# AGENDA
## Department of Business and Professional Regulation
## Drug Wholesale Distributor Advisory Council

**Conference Call Number: 1-888-585-9008**
**Conference Code: 170778661**

**December 17, 2020**
**9:30 a.m.**

Council Members:

Steve Mays, Prescription Drug Wholesalers
Jeenu Philip, Chair, Board of Pharmacy
Joseph Lavino, CVS Health, Retail Pharmacy
Scott Brock, Pharmaceutical Manufacturers
Arlene Elliott, Agency for Health Care Administration
Dean Ellis, Secondary Prescription Drug Wholesalers
Jeffrey Tuller, Vice Chair, Primary Prescription Drug Wholesalers
Patrick Barnes, Hospital Pharmacist
Peter Hart, Medical Gas
Jennifer Goldman, MD, Physician

DBPR Staff:

Walter Copeland, Division Director
Halsey Beshears, Secretary
Tim Page, Deputy Secretary
Renee Alsobrook, Compliance Manager
Stephanie Prine, Government Operations Consultant
Rebecca Burnett, Regulatory Supervisor
Lavontae Warren, Administrative Assistant III

**Call to Order: Jeenu Philip, Chair**

**TAB 1: Chair's Report – Jeenu Philip, Chair**

- **I. September 24, 2020 Meeting Transcript (information only)**
- **II. 499.01211, F. S. – Drug Wholesale Distributor Advisory Council**

**TAB 2: Division Director's Report – Walter Copeland**

- **I. Legislative Update**
  - **a. HB 19**
    - **i. Application for international wholesale distributor**
    - **ii. Registration for Importer and Exporter/foreign seller**
    - **iii. Rules implementing international importation program**
- **II. Proposed Legislation**
  - **a. Temporary permit**
  - **b. Citation program**
  - **c. Cosmetic program**
- **III. DBPR/DDC**
  - **a. HCCE Requirement – who is required to have the permit**
  - **b. Stats on number of permits**
  - **c. Data on percentage time investigation**
  - **d. Applications received and processed etc.**

IV. Lawsuit re importation rule

V. SIP Proposal

VI. Covid-19 Update

a. Vaccine information

b. Permits issued to facilitate distribution

c. Florida Administrative Rule 61N-1.011

TAB 3: Other Business

STATE OF FLORIDA

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

DRUG WHOLESALE DISTRIBUTOR ADVISORY COUNCIL

MEETING

September 24, 2020

Reported by:
RAY D. CONVERY
Court Reporter

P R O C E E D I N G S

MS. ALSOBROOK: Mr. Chairman, this is Rene Alsobrook. You have a quorum to proceed with your meeting, sir.

MR. PHILLIP: Okay. Thank you so much. Okay. So this --

MR. BROCK: Mr. Chairman, Mr. Chairman, this is Scott Brock. I just wanted you to know that I'm also here. I apologize for interrupting. Thank you so much.

MR. PHILLIP: Good morning, members. This is Jeenu Phillip. We're calling the Drug Wholesaler Distributor Advisory Council to order. Just a reminder to those on the call, if you're not speaking, if you wouldn't mind, please keep your phones on mute to minimize any background noise. In addition to that, before speaking, please state your name for the court reporter so that we can accurately get who is actually speaking on the call.

So, with that, we'll go ahead and proceed right into the meeting, moving into Tab 1, the Chair's Report. So in your agenda packet is the July 9th, 2020 meeting transcript for informational purposes only. Assuming there's no other

discussion on it, we can proceed right into Section 2, which is the -- I guess the charge of the meeting. So is there any comment on the previous minutes?

Hearing none, going right into the charge of the committee, just as a reminder, this committee is under 499.01211, Drug Wholesale Distributor Advisory Council. The charge of the Council is to review this part and rules adopted to administer this part annually and provide input to the Department regarding all proposed rules to administer this part, make recommendations to the Department to improve the protection of prescription drugs and public health, make recommendations to improve coordination with other states' regulatory agencies and the federal government concerning the wholesale distribution of drugs, and make recommendations to minimize the impact of regulation to the wholesale distribution industry while ensuring protection of the public health.

So, with that, I will now, I guess, go back -- going back to our agenda, we have -- move right into the Division Director's Report. So I will turn this section over to Mr. Copeland for his

report. Thank you.

MR. COPELAND: Hello, Council. Thank you all for attending. This is Walter Copeland. And if you'll see, the first item on the Tab 2 agenda, legislative update, HB 19, or the Prescription Drug Importation Bill entered into law in June here in Florida. Just to quick update, the Agency for Health Care Administration has advertised for an ITN, an invitation to negotiate, for a vendor as they are required to assist with the Canadian program within HB 19. We've assisted and worked, as we have from the get-go, with the AHCA team and have provided some information on our wholesale distributor permitees currently that we've reached out to just to give them a notice, and we did it broadband to everyone the same, that we were just providing them information on where they could go on the Agency for Health Care web site if any of them were interested in looking at the invitation to negotiate. Don't have any details, can't really get into any details there, just wanted to give you all a quick update on where that stands.

Go to Tab 2. This is our -- the Division of Drugs, Devices and Cosmetics portion of our responsibilities within HB 19 under the

international program, and currently we're ramping up the international prescription drug wholesale distributor application that is a new application we're charged with creating under HB 19 where, again, we're -- we've been editing, going back and forth, and we're right near the end in developing this application.

If you look at letter B, in reference to that application, we're required to develop some financial responsibility rules that would apply to any qualified entities or individuals making application under that new permit type, and those rules will be embedded in the rules that develop the new permit type, and I will just convey to everyone, they're going to be somewhat -- they will mirror the same requirements that we asked for on the wholesale distributor applications currently that we issue.

Rene, is that fair on the financial requirements side, as you understand them?

MS. ALSOBROOK: Yes, sir. This is Rene. Yes, sir, that is an accurate assessment. We're going to mirror the current standards that apply to the wholesale distributors that are licensed in state and out of state.

MR. COPELAND: And letter C, non-resident prescription drug manufacturers, obviously, we issue those permits currently, but, under House Bill 19, there is a provision to allow non-resident prescription drug manufacturers to make an election to participate in the international program, and, in order to do that, they would have to register with DDC and provide additional information that would mirror the additional information required under the international drug wholesale distributor permit. And basically a summary of this, to let you all know that we are right near the end to getting the rulemaking in process, and we're doing that with the realization that there's some federal rulemaking that is not perfectly aligned with our bill, but we've got to get this wrapped up and we don't, you know, want to slow anything down if we're opened up to move forward with the prescription drug importation.

I know that was kind of a lot of detail, but if anyone has any questions we could try to answer, we'll sure do it.

MR. TULLER: Mr. Director, this is Jeff Tuller. I have a question.

MR. PHILLIP: Hey, Jeff, how are you?

MR. TULLER: Hey, Walter. Good morning to everybody.

The assumption, I guess, Rene, is you're going to have a tiered bond structure for financial responsibility and all of the pieces of our regular application will be applicable to this one. Is that what I'm hearing?

MR. COPELAND: That is -- and, again, Rene and I have worked together quite a bit on this, and I have been involved quite a bit on the making sure on the bonding side, being that this will be an international surety bond. You're exactly right, Jeff. Rene, correct me if I misstate anything, but the bonding requirements, my understanding, are going to be the same as the wholesale distributors now or we may have an exception where we don't have the $25,000 option.

MS. ALSOBROOK: That's correct, Director. This is Rene. Mr. Tuller, we looked at -- the DSCSA actually allowed the wholesale distributor bond to drop to 25,000. The Director and I talked about not allowing that low of a bond for the international wholesale distributor and maintaining that at the original $100,000 level that wholesale distributors in the United States had to carry

before the DSCSA because we don't believe that the DSCSA applies to the international wholesaler permit.

MR. TULLER: Agreed. So noted, thank you.

MR. COPELAND: Jeff, did that get what you need for right now?

MR. TULLER: Yes, sir. Thank you very much.

MR. COPELAND: Great. Any other questions before we move to 3?

All right. CDR, or certified designated representative examination, we have that available now on line through -- Pearson VUE are our testing -- or our agency's testing contractor. Obviously, this is -- the on-line applications are the off site --

(Music playing.)

MR. COPELAND: Somebody's got some juke joint --

(Music playing, then stops playing.)

MR. COPELAND: But, on the CDR examination, many of the other divisions here in the agency during this pandemic have worked with Pearson VUE to allow those taking exams to have them proctored off site, and we -- our CDR examination is included in there, and I will say that we worked with our

testing division here to make sure that the proctoring and the security of this was absolutely -- there was no hiccups. So we're comfortable with that. It's another option that will help stakeholders not get held up when they're running into CDR issues and testing issues that we've run into due to testing site availability during the pandemic.

Did anybody have any further questions on that issue?

MR. TULLER: Mr. Director, this is Jeff Tuller. I do have a question on that. So, going forward, the CDRs can take an exam via the web linked into Pearson VUE. Is that what I'm hearing?

MR. COPELAND: That's correct, Jeff. And, if you go on our web site, there's some pretty detailed information, and it actually links you to the Pearson VUE web site, where -- I can't give you all the details, it's been a while since I looked at it, but it's -- it kind of walks you through it, or walks a potential test-taker through the process, but, yes; you're correct.

MR. TULLER: Great, great, thank you.

MR. COPELAND: All right. Roman numeral IV, licensure count for this fiscal year. You'll see

we've got this broken down by license types that are active currently or here just recently, and it's about 16,000 plus or minus active licenses that we're currently -- currently have open. You will see there at the bottom, the health care clinic establishment permits. That's been a big-volume item here since going into play three or four years ago, and we just wanted to share this with you all to kind of -- to let you see what we're dealing with and what the volume is on each permit type as a snapshot. I'm going to -- no questions there.

Roman numeral V, I'm going to let Chief Alsobrook take this one -- it's in her wheelhouse -- and let her give you a summary of the trends and conditions of our enforcement and compliance unit.

MS. ALSOBROOK: Thank you, Director. This is Rene. What we wanted to demonstrate to the Council is some data that kind of shows or does show the adjustment in enforcement's direction as far as our efforts to move towards nondisciplinary interventions, in other words, compliance, before we head towards enforcement or regulatory action resulting in fines. So I think this graph kind of

shows us where we're headed.

We have peaked with our nondisciplinary interventions, and those are providing guidance, education, notices of inspections, information on the entry and notice of inspection report to the firms that we go talk to about what they might do to improve their compliance.

What we don't do is subject the public to a health issue. So, if it's a violation that could lead to the -- a serious health issue or death, then clearly that would be something that we would have to take regulatory action against, but, if it's something that the firm could correct, if it's a first-time violation, and even in some cases if it's not serious, a second violation that we find upon inspection, the inspectors are leaning to more issuance of a non regulatory -- in other words, they don't write an investigative case, a more compliance-oriented action with that subject. So I'm kind of proud of that, and I wanted you to see a huge growth in that activity with the inspectors. So we've provided this graph for you. Sorry it's not in color, I'm sure, in your books, but I think the numbers at the bottom show the nondisciplinary interventions have grown to over a thousand in the

last few years, and we continue that activity, notwithstanding the growth in the number of complaints that we're trying to resolve in some other way.

Any questions about those? Excellent.

MR. COPELAND: Chief Alsobrook, this is Walter Copeland. I just wanted to piggyback on Rene's comments there. I'm extremely pleased with the assistance and approach that our compliance unit has had based on, obviously, number one, making sure safety is the primary concern, but, number, two, using common sense with our stakeholders, and treating their job like they're owners.

I can tell you this: We posted -- I may have mentioned this, but earlier on we posted everybody's contact information on our web site, and I hear our team and our compliance team constantly assisting stakeholders in mitigating process -- you know, mitigating any processes that would normally be fines or penalties of sorts. So we're not lowering our guard. We're just working to get people in compliance I feel in a common-sense fashion, and I haven't been involved much with that, but I'm very pleased with our team's approach, and I just, again, wanted to

compliment them.

MS. ALSOBROOK: Thank you, Director. Again, this a Rene. On our percentage of time spent on permit types, I know I don't have a document to show you all for that, and hopefully by the next meeting I will have something, but one of the things that I do is I keep a running total of the percentage of time the inspectors bill to each permit type, and *bill* is a loose term, but I guess dedicate to each permit type is a better idea, but we started doing this in the second half of the year 2017, and it's still an ongoing project for us.

We do it for a couple of reasons, but the primary reason for me was to see how much time was being spent on each permit type because, for me, there are permit types that do have an impact on health, safety, and there are permit types that aren't as focused on health, safety and welfare. So I kind of wanted to get that idea. And I also wanted to see if we were, you know, just working on, for example, the wholesale distributors, or were we also looking at our out-of-state wholesale distributors who bring the same drugs into the state as our in-state wholesale distributors

because I have a little bit of a problem with not spending some regulatory time on our out-of-state wholesale distributors who are bringing in the same drugs as our in-state wholesale distributors because I kind of didn't think that regulation of only our in-state wholesale distributors was appropriate.

So I'll give you an example of what I was looking at. So, for example, our in-state wholesale distributors, our average regulatory efforts are about 17 percent, and our out-of-state wholesale distributors, our average regulatory activity is about three percent, but the drugs that are coming in are about the same. So I had a little bit of a problem with not doing more increased regulatory activity on our out-of-state wholesale distributors. So I made it kind of a challenge to my inspectors to do a little bit more regulatory activity with our out-of-state wholesale distributors, and we can find that information by looking at, you know, invoices, et cetera, when we do inspections.

So we have increased this year our regulatory activity for out-of-state wholesale distributors to seven percent, and I want us to continue to do that

because, as I indicated, the drugs are the drugs are the drugs are the drugs, whether they come from in state or out of state, and I do think that our out-of-state wholesale distributors should be facing very similar regulatory activities as our in-state wholesale distributors. So I wanted to point that kind of to your attention that we have identified that our non-resident permit holders should be looking at similar regulatory activity as our in-state folks. So that is something that we are trying to pay a little more attention to and devote a little more regulatory activity to.

You know, we do expect that the resident state does regulate them, but Florida should also be looking at their compliance with Florida law when they are subjecting Florida residents to the same potential for health, safety and welfare as our in-state folks are. Any questions about that?

MR. ELLIS: Hi, Rene, this is Dean Ellis. I just wanted to give you kudos for that because we spend a lot of time trying to educate out-of-state vendors to our laws and regulations. So I think that's going to prove to be very helpful. Thank you.

MS. ALSOBROOK: Thank you, sir. Yes, I do

know that there are several of our licensees, permit holders that spend a considerable amount of time with their compliance team trying to get out-of-state folks to comply particularly with Florida recordkeeping requirements, and they get a lot of push-back, and we try to be responsive and assist the permit holders in those phone calls with out-of-state permit holders to try to get them to understand that, yeah, you've got to do it. I mean, we're going to find a case against you if you don't. So, yes, Mr. Ellis; thank you very much.

If there are no more questions on that, the next item that I was going to talk to you about was the federal rule draft status. You know that it's been sent over to -- the federal rule on the importation of drugs from Canada -- I use the word Canada, although the rule does not specifically limit it to Canada. Specifically, the Office of Management and Budget, I checked again this morning. I don't see any movement of that. Generally speaking, the Office of Management and Budget has 90 days to review a rule that's been sent over there for review. They can, as I understand the process, extend that for an additional 30 days. So, technically I guess they

have 90 days -- excuse me -- 120 days to review a proposed rule sent by the Department of Health and Human Services, but I haven't seen any information from it. You may know more than I know, those members who have more access to information coming out of Washington than I do, but I don't have a status to update you on other than the draft has been sent to the Office of Management and Budget for their review of the rule and input to the Department of HHS as to its impact on the stakeholders. And you all are aware that the executive order from President Trump in July -- I think it was July 24th of 2020 -- did encourage continuing with the importation of drugs from Canada. So that is a push, I guess, towards proceeding with the rule.

That's all I have. If you have any questions, I'll be glad to try to answer them. Thank you, Director, that's all I have.

MR. COPELAND: All right. I'm going to take Item 8, Legislative Proposal to Provide DDC Statutory Authority to Issue Citations. When we were asked to provide legislative suggestions for change for our division, we came up with -- well, currently, our division in our enforcement and

compliance tool box we don't have the ability to cite, and in not having that ability, we kind of have a donut hole between -- you know, either we have to involve legal and spend a lot of time and effort for what I -- or for what we see are nonsubstantive violations, but violations that it wouldn't be fair for us or statutorily compliant for us not to address.

We have come up with a proposed, you know, statutory authority that we've sent with our legislative request that would allow us the ability to cite stakeholders for certain violations, and these, again, are nonsubstantive violations, and we see this as a win-win for the Division and for the stakeholders. We're going to spend a lot less money in legal, in time, and we're going to get a faster resolution, and, where I can't give you all the details off the top of my hat of the proposed wording, I will tell you that this was proposed in I believe 2012, and we went back and made some revisions based on some input from stakeholders, and what I'll be glad to do is send this proposed wording to each of you because what we want is we want input from the Council, and -- but, again, I just see this as a win-win for everyone, but I

would ask, if it's okay, that I could send this offline to each one of you individually and, respectfully, if you would provide any input you may have, we're asking for that.

Any input? I know I can't give you a lot of the details there, but I can -- yeah.

MR. PHILLIP: Mr. Copeland, this is Jeenu Phillip, Chair.

MR. COPELAND: Yes.

MR. PHILLIP: Yes. You know, I think the only thing I would say is that the Board of Pharmacy probably about a year ago changed their rules to allow for, you know, the inspectors to provide citations to fill that gap that you talked about. It's worked out well. I think the -- you know, I think the key here is proper discretion in terms of how they use the ci -- you know, the investigators use those citations, and just as long as it's used appropriately and proportionally I think is really the key. If it's done with the understanding that we're going to focus on, you know, getting people to compliance first, and then use citations as -- you know, kind of the next lever to pull if necessary, I think that seems to be the right way to go about it, you know, and -- you know, just as

Ms. Alsobrook pointed out, the nondisciplinary interventions generally work the best if we can get people into compliance without having to enforce -- you know, disciplinary action seems to be, I think, about the best way to go about things, both in terms of building good will and trying to drive people towards doing the right thing.

MR. COPELAND: Chair, I concur with you 100 percent there. And, as we look through our -- you know, our monthly metrics and our fine and settlement numbers compared to prior years and the metrics on those, I'd be perfectly happy if they got down to nothing, and -- but that would mean everybody was complying, and so there are some provisions in our proposal that allow people to correct the areas identified within a certain time, and then the citation would be rescinded.

So, good input, and we will check out the Board of Pharmacy statute on that also, but you all -- if you all will just look for an email, we'll shoot that to you, and please provide your additional input, but that was good. I think -- well, nothing else on that.

MR. HART: Director, this is Peter Hart. Just a quick question. Is -- and I look forward to

reading the proposed language, and, of course, be glad to comment. Just a quick question, though. Several other states around the country for companies like ourselves that operate in all 50 states, we run into situations where there are -- in the punitive capacity, their legislation allows them to assess fines based on inspectional information, based on other states that they require reporting of -- say, if I receive an observation in the state of Utah, that I have to report it to the State of Hawaii, and Hawaii then will punitively fine against the action observation from Utah. Are you going down that road? I'm curious.

MR. COPELAND: Mr. Hart, I'm going to let Chief Alsobrook weigh in after I give you my input on that, but that's an area, when I review settlements and I review the settlement proposals and counterproposals with Chief Alsobrook and her team, we see that -- I call it piggybacking off of the other states, and we do see that quite often. Rene, correct me if I'm wrong, but I am -- as long as the initial substantive violation that generated the other state's issuing any kind of violation, we don't make it a practice to continue that process

when Florida identifies it. Now, Rene, step in, and I know that that's my fault.

MS. ALSOBROOK: Thank you, Director. This is Rene. Mr. Hart, I'm going to take your question as two parts. The first part is, as to the citation, the citation would clearly be labeled nondisciplinary. So we will do it -- it should not be treated by another state as disciplinary action in any way by the state, by any other state, and it should not result in any action by another state because it is going to be clearly labeled as nondisciplinary action.

Now, you know, we obviously can't control it, but that's what why we want your input and that's why we brought it to you guys and that's why we'll bring it back to you guys when we get a rule draft, because one of the other things we would want to do is develop a rule that puts forth the types of violations, along with the penalty amount that would be set out in the citation, and I use the word penalty. That wouldn't be the right word. The citation amount would go along with the violation that we cite because the rule (inaudible) that we cite, because we want that kind of input.

So we want to make it clear that this citation

process is to avoid a legal action and the perception that it is discipline, because it's not discipline. It's a way to encourage corrective action after we've asked somebody to get this corrected two or three times because, what's happening now is, after we've asked them to correct it the second and third time, we have nothing to do but to write an investigative case that results in costly legal action both to ourselves and to the firm, and what we're trying to do by the citation process is to prevent the delay from issuing a permit because you've got a pending case and the process is you can't get your permit issued until you resolve your pending case, your legal case. We don't think that's appropriate when it's a minor violation, but it's nonetheless a violation of the law that has to be addressed.

The second thing that we think this citation can avoid are questions by other states of why you have an open case in the state of Florida because we can get that case wrapped up pretty quickly. If you're renewing in another state, you won't have a case because there's not a case. It's like a traffic ticket that's been resolved.

And the third thing is, as I indicated, it

should resolve the legal costs for both us and for your firm. But we do want to make it very clear that these are nondisciplinary actions. They should not be held against you by us. They would not be held against you by another state.

Now, there's one caveat to that. If you do it again, I've got notice I've told you not to do it because, my goodness, you've been told once in an inspection, you've been told a second time in a notice of inspection, and now you've been told with a citation. So your fourth time at the Ferris wheel you're going to get a case, and I would hope that you wouldn't come to us with a defense of I didn't know.

But the bottom line is, Mr. Hart -- and it was a very good question -- it should not be held against you by another state because it isn't discipline and we're clear that it's not discipline.

MR. HART: Thank you, Chief Alsobrook. I greatly appreciate your clarity, and, as usual, you guys give us common sense and I greatly appreciate it. Thank you.

MS. ALSOBROOK: Now, for the second part of your question, Mr. Hart, the carousel of terror, as

I call them, when you're disciplined in another state and we get the information about your discipline in another state, the director usually does not have me take action. We simply record it, particularly if it's action from Alabama because they fine you on everything, but there is an exception to that. If you are a wholesale distributor and you did something really bad, like distribute controlled substances without a DEA permit, you're probably going to hear from us. But it is not automatic that we will open a case against you because you were disciplined in another state. It tends to be for some substantial violations, like not having a CDR or selling to somebody without a permit. And, if you do that, we probably will open a case against you in Florida for being disciplined by a state for those kind of substantive violations. But, again, it's a risk assessment.

We only have nine inspectors. We only have so much time in a day. And if your violation wasn't substantive in the resident state, then we probably will not get a case against you. You may get a warning letter which would be opening a case and me telling you don't do that again, or let us know,

and try to behave, but we're not going to try to fine you. We're trying to really apply some common sense and assessment of resources that we have here in Florida.

Does that help with those disciplines-in-another-state kind of cases?

MR. HART: This is Peter. That's -- absolutely. I appreciate it greatly.

I also want to take just a second to compliment the team. Mr. Director, with all of your folks, your transparency on giving us contact numbers, especially since we're working through the hurricane season that has been so lively, I can't say enough good things about how your state organization has proactively worked through preparation for that. And it's been -- as almost every year, it's been a stellar experience of handling tough situations, and I just want to say thanks to you and your whole team for that.

MR. COPELAND: Well, I inherited a good deal. So I'm just trying to navigate it and keep it in the right direction, but it's -- we do have a good group here, and everybody's -- again, I see them treating this like they're owners, and that's what I asked for, and so -- and we appreciate you all's

input, and we've had -- you know, no excuses, but we've had some hiccups here last -- it's been a little abnormal. So, our intent I know is to involve the Council more, and we've got some great resource in each of you. So hopefully we can do that and we can start with this citation proposal.

But, just real quick to wrap up on the citation proposal: As Chief Alsobrook had referred to, it's just a cost/benefit approach in my opinion. We have a limited legal team, a limited number of inspectors, and I'm afraid, if we don't figure out a more efficient process to address these smaller violations, the time that's going to take away from us identifying the more substantive and safety issues is -- we don't want to take that time away. We want to free them up so they can find more of the ones we need to find.

So, that's, I think -- again, you all, we appreciate the review and we will forward that out to each of you.

MR. MAYS: Mr. Chair, this is Steve Mays.

MR. COPELAND: Hey, Steve.

MR. MAYS: And I just wanted to make a comment. I think, with the data that the Department is using, with, you know, the numbers of

permitees and the inspections and the investigations and the -- you know, what type of action is being taken, I think it's very smart, especially given limited resources that, you know, most state governments have to investigate things, that I think a risk-based approach totally makes sense, and I think that's a great way that you guys are going. So I think I fully support that. I think it's a good approach.

MR. COPELAND: I appreciate that, Steve.

And is there any other input or questions related to the citation proposal?

I guess we're -- Mr. Chair, I think we're on the other business, so --

MR. PHILLIP: Okay. Thank you, Mr. Copeland.

So any -- I don't have anything listed for the other business. So, is there anyone on the call who would like to share anything more?

MS. HARTSFIELD: Mr. Chair, this is Shannon Hartsfield with Holland & Knight. I just want to echo the comments about how much I think stakeholders appreciate the transparency and assistance provided by the Office of Drugs, Devices and Cosmetics, Chief Alsobrook, and all the other staff. I guess I'm just -- can the proposal

regarding the citations be distributed to the interested-party list?

MR. COPELAND: Absolutely, Shannon.

MS. HARTSFIELD: Thank you.

MR. PHILLIP: Any further comments?

MS. ALSOBROOK: Mr. Chair, this is Rene. Could we get the court reporter to identify themselves again? I think they did so before we got on the record.

MR. PHILLIP: I lost you for a second. Can you repeat that?

MS. ALSOBROOK: Yes, sir. This is Rene. Could the court reporter identify himself again, please?

MR. CONVERY: Yes. This is the court reporter. My name is Ray Convery, C-o-n-v-e-r-y, and I'm with For the Record Reporting.

MS. ALSOBROOK: Thank you, sir.

MR. PHILLIP: Well, seeing nothing else on the agenda and looking as we're at the end, I'll take a motion to adjourn.

UNIDENTIFIED SPEAKER: So moved, motion.

MR. BARNES: Second, this is Patrick.

MR. PHILLIP: All right. So we have a motion and a second. All in favor signify by saying aye.

(Chorus of ayes.)

MR. PHILLIP: Opposed? Okay. Hearing none, the motion passes. Thank you all.

(Excerpt of proceedings concluded.)

499.01211 Drug Wholesale Distributor Advisory Council.—

(1) There is created the Drug Wholesale Distributor Advisory Council within the department. The council shall meet at least once each calendar quarter. Staff for the council shall be provided by the department. The council shall consist of 12 members who shall serve without compensation. The council shall elect a chairperson and a vice chairperson annually.

(2) The Secretary of Business and Professional Regulation or his or her designee and the Secretary of Health Care Administration or her or his designee shall be members of the council. The Secretary of Business and Professional Regulation shall appoint 10 additional members to the council who shall be appointed to a term of 4 years each, as follows:

(a) Three persons, each of whom is employed by a different prescription drug wholesale distributor permitted under this part which operates nationally as defined in s. 499.003.

(b) One person employed by a prescription drug wholesale distributor permitted under this part as defined in s. 499.003.

(c) One person employed by a retail pharmacy chain located in this state.

(d) One person who is a member of the Board of Pharmacy and is a pharmacist licensed under chapter 465.

(e) One person who is a physician licensed pursuant to chapter 458 or chapter 459.

(f) One person who is an employee of a hospital licensed pursuant to chapter 395 and is a pharmacist licensed pursuant to chapter 465.

(g) One person who is an employee of a pharmaceutical manufacturer.

(h) One person who is an employee of a permitted medical gas manufacturer or medical gas wholesale distributor and who has been recommended by the Compressed Gas Association.

(3) The council shall review this part and the rules adopted to administer this part annually, provide input to the department regarding all proposed rules to administer this part, make recommendations to the department to improve the protection of the prescription drugs and public health, make recommendations to improve coordination with other states' regulatory agencies and the federal government concerning the wholesale distribution of drugs, and make recommendations to minimize the impact of regulation of the wholesale distribution industry while ensuring protection of the public health.

History.—s. 17, ch. 2003-155; s. 23, ch. 2007-6; s. 105, ch. 2008-6; s. 14, ch. 2008-207; s. 41, ch. 2010-161; s. 4, ch. 2012-143; s. 5, ch. 2014-89; s. 78, ch. 2018-110.

Agenda Item II

Cosmetic Cottage Industry Permit
Amend the provisions of chapter 499, to create a cosmetic cottage industry registration which would allow small entities (sales less than $25,000/year) that make certain types of products (limitations placed on certain ingredients and application methods) to enter the market place with minimal costs ($25 application fee; $100 annual registration; no registration of products) and no inspection.

Temporary Expiring Permit
Amend provisions of chapter 499, to create a 90 day, nonrenewable, temporary permit for DDC permittees. The temporary permit would only be available to entities that have paid the temporary permitting fee (1/4 of the regular fee) and simultaneously submitted a permit application and regular fee for the appropriate permit.

Non-disciplinary Citation Program
Amend the provisions of chapter 499 to allow the department to adopt rules to allow the issuance of remedial, non-disciplinary citations which would also set the penalty amounts/provisions allowed under such citation authority.

Proposed language for the citation program is set forth below:

499.066 Penalties; remedies.—In addition to other penalties and other enforcement provisions:
(8)(a) The department shall adopt rules to permit the issuance of remedial, nondisciplinary citations. A citation shall be issued to the person alleged to have committed a violation and contain
the person's name, address, and license number, if applicable, a brief factual statement, the sections
of the law allegedly violated, and the monetary assessment and or other remedial measures imposed.
The person shall have 30 days after the citation is served to contest the citation by providing supplemental and clarifying information to the department. The citation must clearly state that the
person may choose, in lieu of accepting the citation, to have the department rescind the citation and
conduct an investigation pursuant to s. 499.051 of only those alleged violations contained in the citation. The citation shall be rescinded by the department if the person remedies or corrects the violations or deficiencies contained in the citation within 30 days after the citation is served. If the
person does not successfully contest the citation to the satisfaction of the department, or complete
remedial action pursuant to this paragraph, the citation becomes a final order and does not constitute
discipline.
(b) The department shall adopt rules designating violations for which a citation may be issued. The rules shall designate as citable those violations for which there is no substantial threat to the
public health, safety, or welfare.
(c) The department is entitled to recover the costs of investigation, in addition to any penalty provided according to department rule, as part of the penalty levied pursuant to the citation.

(d) A citation must be issued within 6 months after the filing of the complaint that is the basis for the citation.
(e) Service of a citation may be made by personal service or certified mail, restricted delivery, to the person at the person's last known address of record with the department or to the person's
Florida registered agent.
(f) The department has authority to, and shall adopt rules to, designate those violations for which a person is subject to the issuance of a citation and designate the monetary assessments and or
other remedial measures that must be taken for those violations. The department has continuous
authority to amend its rules adopted pursuant to this section.

**INSPECTORS' PERCENTAGE OF TIME ALLOCATED TO PERMIT TYPE, INCLUDING UNLICENSED ACTIVITIY FOR FISCAL YEAR JULY 1, 2019 THROUGH JUNE 30, 2020**

**DRUG INSPECTORS**

| | |
|---|---|
| Third Party Logistic Provider | 3.27 |
| Cosmetic Manufacturer | 10.48 |
| Product Registration OTC | 0.08 |
| Product Registration RX | 0.14 |
| Ether | 0.02 |
| Exemp tions | 0.02 |
| RX Manufacturer | 10.54 |
| OTC Manufacturer | 6.6 |
| RX Wholesale Distributor | 12.96 |
| Out of State RX Wholesale Distributor | 6.61 |
| Retail Pharmacy Drug Wholesale Distributor | 8.2 |
| Veterinary RX Retail Establishment | 0.54 |
| Nonresident RX Manufacturer | 3.25 |
| Freight Forwarder | 0.13 |
| RX repackager | 1.97 |
| RX broker | 1.44 |
| Medical Gas Manufacturer | 0.75 |
| Medical Gas Wholesale Distributor | 1.9 |
| Medical Oxygen Retail Establishment | 2.63 |
| Complimentary Distributor | 1.18 |
| Veterinary RX Wholesale Distributor | 1.10 |
| Limited RX Veterinary Wholesale Distributor | 0.06 |
| Virtual RX Manufacturer | 4.99 |
| Nonresident Virtual Manufacturer | 1.44 |
| Nonresident Repackager | 0.14 |
| Health Clinic Entity | 0.72 |
| Charitable Organization | 0.03 |
| Reverse Distributor | 0.31 |
| Destruction | 0.30 |
| Government Program | 0.02 |
| Institutional Research | 0.01 |
| Blood Establishment | 0.02 |
| Health Care Clinic Establishment | 2.21 |
| 3397-no permit; no versa profile | 9.31 |
| 3398-versa profile but not required permit | 6.63 |

**MEDICAL GAS INSPECTORS**

| | |
|---|---|
| Medical gas manufacturing | 23.72 |
| Medical gas Wholesale distributing | 31.79 |
| Medical Oxygen retail establishment | 40.62 |
| 3397-no permit; no versa profile | 0.44 |
| 3398-versa profile but not required permit | 3.43 |

**FOR DRUG INSPECTORS 3397 AND 3398 TIME**

| | |
|---|---|
| 3397 percentage of time per permit | |
| Health care clinic establishment | 34% |

| | |
|---|---|
| Out of state RX wholesale distributor | 23% |
| Cosmetic Manufacturing | 12% |
| Prescription Drug (RX) Manufacturer | 11% |
| RX Wholesale Distributing | 10% |
| Nonresident RX Manufacturer | 10% |

3398 percentage of time per permit

| | |
|---|---|
| OTC Manufacturer | 19% |
| Out of State Whole Distributor | 27% |
| Nonresident RX Manufacturer | 13% |
| Complimentary Drug Distributor | 6% |
| Heath Care Clinic Establishment | 20% |
| RX Wholesale Distributor | 8% |
| Retail Pharmacy Drug Wholesale Distributor | 7% |

**FOR MEDICAL GAS INSPECTORS 97 AND 98 TIME**

97-NOMINAL-not assigned to permit type

98

| | |
|---|---|
| Medical gas wholesale distributor | 66% |
| Medical oxygen retailer establishment | 34% |

**KEY**

OTC is over the counter

RX is prescription drug(s)

3397 is unlicensed activity with no versa profile; no permit ever and no pending application

3398 is unlicensed activity with a versa profile; some permit but not the required permit; prior permit-changed location, change of owner, expired permit, pending application

# Statement on Litigation Challenging Legality of Administration's Final Rule Permitting State-Sponsored Drug Importation From Canada

**WASHINGTON, D.C. (November 23, 2020)** – Today, the Pharmaceutical Research and Manufacturers of America (PhRMA), Partnership for Safe Medicines (PSM) and Council for Affordable Health Coverage (CAHC) initiated litigation in the U.S. District Court for the District of Columbia challenging action by the U.S. Department of Health and Human Services (HHS) and Food and Drug Administration (FDA) permitting pharmacists and wholesalers, pursuant to state-sponsored programs, to import certain prescription drugs from Canada into the United States without drug manufacturers' authorization or oversight (85 Fed. Reg. 62,094 Oct. 1, 2020) (the "Final Rule").

PhRMA Executive Vice President and General Counsel James C. Stansel stated:

> *"It is alarming that the administration chose to pursue a policy that threatens public health at the same time that we are fighting a global pandemic. FDA has noted it is struggling to keep up with approving medicines while working around the clock to support COVID-19 therapeutics and vaccine development. Despite this, the administration is willing to divert precious FDA resources away from these efforts and to expose Americans to the risks that come with drug importation schemes.*
>
> *"It is particularly disturbing that the administration is punting the responsibility for demonstrating safety and cost savings to state governments despite the clear requirement under federal law that the Secretary of HHS must certify that imported drugs both pose no additional risk to public safety and will lead to significant savings for the American consumer. In fact, the Final Rule fails to overcome the well-documented safety concerns regarding importation expressed for nearly two decades by previous HHS Secretaries across party lines or to make any showing that the proposal would result in any—let alone significant—cost savings to American consumers. The bottom line is that the administration has violated federal law by proceeding without proper certification and, in doing so, is putting the health and safety of Americans in jeopardy."*

PSM Executive Director Shabbir J. Safdar stated:

> *"Since the start of the COVID-19 pandemic, the key role of FDA in ensuring the availability of safe and effective medicines and the integrity of the American pharmaceutical supply chain has become even more clear. Once we weaken the longstanding defenses in place for our drug supply, as this Final Rule does, we open floodgates that cannot be closed. This makes absolutely no sense from a policy standpoint, which is why HHS and the FDA have long opposed and refused to effectuate importation measures like those in the Final Rule from ever seeing the light of day. For nearly 20 years, HHS and FDA heads, appointed by both Republican and Democratic administrations, have seen the dangers of these proposals and always declined to pursue them. The Trump Administration has defied this wisdom for seemingly political reasons at the worst possible time.*
>
> *"The Final Rule would create large gaps in track and trace requirements, which were enacted to help ensure safety of our drug supply chain. It encourages diversion of drugs*

*intended for Canada, a country that opposes the Trump Administration's proposal. And it poses liability issues for pharmacists who would be left dispensing medicine from an untraceable supply chain.*

*"This policy was pursued over the objections of everyone in the supply chain that today safely transits lifesaving medicine from the factory floor to the patient. Safety must always come first."*

CAHC President Joel White stated:

*"The importation scheme envisioned in this Final Rule brings a false promise to Americans that it will result in lower cost. Providers, pharmacists and the patients they serve may no longer trust the medicines they prescribe and dispense are safe and effective. There are better ways to lower costs through increased competition, paying for outcomes, and price transparency for consumers."*

**Additional information about the complaint:**

The complaint alleges the Final Rule disregards key protections of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (FDCA) that are designed to ensure patient safety. Section 804 of the FDCA, 21 U.S.C. § 384, authorizes HHS to permit both the importation of drugs by pharmacists and wholesalers for commercial distribution and the importation of drugs by individual patients. Section 804 is effective, however, only if the HHS Secretary certifies to Congress "that the implementation of this section will—(A) pose no additional risk to the public's health and safety; and (B) result in a significant reduction in the cost of covered products [(*i.e.*, certain prescription drugs)] to the American consumer." § 384(*l*)(1).

In this Final Rule, Secretary Azar has made conclusory statements as to safety and cost savings in his "certification" with no supporting evidence and while punting the responsibility for safety and cost savings to state governments. The complaint, therefore, alleges the Secretary's certification is contrary to Section 804 and unsupported by the record.

In addition, there is no indication that the Final Rule will reduce costs to actual American patients. In the preamble to both the proposed and Final Rule, HHS has acknowledged that it cannot quantify the savings, if any, that would result from its rule, even classifying it as "not economically significant" for purposes of review by the Office of Management and Budget. Indeed, in the budget document released with the rule, the cost savings chart was left blank, suggesting cost savings could not be calculated.

Furthermore, aspects of the Final Rule are contrary to the FDCA, violate manufacturers' First Amendment rights and raise serious questions under the Fifth Amendment Takings Clause.

As such, PhRMA, PSM and CAHC are asking the Court to hold unlawful, set aside and permanently enjoin implementation of the Certification and Final Rule.

###

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**About PhRMA**
The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier and more productive lives. Since 2000, PhRMA member companies have invested nearly $1 trillion in the search for new treatments and cures, including an estimated $83 billion in 2019 alone.

For information on how innovative medicines save lives, please visit:
www.PhRMA.org
www.Innovation.org
www.MAT.org
www.Facebook.com/PhRMA
www.Twitter.com/PhRMA

**About the Partnership for Safe Medicines**
The Partnership for Safe Medicines (PSM) is a public health group comprised of non-profit organizations that are committed to the safety of prescription drugs and protecting consumers against counterfeit, substandard, or otherwise unsafe medicines. To learn more, visit www.safemedicines.org.

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

**November 2020**

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# 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 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 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. 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 regards to prescription drugs, Florida has chosen a more limited set of classes for which to initiate its importation program, focusing on medications that are used to treat certain conditions (e.g., HIV/AIDS, asthma, chronic obstructive pulmonary disease, diabetes, etc.) and that will yield the highest potential savings. 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.

# 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<br>Address: 2727 Mahan Drive, Mail Stop #20<br>Tallahassee, FL 32308 |
| **Importation Program Co-Sponsor:** | The Florida Department of Business and Professional Regulation<br>Address: Division of Drugs, Cosmetics, and Devices<br>2601 Blair Stone Road<br>Tallahassee, FL 32399-1047 |
| **Responsible Individuals:** | Shevaun Harris<br>Shevaun.Harris@ahca.myflorida.com<br>(850) 412- 4264<br>2727 Mahan Drive Bldg. 3 Mailstop 1<br>Tallahassee, FL 32308<br><br>Walter Copeland<br>Walter.Copeland@myfloridalicense.com<br>(850) 717-1800<br>2601 Blair Stone Road<br>Tallahassee, FL 32399-1047 |
| **Name and Address of Foreign Seller** (must include a copy of their license to operate in Canada): | The federal rule allows the SIP sponsor to identify the foreign seller within six months of the initial submission of the SIP. Florida is in the process of identifying a foreign seller and will update its SIP application within the required timeframe when the contract with the foreign seller has been executed. |
| **Name and Address of Importer:** | Importer of Record<br>Dr. Niaz Siddiqui (Licensed Pharmacist)<br>Back-up: Dr. Danyelle Williams (Licensed Pharmacist)<br>The Florida Department of Health (DOH) Central Pharmacy<br>104-2 Hamilton Drive<br>Tallahassee, FL 32304<br><br>The DOH designee for certain functions:<br>LifeScience Logistics, LLC (Licensed Wholesale Distributor)<br>P.O. Box 612226 |

| | |
|---|---|
| | DFW Airport, TX 75261<br>See Attachment C for a copy of the importer and their designee's licenses. |
| **Name and Address of the FDA-Registered Relabeler** (must include inspection history) | Relabeling:<br>LifeScience Logistics, LLC<br>P.O. Box 612226<br>DFW Airport, TX 75261<br><br>See Attachment C for inspection history. |

**Importation Program Summary:**

As stated above, the DOH Central Pharmacy serves as the importer under the Florida program. However, as a state entity, they will need logistics support to fulfill all of the requirements of this program. As such, the State is contracting with a licensed wholesale distributor, LifeScience Logistics, LLC to assist the state and importer with the following:

- Identify a foreign seller and manufacturer(s) capable of participating in the program
- Negotiate drug prices from the foreign seller/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 the all expectations related to safety and efficacy and will describe how it anticipates those requirements will be met throughout the SIP.

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 (F.S.), 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.)
    - Wholesaler 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 difference they should be able to see 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 conservatively projecting that it can save between approximately $80 to $150 million. These savings 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.

# Florida's List of Prescription Drugs to Import

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

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

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

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

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

**Hepatitis C Prescription Drugs**

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

## Psychiatric Prescription Drugs

| Drug Name | Active Ingredient | NDC | U.S. Price | NDA/ ANDA | DIN | Canadian Name | Sold in U.S. |
|---|---|---|---|---|---|---|---|
| Latuda 20mg tab | Lurasidone HCL | 63402-0302-30 | $40.99 | NDA200603 | 02422050 | Latuda | Yes |
| Latuda 40mg | Lurasidone HCL | 63402-0304-10 | $41.00 | NDA200603 | 02387751 | Latuda | Yes |
| Latuda 60mg | Lurasidone HCL | 63402-0306-30 | $41.04 | NDA200603 | 02413361 | Latuda | Yes |
| Latuda 80mg | Lurasidone HCL | 63402-0308-30 | $41.03 | NDA200603 | 02387778 | Latuda | Yes |
| Latuda 120mg | Lurasidone HCL | 63402-0312-30 | $61.13 | NDA200603 | 02387786 | Latuda | Yes |
| Zyprexa 2.5mg tabs | Olanzapine | 00002-4112-30 | $10.06 | NDA020592 | 02229250 | Zyprexa | Yes |
| Olanzapine 2.5mg | Olanzapine | 65862-0561-30 | $0.11 | ANDA202050 | 02276712 | Teva-Olanzapine | Yes |
| Zyprexa 5mg tabs | Olanzapine | 00002-4115-30 | $11.87 | NDA020592 | 02243086 | Zyprexa Zydis | Yes |
| Olanzapine 5mg | Olanzapine | 65862-0562-30 | $0.12 | ANDA202050 | 02276720 | Teva-Olanzapine | Yes |
| Zyprexa 7.5mg | Olanzapine | 00002-4116-30 | $14.38 | NDA020592 | 02229277 | Zyprexa | Yes |
| Olanzapine 7.5mg | Olanzapine | 65862-0563-30 | $0.13 | ANDA202050 | 02276739 | Teva-Olanzapine | Yes |
| Zyprexa 10mg tabs | Olanzapine | 00002-4117-30 | $20.79 | NDA020592 | 02243087 | Zyprexa Zydis | Yes |
| Olanzapine 10mg | Olanzapine | 65862-0564-30 | $0.15 | ANDA202050 | 02276747 | Teva-Olanzapine | Yes |
| Zyprexa 15mg tabs | Olanzapine | 00002-4415-30 | $31.26 | NDA020592 | 02238850 | Zyprexa 15mg | Yes |
| Olanzapine 15mg | Olanzapine | 65862-0565-30 | $0.18 | ANDA202050 | 02276755 | Teva-Olanzapine | Yes |
| Seroquel 100mg | Quetiapine Fumarate | 00310-0271-10 | $6.42 | NDA020639 | 02236952 | Seroquel | Yes |
| Quetiapine Fumarate 100mg | Quetiapine Fumarate | 46708-0136-31 | $0.05 | ANDA203390 | 02316099 | ACT Quetiapine | Yes |
| Seroquel 25mg | Quetiapine Fumarate | 00310027 5-10 | $3.79 | NDA020639 | 02236951 | Seroquel | Yes |
| Quetiapine Fumarate | Quetiapine Fumarate | 46708-0134-31 | $0.04 | ANDA203390 | 02316080 | ACT Quetiapine | Yes |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 25mg | | | | | | | |
| Seroquel 200mg | Quetiapine Fumarate | 00310-0272-10 | $12.07 | NDA020639 | 02236953 | Seroquel | Yes |
| Quetiapine Fumarate 200mg | Quetiapine Fumarate | 46708-0137-31 | $0.11 | ANDA203390 | 02316110 | ACT Quetiapine | Yes |
| Seroquel 300mg | Quetiapine Fumarate | 00310-0274-60 | $15.95 | NDA020639 | 02244107 | Seroquel | Yes |
| Quetiapine Fumarate 300mg | Quetiapine Fumarate | 46708-0138-60 | $0.17 | ANDA203390 | 02316129 | ACT Quetiapine | Yes |
| Clozaril 25mg tabs | Clozapine | 69809-0126-05 | $4.79 | NDA019758 | 00894737 | Clozaril | Yes |
| Clozapine 25mg | Clozapine | 0093-4359-01 | $0.83 | ANDA074949 | 02247243 | GEN-Clozapine | Yes |
| Clozaril 100mg | Clozapine | 69809-0127-05 | 12.06 | NDA019758 | 00894745 | Clozaril | Yes |
| Clozapine 100mg | Clozapine | 0093-7772-01 | 1.38 | ANDA074949 | 02247244 | GEN-Clozapine | Yes |
| Clozaril 50mg tabs | Clozapine | 69809-0130-05 | 10.15 | NDA019758 | 02490668 | Clozaril | Yes |
| Clozapine 50mg | Clozapine | 0093-4404-01 | 1.68 | ANDA074949 | 02305003 | GEN-Clozapine | Yes |
| Clozaril 200mg | Clozapine | 69809-0135-05 | 29.29 | NDA019758 | 02490676 | Clozaril | Yes |
| Clozapine 200mg | Clozapine | 0093-4405-01 | 2.19 | ANDA074949 | 02305011 | GEN-Clozapine | Yes |
| Abilify 5mg tabs | Aripiprazole | 59148-0007-13 | 28.64 | NDA021436 | 02322382 | Abilify | Yes |
| Aripiprazole 5mg | Aripiprazole | 62332-0098-30 | 0.17 | ANDA202101 | 02471094 | APO-Aripiprazole | Yes |
| Abilify 10mg tabs | Aripiprazole | 59148-0008-13 | 28.22 | NDA021436 | 02322390 | Abilify | Yes |
| Aripiprazole 10mg | Aripiprazole | 62332-0099-30 | 0.15 | ANDA202101 | 02471108 | APO-Aripiprazole | Yes |
| Abilify 15mg tabs | Aripiprazole | 59148-0009-13 | 28.55 | NDA021436 | 02322404 | Abilify | Yes |
| Aripiprazole 15mg | Aripiprazole | 62332-0100-30 | 0.16 | ANDA202101 | 02471116 | APO-Aripiprazole | Yes |
| Abilify 20mg tabs | Aripiprazole | 59148-0010-13 | 40.56 | NDA021436 | 02322412 | Abilify | Yes |
| Aripiprazole 20mg | Aripiprazole | 62332-0101-30 | 0.2 | ANDA202101 | 02471124 | APO-Aripiprazole | Yes |
| Abilify 30mg tabs | Aripiprazole | 59148-0011-13 | 40.69 | NDA021436 | 02322455 | Abilify | Yes |
| Aripiprazole | Aripiprazole | 62332- | 0.26 | ANDA20210 | 0247113 | APO- | Yes |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 30mg | | 0102-30 | | 1 | 2 | Aripiprazole | |
| Risperidone 0.5mg | Risperidone | 27241-003-06 | 0.06 | ANDA201003 | 02282127 | APO-Risperidone | Yes |
| Risperidone 1mg | Risperidone | 27241-001-06 | 0.06 | ANDA201003 | 02282135 | APO-Risperidone | Yes |
| Risperidone 2mg | Risperidone | 27241-004-06 | 0.07 | ANDA201003 | 02282143 | APO-Risperidone | Yes |
| Risperidone 3mg | Risperidone | 27241-005-06 | 0.08 | ANDA201003 | 02282151 | APO-Risperidone | Yes |
| Risperidone 4mg | Risperidone | 27241-006-06 | 0.14 | ANDA201003 | 02282178 | APO-Risperidone | Yes |
| Chlorpromazine 25mg tabs | Chlorpromazine | 0781-5914-01 | 2.25 | ANDA084112 | 00232823 | TEVA-Chlorpromazine | Yes |
| Chlorpromazine 50mg tabs | Chlorpromazine | 0781-5915-01 | 3.17 | ANDA084113 | 00232807 | TEVA-Chlorpromazine | Yes |
| Chlorpromazine 100mg tabs | Chlorpromazine | 0781-5916-01 | 4.78 | ANDA084114 | 00232831 | TEVA-Chlorpromazine | Yes |
| Fluphenazine 1mg tabs | Fluphenazine | 60219-1678-01 | 2.31 | ANDA213647 | 00405345 | Fluphenazine | Yes |
| Fluphenazine 5mg tabs | Fluphenazine | 60219-1680-01 | 5.61 | ANDA213647 | 00405361 | Fluphenazine | Yes |

**Diabetes Prescription Drugs**

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

## Asthma and Chronic Obstructive Pulmonary Disease Prescription Drugs

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

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 500-50 | | | | | | Salmeterol DPI | |
| Wikela 500-50 | Fluticasone Propion, Salmeterol | 00378-9322-32 | $199.20 | ANDA208891 | 02495619 | Wixela Inhub | Yes |
| Atrovent HFA 17mcg | Ipratropium Bromide | 00597-0087-17 | $396.50 | NDA021527 | 02247686 | Atrovent HFA | Yes |
| Incruse Ellipta 62.5 mcg #30 | Umeclidinium | 00173-0873-10 | $329.40 | NDA205382 | 02423596 | Incruse Ellipta | Yes |

## HIV/AIDS Prescription Drugs

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

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | Emtricit, Tenofovir Disop | 1201-01 | | | | | |
| Truvada 200-300mg | Emtricitabine, Tenofovir DF | 61958-0701-01 | $59.70 | NDA021752 | 02274906 | Truvada | Yes |
| Emtricitabine, Tenofovir DF 200-300mg | Emtricitabine, Tenofovir DF | 00093-7607-56 | $45.69 | ANDA090894 | 02399059 | TEVA-Emtricitabine, Tenofovir | Yes |
| Odefsey | Emtricit, Rilpivirine, Tenofovir Ala | 61958-2101-01 | $95.77 | NDA208351 | 02461463 | Odefsey | Yes |
| Invirase | Squinavir Mesylate | 00004-0244-51 | $9.76 | NDA020628 | 02279320 | Invirase | Yes |
| Edurant | Rilpivirine HCL | 59676-0278-01 | $37.58 | NDA202022 | 02370603 | Edurant | Yes |
| Intelence 100mg | Etravirine | 59676-0570-01 | $10.92 | NDA022187 | 02306778 | Intelence | Yes |
| Intelence 200mg | Etravirine | 59676-0571-01 | $22.41 | NDA022187 | 02375931 | Intelence | Yes |
| Intelence 25mg | Etravirine | 59676-0572-01 | $2.88 | NDA022187 | 02396750 | Intelence | Yes |
| Triumeq | Abacavir, Dolutegravir, Lamivudi | 49702-0231-13 | $98.19 | NDA205551 | 02430932 | Triumeq | Yes |
| Juluca | Dolutegravir, Rilpivirine | 49702-0242-13 | $91.75 | NDA210192 | 02475774 | Juluca | Yes |
| Biktarvy | Bictegravir, Emtricit, Tenofovir Ala | 61958-2501-01 | $104.52 | NDA210251 | 02478579 | Biktarvy | Yes |
| Isentress 400mg | Raltegravir | 00006-0277-61 | $26.74 | NDA022145 | 02301881 | Isentress | Yes |
| Descovy | Emtricitabine, Tenofovir 200mg-25mg | 61958-2002-01 | $59.67 | NDA208215 | 02454424 | Descovy | Yes |

## 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 in Attachment B with the exception of the foreign seller. The State will submit the required information for the foreign seller once an entity has been selected.

## 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 7 years prior to submission of the SIP Proposal.
- The Health Canada inspectional history for the Foreign Seller for the previous 5 years or, if the Foreign Seller has been licensed for less than 5 years, for the duration of its period of licensure; and 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.

The State's importers are employed by the Florida Department of Health (DOH) Central Pharmacy. The DOH Central Pharmacy has an exemplary track record and performance history. Evidence of the importer's performance is provided in Attachment A.

Florida is also including the inspectional history for LifeScience Logistics, LLC. This information is included in Attachment C.

Following the selection of a foreign seller, Florida will submit the required information as specified in the FDA's final rule.

## 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.

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 page 8 that identifies drug names, active pharmaceutical ingredients, National Drug Codes (NDC), and shared manufacturers with locations in both the U.S. and Canada.

# 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. The State intends to make every effort to partner with manufacturers that will perform the FDA required testing on each imported drug. Some of the eligible prescription drugs Florida proposes to import are manufactured by the same companies for the U.S. and Canadian markets. In addition, these products are produced in the same facilities, on the same manufacturing lines, and contain identical specifications and standards. Because these Canadian products are fully compliant with FDA-approved New Drug Applications (NDA) (except for labeling), it will not be necessary to perform statutory testing on these products.

The State will provide to the FDA evidence to establish that these products are manufactured according to the specifications in the FDA-approved NDAs and will ensure that these products are relabeled appropriately. This will avoid duplicative testing efforts and reduce overall costs by avoiding unnecessary markups for added steps as drugs proceed through the supply chain. However, if that is not possible, through its contracted entities, the State will ensure that a qualifying laboratory will test statistically valid sample batches or shipments of imported prescription drugs in accordance with the FDA's current and good manufacturing practices (CGMPs) as specified in Title 21 Code of Federal Regulations Sections 211 and 251.16.

The qualifying lab will obtain a statistically valid sample sufficient for testing and retesting as necessary. 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 considering utilization 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**

When assessing the authenticity of a prescription drug, Florida will require its qualifying lab to use visual inspections, spectrometry, and chromatography. 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 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. If a sample fails in any one of the categories, its originating batch will be removed from the supply chain and dispositioned.

**Visual Inspections:** 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. Counterfeits sometimes lack expiration dates or instructions and can use poor quality ink or have grammatical mistakes. Additionally, pills improperly colored or that have 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.

**Laboratory Testing:** Florida will require its qualifying laboratory to verify authenticity based on the results of multiple tests. This is due to no single technique delivering the universal results needed for verification. Additionally, the qualifying lab will have the necessary equipment to perform detailed testing on the samples using spectroscopic and high-performance liquid chromatography, as applicable, based upon the methods specified by the manufacturer

**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. The qualifying lab will

have the necessary equipment to perform either stability test on the sample batch, based upon the method specified by the manufacturer.

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**

To evaluate whether a batch poses biological hazards, 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 and blister packs, although the risk of biological contamination in blister packs is reduced. 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 will use the following laboratories to meet the testing requirements:

| Contract Laboratories | | |
|---|---|---|
| **Name of the Organization / Address** | **Registrations** | **FDA Audit History** |
| **Micro Quality Labs**<br>3125 N. Damon Way<br>Burbank, California 91505<br>818-845-0070<br>www.microqualitylabs.com | FDA Registered (DUNS 149592615)<br>ISO 17025 (Certificate 3034.1) | Feb 2018 – FDA<br>(in good standing) |
| **Avomeen, LLC**<br>4840 Venture Drive<br>Ann Arbor, MI 48108<br>833-507-6831<br>www.avomeen.com | FDA Registered (FEI 3008808597)<br>ISO 17025 (Certificate L19-183) | Jun 2016 – FDA<br>Mar 2018 – FDA<br>Oct 2018 - FDA<br>(in good standing) |
| **Avista Pharma Solutions, Inc dba Cambrex Corp**<br>104 Gold St<br>Agawam, MA 01001<br>843-312-6529<br>www.cambrex.com | FDA Registered (FEI 1220785)<br>ISO 17025 (Certificate L2190) | 2016 – FDA<br>2018 – FDA<br>2019 – FDA<br>(in good standing) |
| **BioChroma Analytical**<br>1309 Record Crossing Rd<br>Dallas, TX 75235<br>972-454-9166<br>www.biochromalabs.com | FDA Registered (FEI 3012816120)<br>ISO 17025 (Certificate L20-206) | Feb 2017 - FDA<br>(in good standing) |

## 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.

For this submission, the State is providing in Attachment D a sample of the label that it will use for imported prescription drugs when they are distributed in Florida.

As for the remaining components, the State will include the following in a forthcoming submission:

- FDA-approved labels for prescription drugs that it seeks to import from Canada
- Proposed labeling for each imported prescription drug
- HPFB-approved labeling for each imported prescription drug
- Side-by-side comparison of the FDA-approved labeling and proposed labeling

# 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.

The Agency for Health Care Administration collected information from each participating state agency on the amount spent on all prescription drugs in the second quarter of calendar year 2018 and then compared the unit cost of each drug to its Canadian equivalent formulation. Because many of the state programs already benefit from deep discounts through other government programs (e.g., 340B covered entities, Medicaid supplemental rebate program requirements, etc.), the State removed drugs that were already deeply discounted and would not yield any greater savings or were ineligible for inclusion due to other restrictions. This analysis will be performed on a quarterly basis to continually assess opportunities to focus in on a narrow list of prescription drugs that yields the greatest amount of savings.

Florida has identified the initial list of prescription drugs that will be included in the initial launch of the importation program. As previously stated, the State will be evaluating the list on a quarterly schedule to determine if changes are needed and if it continues to be cost-effective to import those specific drugs.

Following full implementation, Florida is projecting over $150 million dollars in annual savings. The below table presents 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 (the data represents utilization and costs for one quarter of 2018).

| Brand Name | Utilization | Net Unit Cost | Total Spend/Actual Spend | Canadian Unit Cost * | Potential Spend | Estimated Difference |
|---|---|---|---|---|---|---|
| Atripla Tablet | 48,513 | $ 87.90 | $ 4,264,305 | $ 42.25 | $ 2,049,674 | $ 2,214,618 |
| Complera Tablet | 15,477 | $ 85.66 | $ 1,325,757 | $ 42.65 | $ 660,094 | $ 665,666 |
| Genvoya Tablet | 225,815 | $ 94.98 | $ 21,448,515 | $ 47.63 | $ 10,755,568 | $ 10,692,340 |
| Isentress 400 Mg Tablet | 104,607 | $ 24.15 | $ 2,525,748 | $ 12.51 | $ 1,308,634 | $ 1,217,625 |
| Odefsey Tablet | 66,699 | $ 86.46 | $ 5,766,699 | $ 42.66 | $ 2,845,379 | $ 2,921,416 |
| Prezista 800 Mg Tablet | 71,933 | $ 51.09 | $ 3,675,303 | $ 21.26 | $ 1,529,296 | $ 2,145,761 |
| | | | | | | $ 19,857,428 |

*includes a markup

The State has included a markup on the Canadian price to account for additional costs potentially imposed by the foreign seller.

Since Florida's program exclusively focuses on serving consumers who are receiving their medications through government programs (some funded with both state and federal dollars), any savings derived will benefit all American taxpayers. The savings will not only reduce the overall state budget, but those dollars can be reinvested in other programs/services that support Floridians. To the extent consumers pay co-payments on the imported drugs, the savings can

also be used to offset copayment amounts, again resulting in savings to the American consumer.

# 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.
- 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 Section 205.50 and Section 499.0121, F.S. (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 Florida. This will prevent the possibility of inadvertently comingling drug products from the program with

other drug products and distribution channels. 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 transactional information to include Canadian information such as Drug Identification Numbers and Health Products and Food Branch (HPFB) proprietary names.

LifeScience Logistics will also physically inspect each drug shipment received from the foreign seller 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 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 United States. 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 Section 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 United States 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 United States
- 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.

# 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.

**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.

# Recall and Return Plan

The FDA final rule language requires the SIP proposal to:

- Include the SIP's recall plan, including an explanation of how the SIP Sponsor will obtain recall or market withdrawal information and how it will ensure that recall or market withdrawal information is shared among the SIP Sponsor, the Foreign Seller, the Importer, and FDA and provided to the manufacturer.
- 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.

Currently, U.S. prescription drug manufacturers have to 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 State will monitor FDA recall alerts as well as Canadian recalls.

If a recall is ordered on a shipment of imported prescription drugs, the Agency and DBPR will immediately halt the importation of affected prescription drugs under the SIP in accordance with the FDA's Importation of Prescription Drugs final rule. Additionally, they will take actions to work with the importer or its designee and those participating in the SIP to communicate the need to isolate those drugs and return them for disposition. To inform stakeholders and affected parties, the Agency and DBPR understand that messaging must go out to health plans, pharmacies, state run facilities (e.g., public health clinics, prisons, state mental hospitals), and other state agencies. The importer's (or their designee'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 DBPR determines that an issue is present in the SIP, it can issue a recall and halt the importation of prescription drugs. Below is the recall and return plan that the State will follow when the SIP becomes operational.

### Agency and DBPR 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 DBPR 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.

- **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.

Given the consequences of delayed or insufficient action, the Agency and DBPR will implement immediate measures beginning with communication to all stakeholders involved in the importation program, including: SMMC health plans, participating pharmacies, county health departments, state-run facilities, and state agencies. Communications will be made via email blasts and direct calls to administrators to inform them of the recall and potential risks as well as instructions for returning drugs to the importer. Those entities will be responsible for notifying patients that have received the recalled medications.

While the Agency and DBPR handle communications with stakeholders, the importer or its designee will administer collecting the recalled prescription drugs and their disposition. Additionally, the importer will submit a report to the Agency and DBPR explaining the quantity of prescription drugs recovered, the dates of recovery, the number of those unaccounted for, and where they 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 DBPR 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 and DBPR 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:

- Section 804 serial identifier (SSI), National Drug Code (NDC), Drug Identification Number (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 or its designee will be responsible for collection, documentation, storage, and destruction of the suspect prescription drugs. In addition, it will also halt the importation of affected prescription drugs in accordance with federal rule. While the Agency and DBPR oversee the communications aspect, the importer or its designee 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 in a single facility under quarantine. Depending on the reasons for the recall, the importer or designee 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 or its designee 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 or its designee 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 and DBPR.

- 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 (or designee) will provide daily updates to the Agency and DBPR on the quantities collected for Tier 1 and 2 recalls. For Tier 3, the importer can provide one update per week. The importer will provide updates 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 or its designee 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 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 and DBPR are granting the importer this same ability. If at any time, the importer or its designee determines that a recall is necessary, it can issue one.

**Return Plan**

For imported prescription drugs that must go through the return process, the Agency and DBPR will require the importer to ensure that all collected products remain in the original supply chain (e.g., its own storage facilities). The importer or its designee will return the prescription drugs to its storage facility and keep them isolated from non-recalled ones. At no time, can the importer send returned prescription drugs to an outside facility or transport them via a different means without direct approval from the Agency and DBPR 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 State 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 or its designee 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 and DBPR. In addition, the importer will not begin redistributing the prescription drugs until the Agency and DBPR have given approval.

# 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, relabelers, repackagers, 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, F.S. 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. Since LifeScience Logistics will be performing many duties on behalf of the importer and State (as described earlier), the following is a list of key corporate executive staff and their qualifications:

| **Key Personnel Name:** Richard Beeny | |
|---|---|
| **Key Personnel Position:** Chief Executive Officer | |
| April 2006 - Current | Richard is Co-founder and Chief Executive Officer of LifeScience Logistics. He has more than 25 years of supply chain experience and has held a variety of operations, marketing and business development roles. Richard has held leadership positions at United Parcel Service and has served in both the U.S. Navy and U.S. Coast Guard. He holds a Bachelor of Arts degree from the University of Texas at Arlington and a Master of Business Administration from Southern Methodist University. |

| **Key Personnel Name:** David Mastromatteo | |
|---|---|
| **Key Personnel Position:** Chief Operating Officer | |
| July 2015 - Current | David was named Chief Operating Officer in November 2016. Previously, he joined LifeScience Logistics as Managing Director in July 2015. He has over 30 years of experience in operations, quality, and business development with specific emphasis on health care logistics and supply chains. Prior to joining LifeScience Logistics, David held leadership roles at Beckman Coulter and Apria Healthcare and was an industry consultant in health care logistics. He is a trained auditor for ISO 9001 and ISO 13485 and holds a Bachelor of Arts degree and MBA from Chapman University in Orange, California. |

| **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:** Director, Quality Assurance and Regulatory Affairs |

| | |
|---|---|
| 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:** Director of Client Services | |
| 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 are appointing the following staff members to oversee compliance with the importation program. Each individual will monitor areas specific to their own expertise.

| **Key Personnel Name:** Erica Floyd Thomas |
|---|
| **Key Personnel Position:** Chief of Medicaid Policy |
| **Responsibility:** Oversight of the contract with LifeScience Logistics and day to day workflow of the state of Florida Canadian Drug Importation Program. |

| **Key Personnel Name:** Renee Alsobrook |
|---|
| **Key Personnel Position:** Chief of the Bureau of Compliance and Enforcement |
| **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.

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 current and good manufacturing practices, 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 through yearly 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, F.S.; 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 it has received approval for all educational and training materials.

**Lines of Communication**

The Agency 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 for complaints that consumers can use. In regard to whistleblowers, the Agency, DBPR, and the importer will be compliant with the Federal Whistleblower Protection Act.

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

# 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, F.S.). 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, F.S.) do 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.

# Attachment A

Florida Department of Health Central Pharmacy Licenses, Disciplinary and Inspection Reports, and Attestation

Florida dbpr Department of Business & Professional Regulation

Walter Copeland, Director
Drugs Devices, and Cosmetics
2601 Blair Stone Road
Tallahassee, Florida 32399-1047
Phone: 850.717.1800 • Fax: 850.414.8240

**Halsey Beshears,** Secretary — **Ron DeSantis,** Governor

October 26, 2020

RE: Inspections/Disciplinary Actions

To whom it may concern;

*Chapter 119.01(1), Florida Statutes, provides that it is the policy of this state, county, and municipal records are open for personal inspection and copying by any person. Providing access to public records is a duty of each agency.*

After a review of our Department's records and databases no disciplinary action has been taken against the below entity.

*Chapter 499.051, Florida Statutes, provides that the agents of the Department of Business and Professional Regulation and of the Department of Law Enforcement, after they present proper identification, may inspect, monitor, and investigate any establishment permitted pursuant to this chapter during business hours for the purpose of enforcing this chapter and the rules of the department that protect the public health, safety, and welfare.*

*Rule 61N-1.019(2), Florida Administrative Code, states the department may inspect, monitor, and investigate all drugs, device and cosmetic manufacturers, wholesalers, repackagers, distributors, or other establishments where drugs, devices or cosmetics are made, stored, sold, offered for sale, exposed for sale, or kept for sale or use, for the purpose of determining compliance with the provisions of chapters 499 and 893, Florida Statutes, or any rules adopted thereunder and to secure evidence of any non-compliance.*

Inspections are conducted on initial permit applications. Inspections conducted by the division may be announced or unannounced and are not scheduled routinely or on a yearly basis.

The last know inspection conducted at:

DOH Central Pharmacy
104-2 Hamilton Park Drive
Tallahassee, Florida 32304
Permit Number 28:29

was conducted on **October 10, 2019** with a result of **PASS.**

Regards,

Walter Copeland
Division Director

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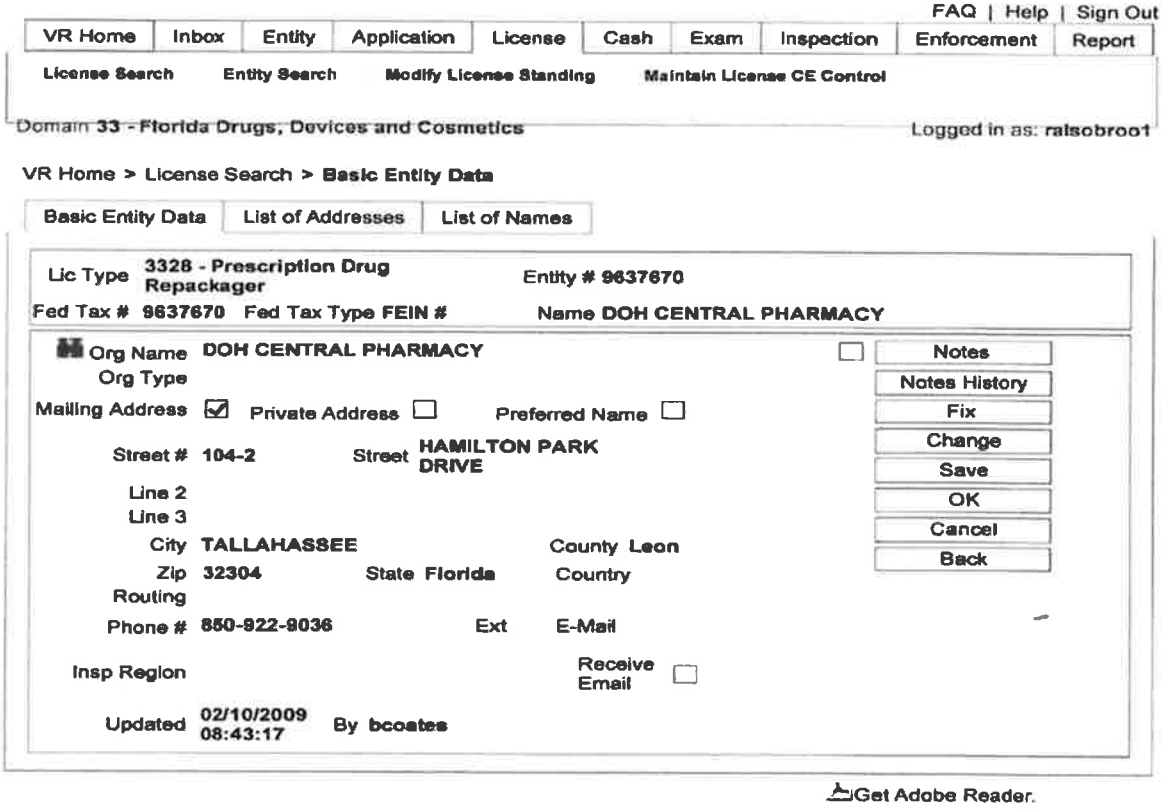
The State upon completion of the negotiation process and selection of the Foreign Seller will obtain complete history as mandated by federal law. This includes the following:

- All disciplinary actions from the past seven years issued by federal, state, or Canadian authorities
- The Health Canada inspectional history for the foreign seller for the previous 5 years or duration of license if less
- The state and federal inspectional history for the importer for the previous 5 years or duration of license if less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License Search
Entity Search
Modify License Standing
Maintain License CE Control
Domain 33 - Florida Drugs, Devices and Cosmetics
Logged in as: ralsobrook
VR Home > License Search > Basic Entity Data
Basic Entity Data
List of Addresses
List of Names
Lic Type 3328 - Prescription Drug Repackager
Entity # 9637670
Fed Tax # 9637670 Fed Tax Type FEIN #
Name DOH CENTRAL PHARMACY
Org Name DOH CENTRAL PHARMACY
Org Type
Mailing Address
Private Address
Preferred Name
Street # 104-2
Street HAMILTON PARK DRIVE
Line 2
Line 3
City TALLAHASSEE
County Leon
Zip 32304
State Florida
Country
Routing
Phone # 850-922-9036
Ext
E-Mail
Insp Region
Receive Email
Updated 02/10/2009 08:43:17
By bcoates
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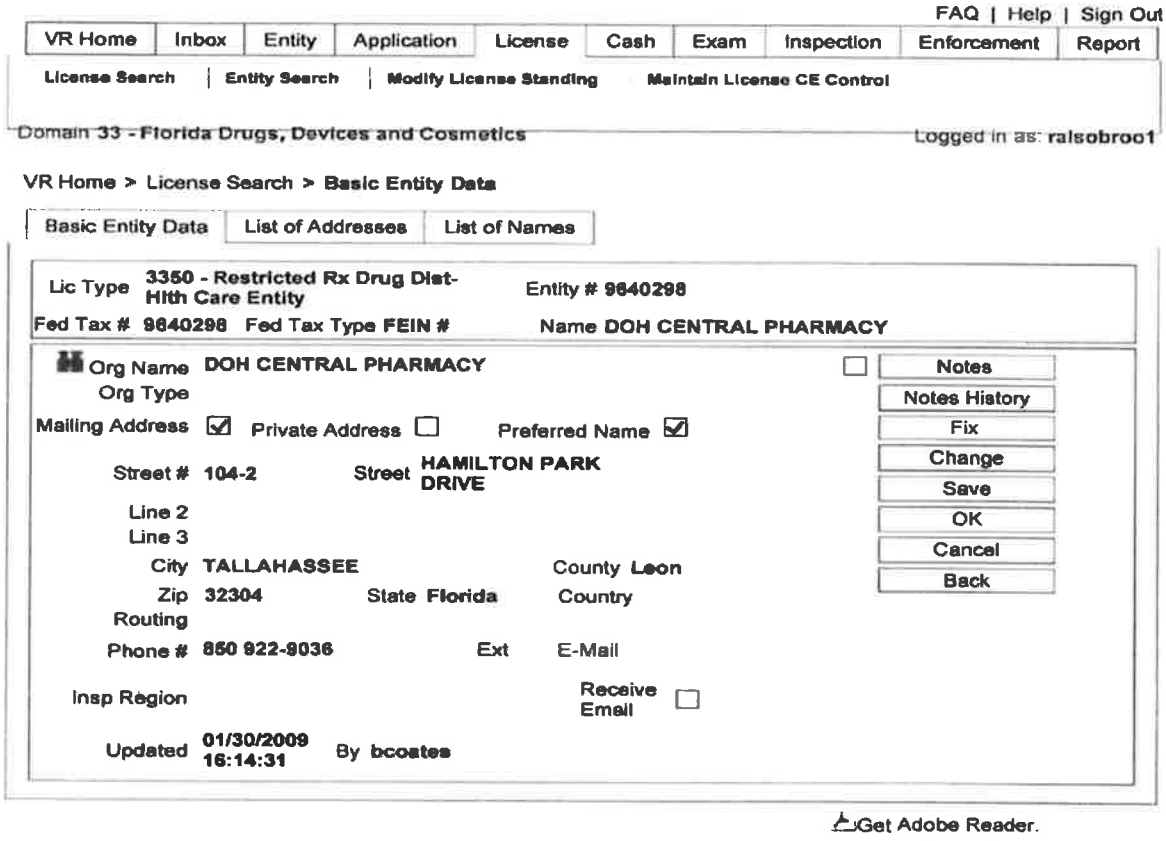
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License Search
Entity Search
Modify License Standing
Maintain License CE Control
Domain 33 - Florida Drugs, Devices and Cosmetics
Logged in as: ralsobroo1
VR Home > License Search > Basic Entity Data
Basic Entity Data
List of Addresses
List of Names
Lic Type 3350 - Restricted Rx Drug Dist-Hlth Care Entity
Entity # 9640298
Fed Tax # 9640298 Fed Tax Type FEIN #
Name DOH CENTRAL PHARMACY
Org Name DOH CENTRAL PHARMACY
Org Type
Mailing Address
Private Address
Preferred Name
Street # 104-2
Street HAMILTON PARK DRIVE
Line 2
Line 3
City TALLAHASSEE
County Leon
Zip 32304
State Florida
Country
Routing
Phone # 850 922-9036
Ext
E-Mail
Insp Region
Receive Email
Updated 01/30/2009 16:14:31
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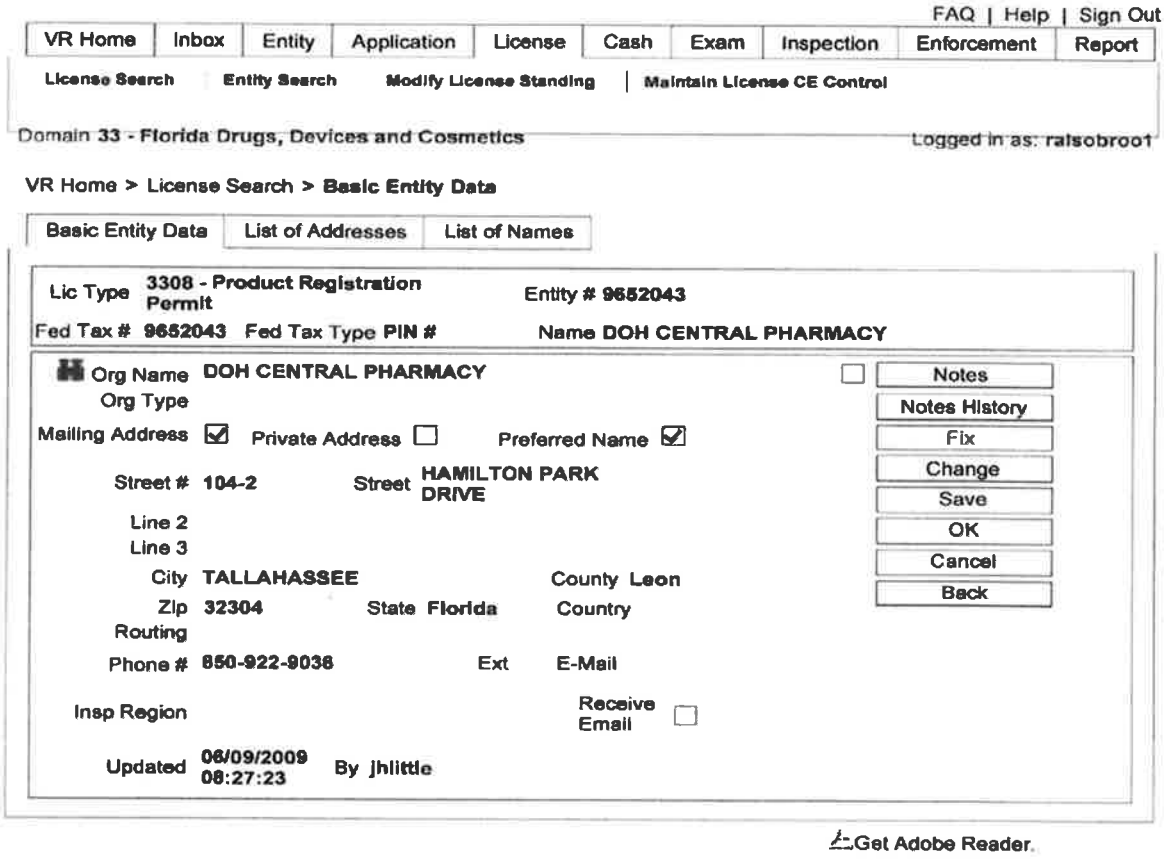
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Maintain License CE Control
Domain 33 - Florida Drugs, Devices and Cosmetics
Logged in as: ralsobrook1
VR Home > License Search > Basic Entity Data
Basic Entity Data
List of Addresses
List of Names
Lic Type 3308 - Product Registration Permit
Entity # 9652043
Fed Tax # 9652043
Fed Tax Type PIN #
Name DOH CENTRAL PHARMACY
Org Name DOH CENTRAL PHARMACY
Org Type
Mailing Address
Private Address
Preferred Name
Street # 104-2
Street HAMILTON PARK DRIVE
Line 2
Line 3
City TALLAHASSEE
County Leon
Zip 32304
State Florida
Country
Routing
Phone # 850-922-9038
Ext
E-Mail
Insp Region
Receive Email
Updated 06/09/2009 08:27:23
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Domain 33 - Florida Drugs, Devices and Cosmetics
Logged in as: ralsobroo1
VR Home > License Search > Basic Entity Data
Basic Entity Data
List of Addresses
List of Names
Lic Type 3328 - Prescription Drug Repackager
Entity # 9637670
Fed Tax # 9637670 Fed Tax Type FEIN #
Name DOH CENTRAL PHARMACY
Type
Name
Status
Lic Type
File #
Updated By
Preferred
Primary
DOH CENTRAL PHARMACY
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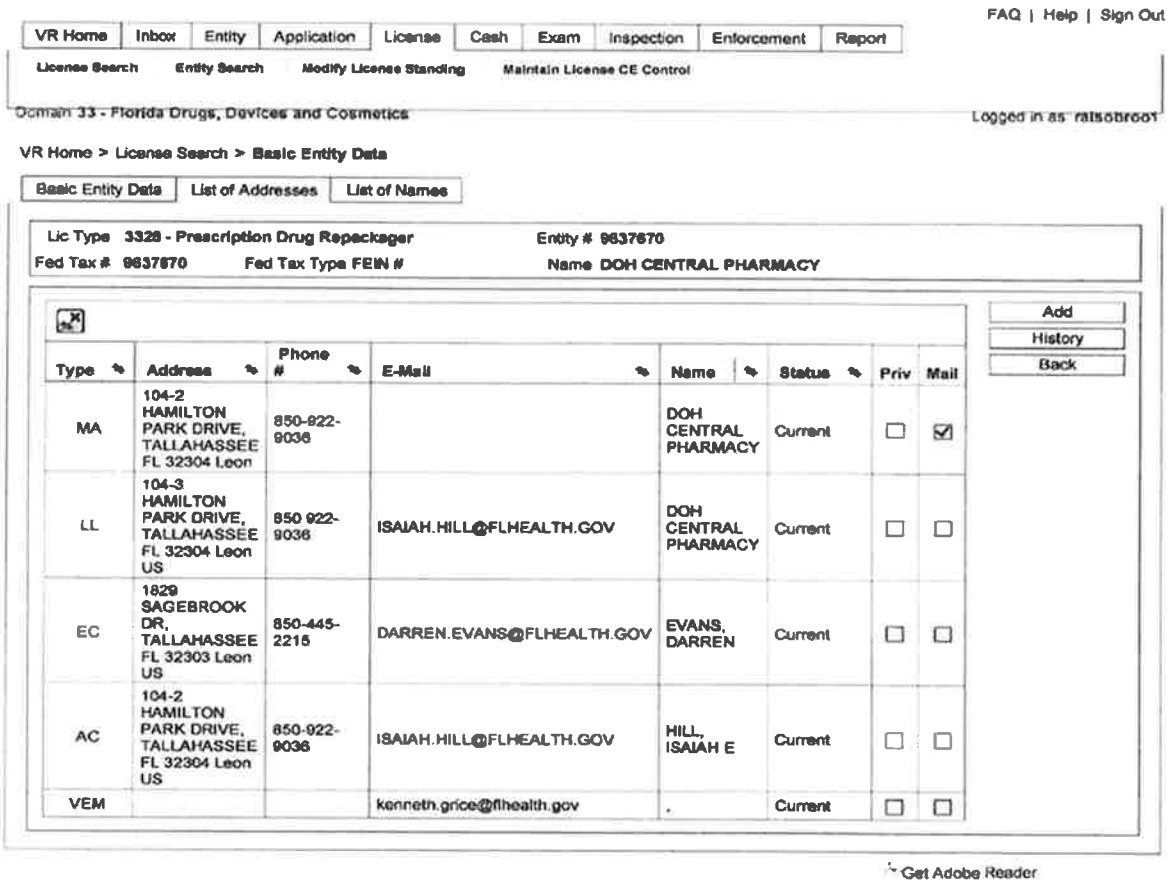

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VR Home | Inbox | Entity | Application | License | Cash | Exam | Inspection | Enforcement | Report

License Search | Entity Search | Modify License Standing | Maintain License CE Control

Domain 33 - Florida Drugs, Devices and Cosmetics

Logged in as raisobroot

VR Home > License Search > Basic Entity Data

Basic Entity Data | List of Addresses | List of Names

Lic Type 3328 - Prescription Drug Repackager  Entity # 9637670

Fed Tax # 9637670  Fed Tax Type FEIN #  Name DOH CENTRAL PHARMACY

Add | History | Back

| Type | Address | Phone # | E-Mail | Name | Status | Priv | Mail |
|---|---|---|---|---|---|---|---|
| MA | 104-2 HAMILTON PARK DRIVE, TALLAHASSEE FL 32304 Leon | 850-922-9036 | | DOH CENTRAL PHARMACY | Current | ☐ | ☑ |
| LL | 104-3 HAMILTON PARK DRIVE, TALLAHASSEE FL 32304 Leon US | 850 922-9036 | ISAIAH.HILL@FLHEALTH.GOV | DOH CENTRAL PHARMACY | Current | ☐ | ☐ |
| EC | 1829 SAGEBROOK DR, TALLAHASSEE FL 32303 Leon US | 850-445-2215 | DARREN.EVANS@FLHEALTH.GOV | EVANS, DARREN | Current | ☐ | ☐ |
| AC | 104-2 HAMILTON PARK DRIVE, TALLAHASSEE FL 32304 Leon US | 850-922-9036 | ISAIAH.HILL@FLHEALTH.GOV | HILL, ISAIAH E | Current | ☐ | ☐ |
| VEM | | | kenneth.grice@flhealth.gov | . | Current | ☐ | ☐ |

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# License Verification

Printer Friendly Version

## DANYELLE BRIONNE WILLIAMS

## License Number: PS53818

*Data As Of 10/26/2020*

License Information | Secondary Locations | Discipline/Admin Action | Subordinate Practitioners

| Name | Relationship | Profession | License | Effective Date |
|---|---|---|---|---|
| WILLIAMS, DANYELLE BRIONNE | PHARMACISTSUBORDINATE | CONSULTANT PHARMACIST | 8210 | 6/5/2018 |

Click on the License Number to view License Details for that Practitioner

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For instructions on how to request a license certification of your Florida license to be sent to another state from the Florida Department of Health, please visit the License Certifications web page.

Primary Source Verified

Department of Health

# DANYELLE BRIONNE WILLIAMS

## License Number: PS53818

*Data As Of 10/26/2020*

| | |
|---|---|
| **Profession** | Pharmacist |
| **License** | PS53818 |
| **License Status** | CLEAR/ACTIVE |
| **Qualifications** | Certified To Administer Immunizations |
| **License Expiration Date** | 9/30/2021 |
| **License Original Issue Date** | 08/05/2015 |
| **Address of Record** | 104-2 HAMILTON PARK DRIVE<br>TALLAHASSEE, FL 32304 |
| **Discipline on File** | No |
| **Public Complaint** | No |

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Department of Health

# License Verification

Printer Friendly Version

## NIAZ AHMED SIDDIQUI

## License Number: PS42647

*Data As Of 10/26/2020*

License Information | Secondary Locations | Discipline/Admin Action | Subordinate Practitioners

| Name | Relationship | Profession | License | Effective Date |
|---|---|---|---|---|
| SIDDIQUI, NIAZ AHMED | PHARMACISTSUBORDINATE | CONSULTANT PHARMACIST | 7204 | 2/7/2013 |

Click on the License Number to view License Details for that Practitioner

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Primary Source Verified

Department of Health

## NIAZ AHMED SIDDIQUI

## License Number: PS42647

*Data As Of 10/26/2020*

| | |
|---|---|
| **Profession** | Pharmacist |
| **License** | PS42647 |
| **License Status** | CLEAR/ACTIVE |
| **Qualifications** | Certified To Administer Immunizations |
| **License Expiration Date** | 9/30/2021 |
| **License Original Issue Date** | 08/01/2007 |
| **Address of Record** | 1100 SW 11TH ST<br>LIVE OAK, FL 32060 |
| **Discipline on File** | No |
| **Public Complaint** | No |

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# ENTRY NOTICE AND ON-SITE INSPECTION REPORT

| | | | |
|---|---|---|---|
| DBA Name: | | Form Date: | Nov 19, 2019 10:54 - Nov 19, 2019 13:05 |
| Full Legal Name: | DOH CENTRAL PHARMACY | Permit Number: | 29 Rank: 28 |
| Inspection Reason: | Chg Locate - X | Telephone Number: | 850-922-9036 |
| Address: | 104-3 HAMILTON PARK DRIVE<br>TALLAHASSEE FL 32304 | Inspection Visit ID: | 7123926 |
| | | File Number: | 5931 |
| | | Permit Type: | 3328 |

**INSPECTION RESULT Completed**

## Inspection Authority 499.051 F.S., 61N-1.019, F.A.C. (03/10/2017)

**Person Receiving Report/Title** Danyelle Williams, Interim Bureau Chief.

## Facility Hours 61N-1.015(2)(c), F.A.C.

| Hours | Monday | Tuesday | Wednesday | Thursday | Friday | Saturday | Sunday |
|---|---|---|---|---|---|---|---|
| Open | See notes | | | | | | |
| Close | | | | | | | |

## FACILITY/STORAGE [(Rx drug establishments) FS 499.01(2) and 499.0121(1)(b),(d),(e)]

| | | |
|---|---|---|
| 1. Is the establishment a residence? [F.S. 499.012(1)(b)] | No | |
| 2. Lighting adequate? [(OTC drug manufacturers) FS 499.01(2)(n)3 and 21 CFR 211.44] [(Cosmetic manufacturers) 61N-1.010(2)(e), F.A.C.] | Yes | |
| 3. Pest Free? [(OTC drug manufacturers) FS 499.01(2)(n)3 and 21 CFR 211.56] [(Cosmetic manufacturers) 61N-1.010(2)(b), F.A.C.] | Yes | |
| 4. Clean and orderly? [(OTC drug manufacturers) 61N-1.014(4), F.A.C.] [(Cosmetic manufacturers) 61N-1.010(2)(a), F.A.C.] | Yes | |

## RECORD KEEPING [F.S. 499.0121(6)] [61N-1.012 F.A.C.]

| | | |
|---|---|---|
| 5. All records computer based? | No | Electronic and Manual. |
| 6. Location of hard copy? | | On site |
| 7. All records manual? | No | Electronic and Manual |
| 8. On-site storage? | Yes | |
| 9. Shares facility? | No | |
| 10. If yes to #9, separate records? | N/E | |

## PRESCRIPTION DRUG ESTABLISHMENT

| | | |
|---|---|---|
| 11. Is the name identical to another person authorized to purchase legend drugs? [F.S. 499.012(1)(c)] [61N-1.015(2)(b), F.A.C.] | N/E | The firm has not yet been issued the repackager permit for this location |
| 12. Is the person a broker only as defined under [61N-1.001(2)(d), F.A.C.]? | No | |

## SECURITY [(Rx drug establishments) FS 499.0121(2)(a), (b) and 499.0121(10)(b) or 61N-1.013(1), F.A.C.]

| | | |
|---|---|---|
| 13. Access restricted? [(OTC drug manufacturers) FS 499.01(2)(n)3 and 21 CFR 211.28(c)] [(Cosmetic manufacturers) 61N-1.010(4)(f), F.A.C.] | Yes | Employees have a swipe badge to enter. Visitors have to be buzzed in by the firm. |
| 14. Drug facility alarmed? | Yes | |

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| | | |
|---|---|---|
| 15. Telephone monitoring? | Yes | Sonitrol |
| 16. Controlled substance cage (CIII-CV)? [21 CFR 1301.72] | N/E | This location will not stock or distribute controlled substances. |
| 17. Controlled Substance CII vault? [21 CFR 1301.72] | N/E | |

**STORAGE [(Rx drug establishments) FS 499.0121(3)(5) or 61N-1.013(3)(4), F.A.C.] [(OTC drug manufacturers) 61N-1.014, F.A.C., and/or FS 499.01(2)(n)3 and 21 CFR 211.46] [(Cosmetic manufacturers) 61N-1.010(2), F.A.C.]**

| | | |
|---|---|---|
| 18. Quarantine area? | Yes | |
| 19. Air conditioner? | Yes | |
| 20. Method of monitoring? | | Electronic |
| 21. Refrigeration present? | No | |
| 22. Handles drugs or cosmetics requiring refrigeration? | | NA |
| 23. Method of monitoring refrigeration? | | NA |
| 24. Freezer present? | No | |
| 25. Handles drugs or cosmetics requiring freezing? | No | |
| 26. Method of monitoring freezing temperatures? | | NA |

**WRITTEN POLICIES AND PROCEDURES [(Rx drug establishments and OTC manufacturers) FS 499.0121(6)(8)(10), 499.01(2) and/or 21 CFR Part 211] [(Cosmetic manufactures) 61N-1.010, F.A.C.]**

| | | |
|---|---|---|
| 27. Exist? | Yes | |
| 28. Rx drug annual examination? [F.S. 499.0121(5)(a)2] | Yes | |
| 29. Drug FIFO inventory? | Yes | |
| 30. Recalls/emergencies? | Yes | |
| 31. Natural disasters for Rx drug establishments? | Yes | |
| 32. Receipt and distribution business records? | Yes | |
| 33. Transaction Information, History and Statement (T3) for Rx drug products? | N/E | |

**INBOUND PRESCRIPTION DRUG BUSINESS RECORDS (Purchases and/or Receipts) [FS 499.0121(6)(b)] [61N-1.012(1)(a),(2)(a), F.A.C.]**

| | |
|---|---|
| 34. What are firm's all-inclusive inbound business records that it receives from its Rx drug source(s) per firm for this establishment? | Invoice |

**OUTBOUND PRESCRIPTION DRUG BUSINESS RECORDS (Sales or Otherwise) [FS 499.0121(6)(b)] [61N-1.012(1)(a),(2)(a), F.A.C.]**

| | |
|---|---|
| 35. What are firm's all-inclusive typical outbound business records (e.g., sales invoice, packing list, etc.) that it provides to the purchaser and recipient for each Rx drug distribution from this establishment according to firm? | Invoice. Firm also provides a repack order and a shortage/overage report. Firm states the shortage/overage report accounts for any discrepancies between the bottle count and the repackaged drug count |
| 36a. Did firm provide its all-inclusive outbound business records for one (1) of its typical Rx drug distribution? | Yes |
| 36b. If yes to 36a, what is the tracking number (e.g., sales invoice or order number, etc.) and distribution date for this provided distribution document? | Invoice number. |
| 37. Of the document(s) provided in 36a, which document contains the minimum required recordkeeping business elements according to firm? | Invoice |

38. For the document type referenced in 37 regarding this establishment's outbound Rx drug distributions:

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| | | |
|---|---|---|
| 38a. Did firm mark "A" next to the field that lists the seller's name and address? | Yes | |
| 38b. Did firm mark "B" next to the field that lists the seller's Florida permit number? | Yes | |
| 38c. Did firm mark "C" next to the field that lists the shipper's name and address when different from the seller? | Yes | Ship from and sold from will always be the same |
| 38d. Did firm mark "D" next to the field that lists the distribution date? | Yes | |
| 38e. Did firm mark "E" next to the field that lists the name, strength, dosage form, quantity, and (when assigned) the National Drug Code (NDC) of the Rx drug? | Yes | |
| 38f. Did firm mark "F" next to the field that lists the financial data? | Yes | |
| 38g. Did firm mark "G" next to the field that lists the purchaser's name, address, and Florida permit number? | Yes | |
| 38h. Did firm mark "H" next to the field that lists the physical recipient's name, address and permit or license number, when the recipient is different from the purchaser? | Yes | |

**N/E = Not Evaluated**

**Inspection Notes**

Change of Address inspection Rx Drug Repackager. The Firm is relocating from 104-2 Hamilton Park Drive, Tallahassee, FL to 104-3 Hamilton Park Drive, Tallahassee, FL

Arrived at Facility approximately 1000

Credentials and Bill of Rights presented to Isaiah Hill. Government Consultant II. Also present representing the firm was Carolyn Albaugh, Business manager.

I. PERMITS/LICENSES:

A. FDA REGISTRATION – The Firm currently holds establishment registration at 104-2 Hamilton Park Drive, Tallahassee, FL Registration # 1036356 – Repackager.

B. DEA Registration

The Firm is already registered at this location with the DEA. RF0356015.
registration is under the name of FL DOH Bureau of Public Health Pharmacy

Business Activity is listed as Chempack/SNS Distributor
Schedules covered are listed as II, III, IV and V.

C. PHARMACY PERMITS – Firm holds Community Pharmacy permit PH 23821 located at 116 A Hamilton Park Drive, Tallahassee, FL.

D. DBPR PERMITS –
The Firm holds the following permits with DBPR at 104-2 Hamilton Park Drive, Tallahassee, FL
RPK – 2082 - This permit will be transferred to 104-3 Hamilton Park Drive, when issued.

50:238
54:33
28:29 – This permit will be transferred to 104-3 Hamilton Park Drive, when issued.

The firm holds the following permits with DBPR at 116-A Hamilton Park Drive, Tallahassee, FL

50:237
54:29

The firm hold DBPR permit 54:258 at this location (104-3 Hamilton Park Drive)
This permit is for Emergency Preparedness. Firm states they will need to keep this permit at this location.

II. DESCRIPTION OF BUSINESS:

Hours of Operation - 0700 - 1700. Monday through Friday

Approximate size of facility - 7000 square feet

Number of employees - 10 -12

Any other business operating at this address? Firm states permit 54:258 will continue to operate from this location.
The firm states the Emergency Preparedness permit is used in order for the facility to store Rx drugs to only be distributed in the event of an in State emergency. Example Cipro for Anthrax, Tamiflu for Influenza outbreaks.

The firm states this permit will also be used in order to distribute Rx drugs to State Prisons.

Any off-site storage and/or warehouses? The firm stores drugs at other permitted locations.

Explain Day to Day Operations

Firm receives Rx drugs from Cardinal. The firm states the majority of the Rx drugs are paid for by the individual prisons and are shipped to this location from Cardinal to be repackaged at this location. Once repackaged the firm will distribute the repackaged Rx drugs to the prisons. The drugs that are intended to be repackaged for the prison is paid for by the prison and shipped to DOH for repacking. DOH does not purchase these drugs.

The firm states the only reimbursement they receive for the repackaged drugs is the cost of the repackaging.

The firm states they do purchase some Rx drugs from Cardinal pursuant to the STD specialty care program. These drugs are distributed to the DOH Pharmacy located 116 A Hamilton Park Drive. Once received by the pharmacy these drugs are dispensed by the pharmacy to the prison on a patient specific basis.

The Department is reimbursed by the prisons for the STD specialty care program drugs. The firm states the Rx drugs purchased for the STD specialty care program are purchased using their 54 permit.

The firm creates a batch production and control record for each drug that is repackaged. The records provides instructions on how that particular drug is to be repackaged. Also includes elements such as name of drug, strength of drug, lot number and expiration dates.

III. PRODUCT REGISTRATION - F.S. 499.015 and Rule 61N-1.016 FAC

The firm has applied for a product registration permit for this location. The firm previously had a product registration permit for 104-2 Hamilton Park drive

The firm provided a list of products they have previously registered for review. The list indicates the firm has registered 116 products

IV.CONTROLLED SUBSTANCE REPORTING

A. Has firm registered with the Department's CSR system? The firm states they will not repackage or distribute any controlled substances.from this location with either the Restricted Distributor and/or the Repackager permit.

V. VENDOR LIST -

Firm states their only vendor is Cardinal Health. A review of the invoices for 104-2 Hamilton Park Drive indicates the drugs are being received from Cardinal Health, 2045 Interstate Drive. Lakeland, FL Permit 22:913

VI. CUSTOMER LIST - All State correctional facilities. The firm states they distribute to (5) facilities. The firm states these (5) facilities will then further distribute to the rest of the State correctional facilities.

VII. INBOUND DOCUMENTS - Reviewed Cardinal Invoices from 104-2 Hamilton. Park Drive. Firm will continue to receive from Cardinal once they have relocated.

VIII. OUTBOUND DOCUMENTS

A. Outbound Business Record Template Provided? Yes

IX. SECURITY – Sonitrol
Firm has Indoor/Outdoor cameras that monitor entry and exit points.
Firm has door badge scanners for entry into building.

X. Equipment

The firm has (3) Autobond repacking machines. The firm states these are used for repackaging smaller quantities. (1) of the Autobonds is used to repackage Penicillin only.

(4) 400 repackaging machines
(1) 500 repackaging machines which is for the largest quantities.

Firm has a self contained clean room located at 104-2 Hamilton Park Drive which has not been relocated. Firm states they no longer provide beta lactam drugs to DOC as such; the firm will not be relocating the clean room.

A) Description

B) Maintenance Performed by? Omnicell

C) Calibration Performed by? Omnicell. Firm states the machines are calibrated annually.

D) Firm states clean room is certified by EOC-1

D) Cleaning Schedule. - Firm states the repacking machines are cleaned every time they change drugs that are being repackaged, as such; the firm states these may be cleaned multiple times daily. The firm states at a minimum the machines will be cleaned once daily.
Firm states they clean with isopropyl alcohol.

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Department of Business & Professional Regulation

2601 Blair Stone Road
Tallahassee, Florida 32399-1047
(850) 717-1800
www.myfloridalicense.com

XI. Temperature/Humidity Monitoring:

A) Room Air Monitored? Number/Location of Sensors/Thermometers

Firm has (1) electronic temperature and humidity monitors installed. Firm states the electronic monitor cards are changed monthly and stored onsite.
The firm has an additional electronic temp/humidity monitor at 104-2 Hamilton Park Drive that they intend to move to this location.

B) Refrigerated Present? No, Firm states they will not stock, repackage and/or distribute any refrigerated drugs.

C) Freezer Present? No, Firm states they will not stock, repackage and/or distribute any refrigerated drugs.

The firm does not have a refrigerator or freezer present at this time.

XII. Policies and Procedures:

The firm states they have P & P's for storage and handling of Rx drugs in their Pharmacy located at 116 A Hamilton Park Drive, however; they state they do not have written P & P's for this location. The firm states the Rx drugs are repackaged and distributed upon receipt, as such; the firm states they do not have P &P's for rotating stock, checking for expiration dates etc.

XIII. MISCELLANEOUS

A. How are Rx Drugs delivered to customers? FedEx and UPS

B. Destructions/Returns handled by? Inmar.

C. Does firm have a copy of FS 499 and Rule 61N-1 FAC onsite? Emailed to facility by inspector

XIV. TOUR OF FACILITY

Firm has a 2 bay doors in the receiving area where drugs are received from Cardinal. Once the firm has verified the contents of the totes from Cardinal the drugs will be transferred to the prep room where they are transferred from the stock bottle into labeled plastic bags. The bags indicate pertinent drug information, i.e. Name of drug, strength, lot # expiration dates etc.
from there the drugs are transferred to the actual area where they will be repackaged. After the drugs are repackaged they are transferred to QC (quality control area) where they are checked for accuracy. The drugs are then boxed and ready for shipment.

XV. EXIT INTERVIEW

1) Requested the firm to relocate the 2nd temp/humidity monitor as from 104-2 Hamilton Park Drive to 104-3 as quickly as possible.

email picture to inspector when relocated.

Florida dbpr
Department of Business & Professional Regulation

2601 Blair Stone Road
Tallahassee, Florida 32399-1047
(850) 717-1800
www.myfloridalicense.com

Licensee or Owner Signature

Danyelle Williams
Interim Bureau Chief
Nov 19, 2019 13:05

Inspector Signature

Donald Yarbey
Drug Inspector
Nov 19, 2019 13:05

November 19, 2019 at 1:05:58 PM EST
Location:
License #: 2629
Inspector: Donald Yarbey

November 18, 2020

Center for Drug Evaluation and Research
Office of Communicatons
10001 New Hampshire Avenue
Hillandale Building, 4th Floor
Silver Spring, MD 20993

The Florida Department of Health (DOH) attests, to the best of our knowledge, that there are no past criminal convictions or violations of State, Federal, or Canadian laws regarding drugs or devices against or by the responsible individual(s). Further, DOH attests that the responsible individual(s) have not been involved in, or convicted of, any such violations and there have been no disciplinary actions against the responsible individual(s),

The DOH's Pharmacists are Danyelle Brionne Williams, Pharmacist and Consultant Pharmacist License Number PS53818 and Niaz Ahmed Siddiqui, Pharmacist and Consultant Pharmacist License Number PS42647.

Please contact Doug Woodlief, (850) 245-4230 if you have any questions regarding this attestation.

Sincerely,

Doug Woodlief
Division Director
Emergency Preparedness and Community Support

DHW/vj

# Attachment B

LifeScience Attestations and Inspectional History

2600 Regent Blvd.
DFW Airport, TX 75261

Telephone: (469) 844-3701
Fax: (972) 456-1832

November 17, 2020
Center for Drug Evaluation and Research
Office of Communications
10001 New Hampshire Avenue
Hillandale Building, 4th Floor
Silver Spring, MD 20993

LifeScience Logistics (LSL) attests that there are no 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. Further, LSL attests that the responsible individual(s), Foreign Seller or Importer has not been involved in, or convicted of, any such violations. LSL's principal owners (owning 10 percent or greater of outstanding stock) are Richard Beeny and Max Kamhi.

Lastly, there have been no disciplinary actions 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 7 years prior to submission of the SIP Proposal, with the exception of the following three administrative fines to LSL from the referenced bodies (continued on Page 2):

| Detail | Comments |
|---|---|
| Case # 2016-3687 | Colorado State Board of Pharmacy issued an Administrative fine of $1500 on 19 Jul 2016 for having a change of DR notice outside of the 30-day reporting window for LifeScience Logistics, 1105 E Northfield Drive, Suite 300-400, Brownsburg, IN 46112. This reporting delay occurred in November 2015. |
| Citation CI 2017 78097 | California State Board of Pharmacy issued an Administrative fine of $900 on 30 Apr 2018 for having a change of DR notice outside of the 30-day reporting window for LifeScience Logistics LLC, 4475 South Fulton Parkway Building 5 Suite C, Atlanta, GA 30349. This reporting delay occurred in September 2016. |
| Case # 18-L-0075 | Alabama State Board of Pharmacy issued a reciprocal administrative fine of $1000 on 29 Oct 2018 for the same incident in relation to the California State Board of Pharmacy Citation CI 2017 78097. |

Warm regards,

Richard Beeny
CEO and Co-founder

LifeScience Logistics®

**Life Science Logistics, LLC Five Year Regulatory Audit History**
**(FEI# 968727565)**

17 FEB 2016 - DEA Import/Export - no observations

26 FEB 2016 - Indiana Dept. of Environmental Management - no observations

31 MAR 2016 - ISO 13485:2003 - no observations – ISO Certificate issued

22 AUG 2016 - Verified-Accredited Wholesale Distributors (VAWD) - no observations – Renewed

23 SEP 2016 - Indiana Board of Pharmacy – Pass, no observations

14-16 FEB 2017 -ISO 13485:2003 one-year surveillance audit - 2 minor observations (closed)

14 MAR 2017 - FDA - no observations

25 AUG 2017 - DEA Export - 1 minor observation (closed)

07 MAR 2018 - ISO 13485:2003 one-year surveillance audit - 1 minor observation (closed)

08 MAR 2018 - ISO 13485 transition audit to 2016 standard – ISO 13485:2016 Certificate issued

14 JUN 2018 - DEA Import and Distributor - 3 minor observations (closed)

21 FEB 2019 - ISO 13485:2016 commercial recertification audit – 1 minor observation (closed)

23 May 2019 - Verified-Accredited Wholesale Distributors (VAWD) - no observations – Renewed

14 Jan 2020 - ISO 13485: 2016 corporate one-year surveillance audit – no observations

21 JAN 2020 - ISO 13485: 2016 commercial one-year surveillance audit – no observations

24 APR 2020 - DEA Export – no observations

26 JUN 2020 - FDA Risk Evaluation & Mitigation Strategies program (REMS) – no observations - Certified

Paul Hayward 14 May 2020

Paul Hayward
Director, Quality Assurance and Regulatory Affairs

LifeScience Logistics®

**Life Science Logistics, LLC Seven Year Disciplinary History**
**(FEI# 968727565)**

There have been no disciplinary actions against the responsible individual(s) 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 7 years prior to submission of the SIP Proposal, with the exception of the following three administrative fines to the entire Life Science Logistics facility network from the referenced state bodies:

| | |
|---|---|
| Case # 2016-3687 | Colorado State Board of Pharmacy issued an Administrative fine of $1500 on 19 Jul 2016 for having a change of DR notice outside of the 30-day reporting window for LifeScience Logistics, 1105 E Northfield Drive, Suite 300-400, Brownsburg, IN 46112. This reporting delay occurred in November 2015. |
| Citation CI 2017 78097 | California State Board of Pharmacy issued an Administrative fine of $900 on 30 Apr 2018 for having a change of DR notice outside of the 30-day reporting window for LifeScience Logistics LLC, 4475 South Fulton Parkway Building 5 Suite C, Atlanta, GA 30349. This reporting delay occurred in September 2016. |
| Case # 18-L-0075 | Alabama State Board of Pharmacy issued a reciprocal administrative fine of $1000 on 29 Oct 2018 for the same incident in relation to the California State Board of Pharmacy Citation CI 2017 78097. |

14 Nov 2020

Paul Hayward
Director, Quality Assurance and Regulatory Affairs

# Attachment C

LifeScience Logistics Inspection Records

Indiana Department of Environmental Management
*We Protect Hoosiers and Our Environment.*
100 N. Senate Avenue • Indianapolis, IN 46204
(800) 451-6027 • (317) 232-8603 • www.idem.IN.gov
Michael R. Pence
*Governor*
Carol S. Comer
*Commissioner*

March 2, 2016

VIA E-MAIL
Mr. Christoph Erdel
Life Science Logistics LLC
1105 E. Northfield Dr.
Brownsburg, IN 46112

Re: Inspection Summary Letter
Life Science Logistics LLC
INR000137521
Brownsburg, Hendricks County

Dear Mr. Erdel:

On 2/26/2016, a representative of the Indiana Department of Environmental Management, Office of Land Quality, conducted an inspection of Life Science Logistics LLC, located at 1105 E. Northfield Dr., Brownsburg, IN. This inspection was conducted pursuant to IC 13-14-2-2. For your information, and in accordance with IC 13-14-5, a summary of the inspection is provided below:

| | |
|---|---|
| Type of Inspection: | Compliance Evaluation Inspection<br>Multi-Media Screening Evaluation |
| Results of Inspection: | No Violation(s) Discovered |

Please direct any response to this letter and any questions to me at (317) 417-7891.

Sincerely,

Debbie Chesterson

Debbie Chesterson
Hazardous Waste Compliance Section
Compliance and Response Branch

Enclosure
cc: Hendricks County Health Department

**INDUSTRIAL/HAZARDOUS WASTE INSPECTION REPORT**
INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT

| | |
|---|---|
| Inspector's Name: | Debbie Chesterson |
| Others Present | |
| Date: | Friday, February 26, 2016 |
| Time In: | 8:50 AM |
| Time Out: | 10:00 AM |
| Inspection Type | Compliance Evaluation Inspection<br>Multi-Media Screening Evaluation |

## General Information

| Facility Information | |
|---|---|
| Facility Name | Life Science Logistics LLC |
| Facility Location | 1105 E. Northfield Dr.<br>Brownsburg, IN 46112<br>Hendricks County |
| Facility Mailing Information | Same Address as Facility |
| Facility Contact | Same as Primary Facility Contact |
| Primary Facility Contact During Inspection | Christoph Erdel<br>Operations Supervisor<br>317-456-0257<br>cerdel@lslog.com |

Other Facility Contact(s) During Inspection

| Salutation | First Name | Last Name | Title | Phone Number | Email |
|---|---|---|---|---|---|
| Ms. | Heather | Laurin | QA Specialist | 317-489-5036 | hlaurin@lslog.com |

| Facility ID | | | |
|---|---|---|---|
| EPA ID Number | INR000137521 | NAICS Code | 49311, 424210 |

| Facility Status | | | |
|---|---|---|---|
| File Status | Conditionally Exempt Small Quantity Hazardous Waste Generator | Other Activities | |

| Outstanding Issues | |
|---|---|
| Last Inspection Date | No prior RCRA inspections |
| Previous Violations | ○ Yes ◉ No |
| Details | |

## Inspection Narrative

Life Science Logistics LLC operates as a third party logistics provider for the healthcare industry. The distribution warehouse stores pharmaceuticals, medical devices and over-the-counter (OTC) items for over twenty clients in Suite 300. Suite 200 is currently unoccupied. Suite 400 warehouses healthcare items for the federal government. They began operations at this location in 2011.

This was the first RCRA inspection at the facility. They began operations at this location in 2011. The facility is notified as a conditionally exempt small quantity generator of hazardous waste. To date, no hazardous waste has been stored or shipped from this location. Hazardous waste generation could occur through damaged or expired products that are stored within the facility; hence they obtained an EPA identification number for the site.

No violations were noted during the inspection.

| Regulatory Status | | | |
|---|---|---|---|
| **Observed Activity** | Conditionally Exempt Small Quantity Generator | **Other Activities** | Universal Waste Handler |
| **Documents Reviewed** | Manifests | | |
| **Comments** | | | |

**Waste Management**

Comments:

**Waste Stream(s) Information**

**Waste Streams**

(•) Yes ( ) No ( ) Not Inspected ( ) Not Applicable

List waste stream(s) information that varies from the most recent Annual Report (Example: additional waste streams, waste streams no longer generated, significant increase/decrease in generation rate, etc.)

| EPA Waste Codes | Description | Source | Generation Rate | Disposition |
|---|---|---|---|---|
| No hazardous waste generation to date | | | | |

**Exempted/Excluded** ( ) Yes (•) No ( ) Not Inspected ( ) Not Applicable

**Explanation**

**Waste Management Areas**

**Container Management Area(s)** (•) Yes ( ) No ( ) Not inspected ( ) Not applicable

| EPA Waste Codes | Location | Number | Size | Type of Container |
|---|---|---|---|---|
| No hazardous waste present | | | | |

**Satellite Area(s)** ( ) Yes (•) No ( ) Not inspected ( ) Not applicable

**Tanks, Restricted Waste Sites, and Other Regulated Units**

( ) Yes (•) No ( ) Not inspected ( ) Not applicable

**Environmental Releases**

**Visible Releases/Contamination/Discharges** ( ) Yes (•) No Release Observed

**Compliance Assistance**

**P2 Information**

The following P2 suggestions could possibly save money, reduce waste and/or minimize risk. You might consider having a P2 assessment, or a voluntary technical assistance consultation from IDEM staff. Please visit the agency's P2 web site at http://www.in.gov/idem/5298.htm for additional information.

**Contact by IDEM OPPTA Requested** ( ) Yes ( ) No

**P2 Suggestions**

**Guidance Materials**

| Guidance Materials Provided to Facility | |
|---|---|

| Multi-Media Screening (Checked box indicates a concern) | |
|---|---|
| Comments: | |
| **Multi-Media Screening Conducted** | (•) Yes ( ) No |

**Water Concerns**
- ☐ Process wastewater discharge to a POTW collection system (i.e. sewer) without a permit
- ☐ Direct discharge (from industrial process, industrial wastewater treatment or non-contact cooling water) to receiving water near the facility without an NPDES permit
- ☐ Process materials such as cleaners, solvents, paints, lubricants, etc. are escaping through floor drains

**Air Concerns**
- ☐ Visible emissions from stacks or vents
- ☐ Dust crossing property lines
- ☐ Open solvent containers
- ☐ Spray booth filters not securely in place
- ☐ Open burning

**Storm Water Concerns**
- ☐ NOI for Rule 6 (see applicable SIC codes)
- ☐ Storm Water Pollution Prevention Plan (must be developed within 365 days of NOI).
- ☐ Storm water annual sample
- ☐ Measures to ensure contaminants from industrial activities aren't exposed to storm water
- ☐ Documented quarterly inspections of storm water run-off conveyances
- ☐ Documented annual employee training on SWP3
- ☐ Rule 5 storm water permit for land disturbing activities greater than 1 acre
- ☐ Signs of erosion or off-site sedimentation into waters of the state from construction sites

**Drinking Water Concerns**
- ☐ PWSID# (applies to 25 or more employees on self-supplied drinking water system)
- ☐ Contamination within 200 ft of wellhead

**TRI Concerns**
- ☐ Lack of TRI report (applies to 10 or more employees in applicable SIC codes)

**UST Concerns**
- ☐ Unregistered UST containing petroleum or hazardous substance

| Checklist (Checked box indicates a compliance concern) | |
|---|---|

**Standards**
- ☐ Hazardous Waste Determination
- ☐ EPA Identification Number(s)
- ☐ Manifest General Requirements
- ☐ Use of the Manifest
- ☐ Biennial Report

**Satellite Accumulation – SQG and LQG**
- ☐ Satellite Accumulation - 55 Gallon
- ☐ Satellite Accumulation - Label
- ☐ Satellite Containers Closed

**Container Management – LQG**
- ☐ Accumulated On-site for 90 Days or Less
- ☐ Hazardous Waste Container Condition
- ☐ Hazardous Waste Container Compatibility
- ☐ Hazardous Waste Containers Closed
- ☐ Hazardous Waste Container Handling

**Container Management – SQG**
- ☐ Accumulate for 180 Days or Less
- ☐ May not Exceed 6000 Kg (13,200 Lbs)
- ☐ Hazardous Waste Container Condition
- ☐ Hazardous Waste Container Compatibility
- ☐ Hazardous Waste Containers Closed

| | |
|---|---|
| ☐ Hazardous Waste Container Inspections<br>☐ Accumulation Start Date Clearly Marked and Visible<br>☐ Marked Clearly with Words "Hazardous Waste" | ☐ Hazardous Waste Container Handling<br>☐ Hazardous Waste Container Inspection<br>☐ Accumulation Start Date Clearly Marked and Visible<br>☐ Marked Clearly with the Words "Hazardous Waste" |
| **Preparedness and Prevention – LQG and SQG**<br>☐ Maintained and Operated to Minimize Possibility of a Release<br>☐ Required Equipment<br>☐ Communication & Alarm Access<br>☐ Aisle Space | **Contingency Plan and Emergency Procedures – LQG**<br>☐ Contingency Plan Developed<br>☐ Contingency Plan Content<br>☐ Contingency Plan Maintained at Facility |
| **Personnel Training – LQG**<br>☐ Personnel Training | **Training and Emergency Procedures – SQG**<br>☐ SQG Emergency Coordinator<br>☐ Emergency Information Posted<br>☐ Employee Training |
| **Tank Requirements – LQG**<br>☐ Integrity Assessment<br>☐ Containment and Release Detection<br>☐ Tank General Requirements<br>☐ Tank Inspections<br>☐ Subpart BB - Monthly Pump and Valve Monitoring<br>☐ Subpart CC - Annual Inspection/Monitoring | **Used Oil – All Facilities**<br>☐ Rebuttable Presumption Applies<br>☐ Containers and Tanks in Good Condition<br>☐ Containers/Tank Labeling<br>☐ Release Clean Up and Containment<br>☐ Burning Restrictions - Generated On-site or Dly, .5M BTU |
| **Additional Requirements – LQG and SQG**<br>☐ Release to the Environment, Disposal of Solid Waste<br>☐ Illegal Dumping<br>☐ Land-Ban Notification<br>☐ Other Violation | **Universal Waste – All Facilities**<br>☐ Universal Waste Labeling<br>☐ Containers - Closed, Good Condition, No Evidence of Leaks<br>☐ Universal Waste - Bulb Crushing Prohibition |

| Description of Violation(s) |
|---|
| |

| Inspection Documentation | | |
|---|---|---|
| **Photographs** | ○ Yes<br>◉ No | |
| **Map** | ◉ Maps | |
| **GPS Location Collected** | ○ Yes<br>◉ No | |
| **Analytical Screening Conducted** | ○ Yes<br>◉ No | |

| | | |
|---|---|---|
| **Lab Sample** | ○ Yes<br>◉ No | |

| Inspection Results/Actions | |
|---|---|
| Comments: | |
| **Inspection Results** | |
| No Violation(s) Discovered | |
| **Multi-Media Screening Results** | |
| No violations | |

| Finalize Inspection | | |
|---|---|---|
| **Written Summary of Inspection** | Notice of Inspection and Verbal Summary Provided | |
| **Inspector Information** | Printed/Typed Name | Debbie Chesterson |
| | Phone Number: | (317) 417-7891 |
| | Email Address: | djcheste@idem.in.gov |
| | Signature: | Signature obtained on the Notice of Inspection |
| **Facility Representative Signature** | Printed/Typed Name: | Christoph Erdel |
| | Signature: | Signature obtained on the Notice of Inspection |

**NOTICE OF INSPECTION**
State Form 50890 (R3 / 11-05)

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
100 N. Senate Avenue
Indianapolis, IN 46204-2251
Telephone: (800) 451-6027 or (317) 232-8603

This is to notify you that on 2/26/16 an inspection of Life Science Logistics LLC was conducted by the undersigned representative of the Indiana Department of Environmental Management (IDEM), Office of Land Quality

**Type of Inspection (may include more than one):**

- ☑ Compliance Evaluation Inspection
- ☐ Hazardous Waste
- ☐ _____
- ☐ Complaint
- ☑ Multi-Media Screening Evaluation
- ☐ Other _____

**Preliminary Inspection/Screening Findings:**
These findings are considered preliminary and identify specific compliance issues discovered during the above-noted inspection that the designated agent of IDEM believes may be a violation of a statute(s), rule(s) or permit(s) issued by IDEM.

**Single Media Inspection:**

- ☑ No violations were discovered with respect to the particular items observed during the inspection.
- ☐ Violations were discovered but corrected during the inspection.
- ☐ Violations were discovered and require a submittal from you and/or follow-up inspection by IDEM.
- ☐ Violations were discovered and may subject you to an appropriate enforcement response.
- ☐ Additional information/review is required to evaluate overall compliance.
- ☐ Other / Comments (attachment may be included)_____

**Multi-Media Screening (Please note that a multi-media screening is not a comprehensive evaluation of the compliance status of the facility):**

- ☐ Multi-media screening not conducted.
- ☑ No violations were discovered with respect to the limited multi-media screening conducted by IDEM.
- ☐ Potential violations were discovered but corrected during the inspection.
- ☐ Potential violations were discovered and may be further investigated.

**Pollution Prevention:**
Pollution prevention is the preferred means of environmental protection in Indiana. The goal of pollution prevention is to promote changes in business and commercial operation, especially manufacturing processes, so that Indiana businesses increase productivity, generate less environmental wastes, reduce their regulatory responsibilities and become more profitable. Your participation in Indiana's pollution prevention program is entirely voluntary. If you have any pollution prevention questions, you may contact our Office of Pollution Prevention and Technical Assistance (OPPTA) at (317) 232-8172 or (800) 988-7901, or visit OPPTA's Web site at www.idem.IN.gov/oppta/p2/. Would your company like to be contacted by IDEM's Office of Pollution Prevention and Technical Assistance? ☐ Yes ☐ No

**Compliance Assistance:**
In addition to the compliance assistance offered by IDEM's individual programs, IDEM's Compliance and Technical Assistance Program (CTAP) offers free, confidential compliance assistance to regulated entities, including small businesses and municipalities, throughout Indiana. In the future, if you would like to request free, confidential compliance assistance, call (317) 232-8172 or (800) 988-7901, or visit CTAP's Web site at www.idem.IN.gov/ctap.

A summary of violations and concerns noted during the inspection was verbally communicated to the undersigned representative during the inspection. The facility should correct any violations noted as soon as possible. Violations identified and corrected during the inspection may still be cited as violations.

A written inspection summary will be provided within 45 days. In accordance with IC 13-14-5-4, matters not evident to IDEM at the time of the inspection might not be included in either the verbal or written inspection summary.

**IDEM Representative:**

| Printed Name | Signature | Phone Number | Date | Time |
|---|---|---|---|---|
| Debbie Chesterson | Debbie Chesterson | 317-417-7891 | 2/26/16 | In: 4:30 pm<br>Out: 6:00 pm |

**Owner/Agent Representative:**

| Printed Name | Signature | Title | Phone Number | Date |
|---|---|---|---|---|
| CHRISTOPH F. ERBEL | | OPERATIONS SUPERVISOR | 317 456 0757 | 26 FEB 2016 |

DISTRIBUTION: White – IDEM Public File; Canary – Office of Public Information

U.S. FOOD & DRUG ADMINISTRATION

May 25, 2017

Cory Green, Senior Manager
Commercial Operations
Lifescience Logistics
1105 E. Northfield Drive, Suite 400
Brownsburg, IN 46112-2530

FMD-6981-17

Dear Mr. Green:

The U.S. Food and Drug Administration (FDA) or a state agency contracted by the FDA, conducted an inspection at 1105 E. Northfield Drive, Suite 400, Brownsburg, IN, ending on March 14, 2017. Effective April 1, 1997, when the Agency determines an inspection is closed under 21 C.F.R. 20.64 (d)(3), FDA released a copy of the inspection report to the inspected firm.

You will find a copy of the FDA Establishment Inspection Report or state contracted inspection report attached, FDA may have redacted some information in accordance with the Freedom of Information Act (FOIA) and Title 21, C. F. R., Part 20. Firms may request a copy of their FDA inspections completed prior to April 1, 1997 through FOIA.

FDA is working to make its regulatory process and activities more transparent to the regulated industry. Part of this effort is releasing a copy of your inspection report or summary to you.

Any questions regarding this letter or the release of this report should be directed to FMD Coordinator, U.S. Food and Drug Administration, 300 River Place, Suite 5900, Detroit, Michigan 48207. Telephone 313-393-8110; fax 313-393-8139.

Sincerely,

LCDR Kelli L. Wilkinson
Director of Compliance
Detroit District Office

Enclosure: EIR,
ded

U.S. Food and Drug Administration -- Detroit District
300 River Place, Suite 5900
Detroit, MI 48207
Telephone: 313-393-8100
FAX: 313-393-8139
www.fda.gov

TABLE OF CONTENTS



## SUMMARY

This was a pre-approval inspection (PAI) of a large contract finished drug storage and distribution warehouse. This firm was identified as a warehousing and distribution facility [redacted] USA Inc.

This inspection was performed in accordance with compliance program 7356.002 *Drug Manufacturing Inspections* as well as 7346.832 *Pre-Approval Inspections/Investigations* and is being reported under FACTS assignment number 11715051.

The firm was previously inspected on 8/21/12 under the biologics program. No inspection observations were issued at the conclusion of the August 2012 inspection.

The current inspection was the firm's first inspection under the drug program and included coverage of the firm's Quality, Facilities & Equipment, and Materials systems. No inspection observations were issued at the conclusion of this inspection.

No refusals were encountered and no samples were collected.

**ADMINISTRATIVE DATA**

| | |
| --- | --- |
| Inspected firm: | Lifescience Logistics |
| Location: | 1105 E Northfield Dr Ste 300-400<br>Brownsburg, IN 46112-2530 |
| Phone: | 317-456-0254 |
| FAX: | - |
| Mailing address: | 1105 E Northfield Dr Ste 300-400<br>Brownsburg, IN 46112-2530 |
| Dates of inspection: | 3/14/2017 |
| Days in the facility: | 1 |
| Participants: | **Robert M Barbosa, Investigator** |

Upon arrival I, Investigator Robert M. Barbosa, presented credentials and a prepared FDA 482 Notice of Inspection to Mr. Derek Gates (Supervisor of Operations). Mr. Gates identified himself as the most responsible onsite and accepted the notice. Also in attendance was Mr. Henry Tillman (QA Specialist) and Mr. David Mastromatteo (COO). I relayed the purpose and scope of my inspection to the aforementioned individuals.

An inspection closeout meeting was held with Mr. Tillman and Mr. Mastromatteo later that day. No observations were issued at the conclusion of the inspection.

**HISTORY**

LifeScience Logistics (abbreviated as LSL) operates as a contract domestic warehousing and distribution facility of finished pharmaceuticals and other regulated products including biotech, medical devices, and biologics. The firm operates four facilities located proximal to Dallas-FW, TX; Baltimore, MD; Indianapolis, IN; and Atlanta, GA. The Indiana site specifically provides contract warehousing and distribution of finished pharmaceuticals (including category I-V) and biologics (animal plasma). The firm also provides storage of finished pharmaceuticals (including category I-V) for [redacted] In addition to controlled room temperature storage (CRT), the facility is equipped for storage of refrigerated (2-8°C) and frozen (-25 to -35°C) products.

The facility was last inspected under the biologics program on 8/21/12. No observations were issued at the conclusion of that inspection.

Please direct all post inspectional correspondence, including FMD-145 to:

Mr. Cory Green,

Sr. Manager of Commercial Operations
1105 E. Northfield Dr., Suite 400
Brownsburg, IN 46112

**INTERSTATE (I.S.) COMMERCE**
Mr. Tillman stated that approximately 60-70% of all shipments into and out of the Brownsburg facility move in interstate commerce.

**JURISDICTION (PRODUCTS MANUFACTURED AND/OR DISTRIBUTED)**
The firm provides contract warehousing and distribution services of finished pharmaceuticals (including category I-V) as well as other regulated products including biotech, medical devices, and biologics (animal plasma). The firm also provides storage of finished pharmaceuticals (including category I-V) for [redacted] In addition to controlled room temperature storage (CRT), the facility is equipped for storage of refrigerated (2-8°C) and frozen (-25 to -35°C) products. All registrations were verified as current.

**INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED**
Mr. Richard Beeny is the firm's current CEO. The site's commercial warehousing and distribution operation is led by Mr. Cory Green (Sr. Manager of Commercial Operations). Mr. Green is temporarily reporting to Mr. Mastromatteo until the vacant position of Operations Manager for the Brownsburg, IN site is filled.

Mr. Tillman is the head of the quality organization at the Brownsburg, IN site. Mr. Tillman reports directly to Ms. Samantha Nash (QA Supervisor). Ms. Nash in-turn reports to Mr. Paul Hayward (Director of Quality and Regulatory Affairs).

Mr. Mastromatteo, Mr. Tillman, and Ms. Clara Walker (QA Coordinator) accompanied me during my walkthrough of the facility. All general operation questions were addressed by Mr. Mastromatteo. All document requests were directed to and fulfilled by Mr. Tillman and Ms. Walker.

A copy of the firm's organizational chart is included here as **Exhibit RMB1**.

**FIRM'S TRAINING PROGRAM**
The firm's training program is defined in procedure no. SOP 1800 *Training and Qualification*. Training falls into three main categories; read-only, instructor led, and non-procedure training. Training is recorded on hard copy training forms and maintained in a training file. The firm's training program was not reviewed during this inspection.

**MANUFACTURING/DESIGN OPERATIONS**
*Facility Overview:*

The LSL facility is located in a large single concrete structure. The facility is divided into two suites identified as 300 and 400. Suite 300 supports the firm's regulated commercial product operation and includes approximately 350,000ft$^2$. Suite 400 supports [redacted] of the operation and was not evaluated during this inspection. Both suites are managed separately but share a common quality unit.

The firm maintains separate personnel for each suite and access is managed through card key for each area. The commercial product operation consists mainly of a large number of product storage pallet bays, an extensive receiving/shipping area, return/reject cage, a large walk-in refrigeration unit, and smaller upright units for frozen storage.

*Quality System Review:*

The firm has procedures in place for managing all deviations and change controls. All deviation investigations are performed per procedure number SOP 1350 *Deviation/CAPA-Commercial*. I reviewed a list of deviations initiated between January 1, 2017 and March 2017. Three deviation investigations were selected for review. I noted no issues during my review of these investigations. All reports were observed to have been completed per the procedure

All change controls are managed through procedure number SOP 1002 *Change Control*. I reviewed a list of change controls initiated between January 1, 2016 and March 2017. I reviewed change control number CR-INC-16-0031. I noted no issues during my review of this change control. The processes documented within the report were observed to have been completed per the procedural requirements.

*Facilities & Equipment System Review:*

As part of my review of the facilities and equipment system, I reviewed the firm's calibration and maintenance of the temperature reporting probes located throughout the ambient storage warehouse expansion area which was qualified for use in December 2016. Initial probe calibration was performed at that time along with the initial temperature mapping of the warehouse expansion area. I reviewed the recent probe calibration data as well as the temperature mapping data without note. Each of the temperature reporting probes were observed to be uniquely identified and within calibration tolerance. I also reviewed a trend of the temperature readings reported throughout the expanded warehouse storage area between December 2016 and March 2017. All reported temperature readings were within acceptable limits.

*Materials System Review:*

Review of the materials system focused mainly on material receipt and material control through the firm's inventory control system TECSYS Elite Series Warehouse Management System. All materials and material status is controlled using this validated inventory management system. The system is designed to interface with the firm's client's inventory systems as well (specifically [redacted] Orders are transferred into the system electronically by the client and product is rotated

based on oldest expiry date for fulfillment of those orders. Staff will collect the appropriate products, package, and ship them to the designated customer. All products are received into the system in a "PR Hold" status. Product is released for use by quality assurance after notification by the client. Material cannot be allocated to fill orders unless it has been made available for use in the system.

The system validation was documented in a series of six validation documents. A copy of validation summary report no. CSV-WMS-007 was provided and reviewed. All test scripts for the system were included in the firm's IQ and PQ protocols. The summary report stated that the TECSYS system is hosted by the software owner which acts as a 3rd party for tech support and maintenance of inventory data. The software owner was audited as part of the validation effort. The summary report from this audit was provided and reviewed. The audit findings identified several corrective areas but overall no significant issues were noted.

## MANUFACTURING CODES

The firm does not assign manufacturing codes to the finished drug products it receives or distributes out of its facilities. All manufacturing codes used are provided by the firm's clients and entered into the inventory tracking system. The manufacturing codes provided vary from client to client.

## COMPLAINTS

Complaint investigations responsibilities for LSL are detailed in the firm's signed quality agreement with their client [redacted] The agreement states that LSL will conduct investigations into any complaints due to "missing, overage or damaged product, late delivery etc."

Handling of product complaints is performed per procedure number SOP 4001 *Handling of Product Complaints*. The procedure describes the process for evaluating and investigating the complaints. Additionally all complaints are tracked and trends are reviewed periodically. All observed trends are investigated with CAPAs being initiated when determined to be appropriate.

I reviewed two complaint investigations as well as a recent trend investigation. I noted no issues during my review of these investigation forms.

## RECALL PROCEDURES

Mr. Mastromatteo explained that as a contract service provider, LSL does not actively conduct product recalls and that all formal notifications regarding product recalls are issued by the firm's various clients. He did state however that LSL may provide assistance with product recalls per the client's request. This would include providing of distribution information as well as handling of recalled product returns and forwarding for destruction.

Any activities performed in support of a client's recall as well as any responsibilities which the client may require would be stated in writing and/or as part of a quality agreement with the client. The

product recall requirements between LSL and [redacted] were verified during my review of the firm's Quality agreement.

**OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE**
No inspection observations were issued.

**REFUSALS**
No refusals were encountered.

**GENERAL DISCUSSION WITH MANAGEMENT**
None.

**ADDITIONAL INFORMATION**
None.

**SAMPLES COLLECTED**
No samples were collected.

**VOLUNTARY CORRECTIONS**
N/A

**EXHIBITS COLLECTED**
1 Organizational Chart, 16 pages

**ATTACHMENTS**
1 FDA 482, 3 pages

Robert M. Barbosa -S

Digitally signed by Robert M. Barbosa -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000367409, cn=Robert M. Barbosa -S
Date: 2017.05.22 12:08:10 -04'00'

bsi.

**AMCF061**(A1252)

**Acceptance of Corrective Action Plan**

**Revision 2 (March 2013)**

01AUG2017

Paul Hayward
LifeScience Logistics
1105 East Northfield Drive
Suite 300
Brownsburg
Indiana

DearMr Hayward,

**Acceptance of Corrective Action Plan from ISO 13485:2003**

**Report No.: 8515524**

Thank you for providing your corrective action plan, detailing your actions to resolve the nonconformities raised during the recent audit.

I can confirm that I have now had an opportunity to review and accept the correction, associated root cause analysis and the corrective action, and the actions and timescales specified appear to be appropriate for all nonconformities identified in the audit.

Verification of effectiveness of the nonconformities will be performed at your next scheduled surveillance audit, and the duration of this visit may be increased to allow time for the verification. Any additional time requirements will be confirmed prior to the visit.

If you have any queries on the above, please contact me.

Yours Faithfully,

] Gregory Jones
AVP Healthcare 2

April 26, 2018
Paul Hayward
LifeScience Logistics, LLC
1105 East Northfield Dr
Brownsburg,
Indiana
46112

Dear Paul,

**Acceptance of Corrective Action Plan from Report No. 8619861**

Thank you for providing your corrective action plan, detailing your actions to resolve the nonconformities raised during the recent audit.

I can confirm that I have now had an opportunity to review and accept the correction, associated root cause analysis and the corrective action, and the actions and timescales specified appear to be appropriate for all nonconformities identified in the audit.

Verification of effectiveness of the nonconformities will be performed at your next scheduled surveillance audit, and the duration of this visit may be increased to allow time for the verification. Any additional time requirements will be confirmed prior to the visit.

If you have any queries on the above, please contact me.

Yours Faithfully,

**Jeremy Ward**
**BSI Client Manager**
**jeremy.ward@bsigroup.com**
**571-353-4914**

NABP
National Association of Boards of Pharmacy
www.nabp.pharmacy

1600 Feehanville Drive
Mount Prospect, IL 60056
T) 847/391-4406
F) 847/375-1114

June 4, 2019

Stephen Spelman
LifeScience Logistics, LLC
dba LifeScience Logistics
1105 E Northfield Drive
Brownsburg, IN 46112

Dear Mr Spelman:

On behalf of the National Association of Boards of Pharmacy® (NABP®) and Verified-Accredited Wholesale Distributors® (VAWD®) staff, I would like to take this opportunity to thank you and the team members at your facility for the hospitality extended to Rich Paul during the recent VAWD reaccreditation survey.

Information provided by the surveyor indicates your facility is operating in compliance with program criteria. NABP will conduct a final assessment of all reaccreditation materials, survey findings, and responses to confirm if your facility continues to meet VAWD program criteria. The Accreditation Committee will then render a decision on reaccreditation. NABP would like to assure you that we will move through the process as expediently as possible.

Thank you for your continued support of the VAWD program and for the courtesy you and your staff have extended during the process. If you have questions or concerns, feel free to contact VAWD staff via email at vawd@nabp.pharmacy.

Sincerely,

Dawn Bibbs-Morrissey
Accreditation Manager

**Pharmacy**
**402 W. Washington Street**
**Indiana Government Center South, Room W072**
**Indianapolis, IN 46204**
**317-234-2067(PHONE) • 317-233-4236(FAX)**

**FACILITY**
LifeScience Logistics
1105 East Northfield Drive Suite 300-400
Brownsburg IN 46112
Phone: 3174560250
Owner: Richard Beeny
Ownership Type:

**LICENSE**
License No: 61100944B
**Profession: Pharmacy**
License Type: CSR
1105 East Northfield Drive Suite 300-400
Brownsburg IN 46112
Phone: 3174560250

| | |
|---|---|
| Inspection Type: | Controlled Substances Inspection |
| Scheduled Date: | 08/08/2016 |
| Inspection Date: | 9/23/2016 |
| Announced? | N |
| Result: | Pass |

Remarks: If you have any questions or concerns please feel free to contact me.



As the undersigned representative of the licensee. I affirm that the information provided during the inspection is true and accurate to the best of my knowledge. I understand that the licensee is responsible for the legal operations of the facility and I am executing this inspection form as. or on behalf of the licensee.

I understand that the licensee is on notice of the violation(s) listed herein and said violation(s) must be corrected within thirty (30) days of notification. Resolution of noncompliance shall occur as stipluated and the licensee shall fully comply with Indiana law. statutes. rules. and professional standards governing their practice. If necessary. a plan of corrective action shall be submitted to the Indiana Professional Licensing Agency within five (5) business days of the initial inspection. This plan of correction shall specify the immediate action to be taken to correct all noted deficiencies.

A plan of corrective action can be either emailed to PLACompliance@pla.IN.gov. or mailed to: Indiana Professional Licensing Agency. Attn: Compliance Division. 402 W. Washington Street. RM W072 Indianapolis. IN 46204. (Postmark must be within five (5) business days after the initial inspection). Failure to timely submit a corrective action plan will result in a personal appearance before the appropriate licensing board. If subsequent inspections identify a failure to address previous violations the facility will "fail" the inspection and disciplinary proceedings will be initiated against licensure.

9/23/2016

Signature of Inspector

Date

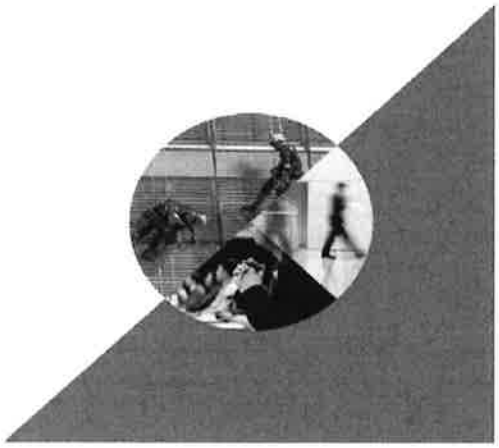
Signature of Owner/Licensee/Representative

bsi.

# Assessment Report

# LifeScience Logistics, LLC

| | |
|---|---|
| Assessment dates | 02/25/2020 to 02/25/2020 (Please refer to Appendix for details) |
| Assessment Location(s) | Brownsburg (000) |
| Report Author | Myles Frohling |
| Assessment Standard(s) | ISO 13485:2016 |





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## Table of contents

# Executive Summary

The objectives of the assessment were met.

Obstacles, Omissions and Reliability

There were no obstacles encountered during the course of the audit. No factors were encountered during the audit that would affect the reliability of this assessment.

Areas Not Audited
All areas were covered per the assessment plan.

Identification and Dating

Audit report authors are as per the assessment team listed. The recommendation included in this assessment is based on the assessment of the sites documented in the 'assessed locations' table towards the rear of this report. This table also defines the assessment duration.

The report was finalized and issued on 25 Feb 2020.

If this visit is part of a multi-location assessment, the final recommendation will be contingent on the findings from all assessments.

CONTINUING ASSESSMENT

Please note that all recommendations are subject to independent review.

The management system has effectively implemented. The system addresses the scope of registration and is in accordance with the company objectives, applicable requirements of the management standard & BSI Conditions of Contract. The result of this assessment is a recommendation for certification.

ISO 13485:2016
All requirements of ISO13485:2016 are effectively implemented within the management system.

## Changes in the organization since last assessment

There is no significant change of the organization structure and key personnel involved in the audited management system.

No change in relation to the audited organization's activities, products or services covered by the scope of certification was identified.

There was no change to the reference or normative documents which is related to the scope of certification.

## NCR summary graphs

There have been no NCRs raised.

## Your next steps

### NCR close out process

There were no outstanding nonconformities to review from previous assessments.
No new nonconformities were identified during the assessment. Enhanced detail relating to the overall assessment findings is contained within subsequent sections of the report.

Please refer to Assessment Conclusion and Recommendation section for the required submission and the defined timeline.

# Assessment objective, scope and criteria

Assessment Scope
The management system processes at the address defined in the 'assessed locations table' towards the rear of this report.

Assessment Objectives
SURVEILLANCE
To conduct a surveillance assessment to determine the continued effectiveness of implementation of the company's management system, in accordance with the company objectives, policies and procedures, the management standards and applicable regulatory requirements from relevant regulatory authorities & BSI Conditions of Contract. To ensure that all requirements are covered during the certification period and to determine whether a recommendation for continuing certification can be made.

ISO 13485:2016
To verify that all of the requirements of ISO13485:2016 are effectively implemented within the management system.

The scope of the assessment is the documented management system with relation to the requirements of ISO 13485:2016 and the defined assessment plan provided in terms of locations and areas of the system and organization to be assessed.

ISO 13485:2016
LifeScience Logistics, LLC. management system documentation

## Assessment Participants

| Name | Position | Opening Meeting | Closing Meeting | Interviewed(processes) |
|---|---|---|---|---|
| Paul Hayward | Director of Quality & Regulatory Affairs | X | X | X |
| Teri Johnson | Supervisor of Quality & Regulatory Affairs | X | X | X |
| Teurayi George | QA Specalist I | X | X | X |
| Nate Roberts | Director of Operations | X | X | |
| David Davis | Operations Manager | | X | |

## Assessment conclusion

BSI assessment team

| Name | Position |
|---|---|
| Myles Frohling | Team Leader |

Assessment conclusion and recommendation

Audit objectives are met.

**RECOMMENDED** - The audited organization can be recommended for certification / recertification / continued certification to the above listed standards and has been found in general compliance with the audit criteria as stated in the above-mentioned audit plan.

Use of certification documents, mark / logo or report

The use of the BSI certification documents and mark / logo is effectively controlled.

## Findings from this assessment

### Opening meeting: QMS System Review, QMS, Business, Product & Process Changes and Improvements
### Objectives and Targets Management Responsibility and Changes:4.1, 4.2, 5.1, 5.2, 5.3, 5.4, 5.5, 6.1, 8.1, 8.5.1

Opening Meeting, Manufacturer Information and Changes

The opening meeting was conducted with the presence of the Senior staff, Director of operations and Management Representative/Responsible Engineering Manager.

The assessment plan, objectives and scope of the assessment were confirmed.

The opening meeting and full assessment was performed in English.

Scope of Certification:
The registration certificates and scope of the registration were confirmed as follows:
Third Party Logistics for medical device companies, logistic provider performing relabeling, repackaging and distribution activities for medical device companies outside of manufacturing requirements.

Quality Manual Version: Quality Manual – Quality Manual – Rev. 019 – Eff. 24 Jun 2019

Exclusions and Non-Applications of Requirements in the QMS:
Exclusions:
7.3 Design and Development. This registration does not design or develop new products.

Non-Applications:
7.5.2 Cleanliness of Product and Contamination Control
7.5.3 Installation activities
7.5.5 Particular requirements for sterile medical devices (maintain records) 7.5.9.2 Particular requirements for implantable medical devices

Significant Changes:
There have not been any major or significant changes to the QMS, organizational structure, products or process since the last visit.

Adverse Incidents, Field Safety Corrective Actions and Recalls:
There have been no adverse incidents, recalls, or requirement for field safety corrective actions since the last report.

Corporate Identity of the Manufacturer:
Logistics Facilities: ATL - 4475 S. Fulton Pkwy Bldg. 5 Suite C, Atlanta GA 30349 (Approx. 255,000 sq. ft BWI – 8901 Snowden River Parkway Suite 150 Columbia, MD 21046 (Approx. 285,000 sq ft)

DFW – 2600 Regent Blvd, DFW Airport, TX 75261 (Approx. 405,000 sq ft) IND – 1105 Northfield Drive, Suite 400 Brownsburg, IN 46112 (Approx. 330,000 sq. ft)

Description of the manufacturer:
LifeScience Logistics offers supply chain solutions to customers that range from Big Pharma to small startups. The LSL's cGMP compliant facilities allow Pharmaceutical, medical device, plasma, and biotech clients to distribute frozen, refrigerated and controlled ambient temperature products to customers.

Critical Subcontractors:
LifeScience provides logistical services to government and medical device companies and does not manufacture/produce any medical devices, therefore there are no critical Subcontractors/Suppliers for the this site.

Senior Management of the Assessment Location(s).
[Confirm and record the name and title of the most senior individual]

Audit Duration Rationale:
Staffing and effective staffing numbers were reviewed against IAF MD9 annex D and MDP200 (CP0200). The effective number of staff was stated to be 106. 20% reduction is permissible due to this audit being of a distribution facility, no manufacturing is performed at this facility. Based on the number of effective staff and the recommended 20% reduction, the audit days are appropriate at 1.5 day surveillance and 3 days recertification.

Competency Code:
The competency code T71F is correct for the client and the competency code was covered over the certification cycle.

## Quality Manual, Top Management, Management Review, Quality Objectives, Quality Policy, Analysis of data:5.1, 5.6, 5.4, 8.4, 4.2

Quality Manual was reviewed. Quality Manual Quality Manual – Quality Manual – Rev. 019 – Eff. 24 Jun 2019
and The Director of Quality & Regulator Affairs, was interviewed about this document in the Suite 300 conference room. The non-applications are documented and still reference to the older standard for some of the clauses. The non-Applications are documented as 7.5.3 – Installation Activities, 7.5.4 – Servicing Activities and Requirements for Active Implantable Devices.

It is based on the ISO 13485:2016 standard clauses and captures all the requirements per the standard. There are four levels of document structure. The Organization Chart was reviewed.

Quality Policy was reviewed, and it is approved.

Quality Objectives are defined in the Quality Manual and confirmed that they are defined in the Quality Manual.

These Quality Objectives are measurable, and they have metrics defined.
Based upon the objective evidence reviewed the planned arrangements, implementation, delivery and monitoring for Quality Objectives were found to be effective to meet the needs of the business and compliant with the requirements of ISO 13485:2016.

Management review was assessed. Management review is controlled by SOP 1004 - Management Review – Rev. 007 – 19 Jan 2020. The Director of Quality & Regulatory Affairs and the Supervisor of Quality & Regulatory Affairs was interviewed in the Suite 300 QA conference room and demonstrated implementation of the process. A sample of Management review minutes was taken. The Director of Quality & Regulatory Affairs is the Management Representative. Management Review is performed once a year. Inputs and Outputs are all defined in the SOP. The Management review meeting completed on 12 Feb 2019 was reviewed and Meeting Agenda was reviewed. The meeting minutes and the overall summary was reviewed. The MR process adequately captures all the inputs per Clause 5.6.2 and the outputs per Clause 5.6.3.

Based upon the objective evidence reviewed the planned arrangements, implementation, delivery and monitoring for Management Review were found to be effective to meet the needs of the business and compliant with the requirements of ISO 13485:2016.

Analysis of Data was assessed. Analysis of Data is controlled by SOP 1005 – Statistical Techniques - Rev. 004 – 18 Oct 2019. The Director of Quality & Regulatory Affairs and the Supervisor of Quality & Regulatory Affairs was interviewed in the Suite 300 QA conference room and demonstrated implementation of the process.

Based upon the objective evidence reviewed the planned arrangements, implementation, delivery and monitoring for Analysis of Data process was found to be effective to meet the needs of the business and compliant with the requirements of ISO 13485:2016.

Documents and Records Reviewed:
Quality Manual – Quality Manual – Rev. 019 – Eff. 24 Jun 2019
SOP 1004 - Management Review – Rev. 007 – 19 Jan 2020
SOP 1005 – Statistical Techniques - Rev. 004 – 18 Oct 2019
Organization Chart – Last Refreshed 23 July 2019
Quality policy reviewed during Management Review (12 Feb 2019)
Quality objectives
Management Review Dated: 12 Feb 2019 for review of FY 2018
Prior Management review Feb 2018
Next Management Review scheduled for 11 Feb 2020
Attendance Record – Management Review

Personnel Interviewed:
Paul Hayward – Director of Quality & Regulatory Affairs
Teri Johnson – Supervisor of Quality & Regulatory Affairs

## Internal Audit:8.2.2, 4.2.4, 8.2.3, 8.2.4

Internal audit was assessed. Internal audit is controlled by SOP 1501 – Internal Audits – Rev. 008 – Eff. 10 Jan 2020
and an issued schedule which was approved and issued on SOP 1501.01 Rev. 04 – Internal Audit Schedule FY: 2020 (Created 07 Oct 2019). The Director of Quality & Regulatory Affairs and the Supervisor of Quality & Regulatory Affairs was interviewed in the Suite 300 QA Conference Room and implementation of the process was confirmed in a review of the sample that was taken. A sample of internal audit records was taken and no issues were noted in the sample reviewed.

Based upon the objective evidence reviewed the planned arrangements, implementation, delivery and monitoring for internal audit were found to be effective to meet the needs of the business and compliant with the requirements of ISO 13485:2016.

Documents and Records Reviewed:
SOP 1501 – Internal Audits – Rev. 008 – Eff. 10 Jan 2020
SOP 1501.01 Rev. 00 - Internal Audit Schedule FY: 2019 (Created 16 Nov 2018)
SOP 1501.01 Rev. 04 – Internal Audit Schedule FY: 2020 (Created 07 Oct 2019)
Internal Audit Plan
SOP 1501.13 – Internal Audit Quality Checklist – Rev. 004 – Eff. 07 Jan 2020
SOP 1501.08 – Internal Audit Checklist – DEA – Rev. 002 – Eff. 10 Jan 2020
SOP 1501.02 – Internal Audit Cover Page – Rev. 003 – Eff. 15 Dec 2016

Internal Audit Reports sampled: IA-INC-19 (13 May 2019 – 16 May 2019)
- Major – 2
- Minor – 16
- Observations – 0
- K. Ashley (LA), D. Cherry, S. Nash, V. Schmidt
- Report Date: 05 June 2019

Personnel Interviewed:
Paul Hayward – Director of Quality & Regulatory Affairs
Teri Johnson – Supervisor of Quality & Regulatory Affairs

## Feedback Processes, Complaints and Vigilance:7.2.3, 8.2.1

Feedback processes, including complaint handling and vigilance procedures were assessed. Complaints are controlled by SOP 4001 – Handling of Product Complaints – Rev. 007 – 01 Nov 2019. The Director of Quality & Regulatory Affairs and the Supervisor of Quality & Regulatory Affairs was interviewed in the Suite 300 QA Conference Room and demonstrated implementation of the process. A sample of complaints was taken, and no issues were noted in the sample reviewed.

Based upon the objective evidence reviewed the planned arrangements, implementation, delivery and monitoring for feedback processes, including complaint handling and vigilance procedures were found to be effective to meet the needs of the business and compliant with the requirements of ISO 13485:2016.

Documents and Records Reviewed:
SOP 4004 – Client/ Customer Feedback – Commercial – Rev. 004 – Eff. 28 Aug 2018
SOP 4001 – Handling of Product Complaints – Rev. 007 – 01 Nov 2019
SOP 1301 – Risk Management – Rev. 005 – Eff. 20 Feb 2019
Complaint Log (2019): Qty. Open: 1973, Closed: 1817
Complaint Log (2020): Qty. Open: 158, Closed: 10
Reportable(s) (Any injury or death) = N/A
Complaints examined:
- CCF-AA-2020-0155 – Opened 20 Jan 2020 – Shipping Instructions Not Followed – Status: Open
- CCF-AA-2020-0153 – Opened 8 Jan 2020 – Shortage of product – Status: Investigation in Progress
- CCF-AN-2019-1477 – Opened 18 Sept 2019 – External Damage to product – Status: QA Review
- CCF-AN-2020-0035 – Opened: 20 Dec 2019 – Wrong Product – Status: QA Review
- CCF-AA-2020-0157 – Opened: 8 Jan 2020 – Transportation Issue. Order has not moved – Status: Closed a duplicate of CCF-AA-2020-0153 Closed 21 Jan 2020

Personnel Interviewed:
Paul Hayward – Director of Quality & Regulatory Affairs
Teri Johnson – Supervisor of Quality & Regulatory Affairs

## Improvement: Corrective and Preventive Action:8.5.1, 8.5.2, 8.5.3

Corrective and preventive action processes were assessed. Corrective and preventive action is controlled by SOP 1350 – Deviation/ CAPA – Commercial – Rev. 003 – Eff. 25 Feb 2019. The Director of Quality & Regulatory Affairs and the Supervisor of Quality & Regulatory Affairs was interviewed in Suite 300 QA Conference Room and demonstrated implementation of the process. A sample of corrective and preventive actions was taken and all issues that were identified in the samples reviewed were addressed in an open CAPA and procedure change request that was circulating for approval.

Based upon the objective evidence reviewed the planned arrangements, implementation, delivery and monitoring for corrective and preventive action were found to be effective to meet the needs of the business and compliant with the requirements of ISO 13485:2016.

Documents and Records Reviewed:
SOP 4004 – Client/ Customer Feedback – Commercial – Rev. 004 – Eff. 28 Aug 2018
SOP 4001 – Handling of Product Complaints – Rev. 007 – 01 Nov 2019
SOP 1301 – Risk Management – Rev. 005 – Eff. 20 Feb 2019
SOP 1350 – Deviation/ CAPA – Commercial – Rev. 003 – Eff. 25 Feb 2019
SOP 1350.02 – Deviation Report e-log
SOP 1350.01 – Deviation Report

Complaint Log (2019): Qty. Open: 1973, Closed: 1817
Complaint Log (2020): Qty. Open: 158, Closed: 10
Reportable(s) (Any injury or death) = N/A
Complaints examined:
- CCF-AA-2020-0155 – Opened 20 Jan 2020 – Shipping Instructions Not Followed – Status: Open

- CCF-AA-2020-0153 – Opened 8 Jan 2020 – Shortage of product – Status: Investigation in Progress
- CCF-AN-2019-1477 – Opened 18 Sept 2019 – External Damage to product – Status: QA Review
- CCF-AN-2020-0035 – Opened: 20 Dec 2019 – Wrong Product – Status: QA Review
- CCF-AA-2020-0157 – Opened: 8 Jan 2020 – Transportation Issue. Order has not moved – Status: Closed a duplicate of CCF-AA-2020-0153 Closed 21 Jan 2020

NCs (Deviations)
DEV-INC-19-0008:
SOP 1350.01 – Deviation Report – Commercial – Rev. 004 – Eff. 27 Nov 2017
- Date 24 Feb 2019 – Deviation Type: 3 – Description: There was a temperature excursion in Zone 44 of System 1. – Status: Closed 4 Mar 2019
- DEV-INC-19-0008 Att. A – Detailed Temperature Report
- Att. B – Temp. Report
- Att. C – Explanation of the Preliminary Monthly Climate Data
- Att. D – Zone 44 Primary Probe Photos
- Email of information

DEV-INC-19-0017:
SOP 1350.01 – Deviation Report – Commercial – Rev. 004 – Eff. 27 Nov 2017
- Date 23 May 2019 – Deviation Type: 2 – Description: On 23 May 2019, BF QA communicated via telephone and follow-up email, that a packager received containers from the LSL that have Next Inspection Dates on the label that do not match dates in SAP – Status: Closed 29 Oct 2019
- SOP 1350.05 – Deviation/ CAPA Report Extension Request – Commercial – Rev. 001 – Dated: 26 June 2019 Approved
- SOP 1350.05 – Deviation/ CAPA Report Extension Request – Commercial – Rev. 001 – Dated: 23 July 2019 Approved
- Line Item spreadsheets

DEV-INC-19-0018:
SOP 1350.01 – Deviation Report – Commercial – Rev. 004 – Eff. 27 Nov 2017
- Dated: 24 May 2019 – Deviation Type: 1 & 2 – Description: Operations has a receiving error for items QD507Q and QD509B. These items received and put into the system in the BF Cage when they needed to bin in refrigerator storage 2-8C. – Status: Closed 26 June 2019
- Att. 1 – Spreadsheet of lots with locations
- Att. 2 – BF.001 – Receiving – Rev. 002 – Eff. 01 May 2019 (Training Record) – Date: 18 June 2019

DEV-INC-19-0028:
SOP 1350.01 – Deviation Report – Commercial – Rev. 004 – Eff. 27 Nov 2017
- Dated: 09 Oct 2019 – Deviation Type: 5 – Description: On 9 Oct 2019, AS Team member notified QA , facilities, and operations of a mechanical failure in cooler 20B causing the fans to distribute moisture into the chamber affecting 11 pallets of AS product. – Status: 7 Nov 2019
- Att. 1 – QA hold printout
- Att. 2 – Damaged Product Form – Rev. 002 – Eff. 28 Aug 2017 – Dated 9 Oct 2019
- Att. 3 – WI 100.04.008 – Request for Reactive Maintenance – ALL – Dated: 9 Oct 2019
- Att. 4 – Emails of explanation of incident
- Att. 5 – WI 100.04.037 – Reactive Maintenance Form – ALL – Dated: 28 Oct 2019

CAPA:

CAPA-INC-19-0001 – Opened 31 July 2019 – escalated from DEV-INC-19-0017

Personnel Interviewed:
Paul Hayward – Director of Quality & Regulatory Affairs
Teri Johnson – Supervisor of Quality & Regulatory Affairs

## Product Realization: Planning and Customer Related Processes:7.1, 7.2.1, 7.2.2, 4.2.4

Product realization processes were assessed including planning, risk assessment and customer related processes. Product Realization is controlled by:
SOP 2002 – Handling, Storage, Packaging & Distribution – Rev. 009 – Eff. 15 May 2018
WI 400.04 – Commercial Pick Pack and Ship – Rev. 012 – Eff. 26 Aug 2019. The Director of Quality & Regulatory Affairs and the Supervisor of Quality & Regulatory Affairs was interviewed in the Suite 300 QA Conference Room and demonstrated implementation of the process with no apparent issues. A sample of a customer related process was taken and there were no apparent issues noted with the process.

Based upon the objective evidence reviewed the planned arrangements, implementation, delivery and monitoring for product realization were found to be [ effective [NO NC]/generally effective [MINOR NC]/not effective [MAJOR NC]] to meet the needs of the business and compliant [NO NC/not fully compliant [MINOR NC]/ not compliant [MAJOR NC]] with the requirements of ISO 13485:2016 / MDD 93/42 EEC.

Documents and Records Reviewed:
WI 400.01 – Commercial Receiving – Rev. 012 – Eff. 24 Oct 2018
SOP 2002 – Handling, Storage, Packaging & Distribution – Rev. 009 – Eff. 15 May 2018
WI 400.04 – Commercial Pick Pack and Ship – Rev. 012 – Eff. 26 Aug 2019
BF.001 – Receiving – Rev. 004 – Eff. 21 Jan 2020
SOP 1301 – Risk Management – Rev. 005 – Eff. 20 Feb 2019

Client Code BQ (name redacted) SOP for Inbound Shipments, Storage, Packing, Outbound Shipping – Version 3.3 – Eff. 3 July 2019

Personnel Interviewed:
Paul Hayward – Director of Quality & Regulatory Affairs
Teri Johnson – Supervisor of Quality & Regulatory Affairs

## Purchasing and Supplier Management:7.4.1, 7.4.2, 7.4.3

Purchasing and supplier management was assessed. Purchasing is controlled by SOP 1007 – Purchasing Process and Controls – Rev. 000 – Eff. 16 Jan 2019 and supplier management is controlled by SOP 1031 – Vendor Qualification – Rev. 011 – Eff. 06 Nov 2019. The Director of Quality & Regulatory Affairs and the Supervisor of Quality & Regulatory Affairs was interviewed in the Suite 300 QA Conference Room and demonstrated implementation of the process. A sample of supplier agreements, purchase orders and supplier audits was taken and the only issue that was noted is that purchasing related to product is all completed at the corporate headquarters, not here. There were no issues noted in the samples that were reviewed.

Based upon the objective evidence reviewed the planned arrangements, implementation, delivery and monitoring for purchasing and supplier management were found to be effective to meet the needs of the business and compliant with the requirements of ISO 13485:2016.

Documents and Records Reviewed:
SOP 1007 – Purchasing Process and Controls – Rev. 000 – Eff. 16 Jan 2019
SOP 1031 – Vendor Qualification – Rev. 011 – Eff. 06 Nov 2019
SOP 1031.04 – Controlled Supplier List – All – Rev. 033 – Eff. 13 Jan 2020

Service Agreement
OPC Pest Control – Dated 4/2019 – 3/2020
Ryan Fire Protection, Inc. – 10 Dec 2019
Mold Diagnostics – No Agreement

Certificate of Liability Insurance
OPC Pest Control – Good through Jan 2021
Ryan Fire Protection, Inc. – 30 Dec 2020
Mold Diagnostics – Exp. 1 Jan 2021

Vendor Acknowledgement of Warehouse Policies Form
OPC Pest Control – 18 Sept 2019
Ryan Fire Protection, Inc. – 16 Jan 2020
Mold Diagnostics – No Form at this time

Controlled Vendor Qualification Questionnaire
OPC Pest Control – Established Vendor No Questionnaire
Ryan Fire Protection, Inc. – 23 Dec 2019
Mold Diagnostics – Established Vendor No Questionnaire

Vendor Evaluation
OPC Pest Control – 23 Sept 2019
Mold Diagnostics – 23 Sept 2019
Ryan Diagnostics – Does not have one because vendor is less than a year old

Personnel Interviewed:

Paul Hayward – Director of Quality & Regulatory Affairs
Teri Johnson – Supervisor of Quality & Regulatory Affairs

## Resources: Human Resources, Infrastructure and Work Environment:6.1, 6.2, 6.3, 6.4

Resource provision including human resources, infrastructure and work environment was assessed. Human resource management is controlled by SOP 1800 – Training and Qualification – Rev. 017 – Eff. 11 Dec 2019.
Maintenance of the work environment and infrastructure is controlled by SOP 204 – Business Continuity Plan – Rev. 005 – Eff. 08 July 2019. The Director of Quality & Regulatory Affairs and Supervisor of Quality & Regulatory Affairs was interviewed in Suite 300 QA Conference Room area and demonstrated implementation of the process and there were no issues noted in the samples taken and reviewed. A sample of training records to provide objective evidence of competency, awareness and training was taken and there were no noted issues with the sample that was reviewed. A sample of planned preventive maintenance records was taken and there were no issues noted with the sample that was taken and reviewed.
Based upon the objective evidence reviewed the planned arrangements, implementation, delivery and monitoring for resource provision including competency, awareness and training and management of infrastructure and work environment were found to be effective to meet the needs of the business and compliant with the requirements of ISO 13485:2016.

Documents and Records Reviewed:
SOP 1800 – Training and Qualification – Rev. 017 – Eff. 11 Dec 2019
Training Role Reports
Employee Training Form
SOP 1800.02 Procedure Training Form
SOP 1800.03 Non-Procedure Training Form
SOP 3001 – Emergency Response Plan – Rev. 008 – Eff. 09 Oct 2019
SOP 3002 – Pest Control – Rev. 007 – Eff. 16 Apr 2018
SOP 204 – Business Continuity Plan – Rev. 005 – Eff. 08 July 2019
WI 100.02 – Facility Sanitation – Rev. 009 – Eff. 20 Dec 2019
WI 100.02.03 – Master Cleaning Schedule-Commercial – Rev. 000 – Eff. 06 Dec 2018
SOP 2002 – Handling, Storage, Packaging & Distribution – Rev. 009 – 15 May 2018
WI 100.03 – Temperature Review – Rev. 012 – Eff. 23 Aug 2019
SOP 1001.08 – Annual cGMP Training – Rev. 003 – Eff. 23 Apr 2019

Training Role Report:
Teurayi George – QA Specialist I
Brook Austin – Warehouse Lead
John Graham – Warehouse Personnel

Training Records were reviewed in the MQ1 system for:
Teurayi George
Brook Austin
John Graham

Job Description:
Quality Assurance Specialist I
Warehouse Lead
Warehouse Personnel

WI 100.02.03 – Master Cleaning Schedule – Commercial – Rev. 000 – Eff. 06 Dec 2018
- Jan 2020
- Dec 2019
- Nov 2019

Pest Control Logs
- January – Being conducted today Pest control is on site
- December – 5 Dec 2019 – OPC-4
- November – 8 Nov 2019 – OPC-4
- October – 3 October 2019 – OPC-4

Personnel Interviewed:
Paul Hayward – Director of Quality & Regulatory Affairs
Teri Johnson – Supervisor of Quality & Regulatory Affairs
Teurayi George – QA Specialist I

## Control of Nonconforming Product:4.2.5, 8.3

Control of nonconforming product was assessed. Control of nonconforming product is controlled by SOP 1350 – Deviation/ CAPA – Commercial – Rev. 003 – Eff. 25 Feb 2019. The Director of Quality & Regulatory Affairs and Supervisor of Quality & Regulatory Affairs was interviewed in the Suite 300 QA Conference Room area and demonstrated implementation of the process. A sample of internal nonconforming product records was taken and there were no noted issues within the sample reviewed.
Based upon the objective evidence reviewed the planned arrangements, implementation, delivery and monitoring for control of nonconforming product were found to be effective to meet the needs of the business and compliant with the requirements of ISO 13485:2016.

Documents and Records Reviewed:
SOP 4004 – Client/ Customer Feedback – Commercial – Rev. 004 – Eff. 28 Aug 2018
SOP 4001 – Handling of Product Complaints – Rev. 007 – 01 Nov 2019
SOP 1301 – Risk Management – Rev. 005 – Eff. 20 Feb 2019
SOP 1350 – Deviation/ CAPA – Commercial – Rev. 003 – Eff. 25 Feb 2019
SOP 1350.02 – Deviation Report e-log
SOP 1350.01 – Deviation Report

NCs (Deviations)
DEV-INC-19-0008:
SOP 1350.01 – Deviation Report – Commercial – Rev. 004 – Eff. 27 Nov 2017
- Date 24 Feb 2019 – Deviation Type: 3 – Description: There was a temperature excursion in Zone 44 of

System 1. – Status: Closed 4 Mar 2019
- DEV-INC-19-0008 Att. A – Detailed Temperature Report
- Att. B – Temp. Report
- Att. C – Explanation of the Preliminary Monthly Climate Data
- Att. D – Zone 44 Primary Probe Photos
- Email of information

DEV-INC-19-0017:
SOP 1350.01 – Deviation Report – Commercial – Rev. 004 – Eff. 27 Nov 2017
- Date 23 May 2019 – Deviation Type: 2 – Description: On 23 May 2019, BF QA communicated via telephone and follow-up email, that a packager received containers from the LSL that have Next Inspection Dates on the label that do not match dates in SAP – Status: Closed 29 Oct 2019
- SOP 1350.05 – Deviation/ CAPA Report Extension Request – Commercial – Rev. 001 – Dated: 26 June 2019 Approved
- SOP 1350.05 – Deviation/ CAPA Report Extension Request – Commercial – Rev. 001 – Dated: 23 July 2019 Approved
- Line Item spreadsheets

DEV-INC-19-0018:
SOP 1350.01 – Deviation Report – Commercial – Rev. 004 – Eff. 27 Nov 2017
- Dated: 24 May 2019 – Deviation Type: 1 & 2 – Description: Operations has a receiving error for items QD507Q and QD509B. These items received and put into the system in the BF Cage when they needed to bin in refrigerator storage 2-8C. – Status: Closed 26 June 2019
- Att. 1 – Spreadsheet of lots with locations
- Att. 2 – BF.001 – Receiving – Rev. 002 – Eff. 01 May 2019 (Training Record) – Date: 18 June 2019

DEV-INC-19-0028:
SOP 1350.01 – Deviation Report – Commercial – Rev. 004 – Eff. 27 Nov 2017
- Dated: 09 Oct 2019 – Deviation Type: 5 – Description: On 9 Oct 2019, AS Team member notified QA , facilities, and operations of a mechanical failure in cooler 20B causing the fans to distribute moisture into the chamber affecting 11 pallets of AS product. – Status: 7 Nov 2019
- Att. 1 – QA hold printout
- Att. 2 – Damaged Product Form – Rev. 002 – Eff. 28 Aug 2017 – Dated 9 Oct 2019
- Att. 3 – WI 100.04.008 – Request for Reactive Maintenance – ALL – Dated: 9 Oct 2019
- Att. 4 – Emails of explanation of incident
- Att. 5 – WI 100.04.037 – Reactive Maintenance Form – ALL – Dated: 28 Oct 2019

Personnel Interviewed:
Paul Hayward – Director of Quality & Regulatory Affairs
Teri Johnson – Supervisor of Quality & Regulatory Affairs
Teurayi George – QA Specialist I

## Control of Documents and Records:4.2.3, 4.2.4, 4.2.5

Control of documents and records were assessed.
Control of Documents are controlled by SOP 1100 – Document Control – Rev. 012 – Eff. 09 Oct 2019. Control of records processes are controlled by SOP 1101 – Control of Records – Rev. 022 – Eff. 14 Oct 2019. The Director of Quality & Regulatory Affairs and Supervisor of Quality & Regulatory Affairs was interviewed in the Suite 300 QA Conference Room and demonstrated implementation of the process. Based upon the objective evidence reviewed the planned arrangements, implementation, delivery and monitoring for control of documents and records were found to be effective to meet the needs of the business and compliant with the requirements of ISO 13485:2016.

Documents and Records Reviewed:
Document Master List – In MQ1
SOP 1100 – Document Control – Rev. 012 – Eff. 09 Oct 2019
SOP 1101 – Control of Records – Rev. 022 – Eff. 14 Oct 2019
SOP 1002 – Change Control – Rev. 010 – Eff. 11 Apr 2019
WI 100.03 – Temperature Review – Rev. 012 – Eff. 23 Aug 2019 – CR# 0011411
SOP 2002 – Handling, Storage, Packaging & Distribution – Rev. 009 – Eff. 15 May 2018 – CR#001046
WI 100.02 – Facility Sanitation – Rev. 009 – Eff. 20 Dec 2019 – CR# 001423
SOP 3001 – Emergency Response Plan – Rev. 008 – Eff. 09 Oct 2019 – CR#001417
SOP 2004 – Business Continuity Plan – rev. 005 – Eff. 08 Jul 2019 – CR# 001377
Wi 100.19 – Emergency Response Plan – Rev. 006 – Eff. 30 July 2019 – CR# 001390
SOP 3002 – Pest Control – Rev. 007 – Eff. 16 April 2018 – CR#00970

Personnel Interviewed:
Paul Hayward – Director of Quality & Regulatory Affairs
Teri Johnson – Supervisor of Quality & Regulatory Affairs

# Next visit objectives, scope and criteria

Assessment Scope
The management system processes at the address defined in the 'assessed locations table' towards the rear of this report.

Assessment Objectives

SURVEILLANCE
To conduct a surveillance assessment to determine the continued effectiveness of implementation of the company's management system, in accordance with the company objectives, policies and procedures, the management standards and applicable regulatory requirements from relevant regulatory authorities & BSI Conditions of Contract. To ensure that all requirements are covered during the certification period and to determine whether a recommendation for continuing certification can be made.

ISO 13485:2016
To verify that all of the requirements of ISO13485:2016 are effectively implemented within the management system.

The scope of the assessment is the documented management system with relation to the requirements of ISO 13485:2016 and the defined assessment plan provided in terms of locations and areas of the system and organization to be assessed.

ISO 13485:2016
LifeScience Logistics, LLC. management system documentation
Please refer to BSI terms and conditions regarding cancellation of planned visits.

## Next Visit Plan

| Date | Auditor | Time | Area/Process | Clause |
|---|---|---|---|---|
| 01/19/2021 | | | Opening Meeting | |
| 01/19/2021 | | | Site Tour | |
| 01/19/2021 | Assessor 1 | | Certificate Scope, Quality Manual, Quality Policy and Quality Objectives and Analysis of Data | |
| 01/19/2021 | | | Leadership, Management Commitment, Management Responsibility, Management Review, and Analysis of Data | |
| 01/19/2021 | | | Feedback, Continual Improvement, Complaints, Adverse Event Reporting, Recalls, and Advisory Notices | |
| 01/19/2021 | | | Regulatory, Combined Checklist, Progress Toward Transition to ISO 13485:2016 | |
| 01/19/2021 | | | Internal Audits | |
| 01/19/2021 | | | Lunch | |
| 01/19/2021 | | | Corrective Actions and Preventive Actions | |
| 01/19/2021 | | | Preservation of Product, Receiving, Receiving Inspection, and Control of Nonconforming Product | |
| 01/19/2021 | | | Shipping, Distribution, Identification, Traceability, Inspection (including cold storage and ambient temperature), and Control of Nonconforming Product | |
| 01/20/2021 | | | Calibration, Preventive Maintenance, Control of Monitoring and Measuring Devices and Validation of Processes | |
| 01/20/2021 | | | Training and Competency, HR and Provision of Resources | |
| 01/20/2021 | | | Report Preparation | |
| 01/20/2021 | | | Closing Meeting | |

# Appendix: Your certification structure & ongoing assessment program

## Scope of Certification

**FM 646928 (ISO 13485:2016)**

Third Party Logistics for medical device companies, logistic provider performing relabeling, repackaging and distribution activities for medical device companies outside of manufacturing requirements.

Certificate Scheme:

Scheme manager:

## Assessed location(s)

The audit has been performed at Permanent Locations.

**Brownsburg / FM 646928 (ISO 13485:2016)**

| | |
|---|---|
| **Location reference** | 0047585260-000 |
| **Address** | LifeScience Logistics, LLC<br>1105 East Northfield Drive<br>Suite 300<br>Brownsburg<br>Indiana<br>46112<br>USA |
| **Visit type** | Special Audit |
| **Assessment reference** | 3158671 |
| **Assessment dates** | 02/25/2020 |
| **Audit Plan (Revision Date)** | 01/11/2020 |
| **Deviation from Audit Plan** | No |
| **Total number of Employees** | 106 |
| **Effective number of Employees** | 106 |
| **Scope of activities at the site** | Third Party Logistics for medical device companies, logistic provider performing relabeling, repackaging and distribution activities for medical device companies outside of manufacturing requirements. |
| **Assessment duration** | 0.5 Day(s) |

## Certification assessment program

**Certificate Number - FM 646928**
**Location reference - 0047585260-000**

| | | Audit1 | Audit2 | Audit3 |
|---|---|---|---|---|
| **Business area/Location** | **Date (mm/yy):** | 01/19 | 1/20 | 1/21 |
| | **Duration (days):** | 2.0 | 1.5 | 1.5 |
| Certificate Scope, Quality Manual, Quality Policy and Quality Objectives and Analysis of Data | | X | X | X |
| Leadership, Management Commitment, Management Responsibility, Management Review, and Analysis of Data | | X | X | X |
| Feedback, Continual Improvement, Complaints, Adverse Event Reporting, Recalls, and Advisory Notices | | X | X | X |
| Regulatory, Combined Checklist, Progress Toward Transition to ISO 13485:2016 | | X | X | X |
| Internal Audits | | X | | X |
| Corrective Actions and Preventive Actions | | X | X | X |
| Preservation of Product, Receiving, Receiving Inspection, and Control of Nonconforming Product | | X | | X |
| Purchasing, Supplier Qualification and Supplier Monitoring | | X | X | |
| Shipping, Distribution, Identification, Traceability, Inspection (including cold storage and ambient temperature), and Control of Nonconforming Product | | X | | X |
| Planning of Product Realization including Risk Management and Customer Related Processes | | X | X | |
| Calibration, Preventive Maintenance, Control of Monitoring and Measuring Devices and Validation of Processes | | X | | X |
| Work Environment including Pest Control, Infrastructure | | X | X | |
| Training and Competency, HR and Provision of Resources | | X | | X |
| Control of Documents and Control of Records | | X | X | |
| Stage 1 Assessment | | | | |
| Stage 2 Assessment | | | | |

| | | | |
|---|---|---|---|
| Interview with Top Management | X | | |
| Continuing Surveillance Assessment (CAV) | | | |
| Recertification Assessment | X | | |

## Definitions of findings:

Nonconformity:
Non-fulfilment of a requirement.

Major nonconformity:
Nonconformity that affects the capability of the management system to achieve the intended results. Nonconformities could be classified as major in the following circumstances:
- If there is a significant doubt that effective process control is in place, or that products or services will meet specified requirements;
- A number of minor nonconformities associated with the same requirement or issue could demonstrate a systemic failure and thus constitute a major nonconformity.

Minor nonconformity:
Nonconformity that does not affect the capability of the management system to achieve the intended results.

Opportunity for improvement:
It is a statement of fact made by an assessor during an assessment, and substantiated by objective evidence, referring to a weakness or potential deficiency in a management system which if not improved may lead to nonconformity in the future. We may provide generic information about industrial best practices but no specific solution shall be provided as a part of an opportunity for improvement.

Observation:
It is ONLY applicable for those schemes which prohibit the certification body to issue an opportunity for improvement.
It is a statement of fact made by the assessor referring to a weakness or potential deficiency in a management system which, if not improved, may lead to a nonconformity in the future.

## How to contact BSI

'Just for Customers' is the website that we are pleased to offer our clients following successful registration, designed to support you in maximizing the benefits of your BSI registration - please go to www.bsigroup.com/j4c to register. When registering for the first time you will need your client reference number and your certificate number

Should you wish to speak with BSI in relation to your certification, please contact your local BSI office – contact details available from the BSI website:
https://www.bsigroup.com/en-US/contact-us/

## Notes

*This report and related documents are prepared for and only for BSI's client and for no other purpose. As such, BSI does not accept or assume any responsibility (legal or otherwise) or accept any liability for or in connection with any other purpose for which the Report may be used, or to any other person to whom the Report is shown or in to whose hands it may come, and no other persons shall be entitled to rely on the Report. If you wish to distribute copies of this report external to your organization, then all pages must be included.*

*BSI, its staff and agents shall keep confidential all information relating to your organization and shall not disclose any such information to any third party, except that in the public domain or required by law or relevant accreditation bodies. BSI staff, agents and accreditation bodies have signed individual confidentiality undertakings and will only receive confidential information on a 'need to know' basis.*

*This audit was conducted on-site through document reviews, interviews and observation of activities. The audit method used was based on sampling the organization's activities and it was aimed to evaluate the fulfilment of the audited requirements of the relevant management system standard or other normative document and confirm the conformity and effectiveness of the management system and its continued relevance and applicability for the scope of certification.*

*As this audit was based on a sample of the organization's activities, the findings reported do not imply to include all issues within the system.*

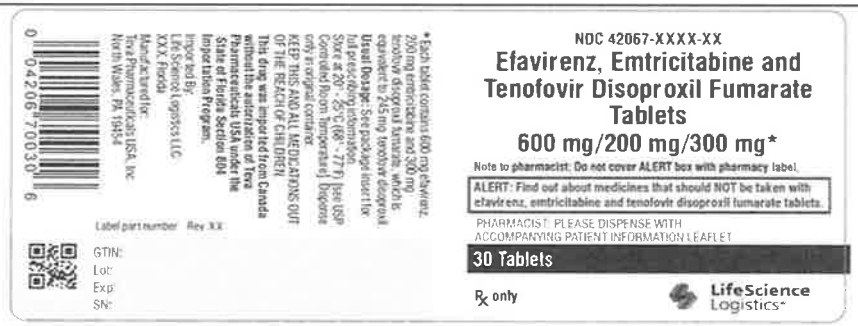
## Regulatory compliance

*BSI conditions of contract for this visit require that BSI be informed of all relevant regulatory non-compliance or incidents that require notification to any regulatory authority. Acceptance of this report by the client signifies that all such issues have been disclosed as part of the assessment process and agreement that any such non-compliance or incidents occurring after this visit will be notified to the BSI client manager as soon as practical after the event.*

# Attachment D

**Sample Label for Imported Prescription Drugs**

## Efavirenz, Emtricitabine and Tenofovir Disoproxil Fumarate Tablets (ANDA 091215) Product Label Comparison Table

| | | |
|---|---|---|
| **ANDA 091215 Approved Bottle Label** |  | **Label Comparisons:**<br>-Canadian label contains both English and French languages<br>-Canadian label specifies dosing regimen on the label<br>-Canadian label specifies storage conditions of 15-30°C vs standard controlled room temperature.<br>-Canadian label and US label specify same APIs and concentration statements per tablet.<br>-Proposed label contains all current approved ANDA labeling statements and storage conditions.<br>-Proposed label has all required additional requirements as specified in Part 251.13 of Section 804 Importation Program. |
| **Proposed Bottle label for Imported Drug Product** |  | |
| **Canadian Product Label DIN 02393549** |  | |

**Efavirenz, Emtricitabine and Tenofovir Disoproxil Fumarate Tablets (ANDA 091215) Product Comparison Table**

| | **US Product ANDA 091215 (NDC 0093-5234-56)** | **Equivalent Canadian Import (DIN 02393549)** |
|---|---|---|
| **Product Name** | Efavirenz, Emtricitabine and Tenofovir Disoproxil Fumarate Tablets | TEVA-Efavirenz, Emtricitabine and Tenofovir Disoproxil Fumarate Tablets |
| **Route of Administration** | Oral | Oral |
| **Active Ingredients** | **Each tablet contains:**<br>600 mg of efavirenz<br>200 mg of emtricitabine<br>300 mg of tenofovir disoproxil fumarate, which is equivalent to 245 mg of tenofovir disoproxil<br><br>**API Manufacturer:**<br>Unknown currently | **Each tablet contains:**<br>600 mg of efavirenz<br>200 mg of emtricitabine<br>300 mg of tenofovir disoproxil fumarate, which is equivalent to 245 mg of tenofovir disoproxil<br><br>**API Manufacturer:**<br>Unknown currently |
| **Inactive Ingredients** | **Each tablet contains:**<br>carmic acid, silicon dioxide, crospovidone, hydroxypropyl cellulose, ferric oxide red, ferric oxide yellow, lactose monohydrate, magnesium stearate, mannitol, microcrystalline cellulose, poloxamer 407, polyethylene glycol 3350, polyvinyl alcohol, povidone K30, sodium starch glycolate type a potato, talc, and titanium dioxide | **Each tablet contains:**<br>carmine, colloid silicon dioxide, crospovidone, hydroxypropyl cellulose, iron oxide red, iron oxide yellow, lactose monohydrate, magnesium stearate, mannitol, microcrystalline cellulose, poloxamer, polyethylene glycol, polyvinyl alcohol, povidone, sodium starch glycolate, talc, and titanium dioxide |
| **Manufacturer / Labeler** | **Manufactured in Croatia By:**<br>Pliva Hrvatska d.o.o.<br>Prilaz Baruna Filipovica 25, Zagreb, Croatia<br>FEI# 3002807904<br><br>**Manufactured For:**<br>Teva Pharmaceuticals USA, INC<br>North Wales, PA 19454 | **Manufacturer:**<br>TEVA Canada Limited<br>5691 Main St, Stouffville, Ontario<br>FEI# 3002807750<br>DEL# 101810 |

| | | |
|---|---|---|
| **Tablet Characteristics** | Color – Pink<br>Shape - Oval<br>Imprint Code – TV;C72 | Color – Pink<br>Shape - Capsule<br>Imprint Code – TV;5234 |
| **Storage Conditions** | Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Keep container tightly closed. Dispense only in original container. | Store at 15°C–30° C (59°F–86° F). Keep container tightly closed. Dispense only in original container.<br><br>**Difference: Storage conditions have wider specification within the allowable excursion limits of USP controlled room temperature, however, proposed drug label will require 20-25°C.** |

**61N-1.011 Wholesale Distribution of Prescription Drugs – Exceptions and Specific Distributions Authorized.**

(1) The exemption from the definition of wholesale distribution in Section 499.003(48)(b)2., F.S., for "emergency medical reasons" includes:

(a) Transfers of a prescription drug between health care entities or from a health care entity to a retail pharmacy to alleviate a temporary shortage of a prescription drug arising from delays in or interruption of regular distribution schedules, and should not occur between the parties so as to amount to the health care entity regularly and systematically supplying that drug;

(b) Transfers of prescription drugs by a health care entity to an emergency transport vehicle which is under the direction of a medical director of an emergency medical service provider licensed under Chapter 401, F.S., for use in the treatment of persons transported to that health care entity to immediately restock a licensed vehicle or an emergency medical kit for prescription drugs used on that person or to immediately restock prescription drugs on the vehicle which have become unsuitable for use. This exception does not extend to the stocking of supply inventory or for warehousing of prescription drugs used by emergency medical service providers;

(c) Emergency transfers of prescription drugs as authorized in Rule 59A-4.112, F.A.C., for nursing homes or Rule 64B16-28.6021, F.A.C., of the Florida Board of Pharmacy; or

(d) Transfers of prescription drugs by a retail pharmacy to another retail pharmacy or to a health care entity to alleviate a temporary shortage, but not for the regular and systematic supplying of that prescription drug;

(e) Transfers of prescription drugs in an emergency declared pursuant to Section 252.36, F.S., until the state of emergency is lifted, under the following conditions:

1. The manufacturer, wholesaler, or other person supplying the prescription drugs is authorized by Florida law to distribute prescription drugs in or into Florida; and either:

a. The prescription drugs are delivered to a temporary emergency medical station, officially designated by the state emergency operation center as a Disaster Medical Assistance Team or State Medical Response Team site; or

b. The prescription drugs are delivered to a Pharmacy licensed under Chapter 465, F.S.;

2. The prescription drugs are transferred by a prescription drug wholesale distributor located outside of this state and not permitted by the Department on behalf of a prescription drug wholesale distributor located in the State of Florida for the purposes of supplying prescription drugs to authorized customers located in Florida, if the out-of-state prescription drug wholesale distributor meets the following conditions:

a. The out-of-state prescription drug wholesale distributor holds a current and active license as a wholesale distributor in its resident state, or is currently licensed as a prescription drug wholesale distributor pursuant to the federal act; and

b. The Florida prescription drug wholesale distributor holds a current and active prescription drug wholesale distributor permit with the Department; and

c. Both the in-state and out-of-state prescription drug wholesale distributors are under common ownership. For the purposes of this subsection, "common ownership" means that one prescription drug wholesale distributor owns the other prescription drug wholesale distributor or both prescription drug wholesale distributors share a common owner or ultimate parent company that has the authority to control the management and operations of both entities; and

d. The permitted Florida prescription drug wholesale distributor shall be responsible for ensuring the activities of the out-of-state prescription drug wholesale distributor conducted in Florida on its behalf during the state of emergency are in compliance with applicable Florida and federal requirements; and

e. The distributions of prescription drugs pursuant to this section shall terminate no more than thirty (30) days after the expiration of the state of emergency.

(f) Transfers of prescription drugs from a health care entity to a pharmacy or other end-user practitioner for a named patient to treat or prevent a serious medical condition when a shortage of the product is documented by the manufacturer;
but does not include regular and systematic sales of prescription drugs to licensed practitioners that will be used for routine office procedures.

(g) Transfers of prescription drugs by or on behalf of the Department of Health to the medical director of an advanced life support service provider, licensed under Chapter 401, Part III, F.S., and for further distribution to an emergency transport vehicle operated by the advanced life support services provider, for use in the treatment of persons in need of emergency medical services;

(h) Transfers of prescription drugs by or on behalf of the Department of Health to a health care entity authorized to purchase prescription drugs, for storage and use in the treatment of persons in need of emergency medical services, including controlling

communicable diseases or providing protection from unsafe conditions that pose an imminent threat to public health;

(i) Transfers of prescription drugs by or on behalf of the Department of Health to the licensed medical director of a government agency health care entity, authorized to purchase prescription drugs, for storage and use in the treatment of persons in need of emergency medical services, including controlling communicable diseases or providing protection from unsafe conditions that pose an imminent threat to public health.

(j) Transfers of prescription drugs by or on behalf of the Department of Health to a community pharmacy authorized to purchase prescription drugs, for dispensing to persons in need of emergency medical services, including controlling communicable diseases or providing protection from unsafe conditions that pose an imminent threat to public health.

(2) The revocation of a sale or the return of a prescription drug purchased by a hospital or other health care entity, or acquired at a reduced price by or donated to a charitable institution to the manufacturer or the wholesale distributor that sold, donated, or supplied the prescription drug, is not a wholesale distribution prohibited by Section 499.005(21), F.S., provided:

(a) The hospital, health care entity or charitable institution forwards a copy of the documentation for the return to the manufacturer of the product. This documentation must at a minimum comply with the requirements of Rule 61N-1.012, F.A.C.; and

(b) The value of any credit, refund, or exchange for the returned product does not exceed the purchase price or, if a donation, the fair market price of the returned product.

(c) Prescription drugs returned or to be returned to a manufacturer or wholesale distributor must be kept under proper conditions for storage, handling, and shipping as set forth in Section 499.0121, F.S.; and written documentation showing that these conditions were or were not maintained must be provided to the manufacturer or wholesale distributor to which the prescription drugs are returned.

(3) A person authorized to possess non-dispensed prescription drugs can donate prescription drugs that are not misbranded or adulterated to a charitable organization that has been granted an exemption under s. 501(c)(3) of the Internal Revenue Code of 1986, as amended, and that is authorized to possess prescription drugs provided the transfer is not for sale or trade and the donor receives no financial benefit (except for tax benefits related to charitable contributions) either directly or indirectly. Records to document the transfer must comply with Section 499.0121(6), F.S., and paragraph 61N-1.008(2)(c), F.A.C.

(4) A person who uses prescription drugs for lawful research, teaching, or testing may obtain a registration number from the department to authorize acquisition of the requisite prescription drugs for this activity. The person must submit correspondence to the department explaining the conditions of the lawful research, teaching, or testing, along with a statement signed by the individual who will be responsible for the prescription drugs that the drugs will be secured, access will be restricted to authorized individuals, and that the prescription drugs are not for resale. If applicable, this correspondence should also identify the name in which purchases will be made, the specific prescription drug(s) required for the activity, the quantity which will ordinarily be purchased, the frequency of the purchases, and the name and state permit or license or permit number of suppliers of the prescription drugs. A letter and registration number will be assigned to the person which authorizes the purchase or other acquisition and possession of prescription drugs. This registration number must be included on invoices as required by Section 499.0121(6)(a), F.S.

*Rulemaking Authority 499.003(48)(b), 499.012, 499.03, 499.05 FS. Law Implemented 499.003(48)(b), 499.012, 499.03, 499.05 FS. History–New 7-1-96, Formerly 10D-45.0525, Amended 1-26-99, 4-17-01, 1-1-04, 10-4-07, 12-13-09, 6-8-10, Formerly 64F-12.011, Amended 11-24-19.*