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

IN RE: RULE NOs. 61N-1.001,

N-1.002, and 61N-1.003

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RULE WORKSHOP

June 10th, 2015

9:00 a.m. - 10:00 a.m.

1940 North Monroe Street
Board Room, Northwood Centre
Tallahassee, Florida

Reported by:

SCHEDALE WOODS, Court Reporter
For the Record Reporting, Inc.
1500 Mahan Drive - Suite 140
Tallahassee, Florida, 32308

ORIGINAL

PRESENT

REGINALD DIXON

RENEE ALSOBROOK

DINAH GREENE

BRITTANY GRIFFITH

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P R O C E E D I N G S

MR. DIXON: Good morning. Today is June 10th, 2015. The time is approximately 9:02. My name is Reginald Dixon. I'm the Executive Director for the -- I'm sorry. I'm the Division Director for the Division of Drugs, Devices, and Cosmetics.

This morning we have a -- we're having a rules hearing on Rule 61N-1.001, a rule hearing -- I'm sorry. We're having a rules workshop.

The purpose of this rules workshop is to provide language to the industry, which was properly noticed regarding the definitions of "limited quantities" in 61N-1.001, as well as the record-keeping requirements and the storage requirements for those entities who will be engaging in the possession of either at the pharmaceutical ingredient, or prescription drugs that is received in limited quantities from entities outside of the state of Florida, who do not have a Florida non-resident manufacturer permit, or a non-resident or out-of-state wholesale distributor permit.

This meeting is in response to -- or a follow-up to our previous meeting, where we received input from the industry on language that

we thought would facilitate the ability to engage in those substances without hampering businesses in the state of Florida. So what you have in front of you is the -- or what you have may be online or what you're looking at, is the most recent language that this Division has put together. And unless we receive negative input from the industry on it or input that we don't believe merits a change in the proposed language, this is the language that we will be moving forward with in our next notice of rulemaking.

What I would ask, as a preliminary manner, before we open it up to comments from folks either on the phone and in the audience, is that it's kind of difficult conducting some of these meetings over the phone. So if you're on the phone and you have a comment, what we would appreciate you doing is identifying yourself first, and then making your comment. For the folks in the room, we'd ask the same thing. We have a table. So we ask that you come up to identify yourself just so we have a correct, complete record of who appeared and who made presentations before the Division.

What I'll do is I'll go ahead and just read the language because some folks may or may not have

the language in front of them. And then we'll open it up for comments after each.

The proposed language that we want with regards to limited quantities, which is 61 -- it's paragraph 61N-1.001(2)(n). And the Florida Administrative Code reads as follows: "Limited quantities pursuant to Section 499.01(3) and (4) -- subsection -- (4)(b) of Florida Statutes means the number of transactions necessary for research and development purposes, the number of transactions necessary for research and development purposes to obtain the final FDA approval or the number of transactions necessary for research and development purposes to obtain a final approval from a foreign regulatory authority. All transactions must be based on requirements set forth in the inquiring entity's research and development records created contemporaneously with the research and development activity."

That is the language that the Division proposes to file a notice of rulemaking on. And we would open it up to anyone on the phone or anyone in the room who may have any questions or concerns that they'd like to share with the Division on that proposed language.

Okay. Going once. Is there anyone on the phone? There is no one in the room here who has stepped up to the microphone. So is there anyone on the phone who has anything they would like to contribute or any questions they may have regarding the particular language that I just read?

Okay. What we'll do is we'll move towards the -- to the next proposed amendment. The next proposed amendment deals with the records that must be created. This deals with Rule 61N-1.012(17) of Florida Administrative Code.

The proposed language reads as follows: "For the purposes of prescription drugs obtained in limited quantities for research and development in parenthesis (R&D), purposes under Section 499.01(3) and (4)(b), Florida Statutes and paragraph 61N-1.01(2)(n) of Florida Administrative Code, the required records must identify the requirements and schedule the acquisition of use of each such drug relative to anticipated ongoing R&D activities. These records must be created in advance or within 30 calendar days of the particular R&D activities and are subject to inspection under Section 499.051 of Florida Statutes. Non-clinical/pre-clinical R&D quantities must be updated annually and clinical

quantities must be updated semi-annually. The researcher must maintain all records required under Chapter 499, including, without limitations, Section 499.01(3) or (4)(b) of Florida Statutes and applicable federal laws."

Is there anyone in the room here today that would like to provide any comment to the Division with regards to that particular language? Okay. Is there anyone on the phone, on the conference call who would like to provide any comment to the Division regarding that proposed language?

Okay. Hearing nothing, then I will go to the third proposed change, which is "Storage and Security Requirements" for the folks who are engaging in those limited quantities. This is a change to -- a proposed change to 61N-1.013(3) -- (d)(3) of the Florida Administrative Code. That proposed language reads as follows:

"Prescription drugs obtained in limited quantities for research and development, in parenthesis (R&D) for purposes under Section 499.01(3) and (4)(b) of Florida Statutes, and paragraph 61N-1.001(2)(n) of the Florida Administrative Code, must be physically segregated from all other products intended for manufacturing,

compounding, dispensing, or administration. In a manufacturer's establishment, these drugs must also be stored and maintained in a separate and clearly designated area."

Is there anyone in the room who has any comments or any input they'd like to provide to the Division with regards to that proposed language? Is there anyone on the phone who would like to have any input or any comment that they would like to provide to the Division in regards to this specific language that was read?

Did anyone on the panel have any comments or any suggestions?

Okay. As we have not heard from anyone, I believe -- well, let me ask a question. Since this rule was noticed -- or the hearing was noticed from 9:00 to 10:00, do we have to continue the hearing until 10:00? Or can we conclude it at this point? I think we have to go until 10:00. Okay. Right. So --

MS. ALSOBROOK: I think we'll sit here.

MR. DIXON: Yeah. So hearing nothing, I guess we will continue to -- we'll have the microphone open until 10:00. And if we don't hear anything after that, we will conclude the hearing at 10:00.

(Whereupon, a pause was had in the proceeding.)

MR. DIXON: This is Reginald Dixon. It is 10:00, and we have not heard any other further input with regards to the rules that we suggested. So at this time, we will be concluding our rules workshop.

The next rules workshop will start at 10:30, and that will deal with the emergency -- the distribution of emergency use of medical oxygen. Thank you.

THE WITNESS: (Whereupon, the proceedings were concluded at 10:00 a.m.)

CERTIFICATE OF REPORTER

STATE OF FLORIDA )

COUNTY OF LEON )

I, SCHEDALE L. WOODS, Court Reporter and Notary Public, do hereby certify that the foregoing proceedings were taken before me at the time and place therein designated; that my shorthand notes were thereafter translated under my supervision; and the foregoing pages numbered 3 through 9, are a true and correct record of the aforesaid proceedings.

I FURTHER CERTIFY that I am not a relative, employee, attorney or counsel of any of the parties, nor relative or employee of such attorney or counsel, or financially interested in the foregoing action.

Dated this 18th day of June, 2015.

SCHEDALE L. WOODS
FOR THE RECORD REPORTING
1500 Mahan Drive, Suite 140
Tallahassee, FL 32308
(850)222-5491