

**FDA Webinar: Coordinated Development of Antimicrobial Drugs
and Antimicrobial Susceptibility Test Devices**

Moderator: Irene Aihie

February 12, 2019

3:00 pm ET

Coordinator: Good afternoon and thank you for standing by. I'd like to inform all participants that your lines have been placed in a listen-only mode until the question-and-answer session of today's call. Today's call is also being recorded. If anyone has any objections, you may disconnect at this time. I would now like to turn the call over to Ms. Irene Aihie. Thank you. You may begin.

Irene Aihie: Hello, and welcome to today's FDA webinar. I am Irene Aihie of CDRH's Office of Communication and Education. On January 17 the FDA issued the final guidance document, Coordinated Development of Antimicrobial Drugs and Antimicrobial Susceptibility Test Devices. The goal of the guidance is to minimize time between the approval of new antimicrobial drugs and the clearance of antimicrobial susceptibility tests for those drugs, and to provide recommendations to the medical device and drug industry, on how to work together to facilitate timely antimicrobial susceptibility test device clearance by the FDA.

Today, Dr. (Ribhi Shawar), Branch Chief in the Division of Microbiology Devices, here in CDRH, will present an overview of the guidance document.

Following the presentation, we will open the lines for your questions, related to the information provided during the presentation. Additionally, there are other center subject matter experts here, to assist with the Q&A portion of today's webinar. Now, I give you (Ribhi).

Dr. (Ribhi Shawar): All right. Thank you, Irene, and thanks to Dr. John Farley being here as well. Good afternoon everyone and welcome to the AST coordinated development webinar. We'll go over the outline of the presentation. First, we'll go over some background and types of devices and important regulations. Then go over some FDA review of traditional drug and device submission. Highlight the concerns about the antimicrobial drug approvals and availability of AST devices.

And talk about coordinating development activities that have been growing on FDA mind and finally end with some highlights. our objectives. The aim of the webinar is to familiarize stakeholders with the (history) of coordinated development of antimicrobial drugs and antimicrobial susceptibility test devices. And you will hear me a lot saying AST devices that have from now on, but for the couple of times perhaps we'll say the full words, so that people understand.

And so, we go over that again, the peer review process for the availability of AST devices. And also, to provide an update on FDA guidance for coordinated development and the various supportive activities. On slide number 5, perhaps we'll start with some definitions. Like I said, antimicrobial susceptibility test devices or AST devices. Suffice it to say that these devices and drugs are regulated by FDA as many of the people on the call of course, know. But specific to this topic today, what is an antimicrobial susceptibility test device?

Is an antimicrobial susceptibility test that incorporates concentrations of antimicrobial agents into the system? So, the purpose of determining and retest susceptibility of isolates that are selected from clinical specimens typically. Test results steps, are used to determine the antimicrobial agent of choice or help the physician in their choice of diseases.

That's the regulatory devices and the different regulations and uses multiple products depending on the device. And on slide 6, again, I think many of the people I expect who are on the call and have interest in these devices, do not need a lot of definitions here. But for the purpose of that and so everybody is on the same page, there are various types of AST test devices, from (film) devices such as the fusion based devices, they may have or they're valuation based devices, which come in also various formats.

And concentration, for example, those devices, there are . Those devices that are instrument for example, such as both and they have algorithm in other the type of result that the has. There are variations in test methods and those can include the method and conflicts of their implementation. The point on this slide is really not to again, lecture on this topic specifically.

But to highlight that because of these differences in devices the point of the slide is to provide a value that - or highlight that because of these differences, there are - I think they could be considered or should be considered, particularly on this topic of development, because some development will require a little bit more elaborate studies up front than other. On this - on slide 7 now, these are the relevant susceptibility test devices; their reviews, their regulations, and guidelines. These devices are two devices. They require a five market notification and therefore they are nonexempt.

But in the detailed timeline they are subject to the same type of timelines that are other devices as well. They're subject to a 90 day review cycle. They are under the regulations in regulation, and there are numbers here of the various regulations the slide. But suffice to say, that depending on the device side, your tactical regulation is outlined there.

(CDER), our sister agency center, for research, and (TVRS), have various guidelines that outline the type of studies, the data requirements, evaluation criteria. And there are in addition, many FDA recognized guidance and standards, for example, such as standards from standards that also are needed to govern the type of study and evaluations that are invested for these studies.

Now on this slide this is a slide that actually is just showing here the diversity of for AST test devices and devices that have the resistance marker. I'm not going to read this slide again. Suffice it to say that you see on the slide the various test methods. For example, subculture media that detect resistance for test devices that are disks for regulation for a connected system. Another regulation for nucleic acid tests and direct for specimen, are also for manual susceptibility test devices.

Lot of abbreviations on this slide and some of them are defined below. Again, I'm showing this slide in order to also highlight that because of the various regulations, there are indeed in these various CFR, the data and the performance that is required, is part of that kind of evaluation that we have to go through, because of the differences that are taken into consideration.

Now the - this is a - on this slide 9, so this is a review of traditional drug and device submissions. Here are two sides of this. There's the drug manufacturer and there's a device manufacturer. So, we go on the left side first. The drug manufacturer, this is the usual, traditional process. By no

means is this is oversimplifying obviously the drug reviews as well as the device reviews.

But it was the first . The drug manufacturers usually have investigation in a drug or (RND) application. These are reviews. Then the new drug application submission and is reviewing that on the device side. The traditional way the device manufacture then they do the studies, have met the direct for review, and then an AST susceptibility review test is clear.

And the center on the slide, the final breakpoint and indicated all of this are the factors that play into the type of evaluation that needs to be conducted and that of the firm analysis such as the evidence on the break points, for evaluation of the . There are a couple of slides here that I'm going to go over. The as the devices - to highlight what are the studies, the usual studies that are associated with which thing. And this slide is about the drug and again, this is not meant to really - it was meant only to highlight the - in a high level, the type of surveys that are conducted in which (way).

When is it meant to give a detailed look on how things are evaluated? So, for anything like those drugs, the timelines usually are the phase ones, are (IMDM) and then phase one for two and three, and then the NDA. And various activities are taking place at the various phases. For example, in the (IMDM) phase one, there's basic microbiology profiling, research and development. There's not an evaluation mechanism of action .

Then later on the - for example, the potency studies are included as - in later phases and then microbiology trial, that his data is part of the NDA, which includes reference methods for consolidation. For example, in (CDER) review the quality (control rates) and breakpoints and decide on that. The

next is about the AST device time management. And the first one is for the form of AST devices that we think of as the disk diffusion. That's us.

And in that the - just for simplicity here two phases as an area of research and development, where the drug manufacturer perhaps is working with the disk manufacturer to produce either an investigational or RUO disk for that particular drug for the in terms to do. And then following that, the current traditional path is that the disk manufacturer data to CDRH if the data was already submitted to (CDER) for evaluation during the drug of the evaluation.

In that scenario, the device comes in as it has been to (CDRH)). And I will explain some other scenarios for other types of submission to CDRH. So that is if the device is a disk. If the device is a concentration, again similar processes going on the device manufacturer is working to develop a particular test so that it's a manual test, whether it's a and algorithm driven assessment or instrumentation.

And once that data is collected the (510K) is submitted and the CDRH evaluates the data including the MIC and the breakpoint for the indicators' organism. Again, that's the review of the 90 days and some additional information data is needed. So, this is now getting really to the meat of the topic of today. The - this is the kind of vision that we have been noticing when FDA began looking into this topic and hearing information from stakeholders, about the delay in availability of antimicrobial susceptibility test devices after a drug approval.

So, let me explain this graphic a little bit more on the - you see the drug approval time point of the zero and then we have on the X - on the X axis the time in months. The main point of this slide is blue is bad, because blue is a long time for a device manufacturer to have come into FDA in order to

request for clearance. So, this is really nothing to do with FDA review at CDRH per se. So, when we observed this, we saw that given for some of the devices as I mentioned earlier, the AST disk is a simple device. Even some of those we're requiring upwards of almost like eight months for some of these devices.

And the longer ones are the devices that measure antimicrobial susceptibility tests by MIC for example. And some of these devices are automated devices. So, the length of time where there is no AST device, but the drug on the market has been a great and that really what has led the FDA and others, to come together and to do something about it.

And so, we are now into this coordinated development where it requires various stakeholders in order for this program to be successful. The drug manufacturer needs to be involved, the device manufacturer needs to be engaged, and (CDER) and CDRH internally here as well as externally, with the respective manufacturer, be working together to make this program effective.

And so, SDA on had a coordinated development workshop in September of 2016 and coinciding with that date as well, issued the drug that we are today discussing the final version of it. There in the workshop as well as in later information that was exchanged through the , FDA invited to the workshop, and we went through an overview of AST devices landscape and had some different perspective from the perspective of the commercial, from the perspective of the lab, drug sponsors and diagnostic (devices) as well as other stakeholders such as the (ISM), CDC and others.

And two panels were dedicated to help clarify some of the questions from the audience of the workshop. On slide 16 now after the guidance document,

after the draft guidance document was issued, there was a docket open for that and received comments. So, here I'm summarizing the - in general kind of comments that were received from stakeholders. Fifty-four comments were received, 46 were from industry, 11 from professional (societies), 7 from (data) associations. There were four common themes or types of the comments, if you will.

Ten were about policy, nine were from comments, 19 were about procedure issues and 16 were technical. There were substantive changes to the content of the draft guidance and we'll go through some of that here. But here is the scope of the guidance. The scope of the guidance, it is in terms to assist drug sponsors and device manufacturers that are planning to develop new and and AST devices.

Specifically, the guidance intends to accomplish the following, describe the interactions that are needed in order to achieve coordinated development, extend the consideration for submitting separate application, for example, (CDER) for evaluation of the drug and CDRH for the evaluation of the device .

The driver is to clarify the review of both the antimicrobial drug product and the antimicrobial AST device when independent and separate. So hence, the idea is coordinated and not necessarily (co-linked). So, the goal of the guidance is to be summarized by . It provides recommendations to the device and the drug indices and how to work together to facilitate the time to clearance of AST devices by FDA.

Then hopefully achieve the goal of memorizing the time that you need approval of the new drug and the other commercial AST test that is used to determine the potential effectiveness of the drug. On slide 19 I'm showing

side by side, the draft of the final published guidance, the document. So, while we go over a couple of slides about what some of the highlights of the changes that put this from a draft to a final, services summary of those joined.

First, on the threshold circle development, the final version of the guidance we hope, clarifies the process and timeline for coordinated development and in AST devices. And added a flowchart that depicts the recommended interaction between drug and device manufacturers, (CDER) and CDRH to facilitate coordinated development. And one other important point was added to the guidance the final guidance document, is the applicability of the guidance of molecular devices.

As we all know, there's more and more of these types of molecular devices that detect antimicrobial resistance for example. So, the to indicate that if there were an effort to coordinate development of a device that is a (molecular) type of device, that there are the principles that apply here to regular routine AST devices, are also applicable (molecular) markers of resistant type of devices.

Now there are changes to considering that changes to the final guidance, based on comments to the . There were clarifications of the following as well. The need for improved coordination between drug and device development; process for coordinated development clarified; the types of antimicrobial - AST devices to include medical devices as I just mentioned; recommended timing for submission of AST CDRH iteration submission of new drug application to (CDER). I'll explain this a little bit more.

And the process according without a pre-submission that could be also received without then need for for a pre-submission. And the content of a pre-submission, if that is what . This - we'll spend some time on slide 22

because this in fact is one of the main additions that were made to coordinated development final guidance. So, the flowchart just provides a little bit more transparency about the kinds of steps that are needed. So, from an AST device manufacturer, for example, could if that - if they were the ones initiating a process for coordinating development because the pre-submission process can also be initiated by drug sponsors as well.

This is something important I wanted to also mention. But for the sake of this slide, it's showing an AST device manufacturer submitting for example, a pre-submission or a pre-submission supplement, depending on if there were more than one communication on the topic. In that, a sponsor, a device manufacturer will put their plans to coordinate development, they are described - description of their relationship with the drug sponsor for example.

The anticipated need for an IDE in case of such a device for example, would be more applicable to a new device or another device that is providing results that may perhaps be useful for the patient to know the results. Again, for the sake of this call, we'll not go beyond that to explain this further. If people have questions, perhaps we can answer that later on.

And they provide the plans for the data collection and analysis and they share their (510K) plan. A pre-submission comes into CDRH for review. A (510K) release submitted, was the new drug application is under review. This is very important. And it has to be coordinated very well between the parties that are involved, because the timeline for the drug and NDA is longer - perhaps longer than the view for CDRH, which is 90 days.

So, but with good coordination it could be a case where the data, all of the data that need to be coming in, so that we can come as close as possible to an AST device being cleared, when the drug gets cleared. The device

manufacturers can work in such a way to coordinate that the submission comes in to see the rest reviews as a (510K), so that the timing of the AST device cleared can be coincidental or close to the time of the drug approval.

We all know that can go and requests can be made by (CDER) for example, or during the review session. But this is assumed that it's a good streamlined process. Then the pre-submission is not necessary, but it is recommended during the development. In other words, if drug and device manufacturers are working together in a coordinated manner, and then the data comes in, in a timely manner, to CDRH, CDRH knows (CDER) actions to be involved in that process. However, we find that the - those two utilize the of receiving feedback, have resulted actually in very good outcome, and I'll share some of this in a later slide.

That the process seemed to work as we all intended, such that patients have the available devices, so that data for their healthcare management. And so, device can either coincide with or be shortly after drug approval. And like I said, I will sure the information in a couple of slides, about how this process is working. But a few points about the functions of coordinated development. And we look at this one as the work does it do and what does it not do.

The coordinated development does not do or it's not meant to change existing regulatory requirements or timelines for either the drug or the device approval or . I wanted to amok that point very, very clear. And I think people on the call do understand that. So that's about coordination and not about changing any of the existing regulatory requirements. (CDER) will require what they will require, CDRH will require what is guided by the various guidance documents that I will share at the end of this slide, some of the reasons.

But what it does which is a logical extension of all that we've been talking about is that the idea is that a streamline the time between the approval and device here, AST device here, promote a meaningful discussion between drug developers and device manufacturers and the branches of FDA. And provide drug developers access to AST device technology, during clinical studies.

This is an option. This is something that perhaps a drug manufacturer might be more interested in coordinating a little bit more of. I mentioned earlier that a pre-submission process for example, for CDRH, is usually typically coming in some device manufacturers. But in fact, we can enhance the drug manufacturers coming in asking for that type of coordination, wherever it is through (CDER) or through CDRH. So, we encourage more of that actually, because they are the ones that are insistent in having those drugs on certain panels for example.

And the coordinated development provides device manufacturer access to organisms again getting and if there is coordination. Those are usually often being hidden in finding certain organs in certain types. And because the drug manufacturer usually is conducting the trials, we have access to that that perhaps would be helpful in coordinating the studies occurring sooner than later. And finally, to patient care is what we are all looking to do. The interaction topics - what can interactions be looking like, or what are the general things that should be considered for when requesting coordinating development or when asking about coordinated development?

In general, it's an outline of the studies that would have been or maybe will be, performed. Information about provisional breakpoints and indicated organism because some of that information may be because you are - the drug is now in early stages of an NDA in some of that. And some version might be

more. And the drug and device manufacturers can work together on that and can ask questions about that.

Expectations of the timeline for example, when we are expected to come in and are ongoing, how long. What important aspect that is getting a little bit technical here, but an assessment of benchmark or valuation variability can be an issue and it has been in the past, an issue. And that has thrown the development of devices, of commercially available devices because of some aspect like that where there may be a need for addressing variability or a certain adjective that is required for methodological changes in the past.

So, those are important aspects to be addressed earlier than later, and therefore, could be issued as topics of interaction in a pre-submission, to talk about coordinated development. And to procurement of resistant or (unstable) for example, could be asked. And if - feedback could be when you from here or maybe you found it here or maybe it can have a case where all of these can become available and I mentioned something about that in the last couple of slides, at the end of the presentation.

We can share information regarding the drug and the device agreement that there are in place between the drug manufacturer and device or any other entity for that matter, and any specific questions to allow better FDA feedback. On slide 25, again, these are specific topics that would be - can be added to the interaction. For example, can be provided by the drug manufacturer? In other words, the drug manufacturer has conducted studies, have collected isolates and could those at a higher dose, could be made available so that they can facilitate the development of AST devices?

Organisms from drug evaluation studies can be used as challenge or .
Questions can be where can we get those; how can we get those; which part of

studies we can include those? Those are the types of questions that can interaction between the sponsored and FDA perhaps (end). One important factor is in planning this studies is the factors, for example it is advised that they should test a wider range of (dimensions).

And this allows flexibility for the changes. I cannot emphasize this point enough because oftentimes we find ourselves delayed in those progressions simply because we need to go back in order to be more steady, had we done the studies using the device that would have covered those breakpoint changes. This point point about this is something I mentioned at the beginning of the call. That in some cases the disk brands are not during the drug trial, and therefore there is no data associated with that particular brand.

And we have had interactions and have made recommendations to manufacturers about how to go about doing that. In those situations, the data is actually reviewed at CDRH, not at (CDER) as would be the case with an NDA and any special information about specifics of the drug can be shared. Now I'm going to activities to date. Many activities have happened. At the beginning of the call we talked about the 2016 where we have the in the draft guidance. And we have one piece of mission at that time.

And it moved from left to right. You will see that at that time, the timeline between a drug approval to device clearance, has been taking upwards of like 14 months. So, 14 months have gone by for some devices to become available for a second drug from day zero of the drug approval. In 2017 we had six piece submission and we had nine just in case, that were submitted. Some of them have come in under a pre-submission for development. Some have were already coordinated between the without necessary pre-submission .

In other words, they conducted the studies earlier so that they can bring the submission through CDRH area. Examples of growth are their success and . And so, a review against the (CDER) drug approval for device, have been short and in some cases for one to two months. So, we are producing in 2018 sort of repeating some story and we had more devices, so more drugs available to patients in an area .

So, this slide appropriately, slide 27, this is the graphic. Appropriately this should be the before and after, not just after. Because a picture is worth 1000 words, in this case the bottom half of this slide, the four bars that have blue; remember at the beginning of the call I said blue bad, well all blue is bad so you see that for these four devices have taken this long in order for them to become available.

And all of it depends on when was submission coming in the end, after drug approval? So, during the blue bar period, that's the period where the device manufacturers were actually doing the study, so that they can submit to CDRH. With coordinated development and with efforts that are taking place earlier than later, we have a case where - we have many cases now, but what's shown on this slide, is three devices were cleared between 33 to 41 days after receipt and in 44 days after drug approval.

In fact, I can ad lib here and say that in one of these cases we were called by the device manufacturer, saying that actually where the device clears and still, they're making the drug for distribution to the field. So, and they're an excellent case where they had the devices, so they're still distributing the drug to the field. I mentioned in a couple of places where there are other initiatives that are add on ways by which FDA and others including in this case CDC, can help availability of certain organisms, such that if they are needed for self-evaluation, they are available.

And for example, we have the FDA CDC bank or call CDC FDA AR bank. Then as we know, not necessarily tells us what they have used, but today we know that it is the on this bank, has contributed to clearances and approvals for AST devices on other - and other infectious disease deaths that were submitted since its launch of 2015.

The the slide has the and people actually with that and how it has facilitated the availability in a streamlined manner, of the susceptibility breakpoint in an easy way, so that people can be having that information rather than digging into the drug labels. And Dr. (John Flatley) here, is with me, in case there are any questions about that, that we think that those advancements, as well as other advancements, not necessarily on this slide, have really contributed to the success and we hope that will consider to contribute to the success of coordinated development.

And so finally, end with the benefits to public health. Obviously earlier availability of diversity of AST devices, do help in improving patient care. We think that they will contribute or can contribute to antimicrobial , by having susceptibility available and needed for testing. Include their ability to monitor for any (imaging) resistance isolate, and will get flexibility in drug testing and reporting with our how devices are labeled. And we have seen a device update and labeling as well.

And with that, I will end with some resources and links to important guidance documents and resources. The AST Special guidance, which pretty much governs many of the (review) for AST devices, according to development guidance obviously and the docket in case anybody wants to connect to that. And the CDC and FDA antimicrobial and finally, the . And with that, I will turn it into Irene. Do we have questions? I'll turn it back to Irene.

Irene Aihie: We'll now take questions.

Coordinator: Thank you. To ask a question, please press star followed by 1. Please insure your phone is unmuted and record your name clearly when promoted. Again, that is star followed by 1 to ask a question. To withdraw your question, press star 2. Again, we would like to remind all parties that we will take one question at a time. And if you would like to ask a follow up question, to please re-queue. One moment, while we wait for parties to call in.

Irene Aihie: So, while we're waiting on participants to ask questions, I believe (Ribhi) has some questions or some comments that he would like to make.

Dr. (Ribhi Shawar): Thank you, Irene. Yes. For example, we've received some questions beforehand. And while people are thinking of questions, don't think too hard, so for example, can FDA clearance in a AST device together as one package? And the answer to this one is no, as I said in several places, I think, I hope. The drug approval is separate from device clearance and they remain to be separate. Those questions I think I also might have answered those as well. How many antimicrobial susceptibility tests have been cleared under the development?

I have the data as of the end of 2018 and 13 devices have been cleared through their coordinated development process. I don't have any other questions at this point.

Irene Aihie: Operator, are there any questions?

Coordinator: At this time, we have no questions. Again, if you would like to ask a question, to press star 1. One moment. (Sharon Cullen), your line is open. You may ask your question.

(Sharon Cullen): Hi (Ribhi). Thanks for the presentation. This was great. I have a question about the (510K) submission and the timing of the NDA. So, if we submit the (510K) and it takes a little bit longer on the NDA, will you simply just put that submission on hold to coordinate then that timing?

Dr. (Ribhi Shawar): Yes, thank you (Sharon). That's a good question. It will depend obviously on the timing and how close it is. And we will not be doing anything without interaction with the sponsors. It is possible that something could be placed on hold and that would not be really our ideal. And that's why the ideal would be to - if people can predict the future, is to time it so that the timing of the drug approval will be in - within the timeframe of the review of the (510K), so that when the drug gets approved an action can be taken on the device.

The main point here is that we cannot - CDRH cannot take an action on clearance of a device, until there is a drug that is marketed in the US or that is approved in the US.

Coordinator: Thank. (Michelle Tamory), your line is open.

(Michelle Tamory): Yes, hi. I just wanted to find out what are some examples of devices and drugs that would need to be coordinated in terms of, you know, both sides CDRH as well. So, what would be a pair where there would need to be coordination; an example of this please?

Dr. (Ribhi Shawar): If I understand the question, for example there's one slide that I showed different antimicrobial agents that have - were under consideration for approval by either, and various device manufacturers were interested in having an AST device available for those. So, those are examples of the type of drugs that are suitable for coordinating development. Really, in reality, any antimicrobial agent for which there will be a commercially available AST device, are and ought to be .

I'll try and turn this maybe to Dr. John Farley from (CDER). Maybe he'll be able to add something else.

Dr. (John Farley): Yes. This is (John Farley). Thanks for that question. So, I think what we've worked hard to do over the last couple of years, and I think as a community, we should be pretty happy with these results, is to be sure that when a new molecular entity, antibacterial drug, is approved, that laboratory scientists have a tool in their lab, to assess susceptibility.

So, it's - so our priority has been new molecular entity antibacterial drugs in terms of this coordinated development program. Folks on the phone think that there are another group that we're missing, you know, please let us know. But we think that devices generally are available for previously approved antibacterial drugs.

(Michelle Tamory): Okay. Thank you very much.

Coordinator: Thank you. Again, if you would like to ask a question, please press star followed by the 1.

Irene Aihie: Thank you. This - thank you. Operator, do we have any other questions?

Coordinator: We do have one final question from (Andy Pracchia). Your line is open.

(Andy Pracchia): Yes. It's actually a question just for CDRH I guess. If you have a drug that's under (Sieber), do you know if this program would also apply?

Dr. (Ribhi Shawar): I do not know that it would apply, but maybe with more specifics may be able to have the better answer. For CBER it is going to be like a biologic of some sort. Yes?

(Andy Pracchia): Yes. It's a biologic, but it's categorized of a drug under (CBER).

Dr. (John Farley): Yes. This is (John Flatley). I can probably take that. So, I think the three centers have been working together very well on a whole lot of different issues. We haven't thought of that and I'm actually really glad that you brought that up. We had a workshop earlier in the year on sort of nontraditional antibacterial drug therapies. So, I'm actually really glad you brought that up.

So, we'll talk with the (Sieber) folks should that situation arise down the road, but I think that the principles that have been established through this process, could certainly apply.

(Andy Pracchia): Great. Thank you.

Coordinator: Thank you. At this time, I will now turn the call back over to Ms. Aihie.

Irene Aihie: Thank you. This is Irene Aihie. We appreciate your participation and thoughtful questions. Today's presentation and transcript, will be made available on the CDRH Web page at www.FDA.gov/Training/CDRHLearn by Wednesday, February 20. If you have additional questions about today's

presentation, please use the contact information provided at the end of the slide presentation. As always, we appreciate your feedback.

Following the conclusion of today's webinar, please complete a short, 13 question survey, about your FDA CDRH webinar experience. This survey can be found at www.FDA.gov/CDRHWebinar, immediately following the conclusion of today's live webinar. Again, thank you for participating. This concludes today's webinar.

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