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**DEPARTMENT OF BUSINESS AND
PROFESSIONAL REGULATION
DIVISION OF DRUGS, DEVICES AND COSMETICS
RULES WORKSHOP**

**MAY 10, 2018
10:00 A.M. - 10:10 A.M.**

**FLORIDAYS RESORT/ORLANDO
12562 INTERNATIONAL DRIVE
ORLANDO, FLORIDA**

**REPORTED BY:
HEATHER HOWARD, COURT REPORTER
NOTARY PUBLIC/STATE OF FLORIDA**

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MEMBERS PRESENT:

DREW WINTERS, DIVISION DIRECTOR
KATHRYN PRICE, ESQUIRE
RENEE ALSOBROOK, COMPLIANCE MANAGER
DINAH GREENE, GOVERNMENT OPERATIONS CONSULTANT

COURT REPORTER:

Heather Howard, American Court Reporting

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P R O C E E D I N G S

May 10, 2018

10:00 a.m.

(The May 10th, 2018 DBPR/Division of Drugs, Devices and Cosmetics Rules Workshop was called to order, after which the following took place:)

MR. WINTERS: Good morning, everybody. We'll go ahead and get this Rules Workshop kicked off.

For the record, my name is Drew Winters. I'm the Director of the Division of Drugs, Devices and Cosmetics. I will be the moderator for today's Rule Development Workshop.

For the record, we are here today in Orlando, Florida at the Floridays Hotel. It is May 10th, 2018 at approximately 10:00 a.m.

And we are here today to receive public comments and suggested -- suggestions regarding language for consideration in the development and creation of Rule 61N-1.0155 regarding the safety, security and storage requirements and development of language regarding that.

The rule development for this particular rule and the notice of workshop was filed with the Florida Administrative Register on April 6,

1 2018. The preliminary -- it is a preliminary
2 workshop and so at this point in time we have
3 not proposed any rulemaking and at this time the
4 Division has also not provided any preliminary
5 language.

6 It is instead requesting that we receive
7 industry input and assistance during the initial
8 language drafting to better understand industry
9 circumstances and business models that should be
10 considered while developing the potential rule
11 language.

12 It is also important to understand that,
13 again, this is just a preliminary workshop and
14 does not prohibit or otherwise prevent us from
15 having future workshops as necessary as we move
16 through the rule development and rulemaking
17 process. Or if it were a workshop or request by
18 any substantially affected party.

19 Any future language proposed for rulemaking
20 will be appropriately noticed, again, in the
21 Administrative Register. And I will discuss
22 specifically with the -- for the record that --
23 regarding the items, but I did want to take care
24 of a few housekeeping items and general rules to
25 ensure that we do have a successful and

1 organized meeting.

2 First, if you've not already done so,
3 please sign in at the back of the room so we can
4 make sure and log your attendance for the
5 record. And take the time to do that before you
6 leave today.

7 Second, if you are planning on providing
8 any public testimony or would like to speak to
9 the panel, please fill out one of the
10 green-colored speaker cards that is located at
11 the back of the room. This will help ensure
12 that we recognize you and don't overlook anybody
13 wishing to make a public comment.

14 If you need to fill out a green speaker
15 card, you may hand it to Dinah Greene. She is
16 located next to the court reporter at the end of
17 the table. And she can make sure that we
18 receive those here at the panel.

19 Next I will also like to ask any assistance
20 for anybody that is going to be addressing the
21 panel that if you clearly identify yourself and
22 the organization that you represent for the
23 record. That way that we can, again, maintain a
24 good record for the Division to use during the
25 development.

1 The Division has arranged for a court
2 reporter to be here and present. So we will
3 have an official record of the proceedings. If
4 you would be mindful of the court reporter. She
5 does have a difficult task in order to maintain
6 an accurate record. When presenting, please
7 speak up and use the microphone provided. And
8 please wait to be recognized before speaking so
9 that we don't speak over any of the other
10 presenters.

11 Also, in recognition of everybody's
12 valuable time, we do ask that if you are going
13 to be speaking and you agree with or otherwise
14 are going to be making the same statements as a
15 previous presenter, that we would ask that you
16 just simply identify yourself, the identity of
17 the previous speaker and let us know that you
18 agree with their comments and then provide any
19 additional comments that you believe pertinent.

20 With that, and at the conclusion of today's
21 meeting we will adjourn the meeting. However,
22 the Division will leave the official record open
23 for a period of 10 days to allow participants to
24 submit additional written comments to the
25 Division.

1 The comments must be received no later than
2 the close of business on May 21st, 2018. And
3 you may submit those comments to
4 Ms. Dinah Greene at 2601 Blainstone Road in
5 Tallahassee, Florida, 32399 or you may e-mail
6 her at dinah.greene@myfloridalicense.com.

7 For the record, that contact information is
8 also contained in our notices that are in the
9 Florida Administrative Register so you may
10 receive that information there. Or you may
11 contact the Division as well to provide that.

12 With that I will move forward with just the
13 presentation of the item, which is, again, Rule
14 61N-1.055 of the Florida Administrative Code as
15 a proposed new rule section.

16 We are in development. It is pursuant to
17 499.01(2)(a) and (2)(c) and (2)(e) of the
18 Florida statutes that establishes the
19 prescription drug manufacturer permit, the
20 nonresident prescription drug manufacturer
21 permit and the prescription drug wholesale
22 distributor permit.

23 And it allows the Department to adopt rules
24 for the implementation of the virtual
25 prescription drug manufacturer permit in

1 Sections (2) (a) and (2) (c) and the broker only
2 wholesale distributor permit under Section
3 (2) (e). You may, again, get those references in
4 499.01(2) (a), (2) (c) and (2) (e).

5 They also allow for us, under the rule,
6 that -- excuse me -- under the statute that we
7 may exempt virtual manufacturers from
8 establishment, security and storage requirements
9 set forth in 499.0121 of the Florida statutes.

10 We are here today to discuss the
11 implementation of the rule and potential
12 language. Excuse me, not implementation, but
13 development of that rule and to discuss what
14 establishment, security and storage requirements
15 that you believe would be prudent for us to
16 exempt those entities from.

17 With that I will turn it over and open up
18 to public comments -- and allow for public
19 comments. So, at this point in time, I do not
20 have any speaker cards that have been provided.
21 Therefore, I will open it up to any individual
22 in the audience that would like to make a
23 comment or to be recognized.

24 MR. ELLIS: Dean Ellis with MedFirst
25 Healthcare Supply.

1 MR. WINTERS: Mr. Ellis, if you could, come
2 to the table.

3 MR. ELLIS: Okay.

4 MR. WINTERS: And use the microphone.

5 MR. ELLIS: Dean Ellis with MedFirst
6 Healthcare Supply.

7 My question is, we're talking about the
8 virtual along with the wholesale distribution
9 permit. Would that -- would that be a separate
10 permit or rolled into -- if you're a wholesale
11 distributor you can also be a virtual
12 distributor?

13 Meaning, if I hold this license can I
14 operate as a virtual?

15 MR. WINTERS: Dean Winters. Again, I think
16 that the purpose of today's discussion is that
17 the permits have already been created and are in
18 existence. At this point in time we have both a
19 virtual manufacturer of prescription drugs in
20 state and a nonresident prescription drug
21 virtual permit as well as a broker only permit.

22 What we're here today as part of the rule
23 development is to -- in the workshop, is to
24 receive comments regarding those requirements
25 under 499 --

1 MR. ELLIS: Okay.

2 MR. WINTERS: -- .0121 that would be
3 appropriate based on the industry circumstances
4 and business models that are in the industry for
5 us to exempt those types of permit holders from
6 those requirements to ensure that we develop by
7 rule and notify everybody of those items that
8 they would be exempt from and, correspondingly,
9 if -- those items that would still remain in the
10 statute that they would need to meet.

11 MR. ELLIS: Okay. Thank you.

12 MR. WINTERS: Any other public comment?

13 Hearing none and seeing no additional
14 comments from any -- hearing nobody and seeing
15 no other requests to make a public comment, at
16 this time what I will do is go ahead and adjourn
17 the meeting for purposes of receiving public
18 comments -- today's meeting.

19 However, again, in closing, I will remind
20 everybody that we are leaving the record open --
21 the official record -- for any person that is in
22 the audience or anyone that is viewing this
23 proceeding on the web stream that is available.

24 If you have any additional comment that
25 you'd like to put into the official record, you

1 may do so. Again, as stated, the Division will
2 leave the record open for a period of 10 days to
3 allow additional written comments.

4 Those comments can be submitted and need to
5 be received no later than May 21st, 2018. And
6 they can be submitted to Ms. Dinah Greene.
7 Again, via mail at 2601 Blainstone Road in
8 Tallahassee, Florida, 32399 or via e-mail at
9 dinah.greene@myfloridalicense.com.

10 Again, that contact information is
11 available in the official FAR notice for this
12 workshop and for the rule development so that
13 you can submit the comment to that.

14 Again, that record will be open at that --
15 until that time and, again, with that I will go
16 ahead and adjourn the meeting at this time and
17 close the proceedings for today.

18 Thank you.

19 (The Rules Workshop was adjourned at 10:10
20 a.m.)
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C E R T I F I C A T E

STATE OF FLORIDA)

COUNTY OF ORANGE)

I, HEATHER K. HOWARD, Court Reporter,
certify that I was authorized to and did report the
aforementioned May 2018 Department of Business and
Professional Regulation/Division of Drugs, Devices
and Cosmetics Rules Workshop, and that the
transcript is a true and complete record of my notes
and recordings.

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

DATED this 31st day of May, 2018.

Heather K. Howard

HEATHER K. HOWARD, Court Reporter
Notary Public, State of Florida
(electronic signature)

Commission Expiration: 06/17/18
Commission No.: FF 119444