SECTION 804 DRUG IMPORTATION PROGRAM APPLICATION

New Mexico Department of Health

Contents

I. Program Justification

New Mexico faces many challenges in removing barriers to healthcare access and affordability, which are exacerbated by a disproportionately rural and frontier population and persistent poverty. The high and ever-increasing cost of prescription drugs is especially burdensome to New Mexicans. The high prevalence of chronic disease in the state is inextricably linked to chronic poverty; many New Mexicans are having to choose between paying for the prescriptions that would enable them to control and manage their health conditions and paying for housing or groceries. This choice has become even more difficult with high out-of-pocket costs for medications and the impact of drug costs on the overall cost of health care coverage.

U.S. consumers pay on average 40% more than other countries for the 27 most frequently used brand name drugs. In effect, consumers in the United States subsidize the cost of drugs for patients in the rest of the world. This is particularly problematic in New Mexico, which has the second lowest per capita income in the country. Even with insurance, many New Mexicans struggle to pay the cost sharing obligations associated with high-cost medications. Were these medications to become affordable, health care costs would be reduced by disease management and the state's citizens could lead healthier and more productive lives.

One of the ways to significantly and positively impact health outcomes for New Mexicans is to lower the cost of the critical medications they need to maintain health and manage disease. New Mexico Governor Michelle Lujan Grisham and the New Mexico Legislature have prioritized finding a way to reduce the price of prescription drugs in New Mexico, thereby increasing access to pharmaceutical therapies and improving the health and well-being of New Mexicans. In 2020, the Legislature passed with overwhelming bipartisan support Senate Bill 1, the Wholesale Prescription Drug Importation Act, to create a Wholesale Prescription Drug Importation Plan ("Drug Importation Plan") to serve all New Mexicans. With support from the federal government, such a plan could result in drug cost savings in the millions of dollars for New Mexicans.

New Mexico will submit its Drug Importation Plan to the federal government on or before December 15, 2020 for approval, paving the way for our state to import from Canada the same high-quality, affordable drugs that are distributed in the U.S. today at a lower price and in a manner consistent with federal law. Before doing so, and consistent with the requirements of Senate Bill 1, this draft of the Drug Importation Plan is being published for public input and comment.

II. Federal Law and Landscape

The Section 804 of the Food, Drug, and Cosmetics Act (FDCA), 21 U.S.C. Section 384 (Section 804) requires the U.S. Health and Human Services/ Federal Drug Administration to establish a program permitting importation of eligible prescription drugs from Canada by pharmacists and wholesale distributors under certain conditions, provided HHS certifies that the program will pose no additional risk to public health and safety and will result in significant reduction in costs to consumers. Section 804 outlines various requirements for importation to ensure drugs imported from Canada to the United States under Section 804 adhere to all FDA regulations and maintain the highest standard of safety and quality. Until recently, Section 804 had never been implemented. In July 2019, HHS released the Safe Importation Action Plan and laid out two pathways for direct importation of drugs from Canada. Pathway One allows for states to design drug importation programs for certain prescription drugs from Canada, while Pathway Two provides guidance to manufacturers seeking to import directly from Canada. In late 2019, with the release of a Notice of Proposed Rulemaking, the federal government proposed processes and standards for states to develop Section 804 Importation Programs (SIPs) and to implement Section 804.

III. New Mexico's Importation Bill/ Overview of Planning Effort

Governor Lujan Grisham prioritized several key legislative items during the 2020 session to address health care costs for New Mexicans. After receiving unanimous support from both chambers of the legislature, Senate Bill 1, The Wholesale Prescription Drug Importation Act, was signed into law by Governor Lujan Grisham on March 4, 2020, see https://www.nmlegis.gov/Sessions/20%20Regular/final/SB0001.pdf. The Wholesale Prescription Drug Importation Act directs the New Mexico Department of Health (Department of Health) to design and implement a drug importation program, pursuant to 21 U.S.C. Section 384 (Section 804 of the Federal Food, Drug, and Cosmetic Act), whereby the state would import prescription medications from Canada through a wholesaler for resale to New Mexican consumers.

The program design must ensure that only eligible prescription drugs meeting the FDA's requirements regarding safety and effectiveness are selected and that the program demonstrates substantial savings for New Mexico consumers. The Department of Health immediately formed an internal SB 1 planning team tasked with the design and eventual implementation of a drug importation program.

The Department of Health, in collaboration with the New Mexico Office of the Superintendent of Insurance (OSI), compiled and conducted a robust analysis of utilization and cost data from the largest insurance firms in the state to fully capture and inform the best formulation for cost savings for consumers in New Mexico. The SB1 planning team supplemented this initial analysis

with potential cost-savings for the unusually high number of uninsured living in NM with high-cost diseases, who pay out of pocket for pharmaceuticals.

Federal law excludes certain drugs from permissible importation. For that reason, New Mexico's proposed drug list is silent on those drugs categorically prohibited by the FDA for state importation. However, New Mexico's statute only explicitly prohibits the importation of controlled substances, providing flexibility for our program to grow alongside any future developments in federal law. Indeed, New Mexico strongly urges the federal government to permit importation of certain safe and effective biologics in the future to help bring down the cost of additional medications for Americans.

New Mexico Senate Bill 1 requires that the Department of Health fully comply with tracking and tracing requirements as outlined in 21 U.S.C. Sections 360eee and 360eee-1, to ensure the program's adherence to safety mechanisms already in place in the supply chain. The Department's senior pharmacy staff worked collaboratively with the New Mexico Board of Pharmacy to develop a co-sponsored program, that will ensure full compliance with every necessary feature of a safe and accountable system of delivery.

SB1 directed the Department of Health to convene an inter-agency advisory committee to review and advise the Department on the development and implementation of the program, including the Secretary of the Department of Health, the Secretary of the New Mexico Human Services Department, the Secretary of the New Mexico General Services Department (which oversees and runs the state's employee health plan), the Executive Director of the New Mexico Board of Pharmacy, and the New Mexico Superintendent of Insurance. That advisory group met on several occasions. In addition, the Department and OSI convened several stakeholder meetings on October 13, 14, and 16th to obtain input from health insurance carriers, pharmacy benefit managers, pharmacists, healthcare providers, consumer advocates, and members of the public with an interest in advising the development of the program. This Section 804 Importation Program (SIP) is being uploaded to the Department of Health Website on October 27th to provide an adequate period for public comment and a hearing on December 2nd before finalizing and submitting the SIP to the USDHHS on or before December 15, 2020.

IV. FDA Final Rule and Limitations for New Mexico

SB1 requires the Department of Health to submit its Section 804 Importation Program to HHS/FDA for approval by December 15, 2020. HHS/FDA issued their final rule on September 24, 2020. There are outstanding issues with several provisions, which we interpret as potentially limiting our ability to implement the New Mexico program effectively. The Department of Health submitted written comments in response to the Notice of Proposed Rulemaking, Importation of Prescription Drugs Docket No. FDA-2019-N-5711, 84 Fed. Reg. 70,796

(December 23, 2019) on March 9, 2020. It is useful to recite our comments here, while discussing more generally the final rules and their impact on the New Mexico program.

New Mexico voiced concern over several provisions of the draft rule, which were adequately or partially accounted for in the final rule, yet several challenging provisions remain. In our first comment, NM cited the definitions section of the proposed rule, 21 CFR § 251.2, requiring the primary sponsor of the SIP to be "a State, tribal, or territorial governmental entity that regulates wholesale drug distribution and/or the practice of pharmacy." The final rule amended this provision to allow states to determine which agency should oversee implementation of its SIP. In New Mexico, like most states, the entity responsible for regulating wholesale drug distribution and the practice of pharmacy is the state Board of Pharmacy. New Mexico's authorizing legislation designated NMDOH as the entity responsible for developing and implementing the state's wholesale prescription drug importation program, not the New Mexico Board of Pharmacy. See https://www.nmlegis.gov/Sessions/20%20Regular/final/SB0001.pdf. The final rule has allowed NM the opportunity to devise a co-administered program, whereby the Board of Pharmacy and the Department of Health have negotiated agreed upon and detailed roles of program oversight, ensuring the safety of the drug supply chain and sensical management of the program by the state.

In comment 2, New Mexico expressed concern over proposed 21 CFR § 251.3(b) and specifically asked that the FDA conditionally approve SIPs that are unable to a designate a foreign seller, importer, and repackager at the time of SIP submission. New Mexico, like other states, is not able to enter into a procurement until the federal government has approved the parameters and scope of the New Mexico program. While the FDA has agreed to conditionally approve SIPs that are unable to designate a foreign seller, importer, and repackager at the time of SIP submission in its final rule, the FDA is requiring states to identify a Foreign Seller within six months of submitting a SIP. That may still require states to identify and establish the terms of an agreement with a foreign seller before the SIP is approved. A foreign seller would be unable to enter into an agreement with the state program before the SIP framework receives approval from the FDA. Accordingly, any contractual terms between the SIP and the foreign seller would likely be subject to change, which would interfere with preliminary negotiations and stifle certain entities from participating altogether. Without conditional approval of a SIP, and later, full approval when information regarding a foreign seller, importer, and repackager can reasonably be submitted, NM (and other states) will be poorly positioned to successfully negotiate and establish a foreign seller.

In comment 3, New Mexico asked the FDA to consider permitting the designation of more than one foreign seller and one importer in initial SIP submissions. The FDA did not incorporate this recommendation into its final rule. New Mexico joined other states in expressing serious concern over this provision as it stifles competitiveness in the supply chain, potentially limits cost savings, and creates undue risk and exposure to foreign sellers, which could be isolated

and cut off entirely by manufacturers. Also concerning is the likelihood that drug manufacturers would respond by applying higher mark-ups to the limited number of foreign sellers and importers participating in state SIPs, restricting state SIPs from achieving significant cost savings for consumers.

New Mexico was also concerned with what it viewed as an overly restrictive and punitive provision related to the conditions for suspension and revocation (Proposed 21 CFR 251.7 Section 251.18(a)). The final rule refuses to allow a SIP to create a corrective plan for any violations in lieu of de-authorizing a SIP completely for any infringement. New Mexico had recommended a more graduated approach for addressing any form of SIP non-compliance. Requiring a SIP to follow a corrective action plan would allow an operational program to continue while immediately addressing the specific issues of non-compliance. Additionally, allowing a SIP sponsor to limit the suspension to a specific program or component or implicated portion of the supply chain may also be reasonable.

Finally, New Mexico expressed deep concern over the severability provision in the final rule as overly broad. This provision risks invalidating the entire rule if any provision of the rule was determined to be invalid. New Mexico had recommended that the rule be amended to direct application of the severability clause to situations in which continued operation of the remaining rule, following a stay or invalidation, could threaten the health and safety of the public, but the final rule left this provision intact.

V. Estimating Health Plan Savings

To determine the set of drugs to import, the Department of Health and its Advisory Committee members have been working with all licensed health insurance carriers in the state, ERISA plan administrators, and the New Mexico public employee plans to produce a list of the most expensive prescription drugs common to most or all plans. The list of proposed import products submitted to the USDHHS will only include drugs as allowed by law and the recently issued federal regulations on drug importation.

The process by which the Department of Health will develop the final proposed list for USDHHS review is described below and will be conducted without the need for the State to obtain proprietary data.

In the first round of analysis, NMDOH requested a list of the 40 top-spend drugs from each of the licensed payers in the state. Plans' calculations of their top spend drugs that were submitted were to be net of all price concessions. NMDOH, with assistance from the University of New Mexico College of Pharmacy, then identified the drugs common to all or most payers.

NMDOH has examined available data on the Canadian price of each of the drugs that are common to New Mexico payers and administrators. The Department of Health has added a 45

percent mark-up to each of the Canadian product prices. NMDOH will pass back to all payers the estimated expected unit cost of the drugs on the common list, including the mark-up for administrative costs.

New Mexico expects administrative costs to be somewhat less than 45 percent of the Canadian price but is using a conservative number for planning purposes. The 45 percent markup estimate was developed by the National Academy for State Health Policy (NASHP) and has been used by other states in estimating savings from Section 804 importation programs.

In the second round of payer analysis, subject to federal approval of our proposed importation plan, each payer will compare the estimated per unit import cost with its own net unit cost of each drug on the list prepared by NMDOH. Each payer will be required to inform the Department of Health which drugs still represent a cost savings for that payer based on unit cost and utilization. With this input, NMDOH will develop a common list of drugs for which payers anticipate savings after accounting for supply chain costs.

The near-final list of potential imports will then be discussed in a third round of analysis with all participating plans, the New Mexico Board of Pharmacy, New Mexico hospitals, medical organizations, New Mexico pharmacists, consumer representatives, patient advocacy organizations, and other interested stakeholders. One issue to be addressed in this third round is whether all the drugs on the list are suitable to dispensers. If all payers are not participating, pharmacies, hospitals, and dispensing physicians will have to stock two versions of any imported product – the import and the US version of the product. The logistical issues of dual stocking may affect the choice of drugs to be imported.

Two other issues to be addressed in the third round include an assessment of whether any prescription drug on the list will lose U.S. patent rights in the next several years and if the state should still pursue importation of those drugs. The second issue will be an exploration of continuity of supply for the drugs on the list. If supply cannot be generally ensured or otherwise addressed, the drug may need to be removed from the list of proposed imports.

Based on the operational issues discussed in the third round, a final list of drugs to be imported under the New Mexico wholesale program will be provided to USDHHS for approval. The list will include the Canadian drug identification number (DIN), the U.S. National Drug Code (NDC), the New Drug Application (NDA) or Abbreviated New Drug Application (ANDA) number, and confirmation that the U.S. version is currently marketed in the U.S., as well other information as specified by USDHHS.

The estimated, aggregate amount of savings on drug spend in dollars and as a percentage of health plan drug spend will be provided to USDHHS at that time, but early estimates project a savings of $40 million if plans replaced all prescriptions with those from the drug importation program. Even with a 15% substitution, savings for the uninsured would amount to $6 million. This estimate seems reasonable given planned program outreach, marketing, and education.

VI. Estimated Savings to Consumers

The New Mexico drug importation program is being developed to significantly reduce the cost of prescription drugs for New Mexico citizens while maintaining the safety and access that they have come to expect. There are multiple benefits to consumers being able to purchase lower cost pharmaceuticals. It is well known that one of the major reasons that patients do not adhere to their prescription regime is due to the out of pocket costs associated with them. As a result, significantly lowering costs will very likely result in positive health outcomes for consumers. In addition to the direct health benefits, there are secondary gains as well. Health insurance premiums should be reduced if drug costs are lowered (or alternately, other benefits can be covered at the same premium levels). Since most Americans get their health insurance through their place of employment, health insurance costs for businesses should be positively impacted as well.

When one compares the costs of pharmaceuticals in the United States to those of all other developed countries, the answer to the question as to whether lowering the cost of pharmaceuticals is a realistic goal is unequivocally "Yes". Consumers in the US spend far more for the identical pharmaceuticals. Figure One is from the report "A Painful Pill to Swallow: U.S. vs. International Prescription Drug Prices", prepared by House Ways and Means Committee Staff in September 2019. For an equivalent sample of proprietary drugs, the United States pays $446.15, while for the identical drugs in other industrialized countries the average is $125.15, significantly less than the prices in the US.

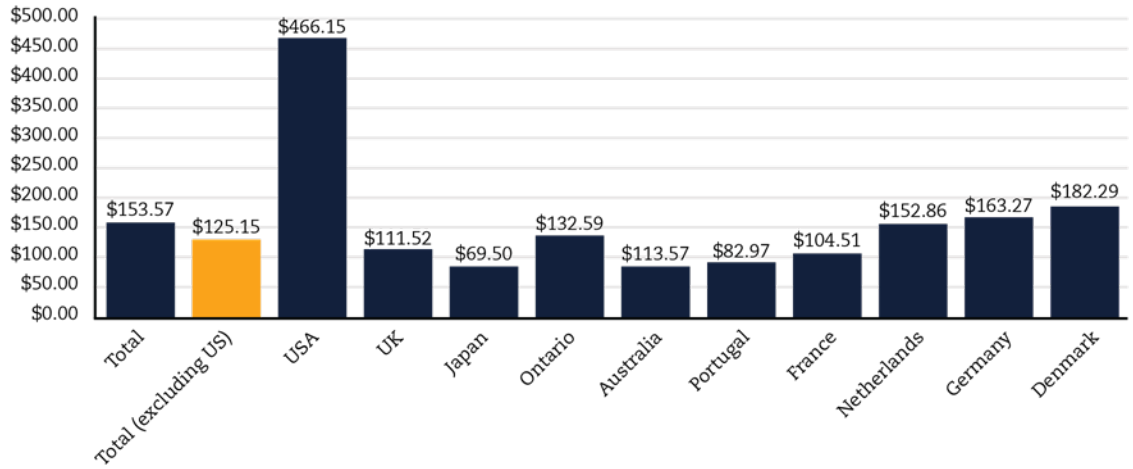

Figure One. Per Capita Pharmaceutical Costs for Developed Nations

The National Academy for State Health Policy (NASHP) has researched and coordinated an effort to assist states interested in applying for importation approval. Their description of the savings potential of such a program is shown in Figure Two. In many cases the Canadian price for a given drug is about 25 to 30% of the list price in the US. NASHP estimates that "transaction costs" i.e., supply chain processing services, dispensing fees, and program management support will be equal to about 45% of the Canadian retail price. Thus, the savings on each compound on the average will generally be > 50% of the current US price and sometimes more

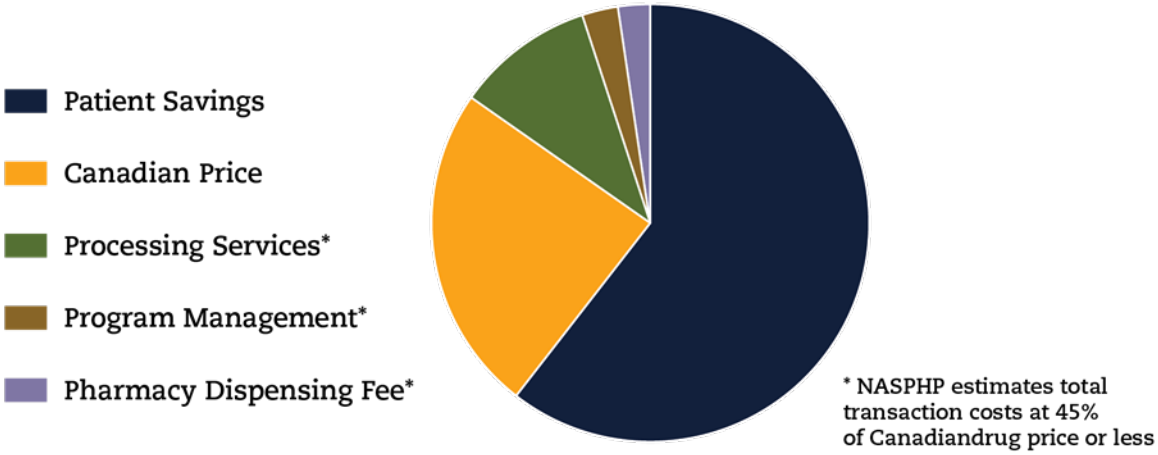

Figure Two. Cost savings potential

New Mexico is a complex state. It has a culturally rich and diverse population including a significant Native American presence. It has the 5th largest geographic area but is 37th in population. As a result, many residents live in rural and frontier settings. Poverty and inequality are significant issues. These factors significantly influence health issues, especially access to needed pharmaceuticals, and they should increase the overall importance of the drug importation program and the need to lower costs to NM consumers.

In principle, to calculate savings from importation, one would a.) Identify usage pattern in terms of volumes prescribed for all pharmaceuticals dispensed in NM; b.) Multiply those volume numbers by the costs associated with each drug to get a total current cost in NM; c.) Identify the Canadian cost for each of the drugs being dispensed including the processing costs associated with them; and d.) Subtract the fully-processed Canadian cost from the current cost in NM today. Unfortunately, there is no state-wide data base for pharmacy utilization in New Mexico. As a result, some defendable approximations must be used to develop steps a.) and b.). There is no single state-wide data base for pharmacy utilization in New Mexico. Instead, the SB1 Importation Team requested utilization and cost data from 12 of the larger commercial

insurance firms in the state. The individual plan data was consolidated into one spreadsheet. However, the reported fields varied from plan to plan. Only medication name and total expenditure was consistently reported across all plans. Medication strength, number of units processed, and number of patients were unavailable in most cases. Additionally, medication unit cost was not always provided. For medications missing unit cost, we utilized AWP in our calculations. Due to a lack of information regarding the number of units processed, we calculated it by diving the total expenditure by the medication's unit cost. Next, two sets of formulary data from Canada were searched to find the best available Canadian cost of the drugs. Following NASHP recommendations, 45% of the Canadian list price was added to obtain the full cost of the Canadian drug in New Mexico. The potential annual savings were calculated as follows: "Calculated Units Processed" x "US net unit WAC cost"- "Calculated Units Processed" x "Canadian Unit Cost (+ 45% Markup)". Medications were excluded if they did not meet the federal definition of an eligible drug, the Canadian unit cost was unable to be located, the medication resulted in a calculated loss, the medication resulted in less than 5% savings, the medication unit cost was less than 25 cents, or the medication was only available in a blister pack. Decisions regard which strengths would be included in the program were made utilizing data provided by the plans when it was available and clinical judgement based on the most frequently prescribed strengths of the medications.

The schematic of the process is shown in Figure Four and the results of the calculation are shown in Table One.

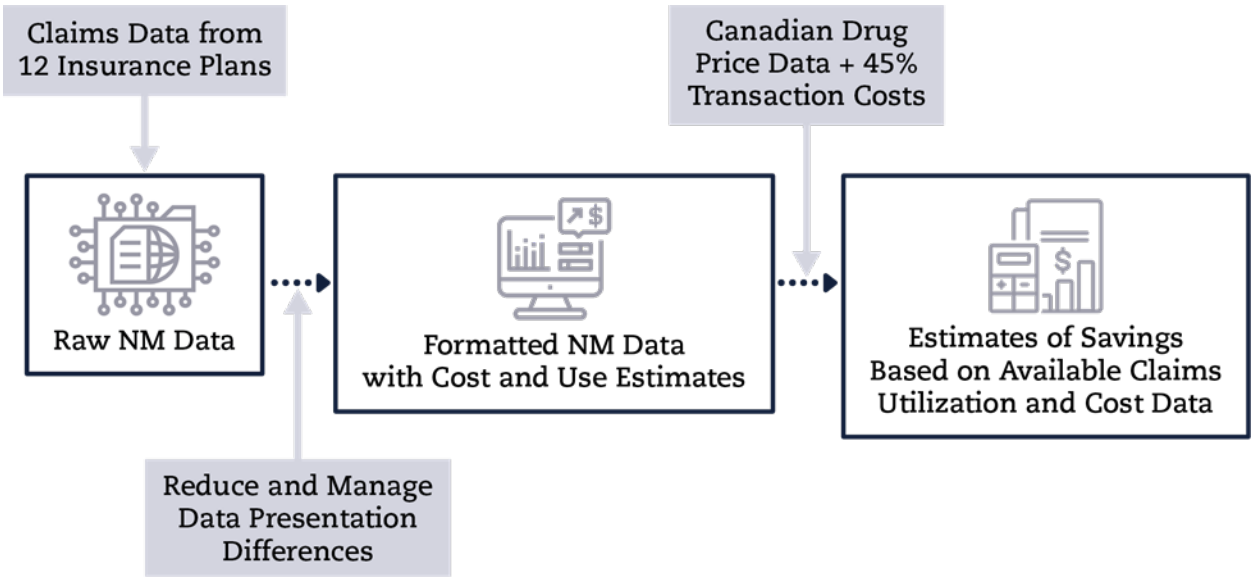

Figure Three. Flow Diagram of Importation Cost-Savings Analysis

From Table One, found in Appendix C we can see that the insurance plans in New Mexico are spending greater than $64 Million dollars/year above what these same drugs cost on the international market. The domestic pharmaceutical market is complicated with insurance formularies, PBMs, rebate structures, etc. but even if 15% of the potential were realized, the $9.8 million (or $6.0 M if HIV drugs are excluded) is a realistic number. The NM drug importation program is committed to developing a transparent and open process by which these potential savings are passed on to those covered in these plans.

Colorado, one of the four other states that has already submitted applications to HHS for drug importation, has an all payer data base that allowed a more detailed estimation of possible consumer savings. Careful analysis of the all payor data yielded > 500 cost drugs with cost savings potential. After eliminating those prohibited by the FDA regulations, 168 compounds remain. CO estimates a 15% replacement cost and savings of $13.2 Million. Given the uncertainties in these calculations and adjusting for population (5.8 million in CO and 2.1 million in NM), size of the economy ($353B vs. $94B), penetration of commercial insurance (60% vs. 28%), and Medicaid (20% vs. 42%), a $4.0 Million savings in NM is reasonable. Vermont used less detailed analysis for its 630,000 citizens and at first estimated about one million in savings, but recently recalculated the potential to be closer to $1.5 M. Again, probably within the margin of error for such calculations.

The benefits of drug importation become even more significant, however, if we consider the uninsured living in New Mexico. In 2019, the Urban Institute estimated that there were 187,000 uninsured individuals under 65 in New Mexico with Native Americans accounting for 16.2% of that group. “The Uninsured in New Mexico”, Banthin, JS, et al, The Urban Institute, December 2019 (I.e., > 30,000 native are unemployed in NM.) These numbers are very conservative considering recent job losses in the ongoing pandemic. The uninsured have no insurance firm or PBM to negotiate on their behalf. This population typically pays full retail prices for their medications and every dollar saved has a direct and positive consequence for them.

A recent JAMA paper listed the costs of the major health conditions in the US and broke down the costs of these conditions into their components inpatient care, ambulatory care, pharmaceuticals, etc. As a result, a cost per capita for each condition can be calculated for each of the components. Table 2 shows the pharmaceutical costs for thirteen of the top fifty conditions. The 13 were chosen because they have the highest pharmaceutical costs of all the conditions. To obtain the per capita costs of pharmaceuticals for each condition, one need only divide the total cost of drugs for the condition by the total population of the country. New Mexico is 35th of 50 in a ranking of healthiest states. Thus, it is not illogical to assume, the consumption of pharmaceuticals is somewhere near the average.

The last column of Table Two shows that the out of pocket costs for the uninsured to purchase appropriate drugs for these major conditions. It does not say that the uninsured are spending that amount today, but it does say that to receive the same level of care the average American is receiving, the uninsured would spend that amount. For these 13 conditions, the potential out of pocket costs would be $106.4 Million dollars.

Rank	**Condition**	**Total Cost of Condition, US$ Billions[1]**	**Pharmaceutical Costs for Condition, US$ Billion[1]**	**Rough estimate NM Uninsured Cost, US$ Millions[2]**
3	Diabetes	111.2	51.5	30.9
7	Skin Disorders	85.0	11.6	7.0
10	Hypertension	79.0	9.5	5.7
13	Depressive Disorders	67.5	14.3	8.6
24	Asthma	41.9	20.2	12.1
26	Rheumatoid Arthritis	33.8	28.3	17.0
33	Atrial Fibrillation	28.4	3.0	1.8
35	Hyperlipidemia	26.4	12.0	7.2
42	ADHD	17.0	8.4	5.0
46	Migraine	14.3	4.7	2.8
47	Multiple Sclerosis	13.9	10.6	6.4
48	Bipolar Disorders	13.7	3.2	1.9
	TOTAL			**106.4**

Table Two. Rough Estimate of Out of Pocket Costs for Uninsured in New Mexico

[1] From Dieleman, J.L., et al, "US Healthcare Spending by Payer and Health Condition, 1996-2016". JAMA 323(9), 2020, p 863-884

[2] (US total pharmaceutical costs/population of US) X population of NM X % uninsured in NM

To validate the order of magnitude of these costs savings for indigents, diabetes is taken as an example. As a measure of its commitment to lower costs of diabetic care, the state of New Mexico passed HB292 last year, which caps the total co-pay for insulin. Table Three compares the cost of the seven diabetic drugs listed in Table One when purchased at a US Walmart and the probable cost of the same drug purchased through the importation program. The drugs costing $2,664,474 at Walmart could be obtained for $513,280 through the importation program – a savings of over 80%. This savings rate is even higher than predicted by the Ways and Means Committee data shown in Table One. That difference might come from an internal Canadian subsidy to reduce the costs even further below the world market price, reducing significantly the cost of disease management. There is an approximation of the number of units of each drug used for the uninsured compared to the units in Table One, which covers the commercial and Medicaid populations. There is considerable uncertainly in this approximation, but that uncertainty does not influence the key finding of the Table, which is that the program's drugs would be available at considerable savings through the importation program.

Drug	**Uninsured Units****	**Price at Walmart, US$**	**US Cost to Uninsured, US$**	**Canadian Cost + 45%, US$**	**Canadian Cost to Uninsured**
Jardiance	19,328	18.47	356,988	2.86	55,278
Invokana	1260	18.30	23,058	2.86	3,603
Farxiga	14,610	16.97	246,470	2.86	41,784
Janumet	2,438	16.90	41,202	1.49	3,632
Januvia	25,374	16.73	424,507	3.49	88,555
Victoza	3,802	339.33	1,518,253	78.70	299,217
Bydureon	299	181.25	54,194	70.94	21,211
TOTAL			**2,664,472**		**513,280**

Table Three. Savings to the Uninsured from Purchasing Diabetic Drugs at Importation Prices.

VII. Controlling Mark Up Along the Supply Chain:

A critical aspect of assuring savings is preventing shadow pricing or profiteering from imported product. Maine, among the collection of states seeking federal approval for its Section 804 Importation Program, anticipates soliciting bids from companies interested in contracting as the program's U.S. wholesale importer and Canadian exporter supplier(s). Successful bids will demonstrate low administrative cost. It is Maine's expectation that contractors will generate margin from administrative fees as opposed to mark-up of product prices, which will serve to increase transparency in the drug supply chain. Maine will encourage participating health plans to reimburse pharmacies at actual acquisition costs (which will be publicly known and not an estimate as it is today) plus a dispensing fee. Like Maine, New Mexico will work with pharmacies and participating health plans to establish appropriate professional dispensing fees that, to the highest extent possible, account for the margin on the U.S. version of the import for pharmacies.

New Mexico will make the list of imported products and the import price publicly available so that people without adequate coverage can be informed of what they should expect to pay if they are uninsured or in a deductible period. New Mexico also will work with plans to ensure enrollees are informed of the out-of-pocket cost of the imported drugs at the point of dispensing.

Participating health plan provider network agreements will be required to include provisions about compliance with rules of the importation program, including preferred use of imports and billing. Health plans will need to know which network pharmacies will participate in the importation program. Health plans and the state will let enrollees and residents know which pharmacies (if any) will not dispense imported product so those establishments can be avoided by patients filling prescriptions for any of the imported products.

VIII. Compliance Plan

The New Mexico SIP is sponsored by the State of New Mexico, through the New Mexico Department of Health (NMDOH) and the New Mexico Board of Pharmacy (NMBOP). Upon SIP approval, a Drug Importation Program Division (NMDIP) shall be created and staffed by NMDOH. NMDIP shall be dedicated solely to implementation of the approved SIP, maintenance of the drug importation program, and to ensuring compliance with the requirements of Section 804 of the FD&C Act [21 U.S.C. 384], the final rule on Importation of Prescription drugs (as codified at 21 CFR 1.74 and Part 251), the Drug Supply Chain and Security Act (DSCSA), other applicable provisions of the FD&C Act and its implementing regulations, and to any applicable state regulations.

The responsible individuals as defined by 21 CFR 251.2 are the Secretary of the New Mexico Department of Health and upon hire, the program manager for NMDIP. NMDIP will work closely with NMBOP, which oversees the licensing of all manufacturers, pharmacies, wholesale distributors, and limited drug clinics. The responsibilities of the state parties involved in the implementation and management of the NMDIP are outlined below:

New Mexico Board of Pharmacy

- Provide NMDIP consultation during drug importation program implementation.
- Provide NMDIP consultation regarding any SIP proposal modifications or renewals prior to FDA submission.
- License all drug supply chain participants of the drug importation program as required and appropriate.
- Require compliance with the DSCSA and applicable state and federal regulations.
- Conduct inspections of all NMBOP licensed resident drug supply chain participants of the drug importation program.
    - For non-resident licensees, NMBOP license applicant must submit documentation of a current satisfactory inspection conducted by the FDA, or state licensing authority, or by a third-party inspection service approved by the FDA or the state authority licensing such entity, or the board.
- Notify the NMDIP of action against a NMBOP license involving non-compliance with NMDIP requirements.
- Ensure, to the extent possible, that NMBOP license information continues to be available in real-time through its website.
- Communicate notification of FDA actions involving non-compliance with NMDIP requirements against a program participant to NMDIP.
- Provide the FDA with requested records relating to the NMDIP which are held by NMBOP, as appropriate.

New Mexico Drug Importation Program

NMDIP shall assume the primary role in program implementation, maintenance, and compliance. Its responsibilities shall include, but are not limited to:

- Register all participants of the drug importation program on annual basis
    - NMDIP shall ensure drug supply chain participants have obtained proper licensure through NMBOP prior to program registration.
- Create written compliance policies, procedures, and protocols in accordance with the policies, procedures, and protocols outlined in the FDA-approved SIP.
- Create auditing procedures and processes with the intent of uncovering and addressing noncompliance, misconduct, and conflicts of interest.

- Complete annual audits of all program registrants and conduct any additional (e.g. for-cause) audits as appropriate.
- Provide drug importation participant education and training
- Create a multimodal education, outreach and marketing plan
- Maintain NMDIP webpage with up-to-date information
- Staff the NMDIP help line to respond to questions regarding the drug importation program
- Staff the NMDIP anonymous tip line for whistleblowers
- Communicate notification of a drug recall to NMBOP
- Implement the recall plan for medications imported through the state program
- Effectuate drug recalls, with cooperation from the applicable SIP participants, when required or otherwise appropriate.
- Communicate any FDA actions against a program participant to NMBOP
- Maintain the NMDIP list of medications eligible for importation under the FDA-approved SIP.
- Assume the primary responsibility for any SIP proposal modifications or renewals
    - Shall seek NMBOP consultation prior to any FDA submission.
- Monitor cost-savings of the program.
- Submit required quarterly reports to the FDA in accordance with section 804 regulations
- Submit required annual report to the state legislature.
- Respond to any FDA records request.

REGISTRATION OF DRUG IMPORTATION PROGRAM PARTICIPANTS

The New Mexico Drug Importation Program will register all program participants from health insurance plans, healthcare providers to the importer and foreign seller. NMDIP shall ensure drug supply chain participants have obtained proper licensure through NMBOP prior to program registration. Registration of program participants will be critical to ensuring that importation can be conducted in a safe manner. Registration will also enable timely communication to all stakeholders during a drug recall. It will provide the program with a comprehensive list of participants so that it may conduct the required annual auditing. It will also aid in obtaining cost savings data for required annual State and Federal reporting.

Drug supply chain security is a critical component of a successful importation program. In order to ensure adequate security and controls for the drug supply chain, only facilities licensed with NMBOP will be eligible to participate in the NMDIP.

LICENSING OF ELIGIBLE PARTICIPANTS

NMDIP will create a registry for drug importation participants involved in the supply chain. The intent of this registry is to ensure that supply chain participants meet the unique set of requirements for drug importation set by state and federal laws and regulations. The registry, with NMBOP facility licensure requirement and state regulations that require compliance with the DSCSA and oversight of the importation program will ensure that program participants are meeting all state and federal requirements. It will also help to ensure that the storage, handling, and distribution practices of supply chain participants, including transportation providers, meet certain requirements (including those requirements in 21 CFR Part 205) and do not affect the quality or impinge on the security of the eligible prescription drugs.

The New Mexico Board of Pharmacy will oversee the licensing of program participants. Apart from the foreign seller, all facilities applying for NMDIP registration as a drug importation program participant must also be licensed with the NMBOP for their facility type. All applicants must be in good standing with the NMBOP to qualify for participation in the drug importation program. The NMBOP may expand requirements for drug importation program licensure at any time. Licenses will be subject to review and bi-annual renewal.

DRUG IMPORTATION PROGRAM PARTICIPANTS **MINIMUM REQUIREMENTS FOR LICENSURE**	
Foreign Seller	• Maintain licensure by Health Canada to wholesale drugs • Maintain registration with a provincial regulatory authority to distribute HPFB-approved drugs • Maintain registration with the FDA as a foreign seller • Shall complete all required foreign seller attestations outlined in section 804. • Shall provide inspectional history for the previous 5 years from Health Canada or the duration of its licensure. • Shall provide a list of all disciplinary actions imposed against the Foreign Seller or the Importer by State, Federal, or Canadian regulatory bodies, including any such actions against the principals, owners, directors, officers, or any facility manager or designated

	representative of such manager for the previous 7 years before submission of the SIP Proposal. • Shall agree to submit to inspections by the FDA. • Shall agree to submit to audits of their books, and records by NMDIP, NMBOP and the FDA • Shall agree with to comply with all other applicable provisions of the FD&C Act and its implementing regulations and the requirements of the NMDIP (for example, applicable DSCSA requirements, having systems in place to determine whether a drug to imported to the U.S. Importer is a suspect product or illegitimate product, and applying the SSI and responding promptly to SSI inquiries). • Shall agree to cooperate with any recalls. • Shall develop a plan for handling any complaints or reported adverse events in accordance with the NMDIP and federal laws and regulations, including facilitating any necessary investigations as to cause, distribution, scope and inventory of the affected drug
Importer	• Maintain licensure as a wholesale distributor or pharmacy with the NMBOP • Maintain registration with the FDA • Shall complete all required importer attestations outlined in section 804. • Shall provide inspectional history for the previous 5 years from their local licensing body or the duration of its licensure if less than 5 years. • Shall provide a list of all disciplinary actions imposed against the Importer by State, Federal, or Canadian regulatory bodies, including any such actions against the principals, owners, directors, officers, or any facility manager or designated representative of such manager for the previous 7 years. • Must be in good standing with NMBOP • Shall agree to submit to inspections by the NMBOP and the FDA.

	• For non-resident licensees, NMBOP license applicant must submit documentation of a current satisfactory inspection conducted by the FDA, or state licensing authority, or by a third-party inspection service approved by the FDA or the state authority licensing such entity, or the NMBOP. • Shall agree to submit to audits of their books, and records by NMDIP, NMBOP and the FDA • Shall agree to cooperate with any recalls. • Shall agree with to comply with all other applicable provisions of the FD&C Act and its implementing regulations and the requirements of the NMDIP for example, developing an acceptable program for and implementing screening of the eligible prescription drugs it imports for evidence that they are adulterated, counterfeit, damaged, tampered with, expired, suspect foreign product, or illegitimate foreign product; submitting adverse event, field alert, and other reports required by the SIP, the Federal Food, Drug, and Cosmetic Act, and the final rule; and facilitating the application of the product identifier. • Shall develop a plan for handling any complaints or reported adverse events in accordance with the NMDIP and federal laws and regulations, including submitting such reports to FDA and the drug manufacturer and facilitating any necessary investigations as to cause, distribution, scope and inventory of the affected drug
Re-labeler of Imported Product	• Maintain licensure as a re-packager with the NMBOP • Maintain applicable registrations with the FDA • Must be in good standing with NMBOP • Shall agree to submit to inspections by the NMBOP and the FDA. • For non-resident licensees, NMBOP license applicant must submit documentation of a current satisfactory inspection conducted by the FDA, or state licensing authority, or by a third-party inspection service approved by the FDA or the state authority licensing such entity, or the NMBOP. • Shall agree to submit to audits of their books, and records by NMDIP, NMBOP and the FDA

	• Shall develop a plan for handling any complaints or reported adverse events in accordance with the NMDIP and federal laws and regulations, including facilitating any necessary investigations as to cause, distribution, scope and inventory of the affected drug
Third-Party Logistics Provider	• Maintain licensure as a third-party logistics provider with the NMBOP • Maintain applicable registrations with the FDA, as required • Must be in good standing with NMBOP • Shall agree to submit to inspections by the NMBOP and the FDA. • For non-resident licensees, NMBOP license applicant must submit documentation of a current satisfactory inspection conducted by the FDA, or state licensing authority, or by a third-party inspection service approved by the FDA or the state authority licensing such entity, or the NMBOP. • Shall agree to submit to audits of their books, and records by NMDIP, NMBOP and the FDA
Drug Warehouse, Pharmacy, and Limited Drug Clinic	• Maintain licensure with the NMBOP • Must be located within New Mexico • Must be in good standing with NMBOP • Shall agree to submit to inspections by the NMBOP and the FDA. • Shall agree to submit to audits of their books, and records by NMDIP as it pertains to the drug importation program, and the FDA • Shall agree to cooperate with any recalls Shall develop a plan for handling any complaints or reported adverse events in accordance with the NMDIP and federal laws and regulations, including facilitating any necessary investigations as to cause, distribution, scope and inventory of the affected drug
Additional requirements may be imposed by the NMBOP	

AUDITING OF DRUG IMPORTATION PROGRAM PARTICIPANTS

The New Mexico Drug Importation Program will conduct audits of all registered program participants to ensure health and safety of New Mexicans, program integrity and compliance with all Federal and State laws and regulations. Audits will occur annually and as needed to address these concerns. Audits will also help NM uncover and address any non-compliance, misconduct, or conflicts of interest. Additionally, audits will ensure that imported products are not being distributed or dispensed outside of the State. NMDIP may take action, based on audit findings, to suspend or revoke the NMDIP registration of a participant, and when appropriate suspend importation and notify FDA.

Audits of the program participants will be conducted to ensure:

- the storage, handling, and distribution practices of supply chain participants, including transportation providers, meet certain requirements and do not affect the quality or impinge on the security of the eligible prescription drugs
- the supply chain is secure
- the Importer screens the eligible prescription drugs it imports for evidence that they are adulterated, counterfeit, damaged, tampered with, expired, suspect foreign product, or illegitimate foreign product
- the Importer fulfills its responsibilities to submit adverse event, field alert, and other reports
- That post-importation pharmacovigilance requirements are being maintained
- Imported medications are not being distributed outside of New Mexico
- The program is resulting in cost-savings for New Mexicans

When auditing pharmacy benefit managers and insurance plans, NMDIP shall work with the Office of the Superintendent of Insurance as appropriate.

INSPECTION OF LICENSED DRUG IMPORTATION PROGRAM PARTICIPANTS

The New Mexico Board of Pharmacy will conduct on-site inspections of licensed resident drug importation program participants to ensure health and safety of New Mexicans, program integrity and compliance with all Federal and State regulations. Inspections will occur routinely and as needed to address concerns regarding health and safety or program integrity. For non-resident facilities, NMBOP will review the inspection reports from the FDA, local licensing body to include, for the Foreign Seller, the applicable Canadian governmental agency, or a NMBOP recognized third party.

EDUCATION OUTREACH AND MARKETING PROGRAM

Upon SIP approval, NMDIP will conduct a three-pronged education outreach program. NMDIP will host a multi-modal outreach and marketing campaign utilizing newspaper, radio, social media, and tv to reach a diverse group of New Mexicans. It will create and staff a helpline to answer questions and address the needs of consumers, employers, health insurance plans, pharmacies, health care providers, and other affected sectors. Finally, it will create a webpage dedicated to educating stakeholders regarding the drug importation program. The webpage will include the following aspects:

- A list of all drugs imported from Canada along with their corresponding national drug codes (NDCs) and prices.
- A list of participating facilities.
- Information specifically tailored for health care professionals, including:
    - An overview of the drug importation program
    - An overview of measures taken to ensure health and safety
    - Information regarding the recall process
    - Information regarding adverse drug event reporting
    - Information regarding how to become a licensed participant of the program
    - Information and links for state and federal regulations pertaining to the program
    - Information on how to anonymously report concerns including the phone number for an anonymous tip line.
- Information specifically tailored for consumers, including:
    - An overview of the drug importation program
    - An overview of measures taken to ensure health and safety
    - Information regarding the recall process
    - Information regarding adverse drug event reporting
    - Information and links for state and federal regulations pertaining to the program
    - Information on how to anonymously report concerns including the phone number for an anonymous tip line.

IMPORTATION PROGRAM COMPLIANCE TRAINING

NMDIP shall offer quarterly training for all program participants. Applicants for participant registration must send a minimum of one representative to the training session annually. If the organization chooses not to send all employees to the NMDIP training, they must provide a plan on how they will educate their employees regarding the NMDIP requirements.

Foreign sellers, importers, qualifying laboratories, and their employees shall also receive education and training. Training for these groups will be tailored to their specific role so that they may understand their compliance-related obligations.

LIMITING SALES OF IMPORTS TO INDIVIDUALS AND ENTITIES WITHIN NEW MEXICO

New Mexico shall limit all distribution, dispensing, and sale of medications imported through its Drug Importation Program to individuals and entities within New Mexico. Limiting sales of imported medications will aid in ensuring the drug supply chain security, recall notification and implementation, auditing, and safety of the imported medications. It will also aid in preventing imported medications from exportation outside of the United States.

All distribution and dispensing of medications imported through the New Mexico Drug Importation Program shall be limited to:

- NMBOP-licensed and NMDIP-registered in-state facilities
- a patient or patient's representative pursuant to a valid prescription
- home delivery within the state of New Mexico pursuant to a valid prescription

All dispensers shall make a good faith effort to ensure that the medication is for a resident of New Mexico and is not being diverted for use outside of the state.

IMPORTATION PROCEDURES FOR ELIGIBLE PRESCRIPTION DRUGS

The contracted importer shall submit a Pre-import Request to the FDA at least 30 days prior to the scheduled date of arrival or entry for consumption. The pre-import request must contain all data elements specified in section 804 and in the final rule implementing section 804. The importer, or authorized customs broker, would be required to electronically file a formal entry for consumption for each prescription drug imported or offered for import into the United States. Entry and arrival of a shipment containing an eligible prescription drug shall occur only through the U.S. Customs and Border Protection (CBP) port of entry authorized by FDA. The eligible prescription drugs may be stored at a licensed facility within the foreign trade zone specified in the pre-importation request. The importer must screen eligible prescription drugs for evidence that they are adulterated, counterfeit, damaged, tampered with, expired, suspect foreign product, or illegitimate foreign product. Medications shall not be released for distribution until Statutory testing has been conducted, all FDA approvals are obtained, and the product has been re-labeled in accordance with FD&C Act requirements.

Drugs refused admission into the United States by the FDA must be exported or destroyed by the importer within 90 calendar days of the refusal.

STATUTORY TESTING OF IMPORTED PRODUCT

All products imported through New Mexico's Drug Importation Program shall undergo the statutory testing required under section 804 of the FD&C Act and FDA regulations prior to distribution. The statutory testing will ensure that imported products meet the FDA-approved drug's specifications. Statutory testing shall be conducted by a qualifying laboratory approved by the FDA. All products shall be held within the Customs and Border Protection (CBP) port of entry or foreign trade zone approved by the FDA until FDA review and approval of the testing results. In addition, the FDA shall be provided with three sets of samples of each imported drug shipment to enable the FDA to also conduct the Statutory Testing as the FDA deems warranted.

LABELING OF IMPORTED PRODUCT

All products imported through New Mexico's Drug Importation Program shall be re-labeled to meet FD&C Act, DSCSA and FDA regulatory requirements prior to release for distribution from the CBP port of entry or approved foreign trade zone. The following labeling requirements shall be met:

- Relabeling shall be done by parties who, and in a manner that meets all state and federal requirements.
- Shall be labeled with the National Drug Code (NDC) assigned to the drug
    - The unique NDC number applied to each drug under the SIP would indicate the drug is part of the state's importation program.
    - At New Mexico's direction, the importer is responsible for proposing an NDC for assignment for each eligible prescription drug imported.
- A product Identifier, meeting Section 582 of the FD&C Act, shall be affixed to or imprinted on each package and homogenous case of imported drug prior to distribution.
- All product shall bear the required FDA approved U.S. labeling information including carton and container labeling, prescribing information, and any patient labeling, such as medication guides, instruction for use documents, and patient package inserts.
- All product shall be labeled with the name and place of business of the manufacture, packer or distributor, as required by law.
- The product shall be labeled in accordance with the approved NDA or ANDA and in accordance with FDA laws and regulations for drug labels (e.g., at 21 CFR Part 201).

- Shall contain section 804 required labeling statement "[This drug was/These drugs were} imported from Canada without the authorization of {Name of Applicant] under the {Name of SIP Sponsor} Section 804 Importation Program".
- Shall be labeled with the name and place of business of the importer. NMDIP will require a 1-800 number be included for consumer complaints and adverse event reporting.
- The labeling requirements ensure that the drug importation program has the ability to track and trace all imported drugs, aids in auditing efforts to ensure that imported product is distributed and dispensed in accordance with state and federal regulations, and makes it possible for recalled product to be removed from the supply chain in a timely manner.

WHISTLEBLOWER PROTECTION

The New Mexico Drug Importation Program shall have available on its webpage information on how to report any illegal or suspicious activity to the NMDIP. The webpage shall supply a number for an anonymous tip line. The tip line shall be set up to ensure the anonymity and confidentiality of the informant.

MANAGEMENT OF SUPPLY CHAIN CONCERNS

Upon receipt of complaints relating to manufacture, storage, transport, or other supply chain concerns relating to drug distribution, NMDIP shall notify the applicable program participants of the issue, and as appropriate the NMDIP will conduct its own full investigation into the validity of the concern. NMDIP will include NMBOP in the investigation as appropriate. If a concern has been deemed valid and there is evidence that any drug under the program is a suspect foreign product or an illegitimate foreign product, supply chain participants shall be issued a notice of investigation of suspect or illegitimate product by NMDIP so that the product may be prevented from further distribution until resolution of the investigation. Upon resolution of the investigation, NMDIP shall inform all affected supply chain participants and the FDA of the outcome of the investigation. NMDIP shall issue a recall for product that has been deemed unfit for distribution.

All parties would also be expected to, and must agree to, meet their own responsibilities under the DSCSA and final rule with respect to suspect and illegitimate product, independent of whether NMDIP initiates an investigation and independent of the status of any such NMDIP investigation.

MANAGING SUSPECT AND ILLEGITIMATE DRUGS

Each supply chain participant shall be responsible for inspecting product prior to distribution. Any product that is determined to be a suspect or illegitimate product must immediately be quarantined until the product is cleared or dispositioned. Further, the Foreign Seller(s) and Importer(s) must also meet all other applicable requirements under the DSCSA and the final section 804 rule with respect to suspect and illegitimate product.

Supply chain participant procedure for suspect and illegitimate product:

- Promptly conduct an investigation in coordination with the importer or foreign seller, as applicable, to determine whether the product is an illegitimate foreign product, and verify the product at the package level, including the section 804 serial identifier (SSI).
- If a product is determined to be legitimate, not suspect, and otherwise in compliance with applicable laws and regulations, the product may be further distributed.
- If a product is determined to be unfit for distribution, it shall remain quarantined until further direction is received by the FDA.
    - Product that has been cleared for destruction shall be processed as an unsaleable return to a FDA registered reverse distributor based in the U.S.

Reporting

- If a product is determined to be unfit for distribution, notification must occur within 24 hours to the FDA, the importer, the foreign seller, and the New Mexico Drug Importation Program.
    - The New Mexico Board of Pharmacy must also be notified if the product has been distributed to a facility or person licensed in New Mexico.
- If a supply chain participant receives a request for verification from FDA for a product, the supply chain participant shall follow the steps listed above. The FDA must receive a response within 24 hours of the determination regardless of the determination.
- Each supply chain participant must maintain all records relating to suspect and illegitimate products for a minimum of 6 years as required by the DSCSA and the final rule.

RECALL PLAN

The drug importation program will leverage the existing robust recall systems that are required of drug wholesalers. Imported drugs are subject to all applicable DSCSA identification, tracing, and verification requirements. The high level of tracing required by the DSCSA will ensure that all recalled products shall be quickly identified and removed at all levels of the supply chain. However, Section 804 places the ultimate responsibility for drug recalls on the SIP sponsor. The

New Mexico Drug Importation Program will oversee program integrity. It will ensure that drug recalls are conducted in a manner that protects public health and safety. Upon identification of a drug recall, New Mexico Drug Importation Program staff shall update the drug importation webpage with all drug recall information to ensure public notification. Additionally, it will utilize its directory of all licensed drug importation participants to send an electronic notification of the drug recall. NMDIP shall require acknowledgement of receipt of the notice. The New Mexico Drug Importation Program staff member shall follow up on all recall notices without acknowledgement within 24 hours to confirm receipt and processing. NMDIP will conduct, at least annually, a review of the Importer and Foreign Seller's policies and procedures. Additionally, upon audit of a licensed importation program participants, NMDIP shall review a percentage of effectuated drug recalls.

All drug importation program supply chain participants will be required to establish a written procedure and communication plan to follow for drug recalls, these procedures must have a specific section to address recalls of drugs products imported under the SIP. Additionally, the New Mexico drug importation program, the foreign seller, and the importer will be responsible for checking daily:

- FDA's recalls https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts
- Health Canada's recalls https://healthycanadians.gc.ca/recall-alert-rappel-avis/index-eng.php?cat=3
- Announcements from the manufacturer(s) of each imported drug

In the event of a recall originating from the drug importation program, manufacturer, foreign seller, or from the importer, the importer shall:

- Notify the FDA, NMDIP, and NMBOP of the recall
- Specify the depth to which the recall will extend;
- Notify the public about any hazards presented by the recalled drug(s) when appropriate to protect the public health;
- Immediately quarantine and cease distribution of recalled drug(s)
- Directly notify consignees of recalled drug(s). Communication shall include how to return or dispose of the recalled drugs
- Conduct recall effectiveness checks to verify that all consignees at the specified recall depth have received notification about the recall and have taken appropriate action;
- Appropriately dispose of recalled product; and,

- Upon request by the FDA, provide the transaction history, information and statement of the recalled drug(s), as those terms are defined in sections 581(25), 581(26) and 581(27) of the FDCA, respectively.

In the event of a recall with any origin, all supply chain participants shall:

- Immediately cease distribution of recalled drug(s) and quarantine any recalled drug still in the possession of the NMDIP participant.
- Directly notify consignees of recalled drug(s). Communication shall include how to return or dispose of the recalled drugs
- Conduct recall effectiveness checks to verify that all consignees at the specified recall depth have received notification about the recall and have taken appropriate action;
    - Pharmacies and dispensers shall be responsible for notifying affected patients for consumer level recalls.
- Appropriately dispose of recalled product; and,
- Upon request by the FDA, provide the transaction history, information and statement of the recalled drug(s), as those terms are defined in sections 581(25), 581(26) and 581(27) of the FDCA, respectively.

In the event of a recall, Importers and Foreign Sellers would be required, upon request by FDA, to provide the transaction history, information, and statement, as those terms are defined in sections 581(25), 581(26), and 581(27) of the FD&C Act, respectively, of the FD&C Act.

RETURN PLAN

Saleable Returns

Drug supply chain participants may return saleable prescription drugs to the importer pursuant to state and federal law and consistent with section 804 requirements. Subject to restrictions on re-exporting drugs relabeled under the NMDIP, saleable returns may be processed in accordance with the importer's return policy and procedures. Saleable returns shall be processed only through a return merchandise authorization (RMA) so that the importer shall have the ability to identify and track the item as a saleable return. All parties shall be responsible for ensuring that all DSCSA requirements are met for the returned product. The importer may re-distribute the returned saleable product to a NMDIP registrant that is also NMBOP licensed.

Non-saleable Returns

Non-saleable returns are subject to the importer's return policy and procedures. Non-saleable returns shall be processed only through a return merchandise authorization (RMA) so that the importer shall have the ability to identify and track the item as a non-saleable return. Upon

receipt of a non-saleable return of imported product, the importer may only distribute the product to a returns processor located in the U.S for destruction.

- Non-saleable products that do not qualify for return shall be sent by the NMDIP registrant to a returns processor located in the U.S for destruction.

Exportation

The importer is prohibited from exporting NMDIP medications that have been relabeled for distribution under the NMDIP. The importer may only return product to the Foreign Seller with the original HPFB labeling under Customs and/or FDA supervision if the drug was refused entry into the U.S. by the FDA. Drugs refused admission into the United States must be exported or destroyed by the importer within 90 calendar days of the refusal.

ADVERSE DRUG EVENT REPORTING

The New Mexico Drug Importation Program will provide education for supply chain participants regarding their adverse drug event reporting obligations. It will also post information on its webpage with instructions on how to complete FDA adverse drug event reporting. Additionally, the program will provide support to participants via its help line. However, the responsibility of adverse drug event reporting rests with the drug supply chain participants and the responsibility for submitting the reports to FDA and to the manufacturer is with the Importer. Reporting shall be conducted utilizing an Individual Case Safety Report (ICSR). Adverse events that the FDA requires expedited reporting must be submitted within 15 days. Adverse events that the FDA does not require to be expedited must be reported within 90 days.

RECORDKEEPING AND REPORTING

NMDIP will ensure that all drug importation program participants adhere to state and federal recordkeeping and reporting requirements in accordance with the FD&C Act, including section 804 and the DSCSA. Listed below are a few key requirements. This list is not inclusive of all reporting requirements.

Federal Recordkeeping Requirements

All drug importation program participants will be required to maintain records in accordance with section 804, FD&C Act, and the DSCSA.

All records that enable supply chain participants to track and trace product shall be retained for a minimum of 6 years.

- DSCSA requires maintenance of all records pertaining to transaction information, transaction history, and transaction statement for a minimum of 6 years.

- Section 804 requires the importer to maintain records linking the product identifier affixed to or imprinted on a package or homogenous case to the SSI that the Foreign Seller Assigned.
- Section 804 requires the foreign seller shall maintain records associating the SSI with the drug identification number from the HPFB and all the records the foreign seller received from the manufacturer upon receipt of the original shipment intended for the Canadian market.

All drug importation program participants including NMDIP shall agree to submit to audits of their books, records, and facilities by the FDA.

Federal Reporting Requirements

- All supply chain participants will be responsible to notify the FDA within 24 hours of any drug recall.
- An importer would be required to submit adverse event, field alert, and other reports to a drug's manufacturer and to FDA
- All licensed drug importation program participants are responsible for compiling adverse event reports for the importer to submit to the FDA and the drug manufacturer.
- NMDIP must submit a quarterly report to the FDA providing the information outlined in § 251.19

State Reporting Requirements

In addition to Federal reporting requirements, the drug importation program shall report annually to the state legislature and the Governor:

- A list of the prescription drugs included in the program
- A list all program participants
- A list of participating health insurance plans
- The number of prescriptions dispensed through the program
- The estimated savings to consumers, health plans, employers, and the state during the previous year and to date.
- Information regarding implementation of audit plan and the correction plans for audit findings
- Any other information requested by the New Mexico Governor, Legislature or Secretary of Health.

ELIGIBLE PRESCRIPTION DRUG CATEGORIES

Eligible prescription drug means a drug subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act that has been approved and has received a Notice of Compliance and a Drug Identification Number (DIN) from the Health Products and Food Branch of Health Canada 2020-199 123 (HPFB) and, but for the fact that it deviates from the required U.S. labeling, also meets the conditions in an FDA-approved new drug application (NDA) or abbreviated new drug application (ANDA) for a drug that is currently commercially marketed in the United States, including those relating to the drug substance, drug product, production process, quality controls, equipment, and facilities

The term eligible prescription drug does not include:

(1) A controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));

(2) A biological product (as defined in section 351(i)(1) of the Public Health Service Act (42 U.S.C. 262(i)(1)));

(3) An infused drug (including a peritoneal dialysis solution);

(4) An intravenously injected drug;

(5) A drug that is inhaled during surgery;

(6) An intrathecally or intraocularly injected drug;

(7) A drug that is subject to a risk evaluation and mitigation strategy under section 505-1 of the Federal Food, Drug, and Cosmetic Act; or

(8) A drug that is not a “product” for purposes of section 582 as defined in section 581(13) of the Federal Food, Drug, and Cosmetic Act.

Appendix A

SENATE BILL 001

WHOLESALE PRESCRIPTION DRUG IMPORTATION ACT

AN ACT

RELATING TO HEALTH; ENACTING THE WHOLESALE PRESCRIPTION DRUG IMPORTATION ACT; PROVIDING POWERS AND DUTIES; CREATING A PROGRAM; CREATING A COMMITTEE; REQUIRING FEDERAL CERTIFICATION; CREATING A FUND; DECLARING AN EMERGENCY.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF NEW MEXICO:

SECTION 1. SHORT TITLE.--This act may be cited as the "Wholesale Prescription Drug Importation Act".

SECTION 2. DEFINITIONS.--As used in the Wholesale Prescription Drug Importation Act:

A. "Canadian supplier" means a manufacturer, wholesale distributor or pharmacy that is appropriately licensed or permitted under Canadian federal or provincial laws and rules to manufacture, distribute or dispense prescription drugs;

B. "committee" means the prescription drug importation advisory committee;

C. "department" means the department of health;

D. "eligible prescription drug" means a drug eligible for importation that:

(1) meets the United States federal food and drug administration's standards related to safety, effectiveness, misbranding and adulteration;

(2) does not violate federal patent laws;

(3) is expected to generate cost savings; and

(4) is not a controlled substance;

E. "program" means the wholesale prescription drug importation program; and

F. "state drug wholesaler" means a licensed wholesale drug distributor that contracts with the state to import eligible prescription drugs from a Canadian supplier.

SECTION 3. ADVISORY COMMITTEE CREATED--MEMBERSHIP--DUTIES.--

A. The "prescription drug importation advisory committee" is created as an interagency advisory committee of the department. The committee consists of:

(1) the secretary of health, who shall serve as the chair of the committee;

(2) the executive director of the board of pharmacy;

(3) the superintendent of insurance;

(4) the secretary of human services; and

(5) the secretary of general services.

B. Members may appoint designees.

C. The committee shall advise the department in developing and implementing the program. The committee shall consult with interested stakeholders and appropriate federal officials as necessary in shaping its advice to the

department. The department shall hold a public hearing on the proposed program prior to submitting the program for federal approval.

SECTION 4. WHOLESALE PRESCRIPTION DRUG IMPORTATION PROGRAM CREATED.--The department, in consultation with the committee, shall design a "wholesale prescription drug importation program" that complies with the applicable requirements of 21 U.S.C. Section 384, including the requirements regarding safety and cost savings. The department shall explore all potential mechanisms, to the extent allowable under law, for the importation of eligible prescription drugs. The program design shall:

A. contract with one or more state drug wholesalers to seek federal certification and approval to import safe, eligible prescription drugs from Canadian suppliers and provide significant prescription drug cost savings to New Mexico consumers;

B. allow the importation of eligible prescription drugs sold by Canadian suppliers;

C. ensure that only eligible prescription drugs meeting the United States food and drug administration's safety, effectiveness and other standards are imported by or on behalf of the state;

D. import only those eligible prescription drugs expected to generate substantial savings for New Mexico

consumers;

E. ensure that, with respect to eligible prescription drugs to be imported pursuant to the program, the program and the state drug wholesaler comply with the tracking, tracing, verification and identification requirements of 21 U.S.C. Sections 360eee and 360eee-1;

F. prohibit the distribution, dispensing or sale of eligible prescription drugs imported pursuant to the Wholesale Prescription Drug Importation Act outside the exterior boundaries of the state;

G. recommend a charge per prescription or another method of support to ensure that the program is funded adequately in a manner that does not jeopardize significant consumer savings; and

H. include an audit function.

SECTION 5. MONITORING FOR ANTI-COMPETITIVE BEHAVIOR.--The department shall consult with the attorney general to identify the potential, and to monitor, for anti-competitive behavior in industries that would be affected by the program.

SECTION 6. FEDERAL COMPLIANCE.--On or before December 15, 2020, the department shall submit a formal request to the secretary of the United States department of health and human services for certification of the state's program.

SECTION 7. IMPLEMENTATION.--Upon certification of approval by the secretary of the United States department of health and human services, the department shall begin implementing the program and begin operating the program within six months of that approval. As part of the implementation process, the department shall:

A. enter into contracts in accordance with the Procurement Code with one or more state drug wholesalers and New Mexico licensed drug distributors and contract with one or more approved Canadian suppliers;

B. consult with interested stakeholders, including the committee, the legislature, health insurance plans, employers, pharmacies, health care providers and consumers;

C. develop a registration process for health insurance plans, pharmacies and prescription drug administering health care providers who choose to participate in the program;

D. make a list of imported eligible prescription drugs and their prices and make that list available to all participating entities and the general public;

E. create an outreach and marketing plan to generate program awareness;

F. create and staff a helpline to answer questions and address the needs of consumers, employers, health insurance plans, pharmacies, health care providers and other

affected sectors;

G. require annual and special audits of the program; and

H. carry out other duties in accordance with the Wholesale Prescription Drug Importation Act that the department, in consultation with the board of pharmacy, determines to be necessary for successful implementation of the program.

SECTION 8. ANNUAL REPORTING.--Annually, after implementation, the department shall report to the governor and the legislature regarding the operation of the program during the previous year, including:

A. which eligible prescription drugs and Canadian suppliers are included in the program;

B. the number of participating pharmacies, health care providers and health insurance plans;

C. the number of prescriptions dispensed through the program;

D. the estimated savings to consumers, health plans, employers and the state during the previous year and to date;

E. information regarding implementation of the audit plan and the correction plans for audit findings; and

F. any other information requested by the governor or the legislature or that the secretary of health deems

relevant.

SECTION 9. WHOLESALE PRESCRIPTION DRUG IMPORTATION FUND.--The "wholesale prescription drug importation fund" is created as a nonreverting fund in the state treasury. The fund consists of money received by the state through the implementation of the program pursuant to the Wholesale Prescription Drug Importation Act and appropriations, gifts, grants, donations to the fund and income from investment of the fund. The department shall administer the fund, and money in the fund is subject to appropriation by the legislature and shall be expended only as provided in the appropriation. Expenditures shall be by warrant of the secretary of finance and administration pursuant to vouchers signed by the secretary of health or the secretary's authorized representative.

SECTION 10. COUNTRIES OTHER THAN CANADA ALLOWED BY FEDERAL LAW.--The provisions of the Wholesale Prescription Drug Importation Act may be extended to any other country allowed by federal law to import prescription drugs into the United States, at the discretion of the department.

SECTION 11. EMERGENCY.--It is necessary for the public peace, health and safety that this act take effect immediately.

Appendix B

WRITTEN COMMENTS IN RESPONSE TO PROPOSED RULEMAKING

MICHELLE LUJAN GRISHAM
GOVERNOR

NEW MEXICO DEPARTMENT OF HEALTH

KATHYLEEN M. KUNKEL
CABINET SECRETARY

March 9, 2020

VIA U.S. Mail, Electronic Submission and Email

Dockets Management Staff (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2019-N-5711 for "Importation of Prescription Drugs"
Written Comments in Response to Proposed Rulemaking
84 Fed. Reg. 70,796 (December 23, 2019)

Dear Sir or Madam:

The State of New Mexico, through its Department of Health ("NMDOH"), submits these written comments in response to Notice of Proposed Rulemaking, Importation of Prescription Drugs Docket No. FDA-2019-N-5711, 84 Fed. Reg. 70,796 (December 23, 2019). Just last week, New Mexico became one of the few states in the nation to pass a law authorizing the development and implementation of a safe and cost-effective wholesale prescription drug importation program pursuant to 21 U.S.C. Section 384 (Section 804 (b)-(h) of the Federal Food, Drug, and Cosmetic Act ("FDCA")). Senate Bill 1, New Mexico's Wholesale Prescription Drug Importation Act, received strong bipartisan support, passed unanimously in both houses of our state legislature during the 2020 Legislative Session and was signed into law by Governor Michelle Lujan Grisham on March 4, 2020.

The State of New Mexico intends to immediately commence preparation of its Section 804 Importation Program ("SIP") proposal for submission to the Food and Drug Administration ("FDA"). We look forward to working closely with the FDA as we design our program and prepare our application to implement a safe and cost-effective wholesale prescription drug importation program for New Mexicans. We submit these comments because we are concerned that the proposed regulations do not provide adequate flexibility to ensure that New Mexico and other states are able to implement a safe and cost-effective wholesale drug importation program for our state residents.

Comment #1

[Proposed 21 CFR § 251.2] – The FDA should broaden the definition of allowable SIP sponsors beyond entities that regulate wholesale drug distribution and/or the practice of pharmacy in a state.

Proposed Rule:

The definitions section of the proposed rule, 21 CFR § 251.2, requires the primary sponsor of the SIP to be "a State, tribal, or territorial governmental entity that regulates wholesale drug distribution and/or the practice of pharmacy."

Comment:

In New Mexico, like most states, the entity responsible for regulating wholesale drug distribution and the practice of pharmacy is the state Board of Pharmacy. New Mexico's authorizing legislation designated NMDOH as the entity responsible for developing and implementing the state's wholesale prescription drug importation program, not the New Mexico Board of Pharmacy. The statute requires NMDOH to work with the Board of Pharmacy to develop the program. See https://www.nmlegis.gov/Sessions/20%20Regular/final/SB0001.pdf. We request that the definition of SIP sponsor be broadened to authorize other state, Tribal or territorial entities designated by the governing legislative bodies to design and operate the state SIP.

Comment #2

[Proposed 21 CFR § 251.3(b)] – The FDA should conditionally approve SIPs that are unable to designate Foreign Sellers, Importers, and Repackagers at the time of SIP proposal submission.

Proposed Rule:

§251.3(b) The proposal must include:
(6) The name and address of the Foreign Seller;
(7) The name and address of the Importer;
(8) The name and address of the FDA registered repackager or relabeler, if different from the importer […]

Comment:

The proposed rule should be revised to allow the FDA to conditionally approve SIPs that are unable to specify the Importer(s), Foreign Seller(s), and Repackager(s) at the time the initial proposal is submitted. The proposed rule requires a SIP proposal to identify the Foreign Sellers, Importers, and Repackagers to be utilized by the implementing SIP. The effect of this prerequisite requires these entities to enter into agreements with state implementing SIP programs before the SIP framework has received approval from the FDA. Accordingly, any contract terms between the

SIP and the entities would likely be subject to change, which would likely interfere with pre-SIP negotiations and stifle certain entities from participating altogether.

The final rule should allow FDA to conditionally approve a SIP and later fully approve the SIP when information regarding Foreign Sellers, Importers, and Repackagers can be submitted for approval.

Comment #3

[Proposed 21 CFR § 251.3, § 251.8] – State Agency SIP Sponsors should be permitted to designate more than only one Foreign Seller and one Importer in their initial SIP proposals.

Proposed Rules:

§251.3 SIP proposal submission requirements

(a) A SIP sponsor must only designate one Foreign Seller and one Importer per initial proposal. Additional Foreign Sellers and Importers may be added to an authorized SIP through a supplement under §251.8

§251.8 Modification or extension of authorized importation programs

(b) A SIP Sponsor can propose to add additional Foreign Sellers or additional Importers to an authorized SIP once it has consistently imported eligible prescription drugs in accordance with section 804 of the Federal Food, Drug, and Cosmetic Act and this part.

Comment:

Restricting initial SIP proposals to designate only one Foreign Seller and one Importer may allow prescription drug manufacturers to discriminate and apply higher markups to the limited number of Foreign Sellers and Importers who participate in state SIPs. For instance, a drug manufacturer that sells an eligible compound at a higher price in the United States is unlikely to sell its product at a lower price directly to a Foreign Seller who they expect will export the drug for profit to a United States SIP. This proposed scenario may restrict the state SIP from obtaining the significant reduction in the cost of prescription drugs for the consumer.

Allowing initial SIP proposals to authorize and utilize more than one Foreign Seller and Importer gives the state the ability to designate alternative sources upon an imposed price increase by a drug manufacturer on an individual Foreign Seller or Importer. A SIP should be permitted to specify multiple Foreign Sellers and Importers that have the option to either export prescription drugs to the United States or direct those prescription drugs to a specified second Foreign Seller in Canada who may have the ability to consolidate supplies for exportation.

Comment #4

[Proposed 21 CFR §251.7, §251.18(a)] – SIP conditions of suspension and revocation for program noncompliance are overly punitive and restrictive.

Proposed Rule:

§251.7 Suspension and revocation of authorized importation programs

(a) FDA may suspend a SIP under the circumstances set forth in §251.18, or under other circumstances in FDA's discretion. Importation of drugs under a SIP that has been suspended is prohibited.

§251.18(a) *Stopping importation*. If at any point a SIP Sponsor determines that a drug, manufacturer, Foreign Seller, Importer, qualifying laboratory, or other participant in or element of the supply chain in the authorized SIP does not in fact meet all applicable requirements of the FDCA, FDA regulations, and the authorized SIP, the SIP Sponsor must immediately stop importation of all drugs under the SIP.

Comment:

The proposed rule grants the FDA with authority and discretion to suspend and revoke a SIP for noncompliance with any FDCA or FDA requirement. For these reasons, Section 251.7 and 251.18(a) are unduly burdensome and overly broad.

The proposed rule should be revised to provide a more graduated approach for addressing SIP noncompliance, such as requiring the FDA to prescribe a corrective action plan rather than ordering the immediate suspension of a SIP. Requiring a SIP to follow a corrective action plan would allow an operational program to continue while immediately addressing the specific issues of noncompliance. Allowing a SIP sponsor to limit the suspension to a specific program component or implicated portion of the supply chain may also be reasonable.

Comment #5

[Proposed 21 CFR §251.20] – The severability provision of this proposed rule is overly broad.

Proposed Rule:

§251.20 Severability
The provisions of this part are not separate and are not severable from one another. If any provision is stayed or determined to be invalid, the remaining provisions shall not continue in effect.

Comment:

The severability provision of the proposed rule is too broad and risks invalidating the entire rule to the extent any part of the rule is determined to be invalid. The proposed rule should be amended to direct application of the severability clause to situations in which continued operation of the remaining rule, following a stay or invalidation, could threaten the health and safety of the public. For instance, the proposed rule could be amended to state the following:

> If any provision of this part is stayed or determined to be invalid, and the stay or invalidation would cause the rule as a whole to no longer adequately protect public health, the remaining provisions shall not continue in effect.

Please include our written comments in the rulemaking record for Docket No. FDA-2019-N-5711 for "Importation of Prescription Drugs."

Sincerely,

Kathyleen M. Kunkel
Cabinet Secretary
New Mexico Department of Health

CC: Governor Michelle Lujan Grisham
Senator Tom Udall
Senator Martin Heinrich
Representative Ben Ray Lujan
Representative Debra Haaland
Representative Xochitl Torres Small

Appendix C

TABLE ONE:
DRUG LIST FOR IMPORTATION
WITH POTENTIAL COST SAVINGS

BRAND	INCLUDED STRENGTHS	INDICATION	TOTAL EXPENDITURE	US NET UNIT WAC COST	CANADIAN UNIT COST (+45% MARK UP)	CALCULATED UNITS PROCESSED	MAX ESTIMATED WAC-BASED CARRIER/ENROLLEE ANNUAL SAVINGS	PERCENT SAVINGS
LATUDA	20 MG, 40 MG, 60 MG, 80 MG	SCHIZOPHRENIA	$ 2,909,292.66	$ 41.42	$ 4.41	70,239	$ 2,599,234.09	89%
VENTOLIN	90 MCG	ASTHMA, COPD	$ 8,032,792.12	$ 55.36	$ 5.95	145,101	$ 7,169,267.97	89%
ADVAIR DISKUS	250/50	ASTHMA, COPD	$ 650,170.70	$ 373.64	$ 46.23	1,740	$ 569,734.10	88%
CHANTIX	0.5 MG, 1 MG	SMOKING CESSATION AID	$ 230,397.88	$ 7.49	$ 1.00	30,761	$ 199,552.09	87%
DESCOVY	200-25 MG	HIV	$ 6,303,046.18	$ 54.77	$ 7.96	115,082	$ 5,387,369.81	85%
JARDIANCE	25 MG	DIABETES MELLITUS TYPE 2	$ 1,876,102.96	$ 16.70	$ 2.86	112,370	$ 1,555,207.91	83%
INVOKANA	100 MG, 300 MG	DIABETES MELLITUS TYPE 2	$ 120,070.75	$ 16.39	$ 2.86	7,326	$ 99,150.30	83%
FARXIGA	5 MG, 10 MG	DIABETES MELLITUS TYPE 2	$ 1,388,852.01	$ 16.35	$ 2.98	84,945	$ 1,136,089.73	82%
UPTRAVI	1400 MCG	PULMONARY ARTERIAL HYPERTENSION	$ 191,948.09	$ 367.12	$ 69.95	523	$ 155,372.88	81%
TECFIDERA	240 MG	MULTIPLE SCLEROSIS	$ 2,607,733.73	$ 123.65	$ 23.86	21,090	$ 2,104,550.36	81%
XIFAXAN	550 MG	IRRITABLE BOWEL SYNDROME	$ 6,049,138.89	$ 40.40	$ 8.00	149,732	$ 4,851,232.52	80%
JANUMET	50-500 MG, 50-1000 MG	DIABETES MELLITUS TYPE 2	$ 106,047.23	$ 7.48	$ 1.49	14,177	$ 84,876.80	80%
JANUVIA	100 MG	DIABETES MELLITUS TYPE 2	$ 2,348,736.60	$ 15.95	$ 3.49	147,256	$ 1,835,124.79	78%
RAVICTI	1.1 G/ML	UREA CYCLE DISORDERS	$ 1,128,875.58	$ 230.21	$ 52.32	4,904	$ 872,324.10	77%
XARELTO	20 MG	ANTICOAGULANT	$ 2,925,667.48	$ 13.11	$ 3.10	223,163	$ 2,234,867.99	76%
TIVICAY	50 MG	HIV	$ 3,594,016.84	$ 57.75	$ 13.77	62,237	$ 2,737,244.52	76%
COPAXONE	40 MG	MULTIPLE SCLEROSIS	$ 846,809.59	$ 460.97	$ 114.12	1,837	$ 637,171.42	75%
IMBRUVICA	140 MG	CANCER	$ 941,476.11	$ 437.36	$ 109.05	2,153	$ 706,729.82	75%
VICTOZA	18MG/3ML	DIABETES MELLITUS TYPE 2	$ 6,764,638.28	$ 306.01	$ 78.70	22,106	$ 5,024,955.53	74%
TASIGNA	200 MG	CANCER	$ 499,219.92	$ 131.39	$ 38.41	3,799	$ 353,282.43	71%
SPRYCEL	50 MG, 100 MG	CANCER	$ 2,498,420.24	$ 462.23	$ 138.51	5,405	$ 1,749,740.70	70%
ZYTIGA	500 MG	CANCER	$ 375,314.65	$ 176.37	$ 55.18	2,128	$ 257,881.66	69%
XTANDI	40 MG	CANCER	$ 1,069,454.16	$ 90.41	$ 30.89	11,829	$ 704,063.92	66%
OFEV	100 MG, 150 MG	IDIOPATHIC PULMONARY FIBROSIS	$ 157,400.92	$ 174.85	$ 63.92	900	$ 99,862.40	63%
PROMACTA	25 MG, 50 MG	APLASTIC ANEMIA, THROMBOCYTOPENIA	$ 135,060.00	$ 175.72	$ 66.37	769	$ 84,049.11	62%
AFINITOR DISPERZ	2 MG	CANCER	$ 940,211.41	$ 533.62	$ 202.73	1,762	$ 583,005.74	62%
GILENYA	0.5 MG	MULTIPLE SCLEROSIS	$ 1,085,746.14	$ 257.85	$ 98.09	4,211	$ 672,730.21	62%
JAKAFI	10 MG	CANCER	$ 572,932.00	$ 229.57	$ 89.58	2,496	$ 349,356.28	61%
XELJANZ XR	11 MG	RHEUMATOID ARTHRITIS	$ 1,649,479.09	$ 126.09	$ 50.35	13,082	$ 990,830.55	60%
VOTRIENT	200 MG	CANCER	$ 110,540.68	$ 115.15	$ 46.74	960	$ 65,675.21	59%
BYDUREON BCISE	2 MG/0.85 ML	DIABETES MELLITUS TYPE 2	$ 302,984.93	$ 174.33	$ 70.94	1,738	$ 179,689.25	59%
RESTASIS	0.05%	CHRONIC DRY EYE	$ 634,268.90	$ 9.26	$ 3.99	68,518	$ 360,933.65	57%
BIKTARVY	50-200-25 MG	HIV	$ 23,031,584.45	$ 102.04	$ 47.96	225,711	$ 12,206,845.30	53%
CABOMETYX	20 MG, 40MG, 60MG	CANCER	$ 517,841.78	$ 671.71	$ 319.72	771	$ 271,362.66	52%
GENVOYA	150-150-200-10 MG	HIV	$ 3,600,712.41	$ 97.19	$ 47.96	37,048	$ 1,823,943.58	51%
TRIUMEQ	600-50-300 MG	HIV	$ 473,350.10	$ 99.72	$ 49.47	4,747	$ 238,510.26	50%
ODEFSEY	200-25-25 MG	HIV	$ 599,848.57	$ 93.40	$ 47.96	6,422	$ 291,842.82	49%
TRUVADA	200-300 MG	HIV	$ 6,365,163.47	$ 57.90	$ 30.19	109,934	$ 3,046,049.51	48%
ELIQUIS	5 MG	ANTICOAGULANT	$ 1,406,388.88	$ 6.67	$ 4.15	210,853	$ 530,768.30	38%

TOTAL $ 64,820,480.25

Appendix D

DRUG LIST WITH REQUIRED HPFB & FDA DATA ELEMENTS

CANADIAN PROPRIETARY NAME	CANADIAN GENERIC NAME	DIN	COMPANY	ADDRESS	STRENGTH	DOSAGE FORM	NUMBER OF ACTIVE INGREDIENTS	CANADAIAN INGREDIENTS	U.S. PROPRIETARY NAME	U.S. GENERIC NAME	NDC	NDA	NDA APPLICANT HOLDER NAME AND ADDRESS	U.S. INGREDIENTS
LATUDA	LURASIDONE	02422050	SUNOVION PHARMACEUTICALS CANADA INC	7025 Langer Drive, Suite 301 Mississauga Ontario Canada L5N 0E8	20 MG	TABLET	1	lurasidone hydrochloride, carnauba wax, croscarmellose sodium, hypromellose, magnesium stearate, mannitol, Opadry® (hypromellose, polyethylene glycol, and titanium dioxide), pregelatinized starch; 80 mg tablet also contains: FD&C Blue No.2 Aluminum Lake and yellow ferric oxide.	LATUDA	LURASIDONE	63402-302-30	200603	Sunovion Pharmaceuticals, Inc. One Bridge Plaza, Suite 510 Fort Lee, NJ 07024	Each tablet contains 20 mg of lurasidone hydrochloride. Inactive ingredients are mannitol, pregelatinized starch, croscarmellose sodium, hypromellose, magnesium stearate, Opadry® and carnauba wax. Additi
LATUDA	LURASIDONE	02387751	SUNOVION PHARMACEUTICALS CANADA INC	7026 Langer Drive, Suite 301 Mississauga Ontario Canada L5N 0E8	40 MG	TABLET	1	lurasidone hydrochloride, carnauba wax, croscarmellose sodium, hypromellose, magnesium stearate, mannitol, Opadry® (hypromellose, polyethylene glycol, and titanium dioxide), pregelatinized starch; 80 mg tablet also contains: FD&C Blue No.2 Aluminum Lake and yellow ferric oxide.	LATUDA	LURASIDONE	63402-304-30	200604	Sunovion Pharmaceuticals, Inc. One Bridge Plaza, Suite 510 Fort Lee, NJ 07025	Each tablet contains 40 mg of lurasidone hydrochloride. Inactive ingredients are mannitol, pregelatinized starch, croscarmellose sodium, hypromellose, magnesium stearate, Opadry® and carnauba wax. Additi
LATUDA	LURASIDONE	02413361	SUNOVION PHARMACEUTICALS CANADA INC	7027 Langer Drive, Suite 301 Mississauga Ontario Canada L5N 0E8	60 MG	TABLET	1	lurasidone hydrochloride, carnauba wax, croscarmellose sodium, hypromellose, magnesium stearate, mannitol, Opadry® (hypromellose, polyethylene glycol, and titanium dioxide), pregelatinized starch; 80 mg tablet also contains: FD&C Blue No.2 Aluminum Lake and yellow ferric oxide.	LATUDA	LURASIDONE	63402-306-30	200605	Sunovion Pharmaceuticals, Inc. One Bridge Plaza, Suite 510 Fort Lee, NJ 07026	Each tablet contains 60 mg of lurasidone hydrochloride. Inactive ingredients are mannitol, pregelatinized starch, croscarmellose sodium, hypromellose, magnesium stearate, Opadry® and carnauba wax. Additi
LATUDA	LURASIDONE	02387778	SUNOVION PHARMACEUTICALS CANADA INC	7028 Langer Drive, Suite 301 Mississauga Ontario Canada L5N 0E8	80 MG	TABLET	1	lurasidone hydrochloride, carnauba wax, croscarmellose sodium, hypromellose, magnesium stearate, mannitol, Opadry® (hypromellose, polyethylene glycol, and titanium dioxide), pregelatinized starch; 80 mg tablet also contains: FD&C Blue No.2 Aluminum Lake and yellow ferric oxide.	LATUDA	LURASIDONE	63402-308-30	200606	Sunovion Pharmaceuticals, Inc. One Bridge Plaza, Suite 510 Fort Lee, NJ 07027	Each tablet contains 80 mg of lurasidone hydrochloride. Inactive ingredients are mannitol, pregelatinized starch, croscarmellose sodium, hypromellose, magnesium stearate, Opadry® and carnauba wax. Additi
VENTOLIN HFA	SALBUTAMOL HFA	02241497	GLAXOSMITHKLINE INC	7333 Mississauga Road Mississauga Ontario Canada L5N 6L4	100 MCG/ ACT	*METERED-DOSE AEROSOL*	1	lurasidone hydrochloride, carnauba wax, croscarmellose sodium, hypromellose, magnesium stearate, mannitol, Opadry® (hypromellose, polyethylene glycol, and titanium dioxide), pregelatinized starch; 80 mg tablet also contains: FD&C Blue No.2 Aluminum Lake and yellow ferric oxide.	VENTOLIN HFA	ALBUTEROL HFA	0173-0682-20	020983	GlaxoSmithKline 5 Moore Drive Mailstop 5.5B Research Triangle Park, NC 27709	Active ingredient: albuterol sulfate Inactive ingredient: propellant HFA-134a
ADVAIR DISKUS	SALMETEROL AND FLUTICASONE	02240836	GLAXOSMITHKLINE INC	7333 Mississauga Road Mississauga Ontario Canada L5N 6L4	250/50	POWDER	2	250 mcg fluticasone propionate and 50 mcg salmeterol (as the xinafoate salt)	ADVAIR DISKUS	SALMETEROL AND FLUTICASONE	0173-0696-00	021077	GlaxoSmithKline Five Moore Drive P. O. Box 13398 Research Triangle Park, NC 27709	Active ingredients: fluticasone propionate, salmeterol xinafoate Inactive ingredient: lactose monohydrate (contains milk proteins)
CHANTIX	VARENICLINE	02291177	PFIZER CANADA ULC	17300 Trans-Canada Highway Kirkland Quebec Canada H9J 2M5	0.5 MG	TABLET	1	varenicline tartrate, anhydrous dibasic calcium phosphate, colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, and microcrystalline cellulose. The film-coating contains hypromellose, polyethylene glycol, titanium dioxide and triacetin. The 1.0 mg tablet also contains FD&C Blue #2/Indigo Carmine Aluminum Lake as a colouring agent.	CHANTIX	VARENICLINE	0069-0468-56	021928	PF Prism C V c/o Pfizer, Inc 235 East 42nd Street New York, NY 10017-5755	Each 0.5 mg CHANTIX tablet contains 0.85 mg of varenicline tartrate equivalent to 0.5 mg of varenicline free base; each 1 mg CHANTIX tablet contains 1.71 mg of varenicline tartrate equivalent to 1 mg of varenicline free base. The following inactive ingredients are included in the tablets: microcrystalline cellulose, anhydrous dibasic calcium phosphate, croscarmellose sodium, colloidal silicon dioxide, magnesium stearate, Opadry® White (for 0.5 mg), Opadry® Blue (for 1 mg), and Opadry® Clear.

CANADIAN PROPRIETARY NAME	CANADIAN GENERIC NAME	DIN	COMPANY	ADDRESS	STRENGTH	DOSAGE FORM	NUMBER OF ACTIVE INGREDIENTS	CANADAIAN INGREDIENTS	U.S. PROPRIETARY NAME	U.S. GENERIC NAME	NDC	NDA	NDA APPLICANT HOLDER NAME AND ADDRESS	U.S. INGREDIENTS
CHANTIX	VARENICLINE	02291185	PFIZER CANADA ULC	17301 Trans-Canada Highway Kirkland Quebec Canada H9J 2M5	1 MG	TABLET	1	varenicline tartrate, anhydrous dibasic calcium phosphate, colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, and microcrystalline cellulose. The film-coating contains hypromellose, polyethylene glycol, titanium dioxide and triacetin. The 1.0 mg tablet also contains FD&C Blue #2/Indigo Carmine Aluminum Lake as a colouring agent.	CHANTIX	VARENICLINE	0069-0469-56	021928	PF Prism C V c/o Pfizer, Inc 235 East 42nd Street New York, NY 10017-5756	Each 0.5 mg CHANTIX tablet contains 0.85 mg of varenicline tartrate equivalent to 0.5 mg of varenicline free base; each 1 mg CHANTIX tablet contains 1.71 mg of varenicline tartrate equivalent to 1 mg of varenicline free base. The following inactive ingredients are included in the tablets: microcrystalline cellulose, anhydrous dibasic calcium phosphate, croscarmellose sodium, colloidal silicon dioxide, magnesium stearate, Opadry® White (for 0.5 mg), Opadry® Blue (for 1 mg), and Opadry® Clear.
DESCOVY	EMTRICITABINE AND TENOFOVIR ALAFENAMIDE	02454424	GILEAD SCIENCES CANADA INC	600 6711 Mississauga Road Mississauga Ontario Canada L5N 2W3	200-25 MG	TABLET	2	200 mg emtricitabine, 25 mg tenofovir alafenamide, microcrystalline cellulose, croscarmellose sodium, and magnesium stearate. The grey tablets are film-coated with a coating material containing polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc, and iron oxide black. The blue tablets are film-coated with a coating material containing polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc, and indigo carmine aluminum lake.	DESCOVY	EMTRICITABINE; TENOFOVIR ALAFENAMIDE FUMARATE	61958-2002-1)	208215	Gilead Sciences, Inc. 333 Lakeside Drive Foster City, CA 94404	Each 200/25 mg tablet contains 200 mg of emtricitabine (FTC) and 25 mg of tenofovir alafenamide (TAF) and the following inactive ingredients: croscarmellose sodium, magnesium stearate, and microcrystalline cellulose. The tablets are film-coated with a coating material containing indigo carmine aluminum lake, polyethylene glycol, polyvinyl alcohol, talc, and titanium dioxide.
JARDIANCE	EMPAGLIFLOZIN	02443945	BOEHRINGER INGELHEIM (CANADA) LTD LTEE	5180 South Service Road Burlington Ontario Canada L7L 5H4	25 MG	TABLET	1	25 mg of empagliflozin free base, colloidal silicon dioxide, croscarmellose sodium, hydroxypropyl cellulose, hypromellose, lactose monohydrate, magnesium stearate, macrogol, microcrystalline cellulose, titanium dioxide, talc, and yellow ferric oxide.	JARDIANCE	EMPAGLIFLOZIN	0597-0152-30	204629	Boehringer Ingelheim Pharmaceuticals, Inc. 900 Ridgebury Road P.O. Box 368 Ridgefield, CT 06877	25 mg of empagliflozin (free base) and the following inactive ingredients: lactose monohydrate, microcrystalline cellulose, hydroxypropyl cellulose, croscarmellose sodium, colloidal silicon dioxide and magnesium stearate. In addition, the film coating contains the following in
INVOKANA	CANAGLIFLOZIN	02425483	JANSSEN INC	19 Green Belt Drive Toronto Ontario Canada M3C 1L9	100 MG	TABLET	1	100mg of canagliflozin OR 300mg of canagliflozin; Core Tablet: croscarmellose sodium, hydroxypropyl cellulose, lactose anhydrous, magnesium stearate, and microcrystalline cellulose. Film Coat: iron oxide yellow (100 mg tablet only), Macrogol (polyethylene glycol), polyvinyl alcohol, talc, and titanium dioxide.	INVOKANA	CAGLIFLOZIN	50458-0140-30	204042	Janssen Pharmaceuticals, Inc. 1125 Trenton-Harbourton Road PO Box 200 Titusville, Nj 08560-1504	100mg of canagliflozin or 300mg of canagliflozin, croscarmellose sodium, hydroxypropyl cellulose, lactose anhydrous, magnesium stearate, and microcrystalline cellulose. In addition, the tablet coating contains iron oxide yellow E172 (100 mg tablet only), macrogol/PEG, polyvinyl alcohol, talc, and titanium dioxide.
INVOKANA	CANAGLIFLOZIN	02425491	JANSSEN INC	19 Green Belt Drive Toronto Ontario Canada M3C 1L9	300 MG	TABLET	1	100mg of canagliflozin OR 300mg of canagliflozin; Core Tablet: croscarmellose sodium, hydroxypropyl cellulose, lactose anhydrous, magnesium stearate, and microcrystalline cellulose. Film Coat: iron oxide yellow (100 mg tablet only), Macrogol (polyethylene glycol), polyvinyl alcohol, talc, and titanium dioxide.	INVOKANA	CAGLIFLOZIN	50458-0141-30	204042	Janssen Pharmaceuticals, Inc. 1125 Trenton-Harbourton Road PO Box 200 Titusville, Nj 08560-1504	100mg of canagliflozin or 300mg of canagliflozin, croscarmellose sodium, hydroxypropyl cellulose, lactose anhydrous, magnesium stearate, and microcrystalline cellulose. In addition, the tablet coating contains iron oxide yellow E172 (100 mg tablet only), macrogol/PEG, polyvinyl alcohol, talc, and titanium dioxide.
FORXIGA	DAPAGLIFOZIN	02435462	ASTRAZENECA CANADA INC	1004 Middlegate Road, Suite 5000 Mississauga Ontario Canada L4Y 1M4	5 MG	TABLET	1	5 mg or 10 mg dapagliflozin as dapagliflozin propanediol monohydrate, anhydrous lactose, crospovidone, magnesium stearate, microcrystalline cellulose, silicon dioxide. In addition, the film coating contains the following inactive ingredients: polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc and yellow iron oxide.	FARXIGA	DAPAGLIFLOZIN	00310-6205-30	202293	ASTRAZENECA LP PO BOX 15437 WILMINGTON, DE 19850	5 mg dapagliflozin as dapagliflozin propanediol or the equivalent of 10 mg dapagliflozin as dapagliflozin propanediold, microcrystalline cellulose, anhydrous lactose, crospovidone, silicon dioxide, and magnesium stearate. The film coating contains: polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc, and yellow iron oxide.

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FORXIGA	DAPAGLIFOZIN	02435470	ASTRAZENECA CANADA INC	1004 Middlegate Road, Suite 5000 Mississauga Ontario Canada L4Y 1M4	10 MG	TABLET	1	5 mg or 10 mg dapagliflozin as dapagliflozin propanediol monohydrate, anhydrous lactose, crospovidone, magnesium stearate, microcrystalline cellulose, silicon dioxide. In addition, the film coating contains the following inactive ingredients: polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc and yellow iron oxide.	FARXIGA	DAPAGLIFLOZIN	00310-6210-30	202293	ASTRAZENECA LP PO BOX 15437 WILMINGTON, DE 19850	5 mg dapagliflozin as dapagliflozin propanediol or the equivalent of 10 mg dapagliflozin as dapagliflozin propanediold, microcrystalline cellulose, anhydrous lactose, crospovidone, silicon dioxide, and magnesium stearate. The film coating contains: polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc, and yellow iron oxide.
UPTRAVI	SELEXIPAG	02451212	JANSSEN INC	19 Green Belt Drive Toronto Ontario Canada M3C 1L9	1400 MCG	TABLET	1	Selexipag 1400mg, carnauba wax, corn starch, D-mannitol, hydroxypropyl cellulose, hypromellose, iron oxide yellow (E172), low substituted hydroxypropyl cellulose, magnesium stearate, propylene glycol, titanium dioxide (E171)	UPTRAVI	SELEXIPAG	66215-0614-06	207947	Actelion Pharmaceuticals US, Inc. 5000 Shoreline Court, Ste. 200 South San Francisco, CA 94080, USA	selexipag 1400mg Inactive ingredients: D-mannitol, corn starch, low substituted hydroxypropylcellulose, hydroxypropylcellulose, and magnesium stearate. The tablets are film coated with a coating material containing hypromellose, propylene glycol, titanium dioxide, carnauba wax along with iron oxide red, iron oxide yellow, or iron oxide black.
TECFIDERA	DIMETHYL FUMARATE	02420201	BIOGEN CANADA INC	90 Burnhamthorpe Road West, Suite 1100 Mississauga Ontario Canada L5B 3C3	240 MG	CAPSULE (DELAYED-RELEASE)	1	240 mg of dimethyl fumarate, colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, methacrylic acid copolymer (type A), methacrylic acid copolymer dispersion, polysorbate 80, silicified microcrystalline cellulose, simethicone, sodium lauryl sulfate, talc and triethyl citrate. The capsule shell contains black iron oxide, FD&C Blue 1, gelatin, titanium dioxide and yellow iron oxide	TECFIDERA	DIMETHYL FUMARATE	64406-0006-02	204063	Biogen IDEC Inc 225 Binney Street Cambridge, MA 02142	240mg dimethyl fumarate, microcrystalline cellulose, silicified microcrystalline cellulose, croscarmellose sodium, talc, silica colloidal silicon dioxide, magnesium stearate, triethyl citrate, methacrylic acid copolymer - Type A, methacrylic acid copolymer dispersion, simethicone (30% emulsion), sodium lauryl sulphate, and polysorbate 80, gelatin, titanium dioxide, FD&C blue 1; brilliant blue FCF, yellow iron oxide and black iron oxide.
ZAXINE	RIFAXIMIN	02410702	SALIX PHARMACEUTICALS INC	400 Somerset Corporate Boulevard Bridgewater, NJ 08807	550 MG	TABLET	1	Rifaximin 550mg, colloidal silicon dioxide, glyceryl distearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, red iron oxide, gluten-free sodium starch glycolate, talc, and titanium dioxide.	XIFAXAN	RIFAXIMIN	65649-0303-02	022554	SALIX PHARMACEUTICALS 1700 Perimeter Park Drive Morrisville, NC 27560	Rifaximin 550mg, colloidal silicon dioxide, disodium edetate, glycerol palmitostearate, hypromellose, microcrystalline cellulose, propylene glycol, red iron oxide, sodium starch glycolate, talc, and titanium dioxide.
JANUMET	METFORMIN/SITAGLIPITN	02333856	MERCK CANADA INC	16750 Route Transcanadienne Kirkland Quebec Canada H9H 4M7	50-500 MG	TABLET	2	64.25 mg sitagliptin phosphate monohydrate and metformin hydrochloride equivalent to: 50 mg sitagliptin as free base and 500 mg metformin hydrochloride (JANUMET® 50 mg/500 mg), 850 mg metformin hydrochloride (JANUMET® 50 mg/850 mg) or 1000 mg metformin hydrochloride (JANUMET® 50 mg/1000 mg); microcrystalline cellulose, polyvinylpyrrolidone, sodium lauryl sulfate, and sodium stearyl fumarate. In addition, the film coating contains the following inactive ingredients: polyvinyl alcohol, polyethylene glycol, talc, titanium dioxide, red iron oxide, and black iron oxide.	JANUMET	SITAGLIPTIN/METFORMIN HCL	00006-0575-61	022044	MERCK SHARP DOHME 2000 Galloping Hill Road Kenilworth, NJ 088889	sitagliptin and metformin, microcrystalline cellulose, polyvinylpyrrolidone, sodium lauryl sulfate, and sodium stearyl fumarate. The tablet film coating contains the following inactive ingredients: polyvinyl alcohol, polyethylene glycol, talc, titanium dioxide, red iron oxide, and black iron oxide

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JANUMET	METFORMIN/SITAGLIPITN	02333872	MERCK CANADA INC	16750 Route Transcanadienne Kirkland Quebec Canada H9H 4M7	50-1000 MG	TABLET	2	64.25 mg sitagliptin phosphate monohydrate and metformin hydrochloride equivalent to: 50 mg sitagliptin as free base and 500 mg metformin hydrochloride (JANUMET® 50 mg/500 mg), 850 mg metformin hydrochloride (JANUMET® 50 mg/850 mg) or 1000 mg metformin hydrochloride (JANUMET® 50 mg/1000 mg); microcrystalline cellulose, polyvinylpyrrolidone, sodium lauryl sulfate, and sodium stearyl fumarate. In addition, the film coating contains the following inactive ingredients: polyvinyl alcohol, polyethylene glycol, talc, titanium dioxide, red iron oxide, and black iron oxide.	JANUMET	SITAGLIPTIN/METFORMIN HCL	00006-0577-61	022044	MERCK SHARP DOHME 2000 Galloping Hill Road Kenilworth, NJ 088889	sitagliptin and metformin, microcrystalline cellulose, polyvinylpyrrolidone, sodium lauryl sulfate, and sodium stearyl fumarate. The tablet film coating contains the following inactive ingredients: polyvinyl alcohol, polyethylene glycol, talc, titanium dioxide, red iron oxide, and black iron oxide
JANUVIA	SITAGLIPTIN (SITAGLIPTIN PHOSPHATE MONOHYDRATE)	02303922	MERCK CANADA INC	16750 Route Transcanadienne Kirkland Quebec Canada H9H 4M7	100 MG	TABLET	1	128.5 mg of sitagliptin phosphate monohydrate, which is equivalent to 100 mg, respectively, of free base, microcrystalline cellulose, anhydrous dibasic calcium phosphate (calcium hydrogen phosphate, anhydrous), croscarmellose sodium, magnesium stearate, and sodium stearyl fumarate. In addition, the film coating contains the following inactive ingredients: polyvinyl alcohol, polyethylene glycol (macrogol), talc, titanium dioxide, red iron oxide, and yellow iron oxide.	JANUVIA	SITAGLIPTIN PHOSPHATE	00006-0277-31	021995	MERCK SHARP DOHME 2000 Galloping Hill Road Kenilworth, NJ 088889	128.5 mg of sitagliptin phosphate monohydrate, which is equivalent to 100 mg, respectively, of free base and the following inactive ingredients: microcrystalline cellulose, anhydrous dibasic calcium phosphate, croscarmellose sodium, magnesium stearate, and sodium stearyl fumarate. In addition, the film coating contains the following inactive ingredients: polyvinyl alcohol, polyethylene glycol, talc, titanium dioxide, red iron oxide, and yellow iron oxide.
RAVICTI	GLYCEROL PHENYLBUTYRATE	02453304	HORIZON THERAPEUTICS IRELAND DAC	1st Floor, Connaught House 1 Burlington Road Dublin 4 Ireland D04 C5Y6	1.1 G/ML	ORAL LIQUID	1	1.1 g/mL glycerol phenylbutyrate (delivers 1.02 g/mL of PBA). There are no excipients.	RAVICTI	GLYCEROL PHENYLBUTYRATE	76325-0100-04	203284	Horizon Therapeutics, LLC. 520 Lake Cook Rd Suite 520 Deerfield, IL 60015	1.1 g/mL of glycerol phenylbutyrate (delivers 1.02 g/mL of phenylbutyrate).
XARELTO	RIVAROXABAN	02378612	BAYER INC	2920 Matheson Blvd East Mississauga Ontario Canada L4W 5R6	20 MG	TABLET	1	Rivaroxaban, cellulose microcrystalline, croscarmellose sodium, hypromellose 5 cP, lactose monohydrate, magnesium stearate, sodium lauryl sulphate, ferric oxide yellow (2.5 mg), ferric oxide red (10 mg, 15 mg, 20 mg), hypromellose 15 cP, polyethylene glycol, titanium dioxide	XARELTO	RIVAROXABAN	50458-0579-30	022406 202439	Janssen Pharmaceuticals, Inc. 1125 Trenton-Harbourton Road PO Box 200 Titusville, Nj 08560-1504	rivaroxaban, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, and sodium lauryl sulfate, ferric oxide red, polyethylene glycol 3350, polyvinyl alcohol (partially hydrolyzed), talc, and titanium dioxide.
TIVICAY	DOLUTEGRAVIR (DOLUTEGRAVIR SODIUM)	02414945	VIIV HEALTHCARE ULC	245 Boulevard Armand-Frappier Laval Quebec Canada H7V 4A7	50 MG	TABLET	1	52.6 mg of dolutegravir sodium, which is equivalent to 50 mg dolutegravir free acid, respectively, and the following inactive ingredients: D-mannitol, microcrystalline cellulose, povidone K29/32, sodium starch glycolate, and sodium stearyl fumarate. The tablet film-coating contains the inactive ingredients iron oxide yellow (25 mg and 50 mg tablets only), macrogol/PEG, polyvinyl alcohol – part hydrolyzed, talc, and titanium dioxide	TIVICAY	DOULTEGRAVIR	49702-0228-13	204790	VIIV HEALTHCARE Five Moore Drive Research Triangle Park, NC 27709	10.5, 26.3, or 52.6 mg of dolutegravir sodium, which is equivalent to 50 mg dolutegravir free acid, respectively, D-mannitol, microcrystalline cellulose, povidone K29/32, sodium starch glycolate, and sodium stearyl fumarate. The tablet film-coating contains the inactive ingredients iron oxide yellow (for the 25-mg and 50-mg tablets only), macrogol/PEG, polyvinyl alcohol-part hydrolyzed, talc, and titanium dioxide.
COPAXONE	GLATIRAMER ACETATE	02456915	TEVA CANADA LIMITED	30 Novopharm Court Toronto Ontario Canada M1B 2K9	40 MG	SOLUTION	1	glatiramer acetate, mannitol and sterile water for injection.	COPAXONE	GLATIRAMER ACETATE	68456-0325-12	020622	TEVA PHARMACEUTICALS USA 400 Interpace Parkway #3 Parsippany, NJ 07054	ng of glatiramer acetate, 40 mg of mannitol mani

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IMBRUVICA	IBRUTINIB	02434407	JANSSEN INC	19 Green Belt Drive Toronto Ontario Canada M3C 1L9	140 MG	CAPSULE	1	140 mg of ibrutinib, colloidal silicon dioxide, croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, and sodium lauryl sulfate. The tablet film coatings contain black iron oxide (140 mg, 280 mg and 420 mg tablets), polyethylene glycol, polyvinyl alcohol, red iron oxide (280 mg and 560 mg tablets), talc, titanium dioxide, and yellow iron oxide (140 mg, 420 mg and 560 mg tablets).	IMBRUVICA	IBRUTINIB	57962-0140-09	205552	PHARMACYCLICS INC 999 East Arques Avenue Sunnyvale, CA 94085	CAPSULES: ibrutinib (active ingredient) and the following inactive ingredients: croscarmellose sodium, magnesium stearate, microcrystalline cellulose, sodium lauryl sulfate. The capsule shell contains gelatin, titanium dioxide, yellow iron oxide (70 mg capsule only), and black ink. TABLETS: ibrutinib (active ingredient) and the following inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, and sodium lauryl sulfate. The film coating for each tablet contains ferrosoferric oxide (140 mg, 280 mg, and 420 mg tablets), polyvinyl alcohol, polyethylene glycol, red iron oxide (280 mg and 560 mg tablets), talc, titanium dioxide, and yellow iron oxide (140 mg, 420 mg, and 560 mg tablets).
VICTOZA	LIRAGLUTIDE	02351064	NOVO NORDISK CANADA INC	101-2476 Argentia Road Mississauga Ontario Canada L5N 6M1	18MG/3ML	SOLUTION	1	6 mg/Ml Liraglutide, Disodium phosphate dihydrate, propylene glycol, phenol and water for injections	VICTOZA	LIRAGLUTIDE	00169-4060-13	022341	NOVO NORDISK INC 800 Scudders Mill Road Plainsboro, NJ 08536	Each 1 mL of VICTOZA solution contains 6 mg of liraglutide and the following inactive ingredients: disodium phosphate dihydrate, 1.42 mg; propylene glycol, 14 mg; phenol, 5.5 mg; and water for injection. VICTOZA has a pH of approximately 8.15, hydrochloric acid or sodium hydroxide may be added to adjust pH. Each pre-filled pen contains a 3 mL solution of VICTOZA equivalent to 18 mg liraglutide (free-base, anhydrous)
TASIGNA	NILTINIB (NILOTINIB HYDROCHLORIDE MONOHYDRATE)	02315874	NOVARTIS PHARMACEUTICALS CANADA INC	385 Bouchard Blvd Dorval Quebec Canada, H9S 1A9	200 MG	CAPSULE	1	200 mg nilotinib base (as hydrochloride monohydrate), Colloidal silicon anhydrous; Crospovidone; Lactose monohydrate; Poloxamer 188; Magnesium stearate. Capsule shell: Gelatin; Titanium dioxide; Iron oxide, yellow. Printing ink: includes red iron oxide	TASIGNA	NILOTINIB HYDROCHLORIDE	00078-0526-87	022068	NOVARTIS One Health Plaza East Hanover, NJ 07936	200 mg nilotinib base, anhydrous (equivalent to 55 mg, 166 mg, and 221 mg nilotinib monohydrochloride monohydrate respectively) with the following inactive ingredients: colloidal silicon dioxide, crospovidone, lactose monohydrate, magnesium stearate and poloxamer 188. The capsules contain gelatin, iron oxide (red), iron oxide (yellow), iron oxide (black), and titanium dioxide.
SPRYCEL	DASATINIB (DASATINIB MONOHYDRATE)	02293137	BRISTOL-MYERS SQUIBB CANADA	2344 Boul. Alfred-Nobel Suite 300 Montreal (St-Laurent) Quebec Canada H4S 0A4	50 MG	TABLET	1	50 mg and 100 mg dasatinib (as monohydrate) containing the following non-medicinal ingredients for the tablet core: croscarmellose sodium, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate and microcrystalline cellulose. The film-coating contain the following inactive ingredients: hypromellose, polyethylene glycol and titanium dioxide.	SPRYCEL	DASATINIB	00003-0528-11	021986	BRISTOL MYERS SQUIBB 430 E 29th Street 14th Floor New York, NY 10016	dasatinib, with the following inactive ingredients: lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, hydroxypropyl cellulose, and magnesium stearate. The tablet coating consists of hypromellose, titanium dioxide, and polyethylene glycol.

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SPRYCEL	DASATINIB (DASATINIB MONOHYDRATE)	02320193	BRISTOL-MYERS SQUIBB CANADA	2344 Boul. Alfred-Nobel Suite 300 Montreal (St-Laurent) Quebec Canada H4S 0A4	100 MG	TABLET	1	50 mg and 100 mg dasatinib (as monohydrate) containing the following non-medicinal ingredients for the tablet core: croscarmellose sodium, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate and microcrystalline cellulose. The film-coating contain the following inactive ingredients: hypromellose, polyethylene glycol and titanium dioxide.	SPRYCEL	DASATINIB	00003-0852-22	021986	BRISTOL MYERS SQUIBB 430 E 29th Street 14th Floor New York, NY 10016	dasatinib, with the following inactive ingredients: lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, hydroxypropyl cellulose, and magnesium stearate. The tablet coating consists of hypromellose, titanium dioxide, and polyethylene glycol.
ZYTIGA	ABIRATERONE ACETATE	02457113	JANSSEN INC	19 Green Belt Drive Toronto Ontario Canada M3C 1L9	500 MG	TABLET	1	500MG abiraterone acetate, colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, silicified microcrystalline cellulose, and sodium lauryl sulfate. The tablet film coating contains iron oxide black, iron oxide red, macrogol 3350, polyvinyl alcohol, talc, and titanium dioxide.	ZYTIGA	ABIRATERONE ACETATE	57894-0195-06	202379	JANSSEN BIOTECH, INC. 800 Ridgeview Road Horsham, PA 19044	500 mg abiraterone acetate, colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, silicified microcrystalline cellulose, and sodium lauryl sulfate. The coating, Opadry® II Purple, contains iron oxide black, iron oxide red, polyethylene glycol, polyvinyl alcohol, talc, and titanium dioxide.
XTANDI	ENZALUTAMIDE	02407329	ASTELLAS PHARMA CANADA INC	SUITE 500 675 Cochrane Drive, West Tower Markham Ontario Canada, L3R0B8	40 MG	CAPSULE	1	40 mg of enzalutamide and the inactive ingredients caprylocaproyl macrogolglycerides, butylhydroxyanisole and butylhydroxytoluene. The ingredients of the capsule shell are gelatin, sorbitol sorbitan solution, glycerol, titanium dioxide (E171), and purified water. The ingredients of the ink are: ethanol, ethyl acetate, propylene glycol, iron oxide black (E172), polyvinyl acetate phthalate, purified water, isopropyl alcohol, macrogol 400, and ammonia solution concentrated.	XTANDI	ENZALUTAMIDE	00469-0125-99	203415	ASTELLAS One Astellas Way Northbrook, IL 60062	40 mg of enzalutamide as a solution in caprylocaproyl polyoxylglycerides. The inactive ingredients are caprylocaproyl polyoxylglycerides, butylated hydroxyanisole, butylated hydroxytoluene, gelatin, sorbitol sorbitan solution, glycerin, purified water, titanium dioxide, and black iron oxide
OFEV	NINTEDANIB (NINTEDANIB ESILATE)	02443066	BOEHRINGER INGELHEIM (CANADA) LTD LTEE	5180 South Service Road Burlington Ontario Canada L7L 5H4	100 MG	CAPSULE	1	100 and 150 mg of nintedanib (as a free base) corresponding to 120.40 mg and 180.60 mg of nintedanib ethanesulfonate (esilate), respectively: Capsule fill: Medium chain triglycerides, hard fat, soya lecithin (E322) Capsule shell: Gelatin, glycerol 85 %, titanium dioxide (E171), iron oxide red (E172), iron oxide yellow (E172), black ink (Opacode®) Black ink: Shellac glaze, iron oxide black (E172), propylene glycol (E1520)	OFEV	NINTEDANIB ESYLATE	00597-0143-60	205832	Boehringer Ingelheim Pharmaceuticals, Inc. 900 Ridgebury Road P.O. Box 368 Ridgefield, CT 06877	100 mg or 150 mg of nintedanib (equivalent to 120.40 mg or 180.60 mg nintedanib ethanesulfonate, respectively). The inactive ingredients of OFEV are the following: Fill Material: triglycerides, hard fat, lecithin. Capsule Shell: gelatin, glycerol, titanium dioxide, red ferric oxide, yellow ferric oxide, black ink.
OFEV	NINTEDANIB (NINTEDANIB ESILATE)	02443074	BOEHRINGER INGELHEIM (CANADA) LTD LTEE	5180 South Service Road Burlington Ontario Canada L7L 5H4	150 MG	CAPSULE	1	100 and 150 mg of nintedanib (as a free base) corresponding to 120.40 mg and 180.60 mg of nintedanib ethanesulfonate (esilate), respectively: Capsule fill: Medium chain triglycerides, hard fat, soya lecithin (E322) Capsule shell: Gelatin, glycerol 85 %, titanium dioxide (E171), iron oxide red (E172), iron oxide yellow (E172), black ink (Opacode®) Black ink: Shellac glaze, iron oxide black (E172), propylene glycol (E1520)	OFEV	NINTEDANIB ESYLATE	00597-0145-60	205832	Boehringer Ingelheim Pharmaceuticals, Inc. 900 Ridgebury Road P.O. Box 368 Ridgefield, CT 06877	100 mg or 150 mg of nintedanib (equivalent to 120.40 mg or 180.60 mg nintedanib ethanesulfonate, respectively). The inactive ingredients of OFEV are the following: Fill Material: triglycerides, hard fat, lecithin. Capsule Shell: gelatin, glycerol, titanium dioxide, red ferric oxide, yellow ferric oxide, black ink.

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REVOLADE	ELTROMBOPAG (ELTROMBOPAG OLAMINE)	02361825	NOVARTIS PHARMACEUTICALS CANADA INC	385 Bouchard Blvd Dorval Quebec Canada, H9S 1A9	25 MG	TABLET	1	25 mg or 50 mg of eltrombopag as eltrombopag olamine. The tablet also contains the following nonmedicinal ingredients: magnesium stearate, mannitol, microcrystalline cellulose, povidone, sodium starch glycolate, hypromellose, macrogol and titanium dioxide. REVOLADE 25 mg tablets also contain polysorbate. REVOLADE 50 mg tablets also contain iron oxide yellow and iron oxide red.	PROMACTA	ELTROMBOPAG OLAMINE	00078-0685-15	022291	NOVARTIS One Health Plaza East Hanover, NJ 07936	eltrombopag olamine 25 mg or 50 mg of eltrombopag free acid. The inactive ingredients of PROMACTA tablets are: Tablet Core: magnesium stearate, mannitol, microcrystalline cellulose, povidone, and sodium starch glycolate. Coating: FD&C Blue No. 2 aluminum lake (50-mg tablet), FD&C Yellow No. 6 aluminum lake (25-mg tablet), hypromellose, Iron Oxide Black and Iron Oxide Red (75-mg tablet), polyethylene glycol 400, polysorbate 80 (12.5-mg tablet), or titanium dioxide.
REVOLADE	ELTROMBOPAG (ELTROMBOPAG OLAMINE)	02361833	NOVARTIS PHARMACEUTICALS CANADA INC	385 Bouchard Blvd Dorval Quebec Canada, H9S 1A9	50 MG	TABLET	1	25 mg or 50 mg of eltrombopag as eltrombopag olamine. The tablet also contains the following nonmedicinal ingredients: magnesium stearate, mannitol, microcrystalline cellulose, povidone, sodium starch glycolate, hypromellose, macrogol and titanium dioxide. REVOLADE 25 mg tablets also contain polysorbate. REVOLADE 50 mg tablets also contain iron oxide yellow and iron oxide red.	PROMACTA	ELTROMBOPAG OLAMINE	00078-0686-15	022291	NOVARTIS One Health Plaza East Hanover, NJ 07936	eltrombopag olamine 25 mg or 50 mg of eltrombopag free acid. The inactive ingredients of PROMACTA tablets are: Tablet Core: magnesium stearate, mannitol, microcrystalline cellulose, povidone, and sodium starch glycolate. Coating: FD&C Blue No. 2 aluminum lake (50-mg tablet), FD&C Yellow No. 6 aluminum lake (25-mg tablet), hypromellose, Iron Oxide Black and Iron Oxide Red (75-mg tablet), polyethylene glycol 400, polysorbate 80 (12.5-mg tablet), or titanium dioxide.
AFINITOR DISPERZ	EVEROLIMUS	02425645	NOVARTIS PHARMACEUTICALS CANADA INC	385 Bouchard Blvd Dorval Quebec Canada, H9S 1A9	2 MG	TABLET FOR SUSPENSION	1	2mg everolimus, butylated hydroxytoluene (E321), cellulose microcrystalline, crospovidone, hypromellose, lactose monohydrate, magnesium stearate, mannitol, silica colloidal anhydrous.	AFINITOR DISPERZ	EVEROLIMUS	00078-0626-51	203985	NOVARTIS One Health Plaza East Hanover, NJ 07936	2 mg of everolimus and the following inactive ingredients: butylated hydroxytoluene, colloidal silicon dioxide, crospovidone, hypromellose, lactose monohydrate, magnesium stearate, mannitol, and microcrystalline cellulose.
GILENYA	FINGOLIMOD (FINGOLIMOD HYDROCHLORIDE)	02365480	NOVARTIS PHARMACEUTICALS CANADA INC	385 Bouchard Blvd Dorval Quebec Canada, H9S 1A9	0.5 MG	CAPSULE	1	0.5 mg fingolimod (as fingolimod hydrochloride) For the 0.5 mg: Magnesium stearate, mannitol, gelatin, titanium dioxide, yellow iron oxide.	GILENYA	FINGOLIMOD HYDROCHLORIDE	00078-0607-15	022527	NOVARTIS One Health Plaza East Hanover, NJ 07936	0.56 mg of fingolimod hydrochloride, equivalent to 0.5 mg of fingolimod, gelatin, magnesium stearate, mannitol, titanium dioxide, and yellow iron oxide.
JAKAVI	RUXOLITINIB (RUXOLITINIB PHOSPHATE)	02434814	NOVARTIS PHARMACEUTICALS CANADA INC	385 Bouchard Blvd Dorval Quebec Canada, H9S 1A9	10 MG	TABLET	1	10 mg ruxolitinib free base (as ruxolitinib phosphate), hydroxypropylcellulose, 142.90 mg lactose monohydrate, magnesium stearate, microcrystalline cellulose, colloidal silicon dioxide, sodium starch glycolate (Type A), povidone.	JAKAFI	RUXOLITINIB PHOSPHATE	50881-0010-60	202192	INCYTE CORP 1801 Augustine Cut-off Wilmington, DE 19803	ruxolitinib phosphate equivalent to 10 mg of ruxolitinib free base together with microc1ystalline cellulose, lactose monohydrate, magnesium stearate, colloidal silicon dioxide, sodium starch glycolate, povidone and hydroxypropyl cellulose.
XELJANZ XR	TOFACITINIB (TOFACITINIB CITRATE)	02470608	PFIZER CANADA ULC	17300 Trans-Canada Highway Kirkland Quebec Canada H9J 2M5	11 MG	TABLET	1	11 mg tofacitinib (as tofacitinib citrate), sorbitol, hydroxyethyl cellulose, copovidone, magnesium stearate. The Film Coat contains cellulose acetate, hydroxypropyl cellulose, HPMC 2910/hypromellose, titanium dioxide, triacetin, red iron oxide. The Printing ink contains shellac glaze, ammonium hydroxide, propylene glycol, ferrosoferric oxide/black iron oxide	XELJANZ XR	TOFACITINIB CITRATE	00069-0501-30	208246	PFIZER 235 East 42nd Street New York, NY 10017	11 mg tofacitinib (equivalent to 17.77 mg tofacitinib citrate) and the following inactive ingredients: cellulose acetate, copovidone, hydroxyethyl cellulose, hydroxypropyl cellulose, HPMC 2910/Hypromellose, magnesium stearate, red iron oxide, sorbitol, titanium dioxide and triacetin. Printing ink contains, ammonium hydroxide, ferrosoferric oxide/black iron oxide, propylene glycol, and shellac glaze.
VOTRIENT	PAZOPANIB (PAZOPANIB HYDROCHLORIDE)	02352303	NOVARTIS PHARMACEUTICALS CANADA INC	385 Bouchard Blvd Dorval Quebec Canada, H9S 1A9	200 MG	TABLET	1	200MG (pazopanib as pazopanib hydrochloride), magnesium stearate, microcrystalline cellulose, povidone (K30) and sodium starch glycollate. The tablet coating contains the following excipients; hypromellose, iron oxide black (E172 – 200mg tablet), macrogol, polysorbate 80 and titanium dioxide (E171).	VOTRIENT	PAZOPANIB HYDROCHLORIDE	00078-0670-66	022465	NOVARTIS One Health Plaza East Hanover, NJ 07936	200 mg of pazopanib equivalent to 216.7 mg of pazopanib hydrochloride. The inactive ingredients of VOTRIENT are: Tablet Core: Magnesium stearate, microcrystalline cellulose, povidone, and sodium starch glycolate. Coating: Gray filmcoat: Hypromellose, iron oxide black, macrogol/polyethylene glycol 400 (PEG 400), polysorbate 80, and titanium dioxide.

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BYDUREON BCISE	EXENATIDE	02483203	ASTRAZENECA CANADA INC	1004 Middlegate Road, Suite 5000 Mississauga Ontario Canada L4Y 1M4	2 MG/0.85 ML	SUSPENSION (EXTENDED RELEASE)	1	2 mg exenatide (as white to off-white microspheres suspended in a MCT vehicle) Sufficient suspension to deliver 2 mg of exenatide extended-release in 0.85 mL vehicle Composition: Microsphere formulation: Exenatide, poly (D,L-lactide-co-glycolide), sucrose Vehicle: Medium chain triglycerides (MCT)	BYDUREON BCISE	EXENATIDE	00310-6540-04	209210	ASTRAZENECA LP PO BOX 15437 WILMINGTON, DE 19850	2MG exenatide, polylactide-co-glycolide and sucrose Contents of liquid (diluent): Inactive Ingredients: medium chain triglycerides
RESTASIS	CYCLOSPORIN	02355655	ALLERGAN INC	500 85 Enterprise Blvd Markham Ontario Canada L6G 0B5	0.05%	EMULSION	1	0.05% w/v is available as a sterile preservative-free emulsion supplied in low density polyethylene single use vials containing 0.4 mL each. Each mL of emulsion contains cyclosporine 0.5 mg with the following non-medicinal ingredients: Carbomer Copolymer Type A, castor oil, glycerin, polysorbate 80, purified water and sodium hydroxide to adjust the pH.	RESTASIS	CYCLOSPORINE	00023-9163-30	050790	ALLERGAN 5 Giralda Farms Madison, NJ 09740	Each mL of RESTASIS® ophthalmic emulsion contains: Active: cyclosporine 0.05%. Inactives: glycerin; castor oil; polysorbate 80; carbomer copolymer type A; purified water; and sodium hydroxide to adjust pH.
BIKTARVY	EMTRICITABINE, TENOFOVIR ALAFENAMIDE AND BICTEGRAVIR	02478579	GILEAD SCIENCES CANADA INC	600 6711 Mississauga Road Mississauga Ontario Canada L5N 2W3	50-200-25 MG	TABLET	3	50 mg of bictegravir (equivalent to 52.5 mg of bictegravir sodium), 200 mg of emtricitabine, and 25 mg of tenofovir alafenamide (equivalent to 28.0 mg of tenofovir alafenamide hemifumarate), Microcrystalline Cellulose, Croscarmellose Sodium, Magnesium Stearate Film-Coating: Iron Oxide Black, Iron Oxide Red, Polyethylene Glycol, Polyvinyl Alcohol, Talc, Titanium Dioxide	BIKTARVY	**BICTEGRAVIR SODIUM; EMTRICITABINE; TENOFOVIR ALAFENAMIDE FUMARATE**	61958-2501-01	210251	Gilead Sciences, Inc. 333 Lakeside Drive Foster City, CA 94404	50 mg of bictegravir (BIC) (equivalent to 52.5 mg of bictegravir sodium), 200 mg of emtricitabine (FTC), and 25 mg of tenofovir alafenamide (TAF) (equivalent to 28 mg of tenofovir alafenamide fumarate), croscarmellose sodium, magnesium stearate, and microcrystalline cellulose. The tablets are film-coated with a coating material containing iron oxide black, iron oxide red, polyethylene glycol, polyvinyl alcohol, talc, and titanium dioxide.
CABOMETYX	CABOZANTINIB	02480824	IPSEN BIOPHARMACEUTICALS CANADA INC	SUITE 505 5060 Spectrum Way Mississauga Ontario Canada L4W 5N5	20 MG	TABLET	1	cabozantinib as cabozantinib (S)-malate , colloidal Silicon Dioxide, Croscarmellose Sodium, Hydroxypropyl Cellulose, Hypromellose 2910, Iron Oxide Yellow, Lactose Anhydrous, Magnesium Stearate, Microcrystalline Cellulose, Titanium Dioxide and Triacetin.	CABOMETYX	CABOZANTINIB	42388-024-26	208692	Exelixis, Inc. 1851 Harbor Bay Parkway Alameda, CA 94502	20 mg, 40 mg, or 60 mg of cabozantinib, which is equivalent to 25 mg, 51 mg, or 76 mg of cabozantinib (S)-malate, respectively. CABOMETYX also contains the following inactive ingredients: microcrystalline cellulose, lactose anhydrous, hydroxypropyl cellulose, croscarmellose sodium, colloidal silicon dioxide, and magnesium stearate.
CABOMETYX	CABOZANTINIB	02480832	IPSEN BIOPHARMACEUTICALS CANADA INC	SUITE 505 5060 Spectrum Way Mississauga Ontario Canada L4W 5N6	40 MG	TABLET	1	cabozantinib as cabozantinib (S)-malate , colloidal Silicon Dioxide, Croscarmellose Sodium, Hydroxypropyl Cellulose, Hypromellose 2910, Iron Oxide Yellow, Lactose Anhydrous, Magnesium Stearate, Microcrystalline Cellulose, Titanium Dioxide and Triacetin.	CABOMETYX	CABOZANTINIB	42388-025-26	208692	Exelixis, Inc. 1851 Harbor Bay Parkway Alameda, CA 94502	20 mg, 40 mg, or 60 mg of cabozantinib, which is equivalent to 25 mg, 51 mg, or 76 mg of cabozantinib (S)-malate, respectively. CABOMETYX also contains the following inactive ingredients: microcrystalline cellulose, lactose anhydrous, hydroxypropyl cellulose, croscarmellose sodium, colloidal silicon dioxide, and magnesium stearate.
CABOMETYX	CABOZANTINIB	02480840	IPSEN BIOPHARMACEUTICALS CANADA INC	SUITE 505 5060 Spectrum Way Mississauga Ontario Canada L4W 5N7	60 MG	TABLET	1	cabozantinib as cabozantinib (S)-malate , colloidal Silicon Dioxide, Croscarmellose Sodium, Hydroxypropyl Cellulose, Hypromellose 2910, Iron Oxide Yellow, Lactose Anhydrous, Magnesium Stearate, Microcrystalline Cellulose, Titanium Dioxide and Triacetin.	CABOMETYX	CABOZANTINIB	42388-023-26	208692	Exelixis, Inc. 1851 Harbor Bay Parkway Alameda, CA 94502	20 mg, 40 mg, or 60 mg of cabozantinib, which is equivalent to 25 mg, 51 mg, or 76 mg of cabozantinib (S)-malate, respectively. CABOMETYX also contains the following inactive ingredients: microcrystalline cellulose, lactose anhydrous, hydroxypropyl cellulose, croscarmellose sodium, colloidal silicon dioxide, and magnesium stearate.

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GENVOYA	EMTRICITABINE, TENOFOVIR ALAFENAMIDE, ELVITEGRAVIR AND COBICISTAT	02449498	GILEAD SCIENCES CANADA INC	600 6711 Mississauga Road Mississauga Ontario Canada L5N 2W3	150-150-200-10 MG	TABLET	4	Each tablet contains 150 mg of elvitegravir, 150 mg of cobicistat, 200 mg of emtricitabine, and 10 mg of tenofovir alafenamide (as 11.2 mg of tenofovir alafenamide hemifumarate).The tablets also include the following inactive ingredients: croscarmellose sodium, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, silicon dioxide, and sodium lauryl sulfate. The tablets are coated with a coating material containing polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc, indigo carmine aluminum lake, and iron oxide yellow.	GENVOYA	RICITABINE; TENO	61958-1901-1	207561	Gilead Sciences, Inc. 333 Lakeside Drive Foster City, CA 94404	Each tablet contains 150 mg of elvitegravir, 150 mg of cobicistat, 200 mg of emtricitabine, and 10 mg of tenofovir alafenamide (equivalent to 11.2 mg of tenofovir alafenamide fumarate). The tablets include the following inactive ingredients: croscarmellose sodium, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, silicon dioxide, and sodium lauryl sulfate. The tablets are film-coated with a coating material containing FD&C Blue No. 2/indigo carmine aluminum lake, iron oxide yellow, polyethylene glycol, polyvinyl alcohol, talc, and titanium dioxide.
TRIUMEQ	LAMIVUDINE, ABACAVIR AND DOLUTEGRAVIR	02430932	VIIV HEALTHCARE ULC	245 Boulevard Armand-Frappier Laval Quebec Canada H7V 4A7	600-50-300 MG	TABLET	3	nts: D-mannitol, magnesium stearate, mic	TRIUMEQ	ABACAVIR SULFATE; DOLUTEGRAVIR SODIUM; LAMIVUDINE	49702-231-13	205551	ViiV Healthcare Company c/o GlaxoSmithKline Five Moore Drive, P.O. Box 13398 Research Triangle Park, NC 27709	Each film-coated tablet contains abacavir sulfate equivalent to 600 mg of abacavir, dolutegravir sodium equivalent to 50 mg of dolutegravir, and 300 mg of lamivudine. TRIUMEQ tablets are purple, biconvex, oval, debossed with "572 Tri" on one side and contain the inactive ingredients D-mannitol, magnesium stearate, microcrystalline cellulose, povidone, and sodium starch glycolate. The tablet film-coating (OPADRY® II Purple 85F90057) contains the inactive ingredients iron oxide black, iron oxide red, macrogol/PEG, polyvinyl alcohol–part hydrolyzed, talc, and titanium oxide.
ODEFSEY	EMTRICITABINE; RILPIVIRINE HYDROCHLORIDE; TENOFOVIR ALAFENAMIDE FUMARATE	208351	GILEAD SCIENCES CANADA INC	600 6711 Mississauga Road Mississauga Ontario Canada L5N 2W3	200-25-25 MG	TABLET	3	Each tablet contains 200 mg of FTC, 25 mg of RPV (as 27.5 mg of RPV hydrochloride) and 25 mg of TAF (as 28.0 mg of TAF hemifumarate). The tablets also include the following inactive ingredients: croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polysorbate 20 and povidone. The tablets are film-coated with a coating material containing polyvinyl alcohol, titanium dioxide, macrogol/polyethylene glycol, talc, and iron oxide black.	ODEFSEY	EMTRICITABINE; RILPIVIRINE HYDROCHLORIDE; TENOFOVIR ALAFENAMIDE FUMARATE	61958-2101- 1	208351	Gilead Sciences, Inc. 333 Lakeside Drive Foster City, CA 94404	Each tablet contains 200 mg of FTC, 25 mg of RPV (equivalent to 27.5 of rilpivirine hydrochloride) and 25 mg of TAF (equivalent to 28 mg of tenofovir alafenamide fumarate) and the following inactive ingredients: croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polysorbate 20, and povidone. The tablets are film-coated with a coating material containing iron oxide black, polyethylene glycol, polyvinyl alcohol, talc, and titanium dioxide.

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TRUVADA	TENOFOVIR DISOPROXIL AND EMTRICITABINE	02274906	GILEAD SCIENCES CANADA INC	600 6711 Mississauga Road Mississauga Ontario Canada L5N 2W3	200-300 MG	TABLET	2	Each tablet contains 200 mg of emtricitabine and 300 mg of tenofovir DF (which is equivalent to 245 mg of tenofovir disoproxil), as active ingredients. The tablets also include the following inactive ingredients: croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, and pregelatinized starch (gluten free). The tablets are coated with Opadry II Blue Y–30–10701, which contains FD&C Blue #2 aluminum lake, hydropropylmethylcellulose 2910, lactose monohydrate, titanium dioxide, and triacetin. The tablets are blue, capsule-shaped, filmcoated, debossed with “GILEAD” on one side and with “701” on the other side. Each bottle contains 30 tablets and a desiccant (silica gel canister or sachet) and is closed with a childresistant closure.	TRUVADA	EMTRICITABINE; TENOFOVIR DISOPROXIL FUMARATE	61958-0701-1	21-752	Gilead Sciences, Inc. 333 Lakeside Drive Foster City, CA 94404	Each film-coated tablet contains 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate, (which is equivalent to 245 mg of tenofovir disoproxil), as active ingredients. The tablets also include the following inactive ingredients: croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, and pregelatinized starch (gluten free). The tablets are coated with Opadry II Blue Y-30-10701, which contains FD&C Blue #2 aluminum lake, hypromellose, lactose monohydrate, titanium dioxide, and triacetin.
ELIQUIS	APIXABAN	02397714	BRISTOL-MYERS SQUIBB CANADA	2344 Boul. Alfred-Nobel, Suite 300 Montréal (St-Laurent) Quebec Canada H4S 0A4	5 MG	TABLET	1	Active Ingredient: Apixaban Excipients: Tablet core: Anhydrous lactose, microcrystalline cellulose, croscarmellose sodium, sodium lauryl sulfate and magnesium stearate. Film coat: Lactose monohydrate, hypromellose, titanium dioxide, triacetin, and yellow iron oxide (2.5 mg tablets) or red iron oxide (5 mg tablets).	ELIQUIS	**APIXABAN**	0003-0894-21	202155	Bristol-Myers Squibb P.O. Box 4000 Princeton, NJ 08543-4000	Active ingredient: apixaban. Inactive ingredients: anhydrous lactose, microcrystalline cellulose, croscarmellose sodium, sodium lauryl sulfate, and magnesium stearate. The film coating contains lactose monohydrate, hypromellose, titanium dioxide, triacetin, and yellow iron oxide (2.5 mg tablets) or red iron oxide (5 mg tablets).