 25 mg, 21 mg, or 75 mg of cabozantinib (5) malate, respectively. CABOMETY has occurate the following lineathe impedients: microcrystalline cellulose, latose anityfous, place and read of the construction colored construction and magnetium stearate.
NDA APPLICANT HOLDER NAME AND ADDRESS	ASTRAZENECA LP PO BOX 15437 WILMINGTON, DE 19850	ALERGAN 5 Giralda Farms Madison, NI 09740	Gilead Sciences, Inc. 333 Lakeade D'rive Foster City, CA 9440A	CABOZANTINIB 42386.024.26 208692 1353 Harbor Bay Farkway Alameda, CA 94502	CABOZANTINIB 42388-025-26 208692 1353 Harbor Bay Parkway Alameda, CA 94502	Exelixis, inc. 1851 Harbor Bay Parkway Alameda, CA 94502
NDA	209210	050790	210251	208692	208692	208692
NDC	EXENATIDE 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 (0002±9165-30) 05/0790	BICTEGRAVIR SODIUM; TENOFOVIR TENOFOVIR ALAFENAMIDE FUMARATE	CABOZANTINIB	CABOZANTINIB	CABOZANTINIB 42389-023-26 208692
U.S. Proprietary name Generic Name	BYDUREON BGISE	RESTASIS	BIKTARVY	CABOMETYX	CABOMETYX	CABOMETYX
CANADAIAN INGREDIENTS	2 mg exenatide (is white to off-white microspheres suspended in a MCT white) which is placed to a microspheres suspended in a MCT white is many the exenation extended refease in 08 Smr Lethicle Composition; to the comparation: Exenatide, poly (D. Hardroce ogh/ceidel), sucrose Vehicle: Medium chain righycerides (MCT)	0.005% w/v is available as a sterile proservative free remuision supplied in the containing 0.4 mt each. Each int of cernision containing cyclopporine 0.5 mg with the following processing of the containing of the ingredients. Carborner Cospolymer Type A castor of igherin, polyochate 80, purified water to and sodium hydroxide to adjust the pit,	So mg of bictegravi fequivalent to 22.5 mg of bictegravi fequivalent to 22.5 mg of bictegravi sodium), 300 mg of emotionizable, and 25 mg of tendovoir allafenamide (perivalmentale). Microcystalline Celloloso, Crostamideles Sodium, Magnesium Steante Film-Coahvigi sodium, Magnesium Steante Film-Coahvigi Film Oxide Black, Iron Oxide Black, Iron Oxide Black, Iron Oxide Black, Iron Film Steante Film-Coahvigi Polyviny Alcohol, Polyviny Alcohol, Tlannium Dioxide	cabocantinib iss cabocantinib (S)-malate, colloidal Silicon Dioxide, focasemelioes Soldium, Hydroxypropy (Cellulose, Hypromelioes 2910, Iron Oxide Vellow, Lactose Anhydrous, Magesium Searate, Microcrystalline Cellulose, Titanium Dioxide and Triacetin.	cabozantinib sa cabozantinib as cabozantinib Si materio, colloida Silicon Dioxide, Croscarmeliose Sodium, Microspropy Clailouse, hypomeliose 2310, Irno Oxide Vellow, Lactose Anhydrous, Microscymline Calilulose, Titanium Dioxide and Triacelin.	cabozantinib symulate, collodaí Silicon Dioxide, Crosarmellos Sodium, Hydroxypropy (Cellulose, Hypomellose 2910, iren Oside Yellow, Lactose Anhóricos, Magnelium Searate, Microcrystaline Cellulose, Titanium Dioxide and Triacetin.
NUMBER OF ACTIVE INGREDIENTS	1	rd	m	1	1	1
DOSAGE FORM	SUSPENSI ON (EXTENDE D D RELEASE)	EMULSION	TABLET	TABLET	TABLET	TABLET
STRENGTH	2 MG/0.85 (1	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 505 5060 Spectrum Way Mississauga Ontario Canada LAW 5N5	SUITE 505 5060 Spectrum Way Mississauga Ontario Canada L4W 5N6	SUITE 505 5060 Spectrum Way Mississauga Ontario Canada L4W SN7
COMPANY	ASTRAZENECA CANADA INC	ALLERGAN INC	GILEAD SCIENCES CANADA INC	IPSEN BIOPHARMACEUTICA LS 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, TENOFOVIR ALAFENAMDE AND BICTEGRAVIR	CABOZANTINIB 02480824	CABOZANTINIB	CABOZANTINIB
CANADIAN CANADIAN PROPRIETARY NAME GENERIC NAME	BYDUREON BCISE	RESTASIS	BIKTARVY	САВОМЕТҮХ	САВОМЕТҮХ	САВОМЕТҮХ

	The south of the state of the south of the state of the south of the s	articles are supply attended attended to the second of the		
U.S. INGREDIENTS	Each tablet contains 150 mg of eintegravir, 150 mg of celvicitez, 200 mg of eintricitabline, and mg of celosidate, 200 mg of tenoforin aldenamide (equivalent to 11.2 mg of tenoforin aldenamide character). The tablets include the following inactive highestellers to creammeliose adultum, hydroxypropir cellulose, lettose monthydravir, magnesium stearate, minor orphalms are affer-canced and sodium laury data fare. The tablets are filler-canced with a coartier material consolining FD& Ellus No. 2/indige carmine alluminaring FD& Ellus No. 2/indige carmine alluminaring labs. Gen No. 2/indige carmine alluminaring labs.	Each film-coated tablet contains abacavir sulface equivalent to 50 mg of abacavir, dolutegravir sodium equivalent to 50 mg of abacavir, dolutegravir, and some gof laminodimo. TRIUMEC tablets are purple, bloomer, only debooses with "52" for a one said and contain the market high gredients formannic contain the market high gredients formannic magnetism stearate, microprabiline cellulose, povidene, and column starch pictochker. I'll ruptoe 85590057 contains the inactive ingendents for contain the market high coate i'll respect to contain the discholar in the tablet incostain (QCADRY II Purple 85590057) contains the inactive ingendents for on oxide red, macrogol/PEG, prolyviryl alcotol-part Hydrolyred, talk, and	Each tablet contains 200 mg of FIC, 35 mg of RPU, 55 mg of RPU (equivalent to 27.5 of rightwine by Indionicale and 35 mg of TAF (equivalent to 28 mg of tenofolioridate) for tenomine for the migration of the following hardren ingestients: cross-amenios as odium, actoes monoholydrae, magnetium steams on migration and and produce. The tablets are physiciated with a coasting material containing from codice black, polyethylene glycol, polyhylmyl allonder.	
HOLDER NAME AND ADDRESS	Glead Sciences, Inc. 333 Lakeside Dive Froster City, CA 94404	VIV Healthcare Company O/OV Healthcare Company O/O BloosshithKillee Five Moner Drive P. D. Box 13398 Fo. Box 13398 Research fringle Park, NC 27709	Glead Sciences, Inc. 333 Lakscide Dive Froster City, CA 94404	
NDA	207561	205551	208351	
NDC	61958-1901-1	49702-231-13	61958-2101-1 208351	
U.S. GENERIC NAME	NOTABINE, TBNC 61958-1901-1 207561	ABACANIR SULFATE SOUNDIA LAMIVUDINE	EMTRICITABINE; RILPIVIRINE HYDROCHLORID E, TENDOOVIR RAAERDAMIDE FUMARATE	
U.S. PROPRIETARY NAME	GENVOYA	ТЯІОМЕО	A35400	
CANADAIAN INGREDIENTS	Each tablet contains 150 mg of of elothestary, 150 mg of cobicista, 200 mg of emricitations, and 10 mg of tenderial flow of 11.2 mg of 11.2 mg of tenderial elothestary	rts: D. mannitol, magnesium stearste, mic	Each tablet contains 200 mg of FTC, 25 mg of BTC, 25 mg of BTC, 25 mg of BTC and 25 mg of Table to STC and produced to Table to STC and Table to STC and Table to STC and Table to Table to Table to STC and Table to Table t	
ACTIVE INGREDIENTS	4	м	m	
DOSAGE FORM	TABLET	TABLET	TABLET	
STRENGTH	150-150- 200-10 MG	300 MG	200-25-25 MG	
ADDRESS	600 6711 Mississuga Road Mississuga Ontario Canada ISN 2W3	245 Boulevard Armand-Frappier Laval Quebec Canada H7V 4A7	600 6711 Mississauga Road Mississauga Outario Canada LSN 2W3	
COMPANY	CANDA SCIENCES	VIIV HEALTHCARE ULC	GILEAD SCIENCES	
NIQ	02449498	02430932	208351	
CANADIAN GENERIC NAME	EMTRICTABINE, TENOFOVIR ALAFENAMIDE, ELVITEGRAVIR AND COBIGGSTAT	LAMIVUDINE, ABACAVIR AND DOLUTEGRAVIR	EMTRICITABINE; RILPAVIBINE HYDROCHLORID E, TENOFOVIR ALAFENAMIDE FUMARATE	
CANADIAN PROPRIETARY NAME	GENVOYA	ТЯІЈМЕQ	ASSE00	

U.S. INGREDIENTS	Each film coated tablet contains 200 mg of enritcritabrin and 300 mg of trendowl diseasond filmmarse, (which is equivalent to 258 mg of tendorford idiosonol), as active ingredients. The tablets also include the following marker ingredients: cross-meltosy adolum, lackse monohydrate, magnesium sets are, micro-optimic calloliose, and resease with operative films (**). The tablets are contains (**) the lablets of such with contains (**) (**) the subsets of the contains (**) (**) the promism of the contains (**) (**) (**) (**) (**) (**) (**) (**	Active ingredient: aphothen inactive ingredients: anhydrous lactoe, microcrystalline cellulose, crostermileose adolum, soulum laury sulfate, and magnesium stearer. The film costing contains lactose monohydrate hypromeliose; training bodied, triacetin, and yellow more order (5 mg tables) or red iron orde (5 mg tables).	
HOLDER NAME AND ADDRESS	Gilead Sciences, inc. 333 Lakeside Dive Foster City, CA 94404	Bristol-Myers Squibb P.O. Box 4000 Princeton, NJ 08543-4000	
NDA	21-752	202155	
NDC	254-72 1-123	0003-0894-21 202155	
U.S. GENERIC NAME	ENWARTE TRANSPORME TRANSPORME TRANSPORME	APIXABAN	
U.S. U.S. Proprietary name Generic Name	TRUVADA	ELIQUIS	
CANADAIAN INGREDIENTS	Each tables contains 200 mg of emricialmen and 500 mg of tenderion of the control	Active ingredient. Apixaban Excipients: Tables craw Annylarous lateros, microsystaline redisions, crossamiscloss solium. Sodumi launy sulfare and magnesia steamer Film cost: Lacrose monohydrast, sund yellow from colic (2.5 mg balles) or red iron code (5 mg tables).	
ACTIVE INGREDIENTS	2	1	
DOSAGE FORM	TABLET	TABLET	
STRENGTH	200-300 MG	5 MG	
ADDRESS	600 6711 Mississuuga Road Mississuuga Onfario Canada LSN 2W3	2344 Boul, Alfred- Nobel, Suite 300 Montréal (St- Laurent) Quebec Canada H4S 0A4	
COMPANY	GILEAD SCIENCES	BRISTOL-MYERS SQUIBB CANADA	
NIG	02274906	02397714	
CANADIAN GENERIC NAME	TENGFOUR DISOPROLL AND EMTRICTABINE	APIXABAN	
CANADIAN CANADIAN PROPRIETARY NAME GENERIC NAME	TRUVADA	sındnıs	