

# Prescription Drugs States Seek to Import from Canada

#### **Purpose**

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find a collection of all the drug lists from known drug importation applications (SIPs), including previous versions superseded by subsequent filings.

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

#### **Methods**

The drug lists were collected in one of three ways:

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

#### **Notes**

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

SIP applications included in this document are:

Colorado: February 2024<sup>1</sup>, December 2022, and March 2020

Florida: November 2023<sup>2</sup>, October 2023, April 2023, November 2021, September 2021, April

2021, and November 2020. New Hampshire: April 2021

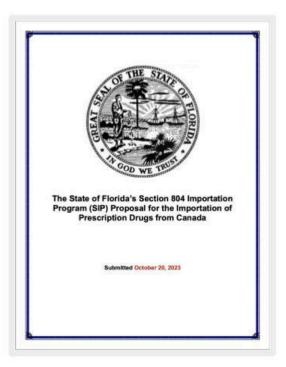
New Mexico: December 2020 and October 2020

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PSM will maintain that collects all drug lists from all known importation applications, including previous versions superseded by subsequent filings

<sup>&</sup>lt;sup>1</sup> Information from this SIP application was added as part of the February 27, 2024 update

<sup>&</sup>lt;sup>2</sup> Information from this SIP application was added as part of the April 15, 2024 update.





Source: FOIA Responsive Document November 16, 2024 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 16, 2023.

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

On the next 2 pages, we have included the original 2 page PDF from Florida's November 16, 2023 application. Please note: the state of Florida indicated revisions or additions to the text of its SIP 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 1**, 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 below.

PRO	TABLE 1* POSED DRUG LIST
Brand Name (active ingredients)	Dose / Dosage Form
Biktarvy (bictegravir-emtricitabine-	50-200-25 mg tablet
tenofovir alafenamide)	30-120-15 mg tablets will not be imported.
Descovy (emtricitabine-tenofovir	200-25 mg tablet
alafenamide)	120/15 mg tablets will not be imported.
Dovato (dolutegravir-lamivudine)	50-300 mg tablet
Genvoya (elvitegravir-cobicistat-	150-150-200-10 mg tablet
emtricitabine-tenofovir alafenamide)	
Juluca (dolutegravir-rilpivirine)	50-25 mg tablet
Odefsey (emtricitabine-rilpivirine-	200-25-25 mg tablet
tenofovir alafenamide)	
Prezcobix (darunavir-cobicistat)	150-800 mg tablet
Prezista (darunavir)	75 mg tablets will not be imported.
·	150 mg tablet
	600 mg tablet
	800 mg tablet
	100mg/ml suspension will not be imported.
Ravicti (glycerol phenylbutyrate)	1.1 g/mL oral liquid
Rexulti (brexpiprazole)	0.25 mg tablet
	0.5 mg tablet
	1 mg tablet

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TABLE 1* PROPOSED DRUG LIST				
Brand Name (active ingredients)	Dose / Dosage Form			
	2 mg tablet			
	3 mg tablet			
	4 mg tablet			
Symtuza (darunavir-cobicistat- emtricitabine-tenofovir alafenamide)	150-800-200-10 mg tablet			
Tivicay (dolutegravir)	10 mg tablets will not be imported. 25 mg tablets will not be imported. 50 mg tablet 5 mg tablets for oral suspension (Tivicay PD) will not be imported.			
Vraylar (cariprazine)	1.5 mg capsule 3 mg capsule 4.5 mg capsule 6 mg capsule			
Xtandi (enzalutamide)	40 mg capsule 40 mg tablets will not be imported. 80 mg tablets will not be imported.			

<sup>\*</sup>Revised to exclude Eliquis, Entresto, and Eucrisa.

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

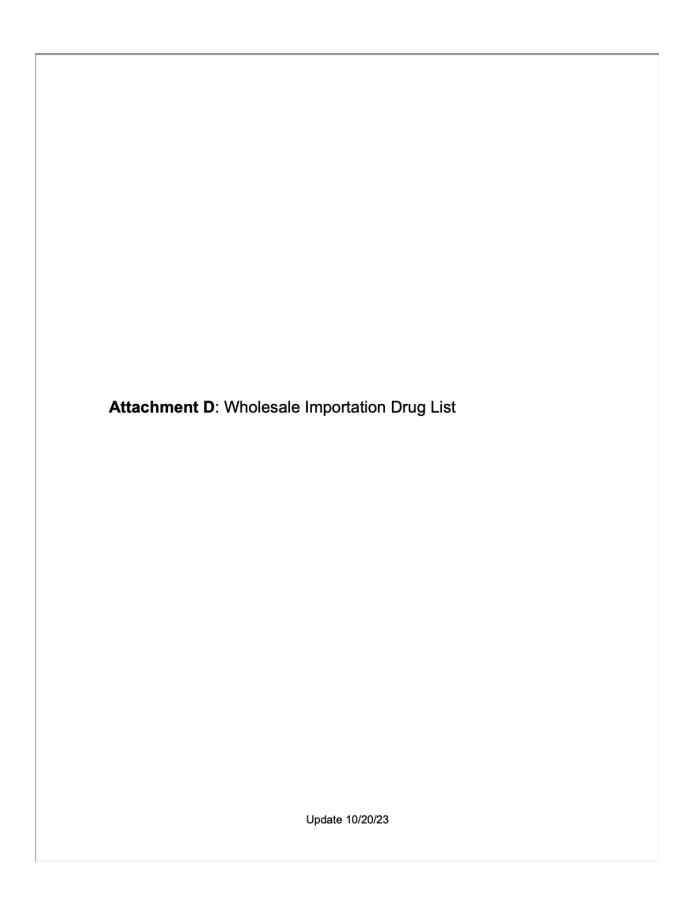
Find the entire application online at our website: www.safemedicines.org

Source: document can be found on PSM's website

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

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

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



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

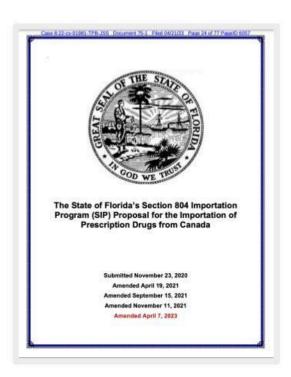
- A drug label cover sheet providing each eligible prescription drug's FDA-approved counterpart, the manufacturer(s) of the finished dosage form and the active ingredient or ingredients of each eligible prescription drug that the SIP Sponsor seeks to import, the legal relationship of these entities to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

#### **Drug Name**

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

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





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

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

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

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

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

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

## Florida's List of Prescription Drugs to Import

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

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

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

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

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

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

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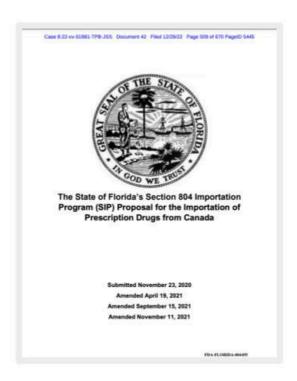
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Rexulti (brexpiprazole)	0.25 mg tablet
	0.5 mg tablet
	1 mg tablet
	2 mg tablet
	3 mg tablet
	4 mg tablet
Symtuza (darunavir-cobicistat-emtricitabine-tenofovir alafenamide)	150-800-200-10 mg tablet
Tivicay (dolutegravir)	50 mg tablet
Vraylar (cariprazine)	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 Name	Sold in
							U.S.
Harvoni 90-	Ledipasvir,	61958-	\$1,098.94	NDA205834	02432226	Harvoni	Yes
400mg	Sofosbuvir	1801-01					
Epclusa 400-	Sofosbuvir,	61958-	\$869.05	NDA208341	02456370	Epclusa	Yes
100mg	Velpatavir	2201-01					
Mavyret 100-	Glecaprevir,	00074-	\$153.11	NDA209394	02467550	Maviret	Yes
40mg	Pibrentasvir	2625-80					
Zepatier 50-	Elbasvir,	00006-	\$260.00	NDA208261	02451131	Zepatier	Yes
100mg	Grazoprevir	3074-01					

#### **Psychiatric Prescription Drugs**

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

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Drug Name	Active	NDC	U.S.	NDA/ ANDA	DIN	Canadian	Sold
	Ingredient		Price			Name	in
							U.S.
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					
Latuda 80mg	Lurasidone HCL	63402-	\$41.03	NDA200603	02387778	Latuda	Yes
		0308-30					
Latuda 120mg	Lurasidone HCL	63402-	\$61.13	NDA200603	02387786	Latuda	Yes
		0312-30					

## **Diabetes Prescription Drugs**

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

## Asthma and Chronic Obstructive Pulmonary Disease Prescription Drugs

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

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

## **HIV/AIDS Prescription Drugs**

Drug Name	Active	NDC	U.S.	NDA/ ANDA	DIN	Canadian	Sold in
	Ingredient		Price			Name	U.S.
Kaletra 200-	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						

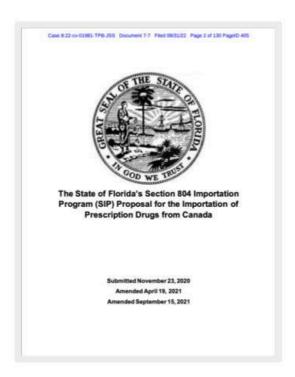
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Drug Name	Active	NDC	U.S.	NDA/ ANDA	DIN	Canadian	Sold in
	Ingredient		Price			Name	U.S.
Isentress 400mg	Raltegravir	00006- 0277-61	\$26.74	NDA022145	02301881	Isentress	Yes
Descovy	Emtricitabine, Tenofovir 200mg-25mg	61958- 2002-01	\$59.67	NDA208215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

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

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

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

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

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

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

## Florida's List of Prescription Drugs to Import

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

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

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

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

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

#### **Hepatitis C Prescription Drugs**

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

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## **Psychiatric Prescription Drugs**

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

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200mg	Seroquel	Quetiapine	00310-	\$12.07	NDA020639	02236953	Seroquel	Yes
Fumarate	· ·	,						
Fumarate	Quetiapine	Quetiapine	46708-	\$0.11	ANDA203390	02316110	ACT Quetiapine	Yes
Seroquel 300mg			0137-31				,	
300mg         Fumarate         0274-60         Sol 1         ANDA203390         02316129         ACT Quetiapine Permarate Pumarate Pumarate Pumarate 10138-60         \$0.17         ANDA203390         02316129         ACT Quetiapine Permarate Pumarate Pumarate 10138-60         \$0.17         ANDA203390         02316129         ACT Quetiapine Permarate Pumarate Pumarate 10138-60         \$0.17         ANDA019758         00894737         Clozaril Permarate Pumarate Pumarate Pumarate 1012-05         \$0.83         ANDA074949         02247243         GEN-Clozapine Permarate Pumarate Pumarate Pumarate Pumarate Pumarate 1012-05         \$0.83         ANDA074949         02247243         GEN-Clozapine Permarate Pumarate Pu	200mg							
300mg         Fumarate         0274-60         Sol 1         ANDA203390         02316129         ACT Quetiapine Permarate Pumarate Pumarate Pumarate 10138-60         \$0.17         ANDA203390         02316129         ACT Quetiapine Permarate Pumarate Pumarate 10138-60         \$0.17         ANDA203390         02316129         ACT Quetiapine Permarate Pumarate Pumarate 10138-60         \$0.17         ANDA019758         00894737         Clozaril Permarate Pumarate Pumarate Pumarate 1012-05         \$0.83         ANDA074949         02247243         GEN-Clozapine Permarate Pumarate Pumarate Pumarate Pumarate Pumarate 1012-05         \$0.83         ANDA074949         02247243         GEN-Clozapine Permarate Pumarate Pu		Quetiapine	00310-	\$15.95	NDA020639	02244107	Seroquel	Yes
Fumarate 300mg	· ·	,	0274-60					
Fumarate 300mg								
Fumarate 300mg	Quetiapine	Quetiapine	46708-	\$0.17	ANDA203390	02316129	ACT Quetiapine	Yes
Clozaril 25mg tabs			0138-60	· .			,	
tabs         Clozapine 25mg         Clozapine         00326-05         So.83         ANDA074949         02247243         GEN-Clozapine         Yes           Clozaril 100mg         Clozapine         69809-0127-05         12.06         NDA019758         00894745         Clozaril         Yes           Clozapine         100mg         103-7772-01         1.38         ANDA074949         02247244         GEN-Clozapine         Yes           Clozaril 50mg         Clozapine         69809-0130-05         10.15         NDA019758         02490668         Clozaril         Yes           Clozapine 50mg         Clozapine         093-4404-01         1.68         ANDA074949         02305003         GEN-Clozapine         Yes           Clozapine 200mg         Clozapine         69809-0135-05         29.29         NDA019758         02490676         Clozaril         Yes           Clozapine 200mg         Clozapine         093-4405-01         2.19         ANDA074949         02305011         GEN-Clozapine         Yes           200mg         Aripiprazole         59148-0007-13         28.64         NDA021436         02322382         Abilify         Yes           5mg         Aripiprazole         59148-0009-30         0.15         ANDA021436         02322390	300mg							
tabs         Clozapine 25mg         Clozapine         00326-05         So.83         ANDA074949         02247243         GEN-Clozapine         Yes           Clozaril 100mg         Clozapine         69809-0127-05         12.06         NDA019758         00894745         Clozaril         Yes           Clozapine         100mg         103-7772-01         1.38         ANDA074949         02247244         GEN-Clozapine         Yes           Clozaril 50mg         Clozapine         69809-0130-05         10.15         NDA019758         02490668         Clozaril         Yes           Clozapine 50mg         Clozapine         093-4404-01         1.68         ANDA074949         02305003         GEN-Clozapine         Yes           Clozapine 200mg         Clozapine         69809-0135-05         29.29         NDA019758         02490676         Clozaril         Yes           Clozapine 200mg         Clozapine         093-4405-01         2.19         ANDA074949         02305011         GEN-Clozapine         Yes           200mg         Aripiprazole         59148-0007-13         28.64         NDA021436         02322382         Abilify         Yes           5mg         Aripiprazole         59148-0009-30         0.15         ANDA021436         02322390	Clozaril 25mg	Clozapine	69809-	\$4.79	NDA019758	00894737	Clozaril	Yes
Clozaril 100mg		·	0126-05	·				
Clozaril 100mg	Clozapine 25mg	Clozapine	0093-4359-	\$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         0993-4404-01         1.68         ANDA074949         02305003         GEN-Clozapine         Yes           Clozapine 200mg         Clozapine         69809-0135-05         29.29         NDA019758         02490676         Clozaril         Yes           Clozapine 200mg         Clozapine         0993-4405-01         2.19         ANDA074949         02305011         GEN-Clozapine         Yes           2000mg         Aripiprazole         59148-0007-13         28.64         NDA021436         02322382         Abilify         Yes           Aripiprazole 5mg         Aripiprazole         62332-0098-30         0.17         ANDA021436         02322390         Abilify         Yes           Abilify 15mg tabs         Aripiprazole         62332-0098-30         0.15         ANDA021436         0232	'		01				'	
Clozapine   Clozapine   O127-05   O1	Clozaril 100mg	Clozapine		12.06	NDA019758	00894745	Clozaril	Yes
Clozapine			0127-05					
100mg	Clozapine	Clozapine		1.38	ANDA074949	02247244	GEN-Clozapine	Yes
Clozaril 50mg tabs	1		01				,	
tabs         0130-05         Modern Program         Clozapine 50mg         Clozapine         0093-4404-01         1.68 ANDA074949         02305003         GEN-Clozapine         Yes           Clozaril 200mg         Clozapine         69809-0135-05         29.29 NDA019758         02490676         Clozaril         Yes           Clozapine 200mg         Clozapine         0093-4405-01         2.19 ANDA074949         02305011         GEN-Clozapine         Yes           Abilify 5mg tabs         Aripiprazole         59148-0007-13         28.64 NDA021436         02322382         Abilify         Yes           Abilify 10mg tabs         Aripiprazole         62332-0098-30         0.17 ANDA202101         02471094         APO-Aripiprazole         Yes           Abilify 10mg tabs         Aripiprazole         62332-0098-30         0.15 ANDA202101         02471094         APO-Aripiprazole         Yes           Abilify 15mg tabs         Aripiprazole         62332-0099-30         0.15 ANDA202101         02471108         APO-Aripiprazole         Yes           Abilify 20mg tabs         Aripiprazole         62332-0099-30         0.16 ANDA202101         02471116         APO-Aripiprazole         Yes           Abilify 20mg tabs         Aripiprazole         62332-00100-30         0.16 ANDA202101         02471116 <td< td=""><td>Clozaril 50mg</td><td>Clozapine</td><td>69809-</td><td>10.15</td><td>NDA019758</td><td>02490668</td><td>Clozaril</td><td>Yes</td></td<>	Clozaril 50mg	Clozapine	69809-	10.15	NDA019758	02490668	Clozaril	Yes
Clozaril 200mg			0130-05					
Clozaril 200mg	Clozapine 50mg	Clozapine	0093-4404-	1.68	ANDA074949	02305003	GEN-Clozapine	Yes
Clozapine			l					
Clozapine	Clozaril 200mg	Clozapine	69809-	29.29	NDA019758	02490676	Clozaril	Yes
200mg			0135-05					
200mg	Clozapine	Clozapine	0093-4405-	2.19	ANDA074949	02305011	GEN-Clozapine	Yes
Abilify 5mg tabs	1	· ·	01				,	
tabs         0007-13         Aripiprazole         Aripiprazole         62332-0098-30         0.17         ANDA202101         02471094         APO-Aripiprazole         Yes           Abilify 10mg tabs         Aripiprazole         59148-0008-13         28.22         NDA021436         02322390         Abilify         Yes           Aripiprazole 10mg         Aripiprazole         62332-0099-30         0.15         ANDA202101         02471108         APO-Aripiprazole         Yes           Abilify 15mg tabs         Aripiprazole         59148-0099-30         28.55         NDA021436         02322404         Abilify         Yes           Aripiprazole 15mg         Aripiprazole         62332-0100-30         0.16         ANDA202101         02471116         APO-Aripiprazole         Yes           Abilify 20mg tabs         Aripiprazole         59148-0101-30         40.56         NDA021436         02322412         Abilify         Yes           Abilify 30mg tabs         Aripiprazole         59148-0101-30         0.2         ANDA202101         02471124         APO-Aripiprazole         Yes           Abilify 30mg tabs         Aripiprazole         59148-011-13         40.69         NDA021436         02322455         Abilify         Yes           Aripiprazole         Aripiprazole	Abilify 5mg	Aripiprazole	59148-	28.64	NDA021436	02322382	Abilify	Yes
Smg         0098-30         28.22         NDA021436         02322390         Abilify         Yes           Abilify 10mg tabs         Aripiprazole         59148- 0008-13         28.22         NDA021436         02322390         Abilify         Yes           Aripiprazole 10mg         Aripiprazole         62332- 0099-30         0.15         ANDA202101         02471108         APO- Aripiprazole         Yes           Abilify 15mg tabs         Aripiprazole         59148- 0009-13         28.55         NDA021436         02322404         Abilify         Yes           Aripiprazole         Aripiprazole         62332- 0100-30         0.16         ANDA202101         02471116         APO- Aripiprazole         Yes           Aripiprazole         Aripiprazole         59148- 0010-13         40.56         NDA021436         02322412         Abilify         Yes           Abilify 30mg tabs         Aripiprazole         59148- 0101-30         0.2         ANDA202101         02471124         APO- Aripiprazole         Yes           Abilify 30mg tabs         Aripiprazole         59148- 0011-13         40.69         NDA021436         02322455         Abilify         Yes           Aripiprazole         Aripiprazole         59148- 0011-30         40.69         NDA021436         02322455<			0007-13				,	
Smg         0098-30         28.22         NDA021436         02322390         Abilify         Yes           Abilify 10mg tabs         Aripiprazole         59148- 0008-13         28.22         NDA021436         02322390         Abilify         Yes           Aripiprazole 10mg         Aripiprazole         62332- 0099-30         0.15         ANDA202101         02471108         APO- Aripiprazole         Yes           Abilify 15mg tabs         Aripiprazole         59148- 0009-13         28.55         NDA021436         02322404         Abilify         Yes           Aripiprazole         Aripiprazole         62332- 0100-30         0.16         ANDA202101         02471116         APO- Aripiprazole         Yes           Aripiprazole         Aripiprazole         59148- 0010-13         40.56         NDA021436         02322412         Abilify         Yes           Abilify 30mg tabs         Aripiprazole         59148- 0101-30         0.2         ANDA202101         02471124         APO- Aripiprazole         Yes           Abilify 30mg tabs         Aripiprazole         59148- 0011-13         40.69         NDA021436         02322455         Abilify         Yes           Aripiprazole         Aripiprazole         59148- 0011-30         40.69         NDA021436         02322455<	Aripiprazole	Aripiprazole	62332-	0.17	ANDA202101	02471094	APO-	Yes
tabs         0008-13         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         59148-0100-13         40.56         NDA021436         02322412         Abilify         Yes           Aripiprazole 20mg         Aripiprazole         62332-0101-30         0.2         ANDA202101         02471124         APO-Aripiprazole         Yes           Abilify 30mg tabs         Aripiprazole         59148-011-13         40.69         NDA021436         02322455         Abilify         Yes           Aripiprazole         Aripiprazole         59148-011-13         40.69         NDA021436         02322455         Abilify         Yes           Aripiprazole         Aripiprazole         59148-011-13         40.69         NDA021436         02322455         Abilify         Yes	1	''	0098-30				Aripiprazole	
Aripiprazole 10mg         Aripiprazole 0099-30         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         Aripiprazole         59148- 0011-13         40.69         NDA021436         02322455         Abilify         Yes	Abilify 10mg	Aripiprazole	59148-	28.22	NDA021436	02322390	Abilify	Yes
Aripiprazole 10mg         Aripiprazole 0099-30         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         Aripiprazole         59148- 0011-13         40.69         NDA021436         02322455         Abilify         Yes	tabs		0008-13					
10mg         0099-30         Aripiprazole         Aripiprazole         59148- 0009-13         28.55         NDA021436         02322404         Abilify         Yes           Aripiprazole tabs         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- 0.2         ANDA202101         02471124         APO- Yes           Abilify 30mg tabs         Aripiprazole         59148- 0011-13         40.69         NDA021436         02322455         Abilify         Yes           Aripiprazole         Aripiprazole         59148- 0011-13         40.69         NDA021436         02322455         Abilify         Yes           Aripiprazole         Aripiprazole         62332- 0.26         ANDA202101         02471132         APO- Yes	Aripiprazole	Aripiprazole		0.15	ANDA202101	02471108	APO-	Yes
tabs         0009-13         Aripiprazole         62332- 0.16 ANDA202101         02471116 APO- Aripiprazole         Yes Aripiprazole           15mg         Aripiprazole         59148- 0010-30         40.56 NDA021436         02322412 Abilify         Yes Aripiprazole           Abilify 20mg tabs         Aripiprazole         62332- 00.2 ANDA202101         02471124 APO- Yes Aripiprazole         APO- Aripiprazole         Yes Aripiprazole           Abilify 30mg tabs         Aripiprazole         59148- 0011-13 Aripiprazole         40.69 NDA021436 ANDA202101         02322455 Abilify         Yes Abilify           Aripiprazole         Aripiprazole         62332- 0.26 ANDA202101         02471132 APO- Yes		''	0099-30				Aripiprazole	
tabs         0009-13         Aripiprazole         62332- 0.16 ANDA202101         02471116 APO- Aripiprazole         Yes Aripiprazole           15mg         Aripiprazole         59148- 0010-30         40.56 NDA021436         02322412 Abilify         Yes Aripiprazole           Abilify 20mg tabs         Aripiprazole         62332- 00.2 ANDA202101         02471124 APO- Yes Aripiprazole         APO- Aripiprazole         Yes Aripiprazole           Abilify 30mg tabs         Aripiprazole         59148- 0011-13 Aripiprazole         40.69 NDA021436 ANDA202101         02322455 Abilify         Yes Abilify           Aripiprazole         Aripiprazole         62332- 0.26 ANDA202101         02471132 APO- Yes	Abilify 15mg	Aripiprazole	59148-	28.55	NDA021436	02322404	Abilify	Yes
Aripiprazole 15mg         Aripiprazole 0100-30         62332- 0100-30         0.16 ANDA202101         ANDA202101         02471116 APO- Aripiprazole         APO- Aripiprazole         Yes           Abilify 20mg tabs         Aripiprazole         59148- 0010-13         40.56 0010-13         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 0011-13         NDA021436         02322455         Abilify         Yes           Aripiprazole         Aripiprazole         62332- 0.26         0.26         ANDA202101         02471132         APO- APO- APO- Yes							,	
15mg         0100-30         Aripiprazole         Aripiprazole         59148- 0010-13         40.56         NDA021436         02322412         Abilify         Yes           Aripiprazole tabs         Aripiprazole         62332- 0101-30         0.2         ANDA202101         02471124         APO- Aripiprazole         Yes           Abilify 30mg tabs         Aripiprazole         59148- 0011-13         40.69 0011-13         NDA021436         02322455         Abilify         Yes           Aripiprazole         Aripiprazole         62332- 0.26         0.26         ANDA202101         02471132         APO- Yes	Aripiprazole	Aripiprazole		0.16	ANDA202101	02471116	APO-	Yes
Abilify 20mg tabs         Aripiprazole         59148- 0010-13         40.56         NDA021436         02322412         Abilify         Yes           Aripiprazole 20mg         Aripiprazole         62332- 0.2 0101-30         ANDA202101         02471124 02471124         APO- Aripiprazole         Yes Aripiprazole           Abilify 30mg tabs         Aripiprazole         59148- 0011-13         40.69 0011-13         NDA021436 02322455         Abilify         Yes           Aripiprazole         Aripiprazole         62332- 0.26 ANDA202101         02471132 APO- Yes		' '	l				Aripiprazole	
tabs         0010-13         Aripiprazole         Aripiprazole         62332- 0101-30         0.2         ANDA202101         02471124         APO- Aripiprazole         Yes Aripiprazole           Abilify 30mg tabs         Aripiprazole         59148- 0011-13         40.69 0011-13         NDA021436         02322455         Abilify         Yes           Aripiprazole         Aripiprazole         62332-         0.26         ANDA202101         02471132         APO-         Yes		Aripiprazole		40.56	NDA021436	02322412		Yes
20mg         0101-30         Aripiprazole         Aripiprazole           Abilify 30mg tabs         Aripiprazole         59148- 0011-13         40.69 NDA021436         02322455 O2322455         Abilify         Yes           Aripiprazole         Aripiprazole         62332- 0.26 ANDA202101         02471132 APO- Yes         Yes			0010-13					
20mg         0101-30         Aripiprazole         Aripiprazole           Abilify 30mg tabs         Aripiprazole         59148- 0011-13         40.69 NDA021436         02322455 O2322455         Abilify         Yes           Aripiprazole         Aripiprazole         62332- 0.26 ANDA202101         02471132 APO- Yes         Yes	Aripiprazole	Aripiprazole	62332-	0.2	ANDA202101	02471124	APO-	Yes
Abilify 30mg tabs         Aripiprazole         59148- 0011-13         40.69 0011-13         NDA021436         02322455         Abilify         Yes           Aripiprazole         Aripiprazole         62332- 0.26         ANDA202101         02471132         APO- Yes	1	' '	0101-30				Aripiprazole	
tabs         0011-13		Aripiprazole	59148-	40.69	NDA021436	02322455		Yes
Aripiprazole Aripiprazole 62332- 0.26 ANDA202101 02471132 APO- Yes								
	Aripiprazole	Aripiprazole		0.26	ANDA202101	02471132	APO-	Yes
	1 ''	''	l				Aripiprazole	

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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	Metformin	67877-	\$0.03	ANDA090564	02460653	APO-	Yes
1,000mg tabs	Hydrochloride	0563-01				Metformin ER	
Farxiga 5mg	Dapagliflozin	00310-	\$16.55	NDA202293	02435462	Farxiga	Yes
tabs	Propanediol	6205-30					
Farxiga 10mg	Dapagliflozin	00310-	\$16.54	NDA202293	02435470	Farxiga	Yes
tabs	Propanediol	6210-30					
Tradjenta 5mg	Linagliptin	00597-	\$14.79	NDA201280	02370921	Tradjenta	Yes
tabs		0140-30					
Januvia 50mg	Sitagliptin	00006-	\$15.13	NDA021995	02388847	Januvia	Yes
tabs	Phosphate	0112-31					
Januvia 25mg	Sitagliptin	00006-	\$15.13	NDA021995	02388839	Januvia	Yes
tabs	Phosphate	0221-31					
Januvia 100mg	Sitagliptin	00006-	\$15.14	NDA021995	02303922	Januvia	Yes
tabs	Phosphate	0277-31					

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## Asthma and Chronic Obstructive Pulmonary Disease Prescription Drugs

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

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

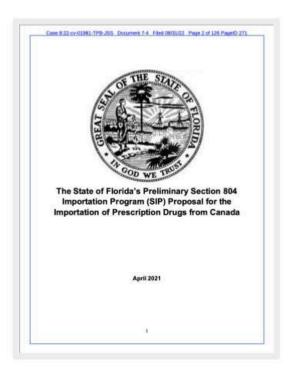
# **HIV/AIDS Prescription Drugs**

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

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





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-	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
			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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Seroquel	Quetiapine	00310-	\$12.07	NDA020639	02236953	Seroquel	Yes
200mg	Fumarate	0272-10					
Quetiapine Fumarate	Quetiapine Fumarate	46708- 0137-31	\$0.11	ANDA203390	02316110	ACT Quetiapine	Yes
200mg							
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	NDC	U.S.	NDA/ANDA	DIN	Canadian	Sold in
	Ingredient		Price			Name	U.S.
Metformin	Metformin	67877-	\$0.02	ANDA090564	02257726	ACT-	Yes
500mg tabs	Hydrochloride	0561-01				Metformin	
Metformin	Metformin	67877-	\$0.03	ANDA090564	02257734	ACT-	Yes
850mg tabs	Hydrochloride	0562-01				Metformin	
Metformin	Metformin	67877-	\$0.03	ANDA090564	02460653	APO-	Yes
1,000mg tabs	Hydrochloride	0563-01				Metformin ER	
Farxiga 5mg	Dapagliflozin	00310-	\$16.55	NDA202293	02435462	Farxiga	Yes
tabs	Propanediol	6205-30					
Farxiga 10mg	Dapagliflozin	00310-	\$16.54	NDA202293	02435470	Farxiga	Yes
tabs	Propanediol	6210-30					
Tradjenta 5mg	Linagliptin	00597-	\$14.79	NDA201280	02370921	Tradjenta	Yes
tabs		0140-30					
Januvia 50mg	Sitagliptin	00006-	\$15.13	NDA021995	02388847	Januvia	Yes
tabs	Phosphate	0112-31					
Januvia 25mg	Sitagliptin	00006-	\$15.13	NDA021995	02388839	Januvia	Yes
tabs	Phosphate	0221-31					
Januvia 100mg	Sitagliptin	00006-	\$15.14	NDA021995	02303922	Januvia	Yes
tabs	Phosphate	0277-31					

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## Asthma and Chronic Obstructive Pulmonary Disease Prescription Drugs

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

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

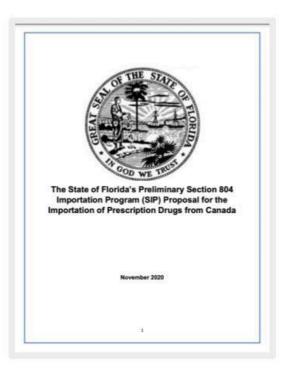
## **HIV/AIDS Prescription Drugs**

Drug Name	Active	NDC	U.S.	NDA/ANDA	DIN	Canadian	Sold in
	Ingredient		Price			Name	U.S.
Kaletra 200-	Lopinovir,	00074-	\$8.53	NDA021906	02285533	Kaletra	Yes
50mg	Ritonovir	2605-21					
Kaletra 100-	Lopinovir,	00074-	\$4.27	NDA021906	02312301	Kaletra	Yes
25mg	Ritonovir	0522-60					
Emtricitabine,	Emtricitabine,	00093-	\$45.69	ANDA090894	02461110	PMS-	Yes
Tenofovir (TDF)	Tenofovir	7607-56				Emtricitabin	
	(TDF)					e, Tenofovir	
	_					(TDF)	
Sustiva 600mg	Efavirenz	00056-	\$8.57	NDA021360	02246045	Sustiva	Yes
tabs		0510-30	40			Tablets	.,
Efavirenz 600mg	Efavirenz	00378-	\$8.57	ANDA091471	02389762	TEVA-	Yes
tabs	Efavirenz	2233-93	ć2.50	ND 4020072	02239886	Efavirenz	Yes
Sustiva 50mg	Efavirenz	00056-	\$3.50	NDA020972	02239886	Sustiva	Yes
caps.	Efavirenz	0470-30 00056-	\$10.50	ND 4020072	02239888	50MG Sustiva	Yes
Sustiva 200mg	Elavirenz		\$10.50	NDA020972	02239888	200MG	res
Caps Genvoya tabs	Fluita - COD	0474-92 61958-	¢104.03	ANDA207561	02440400		Yes
Genvoya tabs	Elviteg, COB, Emtri, Tenof,	1901-01	\$104.93	ANDAZU/561	02449498	Genvoya	res
	Alafen	1901-01					
Atripla tab	Efavirenz,	15584-	\$96.91	ANDA021937	02300699	Atripla	Yes
Attipia tab	Emtricit,	0101-01	330.31	ANDAUZISSI	02300099	Attipia	163
	Tenofovir DF	0101-01					
Efavirenz,	Efavirenz,	00093-	\$73.31	ANDA091215	02393549	TEVA-	Yes
Emtricit,	Emtricit,	5234-56	775.51	711071031213	02333313	Efavirenz,	103
Tenofovir DF	Tenofovir DF					Emtricitabin	
						e, tenofovir	
Complera tabs	Emtricit,	61958-	\$95.52	NDA202123	02374129	Complera	Yes
	Rilpivirine,	1101-01					
	Tenofovir DF						
Stribild	Elviteg, COB,	61958-	\$109.51	NDA203100	02397137	Stribild	Yes
	Emtricit,	1201-01					
	Tenofovir						
	Disop						
Truvada 200-	Emtricitabine,	61958-	\$59.70	NDA021752	02274906	Truvada	Yes
300mg	Tenofovir DF	0701-01					
Emtricitabine,	Emtricitabine,	00093-	\$45.69	ANDA090894	02399059	TEVA-	Yes
Tenofovir DF	Tenofovir DF	7607-56				Emtricitabin	
200-300mg						e, Tenofovir	

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





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

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

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

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

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

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

## Florida's List of Prescription Drugs to Import

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

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

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

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

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

### **Hepatitis C Prescription Drugs**

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

## **Psychiatric Prescription Drugs**

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

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

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

## **Diabetes Prescription Drugs**

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

## Asthma and Chronic Obstructive Pulmonary Disease Prescription Drugs

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

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

## **HIV/AIDS Prescription Drugs**

Drug Name	Active	NDC	U.S.	NDA/ ANDA	DIN	Canadian	Sold in
	Ingredient		Price			Name	U.S.
Kaletra 200-	Lopinovir,	00074-	\$8.53	NDA021906	02285533	Kaletra	Yes
50mg	Ritonovir	2605-21					
Kaletra 100-	Lopinovir,	00074-	\$4.27	NDA021906	02312301	Kaletra	Yes
25mg	Ritonovir	0522-60					
Emtricitabine,	Emtricitabine,	00093-	\$45.69	ANDA090894	02461110	PMS-	Yes
Tenofovir (TDF)	Tenofovir	7607-56				Emtricitabin	
	(TDF)					e, Tenofovir	
			4			(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		0474-92	4			200MG	
Genvoya tabs	Elviteg, COB,	61958-	\$104.93	ANDA207561	02449498	Genvoya	Yes
	Emtri, Tenof,	1901-01					
Atain la tale	Alafen	45504	¢00.01	AND 4024027	02200000	Atologia	V
Atripla tab	Efavirenz,	15584-	\$96.91	ANDA021937	02300699	Atripla	Yes
	Emtricit, Tenofovir DF	0101-01					
Tfinama		00000	ć72.24	ANDA091215	02202540	TEVA-	Yes
Efavirenz,	Efavirenz, Emtricit,	00093- 5234-56	\$73.31	ANDA091215	02393549	Efavirenz,	res
Emtricit, Tenofovir DF	Tenofovir DF	5234-50				Emtricitabin	
Tenotovir Dr	Tenolovii Dr					e, tenofovir	
Complera tabs	Emtricit,	61958-	\$95.52	NDA202123	02374129	Complera	Yes
Completa tabs	Rilpivirine,	1101-01	333.32	NDAZUZIZS	02374123	Completa	163
	Tenofovir DF	1101-01					
Stribild	Elviteg, COB,	61958-	\$109.51	NDA203100	02397137	Stribild	Yes
Stribild	Emtricit,	1201-01	J105.51	NDAZOSIOO	02337137	Stribila	163
	Tenofovir	1201 01					
	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 February 27, 2024

Original Submission: December 5, 2022

Amended February 27, 2024

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

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

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

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

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

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

Figure 3: Final Drug List

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

<sup>18 |</sup> Colorado's Drug Importation Program





### Section 804 Importation Program

Colorado's Drug Importation Program

December 5, 2022



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

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

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

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

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

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

Figure 2. Final Drug List

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



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



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



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



Fluticasone HFA*	110mcg	Respiratory	Generic	\$177.99	\$39.50	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: <a href="https://www.safemedicines.org">www.safemedicines.org</a>

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	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	988	\$247,029.00	\$86,998.86	\$160,030.14	%29
Erivedge	150mg	Cancer	\$319.97	\$402.01	702	378	1080	\$418,977.54	\$345,565.62	\$73,411.92	18%
Estring		Menopause	\$68.26	\$439.16	2643	1423	4066	\$1,723,072.29	\$277,546.88	\$1,445,525.41	84%
Farxiga	10mg	Diabetes	\$2.66	\$15.18	98295	52928	151223	\$2,215,380.43	\$402,914.28	\$1,812,466.15	82%
Farxiga	5mg	Diabetes	\$2.66	\$15.24	34596	18629	53225	\$782,657.67	\$141,812.15	\$640,845.52	82%
Finacea	15%	Inflammation	\$0.65	\$6.83	24312	13091	37403	\$246,372.15	\$24,405.33	\$221,966.82	%06
Firazyr	10mg/1mL / 30mg/3mL	Hereditary Angioedema	\$2,936.25	\$3,699.59	1074	578	1652	\$5,898,916.36	\$4,851,588.46	\$1,047,327.90	18%
Forteo	250 mcg/mL	Osteoporosis	\$80.58	\$1,526.19	2405	1295	3700	\$5,449,943.89	\$3,258,561.51	\$2,191,382.38	40%
Genvoya	150, 150, 200, 10mg	ΛIH	\$47.63	\$92.79	234760	126409	361169	\$32,340,301.82	\$17,203,517.07	\$15,136,784.75	47%
Gilenya	0.5mg	Multiple Sclerosis	\$92.62	\$256.06	61793	33273	99056	\$23,490,701.76	\$8,804,699.25	\$14,686,002.51	63%
Gleevec	400mg	Cancer	\$115.36	\$334.84	2301	1239	3539	\$1,143,658.53	\$408,290.08	\$735,368.45	64%
Gleevec	100mg	Cancer	\$28.84	\$94.13	1050	565	1615	\$146,727.02	\$46,585.69	\$100,141.33	%89
Glucagon Kit	1mg	Hypoglycemia	\$93.17	\$284.48	3032	1632	4664	\$1,280,440.46	\$434,541.38	\$845,899.09	%99
Ibrance	125mg	Cancer	\$276.13	\$591.34	7890	4249	12139	\$6,926,988.85	\$3,351,901.30	\$3,575,087.55	52%
Ibrance	100mg	Cancer	\$276.13	\$570.00	5571	3000	8571	\$4,714,677.28	\$2,366,823.26	\$2,347,854.02	20%
Ibrance	75mg	Cancer	\$276.13	\$592.79	1743	939	2682	\$1,534,276.14	\$740,613.19	\$793,662.95	52%
Imbruvica	140mg	Cancer	\$98.58	\$137.05	11063	5957	17020	\$2,250,951.81	\$1,677,864.75	\$573,087.06	25%
Incruse Ellipta	62.5mcg	Respiratory	\$1.81	\$10.57	41754	22483	64237	\$655,225.42	\$116,430.28	\$538,795.15	82%
Inlyta	5mg	Cancer	\$101.14	\$251.37	450	242	692	\$167,934.50	\$70,020.00	\$97,914.50	28%
Intelence	200mg	HIV	\$11.85	\$22.02	11129	5993	17122	\$363,781.19	\$202,961.99	\$160,819.19	44%
Invokana	300mg	Diabetes	\$2.85	\$15.39	94019	50626	144645	\$2,148,185.56	\$411,768.41	\$1,736,417.16	81%
Invokana	100mg	Diabetes	\$2.85	\$15.47	51992	27995	79987	\$1,194,268.93	\$227,703.11	\$966,565.82	81%
Isentress	400mg	ΛIH	\$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	895
Jakafi	20mg	Myelofibrosis	\$89.38	\$221.06	4080	2197	6277	\$1,338,998.10	\$561,053.87	\$777,944.23	58%
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	58%
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.



Drug Name	Strength	Indication	Candian Unit Cost with 45% Markup adjusted units	Colorado Unit Cost	APCD Units	Self Funded Units*	Total Utilization by Unit	Current CO Price (per total Utilization by Unit)	Importation Price	Total Annual Savings	Percent Savings
Adcirca	20mg	Pulmonary Hypertension	\$13.23	\$61.09	14450	7781	22231	\$1,310,544.97	\$294,221.45	\$1,016,323.52	78%
Advair Diskus	250/50	Respiratory	\$1.64	\$4.54	1848883	995552	2844435	\$12,461,754.45	\$4,675,557.91	\$7,786,196.54	62%
Advair Diskus	500/50	Respiratory	\$2.33	\$5.12	946340	509568	1455908	\$7,193,348.08	\$3,397,232.90	\$3,796,115.18	53%
Advair Diskus	100/50	Respiratory	\$1.37	\$4.67	567013	305315	872328	\$3,931,190.04	\$1,198,311.61	\$2,732,878.43	70%
Afinitor	10mg	Cancer	\$202.28	\$543.12	3097	1668	4765	\$2,497,186.38	\$963,762.58	\$1,533,423.80	61%
Afinitor	5mg	Cancer	\$202.28	\$556.65	938	202	1443	\$775,173.66	\$291,898.38	\$483,275.28	62%
Alecensa	150mg	Cancer	\$45.86	\$65.32	27862	15003	42865	\$2,702,089.48	\$1,965,607.41	\$736,482.07	27%
Anoro Ellipta	62.5-25 mcg	Respiratory	\$2.28	\$6.64	123670	66591	190261	\$1,218,915.82	\$434,509.22	\$784,406.59	64%
Apri 28 Day	.15mg	Contraceptive	\$0.30	\$0.41	683365	367966	1051330	\$416,437.27	\$317,271.78	\$99,165.49	24%
Aptiom	800mg	Anticonvulsant	\$10.40	\$30.59	3859	2078	5937	\$175,252.94	\$61,720.81	\$113,532.13	859
Atripla	600, 200, 300mg	ΛΙΗ	\$42.25	\$83.93	18161	6226	27940	\$2,262,853.44	\$1,180,343.76	\$1,082,509.68	48%
Aubagio	14mg	Multiple Sclerosis	\$55.42	\$238.86	26292	14319	40910	\$9,429,588.46	\$2,267,101.46	\$7,162,487.00	292
Banzel	400mg	Anticonvulsant	\$3.40	\$23.77	19129	10300	29430	\$675,060.08	\$100,168.19	\$574,891.88	85%
Breo Ellipta	100/25	Respiratory	\$2.98	\$5.65	362505	195195	557700	\$3,041,962.54	\$1,661,807.92	\$1,380,154.62	45%
Breo Ellipta	200/25	Respiratory	\$4.24	\$5.63	338917	182494	521410	\$2,835,285.24	\$2,209,541.34	\$625,743.89	22%
Brilinta	90mg	Anticoagulant	\$1.61	\$6.01	146243	78746	224989	\$1,304,488.99	\$362,120.54	\$942,368.45	72%
Cayston	75mg	Antibiotic	\$46.11	\$103.15	7151	3851	11002	\$1,095,105.71	\$507,298.69	\$587,807.02	54%
Climara	0.05mg/day	Menopause	\$5.71	\$12.93	17342	9338	26680	\$332,810.12	\$152,398.66	\$180,411.46	54%
Climara	0.025mg/day	Menopause	\$5.35	\$12.79	8974	4832	13806	\$170,394.76	\$73,832.29	\$96,562.47	27%
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	829	1938	\$490,376.98	\$1,791.87	\$488,585.12	100%
Dexilant	60mg	GERD	\$0.39	\$8.97	204298	110006	314304	\$2,720,294.99	\$124,007.05	\$2,596,287.94	82%
Dexilant	30mg	GERD	\$0.39	\$9.07	26816	14440	41256	\$361,264.41	\$16,277.26	\$344,987.15	85%
Diclegis Dr	10/10mg	Morning Sickness	\$1.38	\$6.80	29019	15625	44644	\$292,812.44	\$61,755.85	\$231,056.59	79%
Difficid	200mg	C.diff	\$86.13	\$185.64	1710	921	2631	\$471,240.97	\$226,573.69	\$244,667.28	52%
Dulera	200/5mg	Respiratory	\$8.03	\$29.90	36123	19451	55574	\$1,603,521.97	\$446,302.09	\$1,157,219.88	72%
Dulera	100/5mg	Respiratory	\$6.53	\$26.91	23714	12769	36484	\$947,433.36	\$238,057.00	\$709,376.36	75%
Eliquis	5mg	Anticoagulant	\$1.74	\$6.93	825823	444674	1270496	\$8,495,548.60	\$2,210,663.66	\$6,284,884.94	74%
Etiquis	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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Drug Name	Strength	Indication	Candian Unit Cost with 45% Markup	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
Janumet XR	100/1000mg	Diabetes	40) USKed Units \$2.98	\$14.55	11030	5939	16969	\$238.267.29	\$50,563.04	\$187.704.25	%62
Januvia	100mg	Diabetes	\$2.85	\$14.08	217062	116879	333941	\$4,538,628.93	\$950,646.53	\$3,587,982.40	79%
Januvia	50mg	Diabetes	\$2.85	\$14.11	22948	12356	35304	\$480,559.33	\$100,502.12	\$380,057.20	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	82%
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	gm09	Schizophrenia, bipolar	\$3.88	\$40.82	30964	16673	47638	\$1,876,699.96	\$184,947.05	\$1,691,752.91	%06
Latuda	120mg	Schizophrenia, bipolar	\$3.88	\$60.64	15747	8479	24226	\$1,417,753.19	\$94,055.51	\$1,323,697.69	93%
Lonsurf	20/8.19mg	Cancer	\$82.92	\$218.94	2683	1444	4127	\$871,960.46	\$342,222.64	\$529,737.82	61%
Lumigan	0.01%	Inflammation	\$58.78	\$71.16	6280	3381	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	86%
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	868
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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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
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	7609	\$283,925.45	\$70,873.06	\$213,052.38	75%
Rexulti	3mg	Schizophrenia, MDD	\$3.81	\$38.82	2835	1527	4362	\$163,388.90	\$16,617.46	\$146,771.44	%06
Rexulti	2mg	Schizophrenia, MDD	\$3.81	\$35.66	17034	9172	76206	\$901,733.43	\$99,744.83	\$801,988.60	%68
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	8m09	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	<b>%E9</b>
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	ΛΗ	\$47.85	\$102.92	5994	3228	9222	\$915,865.10	\$441,251.14	\$474,613.95	52%
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	856	\$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	82%
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	82%
Synthroid	125mcg	Hypothyroidism	\$0.10	\$1.19	216372	116508	332880	\$382,517.94	\$32,544.40	\$349,973.54	91%
Synthroid	88mcg	Hypothyroidism	\$0.09	\$1.19	208644	112347	320991	\$370,033.79	\$29,182.93	\$340,850.87	92%
Tagrisso	80mg	Cancer	\$320.46	\$509.47	7305	3933	11238	\$5,525,245.94	\$3,601,470.31	\$1,923,775.63	35%
Tagrisso	40mg	Cancer	\$320.46	\$511.02	390	210	009	\$295,879.88	\$192,276.35	\$103,603.53	35%
Tarceva	150mg	Cancer	\$87.00	\$281.56	1605	864	2469	\$670,897.14	\$214,823.08	\$456,074.07	%89
Tarceva	100mg	Cancer	\$58.00	\$264.81	999	358	1023	\$261,441.35	\$59,338.42	\$202,102.92	77%
Tasigna	150mg	Cancer	\$29.66	\$118.49	14338	7720	22058	\$2,522,076.66	\$654,257.81	\$1,867,818.85	74%
Tasigna	200mg	Cancer	\$38.33	\$119.15	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	57%
Tracleer	125mg	Pulmonary Hypertension	\$69.79	\$189.04	2705	1456	4161	\$759,089.43	\$290,428.66	\$468,660.77	62%

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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	AIN	\$44.12	\$87.50	98177	52865	151042	\$12,752,982.07	\$6,663,347.29	\$6,089,634.78	48%
Truvada	200/300mg	HIV (PrEP)	\$28.39	\$53.87	378909	204028	582937	\$30,304,085.00	\$16,547,200.25	\$13,756,884.75	45%
Uloric	80mg	Gout	\$1.73	\$10.89	24202	13032	37234	\$391,254.07	\$64,381.93	\$326,872.14	84%
Uptravi	1200mcg	Pulmonary Hypertension	\$69.78	\$292.34	1260	829	1938	\$546,850.76	\$135,268.34	\$411,582.42	75%
Uptravi	400mcg	Pulmonary Hypertension	\$69.78	\$288.49	540	291	1831	\$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	59460	32017	91477	\$8,325,466.89	\$6,813,488.14	\$1,511,978.76	18%
Vimovo DR	500/20mg	Arthritis Pain	\$1.00	\$41.80	3360	1809	5169	\$208,535.30	\$5,171.82	\$203,363.48	%86
Vimpat	100mg	Epilepsy	\$3.61	\$14.06	79711	42922	122633	\$1,664,330.42	\$442,766.31	\$1,221,564.11	73%
Vivelle-Dot	0.05mg	Menopause	\$2.91	\$16.05	18256	9830	28086	\$434,890.82	\$81,857.10	\$353,033.72	81%
Vivelle-Dot	0.1mg	Menopause	\$3.25	\$16.08	15779	8496	24275	\$376,669.13	\$78,802.45	\$297,866.68	%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	9592	5165	14757	\$229,257.81	\$46,138.44	\$183,119.37	80%
Wellbutrin XL	300mg	Depression	\$1.15	\$14.47	33221	17888	51109	\$713,493.80	\$58,615.79	\$654,878.01	92%
Wellbutrin XL	150mg	Depression	\$0.57	\$13.83	12225	6583	18807	\$251,064.84	\$10,782.78	\$240,282.06	%96
Xalkori	250mg	Cancer	\$141.38	\$300.42	1730	932	7997	\$771,599.97	\$376,275.00	\$395,324.97	51%
Xarelto	20mg	DVT Treatment	\$3.09	\$13.79	564085	303738	867823	\$11,546,088.45	\$2,680,271.61	\$8,865,816.84	77%
Xarelto	10mg	DVT Treatment	\$3.09	\$14.02	63897	34406	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	1,2726	\$352,188.73	\$42,431.37	\$309,757.36	88%
Yaz 28	3/0.02mg	Contraceptive	\$0.46	\$4.80	114128	61454	175582	\$814,013.37	\$80,742.42	\$733,270.94	%06
Zelboraf	240mg	Cancer	\$37.12	\$47.97	7073	3809	10882	\$503,732.49	\$403,948.35	\$99,784.15	20%
Zomig	5mg	Migraines	\$15.06	\$73.99	3802	2047	5849	\$417,576.74	\$88,092.51	\$329,484.23	79%
Zytiga	250mg	Cancer	\$30.81	\$86.22	33078	17811	68809	\$4,234,059.97	\$1,568,022.58	\$2,666,037.39	63%
								\$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

18

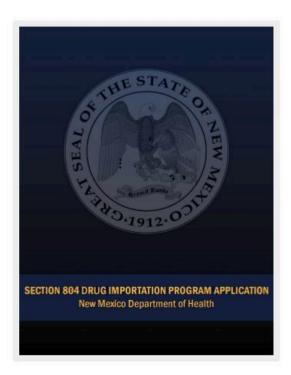
Drug Name	Active Ingredient	NDC	US Price	NDA/ANDA	Canadian Name	Sold in US
Advair Diskus 100- 50mcg	Fluticasone Propion / Salmeterol	00173-0695-00	\$303.60	NDA021077	Advair 100 Diskus	Yes
Advair Diskus 250- 50mcg	Fluticasone Propion / Salmeterol	00173-0696-00	\$377.40	NDA021077	Advair 250 Diskus	Yes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

Drug Name	Active Ingredient	NDC	US Price	NDA/ANDA	Canadian Name	Sold in US
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	64406-0006-02	\$137.93	NDA204063	Tecfidera	Yes
Tradjenta 5mg Tab	Linagliptin	00579-0140-30	\$14.79	NDA201280	Tradjenta	Yes
Triumeq 600-50-300	Abacavir / Dolutegravir / Lamivudi	49702-0231-13	\$98.19	NDA205551	Triumeq	Yes
Truvada 200- 300	Emtricitabine / Tenofovir (TDF)	61958-0701-01	\$59.70	NDA021752	Truvada	Yes

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





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

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

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

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

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

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

U.S. MGREDIENTS	25 mg of empgificion (free base) and the following the hydrosypropy calcidors (free pass) and the following hydrosypropy calcidors, constraining as colour, colored alloco desires and magnetism meaners in addition, the film costrat.	100mg of canglines to 200mg of cangliness, crocameless solem, between yet cangliness, base a highors, comments are served to the comments and emerorations to belone, in seldon, les sides comments in the emeroration of the comments of the emeroration of the comments of the emeroration of the emeror	100mg of anaphilose in 200mg of anaphiloses, researchises soden. Net operation of anaphiloses, researchises soden, Net operation of anaphiloses, transmission some for the sole of the sol	5 ne dapagilisien in dapagilisien proposedia or the equivalent of proposedial or the equivalent to proposedial informyzalisis or enforce arbitrario strategis bestead correspondent, and contact, and well-contact arbitrario strategis. The first controlled or control contact, and well-control contact, posterity factorio, fasterial coloris, posterity factorio, fasterial coloris, posterity factorio, transmit coloris, posterity factorio, transmit coloris, posterity factorio, and proposed pr	5 mg dapagillation in dapagillation proposedule or he separation or proposedule distribution for commentarion in the proposedule microsyndrian endorstroam betterois, crospoologies, alternois endorstroam exterior betterois crospoologies, alternois endorstroam exterior in the costing contents polyment placeds, transmit securities, posteribries princi, title, and yellow to cross the properties of princi, title, and yellow to cross the commentarior and principal properties.	sationing Libraria Ingredients D manninol. corn starts, low substantine lynographicalism, but supersupplications, and majoration steares. The tables are film coasted with a casting material consulting Myrophere library properties gived, tatalism disaste, carriaches was along whit in too ladder publics, and and also believe.	Shory dimensity furnation, microscyclinine residents, stationed accordance in children convergence or software. Existing a second station of second s	Maunin SSOng, colloda illicon dioxide, diodolum edetate, giverel palmitestarata, lyptomeliose, microrystalline cellulose, conservata dioxidese, propieres givosi, red iron entire, sodium starch givosites, tale, and stanium dioxide.	italights and metionmy, microsystaline cololos, polymyrialine cololos, polymyrialine, sodam handlane, and shan darks, an shan stray! fluments the stake into carried extensive before before person in the stake for many control and shan shan shan shan shan shan shan shan
NDA APPLICANT HOLDER NAME AND ADDRESS	Boehringer Ingelheim Fharmaceuticals, Inc. 900 Rögebury Road P.O. Box 368 Rödgelield, CT 06877	Jansen Pharmaceutical, Inc. 1115 Trenten Harbourien Read Tharville, NJ 08560-1564	Jansan Pharmaceuticals, Inc. 1125 Trenten-Harbourten Road PO Box 200 Thurville, NJ 08560-1504	ASTBAZENECA LP PO BOX 15437 WILMINGTON, DE 19850	ASTRAZENICA UP PO BOX 15437 WILMINGTON, DE 19859	Actelion Pharmaceuticals US, Inc. 5000 Sporeline Court, Ste. 200 South San Francisco, CA 94089, USA	Biogen IDIC Inc 275 Binney Street Cambridge, MA 02442	SALIX PHARMACEUTICALS 1700 Perimeter Park Drive Morrisville, NC 27560	MRICS SAAP DOIME 2000 Galoping Ini Bad Serikworth, N 088899
NDA	204629	204042	204042	202293	202293	207947	204063	022554	022044
NDC	0597-0152-30	50458-0140-30	50458-0141-30	00310-6205-30	00310-6210-30	66215-0614-06	64406-0006-02	65649-0303-02	19-5/29-01
U.S. GENERIC NAME	EMPAGLIFLOZIN	CAGLIFLOZIN	CAGLILOZIN	DAPAGLIFLOZIN	DAPAGLIFICZIN	SELEXIPAG	DIMETHYL FUMANATE	RUF AXTIMIN	ть со эосо осы поняния приметивня из
U.S. PROPRIETARY NAME	JARDIANCE	INVOIGNA	INVOICENA	FARNGA	FARNGA	UPTRAVI	TECFDERA	XIFAXAN	LIMITHME
CANADAUAN INGREDIENTS	25 mg of empagificien free base, colloidad silicon classific concernitions of control	DODINg of canagification OR Bildmy of a canagification;  Core T abbet extramenties solution,  hydrospropy of colologo, bettore solution,  steastes, and entire properties of colologo,  steastes, and microrystaline colologo.  steastes, and microrystaline colologo.  steastes, and colorogo and steastes only.  steastes, and colorogo and steastes only.  steastes, and colorogo and color	DOON got can application of storye of canagilloting of canagilloting (over 1 blefs treatmellion soliding, hydroxyeropy cellulose, actors an information of cellulose, actors an information cellulose, actors and incorporabilities cellulose.  Stateste, and incorporabilities cellulose.  Stateste, and cellulose actors from the cellulose.  Filt consist inco mode specific polytring alcohol, talk, and transium dioxide.	5 mg er 10 mg datagliften in atapagliften in propresedel controllett, anlederu bit kater, responsedel controllett, anlederu bit kater, responseden in anlederu bit kater bit anlederu bit anlederu bit anlederu bit anleder bit anlederu bit an	5 mg or 10 mg dasagilfiotin na dasagilfiotin perspeciation in the composition of the conference of the composition of the conference polyviery alcohol, titanium discussion, the first composition of the c	Selezipag J400mg, camasha wax, com starch, D- mannico, Indranyprosyl cellulose, hypomeliose, inco audos yellose (12) os substituted hydroxypropy elululose, magnetium stearste, propylene glycol, stanium dioxide (1271)	28 on get densethy furnation, colloded allono desides, crossamelions soldine, magnesium asserties, metalicite cast coopiumer (pps A), metalicite cast coopiumer (pps A), metalicite cast coopiumer dispersion, polyporate as (parlied metalicite caste) and consistent and parlied metalicite caste and consistent and caste caste caste caste and consistent and caste caste caste caste block on one of the caste caste caste decide and pallere into solds.	Washim's SOme, colloidal silicen dioxide, glycertyl distancate, microcrystalline celluloso, polyethythese spikeline spikeline spikeline spikeline spikeline solde, glyten-free sodium starch spikeline talc, and thankum dioxide, c	(4.2) reg staggin propalate round-year an or- merform hydrochies expension is, 50 mg. Predicative Light 2000 mg. 100
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STRENGTH	25 MG	100 MG	300 MG	S MG	10 MG	1400 MCG	240 MG	550 MG	50-500 MG
ADDRESS	5180 South Service Road Burtlegton Ontario Canada L7L SH4	19 Green Belt Drive Toronto Ontario Canada M3C 119	19 Green Belt Drive Toronto Ontario Canada MSC 119	1004 Middlegate Road, Suite 5000 Massissaga Onzario Canada L4Y 1M4	1004 Middlegate Road, Suite 5000 Mississauga Ontario Canada LAY 1M4	19 Green Belt Drive Toronto Ontario Canada MBC 119	90 Burnhamthorpe Road West, Suite 1100 Mississauga Onzario Cenada LSB 3C3	400 Somerset Corporate Boulevard Bridgewater, NJ 08807	16750 Butte Franzandalene Krichael Guebec Canada H9H 4M7
COMPANY	BOEHRINGER INGELHEIM (CANNDA) LTD LTEE	JANSSEN INC	JANSSEN INC	ASTRAZZNECA CANADA INC	ASTRAZENECA CANADA INC	JANSSEN INC	BIOGEN CANADA INC.	SALIK PHARMACEUTICALS INC	MERCY CANADA INC
NIG	02443945	02425483	02425491	02435462	02435470	02451212	02420201	02410702 5	02333856
CANADIAN GENERIC NAME	EMPAGLFLOZIN	CANAGLIFLOZIN	CANAGLIFLDZIN	DAPAGLIFOZIN	DAPAGLIFOZIN	SELEXIPAG	DIMETHYL FUMMBATE	RIFAXIMIN	METFORMIN/STFAGLIPIT N
CANADIAN PROPRIETARY NAME	JARDIANCE	INVOKANA	INVDKANA	FORKIGA	FORMGA	UPTRAVII	TEGFIDERA	ZAXINE	PANDMET

U.S. INGREDIENTS	200 rg districts have anythrous (residuent to 55 mg, 166 mg, and 25 mg, 166 mg, and 25 mg, 466 mg,	Gazarini, with the following traction hyperferont, licitate monod-plant, excreptation forther constraints condum, property page (and last, and mangarian instants. In white coording consists of hyperonellose, standam disside, and polyethylene glotol.	Gazarini, welt her following tursien hyperferent, licitate monodysellar, corporation fortillo commentero condina, proprietory and condition and an administrate in husbest condition, contains of hyperonellose, standam districts, and polyethylene gloss!	50 mg abentones acents, collodel silons deuds, crossmelores solden, proprieto i laces recorded in myacusa marany, milled incorporation accorded in myacusa marany, milled incorporation accorded in myacusa marany, project plant price of the proprieto accorded in the collection project plant price project project project plant marangement.	On the constitution is a solution to the constitution of the const	Thom go story of intentials (repowhert to 10.00 mg or 18.00)  "Referenced referenced to the properties () The station  and of the properties of the properties () The station  hand for common properties () The station  hand for common properties () The station of the properties () The station of the properties of the properties () The	TOTAL OF THE STREET OF THE STR
NDA APPLICANT HOLDER NAME AND ADDRESS	NOVARTIS One Health Plaza East Hanover, NI 07936	BRISTOL MYERS SQUIBB 4280 ZBH ZHA Fitnet 14th Floor New York, NY 10016	BRISTOL AVTRS SQUIBB 4206 25th Street 14th Floor New York, NY 10016	JANSSEN BIOTECH, INC. 800 Ridgeview Road Horsham, PA 19044	ASTILLAS  One Assessite Way  Hornbrines, I, 60022	Boekringer Ingelledin Pharmaceuticals, Inc. 900 Most John Tool One 168 P.O. Boos 168 Rolgerieds, CT 08877	Bechringer Ingelbeim Phymatestralis, Inc. 900 Riegentralis 7.0 Iou 168 Riegefried, CT 06977
NDA	022068	021986	021986	202379	203415	205832	205832
NDC	00078-0526-87	00003-0528-11	00003-0852-22	5784-0155-06 202379	00469-0125-99	09-810-6500	09-5910-45500
U.S. GENEBIC NAME	NILOTHUB HYDROCHLORIDE	BINLIVSVO	DASATINIB	ABISATERONE ACETATE	BNZALUTAMIDE	NWTEDANB ESTATE	NWEDANG SYLATE
U.S. PROPRIETARY NAME	TASIGNA	112,4845	SPRYCEL	ZYTIĞA	XTANDI	OFEV	OFFW
CANADALAN INGREDIENTS	200 ng milatinib base jan hydrochlentde monodydrate). Colicides alicos anhydrous, Chouplodens, Latonerskydsters, Folosimer 186 hydrochlens steares. Cappus phili George Cappus phili George Transim milatides; livan Oxide, yellow.	So me and storme detaching the monohydrate) containing the following non-medicial impressions to concreme lose sodium, hydrosypropy feedloods, become monohydrate, medicialens the state and monohydrate, medicialens the sim costeting contain the following lasters in egypelentric hydromelions, polyberhydrate glycol and stanium hydromelions, polyberhydrate glycol and stanium hydromelions, polyberhydrate glycol and stanium didnides.	So mg and 100 mg datasinin (se monochydrath containing the billoning non medicinal ingredient for the tablet core crossmellone sodium, hydrosytopy (editious, bustone microsytatien reduces, the sime consideration and contain the billoning has the mosting contain the billoning has the significant in hydromellore, polymylonese glycal and stanium pypomellore, goodney.	SOONS absences actain, cinicial silicen desiriée, crocarmines acidem, hypomelian, lettore roundydate, regentem teature, lettore roundydate, regentem teature, lettore roundydate, regentem teature, letty sidiet. The tablet film couring contains rece code babe, ten code test macropal 3350, polyviny alcelod, talk, and titalium doude.	40 mg of enablements and the humbow beginners carpotypespecies, benilments and protection of accomplications. In the protection of accomplication of the protection of the company of the	TO and 150 mg of introducible in a five based corresponding to 150 din mg and 150	100 and 550 mg of conceivable in a five based of the conceivable of th
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DOSAGE FORM	CAPSULE	TABLET	TABLET	TABLET	CAPSULE	CAPSULE	CAPSUE
STRENGTH	200 MG	SOMG	100 MG	S00 MG	48 MG	100 MG	150 MG
ADDRESS	385 Bouthard Bhd Derval Quebec Canada, H95 LA9	2344 Bout Affred-Nobel Suite 300 Montreal (Striammi) Queboc Canada H45 0M4	2344 Boul Affred-Nobel Suite 300 Montroel (St. Laurent) Queboc Canada H45 (MA	19 Green Belt Drive Troonto Ortatrio Canada M3C 119	SUITE 500 675 Contrast Dries, West Town Markham Ontario Conste, L36088	S.180 South Service Road Burlington Ontario Cinada 171, 5944	S180 South Service Road Burlington Ontario Canada LTL SH4
COMPANY	NDVARTS PHARMACEUTICALS CANADA INC	BRISTOL-MYERS SQUIBB CANADA	BRISTOL-MYERS SQUIBB CANADA	JANSSEN INC	ASTELLAS PHARMA CANADA	BODHBINGER INGELHEIM (CANADA) L'ID L'ITE	изначен иссинам (самаа) гле гле
NIG	02315874 N	02293137	02320193	02457113	02407329	02443066	02443074
CANADIAN GENERIC NAME	NILTINIB (NILOTINIB HYDROCHLORIDE MONOHYDRATE)	DASATINIB (DASATINIB) MONOHIDBATE)	DASATINIB (DASATINIB MONOHTDRATE)	ABIRATEONE ACTATE 0345713	ENGALUTAMIDE	NEMTEDANIS PHINTEDANIS ESLATE;	#MACTIVAN ESACTO
CANADIAN PROPRIETARY NAME	TASIGNA	SPRYCEL	SPRYCEL	ZYTIGA	XTANDI	A340	АЗБО

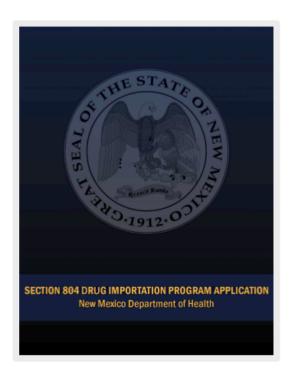
U.S. INGREDIÊNTS	statignis and entitorins, incorposalities calcitos, polymorphiscocachine, for a final facility and statistic and s	13.55 ang of statigation plossible enrockopetate, which is equotated to 10.00 ag, expectationly, of the state and the following exactive interpretations concerning an experiment and physical states of column plossibles, concerning to experiment represents and colomn plossibles, concerning the column registration interpretation and colomn plossibles and plossible and colomn plossibles and plossibles and plossible and colomn plossibles and plossible and colomn plossibles and plossibles are colored and plossibles and plossibles and plossibles are colored and plossibles and plossibles are colored and p	1.1 g/mi. of giyeerol phenybusyrate (delivers 1.02 g/mi. of phenybusyrate).	riveroushan, creazemeliose solium, hyperosilose, lactaes menohydrase, magnaliam steatite, microcrystaline colludose, and solium lauyt sallate, furric cude rest, polyethylene ilycol 3190, polyetny skohol (partisity hydrolyced), tast, and stanium dioode.	195, 5.5.1, or 2.5 on gold debugger roden, which a repulser to gold and gold of the gold o	40 mg of glatismer acetate, 40 mg of mannitol mannitol	COPRIG. Social point represent and the behavior question special and control point represent and the properties or control point represent instead.  For control point and control point the transport instead and control point the transport instead.  FAMITE: instead behavior that the present and the format special control point and point the present and the format point instead control point and control poi	Each 1 m of VCTOX author contains 6 mg if registrice and the following Lates of programs and authorizes 4 mg of the following Lates 1 mg of the contains 4 mg of the VCTOX has performed at 1, by procedure, and or solid hydroxide may be sided to adjust all to prefit of more contains 3 mg is addition of VCTOX expansion. 8 mg and page fall free base, and solid on of VCTOX expansion 18 mg is applicated free base,
NDA APELICANT HOLDER NAME AND ADDRESS	GEREO IN VALUE MANUELLA PROGESSORS DOZIO JAMINO GRANE DELIN	MIRCE SAMP DOHAL 2000 Galloying sail bad Kerhwerth, NI 088899	Horizon Therapeutics, LLC. 520 Lake Cook Rd Suite 520 Deerlield, IL 60015	Janssen Pharmaceuticals, Inc. 1125 Trenton Harbourbon Road PO Box 200 Thusville, NJ 08560-1504	VIVV MEATTHGARE  VIVV MEATTHGARE  Research Transfer Park, NC 27709	TEVA PHARMACEUTICALS USA 400 Interpace Parkway #3 Parsippany, NJ 07054	Same or partial same of the sa	NOVO NORDSK INC 800 Scudders MIII foad Plaintbero, NJ 08536
NDA	022044	021995	203284		204790	020622	205552	022341
NDC	19-1/20-90000	00006-0277-31	76325-0100-04	50458-0579-30 022406	49702-028-13	68456-0325-12	60 0010 29855	00169-4060-13
U.S. GENENIC NAME	STAGLETIVENETTORNS INC. 00006-0577-02	STAGLPTIN PHOSPHATE	GLYCEROL PHENYLBUTYRATE	RIVAROXABAN	DOLITGRAVA	GLATIRAMER ACETATE	BAUTRES	пеласитов
U.S. PROPRIETARY NAME	LIMPTONE	чалон	RAVICTI	XARETO	TVICAY	COPAXONE	MARRIUNICA	WCTOZA
CANADALIAN INGREDIENTS	oppes out perig plat depend out plat depend ou	13.5 on of shallprin phosphate monohydrate, which is equivalent to 100 m; respectively, of the tasts, microscillate entitlents, shallprins a shallprins a shallprins shallprins shallprins shallprins shallprins in shallprins in shallprins in shallprins in shallprins in shallprins in shallprins shall sha	1.1 g/ml, glycerol phenylbutyrate (delivers 1.02 g/ml, of PBA). There are no excipients.	Rivarozabav, cellulose microcystaline, crosscarmellose nodam, riporomolos 5 c <sup>2</sup> , bestose monobystae, magnesiam stasate, sodium itanyi sulphate, ferric oxide yellow (2.5 mg, ferric oxide red (10 mg, 15 mg, 20 mg), hypromeliose 15 c <sup>2</sup> polytetlylene glycu, stanium dioxide	3.6 ing of debapprie codim, wich is equation of 20 and debapprie codim, which is equation of 20 and debappries of 20 and a perpetent. In commontal intercognition enfoliar, professor \$2,921, sodium statut planning professor \$2,921, sodium statut planning content is negline. They debapped in the common and and a their soully manuage (Fig. 6), which is also their soully manuage (Fig. 6), which is also put high olgos, the, and their memorial	glatramer acetate, mannitol and sterile water for injection.	140 mg of brustink, catalodal distant doubde, and the state of the brustink, catalodal distant doubde, and state of the brustink, catalodal distant cataloda, profession, and state of the brusting catalodal profession, prof	6 mg/M Leaghtride, Devolum phosphate dihydrate, propjeen giyool, phenol and water for lightines
NUMBER OF ACTIVE INGREDIENTS	N	च	1	1	-	Ħ	-	Ħ
DOSAGE FORM	7.481.57	ТАВІЕТ	ORALLIQUID	TABLET	TABLET	NOILITIOS	CAPUE	Normon
STRENGTH	50-1000 MG	100 MG	1.1 G/ML	20 MG	SO MG	40 MG	140 MG	18MG/3ML
ADDRESS	16790 Route Transcradiente Orkland Ouelee Carada H961 4M7	16750 Route Transcrudiente Gribad Queboc Canada H984 4M7	1st Floor, Connaught House 1 Burlington Road Dublin 4 Ireland D04 CSYS	2920 Matheson Blvd East Mississauga Ontario Canada LeW SR6	245 Bosievard Armand- Frappier Lavai Quetec Canada HTV 4A7	30 Novopharm Court Toronto Ontario Canada M18 2K9	19 Green Beit Unive Toronio Ontario Canada MSC 119	101:2476 Argentia Road Mississanga Ontario Canada LSN 6M1
COMPANY	MÉRIC CANADA INC	MERCC CANDA INC	HORIZON THERAPEUTICS IRELAND DAC	BAYER INC	VWV HEALTHCARE DLC	TEVA CANADA LIMITED	JANSSEN INC	NOVO NORDISK CANADA INC
NIG	02333872	02303922	02453304	02378612	02414945	02456915	02434607	02351064
CANADIAN GENERIC NAME	METFORMAN STRAGETHET	MONOHOMATE  MONOHO	GLYCEROL PHENYLBUTYRATE	RIVAROXABAN	DOLUTEGRAVIR (DOLUTERAVIR SODUM)	GLATIRAMER ACETATE C	) пенстина	LIRAGIUTIDE
CANADIAN PROPRIETARY NAME	ANIMET	ANUTAN	RAVICTI	XARELTO	TIVICAN	COPAXONE	IMBRUVICA	VICTOZA

U.S. INGREDIENTS	interchengel claimer 2 mg or 5 mg of chemistrague fine soid. The moutest repetation of Productific Assistance are That core: moutest repetation of Productific Assistance are That core: and Section colors of Production Colors of Production Colors of Production and Extra are 3.2 administrated production colors of chairmen last Extra states. In Systematics, two Dicks Bail and Moutest Brook of States and Production and Production Colors Bail and Production Production Colors Bail Colors of Bail and Colors of Production Colors Bail and Colors of	Retrembage claimer 2 in gre 20 ing of demonstrage free and The majorant segment and security states are along, code- magnetic and security of the code of the code- magnetic and security of the code of the code- tion of the code of the code of the code of the code by representative two Code lists and security of the code of the code polymeric spice along the code of the code of the code of the polymeric spice and code lists and security of the code of the polymeric spice and code lists and security of the code of the code of the code of the code of the code of the code of the code of the code of the code of the code of the code of the code of the code of the code of the code of the code of the polymeric spice and code of the code of the code of the code of the code of the code	2 mg of everolima and the following laachte ingredients. Denylated hydroxytolenes, colloidal silicon dioxide, corporations, hydroxytolenes, bictore monohydrate, majoresium stearste, mannitol, and microxytalline cellulose.	O.56 mg of fingolimod hydrochloride, equivalent to 0.5 mg of higolimod, grastin, magnesium stearate, manetol, stavium dioxide, and yellow iron exide.	In my third mission is inquired to a 177 my thickness control and the following eacher grapitettes calcius acreatic, coprollosing. We described the control and control and the control and an advantage of the control and a superior calcius, in several control and a con	201 m of seconds exclude a 21.6.7 mg for except proceducing. In second response a 21.6.7 mg for except Magnetium restore, recoveryulation exchange, providers, and solders second proceducing except in the control of a solders actual policies, code of complete except in the control code back, except proportion and provide and control for and transmitted and code of the code of the code of the for and transmitted and code of the code of the code of the code of the code of the code of the code of the code of the code of the code of the code of	Not assessible, polyheides on physiolog and services Comment of based (Based), through regressions medium chan the properties of the prope	Lacin ne of 1827/1629 applicabile emulion countins. Kinker opdisoprine of 50% kellerken giberrie canter oli, polyporlate \$2; carbonic copolymer type A purified spile and souliam hydroide to adjust \$1.	On my of loci repraise (BIO) (equilaberin to X1 in my of biotographic ages (BIO) (equilaberin to X1 in my of biotographic agents), 2007 my of more interestation (FIO) and my office and my office agent and addressment (FI) (equilaberin to X10 my office and my operations in the more interestant and miscorram and my operation and
NDA APPLICANT HOLDER NAME AND ADDRESS	NOVARTS 22 One Health Bara East Hanner, NI 07936 p	NOVARTIS as Chet Health Basa East Hanner, NI 07936 P	NOVARTIS One Health Plaza East Hanover, NI 07936	NOVARTIS One Health Flaza fit East Hanover, NJ 07936	PATZER 225 East 427nd Street New York, NY 20017	MOVARTIS  One Health Plaza  East Harrover, NO 07936  One Harrover, NO 07936	ASTRAZENICA LP PO BOX 15837 WILMINGTON, DE 19850	ALLEGGAN S Ginzba Farror Madrison, N. 107740	Glead Sciences, Inc. 333 Labeside Drive 1 Frozer City, CJ, 94406
NDA	022291	022291	203985	022527	208246	022465	209210	050050	210251
NDC	03078-0685-15	03078 0686-15	00078-0626-51	00078-0607-15	00069-0501-30	00078-0670-66	00310-6540-04	00023-9163-30	61958-2501-01
U.S. GENERIC NAME	эничи о очичине	ELTROMBOPAG OLANINE	SUMULORIVI	FINGOLIMOD HYDROCHLDRIDE	TOFACTIVIB CITRATE	PAZOPANIB HYDROCHLORIDE	EXEMATIDE	CKCLOSPORNE	BICTEGRANR SODUM; EMTRICTABNE; TRUSOVIR ALATENARIDE FUNNSANTE
U.S. PROPRIETARY NAME	PROMACTA	PROMACTA	AFINITOR DISPERZ	GILENYA	ax zwptax	VOTREENT	BYDUREON BCISE	RESTASIS	BINTARYY
CANADAJAN INGREDIENTS	Is mg or 50 mg of elementoping as elementoping oldernes. The tablest also constains the following connectional profession assessment assessment measures, measured, microsynaline establesta, protentiolars, promotiones, mensuge and statement outside. NOUNGES for guideline and statement outside. NOUNGES for guideline the contain polyvenibutes (NOUNGES for guideline the contain polyvenibutes (NOUNGES) on guidelines and statement models refer also consider red.	Sing or Sing of detroribosing as efrombosing colonies. The salest also centars the following connections the salest and connections between seasons, monored cash affects, supercurs necessaries, monored states followed by promising an experimental processing processing and season modern to the followed by the salest and statement decides. NOUACL'S for statement and seasons polymerate. NOUACL'S for supercursing processing processing seasons and seasons and seasons and seasons and seasons are supercursing the seasons and seasons and seasons are seasons and seasons and seasons are seasons and seasons and seasons are seasons as a season and seasons are seasons as a season and seasons are seasons as a season as	Zing everolimus, basylated hydroxytoluene (E331), celulose microsyvataline, crospovidene, hypromeliose, lactose monohydrate, magnesium stearate, mannitol, silica colloidal anhydross.	0.5 mg fingolimed (as fingolimed hydrochloride) For the 0.5 mg. Magestum stearste, mannitol, geistin, sitanium disoide, yellow iron oxide.	11 mg toticinin la sobicinin crowie, sorbiod, hydroyethy refolio, copositore, magenzium steasat. The first ost carrier selbles settles. First ost carrier selbles settles. First ost carrier selbles settles. First object selbles, First 230 hydroxide, First First selbles carrier selble selbles. First selbles carrier selbles gless, con code. Printing selb course selbles, first selbles Printing selbles gless, con code Printing selbles gless, con code produced proping gless, con code code/black hero code	200M (passare) is passared by decidented, magnetia in season, misconnicial, magnetia in season, misconnicial, magnetia in season, misconnicial, misconnicial	2 ng executide jas white to off white microspheres suspended in a MAT venkile) Sufficient suspended in a MAT venkile) Sufficient suspended of before 2 ang elected control extended evidence 10 £5 mt. venkile extended evidence in 0 £5 mt. venkile extended evidence in 0 £5 mt. venkile evidence (portional) Evidence phytolides, justica per principle evidence (portional) suspense formulation: Evenkile poly (p.). beticle co-gipcolides, justica venkile main trapjectedes (MCT)	(LOSW, w) is available as a stelling preservative free mission supplied in low decady populment and set constraining of mission populment and set constraining of mission of the set of constraining of the set of the set of constraining and constrained as a set of constraining of the set of constraining of	So my olistogravi (equalenti to 3.3 mg of listogravi codeni). So my of entricibilities, and 5 mg of transfer alternative (equalentic to 5 mg or transfer alternative entricibilities). The stransfer of the companion of the Companion of the companion of the Marchael of the companion of the Performance and the Red, into Guide Red, Performance and Angelet Red on Cale Transmit Disoletic.
NUMBER OF ACTIVE INGREDIENTS	1	**	1	**	1		1		м
DOSAGE FORM	TABLET	TABLET	TABLET FOR SUSPENSION	CAPSULE	TABLET	TABLET	SUSPENSION (EXTENDED RELEASE)	EMULSION	TABLET
STRENGTH	25 MG	SOMG	2 MG	0.5 MG	11 MG	200 MG	2 MG/0.85 MIL.	%500	50-200-25 MG
ADDRESS	385 Bouthard Bivd Dorval Quebec Canada, H95 1A9	385 Bouchard Bivd Darval Quebec Canada, H95 1A9	385 Bouchard Blvd Darval Quebec Canada, H95 1A9	385 Bouchard Blvd Dorval Quebec Canada, H95 1A9	17300 Trans Condo Highway Kirkland Quebec Cando H99 2MS	385 Bouchard Bind Dorval Quebec Canada, H95 1A9	1004 Middiegate Road, Suite 5000 Mississauga Ontario Canada LAY 1M4	500 85 Enterprize Blvd Markham Ontario Canada LGG 085	600 6711 Missisrauga Road Mississauga Ontario Canada LSN 2W3
COMPANY	NOWASTS PHARMACEUTICALS	NOVARTIS PHARMAGUTICALS	NOVARTIS PHARMACEUTICALS CANADA INC	NOVARTIS PHARMACEUTICALS CANADA INC	PFIZES CANADA ULC	NOVARTIS PHARMACEUTICALS CANADIA INC	ASTRAZENECA CANNDA INC	ALERGAN INC	GILEAD SCIENCES CANADA INC
NIG	02361825	02361833	02425645	02365480	02470608	02352303	02483203	02355655	02478579
CANADIAN GENERIC NAME	ELTROMBOPAG (ELTROMBOPAG OLAMINE)	ELTROMBOPAG (ELTROMBOPAG OLAMINE)	EVEROLIMUS	FINGOLIMOD (FINGOLIMOD HYDROCHLORIDE)	TOFACTINES (TOFACTINES CTRATE)	PAZOPANIB (PAZOPANIB HYDROCHLORIDE)	EXENATIDE	CYCLOSPORIN	EMPRCTABINE, TENGEOVIR ALAFENANDE AND BICTEGRAVER
CANADIAN PROPRIETARY NAME	RIVOLADE	RIVOLAGE	AFINITOR DISPERZ	GILENYA	XELIANZ XR	VOTRENT	BYDUREON BCISE	RESTASIS	BICTARYY

U.S. INGREDIENTS	25 mg 40 mg or 60 mg of cakeontriebb, wicksh is equivalent to 25 s. 51 mg or 7 mg of cakeontriebb, wicksh is equivalent to 25 s. 51 mg or 7 mg of cakeontriebb (35) makes, requestrieby, CakeOutry Asio contains the fellowing hazaren regressent microcratelisms calledone, interest melherdon, from the cakeontriebb or cake	20 mg, 40 mg, or 60 mg or cakonarien)b, wisch is equivalent to 25 m 3.1 mg, or 70 mg or classoratien(3) (3) prauda, respectively. Cakonarity and cortain in the fellowing instant engoweners, microstratiline calculate, laterate subsequency, in proceedings of control and c	Domg, 40 mg, or 60 mg or chosonteind, wisch is equivalent to 25 mg, 20 mg, or chosonteind, wisch is equivalent to 31 mg, or 35 mg, or disconteined (3) planuals, respectively, CAROMITY also cortain the fellowing harden egpedenter; microcraptaline collabora, lacense shippingous, injection discolled incline discolled incline discolled incline discolled incline discolled, and magnetiskin research.	Lest states contain 11 on gel detegrab. 12 me debicidat. 200 me gel centrales and 200 me debicidat. 200 me gel centrales and 210 me gel centrales debicidates population to 11 me gel rescriber debicidates producedor a debicidate contrales and contrales to the facilitate debicidates debicidates debicidates debicidates contrales and contrales debicidates debicidades produces debicidates debicidades deb	Data film counted tablest constant ablances to affice equivalent to 600 mg of abstracts, discongress continue equations 100 mg of abstracts, discongress continue equations 100 mg of abstracts of the continue of a second properties of a content to the continue of a continue equation of the content to the content to the content to the content to the content of the content (posterior energy (posterior experience) properties in the content (posterior energy (posterior energy)))))))).	Each shelds custing, 200 ag 477. 25 and 470 (equivalents to 22) and physicis in the control of 21 and 470 (equivalents to 22) and reflectablished by 21 and 21 and to 22 and to	Active ingredient: infeptinone hautere ingredients: silicifed microcyptalline calculate, adel matter i physiotist. Mydravpropotylate, adelm halfatte, magnatum insteat Mydravpropotylate, adelm indrakte, magnatum insteat hymoriciles, trainine doods, trucceri, NEK eyle or 20 alminum hymoriciles, trainine doods, trucceri, NEK eyle or 6 alminum lane.
NDA APPLICANT HOLDER NAME AND ADDRESS	Exelbis, Inc. 1851 Harbor Bay Parkway Alameda, CA 94502	Evelinis, Inc. 1851 Harbor Bay Parkway Alameda, CA 94502	Exelitis, Inc. 1851 Harbor Bay Parkway Alameda, CA 94502	Gliead Science, linc. 331 Macrade Drive Foure Chy, CA 94404	WW Heathcare Company  (a) Consorting the Company  (b) Consorting the Consorting the Consorting Park, MC 277799  (b) Consorting Park, MC 277799	Glead Sciences, Inc. 333 Lakeade Deve Foster Chy, CA 94004	Corcept Therapeutics 149 Commonwealth Drive Menlo 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	10 (1994) 10 (1994) 10 (1994) 10 (1994) 10 (1994) 10 (1994) 10 (1994) 10 (1994) 10 (1994) 10 (1994) 10 (1994)	ABACANR SULFATE DOLUTTGRANR SOBUM; LAMIYUDINE	EAFRICTABING, RUP WIRSHE HYDROCHCORDC, TRIOCOMR ALATENAMINE FUNNARATIE	MIEPNSTONE
U.S. Proprietary name	CABOMETYX	CABOMETYX	CABOMETYX	GENOTA	TRUMEQ	ODEFSEY	KORLYM
CANADAIAN INGREDIENTS	cabocamienb (5) malate, colloidal Silicon Dioudes, Crostamienb Solma, for Colloidas, Mayorendious 20diu. More Colloidas, Hayromellose 20diu. More Colloidas, Latone Arbiyd ross, Magensiam Stearate, Microcytalline Celialose, Tranium Dioude and Triacetin.	cabocaminio (5) malate, coloida Silecco Dioxido, Orosamanelos Solani, viltorosporoj (cibulana, Hepromolios 2012, Icno Gode Vellou, Latezoa Anhydrou, Magnesian Stearate, Microcystalline Celludos, Thanlum Dioxide and Trisectin.	caborantinib sy malate, cotoloda Silicon Dioudes, Crossamileo Solimi, Michorogycop (Cellibras, Hydromellos Solimi, Michorogycop (Cellibras, Hydromellos 29 kg, ton Ouder Hellow, Lactora Arbydrows, Magensium Streams, Microcytalline Cellibras, Trantum Dioude and Triaceth.	Each states contain 150 mg of elektroperio, 150 mg of elektroperio, 150 mg of elektroperio, 250 mg of elektroperio, 250 mg of elektroperio, 250 mg of elektroperio, 250 mg of elektroperio 250 mg of elektrope	edients. D mareitol, magnetium stearine, microci	Each stake contain 20 mg of TiC, 25 mg of BVy In 25 mg of Whorkschiedel and 25 mg of BVy Tike is 26 mg of Whorkschiedel and 25 mg of Tike is 26 mg of 124 emelwarent. In tablest also include the following exercise mental-prices, may be a market mental-prices, may be a market mental-prices, may be a market produce in the shade as the meaning sounder market meaning polyvolyme decode, contain granted meaning polyvolyme decode, containing market meaning polyvolyme by sounders and meaning polyvolyme of sounders and meaning polyvolyme of the shade of meaning polyvolyme of the shade of the shade of the shade of t	UNABIE TO LOCATE
NUMBER OF ACTIVE INGREDIENTS	1			4	•	m	UNABLE TO LOCATE
DOSAGE FORM	TABLET	TABLET	TABLET	TABLET	TABLET	TABLET	UNABLE TO LOCATE
STRENGTH	20 MG	40 MG	60 MG	259-150-200-18 MG	DW 005-05-009	200-25-25 MG	UNABLE TO LOCATE
ADDRESS	SUITE 505 5060 Spectrum Way Mississauga Ontario Canada LAW SNS	Surte 505 5060 Spectrum Way Mississauga Ontario Canada L4W 5N6	SUITE 505 5060 Spectrum Way Mississauga Ontario Canada LAW SN7	600 6711 Mississauga Resissauga Mississauga Omario Canuda LN 2W9	248 Boulevard Armand- Frappler Laval Guebec Canada H7V 4A7	600 6711 Mississauga Read Mississauga Ortario Canada ISN 2W3	UNABLE TO LOCATE
COMPANY	IPSEN BIOPHARMACEUTICALS CANADA INC	IPSEN BIOPHARMACEUTICALS CANADA INC	IPSEN BIOPHARMACEUTICALS CANADA INC	GILAD SCIENCIS CANADA INC	VIV HEATHCARE U.C.	GIEAD SCIEWES CANADA INC	UNABLE TO LOCATE
NIG	02480824	02480832	02480840	02449498	02430932	208351	UNABLE TO LOCATE
CANADIAN GENERIC NAME	CABOZANTINIS	CABOZANTINIB	CABOZANTINIB	EMTRICTABNE, TENCHO VEN AAAESMANDE, VENTTGEWARR AND COBIGSTAT	LAMIVUDINE, ABACAVIR AND DOLLITEGRAVIR	EMFROTABNE; BILPWBNE FIRNGOVR AAAFBANDE FUMABATE	UNABLE TO LOCATE
CANADIAN PROPRIETARY NAME	CABOMETYX	САВОМЕТУХ	CABOMETYX	БЕМОУА	TRUMEQ	ASSEGO	UNABLETO LOCATE

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NON APPLICATION OF AP	Gard Science, Inc.  Olited Science, Inc.  1311 Laborate Dove Fronze CB, CA #44404	Britack Myers Squibb A P.D. Box 4000 Princenton, NJ 085-43-4000 Princenton,	
MON	1 21:72	1 202155	
DESK	£ 61956-0701-1	0003-0894-21	
U.S. GENERIC CANAL	DOWNATE TRANSPORTED TO THE TRANSPORTED TRANSPORTED TO THE TRANSPORTED	APIXABAN	
YOU YOUR YOUR YOUR YOUR YOUR YOUR YOUR Y	пилива	Sindria	
CANSOLIN PROFEERS	Lath tablet contion 3D mg of emericables and of treather of plane, are subject as the con- tractive designed, as the contract of the con- tractive designed, as the contract of the con- tractive designed, as the contract of the con- tractive contractive construction scales, the contractive contractive contractive as the texture and contractive contractive contractive the contractive contractive contractive contractive contractive contractive contractive contractive Depart plane 1-0-0-0-0-0-0-0-0-0-0-0-0-0-0-0-0-0-0-0	Active legeotient Apisiobes Europients. Takiet core Anhydrous declarae, microcyptalline enfoldous, transmiserios soldines. Toolien hardy dates and suppressions and trainer solding the supervision in the control trainers and trainers and position to the control trainers, and please to the control trainers, and please are under the trainers and color trainers, and please are under the trainers and position to the color trainers and position to the color trainers.	
ACCUMENTAL OF THE PARTY.	N	1	
DOLAGE FORM	TABLET	TABLET	
нажи	DW 000 000 Z	5 MG	
ACORES	(NO 6711 Melmanaga Menanaga Menanaga Candis UN 199	2344 Boul, Affred Nobel, Suite 300 Montréal (Sr Laurent) Quebec Canada H45 0A4	
ANNANCO	он чемно солись отпо	BRISTOL-AVERS SQUIBB	
8	0027/4906	02397714	
миссими симента	TRIGEO NO DECENDOR. AND ENTRICITABLE.	АРПАВАМ	
WICHWO	TRUVADA	Enguis	





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.

U.S. INGREDIENTS	Each tablet contains 30 mg of luraidone hydrochloride inactive ingredients are mannitol, pregelatiniteed starch, crossamellose sodium, hypromeliose magnesium stearate, Opadry* and camauba wax. Additi	Each tablet contains 40 mg of luraidone hydrochloride, inactive ingredients are manniol, pregelatinised starch, cocarmeliose sodium, hypromeliose, magnesium stearate, Opadry* and camauba wax. Additi	Each tablet contains 60 mg of luraidone Phydrochloride. Inactive ignedients are manniol, preglatinities 6 starth, coosammdiose sodium, hypromeliose, magnesium stearate, Opadry* and camauba wax. Additi	Each tablet contains 80 mg of luraidone Phydrochloride inactive ligredients are manniol, pregelatinised starch, coosameliose sodium, hypromeliose magnesium stearate, Opadry* and carnauba wax. Additi	Active ingredient, albuterol sulfate Inactive ingredient; propellant HFA-134a	Active ingredients: fluticasone propionate, salmeterol xinafoate inactive ingredient: lactose monohydrate (contains milk proteins)	Each 0.5 mg CHANTX tablet contains 0.85 mg of vereficine tarties equivalent to 0.5 mg of vereficine free base, each 1 mg CHANTX tablet contains 1.7 mg vereficine tarties equivalent to 1 mg of vereficine terrate equivalent to 1 mg of vereficine terrate equivalent to 1 mg of vereficine terrate the tablets. microcystalline cellulose, anytytous dibasic cellulose, an
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 Mailtop 5.58 Research Triangle Park, NC 27709	GlaxoSmithKline Five Moore Drive P. O. Box 13398 Research Triangle Park, NC 27709	PF Prism C V d/o Pitzer, Inc 235 Esst 42ad Street New York, NY 10017-5755
NDA	200603	200604	200605	200606	020983	021077	021928
NDC	LURASIDONE 63402-302-30 200603	LURASIDONE 63402-304-30 200604	LURASIDONE 63402-306-30 200605	LURASIDONE 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 GENERIC NAME	LATUDA	LATUDA	LATUDA	LATUDA	VENTOLIN HFA	ADVAIR DISKUS	СНАМТІХ
CANADAIAN INGREDIENTS	lurasidone hydrochloride, carnauba wax, coscarnellose, adount, hydromellose, magnesium stearde, manniol, Opadry, propromellose, postylytime glycol, and titamium diodosk), pregelatinized starch; 80 mg tablet also contains: FD&C Blue No.2 Aluminum alse and yellow ferric oxide.	lurasidone hydrochloride, carnuuba wax, coacamiellose adulum, hygromellose, magnesium stearte, manniol, Opadiv, propriomellose, postyvlives gybycol, and titanium diodick), pregelatinized starch; 80 mg tablet also com	Iurasidone hydrochloride, camauba wax, croscarmellose sodium, hypromellose, ingrapenium steatem, maninol, Opadry- (hypromellose, polyethylene gylool, and trianium dioxide), pregelatinized starch; 80 mg tablet also contains: FD&C Blue No.2 Aluminum Lake and yellow ferric oxide.	lurasidone hydrochloride, carnauba wax, coascamiellosa, calcadum, hydromellosa, magnesium stearate, manniol, Opadiv, propromellose, polytylives glycol, and titamium diodode), pregelatinized starch; 80 mg tablet also comains: FD&C Blue No.2 Aluminum lake and yellow ferric oxide.	lurasidone hydrochloride, carnauba wax, coascamielose soldum, hygromellose, magnesium stearate, manniol, Opadiv, propromellose, progelativiore glycol, and ttannium diodole, progelativicad starch; 80 mg tablet also cornains: FD&C Blue No.2 Aluminum Lake and yellow ferric oxide.	250 mcg fluticasone propionate and 50 mcg salmeterol (as the xinafoate salt)	verencline strette, anhydrous disasic calcium prosphate, collodes silicon dioude, corcermeliore colorum, amagnesium stearies, and microrystaline cellulose. The film-coaline continue, the film-coaline contains hypomeliose, polytivihwe givo, il taminim dioude and trisetin. The 1.0 mg tables sho contains FO&C Blue #27/mgigo Carmine Aluminum Lake as a colorum agent.
NUMBER OF ACTIVE INGREDIENTS	1	1	ī	1	1	2	÷
DOSAGE FORM	TABLET	TABLET	TABLET	TABLET	METERED- DOSE AEROSOL	POWDER	TABLET
STRENGTH	20 MG	40 MG	60 MG	80 MG	100 MCG/ /	250/50	0.5 MG
ADDRESS	7025 Langer Drive, Suite 30.1 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 6L4	7333 Mississauga Road Mississauga Ontario Canada LSN 6L4	17300 Trans- Canada Highway Kirkland Quebec Canada H9J 2MS
COMPANY	SUNOVION PHARMACEUTICALS CANADA INC	SUNOVION PHARMACEUTICALS CANADA INC	SUNOVION PHARMACEUTICALS CANADA INC	SUNOVION 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 CANADIAN PROPRIETARY NAME GENERIC NAME	LATUDA	LATUDA	LATUDA	LATUDA	VENTOLIN HFA	ADVAIR DISKUS	CHANTIX

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

U.S. INGREDIENTS	Each 0.5 mg CHANTIX tablet contains 0.85 mg of verendine a trave equivalent to 0.5 mg of verendine free base, each 1 mg CHANTIX tablet contains 1.21 mg overendine tratrate equivalent to 1 mg of verendine tratrate equivalent to 1 mg of verendine free base. The following plactive ingredients are included in the tablets: microcrystaline cellulose, anyforus disast cellulose, anyforus disaster cellulose, forus disaster cellulose, anyforus disaster cellulose, forus d	Each 2007.5 mg tabler contains 200 mg of emritchiabre (FTC) and 25 mg of tenritchiabre (FTC) and 25 mg of tenritchiabre (FTC) and the following inactive ingredients: corceannelies sodium, magnesium stearste, and microcrystaline celuliaces. The ballets as firm coated with a costing material containing indigo carmine aluminum lake, polyethylene glycol, polykintyl alcohol, tale, and translum dioxide.	25 mg of empagliflooin (free base) and the following in active ingredients: lactore monohydrate, microsystilline cellulose, mydroxypropy feellulose, croscamellose sodium, collodal active diode and magnesium steartes! sincen doode and magnesium steartes! in rediction, the film coating contains the following in	100mg of canagilitatin or 300mg of canagilitatin crostomeliose sodium, hydrosytory for fallacie, bitcose anhydrous, magnesium stearte, and microcrystaline cellulose, in addition, the tablet costoring contains into activity of the solid cost of contains to mo acide yellow ET27 (100 mg tablet contains to mo acide yellow ET27 (100 mg tablet only), macrogol/PES, polyworly alcohol, talc, and titentum dioxide.	100mg of canagillozin or 300mg of canagillozin, croscamellose sodium, hydroxypony cellulozis, barbose arhydrous, magnesium stearte, and microcrystalline cellulose, in addition, the tablet costing contains from oxide yellow ET2 (100 mg tablet contains from oxide yellow ET2 (100 mg tablet contains the addition of the contains and additional properties only), macrogol/PES, polyworly alcohol, talc, and thankun dioxide.	5 mg dapagillotin as dapagillotin propanedicia or the equivalent of 10 mg dapagillotin as propanediold, imcrorystalline cellulose, amedious bacose, cosposidone, alicon diocode, and magnesium stearare. The tim costing contains; polyviny alcohol, Itanium diocide, polyveline legicol, tak, and yellow from oxide.	
NDA APPLICANT HOLDER NAME AND ADDRESS	PF Prism CV c/o Pfites, Inc 235 Ess 42nd Street New York, NY 10017-5756	Glead Sciences, Inc. 333 Lakeside Drive Foster Chy, CA 94404	Boehringer Ingelheim Pharmaceuticals, Inc. 900 Ridgeburry Road P.O. Box 368 Ridgeffeld, CT 06877	Janssen Pharmaceuticals, 1125 Trenton-Harbourton Road PO Box 200 Titusville, NJ 08560-1504	Janssen Pharmaceuticals, inc. 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	EMTRICTABINE; TENGFOVR ALA'EKNAMDE FUMARATE	EMPAGLIFLOZIN 0597-0152-30	CAGLIFLOZIN	CAGLIFLOZIN	DAPAGLIFICZIN 00310-6205-30 202233	
U.S. PROPRIETARY NAME	CHANTX	DESCOVY	JARDIANCE	INVOKANA	INVOKANA	FARXIGA	A ELEMENTS
CANADAIAN INGREDIENTS	varencine tartrate, anhydrous dibasic calcium phosphate, collodes silicon dioxde, crossmellore sodium, magnetium stearets, and mircorystalme eculiose. The firm-coarding contains hypomelose, polybethyleng body Li traulum dioxde and tristerin. The 3.0 mg tablet also contains FD&C Blue ZJ./Indigo Carnine Aluminum Lake 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 cellulose, hypromellose, baccas emondydrate, magnesium stearte, macrogol, microcrystalline cellulose, titanium dioxide, talć, and yellow ferric oxide.	100mg of canagillionin OR 800mg of canagillionin, Core Tablet: croscamelios sodium, hydroxystamic selluloss, inscressium tealinoss, inscressium celluloss, magnesium selluloss, inscressium celluloss. Film Cast: icen anoide velove, 100 mg phosb, polywith alcohol, bolywith alcohol, tale, and ttannium dioxide.	100mg of canagillican OR 300mg of canagillorini, Core Tables canagillorini, Core Tables celluces, lactose anhydroxy, magnesium sesants, and microsynaline cellulose. Film Cast iron oxide vielow (100 mg phost), polywith alcohol, tak, and ttanium dioxide.	5 mg or 10 mg dapagificion as dapagificion proparaded innohydrate, arthrogoda process and process recognition and arthrogoda lactors recorporation material materials, microsystaline fullions, silicion alto acceptant produces and process and proce	DRUG LIST WITH REQUIRED HPFB AND FDA DATA ELEMENTS Page 2 of 10
NUMBER OF ACTIVE INGREDIENTS	t t	2	1	13	1	1	DRUG
DOSAGE FORM	TABLET	TABLET	TABLET	TABLET	TABLET	TABLET	
STRENGTH	1 MG	200-25 MG	25 MG	100 MG	300 MG	5 MG	
ADDRESS	17301 Trans- Canada Highway Kirkland Quebec Canada H9J 2M5	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 SCENCES CANADA INC	BOEHRINGER INGELHEIM (CANADA) LTD LTEE	JANSSEN INC	JANSSEN INC	ASTRAZENECA CANADA INC	
NIQ	02291185	02454424	02443945	02425483	02425491	02435462	
CANADIAN GENERIC NAME	VARENICLINE	EMFRICITABINE AND TENOFOVIR ALAFENAMIDE	EMPAGLIFLOZIN	CANAGLIFLOZIN	CANAGLIFLOZIN	DAPAGLIFOZIN	
CANADIAN PROPRIETARY NAME	СНАМТХ	можа	JARDIANCE	INVOKANA	INVOKANA	FORNGA	

	op s c E X	_ a . a .	e e e e e e e e e e e e e e e e e e e	red	e e o
U.S. INGREDIENTS	5 mg dangilitorin na dangilitorin propanediol or the equivalent of 10 mg dangilitorin as dangilitorin carbonal dangilitorin and ampidros latore, cropsolitoris, cropsolitoris, almidros latores, cropsolitoris, allicon dandiole, and magnesium steaset. The film coating contains polyviny alcohol, transium dioxide, polyetriylene glocol, tarkium dioxide, polyetriylene glocol, tarkium	selecipag 1400mg inactive ingredients: D- manifol, corn starch, low substituted hydroxyposylecitulose, and magnesium approxypcosylecitulose, and magnesium scattarts. The ulastica are film coasted with a costants. The ulastical microlaced with supplience gyloci, Installami dioduce, camada wax along with tren coide red, fino coide yellow, or fron oxide black.	Salong dimethy furnaries, microcrystalline celluloses, silicified microcrystalline celluloses, silicified microcrystalline celluloses, silicified microcrystalline, to silicified colloidal silicified microcrystalline, this silicified colloidal magnetism rate stretch colloidal magnetism rate protection (200 sealer colloidal silicified), solid microcrystalline launy disorder, the Chen Little silicified protection (200 sealers), the colloid silicified protection disorder, the Chen Little silicified protection collider, reference and black front collider.	Rifasimin SSOme, colloidal silicon dioxide, disoulm edetate, giycerol palmitostearate, hypromeliose, microcrystaline cellulose, propylene giyco, red oxide, sodium starch giycolate, talc, and ttelulum dioxide.	sitagliptin and metformin, microcrystalline collection, polyvinyloritotion, collection laury sulfate, and codium steary furnarier. The tablet film coating contains the following the control of the collection polysteritor produces and polysteritor produces from code, and black from code from code, and black from code
NDA APPLICANT HOLDER NAME AND ADDRESS	ASTRAZENECA LP PO BOX 15437 WILMINGTON, DE 19850	Actelion Pharmaceuticals US, 1mc. 5000 Shoreline Court, Ste. South San Francisco, CA 94080, USA	Biogen IDEC Inc 225 Binney Street Cambridge, MA 02142	SALIX PHARMACEUTICALS 1700 Perimeter Park Drive Morrisville, NC 27560	MERCK SHASP DOHNE 2000 Galloping Hill Road Kenilworth, NJ 088889
NDA	202293		204063		022044
NDC	00310-6210-30	66215-0614-06 207947	64406-0006-02 204063	65649-0303-02 022554	PP0720   05204
U.S. GENERIC NAME	DAPAGLIFLOZIN	SELEXIPAG	DIMETHYL FUMARATE	RIFAXIMIN	SITAGLIPTIWME TFORMIN HCL
U.S. PROPRIETARY NAME GENERIC NAME	FARXIGA	UPTRAVI	TECFIDERA	XIFAXAN	JANUMET
CANADAIAN INGREDIENTS	5 mg or 10 mg dapagilitein as dapagilitani proparateloi monohiertas, anyafous lacines, crosporaten magnesium stearate, microcystalline eciliose, silicino floxide in addition, the film coantig contains the following in mo	Seleopag 1400mg, carnauba wax, com 1814rb, Drmanntel, Jindovopropyl cellulose, hypomellose, compression (1717), los vabettuel hydroxypropyl cellulose, magnesium stearate, propylene glycol, itanium stearate,	240 mg of dimethy furnantae, colloidal alligiond deside, accoss/mellos acodum magnesium steasta, methacytic acid copolymet (type A), methacytic acid copolymet dispersion, polysolate 80, silicihed microcytalinie cellulosi, silicihed microcytalinie cellulosi, silicihed microcytalinie cellulosi, and triethy (trate. The opsile shell and triethy (trate. The opsile shell contains black from oxide, PSAC Blac 1, gelastin, titanium dioxide and yellow from oxide	Rifaximin 550mg, colloidai silicon dioxide, giyceryl distearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, red iron oxide, gluten free sodium starch glycolate, lack, and titanlum dioxide, and titanlum dioxide.	64.25 mg sitegliptin phosphate monohydrate and metchmin hydrochloride equivalent to: 50 mg siteglight as the sake and 50 0 mg siteglight as the sake and 50 0 mg mg/500 mg, 550 mg metchmin hydrochloride pong pong pong pong mg/300 mg metchmin hydrochloride pong pong pong pong mg/storolidone, sodium bany hydrochloride, sodium bany sidite, and sodium steam (hymrate in addition, the film coating companients in polynic machine incompanients in polynic mg- than and polynic mg- marchine polynic mg- polynic mg- polynic mg- marchine polynic mg- marchine polynic mg- polynic mg- polynic mg- marchine polynic mg- polynic mg- po
NUMBER OF ACTIVE INGREDIENTS	1		1	£4	2
DOSAGE FORM	TABLET	TABLET	CAPSULE (DELAYED- RELEASE)	TABLET	TABLET
STRENGTH	10 MG	1400 MCG	240 MG ((	550 MG	5W 005-05
ADDRESS	1004 Middlegate Road, Suite 5000 Mississauga Ontario Canada L4Y 1M4	19 Green Belt Drive Toronto Ontario Canada M3C 119	90 Burnhamthorpe Road West, Suite 1100 Mississauga Ontario Canada LSB 3C3	400 Somerset Corporate Boulevard Bridgewater, NJ 08807	16750 Route Transcandienne Kirdand Quebec Canada H9H 4M7
COMPANY	ASTRAZENECA CANADA INC	JANSSEN INC	02420201 BIOGEN CANADA INC	SALIX PHARMACEUTICALS INC	Mercy canda inc
NIQ	02435470	02451212	02420201	02410702	02333856
CANADIAN GENERIC NAME	DAPAGLIFOZIN	SELEXIPAG	DIMETHYL FUMARATE	RIFAXIMIN	METORMIN/SIT AGLPITN
CANADIAN PROPRIETARY NAME	FORXIGA	UPTRAVI	TECFIDERA	ZAXINE	JANUMET

DRUG LIST WITH REQUIRED HPFB AND FDA DATA ELEMENTS Page 3 of 10

U.S. INGREDIENTS	stagistics and hetforms, microcystilline cellulosis, solid market misses and metforms, and metros elicitors, solid market misses in polytics, and existing metros from the fill morals in misses from misses and polytics, polytics polytics, and consider metros from the misses of misses and pack from order and back from order.	128.5 mg of stagilptin phosphate monohydrate, who has equivalent to 100 mg respectively, of free bases and the following history less that conversal me the following mydrous data educin phosphate, crocarmelities codium, magnesium steaares, film coaling contains the following native in film coaling contains the following native ingredients polyvicial actions, to properly the properly and provided in the following native ingredients polyvicial actions, to properly and provided in the following native ingredients polyvicial actions to conference and yellow fron code.	<ol> <li>1.1 g/ml of glycerol phenylbutyrate (delivers 1.02 g/ml of phenylbutyrate).</li> </ol>	rivorcadan, crocamelices codium, hyporentices, bacos monohydrate, magnetium stearte, microsystaline cellotos, and codium landy staffer, left crooker et, polyethylene glocal 3350, polyviniy alcohol (partially hydrolyted), bit., and titanium dioxide.	105, 26.3 or \$2.6 mg of delutegrani sodium, half his equivalent to \$20 mg delutegrani regerint in equivalent to \$20 mg delutegrani respectively. Dramantol, microcrystaline activities, providente \$20.932, sodium stately fluidoste, providente Stealy fluimantae. The tabler flim-costing domains the matcher lander flim-costing domains the matcher lander flim-costing domains the matcher landerest such successforted. The successforted successforted successforted to polyviny alcohol-spart hydrolyted, tale, and proving alcohol-spart hydrolyted, tale, and polyviny alcohol-spart hydrolyted, tale, and	ng of glatiramer acetate, 40 mg of mannitol man
NDA APPLICANT HOLDER NAME AND ADDRESS	MERCK SHARP DOHNE 2000 Galloping Hill Road Kenilworth, NJ 088889	MERCK SHARP DOHNE 2000 Galloping HII Road Kenilworth, NJ 088889	Horizon Therapeutics, LLC. 520 Lake Cook Rd Suite 520 Deerfield, IL 60015	Janssen Pharmaceuticals, inc. 1125 Trenton-Harbourton Road PO Box 200 Titusville, NJ 08560-1504	VIIV HEALTHCARE Five Moore Drive Recent'Th Triangle Park, NC 27709	TEVA PHARMACEUTICALS USA 400 Interpace Parkway #3 Parsippany, NJ 07054
NDA	022044	021995	203284			020622
NDC	00006-0577-61 022044	00006-0277-31 021995	76325-0100-04 203284	50458-0579-30	49702-0228-13	68456-0325-12 020622
U.S. GENERIC NAME	SITAGLIPTIN/ME TFORMIN HCL	SITAGLIPTIN PHOSPHATE	GLYCEROL PHENYLBUTYRA TE	RIVAROXABAN 50458-0579-30 022406	DOULTGRAVIR 49702-0228-13 204790	GLATIRAMER ACETATE
U.S. PROPRIETARY NAME	LEWINERT	JANUVIA	RAVICTI	XARELTO	TIVICAY	COPAXONE
CANADAIAN INGREDIENTS	64.25 mg siteglicini phosphate monohydrate and meteromin hydrochioride squivalent to: 50 mg siteglicin is fee base and 50 ng meteromin hydrochioride (pulkUME* 50 ng mg/500 mg. 550 ng meteromin hydrochioride (pulkUME* 50 mg/500 mg. mg/ indrocynorg meteromin hydrochioride (pulkUME* 50 mg/500 mg.) hydrochioride (pulkUME* 50 mg/500 mg.) hydrochioride (pulkUME* 50 mg/500 mg.) mg), mdrocynorgalime edilose, polyvivlyperoclidora, sodium baury suffase, and sodium stany duffase, and sodium stany duffase, and sodium stany ingresients; polyvini ingresients; polyvini sideolos, polernylene glocol, tac, tanium diodec, nd fore oodes, and tanium diodec, nd fore oodes, and black inn oodes, and sure oodes, and	128.5 mg of slaagijoin phosphate monohydrate, which is equalwient to 100 mg, expectively, of the abuse, microrystaline relialoos, amhdrous of dissist calcium prosphate (calcium dissist calcium prosphate (calcium amhdrous), crossementess coldium stagment materias, and coldium steamy from the film conting contains the following inactive ingredients; polyvimy alcohol, (macrogol), and trainfund ideolde, red from oxide, and yellow from coldie.	1.1 g/mL glycerol phenylbutyrate (delivers 1.02 g/mL of PBA). There are no excipients.	Rivaroxban, cellulose microcrystalline, croscarmellose sodium, hipromellose 5 od by Latose monohydrate, magnesium stearate, sodium launy suphaste, ferric dele wilow (2, 5 mg.) ferric oxide red (10 mg. 15 mg. 20 mg.) kmy composible sub- P, polyethylene glycol, titanium dioxide	\$2.6 for gold dolutegravic sodium, which is equivalent to 50 mg dolutegravir free and, respectively, and the following interfer ingredients: Demantiol, microcystaller echilotos, provident \$29,32, acidum starto picotale, and codium starto picotale, and codium starto picotale, and codium starto picotale, and sodium starto picotale, and sodium starto picotale, toro odde yellow (25 mg and 50 mg talets only, marcegol/PSC, polyniny alcohol, past Mydrosed, lack, and alcohol, past Mydrosed, lack, and tuning and sodium starto picotale.	glatiramer acetate, mannitol and sterile water for injection.
NUMBER OF ACTIVE INGREDIENTS	N	н	1	н	ч	п
DOSAGE	TABLET	TABLET	ORAL	TABLET	TABLET	SOLUTION
STRENGTH	50-1000 MG	100 MG	1.1 G/ML	20 MG	50 MG	40 MG S
ADDRESS	16750 Route Transcandemen Kirkland Guebec Canada H9H 4MP	16750 Route Transcanadieme Krikand Guebec Canada H9H 4M7	1st Floor, Connaught House 1 Burlington Road Dublin 4 Ireland D04 C5Y6	2920 Matheson Blvd East Mississauga Ontario Canada L4W 5R6	245 Boulevard Armand-Frappier Laval Quebec Canada H7V 4A7	30 Novopharm Court Toronto Ontario Canada M1B 2K9
COMPANY	MERCK CANADA INC	MERCK CANADA INC	HORIZON THERAPEUTICS IRELAND DAC	BAYER INC	VIIV HEALTHCARE ULC	TEVA CANADA LIMITED
NIQ	02333872	02303922	02453304	02378612	02414945	02456915
CANADIAN GENERIC NAME	METFORMIN/SIT AGUPITN	SITAGLIPTIN (SITAGLIPTIN PHOSPHAITE MONOHYDRATE	GLYCEROL PHENYLBUTYRA TE	RIVAROXABAN	DOLUTEGRAVIR (DOLUTEGRAVIR SODIUM)	GLATIRAMER ACETATE
CANADIAN CANADIAN PROPRIETARY NAME GENERIC NAME	дамплечт	JANUVIA	RAVICTI	XAREITO	TIVICAY	COPAXONE

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

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U.S. INGREDIENTS	desatinib, with the following inactive ingredients: alcord monohydrate, ingredients: alcord monohydrate, and morocystalline cellulose, crossamellose sodium, hydroxypropy cellulose, and magnesium stearter in the bablec coaring consists of hypomellose, thanking dioxide, and polyecthylene glycol.	500 mg abiraterone acetate, coiloidai silicon dioxide, croscammeliose sodium, hypomeliose, latoce monohydrate, magnestium searate, alleifferd microcystaline cellulose, and sodium launy abilate. The coatage Chaptyr II Purple, contains from oolde black, from onde red, polyhethydene glycol, polyheniyi alicchol, tak; and ttanium dioxide.	40 mg of enzalutamide as a solution in capyfocapuny polywydyterides. The inactive polywydyterides a prathricapuny in polywydyterides, burkete hydroxymaiola, burkjated hydroxymolaules, gedain, sonbiol sorbitan solution, gyfeerin, purfited water, titanium dioxide, and black iron oxide	100 mg or 150 mg of nintedanib (equivalent to 120 mg or 130 mg or 130 om ennedanib ethineseulfonate, respectively). The nactive ingredents of OFt verte following: Fill Material: tribycerides, hard fat, letthin. Capsule Shelf: gelatin, glycerol, Itanium dioxide, red ferit coide, yellow ferric oxide, plack in black inc.	100 mg or 150 mg of nintedanib (equivalent to Lion) mg or 150 mg of sloop mendedanib ethanesulfonate, respectively. The nactive ingredients of OFV we the following: Fill Material: trip/cerdies, had fat, lecthin. Capsule Shell: geldanir, givereol, titanium dloxide, red ferric coide, gellow ferric coide, eldoxide, red ferric coide, eldoxide.
NDA APPLICANT HOLDER NAME AND ADDRESS	BRISTOL MYERS SQUIBB 430 E 29th Street 14th Floor New York, NY 10016	JANSSEN BIOTECH, INC. 800 Ridgeview Road Horsham, PA 19044	ASTELAS One Astelias Way Northbrook, IL 60062	Boehringer Ingelheim Pharmaceuticals, Inc. 900 Riegeury Tood P.O. Box 368 Riegerfeid, CT 06877	Boehringer Ingelheim Pharmaceuticials Inc. 900 Bidgebury Acad P.O. Box 366 Ringerield, CT 06877
NDA	021986	202379	203415	205832	205832
NDC	00003-0852-22 021986	57894-0195-06 202379	00469-0125-99	00597-0143-60 205892	00597-0145-60 205832
U.S. GENERIC NAME	DASATINIB	ABIRATERONE ACETATE	ENZALUTAMIDE 00469-0125-99 203415	NINTEDANIB ESYLATE	NINTEDANIB ESYLATE
U.S. PROPRIETARY NAME	SPRYCEL	ZYTIGA	XTANDI	OFEV	OFFV
CANADAIAN INGREDIENTS	50 mg and 100 mg distatinih (as monohydrata) containing the following mon-medicinal ingedients for the tablet core crossamelose sodium, hydroxyprosil cellulosa, bactoo monohydrate, magnesium stearte and microcystaline cellulosa. The firm coating contain the following hactory impredients; hypomeliosa, polyethylene glycol and titanium dioode.	500MG abiraterone acetate, colloidal silicon dendude, crosarmellose, consarmellose dendum, hypomellose, lactose monohidrate, margersium steante, sileried microcrystaline, and roalium laury silante. The tablest life monohing contains from doeb lack, from coder est, marcogo 3350, polyvinyl acidool, lack, and thanium dioxides.	do mg of enzalutunide and the inactive ingredient caphricaryoristic appropriate caphricaryoristic and business. business caphricaryoristic and business. business capture shell are gletalen, softiol softiam solution. By gletalen, softiol softiam solution, softiol softiam solution, and softiam solution solution. By gletalen, softial softiam disolated is soft to an entire disolately access to propriet extension of the softial softial softial solution solution softial softial solution solution softial solution solution in softial solution solution concentrated.	100 and 150 mg of initedanib (as a free base) corresponding to 120.40 mg and 180.60 mg of initedanib (as of initedanic ethinicalization te (talista), respectively. Cappute fill, Medium chain trigheeride, hard fill and the cap technic (1522) capute shell; celatin, giverno 85 %, transium double (1217), into node red (16172), into mode red (16172), but chick (Opacode*) shell celating the capute (1522) hand the Copacode*) shell celating the capute (1522) hand the (1523) copyliene gives iron node back (15172).	100 and 150 mg of nintedamb (as a free base) corresponding to 120.040 mg and 138.05 mg of nintedamb (as of nintedamb (as of nintedam) capacities (challed). Fragacties (challed)
NUMBER OF ACTIVE INGREDIENTS	ęd	1	1	Ħ	rt
DOSAGE FORM	TABLET	TABLET	CAPSULE	CAPSULE	CAPSULE
STRENGTH	100 MG	500 MG	40 MG 1	100 MG CAPSULE	150 MG
ADDRESS	2344 Boul, Alfred- Nobel Suite 300 Montreal (St- Laurent) Quebec Canada H4S 0A4	19 Green Belt Drive Toronto Ontario Canada M3C 119	SUITE 500 675 Codrane Drive, West Tower Markham Ontario Canada, L3R0BB	5180 South Service Road Burlingcon Ontario Canada IZI SH4	5.180 South Service Read Bullington Ontario Canada L71 SH4
COMPANY	BRISTOL-WYERS SQUIBB CANADA	JANSSEN INC	ASTELAS PHARMA CANADA INC	BOEHRINGER INGELHEIM (CANADA) LTD LTE	BOEHRINGER INGELFEIM (CANADA) LTD LTEE
NIG	02320193	02457113	02407329	02443066	0243074
CANADIAN GENERIC NAME	DASATINIB (DASATINIB MONOHYDRATE )	ABIRATERONE ACETATE	ENZALUTAMIDE	NINTEDANIB (MINTEDANIB ESILATE)	NINTEDANIB (NINTEDANIB ESILATE)
CANADIAN CANADIAN PROPRIETARY NAME GENERIC NAME	SPRYCEL	ZYTIGA	XTANDI	A340	OFEV

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U.S. INGREDIENTS	eltrombopag olamine 25 mg or 50 mg of eltrombopag olamine 25 mg or 50 mg of eltrombopag free acid. The inactive ingerdients of PROMACTA taletas are Taleta Corecytalline schlaubes, povidence, and sodium starch sylvoitet Courine, TRSC Fileta No. 2 aluminum lates (50 mg taleta). Estor Viellow No. 6 aluminum lates (55 mg taleta) taleta (15 mg taleta), polybethylene glycal dOo, polybethylene dOo, polybethylene glycal dOo, polybethylene dOo, poly	eltrombogae clamine 25 mg or 50 mg of eltrombogae clamine 25 mg or 50 mg of eltrombogae (fee soid. 1) hendzive ingerdenta of PROMACTA tablets are Tablet Groe magnesium stearate, mannitol, microcrystalline specialists, pordione and socialism starch globuse, pordione and socialism starch globuse, pordione and socialism starch specialism probact site No. 6 aluminum late (25 mg tablet), hypromeliose, front of the Back and mo Codie Red (27 mg tablet), polystrykene glycox 400, polystrykene glycox 400, polystrombose, front of the Red (27 mg tablet), polystrykene glycox 400, polystrombose (125 mg tablet), or tranium dioxide.	2 mg of everolimus and the following inactive ingredents: Budylated hydroxyoluene, coloidal silicon dioxide, crospovidone, hypromellose, lactose monohydrate, magresium stearder, mannifol, and microxystalline cellulose.	0.56 mg of fingolimod hydrochloride, equivalent to 0.5 mg of fingolimod, gelatin, magnesium stearate, mannitol, titanium dioxide, and yellow iron oxide.	ruxolitinib phosphate equivalent to 10 mg of ruxolitinib free base together with microchystaline fullulose, lactors monochydrate, magnesium stearate, colioidal silicon dioxide, sodium starch givcolate, povidone and hydroxypropyl cellulose.	11 mg tofactinib (equivalent to 17.77 mg tofactinib citrate) and the following inactive ingredients: cellulose sectias, copolidore, hydroxyethy cellulose, hydroxyethycoping cellulose, hydroxyethycolide, fortoxofactic contains, ammonium hydroxide, fortoxofactic contains, ammonium hydroxide, fortoxofactic codebylase from oxide, propyiente giyco, and oxide propyiente giyco, and stheliae giaze.	200 mg of pazopanib equivalent to 216.7 mg of pazopanib equivalente. The narchee ingredents of VOTRIENT are; Tablet core: Magnesium stearate, microcrystalline cellulose, pordione, and soldine starth glycolate. Coating Gray filmozat: hypromeliose, iron oxide black, macroglylobylethylene glycol 400 (PEE 400), polyochate 80, and ttanlum click 400), polyochate 80, and ttanlum click 400, polyochate 80, and ttanlum click 400.
NDA APPLICANT HOLDER NAME AND ADDRESS	NOVARIIS One Health Plaza East Hanover, NJ 07936	NOVARTIS One Health Plaza East Hanover, NJ 07936	NOVARTIS One Health Plaza East Hanover, NJ 07936	NOVARTIS One Health Plaza East Hanover, NJ 07936	INCYTE CORP 1801 Augustine Cut-off Wilmington, DE 19803	PFIZER 235 East 42nd Street New York, NY 10017	NOVARITS One Health Plaza East Hanover, NJ 07936
NDA	122291	222291	603985	722527	202192	108246	722465
NDC	00078-0685-15 022291	00078-0686-15 022291	EVEROLIMUS 00078-0626-51 203985	FINGOLIMOD HYDROCHLORID 00078-0607-15 022527	50881-0010-60 202192	00069-0501-30 208246	PAZOPANIB HYDROCHLORID 00078-0670-66 022465
U.S. GENERIC NAME	ELTROMBOPAG OLAMINE	ELTROMBOPAG OLAMINE	EVEROLIMUS	FINGOLIMOD HYDROCHLORID E	RUXOLITINIB PHOSPHATE	TOFACITINIB	PAZOPANIB HYDROCHLORID E
U.S. PROPRIETARY NAME	PROMACTA	PROMACTA	AFINITOR DISPERZ	GILENYA	JAKAFI	XELJANZ XR	VOTRIENT
CANADAIAN INGREDIENTS	25 mg or 50 mg of eltrombopag as eletrombopag deletrombopag deletrombopa	25 mg or 50 mg of eltrombopag as eletrombopa gradient allocated and eletrombopa gradiente. The tablest also contains the following nonnesdicial ingredients, magnesium stearate, providents, solimin starcit glocates, pondents, solimin starcit glocates, providents, solimin starcit glocates, and consell polyposches, solimin starcit glocates, as deceding the states also contain prolysoches. ReVOLADE 55 mg tablest salso contain to roldotte traditional and iron oxide red.	2mg everolimus, butylated hydroxytoluene (E321), cellulose microcrystalline, crospovidone, hypromeliose, lactose monohydrate, magnesium stearate, manniol, silica colloidal anhydrous.	0.5 mg fingolimod (as fingolimod hydrochloride) For the 0.5 mg: Magnesium stearate, mannitol, gelatin, titanium dioxide, yellow iron oxide.	10 mg ruxollinib free base (ss ruxollinib phosphate), Mydroxprosylcelluloce, 142-90 mg lectose monhydrate, magnesium stearate, microcrystaline cellulose, colloidal sillinool docks, sodium starch gyrolate (Type A), povidone.	11 mg torkacinnib (as tofactinin) circate), sochtel, hovorethyt elialiose, sochtel, hovorethyt elialiose, copoldone, magnesium stearet. He film cast contains reluiose acetae, hydropromeilose, talkout, HPMC, 290/hypromeilose, talkout, red iron oxide. The Printing ink contains shellose, tamenoium hydroide, prosphere gitzel, ammonium hydroide, prosphere gitzel, ferrosoferric oxide/black fron oxide ferrosoferric oxide/black fron oxide.	200MG (paropanile as paropanile hydrocholorid), magnesium stearte, microcypatiline cellulose, powdone (KS) and sodium starch glycolitee. The tablet coaling contains the following excipients; hypomeliose, into node black (E122 – 200mg tablet), macrogol, polysorbus 80 and titralium diodde (E127).
NUMBER OF ACTIVE INGREDIENTS	1	н	1	1	1	1	1
DOSAGE FORM	TABLET	TABLET	TABLET FOR SUSPENSI ON	CAPSULE	TABLET	TABLET	TABLET
STRENGTH	25 MG	50 MG	2 MG	0.5 MG	10 MG	11 MG	200 MG
ADDRESS	385 Bouchard Blvd Dorval Quebec Canada, H9S 1A9	385 Bouchard Blvd Donval Quebec Canada, H95 1A9	385 Bouchard Blvd Dorval Quebec Canada, H9S 1A9	385 Bouchard Blvd Dorval Quebec Canada, H95 1A9	385 Bouchard Blvd Dorval Quebec Canada, H9S 1A9	17300 Trans- Canada Highway Kirkland Quebec Canada H9J 2MS	385 Bouchard Blvd Dorval Quebec Canada, 195 1A9
COMPANY	NOVARTIS PHARMACEUTICALS CANADA INC	NOVATIS OZS61833 PHARMACEUTCALS CANADA INC	NOVARTIS PHARMACEUTICALS CANADA INC	NOVARTIS PHARMACEUTICALS CANADA INC	NOVARTIS PHARMACEUTICALS CANADA INC	PFIZER CANADA ULC	NOVARTIS PHARMACEUTICALS CANADA INC
NIG	02361825	02361833	02425645	02365480	02434814	02470608	02352303
CANADIAN GENERIC NAME	ELTROMBOPAG (ELTROMBOPAG OLAMINE)	ELTROMBOPAG (ELTROMBOPAG OLAMINE)	EVEROLIMUS	FINGOLIMOD (FINGOLIMOD HYDROCHLORID E)	RUXOLITINIB (RUXOLITINIB PHOSPHATE)	TOFACTINIB (TOFACTINIB CITRATE)	PAZOPANIB (PAZOPANIB HYDROCHLORID E)
CANADIAN CANADIAN PROPRIETARY NAME GENERIC NAME	REVOLADE	REVOLADE	AFINITOR DISPERZ	GILENYA	JAKAVI	XELANZ XR	VOTRIENT

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	P.	n m	zi r a abi	e, e	f for the se,	e, ee,
U.S. INGREDIENTS	2MG exenatide, polylactide co-glycolide and contents of liquid (diluent): inactive lingredients: medium chain triglycerides	Each mt. of RESTASS* ophthalmic emulsion contains: Acher exployerine OSS*, inactives: glycerin; castor of ja polysorbate Sib; cutchone copolyme type A; purified water, and sodium hydroidle to adjust pH.	50 mg of bictegravir (BIC) (equivalent to 23.5 mg of bictegravir sodium). 200 mg of mg of bictegravir sodium). 200 mg of mg of bictegravir sodium). 200 mg of bictegravir to 28 mg of tendofori ablemande (marzel). Tendofori ablemande (marzel) and microcyptaline celluloses. Tendofori ablemande (marzel) and microcyptaline code bick, (monde material conditioning from oode bick, (monde material conditioning from oode bick, (monde material conditioning from ode bick, (monded material conditioning from ode bick, (monded material conditioning from ode bick, (monded material conditioning from ode bick).	20 mg, 40 mg or 60 mg of cabozantinib, which equivalent to 25 mg. 21 mg, or 76 mg of cabozantinib (5) minute, respectively. CASOMETY Side coordinate the following inactive ingredients: microcrystalline realitois, crossammlose sodium, collosida sillom dioutide, and magnetium scientistica dioutide, and magnetium scientistica dioutide, and magnetium scientistica.	20 mg, 40 mg, or 60 mg of cabozantinib, which equivalent to 25 mg, 21 mg, or 26 mg of a cabonantinib (5) millian respectively. The abozantinib (5) millian respectively. ACMOMETY 32 mortises the following inactive ingredients: microcytalinine cellulosis, crosses a inheritors. Indiroxyprosyl cellulosis, crosses a mindrosis by homogenium, cellulosis, crosses a mindrosis sedium, cellulosis alliculosidos sedium, cellulosis alliculosidos sedium, cellulosis alliculosidos sedium cellulosis.	20 mg, 40 mg or 60 mg of cabozantinib, which equivalent to 25 mg, 21 mg, or 76 mg of cabozantinib (5) minute, respectively. To CASOMETY State of Cabozantinib (5) minute, respectively. To CASOMETY State of Cabozantini (6) minute inactive ingredients: mircocyclatine cellulose, cross amplicate, and chronyopropy cellulose, cross amplicate, and magnetism scientistic dioxide, and magnetism scientists.
NDA APPLICANT HOLDER NAME AND ADDRESS	ASTRAZENECA IP PO BOX 15437 WILMINGTON, DE 19850	ALLERGAN 5 Giralda Farms Madison, NI 09740	Gilead Sciences, Inc. 333 Likeside Drive Foster City, CA 84404	Evelbris, Inc. 1851 Harbor Bay Parkway Alameda, CA 94502	CABOZANTINIB 42388-025-26 208692 13831 Harbor Buy Parkway Alameda, CA 94502	CABOZANTINIB 42388 023-26 208692 1851 Harbor Bay Parkway Alameda, CA 94502
NDA	209210	050790	210251	208692	208692	208692
NDC	00310-6540.04 209210	00023-9163-30	61958-2501-01 210251	42388-024-26	42388-025-26	42388-023-26
U.S. GENERIC NAME	EXENATIDE	06/250 DE 4916-87000 BINDOSOTION	BICTEGRAVIR SODIUM; EMTRICTRAINE, TENOFOVIR ALAFENAMIDE FUMARATE	CABOZANTINIB 4238-024-26 208692	CABOZANTINIB	CABOZANTINIB
U.S. PROPRIETARY NAME	BYDUREON BCISE	RESTASIS	BIKTARVY	CABOMETYX	CABOMETYX	САВОМЕТУХ
CANADAIAN INGREDIENTS	2 mg exemptide (is white to off white microspheres suspended in a MCT which suspended in a MCT which is suspended to a MCT deliver 2 mg of exemptide extended—refease in 08 5m L which Microsphere formulation: Deemalde, poly (D. L Hardison Composition; poly (D. L Hardison Capitalide), sucrose Vehicle: Medium chain right/cerides. Vehicle: Medium chain right/cerides.	0.05% w/v is available as a sterile proteoratory for emulsion supplied in the proteoratory for emulsion supplied in containing 0.4 mL each. Each mL demission containing 0.4 mL each. Each mL demission containing 0.4 mL each. Each mL of emulsion containing 0.4 mL each make of emulsion or containing make of emulsion or containing make of emulsion or containing or emulsion or containing make or emulsion or containing water part of the proteoratory or containing water or emulsion or containing water proteoratory or containing w	So mg of bictegravir (equivalent to 52.5 mg of mag of bictegravir (equivalent to 52.5 mg of mag of bictegravir scalent). So mg of emotivation and 55 mg of temotovir allateramide (equivalent to 52.0 mg of temotovir allateramide herminar at 10.0 Microcystalline Cellulose, Crosammellose Sodium, Magnesium Steante Film-Coante Sodium, Magnesium Steante Film-Coante Baleck, Iron Oxide Baleck, Iron Oxide Red, Iron Oxide Red, Iron Oxide Red, Iron Polykiny Alcohol, Polykiny Alcohol, Tatanhun Dioxide	cabozantinib as cabozantinib as cabozantinib (5)-malate, colloidaí Silicon Dioxide, Corasemellose Soldum, Hydroxypropyl Cellulose, Hypromellose 2910, Iron Oxde Vellow, Lactose Anhydrous, Magnesium Searate, Microcrystaline Cellulose, Titanium Dioxide and Triacetin.	cabozantinib sa cabozantinib (S)-maites, colloida Silicon Dioxide, Croscarmellose Sodium, Hydroxypropy (Cellulose, Hypromellose 2910, Tron Oxide Yollow, Lactose Arhydrous, Magnesium Stearate, Microcrystalline Cellulose, Trianium Dioxide and Triacetin.	cabozantinib as cabozantinib as bloode, Silicon Dioxide, Crostamelloes Gollum, Hydroxypropyl Cellulose, Hypromelloes 2910, Iron Oxde Yollow, Lactose Anhydrous, Magnesium Stearate, Microcrystalline Cellulose, Titanium Dioxide and Triacetin.
NUMBER OF ACTIVE INGREDIENTS	1	1	m	1	1	1
DOSAGE FORM	SUSPENSI ON (EXTENDE D RELEASE)	EMULSION	TABLET	TABLET	TABLET	TABLET
STRENGTH	2 MG/0.85 ML	%50.0	50·200-25 MG	20 MG	40 MG	60 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 L4W 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	PSEN CABOZANTINIB 02480832 BIOPHARNACEUTICA LS CANADA INC	IPSEN 02480840 BIOPHARMACEUTICA LS CANADA INC
NIQ	02483203	02355655	02478579	02480824	02480832	02480840
CANADIAN GENERIC NAME	EXENATIDE	CYCLOSPORIN	EMTRICITABINE, TENOFOVIR ALAFENAMDE AND BICTEGRAVIR	CABOZANTINIB	CABOZANTINIB	CABOZANTINIB
CANADIAN CANADIAN PROPRIETARY NAME GENERIC NAME	BYDUREON BCISE	RESTASIS	BIKTARVY	САВОМЕТУХ	САВОМЕТҮХ	САВОМЕТУХ

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U.S. INGREDIENTS	Each film-coated tablet contains 200 mg of emritriciabine and 300 mg of trendrow!  disoproful furmares, (which is equivalent to 245 mg of tendrow! disopromil), as active ingredients. The tablets also include the following it each to imperients: crossameliose sodium, tachose monohidrate, magnesium settem micro-optimized calliolose, and pregestationed starch (glutter free). The tablets are contained from the 18 lab vi 3-0.10701, which contains fo RoE Gible et 2 aluminum lake, hypromeliose, lactose monohydrates, transium microsidoxide, and crosses.	Active ingredient; alpikaban, inactive ingredients; anlydrous inclose, microcrystalline ingredients; anythrous alcose, microcration in surface, occarminates sedium, scalaria barban angresium stearate. The film conflete, particles monophylotate, hypomethose trainium doode, trainedm, and yellow from ordes, (2.5 mg tablets) or red from ordes (5.5 mg tablets).
NDA APPLICANT HOLDER NAME AND ADDRESS	Gillend Sciences, Inc. 333 Lukaside Drive Fosser City, CA 54404	Bristol-Myers Squibb P.O. Box 4000 Princeton, NJ 08543-4000
NDA	21-752	202155
NDC	25.17 1.172	APIXABAN 0003-0894.21 202155
U.S. GENERIC NAME	EMTRCITABINE; TENDOTOUR DESPRANTE.	APIXABAN
U.S. PROPRIETARY NAME GENERIC NAME	TAUMON	SINDITIS
CANADAIAN INGREDIENTS	Each tables contains 200 mg of emiricalmen and 200 mg of emiricalmen and 200 mg of 26 for officing by leikholis sequimbent to 12 for officing by leikholis sequimbent to reportament believes to reportament and the section of consumments are the emicrophylates, magnissian stearise, monohylates, particular filed, he microphylates, particular filed, he microphylates, particular filed, he microphylates, particular filed, he microphylates, particular filed, he hydroprophylates, trainini decides, not fureetin. The tables are buc, and fureetin. The tables are buc, and microphylates, trainini decides, not not ender side. Each bottle and shaped, immorated, debosed microphylates and exercized (filed contains of balles and a descent filed ged canister or saving had contains of balles and a descent filed ged canister or saving had a childresistant docume.	Active Ingredient Apiadahan Dacipientss Tablet coare Aningrous lateroes, microsystalline cellulose, cross-aninellos sodium sodium laury sulfate and magnesium steanet film cost. Lectore monohydrate, hypomenicose, transine dioxide, trincatin, and yellow iron oxide (2.5 mg tablet) or red iron oxide (5 mg tableta) or red iron oxide (5 mg
NUMBER OF ACTIVE INGREDIENTS	~	н
DOSAGE FORM	TABLET	TABLET
STRENGTH FORM	200-300 MG	s MG
ADDRESS	600 6711 Mississurga Road Mississurga Onfario Canada LSN 2W3	2344 Boul, Alfred- Nobel, Suite 300 Montréal (St- Laurent) Quebec Canada H4S 0A4
COMPANY	GILEAD SCIENCES CANADA INC	BRISTOL-MYERS SQUIBB CANADA
NIG	02274906	02397714
CANADIAN GENERIC NAME	TENGFOVIR DISOPROXIL AND EMTRICITABINE	APIXABAN
CANADIAN CANADIAN PROPRIETARY NAME GENERIC NAME	TRUVADA	ELIQUIS

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