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Drugs, Devices and Cosmetics

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

IN RE: GENERAL BUSINESS

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

1 Council Members:

2 STEVE MAYS, CHAIR
3 JEENU PHILLIPS, VICE CHAIR
4 SCOTT BROCK
5 DEAN ELLIS
6 BRIAN FILES
7 MICHAEL MONE
8 PATRICK BARNES
9 PETER HART
10 JEFFREY TULLER

11 DBPR Staff:

12 REGGIE DIXON, DIVISION DIRECTOR
13 RENEE ALSOBROOK
14 DINAH GREENE

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TELEPHONIC PROCEEDINGS

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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.

1 MS. GREENE: Arlene Elliott? Dean Ellis?

2 MR. ELLIS: Here.

3 MS. GREENE: Jeff Tuller?

4 MR. TULLER: Here.

5 MS. GREENE: Patrick Barnes?

6 MR. BARNES: Here.

7 MS. GREENE: And Peter Hart?

8 MR. HART: Here.

9 MS. GREENE: You have a quorum, Mr. Chair.

10 MR. MAYS: Okay. A few things I'd like to
11 cover before we start -- before we get to the
12 agenda. This is my first meeting as your chair,
13 so I want to start out on the right foot by
14 thanking the council for entrusting me to serve as
15 your chair. And I also want to thank the
16 Department and the Division for working with
17 industry to make Florida a leader in keeping the
18 pharmaceutical supply chain safe.

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

1 achieving the goal of protecting the public
2 health.

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

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

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

20 So 499.01211, Drug Wholesale Distributor
21 Advisory Council. "The council shall review this
22 part and the rules adopted to administer this part
23 annually, provide input to the department
24 regarding all proposed rules to administer this
25 part, make recommendations to the department to

1 improve the protection of prescription drugs and
2 public health, make recommendations to improve
3 coordination with other states' regulatory
4 agencies and the federal government concerning the
5 wholesale distribution of drugs, and make
6 recommendations to minimize the impact of
7 regulation of the wholesale distribution industry
8 while ensuring protection of the public health."

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

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

22 MR. MAYS: Okay.

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

1 MR. MAYS: Sounds good.

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

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

1 recover some of that time back.

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

16 And so that's how we're trying to arrange our
17 inspections and trying to dedicate those resources
18 that way. So some folks may see us, you know,
19 every three to four years and some folks may see
20 us every six to ten years. It just depends. And
21 so what that does is it allows us to kind of
22 direct our resources a little bit more where they
23 need to be at, as well as allow us to implement
24 other alternative form. Say, for instance, the
25 self-inspection survey that we implemented with

1 our health care clinic establishment (inaudible),⁹
2 that's a way for them to have an inspection that
3 is as least intrusive as possible allowing us to
4 get information that can help us determine, you
5 know, if there's some follow-up that needs to be
6 done but also allowing that entity to do some
7 self-reflection and to follow up on any issues
8 that may have been brought to their attention.

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

20 So, you know, as we're looking at our
21 resources and those kind of things that's how we
22 kind of allocate our resources that way in a way
23 that we think is the best or most efficient, and
24 we're looking at that every day. There's not a
25 day that goes by where Renee or the field manager

1 and myself where we kind of sit down and try to
2 think of a better way to do something. So when
3 this came up, we saw this as an opportunity to
4 kind of provide some general information about the
5 different types of inspections that we do and the
6 inspection authority that we have.

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

1 everyday, let's go out, let's do an inspection,
2 let's get people into compliance.

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

16 So let's say, for instance, we get a
17 complaint that there's a belief that someone is
18 purchasing from an unauthorized source. We would
19 do our research -- of course we do our research
20 before we go out anyway, but one of the primary
21 reasons -- one of the primary issues that we will
22 be looking at when we go out there is sources,
23 because we have a complaint that says that these
24 folks have unauthorized sources. So that's kind
25 of the difference between the compliance one

1 versus the complaint instigated type of
2 investigation, because that's the way we're
3 looking at it.

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

13 And so those are generally the three types
14 that we split them out into -- our inspections
15 into. From a perspective of how we go out and do
16 the inspections, they're usually pretty much the
17 same. One of the things that our secretary did
18 when he first came here was to try to, you know,
19 strip away some of the significant formalities
20 that were in other areas of the Department in a
21 sense that we want folks to realize that you have
22 an obligation -- or I mean a right to have a fair
23 inspection, you have a right to speak to the
24 supervisor of the person doing the inspection, you
25 have a -- and so what they means -- and so out of

1 that -- you know, out of our mission, which is to,¹³
2 you know, treat people fairly, you know, inspect
3 people fairly, regulate fairly, what we try to do
4 is have our inspectors -- and this is across the
5 agency, not just at DDC -- you know, when they
6 arrive at the inspection to provide their
7 credentials, to provide what we have, what's
8 called an inspection bill of rights, which
9 notifies folks, hey, look, you know, this is the
10 inspector. You're entitled to have a good
11 inspector, you're entitled to have people treat
12 you with respect, and if you have questions about
13 it you can speak to the inspector or you can call
14 their supervisor if you don't think the inspection
15 was done appropriately or there's an issue with
16 it.

17 Our folks will normally go in, try get some
18 basic information about the facility. I mean, of
19 course, we've done our homework, so we've pulled
20 the application file if it's application related.
21 If it's complaint related we still pull
22 (inaudible) disciplinary history to see if they've
23 had a prior history -- you know, I mean the basic
24 due diligence that you would expect us to do
25 before we walk out to your facility. You know, it

1 would be a waste of time, probably, if we just
2 walked out there cold.

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

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

24 And so part of the things that our folks want
25 to do when they get out there is identify

1 themselves and generally pretty quickly,
2 hopefully, identify the person at the facility
3 who's in the best position to help them with the
4 inspection -- help them conduct their inspection.
5 So sometimes that is going to be dependent solely
6 upon the size of the facility. If we go into a
7 place that's got three employees, I'm sure it's
8 one of those three employees there who's going to
9 be the person that we're going to be dealing with.

10 If you go into a place that's got 50, 90 or
11 100 employees, I'm pretty sure we're going to have
12 more than one person. There's going to be a
13 person there who is responsible for the facility,
14 usually the manager, depending on what type of
15 facility it is. If it's a wholesale distributor
16 it might be the CVR, but it may just be the plant
17 manager, a person there who can -- we can identify
18 them, you know, give them their information, you
19 know, we're here to conduct the inspection, here's
20 our authority to do the inspection.

21 And during the course of the inspection, I
22 guess, people should know that we're going to look
23 at the facility, but we also, as part of that, you
24 know, make sure that you're getting the
25 appropriate sources, that you got the according

1 documentation for the distributions or receipts of¹⁶
2 prescription drugs. It's the kind of things that
3 you normally expect -- that you would normally
4 expect to see.

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

16 One of the things that we try to avoid is
17 asking for too much information. We need to ask
18 for enough information that we understand the --
19 how the facilities are operating. You know,
20 sometimes that can be difficult in a sense -- I
21 mean, you know, the larger the facility sometimes
22 the more difficult it is simply because we're
23 trying not to ask for too much records -- too many
24 records, but if you ask for a certain number of
25 distributions on a day or a certain percentage or,

1 you know, just say, hey, can I see your list of
2 distributions for a particular day, (inaudible)
3 pharmaceuticals, I may only have three. You know,
4 if I'm, you know, a large distributor, A, B and C,
5 it may be a jillion of them. And so sometimes,
6 you know, our request may seem a little bit
7 extraordinary but it's because we're trying to
8 judge how many records, what types of records to
9 ask for.

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

22 Like I said, if you're a large facility, you
23 may have multiple folks that you pull in and out
24 to kind of meet with us. 1 person may be
25 responsible for helping us grab the records, when

1 the other person may be responsible for helping
2 tour the facility in different areas to try to
3 determine compliance.

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

13 For instance, if we go there, we're checking
14 sources or something and we see a document that we
15 may want some more information or you see a
16 document that (inaudible) us to request additional
17 information, instead of sitting at the facility
18 for two days or whatever asking for that
19 information, we may just say, hey, look, please
20 get this to us by whatever date, and we try to set
21 that date far enough out that we understand that,
22 hey, look, if we ask for it in a week it ought to
23 be something you can clearly get because the
24 statute requires, you know, 48 hours or 24 hours
25 immediately retrievable or immediately available

1 and retrievable depending on where the facility is¹⁹
2 at and where the records are being kept, those
3 kinds of things.

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

22 1 of the things that I know was an inquiry
23 that we had was what's the possibility -- or would
24 we at least consider possibly having our
25 inspectors kind of sit down with folks and go over

1 the inspections, findings and results of some as
2 they leave. And I know we're looking into that.

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

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

1 answer any questions that anyone may have.

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

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

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

1 And I'll get to my last comment and I'll see ²²
2 if anybody else has any questions. I know that,
3 you know, we have a lot of inspections in a lot of
4 different states and we have DEA inspections and
5 things like that, and sometimes we have inspectors
6 that come to our sites and they do an inspection
7 and sometimes we never know when they're finished
8 or not and they just leave and then, you know, the
9 next thing we know a few months letter we're
10 getting a notice of violation and there may have
11 been things that, you know, we could have
12 mitigated if they had sat down with us and said,
13 you know, here's what our observations are and we
14 think this might be a violation and, you know,
15 that's something -- because I know in most cases
16 if we -- you know, if we've got a problem it's
17 usually not anything -- it's almost always not
18 intentional and it's something we want to correct
19 right away.

20 And again, I applaud the Department for the
21 process and how they do that. And that would be
22 my only recommendation is if there's any way to
23 find the time to do that, to sit down with the
24 firm and do an exit meeting, you know, at the end
25 of the inspection and go over any violations or

1 observations the inspector might see, I think
2 that's always a plus for the firm.

3 Are there any questions from other council
4 members?

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

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

22 One of the things that what we do do -- and
23 we've kind of run numbers -- is we issue notices
24 of inspection results to folks. It's modeled a
25 little bit after the FDA 43 document. And what

1 that notice of inspection result is where there
2 are minor issues that can be readily corrected and
3 we don't think that it should -- that a formal
4 enforcement action should be taken or implemented
5 or instituted, what we'll do is we will give you a
6 document that basically says that these were some
7 of the possible violations that we noticed that
8 you all could resolve.

9 1 of the things that -- and that was well
10 received in a sense that it gives people an
11 opportunity to review those minor issues and it
12 also gives them an opportunity to respond to us to
13 let us know what they've done to address those. I
14 want to say that we have issued -- I had the
15 number somewhere. I want to say it was along the
16 lines of -- let's see. I think last year we did
17 -- let's see. We did over a hundred notice of
18 inspection results.

19 In the past couple of years, let's say we
20 started off at 34 -- I'm sorry. We started off at
21 seven the first year, the next year was eight, the
22 next year was 107 and the next year was 104. So
23 we've had, you know, over the last several years
24 -- the last three years we've had almost 300
25 notice of inspection results where we haven't --

1 we haven't taken the force of action against
2 people but we've given them a document that
3 reflects an alternative way for them to go ahead
4 and get into compliance and kind of get things
5 straightened out.

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

21 We did notice a little bit when we started
22 doing some more of the risk-based inspections. We
23 did open up a little bit more files, more
24 inspections and more (inaudible), but what we
25 found was some of the ones that we opened were

1 folks that we hadn't seen in eight, nine years and²⁶
2 so there was some compliance issues, some major
3 compliance issues in some instances.

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

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

22 But that's a long answer to the short that we
23 can't issue citations, but we have implemented a
24 lot, a lot of different methods to avoid
25 enforcement action and only take enforcement

1 action when we think that it's something that
2 needs to be resolved or something that needs to be
3 brought to the attention of maybe some folks
4 higher up in the company. The people at the local
5 level may not fully understand and grasp the
6 importance of it.

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

11 MR. MAYS: Any other questions from council
12 members?

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

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

18 The next topic on this, under Tab 1, is to
19 gauge the interest of the council and having a
20 DSCSA update provided at the next in-person
21 meeting in February. Heather Zenk from
22 AmerisourceBergen gave us an update last August --
23 August, 2015 and I know there's been quite a bit
24 of activity at the federal level since then, and I
25 wanted to get, you know, some -- gauge the

1 interest of the council on having Heather come
2 back and do an update at our February meeting or
3 we can ask HDA or another industry expert to
4 provide an update. I just wanted to get the
5 councils' thoughts on that.

6 MR. ELLIS: (Inaudible).

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

10 MR. MAYS: Okay. I heard someone else.

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

14 MR. MAYS: Okay. All right.

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

17 MR. MAYS: Yeah.

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

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

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

25 MR. MAYS: Okay.

1 MR. BARNES: This is Patrick.

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

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

5 MR. FILES: Aye.

6 MR. BARNES: Aye.

7 MR. MAYS: Those oppose, likewise.

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

16 MS. GREENE: February 15th, Chair.

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

18 Any questions from council members or other
19 interested parties?

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

23 MR. DIXON: Good morning, again. This is
24 Reginald Dixon. What you have in front of you is
25 a -- on Tab 2 is the Division's Rules Report. As

1 we've indicated before we've tried -- the Division³⁰
2 is trying to go through all of its applications,
3 update applications, simplify the applications and
4 to request the information that is acquired by
5 statute.

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

22 So we try to do our best to kind of go
23 through these applications and through the
24 statutes and put information and marry it up, try
25 to simplify some of the questions, make the

1 questions a little bit better, change the forms
2 around a little bit and make them all a little bit
3 more consistent so over the next, I don't know,
4 maybe six months to a year and a half you will be
5 seeing applications on the agenda until we get all
6 of these applications knocked out.

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

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

25 So we can go through -- we included some of

1 the updates and some of the information on the
2 applications. You'll see the applications
3 themselves. You'll see the letters that the Joint
4 Administrative Procedures Committee sent to us.
5 You can see the response that our office sent to
6 the Joint Administrative Procedures Committee, you
7 know, either telling them, hey, yes, we think
8 you're right. Here's an explanation of why
9 something was asked for. Here's what we'll do as
10 far as we think you're right and we'll change
11 certain things.

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

22 So what you have in front of you are those
23 applications. I can tell you some of the things
24 that we're looking at in the future. We're still
25 looking to do rulemaking. One of the issues that

1 recently came up is what does normal business
2 hours mean. So we're going to be probably doing a
3 notice of a workshop to try to list information on
4 what normal business hours are so we can write a
5 rule on normal business hours.

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

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

22 But just kind of going through the report,
23 the definitions were finalized in October and
24 basically those definitions were the ones that
25 talked about the amount of money -- the amount of

1 distributions by pharmacy in response to some of
2 the changes to Chapter 499, also the language with
3 respect to distributions between (inaudible)
4 pharmacies. We had to kind of clarify those
5 definitions, so those are the definitions that
6 went into effect in October.

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

18 We think that those permits will alleviate or
19 facilitate some folks getting licenses a little
20 easier. We think the nonresident repackaging
21 permit will probably alleviate some of the issues
22 that some folks who were truly repackagers but for
23 whatever reason either got a manufacturer or a
24 wholesale distributor -- a nonresident wholesale
25 -- out-of-state wholesale distributor permit. We

1 think that alleviates some of those needs as well.³⁵

2 So we don't know that it's going to have a
3 huge impact but we think it's the right thing to
4 do and we think it's going to help some folks in
5 the industry who previously had some other issues
6 that -- you know, that were preventing them or
7 making it difficult for them to participate in the
8 industry.

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

23 We're probably about 85 to 90 percent done
24 with the draft. We've got some more things to do.
25 We hope to do get that out in the next two to

1 three weeks and just keep it moving. So does
2 anyone -- I mean that's kind of a summary of what
3 we have and what information you have in front of
4 you. Does anyone have any specific questions
5 about anything, what we're doing as far as the
6 rules that are in the packet or as far as anything
7 else?

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

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

21 It's just a little bit more logistically
22 difficult than we could have ever imagined to try
23 to stagger the permits in such a way that it
24 happens over a period of time that we can actually
25 process the applications and not have a whole

1 bunch of people bundled up at different times.
2 And we're actually trying to write it -- we're
3 trying to draft a rule to set out when people
4 renew, that kind of a thing. It's just -- we're
5 making progress on it but it is -- it's a lot more
6 difficult than we ever -- at least speaking for
7 myself, I imagine that it would be.

8 MR. ELLIS: (Inaudible).

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

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

14 MR. ELLIS: Okay. Thank you.

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

17 MR. ELLIS: Thank you.

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

21 Okay. All right. Is there any other
22 business?

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

25 MR. FILES: Mr. Chairman, I think we -- don't

1 we need to approve the last minutes?

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

5 MR. FILES: Oh, okay. Great.

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

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

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

14 MR. FILES: Brian Files, second.

15 MR. BARNES: Second.

16 MR. MAYS: All in favor, say aye.

17 MR. BARNES: Aye.

18 MR. FILES: Aye.

19 MR. MAYS: Aye. Oppose, likewise.

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

22 MR. FILES: Thank you.

23 (Thereupon, the proceedings were concluded at
24 10:17 a.m.)

25

CERTIFICATE OF REPORTER

STATE OF FLORIDA)

COUNTY OF LEON)

I, Jessica Renchen, 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.



JESSICA RENCHEN, Court Reporter