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

IN RE: RULE NO. 61N-1.001,
RULE NO. 61N-1.012,
RULE NO. 61N-1.013
_____/

RULE WORKSHOP

April 10th, 2015

9:00 a.m. - 9:33 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
(DIVISION DIRECTOR)

RENEE ALSOBROOK
(COMPLIANCE MANAGER)

DINAH GREENE
(GOVERNMENT OPERATIONS CONSULTANT)

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P R O C E E D I N G S

MR. DIXON: Good morning, everyone. This is Reginald Dixon. I'm the Division Director for the Drugs, Devices, and Cosmetics Division. We're going to go ahead and start. It's a little bit after 9:00 o'clock this morning. Today is April 10th, 2015.

Just from a preliminary basis, we have a court reporter here in the room, and so for those of you on the phone and even those of you who are in the room, if you would like to make a comment, it would be very appreciated if you all would state your name and the company that you represent so that we have a clear record on the rulemaking that goes forward from here.

Just to -- kind of an introduction, again, my name is Reginald Dixon. I'm Division Director. Renee Alsobrook is also here from the Division, as well as Dinah Greene, who has been working with us on a lot of our rules. I guess we'll just go ahead and get started unless anyone wanted to make appearances for the record.

(No response.)

All right. The purpose for this workshop this morning is that a couple of years ago, our

legislature passed a statute which authorized manufacturers here in Florida to obtain limited amounts of API, as well as finished product for research and development purposes.

The department initially tried to develop a rule which we thought would allow the industry to continue to do business as they were, but also give the department the ability to do inspections and also ensure that the folks are actually importing and receiving limited amounts of prescription drugs.

We had some comments from that on that rule and so we withdrew the rule and wanted to come back to you all, to the industry, to the folks who would actually be affected by this rule, for you all to give us input on exactly how it is that you think this rule should operate, the language that you would like to see, so that we could hopefully put something together that would both serve the purpose of the statute, as well as not hinder Florida businesses or put you all at a disadvantage.

If you open up the agenda materials, what you'll see -- I'm sorry. The first tab that you have is the version that deals with -- it shows

you the notice, the letter that we received on March 5th from the Joint Administrative Procedures Committee, as well as my letter back to them on March 7th.

But it also has a tab where it says 61N-1.001, which is our general definitions. And the initial language that we had proposed for that to define "limited quantity" is actually included there. Once we -- and I didn't necessarily want to go through all of the languages, unless someone here wanted to do that.

We also, in addition to the trying to define "limited quantities," we also tried to define or put the recordkeeping requirements in there, and also, at Tab 3, the storage and security requirements.

In response to that, we did get several letters. One of the letters, I believe that several folks have commented on, both either to me or in writing, was more in support of the initial letter that we received from Watson or Actavis. Watson gave a thorough explanation of why it is that they felt that the language would be detrimental for companies here in Florida and respectfully requested some changes to that

language.

And so other than the response that we have from Watson, we have not had anyone else to provide the department with any type of substantiative feedback which would help the department develop language. And so what we are seeking today is input from the industry which would give the department some guidance on language that would be both workable, and also, that would allow the industry to continue to operate at a high level.

So what I would like to do, unless someone has any objection, I would like to open it up to the floor for input from anyone who, whether in the room or on the phone, who would like to have some comment.

I could tell you from a departmental standpoint, one thing that would help us is for someone in the industry to give us an idea of exactly what it is and how the process works for them to bring a product to market so that as we try to come up with language, we could keep that in mind as we develop language going forward.

MR. DRAKE: Good morning. My name is Paul Drake. I'm speaking on behalf of Noven

Pharmaceuticals as a qualified representative.

I passed out a addition to the Noven Pharmaceuticals letter that is on the very last page of the agenda packet. I just wanted to add a couple of extra comments. Obviously, I'm here representing Noven and I wanted to assert Noven's position.

We strongly agree with the letter that was written by Watson Laboratories -- well, it was written on behalf of Watson Laboratories -- for several reasons. First of all, in short, the rules can't be "one size fits all." Instead, rules must be flexible enough to allow generic research and development companies the freedom to perform R&D in the way that keeps them competitive in the workplace -- in the global marketplace.

For example, in the proposed rule, it's -- and in several of the rules previously, proposed amendments, it stated timeframes for the ability of -- for limited quantities, anywhere from 30 days to 3 months to 6 months, and that's just not necessarily how the industry works.

The -- some -- for example, some research and development projects can last a year, two years, three years, and my client's even said up to eight

years for some companies and some products.

And to limit them to only being able to purchase a three-month supply or even a six-month supply is a severe handicap, because sometimes they just can't project exactly how long they're going to be working on a certain project. They need to buy all of their API at the same time so they get the best -- they get a consistent batch.

Also, this is how it works in the industry: If a competing company finds out that they're working on a product, they'll attempt to buy up the volume. So it's very important for -- if you want to stay competitive when you're developing these generic drugs, that you are able to buy as much -- all the API that you need or that you can foreseeably need. And so we agree with the Watson amendments that strike the language of the supply, the three-month whatnot, written on Page 3 of the -- of the Watson letter.

Also, we agree with Watson's second rule change regarding -- regarding recordkeeping. It's extremely important that under, of course, for the DDC program, any confidential -- or any documents obtained we -- we strongly suggest and we recommend that they remain confidential and exempt

from disclosure under Chapter 119 as trade secret information.

Any inadvertent or improper disclosure of confidential trade secret information could cost an R&D company potentially millions of dollars. So once again, we agree with the Watson Pharmaceuticals amendment to the -- to the rule change there.

And we just think that the rules as -- the rule changes, as stated, submitted by DDC would -- could potentially cost millions of dollars and hundreds, if not thousands, of jobs in Florida due to handicapping companies like Noven, like Watson, and others from being competitive in the global marketplace. Thank you very much.

MS. ALSOBROOK: Mr. Drake, before you leave, what was your recommendation on the recordkeeping requirement? I think the initial rule had monthly and quarterly. What's the recommendation from Noven as to maintaining records?

MR. DRAKE: We agree with the Noven recommendation on Page 4 of the -- the Watson recommendation on Page 4 of their -- their letter. Their alternative, we agree with that alternative. We also agree with their alternative for the

limited quantities on Page 3, their language for that one as well.

MS. ALSOBROOK: And do you have any comment as to why a period of every six months or quarterly would be too burdensome to the industry?

MR. DRAKE: Well, like I said earlier, it's just very difficult to determine whether -- like, how much product you need at any specific time. Like, if they could only purchase up to three months, there's a good -- there's a chance that that active pharmaceutical ingredient could either have a shortage or competing companies could find out that they're trying to develop that drug, and therefore, purchase the rest of the -- the API of that specific drug that's on the market, therefore handicapping our client and every other company that does this as well.

So it's good to just be able to allow them to purchase in bulk for as long as they need, while still maintaining, obviously, recordkeeping requirements. They're going to be open to, you know, share the information with the DDC, of course --

MS. ALSOBROOK: As long as we can make sure that that -- the trade secret --

MS. DRAKE: Of course.

MS. ALSOBROOK: -- is maintained?

MR. DRAKE: Absolutely. Thank you.

(Whereupon, Exhibit No. 1 was marked for identification.)

MR. DIXON: Did anyone else have any comments that they would like to make at this point?

(No response.)

One of the questions I would like to ask -- this is a follow-up to the question asked by Ms. Alsobrook. With regards to recordkeeping, the division, at one point, had draft language that required monthly updating and quarterly updating. And I know Mr. Drake spoke a little bit towards supporting the Watson proposition that those records only be updated annually.

Does anyone in the room or anyone in the audience, can anyone speak to exactly why updating your recordkeeping, the records that you have, quarterly or bi-annually versus annually would be burdensome to their clients or to their business?

(No response.)

Okay. With regards to the requirement for the storage, the department proposed language

which basically said that any product that was received pursuant to this chapter -- pursuant to these provisions, that those products had to be physically segregated from all other products intended for manufacturing, compound, dispense, or administration and in the manufacturer's establishment. These drugs also had to be stored and maintained separate and clearly -- in a clearly designated area.

Does there anyone on the phone or anyone in the room here have any comments as to whether or not those requirements would be overly burdensome on them or their clients? Okay.

MR. YUDAN: Michael Yudan, Actavis Pharmaceuticals.

I'd like to ask clarification regarding the -- your understanding of whether quantities are to be updated at least annually or quarterly. Are you referring to R&D-branded quantities that we use for -- I'm sorry, for branded products that we use for R&D development and for new projects, or are you talking about updating the inventory annually and making sure that the quantities that you bring in match the quantities that are in your inventory?

MR. DIXON: I'm sorry, say that one more time.

MR. YUDAN: Yeah. I'm not exactly sure your question regarding -- where you're taking -- the question about whether or not quantities should be updated quarterly.

MS. ALSOBROOK: We're looking at the letter written on behalf of Actavis -- Watson/Actavis by Mr. Serio back in 2013. And it's Paragraph 17, and it's on Page 4 of that letter.

MR. YUDAN: Okay.

MS. ALSOBROOK: Paragraph 17 specifically. You see, it's like Line 3 of the proposed rule where the recommendation was "updated at least annually." It says specifically, "These records must be created in advance of or contemporaneously with particular R&D activities and are subject to" -- I'm sorry -- "and are subject to inspection under Section 499.051, Florida Statute. R&D quantities for all phases must be updated at least annually." That was the proposal that was set forth on your behalf.

MR. YUDAN: Right.

MS. ALSOBROOK: It's my understanding that that would be your records and the quantity left,

or the amount you're holding for R&D, would be updated annually. We're asking specifically if it would be a burden for you to update the amount of API you're holding for R&D quarterly or semi-annually?

MR. YUDAN: I guess what I can say is that the -- since we're a GMP facility, which is we follow good manufacturing practices that maintain an inventory -- and actually live --

MS. ALSOBROOK: Yes.

MR. YUDAN: -- is what is followed. So we follow annually inherently in the fact that we are a GMP facility. And we -- it's more of a sort of live sort of exercise, so the inventory is always live. Does that make sense?

MS. ALSOBROOK: Yes, it does. And I guess that's why we're asking, because if you're following the GMP procedure, it seems like almost daily, you know what your inventory is.

So I guess what I'm trying to understand, as the Chief of Enforcement, if I came into your facility and asked you on any day, what is your current inventory of API, I would expect that you would know that as a good manufacturer.

I'm just not trying to make you generate a

record, so that's what I'm trying to learn from you, how would I find that out? I mean, if you ordered 1,000 kilos for your research project to go eight years and I come in there in year two, I would want to know, how much do you have?

But I don't want to inflict upon you some silly recordkeeping requirement if you can produce that in some manner. So is there some GMP terminology that you could give me that I could insert into a record-keeping requirement?

If you could write -- I mean, I hope the director would leave the record open so that you can come back and think about something that you could tell us that's consistent within the industry that we could put into a recordkeeping requirement so I don't generate some document that you've got to write.

That's the purpose of the workshop, so that I can learn what the industry would call that document. And we could come in and say, oh, well, they've used "X" amount of these developments in their inventory of 100,000 kilograms or 8 kilograms is down to "X", based upon what they've used. You understand where I'm trying to go?

MR. YUDAN: I understand.

MS. ALSOBROOK: Thank you.

Did I confuse everybody else or was I successful? No. Good.

Brittany, did I get you all confused since you've got to help me?

Now, back to the director's question about separation, is that still okay with everybody? You could maintain a separation of your research and development drugs from others?

MR. DIXON: Did anybody have any comments on that at all? The reason we're asking, truthfully, and what we're looking for is we're looking for input from the industry. And what we would hope is that we would get input, so that once we wrote the language, we would avoid necessarily having to have a rule challenge and having to go through all of this again.

So that is why -- that is one of the reasons for having this -- this type of an open discussion where we could gather information from folks. So it's almost like voting. If you don't vote, you can't complain about the person that you -- get elected. Does anyone have any concern about the requirement that you keep the API segregated?

MR. DRAKE: Paul Drake again.

When you say "physically segregated," how would that -- how would that be? Would it just have to be in a separate locker? Would it just be, kind of like, a separate area of a shelf? I mean, how strenuous is this going to have to be?

MR. DIXON: Generally speaking, sort of like a quarantine area in the sense that it's just got to be a separate area of your facility where you designate, this is the API for research and development.

MR. YUDAN: Could it possibly be in the same room as others?

MR. DIXON: I do not believe that we have -- that this draft would require a separate room or anything. The only thing that we're always looking for when we go in, from an enforcement perspective, is that you have it clearly designated and separated.

MS. ALSOBROOK: I think that the other thing in the room was probably the previous rule's use of the term "transactions." I'm understanding from all of you that that is something that we just can't use in the rule, the number of transactions.

If you looked at the prior draft, they have

used -- let me go to the previous draft real quick. I'll read just quickly. "Limited quantities, non-clinical, pre-clinical for purposes of non-clinical research and development, the number of transactions necessary to advance the program to a clinical stage, provided that the researcher may not acquire or have on hand one of the three-months supply of any product." And it goes on.

That phraseology is not consistent with industry practices. Is that what I understand from the comments we've been receiving? Can anybody speak to that?

Good deal. Thank you. One more time for the record, give us your name.

MR. YUDAN: Michael Yudan, Actavis Pharmaceuticals.

Can I get some clarification on your question again?

MS. ALSOBROOK: Well, I think that when the draft was written, the thought was, because we aren't manufacturers, that maybe you just ordered API periodically throughout the research project, and that periodically, through the process, you ordered API and those were transactions. That's

the phrase we were, I think, using. I'm gathering that that is not the case, that you order API for the entire project; is that correct?

MR. YUDAN: That's correct.

MS. ALSOBROOK: Okay. And not to lead you, because as a lawyer, I would do that, but is that to maintain the consistency in the API that you use for the project, as well as to keep other competitors from obtaining the API? Or what is the basis for ordering a bulk of the API for the research project?

MR. YUDAN: Those two are also reasons, but there are other reasons besides that. The -- one of the reasons, in addition to the other two that you just mentioned, was that it takes a long time to synthesize the API.

So when we start a project, a generic project actually has a shorter duration from start -- from inception of the project to the actual submission of the ANDA to the FDA than a branded product does, so we have a shorter time to develop and submit.

And obtaining -- in some cases, the API takes months to synthesize. So we want to obtain as much API as we can IN the beginning so we know we

don't have to have that synthesize -- the synthesis -- they don't have to synthesize later down the road, which would impact the timeline.

The other thing is variability. So there is lot-to-lot variability. So in order for us to reduce the variability, you want to order all of one lot as much as we can in the beginning so we could reduce that variability down the road because we --

MS. ALSOBROOK: That -- okay. That, I understand. Okay. Thank you. Thank you very much.

MR. DIXON: Okay. One more time, does anyone else have any other comments that they would like for the department to consider with regards to the definition of "limited quantities," any of the recordkeeping requirements, or the storage requirements that are proposed, or anything that you would allow -- that you at least want the department to consider in going forward? As it goes forward, we're trying to put language together on these rules.

MR. RUSSELL: I have a general question or comment. My name is Joey Russell. I'm with Nephron Pharmaceuticals.

MR. DIXON: Go ahead, Mr. Russell.

MR. RUSSELL: It seems that the -- and I'm just -- I'm assuming these things. I don't know them. But it seems like the original intent of the language in Chapter 499 was to provide exemptions for non-permitted entities to distribute materials within the state.

And I'm just wondering if -- because in 499, section (3), it's the exemption for a non-resident prescription drug manufacturer. And (4)(b), it has to do with a -- distributing limited quantities, again, in the states from an establishment located in the United States to an establishment -- anyway, it's a -- it's a way to control non-permitted entities from distributing drugs in the state.

I'm wondering if now, with the passage of the Drug Quality and Securities Act and the permitting requirements that are outlined within it, if maybe the -- maybe the thinking on the topic has changed at all?

MR. DIXON: I think that I -- well, let me put it this way: I understand your question but I do not believe that the answer to your question is relevant to the actual -- the rule workshop, in

the sense that I understand that you're saying that there may be some additional licensing requirement because the DQSA has implemented it and it may require licensing, whereas, other folks may have thought it exempted licensing.

But the truth of the matter is Florida Statutes have not changed, and unless and until they do, then we've got a legal obligation to try to go forward with developing a rule that allows companies to actively engage with the possession of these products or these substances. I won't say "products," because "products" is a DQSA term now.

But we have to try to come up with a rule that gives meaning to our statute. So unless and until our statutes have changed -- I know that's a long answer -- that's a long non-answer to your question, but it would not be a good idea for us to try to give you, you know, legal interpretation of what the requirements of DQSA are and how they impact these exemptions set up under 499.01.

MR. RUSSELL: Okay, that's a fair response. And my comments then on the -- on the "limited quantities" language -- and I can only look at this from a manufacturer because that's the --

that's the environment that I'm in.

But from our perspective, we have -- we have so many recordkeeping requirements that we have to meet in terms of the -- just the federal requirements and the GMP requirements, the additional layers of recordkeeping, I think, is what we get hung up on from time to time.

So I think our general recordkeeping practices -- and it sounds like the other comments previously alluded to this as well -- our normal and our standard recordkeeping requirements for commercial products would seem to be adequate for the kinds of information that you're looking for.

MR. DIXON: Thank you.

Does anyone else have any comment about the recordkeeping requirements? We're not going to hold you guys to the comments. We're just -- we really are just looking for input from the industry. We're not going to tie you down, that you told us to this so you have to follow it.

MR. YUDAN: Mike Yudan again.

We agree with the statements that was just made. Yeah.

MR. DIXON: Okay. Did anyone else have any comments at all regarding the drafts that are

available for you, or anything else that you would like the department to consider going forward? Going once.

(No response.)

Okay. Well, as always, I guess if you all have some more comments that you subsequently develop after having had some time to think about this, we would ask that you submit those to our office, to Ms. Greene, I guess we could say by -- what we would like to do is leave this record open for a week. That would be until next Friday, 5:00 o'clock next Friday, April 17th, to submit additional submissions.

If you have additional language, or additional comments, or anything else that you would like for the department to consider, forward those documents to Ms. Greene, and what we'll do is we'll attach those to the record of these proceedings, and we will use that and we will consider that information going forward.

Otherwise, I guess we will conclude this workshop. Thank you, everybody.

(Whereupon, the proceedings were concluded at 9:33 a.m.)

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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 24, 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 10th day of April, 2015.

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

DDC Rule Workshop
April 10, 2015

Noven Pharmaceuticals, Inc., affirms the view of Watson Laboratories in their letter to the DDC, regarding changes to Rules 61N-1.001 and 1.012, F.A.C. The DDC's proposed definition of limited quantities will inhibit the ability of R&D drug manufacturers in Florida, like Noven, to compete against similar companies located in other states and around the world. The DDC's proposed rule changes will have the unintended effect of codifying a competitive disadvantage in the marketplace for generic manufacturers engaging in R&D in the State of Florida.

In short, the Rules cannot be one size fits all. Instead, the rules must be flexible enough to allow generic drug R & D companies the freedom to perform R&D in the way that keeps them competitive in the global marketplace.

Provisions that limit the amount of active pharmaceutical ingredients supply to any time limit will be a severe handicap, as the industry does not operate on such strictly defined timetables. Some R&D projects last as long as 8 years, and enough API must be purchased at the beginning of the process to last the length of that project. Furthermore, if a company orders product in batches, and a competing generic manufacturer learns of the orders, the competitor will often attempt to buy up the remaining available volume.

Noven also agrees with Watson's second rule amendment. It is critically important that any confidential R&D documents obtained by the DDC Program, pursuant to its inspection authority under Section 499.051, F.S., remain confidential and exempt from disclosure under Chapter 119 as trade secret information. Any inadvertent or improper disclosure of confidential, trade secret information could cost and R&D company millions of dollars. This will again handicap companies like Noven and Watson, with the potential to put thousands of Floridians out of work.

Thank you for taking your time to consider our view on this matter.