**NWX- HHS FDA CDER**
**Transcription of Teleconference**
**with Innovator Industry**

**Moderator: Michelle Eby**
**August 19, 2016**
**12:30 pm CT**

Coordinator: Welcome and thank you for standing by. At this time all participants are in listen-only mode until the question and answer session of today's conference. At that time you may press star 1 on your phone to ask a question.

I'd like to inform all parties that today's conference is being recorded. If you have any objections, you may disconnect at this time. I would now like to turn the conference over to Michelle Eby. Thank you. You may begin.

Michelle Eby: Thank you. I'm Michelle Eby and I would like to welcome you to this TCON where we will discuss an upcoming FDA Public Meeting on FDA's draft guidance on evaluating the abuse deterrence of generic opioid drug products and testing of innovator and generic abuse-deterrent formulations.

For purposes of questions and answers questioners will not be identified by name in order to protect caller confidentiality. The call is being recorded and will be transcribed.

I would like to introduce Dr. Doug Throckmorton who is CDER's Deputy Director of Regulatory Programs, and Dr. Robert Lionberger who is the Director of the Office of Research and Standards in CDER's Office of

Generic Drugs who will be leading the call for FDA. Thank you again for joining. Dr. Throckmorton.

Doug Throckmorton: Michelle thanks very much and thanks to everybody for making time on this, at least it's a sunny afternoon here in DC to be on this call.

This call is focused on the innovator companies who have approved opioid products and have expressed some interest in developing abuse-deterrent opioids.

We wanted to talk to you about a two-day public meeting that the FDA is planning on holding October 31st and November 1st near Silver Spring. You may have seen the Save the Date Notice the FDA posted on our CDER Meetings web site recently.

In this call, I want to discuss your participation, specifically the industry participation, in that meeting. On day one, FDA will be asking the innovator industry as well as the generics industry to present perspectives on the draft guidance, the "General Principles for the Evaluation of Abuse Deterrence of Generic Solid Oral Opioid Drug Products" that we made available for comment earlier in the year in March I believe.

On the second day of the meeting, we'll be asking the same two industries to give perspectives on the standardization of the in vitro testing that would be useful when evaluating abuse-deterrent formulations.

As you know and as I've talked about it and others have about publicly we, the FDA, want to do what we can to spur the development of successful abuse deterrent opioid products including generics to expand access and use of these products and, in turn, discourage opioid abuse.

We want to talk to you today so you understand what you can do to help that development and that process specifically through participation in that public meeting.

So I have a couple of requests for you. In the first – during the first – on day one we've carved out a period to present the innovator drug industry perspective on the draft guidance. We also have a one hour time slot on day two to present the innovator industry perspective on standardization of the in vitro testing for abuse-deterrent formulations.

We believe the most efficient use of these time slots would be for your companies to work together to develop a central message and have a representative present. This is something we used in 2014. Many of you probably remember. We found it to be very effective and I think both industries and the comments that they made were terrifically useful to us. And I'm hoping it will be something that we'd be able to count on you guys for again.

Separately, FDA is contacting generic manufacturers in this same way. And they'll be given separate time slots on those two days. We'll be asking them in a similar fashion to identify presenters and determine presentation content.

In addition, at the end of each day, there will be a panel discussion. The panel discussion could include a variety of different people. We haven't settled on that specifically yet but could include industry, government experts, academic experts and other stakeholders.

That panel will be asked to give overviews on what they've heard and participate in a general discussion that we plan on putting out specific

questions in the Federal Register Notice about this meeting. And we hope that those questions will drive specific comments related to the topics we need to have help on and focus the discussion. We're hoping that that panel discussion will focus attention on the questions.

As a next step, I'd like to ask the groups on this call to work together to identify a representative speaker in the categories I mentioned above, first, an individual to present the innovator's drug industry perspective on the draft guidance on day one. And an individual to participate in the panel discussion at the end of day one, whether that's one individual that gives the talk in the morning and then participates in the afternoon is up to you.
I also need to ask you for an individual on day two to talk about the standardization of in vitro testing for these deterrent formulations and then an individual or the same individual to participate in the panel discussion at the end of day two.

Those names, once identified, should be sent to Michelle Eby. And it would be useful to have those by beginning of September, September 1st so we can make planning, efficient planning.

I'll just say again it worked really well for us in 2014 and I think it would work very well to have this sort of approach taken here.

Michelle, Rob or myself are happy to answer any questions that people have. If there are written questions, please send them to Michelle Eby and we will work to respond to them quickly. Like I said, there will be an FR Notice that will be coming out as soon as possible. And obviously you'll all be notified when that's published.

This is an important call – issue for the agency. We're taking it seriously. And I look forward to continuing to work with all of you. Michelle, I'll turn this back over to you for any questions.

Coordinator: Thank you. We will now begin the anonymous question and answer session. If you'd like to ask a question, please press star 1. If you need to withdraw your question, press star 2. Again to ask a question, please press star 1. You will be announced by your port number to ask a question. It'll take a few moments for the questions to come through. Please standby.

Our first question is from caller number 1-13-3-18. One moment please. Go ahead your line is open.

Penny Levin: Hi Dr. Throckmorton. And thank you very much. This is Penny Levin from TEVA.

Doug Throckmorton: Hi Penny.

Penny Levin: And I was – hi. How are you?

Doug Throckmorton: Good.

Penny Levin: I'm inquiring a little more about the process as I was intimately involved in the hearing preparation in 2014. So as I understand the expectation is we will get you that information by September 1 and then will Michelle be – what is the next step in bringing the groups together because we'll have an innovator group and we'll have a generic group? So I want to help ensure that I'm bringing this information back to my team properly so that we can get you what you need.

Doug Throckmorton: How did that work in 2014? What was the next steps after the names got back because that worked well?

Penny Levin: Well. Yes.

Doug Throckmorton: I guess unless it was broken I'd suggest we at least start there.

Penny Levin: It did work really well. We wound up having a lead from the innovator side from one company and a comparable lead from the generic. I wound up being on the generic one and then I was leading the generic but I participated in the brand.

And that helped to kind of keep, you know, set up the meetings, get the calls going, put our slides together while all the companies still participated but it kind of gave a little order to it if you will.

And that happened rather rapidly so, you know, if we can help Michelle in any way to facilitate that. And I think what you did is you sought out, did someone want to step up and take that. And you kind of described what was involved in it.

And then other companies said they wanted to participate. And it became – it kind of became clear pretty quickly where those people could do what. But everyone worked really well together through the whole process.

Doug Throckmorton: Yes. I don't know why we should change from that. As you know, that was one of the better meetings of this kind I can recall in my time at the agency so I, you know, whatever worked there I would say we should do again here. I don't know. Rob, you guys have other comments.

Robert Lionberger: No. I think that worked well previously.

Michelle Eby: Yes, that's my understanding as well.

Penny Levin: Okay, great.

Doug Throckmorton: You'll get back to us if there are any issues that we need to be helping with – around that. But yes, to the extent the groups can work – keep each other apprised of where this is going I think that will be really good.

Penny Levin: And one other question. When you put the FR Notice out, will that include times for when you need presentations and so forth or will there be ongoing [telecons] with industry to ensure we get the deliverables to you in a timely manner?

Doug Throckmorton: That will be Michelle's task to keep those things on schedule.

Michelle Eby: Once I hear back from you on September 1st who the speaker will be, I can start working with you. The FR Notice will be published soon after that, and we can work on the time schedule.

Penny Levin: Okay, good.

Michelle Eby: I don't anticipate the timing of the FR Notice to delay us getting the meeting organized.

Penny Levin: Thank you.

Doug Throckmorton: Rob you already have the agenda framed. You and Rik) have the agenda-- correct?

Robert Lionberger: Yes.

Doug Throckmorton: OK once that FR is out, Michelle should be able to share all of that with you guys.

Penny Levin: Thank you.

Coordinator: Our next question is from caller number 1-1-8-19. Go ahead, your line is open. Caller we're unable to hear you. Please press your – unmute your button. Again caller 1-1-8-19, we're unable to hear you.

Dan Cohen: Yes. I can hear you now. I apologize. This is Dan Cohen with Abuse Deterrent Coalition.

My question was just asked by the TEVA rep. It's been answered. So thank you Doug for the presentation. We'll get you more information.

Doug Throckmorton: Thank you very much, yes. And I look forward to it.

Coordinator: We show no further questions at this time. Again as a reminder press star 1 on your phone if you have a question. One moment please. We show no further questions at this time.

Doug Throckmorton: Thank you. I'm looking forward to this meeting. I can tell you that Dr. Califf and I have had a couple of conversations about it. We're very interested in the feedback we get here and hope it's as successful as the one in 2014.

I'll say thank you then unless there are other things we need to talk about.

Michelle Eby: Well thank you very much.

Doug Throckmorton: Great and have a great day guys.

Coordinator: That concludes today's conference. Thank you for participating. You may disconnect at this time.

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