STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND
PROFESSIONAL REGULATION
DIVISION OF DRUGS, DEVICES, AND COSMETICS

IN RE: GENERAL BUSINESS

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DBPR
WORKSHOP

The above-entitled panel convened via conference call on the 1st of December 2016, commencing at 9:30 a.m., EST.

Reported by:

JESSICA RENCHEN
Court Reporter

ORIGINAL

FOR THE RECORD REPORTING TALLAHASSEE FLORIDA 850.222.5491
Council Members:

STEVE MAYS, CHAIR
JEENU PHILLIPS, VICE CHAIR
SCOTT BROCK
DEAN ELLIS
BRIAN FILES
MICHAEL MONE
PATRICK BARNES
PETER HART
JEFFREY TULLER

DBPR Staff:

REGGIE DIXON, DIVISION DIRECTOR
RENEE ALSOBROOK
DINAH GREENE
MR. MAYS: Good morning, everyone. My name is Steve Mays. I'd like to call this meeting of the Drug Wholesale Distributor Advisory Council to order.

First thing I want to do is remind everyone that we have a court reporter on the line, so please identify yourself before you speak so the court reporter will know who's speaking for the record. For anyone that -- for everyone that's on the call, please put yourself on mute when you're not speaking. We're already kind of getting some background noise, and please do not put us on hold so we don't have to listen to your hold music.

So Ms. Green, do you want to do a roll call?

MS. GREENE: Sure will. Steve Mays?

MR. MAYS: Here.

MS. GREENE: Jeenu Phillips?

MR. PHILLIPS: Here.

MS. GREENE: Brian Files?

MR. FILES: Here.

MS. GREENE: Michael Mone?

MR. MONE: Here.

MS. GREENE: Scott Brock.

MR. BROCK: Here.
MS. GREENE: Arlene Elliott? Dean Ellis?
MR. ELLIS: Here.
MS. GREENE: Jeff Tuller?
MR. TULLER: Here.
MS. GREENE: Patrick Barnes?
MR. BARNES: Here.
MS. GREENE: And Peter Hart?
MR. HART: Here.
MS. GREENE: You have a quorum, Mr. Chair.
MR. MAYS: Okay. A few things I'd like to cover before we start -- before we get to the agenda. This is my first meeting as your chair, so I want to start out on the right foot by thanking the council for entrusting me to serve as your chair. And I also want to thank the Department and the Division for working with industry to make Florida a leader in keeping the pharmaceutical supply chain safe.

While they are diligent in their enforcement of Florida prescription drugs statutes and rules, they're always fair when dealing with regulated industry. And I know Mr. Dixon and his staff, I know from personal experience, they've always been great about sitting down with companies to work out any common concerns or issues when it comes to

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achieving the goal of protecting the public health.

As a national distributor I can tell you guys that sometimes it's almost impossible to get some state regulators to even answer the phone, much less sit down with you to discuss your issues or concerns. So again, I want to just thank the Division for being so business friendly and also diligent in their enforcement of the regulations.

I also want to thank Ms. Green for all the work she does behind the scenes to put these meetings together and herd the cat, so to speak. And then I want to also welcome again our new members: Mr. Files, Mr. Mone and Mr. Tuller. We look forward to your contribution to the council.

Finally, as been the practice in past meetings, I won't start the meeting, I'll start reading the goals of the council as stated in Chapter 499 of the Florida Statute.

So 499.01211, Drug Wholesale Distributor Advisory Council. "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 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."

So now on to the agenda. Under Tab 1 you'll see two topics listed in the chair's report. First topic is the Drugs, Devices, Cosmetics Inspection Process. I've asked the Division if they would kindly provide the council an overview of the inspection process. Not really sure who is going to cover that. Is Ms. Alsobrook going to do that, Reggie?

MR. DIXON: Ms. Alsobrook and I, we are both here. I was going to start off giving some general information, and if you all have some questions after that, I think that might be a better way to address it.

MR. MAYS: Okay.

MR. DIXON: And that way anything that we can touch, we'll touch. If something's left out, we can always follow up on it if that's okay?
MR. MAYS: Sounds good.

MR. DIXON: Okay. Good morning. This is Reginald Dixon. I'm the director for the Division of Drugs, Devices, and Cosmetics. We were kind of asked to give a little bit of insight into our inspection process, just some general information. So what we tried to do is put together some information for you all, just some public information to kind of tell you the different types of inspections and stuff that we do.

I want to back up a little bit to give you a little bit of background. You know, for those of you that have been on the council for a while and for those folks out there listening, we have scarce resources in our division. You know, I was looking at something from the grand jury report way back in 2003 and realized that since that time we've only increased our inspection staff by maybe one -- I believe one or two inspectors at the most. So, you know, as we sit here today in 2016 we've got nine drug inspectors and 1.5 medical gas inspectors, and we've gotten OPS positions to -- for medical gas. With the thought being that we get medical gas, OPS positions, that can free up some of our drug inspectors and we can kind of
recover some of that time back.

But with that background, you know, it's interesting that -- you should note that given the number of licensees that we have, we have to be, as a division, as an agency, very creative with our resources. And so to that effect, what we have recently done -- we've been working on it for a while and I know we've been talking about it -- we've been working on what's called a risk-based inspection program or scheduling. And basically the idea is to go out and do inspections of those entities that we think, based on the activity that they have, based on what they're doing, if there was a problem that that potential activity would pose the biggest threat to the public.

And so that's how we're trying to arrange our inspections and trying to dedicate those resources that way. So some folks may see us, you know, every three to four years and some folks may see us every six to ten years. It just depends. And so what that does is it allows us to kind of direct our resources a little bit more where they need to be at, as well as allow us to implement other alternative form. Say, for instance, the self-inspection survey that we implemented with
our health care clinic establishment (inaudible),
that's a way for them to have an inspection that
is as least intrusive as possible allowing us to
get information that can help us determine, you
know, if there's some follow-up that needs to be
done but also allowing that entity to do some
self-reflection and to follow up on any issues
that may have been brought to their attention.

For instance, we found that there's some
health care clinic establishments that don't
distinguish -- that did not understand or fully
understand or comprehend that prescription drugs
are also medications. You know, we did get the
response from a lot of folks that they don't order
prescription drugs, they order medication. And so
we were able to and have been continually able to
provide education to those folks to help them
understand -- to better understand Florida law and
to some other extent some of the federal law.

So, you know, as we're looking at our
resources and those kind of things that's how we
kind of allocate our resources that way in a way
that we think is the best or most efficient, and
we're looking at that every day. There's not a
day that goes by where Renee or the field manager
and myself where we kind of sit down and try to 
think of a better way to do something. So when 
this came up, we saw this as an opportunity to 
kind of provide some general information about the 
different types of inspections that we do and the 
inspection authority that we have.

As you all know, just for -- you know --
for -- for our inspections, we have broad
inspection authority. Basically we have a right
to go onto at any reasonable time and conduct an
inspection of a facility that's in Florida that
manufactures houses or distributes in sales,
prescription drugs. We generally kind of qualify
those into three types: The first type is what we
consider a routine compliance inspection. Those
are the ones that are really, really more
risk-based driven and we go out to do those
inspections just to try to make sure that we're
getting people in compliance. It's not as if we
received a complaint or anything. Those are the
ones that we do on a daily basis outside of having
received a complaint. Of course, we have the
general authority to go in, inspect, seize, all
the other types of things that you see, but the
basis of the routine compliance one is, that's our
everyday, let's go out, let's do an inspection, let's get people into compliance.

The second type of inspection that we have our those that are complaint based or inspections that are more of a -- they're driven by something that came externally. Let's say someone filed a complaint or maybe a complaint was file or a referral was given to us saying, hey, look, we've had this issue, maybe (inaudible) referred it, maybe criminal authorities referred it. Even in those situations, we go out, we would do an inspection, but we also conduct, what we consider, an investigation, as well, to determine compliance and also to address the specific issues that were brought up.

So let's say, for instance, we get a complaint that there's a belief that someone is purchasing from an unauthorized source. We would do our research -- of course we do our research before we go out anyway, but one of the primary reasons -- one of the primary issues that we will be looking at when we go out there is sources, because we have a complaint that says that these folks have unauthorized sources. So that's kind of the difference between the compliance one
versus the complaint instigated type of investigation, because that's the way we're looking at it.

And the third one, the one that we seem to do -- hopefully we'll do a lot more of these, are the new or change of location, change of owner type inspections because a lot of those -- you know, those are the ones that we really, really kind of measure to make sure that we're doing those as quickly as we can, because in our eyes those are the ones that directly lead to people being in business or getting back in business in Florida.

And so those are generally the three types that we split them out into -- our inspections into. From a perspective of how we go out and do the inspections, they're usually pretty much the same. One of the things that our secretary did when he first came here was to try to, you know, strip away some of the significant formalities that were in other areas of the Department in a sense that we want folks to realize that you have an obligation -- or I mean a right to have a fair inspection, you have a right to speak to the supervisor of the person doing the inspection, you have a -- and so what they means -- and so out of
that -- you know, out of our mission, which is to, you know, treat people fairly, you know, inspect people fairly, regulate fairly, what we try to do is have our inspectors -- and this is across the agency, not just at DDC -- you know, when they arrive at the inspection to provide their credentials, to provide what we have, what's called an inspection bill of rights, which notifies folks, hey, look, you know, this is the inspector. You're entitled to have a good inspector, you're entitled to have people treat you with respect, and if you have questions about it you can speak to the inspector or you can call their supervisor if you don't think the inspection was done appropriately or there's an issue with it.

Our folks will normally go in, try get some basic information about the facility. I mean, of course, we've done our homework, so we've pulled the application file if it's application related. If it's complaint related we still pull (inaudible) disciplinary history to see if they've had a prior history -- you know, I mean the basic due diligence that you would expect us to do before we walk out to your facility. You know, it
would be a waste of time, probably, if we just walked out there cold.

So our folks will generally try to get as much background on the company as they can before they go out there so that when they go out there they may know the people that they need to talk to, if there's been a change of ownership you may need to know who you need to speak to when you go out there. So they'll review the application if it's application driven to make sure that they can address their questions to the appropriate people when they get there.

And, you know, you got all different sizes of facilities, so some smaller facilities may have one person that's Johnny on the spot that's responsible for everything. Some facilities are large enough that you may have a person that's your point person who's going to end up having to go gather a team of people, maybe somebody will help them to a facility, maybe someone else to help them grab records, somebody else to answer questions. I mean, you know, we see the whole gamut of it really.

And so part of the things that our folks want to do when they get out there is identify
themselves and generally pretty quickly, hopefully, identify the person at the facility who's in the best position to help them with the inspection -- help them conduct their inspection. So sometimes that is going to be dependent solely upon the size of the facility. If we go into a place that's got three employees, I'm sure it's one of those three employees there who's going to be the person that we're going to be dealing with.

If you go into a place that's got 50, 90 or 100 employees, I'm pretty sure we're going to have more than one person. There's going to be a person there who is responsible for the facility, usually the manager, depending on what type of facility it is. If it's a wholesale distributor it might be the CVR, but it may just be the plant manager, a person there who can -- we can identify them, you know, give them their information, you know, we're here to conduct the inspection, here's our authority to do the inspection.

And during the course of the inspection, I guess, people should know that we're going to look at the facility, but we also, as part of that, you know, make sure that you're getting the appropriate sources, that you got the according
documentation for the distributions or receipts of prescription drugs. It's the kind of things that you normally expect -- that you would normally expect to see.

One of the things that we have been working with our folks is trying to establish time frames for turnaround on information. You know, one of the things that we've been thinking about is -- as you guys are aware, our rules have some very specific time frames, the federal law has some very specific time frames for getting information and results in response to inspections and request for information. Internally we've been thinking about how we go about approaching that and what kind of documentation that we ask for.

One of the things that we try to avoid is asking for too much information. We need to ask for enough information that we understand the -- how the facilities are operating. You know, sometimes that can be difficult in a sense -- I mean, you know, the larger the facility sometimes the more difficult it is simply because we're trying not to ask for too much records -- too many records, but if you ask for a certain number of distributions on a day or a certain percentage or,
you know, just say, hey, can I see your list of distributions for a particular day, (inaudible) pharmaceuticals, I may only have three. You know, if I'm, you know, a large distributor, A, B and C, it may be a jillion of them. And so sometimes, you know, our request may seem a little bit extraordinary but it's because we're trying to judge how many records, what types of records to ask for.

But the bottom line is when our folks get there, what people can expect to see during the course of inspection is folks who show up usually early in the morning, introduce themselves, present their bill of rights, let folks know that they're due to do an inspection, pretty quickly try to identify the person that's responsible for the facility who can best help us conduct the inspection. Those folks will probably -- based on our interactions with them, it will probably be -- give us more idea of who else we may need to speak with.

Like I said, if you're a large facility, you may have multiple folks that you pull in and out to kind of meet with us. 1 person may be responsible for helping us grab the records, when
the other person may be responsible for helping tour the facility in different areas to try to determine compliance.

Generally speaking, at the end of the inspection, you'll have an inspection report that kind of summarizes what is going on. A lot of times our inspectors will actually type -- they will type the inspection report there and give the inspection report to the person there. Some issues that come up sometimes, and we'll just try to figure out the logistics of it is, there may be pending information requests.

For instance, if we go there, we're checking sources or something and we see a document that we may want some more information or you see a document that (inaudible) us to request additional information, instead of sitting at the facility for two days or whatever asking for that information, we may just say, hey, look, please get this to us by whatever date, and we try to set that date far enough out that we understand that, hey, look, if we ask for it in a week it ought to be something you can clearly get because the statute requires, you know, 48 hours or 24 hours immediately retrievable or immediately available.
and retrievable depending on where the facility is at and where the records are being kept, those kinds of things.

And so sometimes -- and we do give extensions just because we realize sometimes you don't want people scurrying and grabbing the wrong information. But on some respect, you also -- we want to make sure that we don't give people a billion hours so they go out and possibly make up records that they wouldn't necessarily have. So, you know, it's trying to find a balance between the two. Obviously some folks have records -- some peoples' record keeping is a whole lot better than others, and some folks are still learning on how to maintain records and how to keep track of it. And for those of you that go across different states, we realize that, you know, some states require (inaudible). That's the whole point of the DQSA, hopefully, was to kind of standardized some of the records that you're keeping with respect to certain products.

1 of the things that I know was an inquiry that we had was what's the possibility -- or would we at least consider possibly having our inspectors kind of sit down with folks and go over
the inspections, findings and results of some as
they leave. And I know we're looking into that.

One of the issues that really -- we're
concerned about on that is sometimes it's a
resource issue. Sometimes they haven't really
fully formulated all of the findings. You know,
we can -- if we have -- we got pending records
requests and those kind of things, then it's
difficult to kind of sit down and go through
everything. But that is something that we're
looking at just because we know that sometimes
that can be a useful tool for the facilities that
are under inspection, that have received an
inspection. A lot of times we do do
semi-consulting with people to try to bring them
into compliance, so hopefully you all in the
industry will see that. Hopefully that's been a
positive -- I think that's been a positive aspect
the way we do business here.

But as I indicated -- I know Mr. Mays and I
we've had a couple of conversations about it.
That's a general overview of what we do. We're
open to answer any questions that you guys might
have. I can't promise that we'll be able to
answer all of them, but we'll do our best to
answer any questions that anyone may have.

Suggestions that you might have, we always welcome suggestions. By no means do we think that we are the end of all of the knowledge on how to conduct inspections and that kind of thing. If you all have suggestions, we're always willing to consider those, and we'll follow up with you on whether or not we accept those suggestions.

So I guess -- I guess this would be -- this might be a good checkup point to kind of break this to see if anyone on the line or any council members might have any specific questions that they'd like for us to try to answer.

MR. MAYS: Reggie, this is Steve -- Mr. Mays. I'd like to -- you know, first of all I think the -- the risk-based approach to your audit frequency I think is a good thing. You know, that's a positive comment, because you kind of answered 1 of my questions because I was going to ask what the typical cycle is for the routine compliance inspections, and I think the -- you know, the presenting -- and I know with our distribution center in Florida that the inspector presented the firm's bill of rights document, which I think is very positive touch.

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And I'll get to my last comment and I'll see if anybody else has any questions. I know that, you know, we have a lot of inspections in a lot of different states and we have DEA inspections and things like that, and sometimes we have inspectors that come to our sites and they do an inspection and sometimes we never know when they're finished or not and they just leave and then, you know, the next thing we know a few months later we're getting a notice of violation and there may have been things that, you know, we could have mitigated if they had sat down with us and said, you know, here's what our observations are and we think this might be a violation and, you know, that's something -- because I know in most cases if we -- you know, if we've got a problem it's usually not anything -- it's almost always not intentional and it's something we want to correct right away.

And again, I applaud the Department for the process and how they do that. And that would be my only recommendation is if there's any way to find the time to do that, to sit down with the firm and do an exit meeting, you know, at the end of the inspection and go over any violations or
observations the inspector might see, I think that's always a plus for the firm.

Are there any questions from other council members?

MR. ELLIS: This is Dean Ellis. Reggie, earlier in our previous meetings you had mentioned that the inspector might have the authority to issue administrative notice or something of that sort. Is that still part of this plan?

MR. DIXON: I think what you're referring to was a possible citation. 1 of the things that -- that was part of our legislative package last year that did not get approved. I think there were some folks who may be a little bit concerned about the opposite side of being able to do a citation, i.e., the possibility that the authority might be (inaudible). And that's a valid concern. I don't necessarily think that that's something that would happen, but I mean it's a legitimate concern that some of the folks may avoid to the people who ultimately took it out.

One of the things that what we do do -- and we've kind of run numbers -- is we issue notices of inspection results to folks. It's modeled a little bit after the FDA 43 document. And what
that notice of inspection result is where there are minor issues that can be readily corrected and we don't think that it should -- that a formal enforcement action should be taken or implemented or instituted, what we'll do is we will give you a document that basically says that these were some of the possible violations that we noticed that you all could resolve.

1 of the things that -- and that was well received in a sense that it gives people an opportunity to review those minor issues and it also gives them an opportunity to respond to us to let us know what they've done to address those. I want to say that we have issued -- I had the number somewhere. I want to say it was along the lines of -- let's see. I think last year we did -- let's see. We did over a hundred notice of inspection results.

In the past couple of years, let's say we started off at 34 -- I'm sorry. We started off at seven the first year, the next year was eight, the next year was 107 and the next year was 104. So we've had, you know, over the last several years -- the last three years we've had almost 300 notice of inspection results where we haven't --
we haven't taken the force of action against
people but we've given them a document that
reflects an alternative way for them to go ahead
and get into compliance and kind of get things
straightened out.

I know we have, meaning Renee and myself and
Dinah and all those folks in our office, when we
get phone calls and compliance issues we resolve
those without necessarily having taken enforcement
actions. I mean we've had several hundreds of
those that we've done. So even though we don't do
citations, which might have been a quicker way to
maybe revolve some of the enforcement actions that
we take, we have significantly reduced the
enforcement actions that we've taken. I mean, I
can tell you in 2011 when the program came over
there were 400 plus enforcement cases open. Now
we're less than about 140, 150 of them. And
that's about -- that's about consistent with where
we think we ought to be at.

We did notice a little bit when we started
doing some more of the risk-based inspections. We
did open up a little bit more files, more
inspections and more (inaudible), but what we
found was some of the ones that we opened were
folks that we hadn't seen in eight, nine years and so there was some compliance issues, some major compliance issues in some instances.

But that's the whole point of doing the risk-based inspections. If you go to folks that you haven't gone to in a long time, based on the risk they present, you would hope not to see violations but it's not a surprise that you do see them because, you know, from time to time you need folks to be reminded that they have some responsibilities, you have turnover in offices and that kind of stuff. And maybe the newer people who come in haven't really been trained; they don't know the history behind the corrective action that the company has taken before.

And so, you know, you have any number of reasons why, if we haven't been out with somebody in the last seven or eight years, when we go out there we see a lot of issues. Sometimes people get lax and sometimes with the turnover they just -- they start to forget some of the requirements.

But that's a long answer to the short that we can't issue citations, but we have implemented a lot, a lot of different methods to avoid enforcement action and only take enforcement
action when we think that it's something that needs to be resolved or something that needs to be brought to the attention of maybe some folks higher up in the company. The people at the local level may not fully understand and grasp the importance of it.

MR. ELLIS: That's great, Reggie. I think that's an excellent solution to that. And the way you're going to handle it sounds excellent to me. Thank you.

MR. MAYS: Any other questions from council members?

Okay. Any questions from other interested parties on the line?

Okay. Reggie, I really appreciate the time you've took to walk us through this. I think it's valuable information and I really appreciate it.

The next topic on this, under Tab 1, is to gauge the interest of the council and having a DSCSA update provided at the next in-person meeting in February. Heather Zenk from AmerisourceBergen gave us an update last August -- August, 2015 and I know there's been quite a bit of activity at the federal level since then, and I wanted to get, you know, some -- gauge the
interest of the council on having Heather come back and do an update at our February meeting or we can ask HDA or another industry expert to provide an update. I just wanted to get the councils' thoughts on that.

MR. ELLIS: (Inaudible).

MR. BARNES: Mr. Chair, this is Patrick. I would like to hear an update. I think it's a good idea.

MR. MAYS: Okay. I heard someone else.

MR. ELLIS: Mr. Chairman, this is Dean Ellis. I agree with that, any updated information we can get to the (inaudible) would be appreciated.

MR. MAYS: Okay. All right.

MR. BARNES: Mr. Chair, do we need a motion or --

MR. MAYS: Yeah.

MR. BARNES: -- is it something that you can do by executive action, I guess?

MR. MAYS: Well, if we -- do we have a motion?

MR. BARNES: I would like to make a motion that we have an update in our February meeting on the DQSA.

MR. MAYS: Okay.
MR. BARNES: This is Patrick.

MR. FILES: This is Brian Files. I second.

MR. MAYS: Okay. All those in favor, say aye. Aye.

MR. FILES: Aye.

MR. BARNES: Aye.

MR. MAYS: Those oppose, likewise.

Okay. Then we will make sure we put that on the agenda for the February in-person meeting. I had already reached out do Heather and she's willing to come back to do that update. So I'll make sure to arrange for her to come and give us that presentation for at that in-person meeting -- I don't remember the exact date in February, but I believe it's in February.

MS. GREENE: February 15th, Chair.

MR. MAYS: Okay. Thank you, Ms. Green.

Any questions from council members or other interested parties?

Okay. All right. Well, I will turn it over to Mr. Dixon now to give us the division director's report under Tab 2.

MR. DIXON: Good morning, again. This is Reginald Dixon. What you have in front of you is a -- on Tab 2 is the Division's Rules Report. As
we've indicated before we've tried -- the Division
is trying to go through all of its applications,
update applications, simplify the applications and
to request the information that is acquired by
statute.

There was some issues -- one of things -- and
I guess it may be a downside or it may be an
upside to both Renee and myself being lawyers is
that, you know, if the statute requires a certain
thing, we want to make sure the applications
require that, and so that -- that we're doing what
we're required to do. Now, if for some reason,
you know, the statutes change and that kind of a
thing then that can be handled as well. But it
becomes very difficult sometimes to process an
application where we're not asking for something
that the statute requires and the person thinks
they filled out the application and then we send
them a deficiency letter because they haven't
given us something that's not on the application
but it is required by statute.

So we try to do our best to kind of go
through these applications and through the
statutes and put information and marry it up, try
to simplify some of the questions, make the
questions a little bit better, change the forms around a little bit and make them all a little bit more consistent so over the next, I don't know, maybe six months to a year and a half you will be seeing applications on the agenda until we get all of these applications knocked out.

But also there will be some other rulemaking that we're doing, so we want to always bring that to the council, let the council have a chance to look at it. That's what this report represents. We tried to color-code it a little bit hopefully to give you an idea, make it a little easier on the eye.

The green is the most recent rule or rule that went into effect, which is October 10th. The beige are those -- I'm sorry. The blue are those ones that are in the intermediate stage, meaning we've already filed a notice of rulemaking, we've drafted applications and then we've published those applications so that now we're open, waiting on comment. And the beige -- the beige is where we've filed a notice of development but we still have not finalized those application forms yet and we haven't published the applications form.

So we can go through -- we included some of
the updates and some of the information on the applications. You'll see the applications themselves. You'll see the letters that the Joint Administrative Procedures Committee sent to us. You can see the response that our office sent to the Joint Administrative Procedures Committee, you know, either telling them, hey, yes, we think you're right. Here's an explanation of why something was asked for. Here's what we'll do as far as we think you're right and we'll change certain things.

So that's kind of the process, and I know -- I'm not sure how other states do it. I know sometimes it can be long and a little bit arduous for us to do this, but that's why it's important to try to get it right, that we try to ask for information that we can ask for, that we put folks on as much notice as we can with respect to our applications and hopefully we just have a better product that helps us process the applications more efficiently and quicker.

So what you have in front of you are those applications. I can tell you some of the things that we're looking at in the future. We're still looking to do rulemaking. One of the issues that
recently came up is what does normal business hours mean. So we're going to be probably doing a notice of a workshop to try to list information on what normal business hours are so we can write a rule on normal business hours.

We're all -- if there are issues that any council member or anyone in the public thinks that we probably need to look at our rules on we ask that they submit those to our office. If you submit those to Dinah Greene or to submit those to me by e-mail or give us a call, what we can do is we can internally discuss those, and we're coming up with a list of what we're trying to think about doing (inaudible).

So if someone's got ideas and things they would like us to look at this is the time to get those to us. I mean you should always be doing it but this is a special time because towards the end of the year you start to think about and reflect on the things that you want to do going into next year, and so we just think that's a smart policy.

But just kind of going through the report, the definitions were finalized in October and basically those definitions were the ones that talked about the amount of money -- the amount of
distributions by pharmacy in response to some of
the changes to Chapter 499, also the language with
respect to distributions between (inaudible)
pharmacies. We had to kind of clarify those
definitions, so those are the definitions that
went into effect in October.

With respect to the current applications that
are out there, the application for a nonresident
prescription drug manufacturer, the virtual
permit, the state resident virtual manufacturer
permit, as well as the nonresident repackaging
permit, those are in the final stages we responded
to in the letter from the Joint Administrative
Procedures Committee. And so the next step in
that, unless we hear anything else, is to go ahead
finalize those applications and then begin issuing
those permits.

We think that those permits will alleviate or
facilitate some folks getting licenses a little
easier. We think the nonresident repackaging
permit will probably alleviate some of the issues
that some folks who were truly repackagers but for
whatever reason either got a manufacturer or a
wholesale distributor -- a nonresident wholesale
-- out-of-state wholesale distributor permit. We
think that alleviates some of those needs as well. So we don't know that it's going to have a huge impact but we think it's the right thing to do and we think it's going to help some folks in the industry who previously had some other issues that -- you know, that were preventing them or making it difficult for them to participate in the industry.

Just from a scheduling perspective, I can tell you the next application that we're working on right now is the wholesale distributor permit application. That application has needed some work for a while. Rebecca Burnett and I -- she has looked at my last draft of it. We're going to be -- our plan is to split those out into two applications instead of one. The one application's going to be for those people who are in the State of Florida, meaning the prescription drug wholesale distributors and the brokers. And the second application is going to be a separate application for the out-of-state wholesale distributors.

We're probably about 85 to 90 percent done with the draft. We've got some more things to do. We hope to do get that out in the next two to
three weeks and just keep it moving. So does anyone -- I mean that's kind of a summary of what we have and what information you have in front of you. Does anyone have any specific questions about anything, what we're doing as far as the rules that are in the packet or as far as anything else?

MR. ELLIS: Reggie, this is Dean Ellis again. Was there progress made on the two-year -- or permit that we had discussed at one time? Is that on the agenda to come up or where is that?

MR. DIXON: We're still working on it. The difficulty that we're having and -- I chuckle a little bit because, as easy as it seems, it actually is a lot more difficult than it seems in that to do that we've got to modify the application and modify the fees on the application such as that -- that the person who is renewing knows what type of permit they're renewing and the period of time in which they're renewing it.

It's just a little bit more logistically difficult than we could have ever imagined to try to stagger the permits in such a way that it happens over a period of time that we can actually process the applications and not have a whole
bunch of people bundled up at different times. And we're actually trying to write it -- we're trying to draft a rule to set out when people renew, that kind of a thing. It's just -- we're making progress on it but it is -- it's a lot more difficult than we ever -- at least speaking for myself, I imagine that it would be.

MR. ELLIS: (Inaudible).

MR. DIXON: So we're trying -- we're making progress.

Yeah, we're still working on it, but it is -- it's a logistical nightmare. I'll just put it that way.

MR. ELLIS: Okay. Thank you.

MR. DIXON: But we are working on it. I will assure you that.

MR. ELLIS: Thank you.

MR. MAYS: Any other questions from council members? How about any other interested parties on the line, any other questions?

Okay. All right. Is there any other business?

Okay. Hearing none, do we have a motion to adjourn?

MR. FILES: Mr. Chairman, I think we -- don't
we need to approve the last minutes?

 MR. MAYS: No. I was talking to Ms. Greene this morning. They sent us a transcript that they don't need to be approved.

 MR. FILES: Oh, okay. Great.

 MR. MAYS: So that information -- and I'm glad -- thank you for bringing that up. I wanted to point out that that is in there for everyone's information. So it's not actual minutes and it's a transcript and it doesn't need to be approved.

 MR. ELLIS: I move to adjourn. This is Dean Ellis.

 MR. MAYS: Okay. Do we have a second?

 MR. FILES: Brian Files, second.

 MR. BARNES: Second.

 MR. MAYS: All in favor, say aye.

 MR. BARNES: Aye.

 MR. FILES: Aye.


 Okay. The meeting is adjourned. Thank you very much.

 MR. FILES: Thank you.

 (Thereupon, the proceedings were concluded at 10:17 a.m.)
CERTIFICATE OF REPORTER

STATE OF FLORIDA)
COUNTY OF LEON)

I, Jessica Rrenchen, Court Reporter and Notary Public for the State of Florida at Large, do hereby certify that I was authorized to and did stenographically report the foregoing telephonic proceedings; and that the transcript is a true record of the telephonic proceedings within the limits and quality of the telephonic proceedings.

I further certify that I am not a relative, employee, attorney, or counsel of any of the parties, nor am I a relative or employee of any of the parties' attorney or counsel connected with the action, nor am I financially interested in the action.

[Signature]
JESSICA RENCHEN, Court Reporter

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