NWX-FDA OC

Moderator: Michelle Eby
Transcription of Teleconference
with Generic Industry
August 19, 2016
1:15 pm CT

Coordinator: Welcome and thank you for standing by. All guests will be in a listen-only mode for the duration of today's conference until the Q & A session at the end of the presentation.

This conference is now being recorded. If you have any objections, you may disconnect at this time. Once again, for the Q & A portion if you would like to ask a question, please press star then one. 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Michelle Eby and I would like to welcome you to this TCON where we will discuss an upcoming FDA public meeting on FDA's draft guidance on evaluating the abuse deterrence of generic opioid drug products and testing of both innovator and generic abuse-deterrent formulations. For purpose of the questions and answers, questioners will not be identified by name in order to protect the caller confidentiality. The call is being recorded and will be transcribed.

I would like to introduce Dr. Doug Throckmorton -- who is Senior Deputy Director of Regulatory Programs -- and Dr. Robert Lionberger -- who is the Director of the Office of Research and Standards and CDER's Office of Generic Drugs, who will be leading the call for FDA. Thank you again for joining. Dr. Throckmorton.

Dr. Doug Throckmorton: Thanks Michelle and thanks to everybody that's made some time on a Friday afternoon to join us on this call. This call is focused on companies that are developing generic products who have an approved opioid product or expressed some interest in developing generic abuse-deterrent opioids. We wanted to talk to you about a two-day public meeting that the FDA is planning to hold on October 31st and November 1st near Silver Spring, Maryland. You may have seen the save the date notice FDA posted on the CDER meetings and Events page on its website already.

What I'd like to talk to you about is the industry participation in that meeting, specifically the generics industry participation. On the first day, FDA is going to be asking industry to present its perspective on the draft guidance, "General Principles for the Evaluation of Abuse Deterrence of Generic Solid Oral Opioid Drug Products" that we made available for comment in March. And we want to make sure that we hear from both the innovator side as well as the generics side.

On day two, we'll also be asking for comments on the standardization of in-vitro testing of abuse-deterrent formulations. And again, we think it's important to hear from the broad spectrum of the industry in this area. As you all know, an important part of FDA's work in opioids is spurring the development of successful abuse-deterrent opioid products, including the development of generic abuse-deterrent opioid products to expand the access to abuse-deterrent formulations that successfully discourage opioid abuse.

So what are we asking you to do in these two days? On day one, we've carved out a one hour time slot for you to present the generic drug industry perspective on the draft guidance. And, on day two we have another one hour time slot to present the generic industry's perspective on the standardization of in-vitro testing of abuse deterrent formulations. We believe the most

efficient use of those time slots is to have the group on this phone call work together as companies to identify an individual to speak for the generics industry and have that representative present that information.

This approach worked well in 2014 for the last meeting on this topic and we hope that the group of companies that are on this phone call could get together and identify an individual like that. If that's not successful, our fallback strategy will be to work with the trade organizations, because we think it's important to have a common voice to present the perspective from the generics side. We are also contacting the innovator manufacturers and those companies will be given separate time slots covering the same topics from their perspective.

At the end of each day, there will be a panel discussion. So there will be a panel discussion at the end of day one and a panel discussion at the end of day two that will include -- among others -- industry and government experts, academic experts, and other stakeholders. Those panel members will be asked to give an overview of what they've heard during the day's discussion and participate in a discussion overall.

FDA plans to put specific questions into a federal register notice similar to what we did in 2014 and we intend to focus the discussion on those questions. We hope that speakers in both the morning sessions as well as the afternoon discussions would answer those questions as best they can for their respective industries. As the next steps, then, I'd ask the groups on this call to work together to identify a representative speaker or speakers for day one to give a generics drug industry perspective on the draft guidance in the morning and then participate in the discussion in the afternoon.

Now, that can either be one individual giving both the presentation and then participating in the discussion or two individuals, one giving the presentation and then another participating in the discussion. It is up to you. Do whichever way is more efficient. And then we would like a second individual to comment on day two about the standardization of in-vitro testing for abuse-deterrent formulations and similarly either participate in the discussion in the afternoon or identify someone else that can participate in that discussion.

I'd ask you to talk amongst yourselves and get those names to Michelle Eby by September 1st - so that we can continue to make planning for the meeting efficient. I'll say again--this worked extraordinarily well in 2014. It was one of the better meetings we've had that I participated in around soliciting discussions like this. And I hope we'll have a similarly successful meeting this time.

Michelle would be happy to answer any written questions that you have; she'll contact myself or Rob or whoever we need to to get you an answer. We are working on the FR notice, including the questions and topic we'd like you to focus on. Obviously, we'll let you all know when that publishes. And I guess let me open it up from here. Let me just say again, this is an important topic for the agency, and an important topic for HHS. Abuse-deterrent formulations are an important part of the action plan that we laid out earlier in the year. And this meeting is an integral part of making our guidance to you a success. Look forward to working with all of you, look forward to seeing you all at the meeting, and I'm happy to answer questions or turn them over to Rob as the case may be.

Michelle Eby: Hello (Karen)?

Coordinator: Thank you. At this time, if you would like to ask a question, please press star then one and record your first and - I'm sorry, record you port number as again this is an anonymous Q & A session. Once again, please report your port number that was given to you earlier in the conference. If you have any questions, please press star then one and record your port number. Thank you. One moment for your first question. Once again, please press star then one if you have any questions at this time. There are no questions at this time.

Dr. Doug Throckmorton: Gosh, I'm good but not that good, folks. We are happy to answer any questions that we can. This really is important for us.

Robert Lionberger: It would also be helpful if one of the organizations on the call would volunteer to begin the coordination process for the generic industry by volunteering and indicating your contact information so that other members on the call who wish to engage in the process can contact you. So we're hoping that one of the organizations on the call will step up and take that role.

Coordinator: Thank you. Once again, please press star then one if you have any comments or you would like to ask a question at this time. We do have one question or comment that just came in from port number 14823. Your line is open.

Man: Yes, how many total representatives are you looking for? Two on the first day, two on the second day? And how many representatives will be coming from the innovator firms?

Robert Lionberger: So we've identified for the generic and the brand industries four potential slots, which is one speaker for the first day, one panelist for the first day, one speaker for the second day, and one panelist for the second day. If the industry wants to send one person to cover all those roles, that's perfectly acceptable. If they want to send four different people or two different people, both of those

approaches are acceptable. But there are up to four individual slots for both brand name and generic industries.

Dr. Doug Throckmorton: There are an equal number of slots for both brand name and generics.

Robert Lionberger: So the same - an equal number for both the brand and the generic industry.

Dr. Doug Throckmorton: And the durations of time are the same as well.

Man: I'm sorry, was that four from the generic industry and four from the innovator industry?

Dr. Doug Throckmorton: Yes, that's correct.

Man: Thank you.

Coordinator: Thank you. There are no further questions or comments at this time. One moment, please. We have a question or comment coming in from port number 111814. Your line is open.

Man: Thank you. I have a question; has the agency received any comments or questions on the draft guidance and if so, will they be part of the two-day meeting? Will that be included to share in this meeting?

Robert Lionberger: So the comments that we received in the docket are all public.

Robert Lionberger: So you can go to the docket for the guidance and you can review the comments that we've received so far. At the meeting, there will be presentations from FDA staff that will address some of the issues raised in the

comments as well and they'll be discussed. And there'll certainly be discussion around the comments at the meeting, both in the panel discussions and hopefully from the industry presentations as well.

Man: Thank you.

Coordinator: Thank you. Once again, please press star then one if you have any questions at this time. There are no further questions or comments.

Dr. Doug Throckmorton: All right, well thank you very much for making time to meet wit us. We look forward to hearing from you. Rob laid out an important next step, having someone step up to help coordinate the industry response for the generic side. Hopefully you'll be able to get us a name or names to Michelle Eby by September 1st and look forward to your active participation in the meeting. Thank you very much.

Michelle Eby: Thank you.

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

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