IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

Case No. 8:22-cv-1981-TPB-JSS

STATE OF FLORIDA, et al.,
Plaintiffs,

v.

FOOD AND DRUG ADMINISTRATION, et al.,
Defendants.

PLAINTIFFS' OPPOSITION TO
DEFENDANTS' MOTION TO STAY COUNTS ONE AND FOUR

The Court should deny Defendants' motion to stay Plaintiffs' claims alleging Defendants have engaged in unlawful and unreasonable delay in adjudicating Plaintiffs' SIP Proposal, which seeks approval to import certain prescription drugs from Canada pursuant to federal law. Defendants' motion is unnecessary and would only further delay resolution of this important case.

The premise of Defendants' motion is that Plaintiffs' supplemental SIP Proposal, which responds to the November 2022 RFI issued by Defendants, will supposedly not be filed "until a date unknown" and thus Defendants face the "Gordian knot" of both trying to adjudicate Florida's SIP Proposal "right now" and also waiting until the supplemental SIP Proposal is submitted. Motion at 2, ECF No. 71.

Both parts of this supposed Gordian knot are unsupported and, in any event, have been caused by Defendants. *First*, Plaintiffs have now submitted their supplemental SIP Proposal, a copy of which (without exhibits) is attached to this opposition. *See* Ex. A. Although Plaintiffs maintain that their SIP Proposal should already have been granted based on their prior submissions and that the November 2022 RFI was primarily a stall tactic by Defendants, this now-submitted supplement ensures there can be no possible hindrance to Defendants promptly reviewing and granting Plaintiffs' SIP Proposal. *Second*, given the lengthy delay that Plaintiffs have already endured (approaching 900 days), including as a result of the suspiciously timed November 2022 RFI itself, there is no evidence that Defendants have demonstrated any interest in adjudicating Florida's SIP Proposal "right now."

Because the premises of Defendants' motion are unsupported, the Court should deny the motion on that basis alone.

There are additional reasons for denying the motion. Defendants' proposed stay would apparently not extend to discovery or Plaintiffs' FOIA claims, *see* Motion at 2 n.2, ECF No. 71, so it is unclear what a stay at this point would accomplish even under Defendants' view. The Court has already set (and adjusted) a schedule for the rest of this case, which remains more than reasonable given that Plaintiffs have now submitted the supplemental SIP Proposal. For example, summary judgment motions are currently due June 14,

which is 54 days away—almost exactly the amount of time Defendants seek for a stay (60 days). *See* ECF Nos. 44 & 62 (setting May 12 for the close of discovery, June 14 for summary judgment briefs, and a November Term trial).

Accordingly, there is no benefit from a stay. But there are certainly resulting harms. Defendants ask the Court to establish a precedent that agencies can delay indefinitely until sued, then rush out a lengthy and largely contrived request for information to stall the case and give the appearance of agency action, then obtain a stay of judicial proceedings on the basis that the agency hasn't yet received a response to its enormous request—all designed to further delay an adverse judgment. Allowing agencies to engage in such gamesmanship undermines the judicial review mandated by Congress in the Administrative Procedure Act and creates a moral hazard for agencies.

Indeed, staying this case would almost certainly result in further delay. Defendants notably propose only to file a "status report" 60 days after Plaintiffs submit their supplemental SIP Proposal. Motion at 6, ECF No. 71. In other words, even after the 60-day period, the case would not automatically resume with a pre-determined briefing date for summary judgment and trial, and Defendants would presumably advocate for filing periodic status reports while it continues to review Florida's SIP Proposal, meaning the case sits even further.

Defendants' proposal thus establishes a presumption of inactivity on the docket, which the parties or Court must affirmatively change to keep the case moving. By contrast, denying the motion for a stay—and thus maintaining the current deadlines for discovery, summary judgment, and trial—will establish a presumption of forward progress, ensuring Defendants do not continue their already lengthy delay in reviewing Florida's SIP Proposal.

Denying the motion to stay and keeping the already-set deadlines is therefore the best way to move this case along and thereby "conserve judicial resources." Motion at 5, ECF No. 71.

CONCLUSION

The Court should deny Defendants' motion.

Dated: April 21, 2023

Respectfully submitted,

ASHLEY MOODY
ATTORNEY GENERAL

/s/ James H. Percival
James H. Percival* (FBN 1016188)
CHIEF OF STAFF

Henry C. Whitaker (FBN 1031175)
SOLICITOR GENERAL

Natalie Christmas (FBN 1019180)
COUNSELOR TO THE ATTORNEY GENERAL

Office of the Attorney General
The Capitol, Pl-01
Tallahassee, Florida 32399-1050
(850) 414-3300
(850) 410-2672 (fax)
james.percival@myfloridalegal.com
* *Lead Counsel*

Counsel for the State of Florida

/s/ R. Trent McCotter
C. Boyden Gray (*pro hac vice*)
R. Trent McCotter (*pro hac vice*)*
Jared M. Kelson (*pro hac vice*)
BOYDEN GRAY & ASSOCIATES, PLLC
801 17th St. NW, #350
Washington, DC 20006
(202) 706-5488
mccotter@boydengrayassociates.com
* *Lead Counsel*

ANDREW T. SHEERAN
General Counsel
Florida Bar I.D. No. 0030599
Andrew.Sheeran@ahca.myflorida.com
Agency for Health Care Administration
2727 Mahan Drive, Mail Stop #3
Tallahassee, Florida 32308
(850) 412-3670

Counsel for Agency for Health Care Administration

CERTIFICATE OF SERVICE

I hereby certify that on April 21, 2023, I filed the foregoing via the Court's CM/ECF system, which will serve all counsel.

/s/ R. Trent McCotter
R. TRENT MCCOTTER

Ex. A

RON DESANTIS
GOVERNOR

JASON WEIDA
SECRETARY

April 21, 2023

Sandi Leigh Verbois, PhD, Director
U.S. Food and Drug Administration
Office of Drug Security, Integrity & Response
Office of Compliance
Center for Drug Evaluation and Research

Re: Florida Agency for Health Care Administration Section 804 Importation Program Proposal

Dear Director Verbois,

Since November 2020, the Florida Agency for Health Care Administration (Agency) and State of Florida have taken bold actions to lower prescription drug prices in our state. Florida's landmark Canadian Drug Importation proposal, the first of its kind in the nation, was developed to accomplish this goal. It is no secret that there has been friction between our state and federal agencies relevant to the program, causing a major delay in the program. While this program is stalled, Floridians are paying the price, which is unacceptable.

On November 16, 2022, the U.S. Food and Drug Administration (FDA) submitted a Request for Information (RFI) to the Agency consisting of two parts. On February 6, 2023, the Agency provided a response to the first request that addresses areas where the RFI lacked clear instructions on the statutory testing requirements and failed to justify the FDA's requests for additional materials pertaining to the cost analysis.

To this day, the FDA has not responded to the Agency to address the questions and concerns voiced in that letter. These questions and concerns remain the same. Therefore, the Agency has provided the second part of its response to the RFI to the best of our ability without the benefit of clarifying information, which was requested more than two years ago.

The Agency has included as attachments to this letter the State of Florida's amended Section 804 Importation Program Proposal, as well as point-by-point responses to the FDA's RFI. These materials include information regarding statutory testing by qualified laboratories, the cost analysis done in accordance with the FDA's requirements, and other elements such as the recall and compliance plans. The Agency has also included new proposed labeling that aligns with an updated list of prescription drugs proposed for importation.

The Agency remains committed to providing a safe and cost-effective importation program that can support Floridians, lower prescription drug prices, and yield cost savings that can be used to expand health care services. We await your feedback and eagerly look forward to making this proposal a reality

Sincerely,

Jason Weida
Secretary
Florida Agency for Health Care Administration

Melanie S. Griffin
Secretary
Florida Department of Business and Professional Regulation

2727 Mahan Drive • Mail Stop #1
Tallahassee, FL 32308
AHCA.MyFlorida.com

Facebook.com/AHCAFlorida
Twitter.com/AHCA_FL

Florida Agency for Health Care Administration Section 804 Importation Program Proposal
State's Response to Food and Drug Administration Request for Information Dated November 16, 2022

Page # of Letter	CFR Reference	Requirement	FDA's request	Florida Response/Status
Information on the Eligible Prescription Drugs				
1	251.3(d)(4)	The overview of the SIP Proposal must include… the approved NDA or ANDA number.	Ensure that SIP proposal includes the correct application number for the drug Genvoya is listed as ANDA 207561. The correct application number is NDA 207561.	See **Attachment D**: Wholesale Importation Drug List.
1	251.3(e)(1)	Identify…the manufacturer(s) of the finished dosage form and the active ingredient or ingredients of each eligible prescription drug that the SIP Sponsor seeks to import, if known or reasonably known…	Please clarify if the manufacturing facilities of the Health Products and Food Branch of Health Canada (HPFB)-approved and FDA-approved drugs are the same, if known or reasonably known. If different, the manufacturing location of the HPFB-approved product should be a location listed in the New Drug Application (NDA) or Abbreviated New Drug Application (ANDA).	See page 10 of the SIP proposal. At the time of this submission, the State does not know the addresses of the manufacturers' facilities that produce the finished dosage forms or active ingredients.
2	251.3(e)(5)	…The SIP Sponsor's importation plan must also include as much of the information that is required by § 251.5 about the HPFB-approved product and its FDA-approved counterpart as is available, including the name and quantity of the active ingredient, the inactive ingredients, and the dosage form.	The SIP Proposal appears to include information about the name and quantity of active ingredients, inactive ingredients, and dosage forms, but does not indicate if this information is applicable for both the HPFB-approved products and FDA-approved counterparts. Please clarify whether this information is the same for both versions. Also, please ensure that the information provided is accurate and as complete as possible given the information that is available. For example, for the drug Tradjenta, only mannitol is listed as an inactive ingredient, and for the drug Triumeq, lamivudine is not listed as an active ingredient. In addition, please note that there are instances where the proprietary names of FDA-approved drugs and HPFB-approved drugs are different. For example, Farxiga is the name of the FDA-approved drug and Forxiga is the name of the HPFB-approved drug.	See **Attachment D**: Wholesale Importation Drug List
			For the list of drugs that follows, please clarify if you are planning to import all strengths and dosage forms that are approved in the U.S. or just those that are listed in the SIP Proposal: Biktarvy, Descovy, Epclusa, Harvoni, Intelence, Isentress, Kaletra, Mavyret, and Spiriva Respimat.	Amended page 12 of the SIP proposal, Proposed Drug List. The State will import only the strengths and dosage forms that are listed in the SIP Proposal. See **Attachment D**: Wholesale

This log is provided only for convenience and should not be relied upon as a formal record of responses.

Florida Agency for Health Care Administration Section 804 Importation Program Proposal
State's Response to Food and Drug Administration Request for Information Dated November 16, 2022

Page # of Letter	CFR Reference	Requirement	FDA's request	Florida Response/Status
				Importation Drug List, for supporting documentation. Epclusa, Harvoni, Intelence, Isentress, Kaletra, Mavyret, and Spiriva Respimat have been removed from the Wholesale Importation Drug List.
2	251.3(e)(6)	Provide adequate evidence that each HPFB-approved drug's FDA-approved counterpart drug is currently commercially marketed in the United States.	You must provide supporting information to demonstrate that, for each HPFB-approved drug you are proposing to import, the FDA-approved counterpart drug is currently commercially marketed in the U.S. We recommend, at a minimum, including information from FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the Orange Book) to show that each drug product is listed in the Active Section.	See **Attachment D:** Wholesale Importation Drug List.
Information on the Statutory Testing Requirements				
2	251.3(d)(11)(i)	The overview of the SIP Proposal must include a summary of how the SIP Sponsor will ensure that the imported eligible prescription drugs meet the Statutory Testing requirements.	The SIP Proposal says that the State intends to partner with manufacturers that will perform required testing on each imported drug, but also suggests that for certain categories of drugs (for example, drugs that the SIP Proposal says are "produced in the same facilities, on the same manufacturing lines, and contain identical specifications and standards") it will not be necessary to perform Statutory Testing on these products. Please clarify that the manufacturer or the Importer will arrange for drugs imported under the SIP to be tested by a qualifying laboratory. Laboratory testing requirements must include that a statistically valid sample of the HPFB-approved drug be subjected to testing to confirm that the HPFB-approved drug meets the FDA-approved drug's specifications and standards, which include the analytical procedures and methods and the acceptance criteria. We also note that to test for degradation, a stability-indicating assay provided by the manufacturer must be conducted on the sample of the drug that is proposed for import.	See red text on pages 17-20 of the SIP proposal.

Florida Agency for Health Care Administration Section 804 Importation Program Proposal
State's Response to Food and Drug Administration Request for Information Dated November 16, 2022

Page # of Letter	CFR Reference	Requirement	FDA's request	Florida Response/Status
3			Further, the SIP Proposal lacks a summary of the State's specific plans to ensure that drugs imported under the SIP meet the FDA-approved drug's specifications and standards.	See red text on pages 17-20 of the SIP proposal.
3	251.3(e)(7)	The SIP Sponsor's importation plan must describe, to the extent possible, the testing that will be done to establish that the HPFB-approved drug meets the conditions in the NDA or ANDA for the HPFB-approved drug's FDA-approved counterpart. The SIP Sponsor's importation plan must also identify the qualifying laboratory that will conduct the Statutory Testing for the Importer, if the Importer is responsible for conducting the Statutory Testing, and it must establish that the laboratory is qualified in accordance with § 251.15 to conduct the tests.	The SIP Proposal briefly states that appropriate testing will be performed on certain drug products that will be imported. However, it only contains a listing of kinds of analytical testing and examination that are to be used in determining a drug's characteristics and compliance with specifications and standards. The SIP Proposal is general in nature and lacks information, for either the HPFB-approved drug or the FDA-approved counterpart, related to the specific testing that will be done to establish that the HPFB-approved drug meets the conditions in the NDA or the ANDA for the FDA-approved counterpart (per § 251.3(e)(7)).	See red text on pages 17-20 of the SIP proposal.
3			To the extent possible, relevant information must be provided that allows the FDA to confirm that the characteristics of the proposed imported drug conform to those of the FDA-approved drug. To the extent possible, please provide a description of and information about specific testing, analytical procedures and methods, and related acceptance criteria that will ensure that the HPFB-approved drug meets the conditions in the NDA or ANDA for the HPFB-approved drug's FDA-approved counterpart (per §§ 251.3(e)(7) and 251.16(d)).	See red text on pages 17-20 of the SIP proposal. See **Attachment D**: Wholesale Drug Importation List, for a side-by-side comparison of package inserts.
3			We acknowledge that the SIP Proposal has stated that each of the four qualifying laboratories is ISO 17025 certified and provided each laboratory's certificate number. However, based on the information provided in the SIP Proposal, FDA is unable to verify that these accreditations are current. Please	See **Table 3**, Contract Laboratories. See **Attachment G**: Laboratory Testing.

Florida Agency for Health Care Administration Section 804 Importation Program Proposal
State's Response to Food and Drug Administration Request for Information Dated November 16, 2022

Page # of Letter	CFR Reference	Requirement	FDA's request	Florida Response/Status
			provide the current ISO 17025 accreditation certificates for the four laboratories identified in the SIP Proposal.	
3			Please note that the acceptability of the qualifying laboratories could change. If a laboratory is inspected and receives an OAI (Official Action Indicated) classification; or, if the ISO 17025 accreditation for one of the labs expires, that laboratory would no longer be considered acceptable. We recommend that the state develop a plan to assure the ongoing compliance of these laboratories and a contingency plan if one, or more, of these laboratories is no longer acceptable.	See page 20 of the SIP proposal.
History of Violations				
4	251.3(e)(2)	Include an attestation and information statement containing a complete disclosure of any past criminal convictions or violations of State, Federal, or Canadian laws regarding drugs or devices against or by the responsible individual(s)… or an attestation that the responsible individual(s)… has not been involved in, or convicted of, any such violations.	Please provide information specified in this section of the final rule for the responsible individuals identified in the SIP Proposal.	See **Attachment A**: SIP Sponsor and Co-Sponsor, **Attachment B**: Importer, and **Attachment C**: Foreign Seller.
4	251.3(e)(3)	Include a list of all disciplinary actions, to include the date of and parties to any action imposed against the responsible individual(s)…by State, Federal, or Canadian regulatory bodies…for the previous 7 years prior to submission of the SIP Proposal.	Please provide information specified in this section of the final rule for the responsible individuals identified in the SIP Proposal.	See **Attachment A**: SIP Sponsor and Co-Sponsor, **Attachment B**: Importer, and **Attachment C**: Foreign Seller.

Florida Agency for Health Care Administration Section 804 Importation Program Proposal
State's Response to Food and Drug Administration Request for Information Dated November 16, 2022

Page # of Letter	CFR Reference	Requirement	FDA's request	Florida Response/Status
General Information				
4	251.3(e)(4)(ii)	The State and Federal inspectional history for the Importer for the previous 5 years or, if the Importer has been licensed for less than 5 years, for the duration of its period of licensure	In the SIP Proposal, LifeScience Logistics is associated with more than one address. Please explain what the role is for each address associated with LifeScience Logistics, LLC, and verify if there is inspectional history and current FDA registration for any address where SIP activities will occur.	See **Attachment B**: Importer.
4	251.3(e)(10)	Explain how the SIP Sponsor will ensure that all the participants in the SIP comply with the requirements of section 804 of the FD&C Act and the final rule	Please indicate the planned frequency of onsite inspections of the Importer's Florida warehouse.	See page 45 of the SIP proposal.
4	251.3(e)(15)(iii)	The SIP Sponsor's importation plan must include the SIP's compliance plan, which must include the creation of written compliance policies, procedures, and protocols.	Please provide specific written compliance policies, procedures, and protocols that have been created as part of the SIP's compliance plan.	See **Attachment I**: Compliance Plan.
5	251.3(e)(15)(iv)	The SIP Sponsor's importation plan must include the SIP's compliance plan, which must include the provision of education and training to ensure that Foreign Sellers, Importers, qualifying laboratories, and their employees understand their compliance-related obligations.	Please provide the frequency of education and training under this requirement.	See page 29 of the SIP proposal.
5	251.3(e)(15)(vi)	The SIP Sponsor's importation plan must include the SIP's compliance plan, which must include the adoption of processes and procedures for uncovering and addressing noncompliance, misconduct, or conflicts of interest.	Please provide processes and procedures for uncovering and addressing conflict of interest.	See pages 39-49 of the SIP proposal. See **Attachment J**: Confidentiality.

Florida Agency for Health Care Administration Section 804 Importation Program Proposal
State's Response to Food and Drug Administration Request for Information Dated November 16, 2022

Page # of Letter	CFR Reference	Requirement	FDA's request	Florida Response/Status
5	251.3(e)(16)	The SIP Sponsor's importation plan must explain how the SIP Sponsor will ensure that any information that the manufacturer supplies to authenticate a prescription drug being tested and confirm that the labeling of the prescription drug complies with labeling requirements under the FD&C Act, and any trade secrets or commercial or financial information that is privileged or confidential that the manufacturer supplies for the purposes of testing or otherwise complying with the FD&C Act and the final rule, are kept in strict confidence and used only for the purposes of testing or otherwise complying with the FD&C Act and the final rule.	Please provide a written policy regarding handling trade secrets or commercial or financial information that is privileged or confidential.	See **Attachment J**: Confidentiality.
Cost Savings				
5	251.3(d)(11)(v)	The overview of the SIP Proposal must include a summary of how the SIP Sponsor will ensure that the SIP will result in a significant reduction in the cost to the American consumer of the eligible prescription drugs that the SIP Sponsor seeks to import.		See pages 22-23 of the SIP proposal and **Attachment E**: Cost Savings.
5	251.3(e)(9)	The SIP Sponsor's importation plan must explain how the SIP Sponsor will ensure that the SIP will result in a significant reduction in the cost to the American consumer of the eligible prescription	Additional information is required to meaningfully evaluate the SIP Proposal's major finding that "Following full implementation, Florida is projecting over $150 million dollars in annual savings." Our evaluation approach starts by attempting to replicate the spending and cost-savings projections of the SIP Proposal, based on the data and assumptions included in the cost-savings	See pages 22-23 of the SIP proposal and **Attachment E**: Cost Savings.

Florida Agency for Health Care Administration Section 804 Importation Program Proposal
State's Response to Food and Drug Administration Request for Information Dated November 16, 2022

Page # of Letter	CFR Reference	Requirement	FDA's request	Florida Response/Status
		drugs that the SIP Sponsor seeks to import. The explanation must include any assumptions and uncertainty, and it must be sufficiently detailed to allow for a meaningful evaluation.	analysis. As drafted, the SIP Proposal does not include the details necessary to enable this first step of cost savings evaluation. Additionally, we need the sponsor to identify the sources of their pricing and spending data, explain any assumptions, and confirm that the costs included in the analysis are comprehensive. Our evaluation will also attempt to verify these sources of data, consider the reasonableness of these assumptions, and determine whether the cost-savings analysis is consistent with the other elements of the SIP Proposal and process outlined in the statute and final rule. a. The SIP Proposal does not contain a projection of the total expenditures the SIP Sponsor anticipates under the 'Plan Scenario' if the SIP Proposal is authorized and implemented. b. The SIP Proposal does not contain a projection of the total expenditures the SIP Sponsor anticipates under a 'Baseline Scenario' if the SIP Proposal is not authorized and implemented. c. The SIP Proposal should project cost savings for each year as the difference between the baseline costs anticipated under the Baseline Scenario and the 'Plan Scenario'.	
6			For the 'Plan Scenario', the SIP Proposal should contain annual projections of the anticipated total expenditures for each year of the proposed SIP, and identify the calendar year, or specific 12-month period covered, for each year of the analysis. a. The SIP Proposal reports a projection of total cost savings covering only one year, and does not identify the calendar year, or specific 12-month period for this projection. b. The SIP Proposal indicates "[W]hat Florida's population can save annually once the importation program's benefit fully matures should amount to the hundreds of millions", without identifying when the SIP Sponsor anticipates these cost savings.	See pages 22-23 of the SIP proposal and **Attachment E**: Cost Savings.

Florida Agency for Health Care Administration Section 804 Importation Program Proposal
State's Response to Food and Drug Administration Request for Information Dated November 16, 2022

Page # of Letter	CFR Reference	Requirement	FDA's request	Florida Response/Status
6			For the Baseline Scenario, the SIP Proposal should contain annual projections of the total expenditures covering at least the following: (1) the time period corresponding to the projections under the 'Plan Scenario', and (2) the time period between the most recent complete year of drug pricing data referenced in the SIP Proposal used to support the 'Plan Scenario' projections and the beginning of the 'Plan Scenario' projections. For example, if the SIP Proposal would be implemented in calendar years 2023 and 2024, and the most recent complete year of drug pricing data is calendar year 2018, the annual projection of the total expenditures under the Baseline Scenario should cover at least calendar years 2018 through 2024.	See pages 22-23 of the SIP proposal and **Attachment E**: Cost Savings.
6			The SIP Proposal should contain expenditure projections for each drug under the 'Plan Scenario' and Baseline Scenario. The sum of these drug-specific expenditure projections should be consistent with the total expenditure projections for each scenario.	See pages 22-23 of the SIP proposal and **Attachment E**: Cost Savings.
6			The SIP Proposal should contain price and quantity projections for each drug under the 'Plan Scenario' and Baseline Scenario. The product of the price and quantity projections should be consistent with the drug-specific expenditure projections for each scenario. a. The SIP Proposal includes price information for the Baseline Scenario for 37 drugs in 2018, and no other years. b. The SIP Proposal includes price, quantity, and drug-specific expenditure data for the Baseline Scenario for 6 drugs in 2018 and no other years. c. The SIP Proposal presents a table with "an example of the analysis conducted to determine the potential cost savings under the SIP using a sample of drugs used to treat HIV/AIDS," referencing data that "represents utilization and costs for one quarter of 2018". This example analysis, which contains several required elements, partially characterizes a 'Counterfactual Scenario' that the SIP Proposal was in effect in 2018; however, it does not include price, quantity, or drug-	See pages 22-23 of the SIP proposal and **Attachment E**: Cost Savings.

Florida Agency for Health Care Administration Section 804 Importation Program Proposal
State's Response to Food and Drug Administration Request for Information Dated November 16, 2022

Page # of Letter	CFR Reference	Requirement	FDA's request	Florida Response/Status
			specific expenditure projections for the Baseline Scenario or 'Plan Scenario' for years covered under the SIP Proposal.	
7			The SIP Proposal should reference drug pricing data that are sufficient to project annual expenditures projections for each drug under the 'Plan Scenario' and Baseline Scenario. a. The analysis contained in the SIP Proposal references data for 6 drugs covering one quarter of 2018. b. As noted above, the November 11, 2021 version of the SIP Proposal does not contain price and quantity projections for each drug under the 'Plan Scenario' and Baseline Scenario for the years covered by the SIP Proposal. Revisions to this SIP Proposal should contain a narrative to justify that the drug pricing data are sufficient to project annual expenditure projections for each drug under the 'Plan Scenario' and Baseline Scenario.	See pages 22-23 of the SIP proposal and **Attachment E**: Cost Savings.
7			The SIP Proposal should explain the sources and magnitude of the uncertainty of the 'Plan Scenario' and Baseline Scenario projections. a. The SIP Proposal suggests the SIP Sponsor has identified a source of uncertainty in the cost saving projections, reporting that "For the first year, the State is conservatively projecting that it can save between approximately $80 to $150 million." The SIP Proposal should explain the sources of the uncertainty that support this range of cost-savings estimates.	See pages 22-23 of the SIP proposal and **Attachment E**: Cost Savings.
7			The analysis contained in the SIP Proposal should be transparent and contain enough information about the data and methods to facilitate the reproducibility of its major findings. The SIP Proposal should clearly set out the basic assumptions, methods, and data underlying the analysis and discuss the uncertainties associated with the estimates.	See pages 22-23 of the SIP proposal and **Attachment E**: Cost Savings.

Florida Agency for Health Care Administration Section 804 Importation Program Proposal
State's Response to Food and Drug Administration Request for Information Dated November 16, 2022

Page # of Letter	CFR Reference	Requirement	FDA's request	Florida Response/Status
			a. The SIP Proposal should provide adequate citations of data sources used in the compiling of the underlying estimates for all quantitative elements, especially for the drug pricing and drug utilization elements. b. The SIP Proposal should explicitly report the magnitude of the markup to be applied to the listed Canadian price that the SIP Sponsor believes is likely to cover additional costs of importation and processing under the SIP. The SIP Proposal should provide sufficient justification for this assumption. c. The SIP Proposal should include estimates of other costs of implementation anticipated by the SIP Sponsor, including the costs of drug samples, testing, and other requirements under Section 804 and the Importation of Prescription Drugs Final Rule. The SIP Proposal should account for these costs when reporting the projected cost savings.	
8			The 'Plan Scenario' and Baseline Scenario projections should be consistent with reasonable assumptions of potentially related trends. a. For example, when projecting drug utilization, the SIP Sponsor could consider population growth rates; and when projecting drug-specific prices, the SIP Sponsor could consider trends in overall drug prices. b. The SIP Sponsor should consider accounting for drug-specific price and utilization trends in the Baseline Scenario. The SIP Proposal should document any drugs that are anticipated to lose marketing exclusivity during the time period covered in the Baseline Scenario, as indicated in FDA's Orange Book. For each of these products, the SIP Proposal should clearly state whether the SIP Sponsor anticipates any impact on the drug-specific price from this loss of exclusivity.	See pages 22-23 of the SIP proposal and **Attachment E**: Cost Savings.
8			In addition to addressing the above issues, please note the following:	See pages 22-23 of the SIP proposal and **Attachment E**: Cost Savings.

Florida Agency for Health Care Administration Section 804 Importation Program Proposal
State's Response to Food and Drug Administration Request for Information Dated November 16, 2022

Page # of Letter	CFR Reference	Requirement	FDA's request	Florida Response/Status
			a. The SIP Sponsor must provide information about how the program will result in a significant reduction in the cost to the American consumer of the eligible prescription drugs that the SIP Sponsor seeks to import. Note that, in response to public comment (85 FR 62101, Response 21), FDA indicated the following: "FDA intends to determine whether a reduction in cost is significant in the context of considering a specific proposal. The information needed to demonstrate anticipated cost savings to the American consumer will be dependent on the specific mechanisms which the SIP Proposal is using to reduce costs for American consumers. The SIP Proposal should clearly articulate the mechanism by which the proposal will reduce costs to consumers and provide relevant information given that context. To demonstrate expected cost savings, a SIP Sponsor could compare anticipated acquisition costs or consumer prices per unit of each eligible prescription drug that the SIP Sponsor is seeking to import. A SIP Sponsor could also compare the current retail cash price of the drugs. If the cost savings do not go to consumers directly, because, for example, they accrue to a healthcare provider or payor, the SIP Proposal would need to show that the SIP will result in a significant reduction in the cost of covered products to the American consumer. We anticipate that some SIP Sponsors may seek to import drugs to be used by patients in State-run programs in which consumers do not directly pay the cost of drugs. In such cases, a SIP Sponsor could submit information about whether cost-sharing expenses are reduced for the participants, or whether the program will result in cost savings that are passed on to consumers in other ways, such as increasing the number of people covered by a State program, or increasing the availability of drugs covered by the program." b. The SIP Sponsor is encouraged to adopt more recent price and utilization data and to provide data covering a longer time period. c. The SIP Sponsor is encouraged to provide a framework for ex-post quantitative evaluation of the SIP Proposal projections, should the SIP	

Florida Agency for Health Care Administration Section 804 Importation Program Proposal
State's Response to Food and Drug Administration Request for Information Dated November 16, 2022

Page # of Letter	CFR Reference	Requirement	FDA's request	Florida Response/Status
			Sponsor seek to renew the SIP at the conclusion of two years. In particular the framework should include: - Details of how the assumed markup to be added to the purchase price of Canadian drugs can be measured over the life of the SIP to enable more accurate future estimates of cost savings related to a renewal of the SIP. - Details of how actualized savings can be measured ex-post implementation of the SIP and compared to initial projections of savings to the American consumer to provide a clear ex-post analysis of the original projections.	
Information on the Recall Plan				
9	251.18(e)(3)(iii)	The recall plan must include sufficient procedures for the SIP Sponsor to specify the depth to which the recall will extend (e.g., wholesale, intermediate wholesale, retail or consumer level) if not specified by FDA.	Please provide information specified in this section of the final rule.	See pages 32-35 of the SIP proposal.
9	251.18(e)(3)(iv)	The recall plan must include sufficient procedures for the SIP Sponsor to notify the public about any hazard(s) presented by the recalled drug when appropriate to protect the public health.	Please provide information specified in this section of the final rule.	See SOP 1003 in **Attachment H**. See page 30-32 of the SIP proposal.
9	251.18(e)(3)(v)	The recall plan must include sufficient procedures for the SIP Sponsor to conduct effectiveness checks to verify that all consignees at the specified recall	Please provide information specified in this section of the final rule.	See SOP 1003 in **Attachment H**. See page 30-32 of the SIP proposal.

Florida Agency for Health Care Administration Section 804 Importation Program Proposal
State's Response to Food and Drug Administration Request for Information Dated November 16, 2022

Page # of Letter	CFR Reference	Requirement	FDA's request	Florida Response/Status
		depth have received notification about the recall and have taken appropriate action.		
Information on the Adverse Event Reporting Requirements				
9	251.3(d)(11)(iv)	The overview of the SIP Proposal must include a summary of how the SIP Sponsor will ensure that the post-importation pharmacovigilance and other requirements of the FD&C Act and the final rule are met.	Please describe how the Importer will fulfill its post-importation pharmacovigilance obligations.	See page 35. Ensuring that Floridians receive imported prescription drugs that are safe, effective, and less expensive is critical to the program's success. As part of achieving this goal, the Agency and importer will implement post-importation pharmacovigilance processes following the distribution of imported prescription drugs that will comply with the FDA's requirements as stated in Title 21 CFR § 314.80. These steps will include procedures for monitoring and reporting adverse events, completing and filing individual case safety reports (ICSRs), and communicating with the FDA. By exercising the following processes, the Agency and importer will provide post-importation surveillance to identify any possible adverse event and take actions as appropriate.
9	251.3(e)(11)(iv)	The SIP Sponsor's importation plan must describe the procedures the SIP Sponsor will use to ensure that the requirements of the final rule are met, including the steps that will be taken to ensure that the	Please describe how the Importer will fulfill its responsibilities for, among other things, the surveillance, receipt, evaluation, reporting to FDA, and recordkeeping of adverse events.	See pages 35-37 of the SIP proposal.

Florida Agency for Health Care Administration Section 804 Importation Program Proposal
State's Response to Food and Drug Administration Request for Information Dated November 16, 2022

Page # of Letter	CFR Reference	Requirement	FDA's request	Florida Response/Status
		Importer fulfills its responsibilities to submit adverse event, field alert, and other reports required by the SIP, the FD&C Act, or the final rule.		
Supply Chain Security				
10	251.3(e)(11)	The SIP Sponsor's importation plan must describe the procedures the SIP Sponsor will use to ensure that the requirements of this part are met, including the steps that will be taken to ensure that the:	Storage, handling, and distribution practices of supply chain participants, including transportation providers, meet the requirements of part 205 of this chapter and do not affect the quality or impinge on the security of the eligible prescription drugs - Please provide evidence of LifeScience Logistics licensure as a wholesale distributor in accordance with part 205.	See **Attachment B**, Importer.
10			Supply chain is secure Please provide more information on the steps the SIP sponsor will take to ensure applicable supply chain security requirements are met. Areas not addressed or lacking specificity include: - Compliance with requirements on the SIP Sponsor, manufacturer, foreign seller, and importer under 21 CFR 251.14, including verification and product identifier requirements described therein. - Evidence that the wholesale drug distributor (WDD) is authorized (e.g., evidence of LifeScience Logistics licensure and annual reporting to FDA). - SIP participants' compliance with section 582 of the FD&C Act, as applicable (see e.g., 21 CFR 251.14(d)(2), (d)(6)). - LifeScience Logistics authorized as repackager – Repacker/relabeler registration included in the SIP Proposal is expired.	See pages 44 and 45 of the SIP proposal and **Attachment I**, Compliance Plan. See **Attachment B**, Importer, for wholesale drug distributor license. See pages 42-44 of the SIP proposal and **Attachment H**, SIP Recall and Return. **Attachment F**, Relabeler, for current repacker/relabeler registration.

Florida Agency for Health Care Administration Section 804 Importation Program Proposal
State's Response to Food and Drug Administration Request for Information Dated November 16, 2022

Page # of Letter	CFR Reference	Requirement	FDA's request	Florida Response/Status
10	251.3(e)(14)	The SIP Sponsor's importation plan must include the SIP's return plan, including an explanation of how the SIP Sponsor will ensure that product that is returned after distribution in the United States is properly dispositioned in the United States, if it is a non-saleable return, in order to protect patients from expired or unsafe drugs, and an explanation of how the SIP Sponsor will prevent the non-saleable returned eligible prescription drugs from being exported from the United States. In the event that a returned eligible prescription drug may be considered saleable, include an explanation for how the returned product will be determined to be saleable and under what circumstances such eligible prescription drugs may be re-distributed in the United States.	Please describe the return plan for ensuring non-saleable returned products (e.g., damaged, expired) are properly dispositioned in the U.S., including: - How the importer or designee will ensure non-saleable returned product is properly dispositioned in the United States. - How non-saleable returned product will be removed from the pharmaceutical distribution supply chain. - Please describe how returned products will be determined to be saleable and under what circumstances such eligible prescription drugs may be re-distributed in the United States.	See **Attachment H**, SIP Recall and Return Processes.
11	251.3(e)(8)	the SIP Sponsor's importation plan must include a copy of the FDA-approved drug labeling for the FDA-approved counterpart of the eligible prescription drug, a copy of the proposed labeling that will be used for the eligible prescription drug, and a side-by-side comparison of the FDA-approved labeling and the proposed labeling, including the Prescribing Information, carton and container labeling, and patient labeling	You have provided the proposed Prescribing Information (PI) and FDA-approved patient labeling for your proposed imported drug followed in sequence by the PI and FDA-approved patient labeling for the source drug. Please provide a side-by-side comparison of the FDA-approved PI for the source drug and the proposed PI for the imported drug with all differences annotated and explained. Similarly, provide a side-by-side comparison of the FDA-approved patient labeling for the source drug and the proposed patient labeling for the imported drug with all differences annotated and explained.	See **Attachment D**: Wholesale Importation Drug List and Supporting Documentation.

Florida Agency for Health Care Administration Section 804 Importation Program Proposal
State's Response to Food and Drug Administration Request for Information Dated November 16, 2022

Page # of Letter	CFR Reference	Requirement	FDA's request	Florida Response/Status
		(e.g., Medication Guide, Instructions for Use, patient package inserts), with all differences annotated and explained. The SIP Proposal must also include a copy of the HPFB-approved labeling		
11			Some of the images for the proposed carton and container labeling are clear; however, others are not clear. Please ensure that the images of all the proposed carton and container labeling are clear and legible. For example, the images of the carton labeling for Combivent Respimat are illegible.	Labels submitted by LSL are legible. See **Attachment D**: Wholesale Importation Drug List and Supporting Documentation.
11			For some of the proposed imported drugs, you submitted some of, but not all, the approved labeling and the proposed labeling. Please ensure that all approved and proposed labeling is provided in the SIP Proposal including all the carton and container labeling. For example, for Combivent Respimat, the carton labeling was provided, but not the inhaler label.	See **Attachment D**: Wholesale Importation Drug List and Supporting Documentation.
11			If your SIP Proposal does not include all the package sizes available for the FDA-approved counterpart, then please revise the HOW SUPPLIED/STORAGE AND HANDLING section of the proposed PI to delete package sizes that are not being imported. For example, the proposed PI for Latuda and Januvia include the bottle or package sizes and NDC numbers of the FDA-approved drug that are not being imported under the SIP Proposal. Thus, please remove such information from the PI.	See **Attachment D**: Wholesale Importation Drug List and Supporting Documentation.
11			Please ensure that your proposed labeling is based on the most recent version of the FDA-approved labeling - The FDA-approved labeling for the NDA drug products can be found on Drugs@FDA. If such labeling is not available on Drugs@FDA, you may be able to obtain the labeling from the manufacturers. You can also obtain it through a Freedom of Information Act (FOIA) request.	Confirmed.

Florida Agency for Health Care Administration Section 804 Importation Program Proposal
State's Response to Food and Drug Administration Request for Information Dated November 16, 2022

Page # of Letter	CFR Reference	Requirement	FDA's request	Florida Response/Status
			- The FDA-approved labeling for Abbreviated New Drug Application (ANDA) drug products are typically not posted on Drugs@FDA. The labeling for FDA-approved ANDA drug products can be obtained through a FOIA request. You may also be able to obtain it from the manufacturers.	
12			Please ensure that references to other labeling that appear in the Importer's labeling are linked to the importer's labeling. - For example, the proposed Instructions for Use for Combivent Respimat lists a link to the website that includes the FDA-approved source drug labeling, not the importer's labeling.	Confirmed.
12	251.13(b)(4)	The labeling of the drug must be the same as the FDA-approved labeling under the applicable NDA or ANDA, with certain exceptions.	Please ensure that the design of the container and carton labeling is the same as the FDA-approved carton and container labeling given that different corporate trade dress, format, and organization is not permitted under 251.13(b)(4). Several of your proposed carton and container have different corporate trade dress, format, and organization than the source drug's carton and container labeling. - Manufacturer's copyright references or logos should not be removed. - Some of your proposed container labels include the following country of origin phrase: 'Made in XXXX'. Please fill in the information. - Please ensure that the proposed labeling does not contain any additional statements not permitted in the final rule. For example, the proposed Emtricitabine and Tenofovir Disoproxil Fumarate Tablets container label states "Do not cover ALERT box with pharmacy label" which is not included in the FDA-approved label.	Corrected. See **Attachment D**: Wholesale Importation Drug List and Supporting Documentation

Florida Agency for Health Care Administration Section 804 Importation Program Proposal
State's Response to Food and Drug Administration Request for Information Dated November 16, 2022

Page # of Letter	CFR Reference	Requirement	FDA's request	Florida Response/Status
12			You proposed to change the term 'distributed by' to 'originally distributed by'. However, the term "originally distributed by" is not an allowable statement under 21 CFR 251.13(b)(4).	Corrected. See **Attachment D**: Wholesale Importation Drug List and Supporting Documentation
12			Please review all labeling for spelling and formatting errors. For example, the proposed Emtricitabine and Tenofovir Disoproxil Fumarate Tablets: - Container label states "Pharmicist" instead of "Pharmacist" and "See package interest" instead of "See package insert". - PI on page 46 states "A I brand" instead of "All brand". - The border lines for Table 2 on page 11 of PI are missing. Also, the Table reference should appear in smaller font under the Table. Currently, the legend appears in the same size font as the following paragraphs and may be misinterpreted to be a heading.	Corrected. See **Attachment D**: Wholesale Importation Drug List and Supporting Documentation
12			Although the labeling you submitted for several of the source drugs were the last FDA approved version, some were not. Given that the labeling of the imported drug must be the same as the FDA-approved labeling with some acceptable differences, please submit the latest version of the FDA-approved labeling and ensure that the imported drug labeling is the same as the FDA-approved labeling except for the allowable exceptions.	Corrected. See **Attachment D**: Wholesale Importation Drug List and Supporting Documentation
13			The revision date should match the revision date of the latest FDA-approved labeling. When there is an update to the FDA-approved labeling in the future, the SIP labeling also needs to be updated.	Confirmed. See **Attachment D**: Wholesale Importation Drug List and Supporting Documentation.
13			Please ensure that the imprint code descriptions match the actual drug proposed to be imported. For example, for Emtricitabine and Tenofovir Disoproxil Fumarate Tablets, the HPFB-approved drug labeling states that the tablets are light blue to blue, "TV" on one side and with "7607" on the other side. However, the proposed labeling states that the tablets are white to off-white with "TV" on one side and "C75" on the other side.	Confirmed. See **Attachment D**: Wholesale Importation Drug List and Supporting Documentation.

Florida Agency for Health Care Administration Section 804 Importation Program Proposal
State's Response to Food and Drug Administration Request for Information Dated November 16, 2022

Page # of Letter	CFR Reference	Requirement	FDA's request	Florida Response/Status
13	251.13(b)(4)(i)	Please ensure that the Importer's NDC replaces the NDC of the FDA-approved drug at the time of importation. For example, NDCs are not replaced in the HOW SUPPLIED/STORAGE AND HANDLING section of the proposed Epclusa PI.	At the time of importation, the Importer's full NDC must replace any other NDC appearing on the label of the FDA-approved drug. Currently, the Importer's NDC is listed as 42067-XXXX-XX. - The contents of linear barcode on the container and carton labeling should contain the importer's NDC.	Corrected. See **Attachment D**: Wholesale Importation Drug List and Supporting Documentation.
13	251.13(b)(4)(iii)	Please ensure you add the name and place of business of the Importer to all proposed labeling including the PI, carton and container labeling, and patient labeling (e.g., Medication Guides (MGs), Instructions for Use (IFUs), Patient Package Inserts (PPIs)).	We recommend you add the importer's information at the end of PI in addition to HOW SUPPLIED/STORAGE AND HANDLING section. We recommend you add the importer's information at the end of the MG, IFU, and/or PPI. - The statement of the place of business should include the street address, city, State, and ZIP Code. The street address can be omitted if it is shown in a current city directory or telephone directory. If the importer's street address is not shown in a current city directory or telephone directory, the street address of the importer should be added.	Corrected. See **Attachment D**: Wholesale Importation Drug List and Supporting Documentation.
13			If the drug container is too small to fit the additional information required by this section or there is another reason to modify the labeling, you may submit a supplemental proposal to modify the labeling of an eligible prescription drug, in accordance with 251.13(d).	We do not need to modify.
13	251.13(b)(4)(iv)	Please ensure that correct firm names are listed in the statement for all labeling. For example, under HOW SUPPLIED/STORAGE AND HANDLING section of the proposed Latuda PI, Gilead Sciences is listed as the name of the applicant instead of the actual U.S. NDA holder, Sunovion Pharmaceuticals Inc.	Please ensure that the complete statement is used. For example, the carton labeling of Combivent Respimat is missing the phrase 'under the [Name of SIP Sponsor] Section 804 Importation Program.'	Corrected. See **Attachment D**: Wholesale Importation Drug List and Supporting Documentation.

Florida Agency for Health Care Administration Section 804 Importation Program Proposal
State's Response to Food and Drug Administration Request for Information Dated November 16, 2022

Page # of Letter	CFR Reference	Requirement	FDA's request	Florida Response/Status
14			Please ensure that the 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" appears in the HOW SUPPLIED/STORAGE AND HANDLING section of the PI. For example, the statement appears in the PATIENT COUNSELING INFORMATION section of the Harvoni PI.	Corrected. See **Attachment D**: Wholesale Importation Drug List and Supporting Documentation.
14	251.13(c)	Please provide the written procedure for the relabeling process of your proposed imported prescription drugs.'	If it is not possible to relabel a product without affecting the container closure system, such as a blister pack, then the product cannot be imported under a SIP as per the rule. The final rule does not allow repackaging of drugs that breaches the container closure system, such as a blister pack, which could introduce unnecessary risk of adulteration, degradation, and fraud for drugs imported under a SIP. The final rule also does not permit affixing a conforming label to the outside of the container closure system in lieu of relabeling the immediate container of the product. (i.e., repackaging the container closure is not permitted).	The Agency has removed such products from the importation drug list.
14			Farxiga, Tradjenta, Zepatier, Mavyret, Spiriva HandiHaler capsules are packaged in blister packs or dose packs according to the approved labeling. If relabeling these drug products would require breaching their container closure systems (e.g., breaking the foil on a blister pack), then that product cannot be imported under a SIP. Confirm that these products can be relabeled without breaching the container closure system. If not, remove any such drugs from the SIP.	The Agency has removed such products from the importation drug list.
14			Wixela is packaged in a moisture-protective foil pouch according to the approved labeling. The labeling also states that Wixela should be stored inside the unopened moisture-protective foil pouch and only removed from the pouch immediately before initial use and discarded 30 days after opening the foil pouch. If relabeling the inhaler would require opening the foil pouch, then Wixela cannot be imported under a SIP.	The Agency has removed such products from the importation drug list.

Florida Agency for Health Care Administration Section 804 Importation Program Proposal
State's Response to Food and Drug Administration Request for Information Dated November 16, 2022

Page # of Letter	CFR Reference	Requirement	FDA's request	Florida Response/Status
14			Incruse Ellipta is packaged in a moisture-protective foil tray according to the approved labeling. The labeling states that once the tray is opened, the inhaler should be discarded after 6 weeks. If relabeling the inhaler would require opening the foil tray, then Incruse Ellipta cannot be imported under a SIP.	The Agency has removed such products from the importation drug list.

The State of Florida's Section 804 Importation Program (SIP) Proposal for the Importation of Prescription Drugs from Canada

Submitted November 23, 2020

Amended April 19, 2021

Amended September 15, 2021

Amended November 11, 2021

Amended April 7, 2023

Table of Contents

REMAINDER OF PAGE INTENTIONALLY LEFT BLANK

THIS PAGE INTENTIONALLY LEFT BLANK.

History of Updates

Version #	Update	Change/Update Details
1.0	11/23/2020	Submission of Section 804 Importation Proposal (SIP) document
1.1	04/19/2021	Updated responsible individual for SIP sponsor and identified the Foreign Seller

1.2	09/15/2021	The following updates were made:
		• Added History of Updates
		• Updated name and contact information for the Responsible Individual of the SIP co-sponsor
		• Updated address of Importer and FDA-registered Relabeler
		• Updated the name and contact information for the State's point of contact
		• Provided updated signatures for the sponsor and co-sponsor
		• Updated key personnel for Importer
		• Updated **Attachment F** with evidence of Relabeler's FDA registration
		• Updated **Attachment D** with information for FDA-approved drug, Health Products and Food Branch (HPFB)-approved drug, proposed labeling, and comparison information between FDA-approved label and proposed label
		• Updated Compliance Plan
		  ○ Lines of Communication and Processes
		  ○ Procedures for Noncompliance, Misconduct, and Conflicts of Interest

1.3	11/11/2021	• Updated status on Foreign Seller • Matched the proposed list of drugs to match attachment
1.4	04/##/2023	The following updates were made: • Updates to Responsible Individuals • Wholesale Importation Drug List • LifeScience Logistics' roles • Laboratory Testing Techniques • Contract Laboratories • Explanation of cost-savings • Training frequency • Recall and Return Plan • Agency and Importer communication plan • Disposal of recalled drugs • Recall status reports • Adverse event reporting requirements • Compliance policies • SIP Sponsor and Co-Sponsor attestations • Foreign seller attachments

		• Clarifications in response to FDA letter dated November 16, 2022

Note: Red text denotes most recent updates.

REMAINDER OF PAGE INTENTIONALLY LEFT BLANK

Introduction

The State of Florida is submitting this proposal for its Section 804 Importation Program (SIP) as a component of the effort to reduce spending on prescribed drugs. With the state's Agency for Health Care Administration serving as the sponsor and Department of Business and Professional Regulation as co-sponsor, Florida is seeking to begin importing medications for consumers receiving services through the following state agencies/government programs:

- Department of Health (patients served through county health departments)
- Department of Corrections (inmates in the custody of the Department of Corrections)
- Department of Children and Families (patients in a public state mental hospital/treatment facility)
- Agency for Persons with Disabilities (clients residing in a public Institution for Individuals with Development Disabilities)
- Agency for Health Care Administration (recipients served in the Medicaid program)

By implementing an importation program across government agencies, the State of Florida will be able to reap significant savings.

This proposal will describe how the Canadian Prescription Drug Importation program will operate alongside our state partners to yield savings to Floridians.

The Agency for Health Care Administration (Agency) is responsible for licensing and regulating over 40,000 health care facilities in the State and is responsible for the administration of the Medicaid program. As, such, the Agency is best poised to implement and administer Florida's importation program. It currently oversees the Statewide Medicaid Managed Care program and provides health care for over four million five hundred thousand recipients. Additionally, the Agency has experience monitoring large-scale programs for quality and compliance with federal regulations. Acting as the co-sponsor, the Department of Business and Professional Regulation (DBPR) enforces regulations and provides oversight of Florida's prescription drug wholesalers. Its expertise in this area will allow it to support compliance with requirements such as supply chain standards, relabeling, repackaging, and recalling suspect products.

Because of the intricacies involved in operating an importation program, the State will enter into contractual relationships with entities to meet all requirements of the program. This will enable the State to establish business relationships with an Importer, Foreign Seller, manufacturer, and Relabeler. (The State will not repackage prescribed drugs imported under this proposal.) In addition, the State will establish relationships with qualifying laboratories to ensure prescription drug authenticity and compliance with U.S. Food and Drug Administration (FDA) requirements. Given the integral role that DBPR plays as the state's regulating authority for drug distribution, it will play a strategic part in implementing Florida's compliance plan, especially related to the handling of recalls and returns.

In regard to prescription drugs, Florida has chosen a limited set of prescription drugs that will yield the highest potential savings. After the program has proven successful, the State intends to amend its SIP to expand the list of medications that will be imported.

Ensuring the safe handling of these prescription drugs and having a secure supply chain is paramount to the SIP's success. To maintain safety, the Agency and DBPR will work with its Importer or their designee and contracted third parties to prevent shipments and batches from becoming lost or contaminated through the process. This begins when the prescription drugs marked for sale in Canada are sold to the Foreign Seller and imported into the U.S. and continues

through laboratory testing, relabeling, repackaging, and distribution in Florida. Strict adherence to safety standards is not only necessary for protecting Floridians but also for instilling public trust and confidence in prescription drug importation.

Contained in the following proposal is key information pertaining to Florida's importation program. In addition, the proposal outlines how the Agency and DBPR will maintain a secure supply chain, test sample batches, and label accordingly, all while bringing substantial savings to the State.

REMAINDER OF PAGE INTENTIONALLY LEFT BLANK

Florida's Canadian Prescription Drug Importation Program

The federal rule requires the SIP proposal to include the name of the program, identify the sponsor and co-sponsors, list prescription drugs to be imported, provide addresses of participating parties and companies, and give a summary of how the importation program will function securely. The chart below provides identifying information for the sponsor/co-sponsor and entities involved in the administration/operation of the program.

Name of the Program:	Florida's Canadian Prescription Drug Importation Program
Importation Program Sponsor:	The Florida Agency for Health Care Administration Address: 2727 Mahan Drive, Mail Stop #20 Tallahassee, FL 32308
Importation Program Co-Sponsor:	The Florida Department of Business and Professional Regulation Address: Division of Drugs, Cosmetics, and Devices 2601 Blair Stone Road Tallahassee, FL 32399-1047
Responsible Individuals:	Secretary Jason Weida Jason.Weida@ahca.myflorida.com (850) 412- 3600 2727 Mahan Drive Bldg. 3 Mailstop 1 Tallahassee, FL 32308 Secretary Melanie S. Griffin Melanie.Griffin@myfloridalicense.com (850) 413-0755 2601 Blair Stone Road Tallahassee, FL 32399-1047
Name and Address of Foreign Seller (must include a copy of their license to operate in Canada)**:**	Methapharm Inc. 81 Sinclair Boulevard Brantford, Ontario N3S 7X6 Canada See **Attachment C**, Foreign Seller, for a copy of the Foreign Seller's attestations, licenses, and inspectional histories.
Name and Address of Importer:	LifeScience Logistics, LLC (Licensed Wholesale Distributor) 3100 Olympus Blvd, Suite 100 Dallas, TX 75019 See **Attachment B**, Importer, for a copy of the Importer and their designee's licenses.
Name and Address of the FDA-Registered Relabeler	LifeScience Logistics, LLC 3100 Olympus Blvd, Suite 100 Dallas, TX 75019 See **Attachment F**, Relabeler, for inspection history.

(must include inspection history):	

Importation Program Summary:

The State is contracted with a licensed wholesale distributor, LifeScience Logistics, LLC to act as the State's Importer and assist the state with the following:

- Work with Methapharm Inc. to import prescription drugs from Canada.
- Negotiate drug prices from Methapharm Inc./manufacturer that will yield savings under the program.
- Relabel and repackage the product.
- Provide logistics support in transporting the eligible drugs into the U.S., including customs clearance, ensuring all laboratory testing is complete, and that the product is trackable and traceable throughout the supply chain.
- Distributing the imported eligible drugs to the end user (pharmacies dispensing on behalf of the state programs).

LifeScience Logistics, LLC is an experienced provider focused solely on the health care supply chain. They are a Verified-Accredited Wholesale Distributor (VAWD), ISO 13485 certified, licensed in all 50 States, and have an excellent state and federal audit/inspection history. They are also fully compliant with the Drug Supply Chain Security Act (DSCSA) requirements. The State is confident in their ability to meet all expectations related to safety and efficacy and will describe how it anticipates those requirements will be met throughout the SIP. See **Attachment B**, Importer, for supporting documentation.

Florida already has robust statutes and rules in place to ensure the safe handling and distribution of prescription drugs, which are more stringent than those of the FDA. As the agency that oversees the regulation of the state's prescription drug market, DBPR will ensure that the SIP participants will adhere to federal, state, and Canadian requirements. This will result in a secure supply chain that verifies the authenticity and purity of imported prescription drugs as well as maintaining strict labeling and packaging standards.

In addition to the statutory requirements listed in Chapter 499, Florida Statutes, DBPR's Division of Drugs, Cosmetics, and Devices is responsible for enforcing the rules listed in Chapter 61N of the Florida Administrative Code (F.A.C.). These rules provide requirements that include but are not limited to the following:

- Drug labeling (Rule 61N-1.006, F.A.C.)
- Product tracking and tracing:
  - Manufacturer requirements (Rule 61N-1.029, F.A.C.)
  - Wholesale distributor requirements (Rule 61N-1.030, F.A.C.)
  - Dispenser requirements (Rule 61N-1.031, F.A.C.)
- Inspections, investigations, and monitoring (Rule 61N-1.019, F.A.C.)

With a rigorous system already in place, DBPR will use its existing infrastructure to oversee the operation of a secure supply chain that safely distributes authentic prescription drugs that complies with and exceeds the FDA's requirements.

Florida intends for its imported prescription drug supply chain to function in the same manner as the domestic one. Once consumers receive their medication, the only visible difference is a label indicating that their medication was imported from Canada.

The total savings that Florida's importation program can realize is open-ended as continual analyses will be performed to optimize the impact. For the first year, the State is projecting significant savings that will also benefit the federal government because less federal financial participation will be required for Medicaid. However, what Florida's population can save annually once the importation program's benefit fully matures should amount to the hundreds of millions of dollars.

REMAINDER OF PAGE INTENTIONALLY LEFT BLANK

Florida's List of Prescription Drugs to Import

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

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

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

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

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

TABLE 2
PROPOSED DRUG LIST

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

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

REMAINDER OF PAGE INTENTIONALLY LEFT BLANK

Attestations and Information Statement

The FDA final rule language requires the SIP to:

> Include an attestation and information statement containing a complete disclosure of any past criminal convictions or violations of State, Federal, or Canadian laws regarding drugs or devices against or by the responsible individual(s), Foreign Seller, or Importer or an attestation that the responsible individual(s), Foreign Seller, or Importer has not been involved in, or convicted of, any such violations. Such attestation and information statement must include principals, any shareholder who owns 10 percent or more of outstanding stock in any non-publicly held corporation, directors, officers, and any facility manager or designated representative of such manager.

The State is including the necessary attestations for named parties in the SIP as follows:

- **Attachment A**, SIP Sponsor and Co-Sponsor
- **Attachment B**, Importer
- **Attachment C**, Foreign Seller

REMAINDER OF PAGE INTENTIONALLY LEFT BLANK

Disciplinary Actions and Inspectional History

The FDA final rule requires the SIP proposal to include:

- A list of all disciplinary actions, to include the date of and parties to any action imposed against the responsible individual(s), Foreign Seller, or Importer by State, Federal, or Canadian regulatory bodies, including any such actions against the principals, owners, directors, officers, quality unit, or any facility manager or designated representative of such manager for the previous seven years prior to submission of the SIP Proposal.
- The Health Canada inspectional history for the Foreign Seller for the previous five years or, if the Foreign Seller has been licensed for less than five years, for the duration of its period of licensure; and the State and Federal inspectional history for the Importer for the previous five years or, if the Importer has been licensed for less than five years, for the duration of its period of licensure.

Florida is also including the inspectional history for LifeScience Logistics, LLC, in **Attachment B**, Importer. LifeScience Logistics, LLC is associated with more than one address. **Table 1**, LifeScience Logistics Sites, provides the role for each address associated with LifeScience Logistics, LLC, and addresses the inspectional history and current FDA registration for any address where SIP activities will occur.

TABLE 1
LIFESCIENCE LOGISTICS SITES

Site Addresses	Site's Role in the Importation Process
LifeScience Logistics (Licensed Wholesale Distributor) 310 N. Galloway Rd. Lakeland, FL 33815	This Florida-licensed warehouse will serve as the point of storage and distribution for imported prescription drugs following their shipment to Florida. This site does not have or require FDA registration. The site's inspectional history is included in **Attachment B**, Importer.
LifeScience Logistics (Relabeler and Repackager) 3860 S 500 E Suite 200 Whitestown, IN 46075	This facility will oversee the storage of imported prescription drugs following importation from Canada and conduct relabeling and repackaging. The FDA registration and inspectional history for the Indiana site are included in **Attachment F**, Relabeler.
LifeScience Logistics (Administrative Office) 3100 Olympus Blvd Suite 100 Dallas, TX 75019	This is the corporate office for LifeScience Logistics and will provide support services for the Canadian Prescription Drug Importation Program. This site does not have a role in the supply chain, does not have or require FDA registration, and does not have an inspectional history.

In addition, the Importer has entered into an agreement with a Canadian prescription drug wholesaler, Methapharm Inc., to serve as the Foreign Seller. See **Attachment C**, Foreign Seller, for supporting documentation.

REMAINDER OF PAGE INTENTIONALLY LEFT BLANK

Evidence that Imported Drugs are Commercially Available

The FDA final rule requires that the SIP proposal provide adequate evidence that each Health Products and Food Branch (HPFB)-approved drug's FDA-approved counterpart drug is currently commercially marketed in the United States (U.S.).

The State has verified that the prescription drugs it seeks to import have FDA-approved counterparts that are readily available in the U.S. market. Florida can provide evidence as listed in the chart beginning on pages 11-12 that identifies drug names, active pharmaceutical ingredients, National Drug Codes (NDCs), and shared manufacturers with locations in both the U.S. and Canada.

Attachment D, Wholesale Importation Drug List, includes evidence from the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* to show that the imported drugs are commercially available in the U.S.

REMAINDER OF PAGE INTENTIONALLY LEFT BLANK

Description of Qualifying Laboratory Testing Techniques

The FDA final rule requires that the SIP proposal:

> Describe, to the extent possible, the testing that will be done to establish that the HPFB-approved drug meets the conditions in the NDA or ANDA for the HPFB-approved drug's FDA-approved counterpart. The SIP Sponsor's importation plan must also identify the qualifying laboratory that will conduct the Statutory Testing for the Importer, if the Importer is responsible for conducting the Statutory Testing, and it must establish that the laboratory is qualified in accordance with § 251.15 to conduct the tests.

Overview

Ensuring prescription drug purity and authenticity is essential to the success of Florida's SIP. By importing certain medications, the State takes on risks of introducing counterfeits or contaminated products into the drug supply. This is due in part to having an extended supply chain that can appear opportunistic to criminals looking to exploit a new program as well as having multiple points of transfer involving potential damage from mishandling or improper storage. To mitigate these risks, the Agency will require robust testing of imported prescription drugs to identify counterfeits, assess stability, and isolate contaminations. Through the Importer's contracted laboratories, Florida will ensure that these medications will undergo testing in accordance with the FDA's current and good manufacturing practices (CGMPs) as specified in Title 21 Code of Federal Regulations (CFR) § 211.

The Canadian manufacturer or Importer must arrange for laboratory testing to occur at a qualifying laboratory following the products' arrival in the U.S. Regardless of which entity arranges for the testing, an identified qualifying laboratory that meets FDA criteria (e.g., ISO 17025 accredited with an FDA inspection history) must perform the tests. All testing must occur in the U.S. following a shipment's clearance by the U.S. Customs and Border Patrol. This requirement applies to both initial and subsequent shipments. If the Canadian manufacturer does not arrange for testing, it must provide all necessary information (e.g., Certificate of Analysis and analytical references) to the Importer within 30 days of being requested, so the Importer can give it to a qualifying laboratory.

The qualifying laboratory will test each imported prescription drug in accordance with its FDA-approved version's specifications as listed in the United States Pharmacopeia (USP). These specifications include appropriate testing methods and acceptance criteria. If an imported prescription drug's testing results do not correspond to the USP's acceptance criteria, the Importer will quarantine the sample's lot to prevent sale or diversion. For imported prescription drugs that are still under their U.S. patents, the qualifying laboratory will either utilize testing methods provided by the manufacturer as required by Title 21 CFR § 251.5 or develop alternative testing techniques that provide consistent, linear results and are developed in accordance with CGMP and International Council of Harmonisation guidelines. The Agency cites the FDA's reference of this resource as guidance for manufacturers of generic drugs. Because the USP guidelines are not available until the U.S. patents expire for certain imported prescription drugs, the Agency and Importer will provide testing methods and acceptance criteria for those medications in the pre-import requests.

For every batch of prescription drugs imported to the U.S., the qualifying laboratory will obtain a sample sufficient for testing and retesting as necessary as indicated by Title 21 CFR § 211.84(b). In addition, it will retain these samples for at least one year following the batch's expiration date as stated in federal rule or longer as necessary.

Each selected sample will undergo testing to evaluate authenticity, stability, and contamination. If a sample fails in any of the three categories, it will be prohibited from distribution and dispositioned.

The following sections outline the specific laboratory tests Florida is planning to utilize when screening imported prescription drugs.

Selecting Samples for Testing

For laboratory testing to accurately verify whether a prescription drug is authentic, the selected samples analyzed must be randomly chosen using a statistically valid sampling plan (i.e., ANSI/ASQ Z1.4-2008 or MIL-STD-105E). To ensure this, the Agency and DBPR will require the Importer or its designee to take the following steps when selecting samples:

- The Importer or its designee must pull samples directly from the shipment or batch and cannot require the Foreign Seller or manufacturer to submit samples separately.
- The selection process must not expose the prescription drugs to possible contamination or adulteration. The Importer cannot unseal containers and reseal them.
- The Importer or its designee must select samples from multiple points in a shipment and not a single area. This is to ensure that temperature and environmental conditions have not adversely affected certain parts of a shipment and not others.
- The Importer or its designee must segregate selected samples from the shipment or batch and ensure they are kept in the same environmental and climate conditions prior to testing.
- The Importer or its designee and qualifying laboratory must not disclose how they selected samples.

Evaluating for Authenticity

The Agency will require the Importer's qualifying laboratory to implement a robust screening regimen that corresponds to each prescription drug's USP specifications and acceptance criteria. Combined, these will examine visual characteristics (color, labeling, identifying marks) and physical properties (active pharmaceutical ingredients and excipients) to determine whether they are identical to their FDA-approved counterparts in the U.S. In addition to identifying any counterfeits, the authenticity testing can also discern whether the prescription drug meets purity requirements by checking for the presence of foreign substances or chemical toxins.

Visual Inspections: Counterfeit medications can range from crude fakes that are easily detected to sophisticated forgeries that use ingredients similar to the actual products. Before testing, laboratories can start ascertaining whether a prescription drug is authentic by examining its visual properties such as labeling, pill color and shape, and pill markings. Additionally, pills improperly colored or having the wrong markings are direct indications of fakes. The qualifying laboratory will be required to have a process to visually inspect selected samples and document their authenticity. Any prescription drugs identified as being inconsistent with the actual product will be dispositioned immediately and not undergo further testing. Additionally, the Importer will compare the HPFB of Canada's labeling and packaging to ensure authenticity.

Laboratory Testing:

When confirming the authenticity of imported prescription drugs, Florida will ensure that each selected sample undergoes testing in accordance with the USP's guidelines and acceptance criteria for the corresponding FDA-approved version. In general, these testing methods consist of spectroscopy and chromatography. The qualifying laboratory will

perform the specific types of these tests as specified in each imported prescription drug's corresponding USP guidelines, testing methods and acceptance criteria provided by the manufacturers, or alternative testing method developed in accordance with CGMP and International Council of Harmonisation guidelines:

- **Spectroscopy:** Used to provide information on chemical structure through measuring the interaction between matter and radiation, this technique can identify the ingredients in any prescription drug in addition to their quantities. Conducted through scanning medications, spectrometry leaves selected samples intact while providing quantitative data. Additionally, mass spectroscopy is sensitive enough to identify the subtlest differences between the most sophisticated counterfeits and the genuine product. Multiple types of spectroscopy are presently available including infrared, Raman, nuclear magnetic resonance, and mass. The qualifying laboratory will conduct spectroscopy as specified by each prescription drug's USP specifications, testing methods and acceptance criteria provided by the manufacturers, or alternative testing method developed in accordance with CGMP and International Council of Harmonisation guidelines.
- **Chromatography:** By separating a prescription drug into its various components, this technique can identify impurities in addition to its active pharmaceutical ingredient and excipients. These abilities make it one of the most common methods for analyzing the content of medications. However, using chromatography destroys the selected sample during the process. Currently, multiple versions of this technique are available, including thin layer chromatography (TLC) and high-performance liquid chromatography (HPLC). The qualifying laboratory will conduct chromatography as specified by each prescription drug's USP specifications, testing methods and acceptance criteria provided by the manufacturers, or alternative testing method developed in accordance with CGMP and International Council of Harmonisation guidelines.

When assessing the authenticity of a prescription drug, Florida will require its qualifying lab to use visual inspections and testing techniques listed by the USP or alternative method. If a sample fails to meet the USP or alternative acceptance criteria, its originating batch will be removed from the supply chain and quarantined.

Assessing Stability

Unlike evaluating for authenticity, laboratory tests for stability do not assess whether a prescription drug is genuine but whether its active pharmaceutical ingredient and excipients will retain their medicinal properties to be of benefit to individuals taking them. This is necessary for not only measuring effectiveness but ensuring that certain ingredients will not become toxic before use, particularly those that are unstable such as nitroglycerine. In addition, analyzing stability provides the opportunity to assign expiration dates to batches. In regard to imported prescription drugs, stability testing is essential to determine those coming into the U.S. have not expired prior to entry and remain just as effective as newly manufactured ones in Canada. To test for stability, two methods are available, real time and accelerated. Florida will use the stability-indicating assay methods provided by the manufacturer, which will likely consist of the accelerated method as described below:

- **Accelerated Stability Testing:** Rather than observe a prescription drug's degradation over a set period and collect data, the accelerated method requires the use of heat to

stress the medication. Applying heat causes the prescription drug to degrade more rapidly and conveys its period of effectiveness. Because prescription drugs remain in their original packaging (e.g., blister packs) until use, stability testing does not remove them from their containers. Thresholds for passing stability tests will be based on degradation and estimated shelf life when compared to FDA-approved prescription drugs.

In addition to testing prescription drugs following entry into the U.S., the qualifying laboratory will be required to retain samples for retesting at certain intervals (e.g., six months, one year) depending upon each product's FDA-approved counterpart's shelf life. Prescription drugs deemed to have expired or will expire before being able to be safely consumed will be designated for disposition.

Testing for Biological Contamination

Prescription drugs can have myriad forms of contamination, ranging from foreign particles and substances to microorganisms. For the former category, chromatography and spectroscopy can identify those. However, such techniques cannot discern whether microorganisms are present.

To evaluate whether a batch poses biological hazards to individuals, the qualifying lab will test for harmful bacteria by using culture media swabs on the selected sample. This includes gathering swabs on pills in bottles or other containers. Following an incubation period of 48 to 72 hours, the qualifying laboratory will identify any microorganisms present and assess whether they can potentially harm humans. Samples that present evidence of contamination will have their originating batches removed and dispositioned.

Names and Addresses of Qualified Laboratories

The State's vendor has contracted with two (2) qualifying laboratories for testing in the event that one of the labs becomes ineligible to provide testing services (e.g., through lapse of ISO 17025 accreditation or an Official Action Indicated (OAI) 4 classification). **Table 3**, Contract Laboratories, identifies the laboratories the State will use to meet the testing requirements:

TABLE 3
CONTRACT LABORATORIES

Name of the Organization / Address	Registrations	FDA Audit History
Element Materials Technology (acquired Avomeen, LLC in 2021) 4840 Venture Drive Ann Arbor, MI 48108 800-930-5450 www.element.com	FDA Registered (FEI 3008808597) ISO 17025 (Certificate L19-183)	Jun 2016 – FDA Mar 2018 – FDA Oct 2018 - FDA (In good standing)
Consumer Product Testing Company 70 New Dutch Lane Fairfield, NJ 07004 www.cptclabs.com	FDA Registered (FEI 1000151293) ISO 17025 (Certificate L22-36)	Aug 2017 – FDA (In good standing)

See Attachment G, Laboratory Testing, for supporting documentation.

REMAINDER OF PAGE INTENTIONALLY LEFT BLANK

Prescription Drug Labeling Comparison

The FDA final rule requires the SIP to:

> Include a copy of the FDA-approved drug labeling for the FDA-approved counterpart of the eligible prescription drug, a copy of the proposed labeling that will be used for the eligible prescription drug, and a side-by-side comparison of the FDA-approved labeling and the proposed labeling, including the Prescribing Information, carton and container labeling, and patient labeling (e.g., medication guide, instructions for use, patient package inserts), with all differences annotated and explained. The SIP Proposal must also include a copy of the HPFB-approved labeling.

See Attachment D, Wholesale Importation Drug List, for supporting documentation.

REMAINDER OF PAGE INTENTIONALLY LEFT BLANK

Explanation of Cost Savings

The FDA final rule requires the SIP to:

> Explain how the SIP Sponsor will ensure that the SIP will result in a significant reduction in the cost to the American consumer of the eligible prescription drugs that the SIP Sponsor seeks to import. The explanation must include any assumptions and uncertainty, and it must be sufficiently detailed to allow for a meaningful evaluation.

Florida's purpose for implementing the Canadian Prescription Drug Importation Program is to generate cost savings that will benefit taxpayers and other State programs while serving as a model for other states to follow. To demonstrate how Florida will realize these savings, the Agency has prepared a cost analysis that consists of a baseline scenario and plan scenario. The former outlines the State's projected expenditures if no importation program existed, and the latter provides an estimate of what prescription drugs would cost if imported from Canada. Because Florida's Medicaid program will constitute most consumers for the Program, both scenarios focus solely on that population. This is also due in part to the Agency having the most accurate and complete data on Medicaid recipients.

After accounting for factors such as rebates, inflation, administrative overhead expenses, and the potential for generic equivalents to enter the market, the Agency projects that importing specific prescription drugs from Canada could yield **$179,346,520.93** in savings during the first year and **$192,462,213.09** in the second year. In addition, the Agency selected eligible prescription drugs that had the highest potential for generating cost savings through importation due to having high net spending during 2020 through 2022, even after accounting for rebates.

For the baseline and plan scenarios, the Agency used Florida Medicaid expenditure data from federal fiscal year 2022 and Canadian prescription drug prices from Health Canada, Ontario and Quebec provinces. Also, both scenarios accounted for federal and supplemental rebates when analyzing expenses. Due to federal statutory requirements mandating the confidentiality of Medicaid prescription drug rebates, the Agency has redacted those numbers from the cost analysis. The FDA can consult the manufacturers and the Centers for Medicare and Medicaid Services (CMS) to verify that information.

Other factors the Agency included consisted of declining enrollment in Medicaid due to the unwinding of the Covid-19 public health emergency. As of December 2023, Florida Medicaid had over 5.4 million recipients (Note: An estimated 720,000 recipients were not using services). After Florida processes re-enrollments, the Agency expects this number to decrease to approximately 3.7 million recipients by the end of 2023.

Regarding currencies, the Agency factored into the cost analysis that the U.S. and Canadian dollars are unequal in value. As a result, it converted Canadian dollars to U.S. dollars based on the exchange rate from March 15, 2023.

To assist with the cost analysis, the Agency worked with its actuarial contractor, Milliman, Inc. (Milliman), which utilized the following methods to prepare the baseline and plan scenarios:

- Baseline Scenario
    - Milliman used expenditure data on the prescription drugs proposed for importation from Florida Medicaid's Managed Care Organizations (MCOs) and adjusted the scale to account for the fee-for-service population as well.

        - Note: The MCOs serve almost 90% of Florida Medicaid recipients.
    - These expenditures served as the baseline for the projections of FFYs 2024 and 2025.
    - The utilization projections in the baseline scenario also account for increases in Florida Medicaid enrollment due to the state's population growth and inflation in accordance with the Medi-Span's database on historical wholesale acquisition cost (WAC) increases per NDC for U.S. prescription drugs.
    - Milliman further accounted for trends in federal and supplemental rebates over the next two years.
    - Because the baseline scenario does not involve having a program, it did not account for administrative expenses.

- Plan Scenario
    - Milliman used the same projected utilization trends in the plan scenario as it did in the baseline scenario. These trends account for the same predicted increases in Medicaid enrollment.
    - To adjust for inflation, Milliman used a 5.1% cap as mandated by Health Canada for Canadian prescription drugs.
    - Because uncertainty exists around the quantity of Canadian prescription drugs Florida will be able to import, the plan scenario provides savings estimates based on 100% and 75% utilization.
    - Milliman used prices based on the same unit sizes and strengths as those used in the baseline scenario.
    - The plan scenario factors in $14,496,000.00 in administrative costs for operating the Program.

The baseline and plan scenarios do not take the following factors into consideration when projecting potential savings:

- Changes in supplemental rebates when the FDA-approved version of an imported prescription drug is dispensed.
- Changes in the prescription drug market for FDA-approved prescription drugs following the implementation of importation.
- Negotiating prices from Canadian manufacturers that are lower than those posted by Health Canada.
- Additional time required to negotiate prices and obtaining sufficient quantities from Canadian manufacturers.

The projected savings consist of the differences between the amounts spent in the baseline and plan scenarios for 75% and 100% utilization. In the case of 75% utilization, the Agency still projects significant savings of **$130,885,890.70** in the first year and **$140,722,659.82** in the second year.

See **Attachment E**, Cost Savings, for supporting documentation.

REMAINDER OF PAGE INTENTIONALLY LEFT BLANK

Storage, Handling, Supply Chain, and Reporting Guidelines

The FDA final rule language requires the SIP proposal to:

- Explain how the SIP Sponsor will ensure that all the participants in the SIP comply with the requirements of Section 804 of the Federal Food, Drug, and Cosmetic Act (FDCA).
- Describe the procedures the SIP Sponsor will use to ensure that the requirements are met, including the steps that will be taken to ensure that the:
  - Storage, handling, and distribution practices of supply chain participants, including transportation providers, meet the requirements and do not affect the quality or impinge on the security of the eligible prescription drugs.
  - Supply chain is secure.
  - Importer screens the eligible prescription drugs it imports for evidence that they are not adulterated, counterfeit, damaged, tampered with, expired, suspect foreign product, or illegitimate foreign product.
  - Importer fulfills its responsibilities to submit adverse event, field alert, and other reports required by the SIP, the Federal Food, Drug, and Cosmetic Act, or this part.

As the most essential element to ensuring that imported prescription drugs are identical to their FDA-approved counterparts, the State understands that maintaining a secure supply chain is integral to the process. By requiring safe storage, handling, and transportation practices along with robust screening regimens, Florida will prevent counterfeit, contaminated, or adulterated drugs from entering the market. In the event that the Importer's screening process detects unfit prescription drugs, it will immediately take actions to maintain the health and safety of Floridians.

Having a robust and closed supply chain beginning in Canada and ending with the delivery of prescription drugs to individuals in Florida requires the Foreign Seller, Importer, and manufacturer to follow multiple requirements. In addition to complying with the U.S. Drug Supply Chain Security Act (DSCSA), participating parties in Florida's program must also adhere to the minimum requirements for storage and handling as specified in Title 21 CFR § 205.50 and § 499.0121, Florida Statutes (Note that Florida's requirements mirror those listed in the CFR). Because Florida is considering the importation of HIV/AIDS medications, all of which have specific temperature requirements, ensuring a secure supply chain and safe handling and storage practices is paramount to providing Floridians reliable imported prescription drugs.

The primary responsibility of ensuring the delivery of safe imported prescription drugs belongs to the Importer or its designee. The Importer (or designee) will maintain all transaction histories, information, and statements in addition to having adequate facilities that meet cleanliness and climate standards. The following describes the supply chain and the handling, storage, and transportation practices Florida's Importer (or designee) will utilize to import prescription drugs.

Storage, Handling, and Distribution

All storage facilities and vehicles used to transport imported prescription drugs must meet specific state and federal guidelines. This includes not only those located within the U.S. but in Canada as well. To further ensure compliance and safeguard the integrity of the supply chain, LifeScience Logistics will provide dedicated and fully licensed distribution space within Indiana and Florida. This will prevent the possibility of inadvertently deviating shipments across other distribution channels or comingling drug products from the program with other drug products. The Importer or its designee will need to provide documentary proof that Canadian facilities and vehicles meet the same requirements as their counterparts in the U.S. These requirements as listed in federal rule include but are not limited to the following:

- Facilities used for storing and/or marketing prescription drugs must have adequate size, storage conditions, quarantine areas, cleanliness, and security.
- Storage areas must have climate control and accurate instrumentation for measuring temperature and humidity.
- Having written policies and procedures that ensure the oldest approved stock is distributed first, handling recalls and withdrawals, ensuring the facility can function during a crisis, and removing outdated prescription drugs from those designated for distribution.

Additionally, the Importer or its designee will need to ensure that the prescription drugs remain in temperature-controlled climates throughout importation and distribution. This is due to HIV/AIDS anti-retroviral medications requiring an environment that cannot exceed 20-25 degrees Centigrade to maintain potency and effectiveness. Due to Florida's tropical climate, controlling temperature becomes more necessary as the imported prescription drugs get distributed across the state.

The Importer or its designee will be responsible for providing the Agency and DBPR with a list of vendor-approved Canadian and U.S. facilities that will store the prescription drugs in addition to the vendor-approved carriers that will transport and distribute. The list must include not only the facility names and addresses but proof that they meet FDA and Health Canada's licensing standards. Also, the Importer or its designee will provide a flow chart that presents the route imported prescription drugs and their active pharmaceutical ingredients (APIs) will take beginning with the country of origin through the port of entry in the U.S. and where they will be stored during laboratory testing and relabeling before going to their final points of distribution in Florida.

Having a Secure Supply Chain

Signed into law in 2013, the DSCSA updated the requirements that pharmaceutical companies, wholesalers, and distributors must follow to prevent counterfeit, adulterated, or contaminated prescription drugs from reaching consumers. As the SIP sponsor, the State will require the Importer or its designee to verify at receipt, maintain, and submit all transaction histories, information, and statements. When monitoring for compliance, the Agency and DBPR will review the transaction documents and verify their accuracy as well as confirm that all prescription drugs being imported meet Health Canada and FDA guidelines.

The State understands the purpose of the DSCSA and plans to hold the Foreign Seller, Importer, and manufacturer accountable for documenting each change of ownership during the process. The State's selected vendor, LifeScience Logistics, LLC fully complies with the DSCSA (including the components that are not yet enforced by the FDA – i.e., serialization). Its system will receive inbound electronic data using industry standard formats, such as the Advance Ship Notice (ASN/856) and Electronic Product Code Information Services (EPICS) documents. Additionally, its system also captures and stores all transaction information, histories, and statements and supports full serialization of the imported product. LifeScience Logistics will also accommodate the transmission of the transaction information, histories, and statements via paper, as allowed by the DSCSA regulations, and its system will capture the following transactional information:

- Product name
- Strength and dosage
- National Drug Code
- Number and size of containers
- Lot number
- Transaction and shipment dates
- Names and addresses of the businesses that complete transactions.

Because these prescription drugs will be imported from Canada, Florida will require the Importer to ensure the Foreign Seller affixes Section 804 Serial Identifiers (SSI) to each package and homogenous case in every shipment. If a shipment lacks adequate SSIs, the Importer will quarantine the prescription drugs immediately and not select samples for statutory testing. In addition, LifeScience Logistics will verify that each SSI corresponds to the shipment's lot and DIN numbers as well as expiration dates.

LifeScience Logistics will also physically inspect each drug shipment received from Methapharm Inc. against shipping paperwork and a set of specifications developed for each drug imported. These specifications include damage, tamper seal intact, lot number, DIN number, and determining whether expiration dating on packaged units aligns with shipping paperwork and if there is no presence of counterfeit or illegitimate products. All packaging inspections will be documented, reviewed by the quality assurance staff, and included in the import receipt files.

Data Availability and Documentation

Florida's importation program will use industry-leading software to provide the required features, functions, and capabilities of a warehouse management system and a transportation management system. When a product is received into the system, important transaction information is captured and stored. Within the Florida warehouse, all products are tracked by their lot numbers. On outbound shipments, all required information is provided in print and electronically to comply with applicable federal regulations. The system also tracks when it receives, stores, and ships by individual serial numbers.

LifeScience Logistics has developed a CGMP compliant set of standard operating procedures (SOPs) that ensure each product is handled, stored, and distributed in accordance with applicable FDA, Drug Enforcement Agency, and State of Florida guidelines. In addition to the guidelines associated with facilities, training, document control, change control, equipment, temperature monitoring, vendor qualification, security, pest control, redundancy, deviation and corrective action/preventative action, Florida will maintain SOPs governing all processes associated with products inbound, inventory management, order management, returns, and preventive/corrective maintenance. The State will also require LifeScience Logistics to maintain policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. They must include in their written policies and procedures:

1. A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement if the deviation is temporary and appropriate.
2. A procedure for addressing any crisis that affects security or operation of any facility if a strike, fire, flood, or other natural disaster, or a local, state, or national emergency occurs.
3. A procedure to ensure that any outdated prescription drugs are segregated from other drugs and returned to the manufacturer or destroyed.
4. A procedure that prevents the diversion of prescription drugs.

LifeScience Logistics leverages a cloud data center provider to supply infrastructure for its technology systems. Specifically, their system provides real-time redundancy across two data centers in different geographic regions within the U.S. The system is load-balanced across these two data centers. A failure of any or all components in a single data center would cause a real-time failover to the second data center with no user impact or loss of data.

Reporting Adverse Incidents and Filing Field Alerts

When an imported prescription drug fails testing, becomes compromised, has a recall issued, or results in patient injury, the Agency and DBPR will require the Importer or its designee to conduct adverse incident reporting and issue field alerts to state and federal agencies. All adverse incidents must be reported to the FDA's Adverse Event Reporting System (FAERS) and the Agency and DBPR. Additionally, LifeScience Logistics is required to follow FDA guidelines when filing field alerts by doing so within 72 hours of becoming informed of one or more of the following issues:

- Patient injury or death
- Labeling problems that can cause the prescription drug to be identified as another product
- Biological contamination
- Changes in the chemical or physical composition of the prescription drug that leads to deterioration, degradation, or toxicity
- Any failure of a shipment or batch of prescription drugs to meet the specifications in its NDA or ANDA

In addition to submitting these reports to state and federal agencies, the State will also require the Importer or its designee to inform Health Canada and the HPFB of any defect, contamination, or adulteration of a prescription drug. The Importer will report these issues formally in accordance with Canadian standards and procedures.

Additional Reporting

The SIP Sponsor and co-sponsor will submit quarterly reports to the FDA consisting of the following information required by Title 21 CFR § 251.19:

- The name, address, telephone number, and professional license number of the Importer
- The name and quantity of the active ingredient of the imported eligible prescription drug(s)
- A description of the dosage form of the eligible prescription drug(s)
- The date(s) on which the eligible prescription drug(s) were shipped; the lot or control number assigned to the eligible prescription drug(s) by the manufacturer of the eligible prescription drug(s)
- The point of origin (i.e., manufacturer) and the destination (i.e., the wholesale, pharmacy, or patient to whom the Importer sells the drug) of the eligible prescription drug(s)
- The per unit price paid by the Importer for the prescription drug(s) in U.S. dollars
- Any other information the FDA determines is necessary for the protection of the public health.

The quarterly reports will also include the Importer's confirmation that it purchased eligible prescription drug(s) directly from the Foreign Seller. In addition, the quarterly reports will include the following documentation:

- A listing of manufacturers of each eligible prescription drug.
- The quantity of each lot of eligible prescription drug received by the Foreign Seller from the manufacturer.
- Proof that the eligible prescription drug was received by the Foreign Seller from the manufacturer and subsequently shipped by the Foreign Seller to the Importer.
- Results of the statutorily required laboratory testing and descriptions of the sample selection methods used for each eligible prescription drug.

The State will ensure that the report contains a certification from the Importer that each shipment of each eligible prescription drug is approved for marketing in the U.S. and is not adulterated or

misbranded and that it meets all labeling requirements under the Federal Food, Drug, and Cosmetic Act. The certifications will note the following:

- That there is an authorized SIP
- That the imported drug is covered by the authorized SIP
- That the drug is an eligible prescription drug as defined by this rule
- That the FDA-approved counterpart of the drug is currently commercially marketed in the U.S.
- That the drug is approved for marketing in Canada.

Lastly, the quarterly reports will also include data, information, and analyses on the SIP's cost savings to the American consumer.

REMAINDER OF PAGE INTENTIONALLY LEFT BLANK

Education and Outreach Plan

The FDA final rule language requires the SIP proposal to:

> Explain how the SIP Sponsor will educate pharmacists, healthcare providers, pharmacy benefit managers, health insurance issuers and plans, as appropriate, and patients about the eligible prescription drugs imported under its SIP.

The SIP is a novel concept, and Florida is a trailblazer by working to influence the cost of prescription drugs. Because of how innovative this program is, the Agency in coordination with DBPR will be taking great steps when considering how to provide education and training resources to state-run facilities, other agencies, and Florida Medicaid providers and recipients.

These will include webpages, webinars, written guides available online, brochures, and infographics. In addition, the Agency will prepare materials to inform Medicaid beneficiaries of what prescription drug importation means and how it does not pose a risk to their health and safety. As the SIP sponsor and co-sponsor, the Agency and DBPR believe that everyone involved in prescription drug importation, beginning with organizations to the consumers should be aware of where their medications originate and how obtaining them from Canada benefits the entire state. The Agency will require training to occur on an annual basis and as needed when circumstances warrant it.

Webpages and Webinars

When seeking to understand new programs and regulations, the State understands that many individuals search for information independently. To accommodate these people, the Agency is contemplating the construction of a webpage that provides detailed information on the SIP and how it works. Available on this page will be resources such as Florida's original concept paper, the approved SIP proposal draft, links to the FDA Importation of Prescription Drugs final rule, the Florida Statutes, a list of all imported prescription drugs, and any guides or brochures created. The goal of the webpage is to serve as a continuous resource to answer any questions about the program. In addition, it will provide a link for consumers to make complaints and offer contact information for further questions. For ease of use, the webpage will be linked to the Agency's homepage, making it accessible with minimal "clicks" to access the page.

During the beginning phases of prescription drug importation, the Agency will also schedule multiple webinars to train relevant stakeholders (state agencies, and providers/facilities). These webinars will go over how the importation program functions and the stakeholder roles to ensure program success.

For interested parties unable to attend a webinar, the Agency will record them and make the recordings accessible on the prescription drug importation webpage. Each webinar will be accompanied by a PowerPoint presentation and provide opportunities for attendees to ask questions.

Written Guides

For detailed information, the Agency and DBPR will prepare written guides that will provide more specific information than what is covered in the webinars and narrative content on the webpage. Each guide will address one of the following importation program components for interested parties to research:

- Labeling and packaging, with detailed visual examples and comparisons
- Qualifying laboratory testing methods and standards

- Safe storage, handling, and transporting processes and procedures
- Recall processes, with specific information on procedures for each of the three tiers

During the drafting process, the Agency and DBPR will work with the Importer or its designee to include thorough and accurate information that can address in-depth questions. As with the webinars and other materials, these written guides will be available on the Agency's prescription drug importation webpage.

Brochures and Infographics

To promote the SIP and generate stakeholder support, the Agency will design multiple brochures and infographics. Each of which will provide high-level information on imported prescription drugs and visuals showing the supply chain, labeling, and how savings will be achieved. Although these materials will not be intended to provide detailed training to providers, they can serve as a useful resource to assist with educating the public and communicating the general purpose and function of the SIP.

Other Education and Training Measures

The State understands that additional training may be needed to fully convey the scope of importing prescription drugs. To ensure that all interested parties are clear on the concept and operationalization of the importation program, both the Agency and DBPR can hold conference calls on an ad hoc basis to discuss specific issues, assign staff to focus solely on handling questions, and send representatives to meetings.

REMAINDER OF PAGE INTENTIONALLY LEFT BLANK

SIP Recall and Return Plan

Currently, U.S. prescription drug manufacturers must follow FDA guidelines when recalling products. However, medications imported to the U.S. under a SIP will not only have to follow domestic policies but adhere to Canadian standards as well. Depending on the medication and where its active pharmaceutical ingredient is manufactured, the Agency will need to monitor not only FDA recall alerts but also Canadian ones.

If a recall is ordered on a shipment of imported prescription drugs, the Agency and Importer (LifeScience Logistics, LLC) will immediately halt the importation of the recalled prescription drug under the SIP in accordance with the FDA's Importation of Prescription Drugs final rule. Additionally, they will take actions to work with those participating in the SIP (e.g., state-run facilities and Medicaid-enrolled pharmacies) to communicate the need to isolate those drugs and return them for disposition. To inform stakeholders and affected parties, the Agency and Importer understand that messaging must go out to Medicaid managed care plans participating in the Medicaid managed care program, pharmacies, state run facilities (e.g., public health clinics, prisons, state mental hospitals), and other state agencies. The Importer's role will be to follow a process for safe handling and disposal of the recalled products in addition to ensuring all non-dispensed inventory is collected.

If at any time, the Agency or Importer determines that an issue is present in the SIP, they can issue their own recall and halt the importation of a particular prescription drug. Also, the Agency and Importer will conduct all recalls in accordance with Title 21 CFR Part 7 and Title 21 CFR § 251.

The Agency will initiate a recall one under the following scenarios:

- The HPFB of Canada issues a recall of an imported prescription drug.
- The FDA issues a recall of a domestic prescription drug that is produced in the same facility as the imported prescription drug equivalent.
    - This type will not apply to recalls implemented due to labeling or other issues that do not apply to the manufacturing of the prescription drug.
- The Importer identifies an issue in the supply chain or improperly relabels, repackages, or stores the imported prescription drugs.

Agency and Importer Communication Plan

In addition to requiring the Importer to monitor the FDA's MedWatch and Health Canada's Recalls and Safety Alerts, the Agency and Importer will check daily for any notifications pertaining to imported prescription drugs. Both the FDA and Health Canada use the following three-tiered system for classifying recalls as specified in Title 21 CFR § 7.3. Based on the level, the Agency and Importer will implement a different strategy to notify Medicaid recipients, state agencies, and state-run facilities. In addition, the Agency will immediately notify the FDA of the recall and submit all transaction documents if requested.

- **Tier 1:** Recalled prescription drug poses severe risks to individuals that can result in serious health complications or death.
- **Tier 2:** Recalled prescription drug may cause a temporary health problem or have a slight chance of posing a serious health complication.
- **Tier 3:** Recalled prescription drug is in violation of labeling or manufacturing laws and does not pose a significant risk to individuals' health.

For each tier, the Agency and Importer will take the following steps to prevent recalled drugs from reaching individuals. The strategies vary based on the risks posed with the most extensive efforts reserved for Tier 1.

Tier 1 Strategy: Given the consequences of delayed or insufficient action, the Agency and DBPR will implement immediate measures beginning with communication to all Medicaid managed care plans, state-run facilities, and state agencies via email blasts and direct calls to administrators. In addition, the Agency will use its Provider Alert system to instantly notify enrolled pharmacies of the emergency, and its Bureau of Recipient and Provider Assistance will begin contacting these pharmacies by phone. Given that Florida Medicaid recipients comprise the largest benefactor group, the Agency will also need to contact those who may have received recalled prescription drugs. The depth of a Tier 1 recall will extend to the consumer level as specified in Title 21 CFR § 7.42(b). Measures used to accomplish this and communicating to other state agencies and facilities include the following:

- Medicaid managed care plans and the Agency must have a verified contact (i.e., recipient acknowledgement) informing about the recall and providing instructions on how to return the compromised prescription drugs and steps to take if those drugs were taken. The Agency and Medicaid managed care plans will instruct Florida Medicaid recipients to return the recalled prescription drugs to the pharmacy where they were originally purchased. Forms of contact can consist of email, telegram, or letter sent via first class mail. The content of the written communication will align with the requirements specified in Title 21 CFR § 7.49. Either the Agency or Medicaid managed care plan must follow up with Florida Medicaid recipients and continue contact attempts until the recipient acknowledges. This is the effectiveness check referenced in Title 21 CFR § 7.42(b). Following acknowledged communication, the Medicaid managed care plan will report to the Agency that it has contacted the affected recipient.

- For other state agencies and their facilities, the Agency and Importer will directly contact the Department of Health, Department of Children and Families, Agency for Persons with Disabilities, Department of Elder Affairs, and the Department of Corrections. Contact will consist of email and telephone calls and will provide instructions on returning the recalled prescription drugs to the Importer. The Agency and Importer will also inform these agencies as to why the recall is occurring and the dangers posed to individuals under their care. Each agency in receipt of suspect product will assume responsibility for preventing individuals from taking them by following their existing procedures for the collecting and removal of recalled prescription drugs.

- All communications to facilities, pharmacies, and other entities involved in distributing and dispensing imported prescription drugs will identify the recalled prescription drug's name, NDC, lot number, and expiration date as well as provide other information as required by Title 21 CFR § 7.49. The communications will also instruct staff and personnel to return the imported prescription drugs to the Importer's Florida warehouse for disposition.

As SIP sponsor, the Agency will notify state and local media about the recalled prescription drugs with information on who to contact and what to do with any quantities of the prescription drugs dispensed to individual patients. Information provided to any media sources will identify the name of the recalled prescription drug, NDC, and expiration date.

This step is in accordance with the public warning requirements specified in Title 21 CFR § 7.42(b). The information will also specify that the labeling indicates that the recalled prescription drug is imported from Canada. The Agency will also request the media sources to provide the Importer's contact information and provide instructions on returning the recalled prescription drugs to the dispensing pharmacy.

Tier 2 Strategy: As with Tier 1, the Agency and Importer will immediately communicate with the Medicaid managed care plans, Medicaid-enrolled pharmacies, and state agencies to inform them of the recall and potential risks as well as instructions for returning drugs to the Importer. For Medicaid recipients, the Agency will utilize the same strategies as Tier 1 for communicating except it will require only three contact attempts via telephone, email, or letter and not require recipient acknowledgement. The Agency and Importer will require state agencies and their facilities to follow the same procedures as they would for Tier 1. The depth of a Tier 2 recall will extend to the consumer level as specified in Title 21 CFR § 7.42(b).

Tier 3 Strategy: The Agency and Importer will take a similar approach to notify Medicaid managed care plans, state agencies, and state-run facilities as it does with Tiers 1 and 2. However, communication will be limited to email and provider alerts. Because a Tier 3 recall does not pose significant adverse health effects on consumers, the Agency and Medicaid managed care plans will extend the depth of the recall to the retail level as specified in Title 21 CFR § 7.42(b). State agencies and facilities will need to take the same measures for Tier 3 as they would for Tier 1.

While the Agency handles communications with stakeholders and recipients, the Importer will administer collecting the recalled prescription drugs and their disposition. Additionally, the Importer will submit a report to the Agency explaining the quantity of prescription drugs recovered, the dates of recovery, the number of those unaccounted for, and where the recovered drugs are stored. The Importer will also include in its report the number of recalled prescription drugs distributed to each provider/facility and the individual quantities recovered from them. For Tier 1 and Tier 2 recalls, the Agency and Importer will contact those providers/facilities unable to collect recalled prescription drugs to determine what actions may be needed to get the products off the market.

The Importer will also need to provide the Agency with specific information on which recalled prescription drugs went through the supply chain and were distributed to providers/facilities. This information must consist of the following:

- SSI, NDC, DIN, and manufacturer's assigned lot number.
- Number and size of containers.
- Dates of transactions and shipments between the Foreign Seller, manufacturer, and Importer.

Importer Recall Plan

If a recall is required, the Importer will be responsible for collection, documentation, storage, and destruction of the suspect prescription drugs. In addition, it will also halt the importation of the recalled prescription drug in accordance with federal rule. While the Agency oversees the communications aspect, the Importer will immediately begin working with distributors, providers, and facilities to collect the recalled products. Once retrieved, the Importer or its designee will gather all the returned prescription drugs and store them at its Florida warehouse under quarantine. Depending on the reasons for the recall, the Importer will also oversee their secure

destruction. Unless otherwise specified, the Importer will follow the same process for all three tiers of recalls.

At the recall's outset, the Importer must use its track and trace procedures as established under the Drug Supply Chain Security Act (DSCSA) to identify which batches or shipments it received require collecting. It will verify this information with the Foreign Seller and manufacturer. The Importer must confirm with the manufacturer that it has identified all suspect shipments by comparing lot numbers, DINs, and dates of transactions and shipments. Additionally, the Importer will locate where all recalled prescription drugs are at in the supply chain (e.g., in storage, at the laboratory, distributed to providers, etc.) and submit a report consisting of the following information to the Agency.

- Transaction documentation from the Canadian manufacturer identifying the name and quantities of prescription drugs sold to the Foreign Seller and Importer.
- Documentation from the U.S. Customs and Border Patrol of the shipments of the recalled prescription drug approved for importation into the U.S.
- Location of each batch and shipment.
- Quantity of prescription drugs at each location.
- Identification information (SSI, DIN, NDC, lot number, dates of transactions and shipments).
- Dates of distribution to providers/facilities, if applicable.

During the recall process, the Importer will provide daily updates to the Agency on the quantities collected for Tier 1 and 2 recalls. For Tier 3, the Importer will provide one update per week until the recall process is complete and then on an ad hoc basis as required.

When disposing of recalled prescription drugs, the FDA and Drug Enforcement Agency (DEA) do not require a specific method for destruction. However, the Importer needs to ensure that disposition occurs in the U.S. and does not involve discarding prescription drugs as trash or possibly contaminating a water supply. In addition, the destruction process needs to ensure the recalled products are physically destroyed or rendered as non-retrievable. Following disposition, the Importer must submit a report to the Agency and DBPR

To accomplish this, the Importer will contract with a facility that is registered or authorized to dispose of prescription drugs. Because the final rule prohibits the importation of controlled substances, the Importer will need to assign only one employee to accompany the recalled shipments to the destruction site. Upon arrival and following confirmation that all quantities are present, the registered or authorized facility will disposition the recalled prescription drugs via incineration at high temperatures. Following disposition, the Importer must submit a report to the Agency specifying that each batch or shipment was destroyed and provide identification information.

In accordance with FDA and Health Canada requirements, manufacturers can voluntarily engage in recalls. To further ensure that suspect imported prescription drugs do not enter the market, the Agency is granting the Importer this same ability. If at any time, the Importer determines that a recall is necessary, it can issue one.

See **Attachment H**, SIP Recall and Return Processes, for supporting documentation:

Recall Status Reports

In accordance with the requirements listed in Title 21 CFR § 7.53, the Agency will provide the FDA with intermittent status reports every two weeks until the FDA terminates the recall. Each biweekly report will consist of the following components that are also specified in federal rule:

- Numbers of wholesalers, retailers, and consumers that received the recalled imported prescription drug.
    - Note: The Agency will also identify the numbers of state-run facilities that were notified.
- Numbers of wholesalers, retailers, and consumers who responded to the notification and the amounts of the recalled imported prescription drugs they have on hand.
- Numbers of wholesalers, retailers, and consumers who did not respond to the notification.
- Numbers of recalled imported prescription drugs returned or if allowed, corrected, by wholesalers, retailers, and consumers.
    - Note: The Agency will not allow for consumers to make corrections to imported prescription drugs if that is the only action required.
- Numbers of effectiveness checks made and the estimated time for completion of the recall.

Return Plan

For imported prescription drugs that must go through the return process, the Agency will require the Importer to ensure that all collected products remain in the original supply chain. The Importer will return the prescription drugs to its Florida warehouse and keep them quarantined from non-recalled drugs. At no time, can the Importer send returned prescription drugs to another facility or transport them via a means without direct approval from the Agency and only with justification (e.g., facility is beyond capacity or has been compromised). By mandating that these prescription drugs remain within the supply chain, the Agency can ensure that they do not enter the black market or are exported to another country.

At each point during the return process, the Agency will review the Importer's reports and assess whether any prescription drugs are missing from the list of batches and shipments. Additionally, the Agency will immediately work with the Importer to resolve any discrepancies. In the event that a discrepancy cannot be resolved, the Agency and Importer will ascertain at which point the prescription drugs became misplaced and issue communications to affected parties or contact law enforcement if theft is suspected.

In the event a recalled prescription drug can be returned to market, the Agency will require its Importer to use the following procedures to ascertain whether the product is saleable. This can only apply to Tier 3 recalls that occurred due to a labeling mishap or other issue that poses no risk to individuals taking the medication.

- Assess whether the prescription drugs have expired, and if not, determine if a reasonable timeframe exists to verify purity and potency and return to the market.
- For non-expired prescription drugs, the Importer must randomly select new samples for testing to evaluate purity, potency, and the presence of contamination.
- For prescription drugs recalled due to labeling issues, the Importer will have all batches and shipments relabeled after they have passed laboratory testing.

Prior to returning to market, the Importer will have verified that the prescription drug is saleable and that the issue prompting the recall was resolved. It will report this information to the Agency. In addition, the Importer will not begin redistributing the prescription drugs until the Agency has given approval.

Adverse Event Reporting Requirements

Ensuring that Floridians receive imported prescription drugs that are safe, effective, and less expensive is critical to the program's success. As part of achieving this goal, the Agency and Importer will implement post-importation pharmacovigilance processes following the distribution of imported prescription drugs that will comply with the FDA's requirements as stated in Title 21 CFR § 314.80. These steps will include procedures for monitoring and reporting adverse events, completing and filing individual case safety reports (ICSRs), and communicating with the FDA. By exercising the following processes, the Agency and Importer will provide post-importation surveillance to identify any possible adverse event and take actions as appropriate.

Monitoring for Safety Signals for Prescription Drugs at Large

- The FDA defines a safety signal as a "concern about an excess of adverse events compared to what would be expected to be associated with a product's use." Because the manufacturing processes for all prescription drugs that qualify for importation must be the same as their FDA-approved counterparts, the Agency and the Importer will monitor post-marketing data, case reports, and domestic as well as international adverse event reporting systems (FDA Adverse Event Reporting System (FAERS) and the World Health Organization (WHO) Programme for International Drug Monitoring) to assess whether batches or lots of imported prescription drugs should not be distributed. When conducting surveillance, the Agency and Importer will follow the FDA's recommendations in its *Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment*. Examples of safety signals that will trigger further investigation include the following:
    - Serious and minor adverse events not listed in the drug labeling.
    - Increased severity of an adverse event listed in the drug labeling.
    - Serious adverse events considered highly rare for the general population.
    - Newly documented interactions when the imported prescription drug is used with other medications, medical devices, or food/dietary products.
    - Identification of a new at-risk population.
    - Confusion regarding an imported prescription drug's name, labeling, packaging, or use.
    - Other concerns regarding use and those identified by the manufacturer, FDA, or HPFB.
- The Agency and the Importer will communicate with the FDA, HPFB, and the manufacturers regarding safety signal trends to assess whether to halt importation of a specific product or initiate recalls.

Pharmacovigilance and Adverse Event Reporting for Imported Prescription Drugs

- The Agency and Importer will collect and maintain all safety information regarding potential adverse events provided by the manufacturer and included on the FDA and HPFB-approved prescription drug labeling. Both entities will assign staff to familiarize themselves with each imported prescription drug's listed adverse effects and will monitor for disproportionate occurrence rates, severity, and affected populations in comparison to rates reported on FAERS and the WHO Programme for International Drug Monitoring.
- If an adverse event regarding a prescription drug imported through the program occurs, the Agency and Importer will immediately ascertain which of the following categories it qualifies for in accordance with Title 21 CFR § 314.80(a):
    - Life-threatening adverse drug experience
    - Serious adverse drug experience
    - Unexpected adverse drug experience

- The Agency and Importer will delegate appropriate staff to investigate and gather required information pertaining to each reported adverse event that includes specific patient information (e.g., history, biometrics), date and outcome of adverse event, relevant diagnostic tests performed, and Importer prescription drug information (e.g., product name, NDC, dosages administered).
- The Agency will delegate responsibility of filing all expedited ICSRs for serious and unexpected adverse events or upon notification by the FDA within 15 calendar days following the completion of the reporting requirements and receipt of the minimal data set for the adverse event.
- The Importer will include all information as required by Title 21 CFR § 251.18(d)(7) when completing ICSRs prior to submission to the FDA. Following staff completion of a draft ICSR, a supervisor will review for completeness, Health Insurance Portability and Accountability Act (HIPAA) compliance, and accuracy before approving.
- For ICSRs involving serious and expected or non-serious adverse events, the Importer will be responsible for filing non-expedited ICSRs with the FDA within 90 calendar days from the date of completion of the reporting criteria and receipt of the minimal date set for the adverse event.
- The Importer will file all ICSRs in accordance with Title 21 CFR § 314.80(g)(1) and the *FDA Regional Implementation Guide for E2B(R3) Electronic Transmission of Individual Case Safety Reports for Drugs and Biological Products*.

Recordkeeping and Patient Privacy

- The Importer will be responsible for storing and maintaining adverse event records for 10 years following submission to the FDA. If the Importer is unable to maintain these records for the required time period, it will transfer those records to the Agency.
- Importer staff tasked with handling adverse event records will undergo training in the following areas upon hiring and again on an annual or ad hoc basis:
    - HIPAA requirements regarding the confidentiality of personal health information (PHI)
    - FDA guidelines regarding the completion and submission of ICSRs in an electronic format
    - Importer's internal information technology and recordkeeping procedures
- Training curricula will consist of internal materials based on the Department of Health and Human Services (HHS) HIPAA materials and the FDA's adverse event reporting guidelines.
- Upon request by the FDA, the Importer will submit any or all records within 5 calendar days of receipt of the notice.

REMAINDER OF PAGE INTENTIONALLY LEFT BLANK

Compliance Plan

The FDA final rule language requires the SIP's compliance plan to include:

- A description of the division of responsibilities among co-sponsors, if any, which includes a plan for timely communication of any compliance issues to the SIP Sponsor.
- Identification of responsible individual(s) and a description of the respective area(s) of the SIP, the Federal Food, Drug, and Cosmetic Act, or this part that will be under each responsible individual's oversight.
- The creation of written compliance policies, procedures, and protocols.
- The provision of education and training to ensure that Foreign Sellers, Importers, qualifying laboratories, and their employees understand their compliance-related obligations.
- The creation and maintenance of effective lines of communication, including a process to protect the anonymity of complainants and to protect whistleblowers.
- The adoption of processes and procedures for uncovering and addressing noncompliance, misconduct, or conflicts of interest.

As the SIP sponsor and co-sponsor, the Agency and DBPR will assume primary responsibility for overseeing compliance with the program's requirements. Because it will manage the contract or agreement with the Importer or its designee, the Agency will monitor performance, while DBPR ensures adherence to state and federal regulations. In addition, the Agency and DBPR will ensure that the Foreign Seller, qualifying laboratory, Relabeler, and other subcontractors comply as well. To maintain transparency, all participating entities will routinely submit detailed reports to the Agency on their performance. Additionally, the Agency, in collaboration with DBPR, will conduct routine on-site visits of these entities and their facilities as well as any of those under their subcontractors.

Working together, the Agency and DBPR will use the following strategy for ensuring compliance. The remainder of this section outlines the multiple components of Florida's compliance plan as specified in the FDA's Importation of Prescription Drugs final rule.

Division of Responsibilities Among Sponsor/Co-Sponsors

The Agency, acting as the importation program sponsor, will manage the contract with the Importer or its designee and monitor its performance. As the importation program co-sponsor, DBPR will collaborate with the Agency to ensure that the Importer or its designee and subcontractors comply with state and federal prescription drug wholesale and distribution regulations, including but not limited to Chapter 499, Florida Statutes and the Drug Supply Chain Security Act (DSCSA).

Identification of Responsible Individual(s) and Their Respective Area(s)

Operationalizing the SIP

The Importer or its designee will assume full responsibility for operationalizing the SIP and submits reports to the Agency that describes compliance with all requirements. LifeScience Logistics will be performing many duties on behalf of the Importer and State (as described earlier). **Table 4**, Key Personnel, provides a list of key corporate executive staff and their qualifications:

TABLE 4
KEY PERSONNEL

Key Personnel Name: David Cheetham	
Key Personnel Position: Chief Executive Officer	
July 2022 – Current	David Cheetham is a highly experienced healthcare distribution executive with over 25 years of experience in improving supply chain solutions throughout the industry, ranging from large companies to startups. Before joining LifeScience Logistics, Cheetham served as the Executive Vice President of United Allergy Services, where he contributed to the company's growth and success. Prior to that, Cheetham served as President and General Manager of the Manufacturer Services division of Amerisource Bergen Corporation, where he successfully led the division's operations and implemented innovative solutions. Cheetham also co-founded Sonexus Health, LLC, where he led the company's expansion and later navigated a successful acquisition transition to Cardinal Health Corporation. Cheetham holds a BA from Tulane University and has been recognized for his contributions to the industry.
Key Personnel Name: Randy McCollom	
Key Personnel Position: Vice President of Operations	
November 2020 – Current	Randy McCollom, Vice President of Operations, has over 20 years of supply chain experience. Prior to joining LifeScience Logistics, Randy held a variety of roles in operations and inventory management with McKesson Corp, Thermofisher, and ConMed Corporation. He is focused on operational efficiency, process improvement and quality control. Randy attended Troy State University and is a Designated Representative in multiple states.
Key Personnel Name: Joseph Fountaine	
Key Personnel Position: Project Manager	
December 2011 – Current	As LifeScience Logistics' Director of Information Technology & Infrastructure Services. Joseph's responsibilities include oversight of Inventory Control, WMS systems, and all facility infrastructure to maintain operational readiness of five CGMP-compliant facilities. In addition, Joseph is currently the Program Manager for five GSA contracts: GS-00T-11-AJC-0010, GS-00T-11-AJC-0008, GS-00T-12-AJC-0002, 47QFCA20C0002, 47QFCA20C0014.
Key Personnel Name: Paul Hayward	
Key Personnel Position: Vice President of Quality & Compliance	
December 2015 – Current	Paul was named Director of Quality Assurance & Regulatory Affairs in December of 2015. Prior to joining LifeScience Logistics, Paul served as the Vice President of Operations for Azaya Therapeutics, UrgentRx, and Pernix Therapeutics. Paul has over 21 years of experience in quality assurance, manufacturing operations, product development, validation, and supply chain management in the pharmaceutical medical device and biologics industries with organizations that include Reckitt Benckiser, and Allergan Pharmaceuticals. Paul holds a Bachelor of Biology and Chemistry from Southwest Baptist University and a Master of Science in Chemistry from Baylor University. He is a member of the American Society for Quality and Regulatory Affairs Professionals Society.

Key Personnel Name: Chris Mizener	
Key Personnel Position: Head of Drug Importation	
September 2012 – Current	Chris joined LifeScience Logistics in 2012 after 16 years with United Parcel Service. At UPS Chris had several roles within operations, industrial engineering, and finance. He was appointed Director of Client Services in 2016 and is responsible for account management and customer service. Chris holds a Bachelor of Arts degree in Accounting from LeMoyne College in Syracuse, New York.

Individuals Responsible for SIP Oversight

The Agency and DBPR have appointed the following staff members to oversee compliance with the importation program. Each individual will monitor areas specific to their own expertise.

Agency for Health Care Administration
Key Personnel Name: Devona "D.D." Pickle
Key Personnel Position: Program Director, Canadian Prescription Drug Importation
Responsibility: Oversight of the contract with LifeScience Logistics and day to day workflow of the state of Florida Canadian Drug Importation Program.

Department of Business and Professional Regulation
Key Personnel Name: Walter Copeland
Key Personnel Position: Director, Division of Drugs, Devices, and Cosmetics
Responsibility: Compliance and oversight of prescription products and administering the provisions of the Florida Drug and Cosmetic Act consistent with Florida Statutes.

Compliance Policies, Procedures, and Protocols

The Agency will maintain policies that govern how this program will operate and approve the standard operating procedures that are developed by LifeScience Logistics in the operation of the program, on the State's behalf. The contract between the Agency and LifeScience Logistics will also outline delegated duties.

Working with a Foreign Seller to import prescription drugs is a novel concept for the U.S. drug supply chain. To ensure that all participants in the Canadian prescription drug importation chain comply with U.S. regulations as well as Title 21 CFR § 251.14, the Agency will monitor the Foreign Seller's adherence with the following requirements:

- Being able to ascertain whether a shipment of Canadian prescription drugs contains suspect products, notifying the FDA of the discovery of suspect products, and having the means to quarantine said products until disposition.
  - The Foreign Seller will retain samples of the suspect products as well as work with the manufacturer and Importer to determine the source of the suspect products and collaborate to prevent further incidents.
  - The Foreign Seller will notify the FDA's Center for Drug Evaluation and Research within 24 hours of the discovery of a suspect product.
  - If the Importer has imported suspect products, the Foreign Seller must provide all track and trace information necessary to locate and quarantine the shipments.

  - The Foreign Seller must have the capacity to store and maintain records on imported prescription drugs for at least 6 years.

- Providing information regarding transactions, labeling, and shipments to the FDA in the event of a recall.
  - The Foreign Seller will handle recalls of imported prescription drugs in accordance with the SIP's recall and return plan and Title 21 CFR Part 7.

- Separating prescription drug shipments intended for the U.S. market from inventory destined for distribution in Canada.

- Assigning Section 804 Serial Identifiers (SSIs) to each package and homogenous case of prescription drugs that Foreign Seller will ship to the U.S.

  - The Foreign Seller will ensure that it attaches all SSIs to blank areas of packaging and that no overlap of information such as the DIN occurs.
  - The Foreign Seller will maintain all records regarding SSIs for at least 6 years.

- Responding to requests from the Importer, Relabeler, or dispensers within 24 hours to verify whether an assigned SSI corresponds with the one physically labeled on the package or homogenous case.
  - If the SSIs do not match, the Foreign Seller must immediately provide instructions to isolate and quarantine the suspect products.
  - To ensure that other SSIs do not differentiate from those listed on the physical labels, the Foreign Seller will work with the Importer to ensure that the labels on all packages and homogenous cases in the current inventory are accurate.

- Providing the following information for each transaction with the Importer:
  - Statements that the Foreign Seller purchased the prescription drugs directly from their manufacturer.
  - Proprietary names of the prescription drugs if applicable.
  - Strength and dose, container size, number of containers, and the lot number assigned by the manufacturer.
  - Dates of the transaction and shipments.
  - Business names and addresses of the Foreign Seller and the Importer.
  - SSI for each package and homogenous case and the DIN for each prescription drug included in the transaction.

Following entry into the U.S., the Agency will require the vendor to ensure imported prescription drugs are shipped, stored, and distributed in accordance with the federal Food, Drug, and Cosmetic Act, the Drug Supply Chain Security Act, and Section 499.0121, Florida Statutes. To meet compliance, the vendor must have a wholesale and distribution facility licensed by the Department of Business and Professional Regulation and notify the Agency of any third parties or subcontractors that will engage in shipping imported prescription drugs. In addition, the facility must be equipped with environmental controls to monitor temperature and have cold storage units available for prescription drugs requiring refrigeration. The facility must also have adequate space for the quarantining of suspect, expired, or recalled products.

The Agency will further require the vendor to have policies and procedures for the handling of imported prescription drugs to prevent mis-labeling, damages, contamination, and mis-deliveries. These are necessary to ensure that Florida Medicaid recipients and participating State agencies receive safe and effective medications in a timely manner.

The Importer will arrange for all Canadian prescription drugs purchased by the Foreign Seller and affixed with Section 804 Serial Identifiers (SSIs) to enter the U.S. through an authorized point of entry. Once cleared by the U.S. Customs and Border Patrol, the shipments will go directly to the Importer's facility in Whitestown, Indiana. Upon arrival, the Importer will review all SSIs and verify that they correspond with the DINs, lot numbers, and other information specific to the shipment. This review will consist of the following steps:

- Receive prior to importation all product information from the Foreign Seller and the corresponding SSIs including HPFB-approved product name(s), DINs, dosage amounts, lot numbers, quantities, and expiration dates.
- Enter all information into the Importer's database prior to the shipment's arrival.
- Upon the shipment's arrival, verify each SSI and confirm that the packages and homogenous cases correctly match the corresponding product information provided by the Foreign Seller.
- If the SSIs and product information matches those from the Foreign Seller, store the imported prescription drugs in accordance with their environmental requirements and proceed with sample selection for statutory testing.

If the Importer identifies any discrepancies, it will treat the shipment as suspect product and place the drugs in quarantine until an investigation determines that they are either able to undergo statutory testing or should be dispositioned. The Importer will notify the FDA, Foreign Seller, and the HPFB if the suspect prescription drugs are illegitimate and retain samples as appropriate.

During the statutory testing phase, the Importer will store and maintain the shipment in the Whitestown, IN facility until the FDA reviews the results and notifies that the prescription drugs can undergo relabeling and enter the U.S. drug supply chain. If the FDA declares the Canadian drugs unfit for domestic distribution, the Importer will either need to arrange for their retesting or disposition.

Following notification from the FDA that it has approved statutory testing results for a shipment of imported prescription drugs, the Importer can begin the relabeling process. This will occur at the facility in Whitestown, IN where the Importer stored the products during the statutory testing phase. Because the relabeling location serves as the first step in the Drug Supply Chain Security Act (DSCSA) for imported prescription drugs, this is the point that the Importer will affix product identifiers simultaneously with the FDA-approved labels. Each product identifier will meet the specifications as specified in Section 581 of the DSCSA and contain the following:

- Machine-readable bar code unique to that particular lot of imported prescription drugs
- National Drug Code (NDC)
- Lot number
- Expiration date

During the relabeling process, the Importer will affix the product identifiers to an area free of content and ensure that the identifiers do not overlap with information on the labeling.

Prior to shipping the imported prescription drugs to the Importer's facility in Lakeland, FL, the Importer will complete the written certification and submit to the FDA, verifying the following:

- That the prescription drug is approved for marketing in the U.S and is not adulterated or misbranded.
- That the prescription drug meets all labeling requirements as specified in the Federal Food, Drug, and Cosmetic Act and Title 21 CFR § 251.

After the imported prescription drugs undergo relabeling, the Importer will prepare transaction statements, histories, and information prior to shipping them to its facility in Lakeland, Florida for distribution. Upon arrival, staff at the Lakeland, FL facility will verify that all products in the shipment correspond to their respective product identifiers and transaction statements, histories, and information. If cleared, facility staff will store the imported prescription drugs according to their environmental requirements and distribute to pharmacies and State-run facilities as ordered. In the event that a shipment does not match the product identifiers or transaction information, statement, or history, the Importer will classify those imported prescription drugs as suspect and conduct an investigation to determine whether they will be safe for distribution or dispositioned. The Importer will notify the FDA of the determination and retain a sample if the product is illegitimate.

Because Florida is in the process of developing rules specific to prescription drug importation, the contract will provide the detailed requirements to operationalize the SIP and consist of the following requirements. Because implementing the SIP's operational components may require multiple contracts or agreements with third parties, the State may delegate these responsibilities across multiple entities.

- Have an organizational structure that is adequately staffed to operate the SIP.
- Have a physical presence in the state of Florida (e.g., corporate office or subsidiary branch dedicated to administering the importation program).
- Have approved agreements in place with a foreign seller registered both in Canada and the U.S., a qualifying laboratory that has ISO 17025 licensing and meets CGMPs, a relabeler, and storage facilities that can provide environmental conditions suitable for the imported prescription drugs.
- Ensure that the foreign seller has an agreement with a manufacturer to purchase the prescription drugs specified in this proposal.
- Ensure adherence with track and trace requirements as specified in the DSCSA by having an electronic tracking system that collects all transaction statements, histories, and information and can document a prescription drug's point of origin through to its distribution.
- Provide quality assurance throughout the importation process and monitor all parties involved in the pharmaceutical supply chain.
- Ensure that prescription drugs deemed unfit for market in Florida are dispositioned.
- Ensure that relabeling and repackaging processes are completed in accordance with FDA guidelines.
- Have a procedure in place that requires the following:
  - Submission of pre-import requests at least 30 days prior to shipping prescription drugs into the U.S.
  - Use of the U.S. Customs and Border Protection's Automated Commercial Environment or other approved means of data exchange.
- Have a recall and return plan in accordance with that outlined in the Recall and Return section of this proposal.

- Have a system for tracking and resolving consumer complaints and an internal quality control plan.

In regard to all the above listed aspects, the Agency and DBPR will conduct regular monitoring every six months for the first year of importation, then yearly through on-site visits, weekly and ad hoc calls, and desk reviews. The Importer or subcontractors will be required to submit monthly deliverables specifying the number of prescription drugs imported, their testing results (e.g., number of selected samples tested, comparisons to FDA-approved prescription drugs), amounts paid, and number and characteristics of complaints (e.g., open and resolved).

If the Importer or subcontractors do not adhere to the contract's terms and conditions, the Agency can impose a corrective action plan, assess liquidated damages, or terminate the agreement.

Provision of Compliance-Related Education and Training

Before entering into any agreement with an Importer or its designee, the Agency will ensure that the Importer or its designee operationalizing the SIP, as well as its subcontractors, fully understands its responsibilities regarding state, federal, and Canadian regulations for prescription drug importation. To ensure that the Importer or its designee is able to sufficiently train all participating parties and staff involved in the SIP, the State will require proof of the following:

- Educational materials used to train staff and third-party subcontractors regarding the following areas:
  - Storage and handling of prescription drugs
  - How to identify counterfeits or adulterated products based on visual inspections
  - Processes for filing pre-import requests and using the U.S. Customs and Border Protection Automated Commercial Environment
  - Policies and procedures of Health Canada and the Canadian Health Products and Food Branch
  - Processes for recalls and returns
  - Rules regarding relabeling and repackaging
  - Overviews of the FDCA; DSCSA; Chapter 499, Florida Statutes; and the Importation of Prescription Drugs final rule
  - Overview of laboratory testing required for imported prescription drugs and the result thresholds to qualify for entry to Florida's market

Prior to dissemination among staff and subcontractors, the Agency and DBPR will review all educational and training materials to ensure they are aligned with state, federal, and Canadian requirements. In addition, participating entities will not be allowed to begin importing prescription drugs until they have received approval for all educational and training materials.

Lines of Communication

The State will require the Importer or its designee to have multiple lines of communication, including a customer service team available to take complaints. In addition, the Agency and DBPR also have separate lines that consumers can use for complaints. In regard to whistleblowers, the Agency, DBPR, and the Importer will be compliant with the Federal Whistleblower Protection Act and the Florida Whistleblower Protection Act.

The Florida Whistleblower Protection Act (Section 448.102, Florida Statutes) prohibits employers from retaliating against employees who report or threaten to report violations of rules or statutes to a government agency. If an employee makes a complaint alleging that his/her employer is engaged in illegal activities, the investigating government agency will protect their identity during the investigative process.

Regarding violations of Florida's prescription drug wholesaler/distributor regulations, DBPR has a specific online portal for the filing of complaints under the Division of Drugs, Devices, and Cosmetics. Individuals may report concerns with the Importer and not have their identities disclosed. In addition to conducting its own investigation, DBPR will communicate the reported issue to the Agency. The Agency will then further investigate as to whether the problem affects compliance with any prescription drug importation regulation that falls beyond DBPR's scope

The Agency also has multiple lines of communication open to the public and employees of the Importer, Foreign Seller, or other subcontracted entity. These include directly contacting the Florida Medicaid Helpline, the Agency's Division of Health Quality Assurance, and/or the Agency's Bureau of Medicaid Program Integrity. All three have full-time teams tasked with handling and responding to complaints while adhering to federal whistleblower protection statutes. If an individual reports an issue pertaining to the SIP, the receiving team will forward to the Agency's Canadian Prescription Drug Importation Program team to address with the Importer.

When communicating and investigating SIP complaints, the Agency will not disclose the reporting individuals' identities. In addition, any employee of the SIP sponsor, SIP co-sponsor, Importer, or subcontracted entity that performs tasks related to the SIP is eligible for whistleblower protection as stated under Section 448.102, Florida Statutes.

Additionally, the Importer is contractually required to have a customer service hotline and personnel dedicated to receiving and responding to complaints. As part of its contractual requirements, the Importer must maintain a dashboard for complaint tracking and submit a monthly report to the Agency that consists of all complaints reported, dates filed, resolutions, and time spent resolving.

Both the Agency and Importer or its designee will also each have a full-time contract manager who will be available to address issues when they arise. The contract managers are dedicated staff with open lines of communication and can quickly receive and disseminate information.

Processes and Procedures for Noncompliance, Misconduct, and Conflicts of Interest

The Agency, in its role as the SIP sponsor, will monitor the Importer to ensure full compliance with the FDA's final rule. Although federal regulators will conduct inspections and document reviews, the Agency will take a proactive approach that can identify deficiencies and implement corrective actions before these occur. In addition, DBPR will routinely inspect and report any issues that violate State regulations for prescription drug wholesaler/distributors (Chapter 499, Florida Statutes and Chapter 61N, F.A.C.). Combined, both agencies will oversee the SIP to ensure full compliance with the FDA's final rule, the FDCA, and the Drug Supply Chain Security Act (DSCSA).

Certain aspects of the Program such as the Importer's distribution facility fall under existing State regulations. DBPR currently monitors prescription drug wholesalers for adequacy of storage space, temperature controls, security, and quarantine areas.

The State will conduct routine monitoring through monthly, quarterly, and ad hoc reports, as well as on-site reviews for program components that are specific to the FDA's final rule:

- Transaction information, statements, and histories in accordance with the DSCSA.
- Pre-import requests prior to their submission to the FDA.
- Vendor's methods for ensuring imported prescription drugs are not contaminated or counterfeit.
- Labeling of each imported prescription drug.
- Transaction documentation between the Foreign Seller and the vendor.

- Laboratory testing documentation.
  - Documentation will consist of types of tests performed and the results in addition to identifying whether the manufacturer or a contracted laboratory completed the testing.
- Adverse event reports and individual case safety reports concurrent with submission to the FDA.
- Quarterly reports prior to submission to the FDA.
  - These reports consist of multiple components that require documentation that verifies purchase from the Foreign Seller, laboratory testing, and certifications that the prescription drugs are eligible for sale in Canada.

The State reserves the right to inspect all records and facilities operated by the vendor, including those of any subcontractor (if applicable). The State will mirror the FDA's areas of oversight to remain proactive in monitoring, identifying, and correcting deficiencies. The State will conduct onsite visits, both announced and unannounced, to verify that the importation process is compliant with the FDA's final rule. Because the logistics of sending Agency staff to Canada will be costly, the Agency will delegate this to the Importer who is contractually responsible for the Foreign Seller's performance.

The State has established criteria that the Importer must use when inspecting the Foreign Seller's Canadian facility, including providing visual evidence of compliance (e.g., photographs, videos), opportunities for Agency staff to ask questions via livestream. Additionally, the Importer's inspections will occur on an annual and ad hoc basis and will observe the following for compliance:

- Separation of inventory that is intended for sale in the U.S.
- Quarantine areas for suspect or illegitimate products.
- Records of Canadian prescription drugs purchased that are intended for sale in the U.S.
  - The Foreign Seller must maintain these records for six years.
- Processes and procedures for receiving, storing, placing identifiers, and shipping prescription drugs intended for sale in the U.S.

Following a completed inspection, the Importer must submit a written report to the State that specifies the Foreign Seller's areas of compliance and deficiencies. The State will direct the Importer to work with the Foreign Seller to make changes and corrections as necessary.

The State has the means to dispatch staff to inspect and assess the Importer's Florida warehouse for compliance. These onsite inspections will consist of the following:

- Guided and unguided tours of the facility.
- Spot checks of randomly selected lots of prescription drugs to verify correct labeling and packaging.
- Interviews of randomly selected staff to assess regulatory knowledge as it applies to their individual job duties.
- Review of database to examine current inventory information and then verify accuracy by confirming the exact specifications on the Florida warehouse floor.
  - The database review will also verify compliance with the DSCSA.

The State will conduct monitoring at least twice per year in the first year of importation and at least annually thereafter.

In the course of conducting its monitoring activities, the Agency will work in collaboration with DBPR, taking note of any obvious discrepancies (e.g., unsecure areas, sanitation issues), advising the Importer to correct them, and notifying DBPR.

In addition to onsite inspections, the State will conduct desk monitoring on a routine basis. This will consist of the vendor submitting draft reports for the FDA, shipment information, laboratory testing results, and labeling examples. If deficiencies are present, the Agency will request an explanation and consider whether an unannounced onsite inspection is necessary to assess severity.

When one of Florida's State agencies contracts with a vendor for the delivery of services, it does so for the best interests of the people of Florida. To ensure that an agreement best serves the public, State agencies must assess whether any conflicts of interest are present that could create an unfair advantage for the vendor or result in substandard services.

For preventing conflicts of interest, Section 287.057(19), Florida Statutes requires state agencies to address and mitigate any such issues prior to awarding a contract. Because the Agency went through the competitive procurement process to establish an agreement with the Importer, the Agency evaluated for any potential conflicts of interest. In addition, the Agency has included standard questionnaires for vendors and contract managers to complete that will identify potential conflicts. These questionnaires require disclosures regarding financial interests and any plans to mitigate a conflict of interest if one emerges. In addition to assessing for conflicts of interest at the time of the procurement, the Agency reassesses its contract managers for conflicts of interest at the time of any contract amendment, renewal, or extension.

REMAINDER OF PAGE INTENTIONALLY LEFT BLANK

Authenticating Information and the Protection of Trade Secrets

The FDA final rule language requires the SIP proposal to:

> Explain how the SIP Sponsor will ensure that any information that the manufacturer supplies to authenticate a prescription drug being tested and confirm that the labeling of the prescription drug complies with labeling requirements under the Federal Food, Drug, and Cosmetic Act, and any trade secrets or commercial or financial information that is privileged or confidential that the manufacturer supplies for the purposes of testing or otherwise complying with the Federal Food, Drug, and Cosmetic Act and this part, are kept in strict confidence and used only for the purposes of testing or otherwise complying with the Federal Food, Drug, and Cosmetic Act and this part.

Supplying Authenticating Information

As co-sponsor, DBPR will ensure that the manufacturer selected to provide imported prescription drugs supplies any necessary information to verify their authenticity and labeling accuracy. This includes not only that specified in the Federal FDCA and DSCSA but also that listed in Florida's rules (Chapter 61N, F.A.C.) and statutes (Chapter 499, Florida Statutes). In addition, the manufacturer will be responsible for providing all information required for the laboratory testing that includes the following:

- Breakdown of the weights and measurements of APIs and excipients per tablet for each medication in accordance with the prescription drugs' FDA-approved NDA or ANDA
  - Note: The qualifying laboratory will conduct testing against the FDA-approved drug as the standard.
- Copies of all Canadian and U.S. labeling, packaging, and instructions
- Images of the U.S. and Canadian prescription drug tablets with identifying marks clearly visible

To verify labeling accuracy, the Importer must submit a sample of the proposed label to the State upon request.

Protection of Trade Secrets

Although Florida prides itself on its transparency and access to public records, it has protections in place for withholding trade secrets and proprietary confidential business information. The State's public records statutes (Chapter 119, Florida Statutes) provide exemptions for the disclosure of trade secrets and proprietary confidential business information. In addition, DBPR has a rule (Rule 61N-1.021, F.A.C.) that provides a procedure for the manufacturer and Importer to make known what needs to remain confidential. Provided that information is identified as a trade secret or confidential business information in documents submitted to DBPR or obtained during an inspection, this information will not be disclosed if sought through a public records request. LifeScience Logistics maintains client and vendor confidentiality through mutual NDAs, business contracts and quality agreements.

To ensure that the authenticating information is protected, the Importer and the designee will have a written policy regarding confidential information and trade secrets. Additionally, the Importer, the designee, and any party receiving confidential information from the manufacturer will provide yearly training to their employees on protecting confidential information and the requirements under the Federal Food, Drug, and Cosmetic Act to protect confidential information from disclosure, specifically confidential information that the manufacturer provided/supplied regarding

the prescription drug(s). The training will also address the penalties associated with failing to maintain the information as confidential.

See **Attachment J**, Confidentiality, for supporting documentation.

REMAINDER OF PAGE INTENTIONALLY LEFT BLANK

Attachments

ATTACHMENTS
Attachment A – SIP Sponsor and Co-Sponsor
• Sponsor and Co-Sponsor Attestation
Attachment B - Importer
• Importer and Designee Licenses • Attestation • Administrative Fines • Indiana and Florida Five Year Regulatory Audit Histories • Seven Year Disciplinary History • Inspectional History • Life Science Logistics, LLC Wholesale Distributor License
Attachment C – Foreign Seller
• Wholesaler Attestation to Qualify as a SIP Foreign Seller • Methapharm License • Methapharm Registration as SIP Foreign Seller
Attachment D – Wholesale Importation Drug List
• Biktarvy • Descovy • Dovato • Eliquis • Entresto • Eucrisa • Genvoya • Juluca • Odefsey • Prezcobix • Prezista • Ravicti • Rexulti • Symtuza • Tivicay • Vraylar • Xtandi
Attachment E – Cost Savings
• Milliman Narrative • Milliman Canadian Drug Importation Analysis • Agency SIP Methodology and Data for Cost Analysis

Attachment F – Relabeler
• Relabeler Registration • Inspectional History of Relabeler Site
Attachment G – Laboratory Testing
• CPT - Qualifications 2023-02 • CPTC Quality Agreement - 03 JAN 2022 • CPTC Regulatory Doc Pkg - Feb 2023 (002) • Element - Debarment 2022-12-15 • Element - FDA Registration 2023 • Element - ISO170252017 Certification 2023 • Element Debarment-GMP Compliance Statement (15Dec22) • Element FDA Registration 2023 (Ann Arbor) • Element-Avomeen Quality Agreement_14 DEC 2021 • ElementISO 170252017 Certification (2023) • LSL SOP 7001 - Prescription DrugProcess Overview • LSL WI 600.07 - Prescription Drug Initial Sampling and Laboratory Testing • USP-NF Apixaban Tablets • USP-NF Darunavir Tablets
Attachment H – SIP Recall and Return Processes
• CPDIP_FL_Recall_Diagram24FEB2023V2 • Prescription Drug Pharmacovigilance, Drug Recall & Return Process Flow • SOP 1003 - Recalls, Removals, and Corrections • SOP 2003 - Commercial Returned Merchandise • SOP 7000 - Prescription Drug Destruction of Products • SOP 7003 - Prescription Drug Returned Merchandise • WI 600.03 Prescription Drug DSCSA Track-Trace Rev 001 • WI 600.11 - Prescription Drug Returns • WI 600.27 - Prescription Drug Vendor Returns and Quarantine Shipping
Attachment I – Compliance Plan
• QS-004.005 Temperature Monitoring During Storage and Transportation-EC • QS-005.005 Sanitation-EC • QS-006.003 Pest Control-EC • QS-007.003 Hygiene-EC • QS-013.006 Receiving Goods-EC • QS-014.005 QA Review and Disposition of Raw Materials and Finished Goods-EC • Quality Plan_CPDIP LSL 12DEC2022_FINAL • SOP 1031 - Vendor Qualification • SOP 1351 - Deviation_CAPA – RX • SOP 1601 - Response to Cargo Thefts • SOP 2002 - Handling, Storage, Packaging & Distribution • SOP 7004 - Prescription Drug Pharmacovigilance

- WI 600.01 - Prescription Drug Procurement
- WI 600.03 - Prescription Drug DSCSA Track, Trace
- WI 600.04 - Prescription Drug Customer Setup
- WI 600.05 - Prescription Drug Receiving
- WI 600.06 - Prescription Drug Hold and Release
- WI 600.08 - Prescription Drug Relabeling Requirements and Process
- WI 600.10 - Prescription Drug Pick, Pack, Ship
- WI 600.14 - Prescription Drug Inventory Adjustments
- WI 600.15 - Prescription Drug Inventory Management
- WI 600.26 - Inspection of Drug Products and Components

Attachment J – Confidentiality

- AHCA 4004 Records Management
- AHCA 4029 Security and Identification Badges Policy
- AHCA 4031 HIPAA-HITECH Compliance (Manual)
- AHCA 4031 HIPAA-HITECH Compliance
- AHCA 5009 Confidential Information Policy
- AHCA 5013 Mobile Computing Policy
- AHCA CM Conflict of Interest Questionnaire_2100-0063_JUL2022
- AHCA JOB AID - Contract Documentation Checklist
- AHCA Risk Report for Life-Science-Logistics-LLC-286600293-2022-12-27_17-48-8
- FL SIP Trade Secret Confidentiality 3-28-23
- LSL_Form_Mutual_NDA

REMAINDER OF PAGE INTENTIONALLY LEFT BLANK