FDA Webinar: Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program - Final Guidances

Moderator: Irene Aihie
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1:00 pm ET

Coordinator: Welcome and thank you for standing by. At this time, I'd like to inform all participants that today's call is being recorded. If you have any objections you may disconnect at this time. All participants will remain on a listen-only mode throughout the duration of the call until the question answer session. At that time, if you would like to ask a question you may do so by pressing star and 1. I would now like to turn the call over to your host Irene Aihie. You may begin.

Irene Aihie: Thank you. Hello and welcome to today's FDA webinar. I am Irene Aihie, of CDRH's Office of Communication and Education. The FDA issued three final guidance documents related to the Accreditation Scheme for Conformity Assessment Pilot Program (ASCA Pilot). These guidance documents outline the goals and implementation of the voluntary ASCA Pilot, intended to increase confidence in testing results from ASCA-accredited testing laboratories for certain FDA-recognized standards and help the FDA ensure safe, effective, and high-quality medical devices are available to patients without unnecessary delay.

Today Stacy Cho, Senior Policy Analyst for the Standards and Conformity Assessment Program here in CDRH, will present an overview of the three final guidance documents, with the primary focus of today's webinar on the guidance document titled, "The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program". She is joined by other Center subject matter experts to assist with the Q&A. Following the presentation, we will open the line for your questions related to information provided during the presentation.

Now, I give you, Stacy.

Stacy Cho: Hello everyone. Thank you for joining us and thank you Irene for the introduction. My name is Stacy Cho and as Irene stated, I will be discussing the recently published final guidance, the Accreditation Scheme for Conformity Assessment or ASCA Pilot Program.

Next Slide, please. Our agenda for today is to go over the objectives of this training session, background information and overview of the ASCA Pilot Program. We will discuss the scheme design, the FDA recognized consensus standards and test methods selected for the pilot and the roles and responsibilities of the different stakeholders, which include the accreditation bodies, testing laboratories, device manufacturers and FDA review staff. We will conclude with key implementation dates that will be of interest to those who want to participate in the pilot.

Next slide. Through today's session, we hope to clearly convey why ASCA was developed, understand how ASCA was developed and explain to you what ASCA is. This webinar will go over the roles of all stakeholders, policies and processes that are specific to each stakeholder and an implementation timeline.

Next slide. The ASCA Pilot is established by statute. During negotiations for MDUFA IV, FDA and Industry agreed to establish a conformity assessment accreditation scheme for testing laboratories that evaluate medical devices according to certain FDA recognized standards. The FDARA amended section 514 of the Food Drug and Cosmetic Act by adding a new sub-section (in D) titled Pilot Accreditation Scheme for Conformity Assessment. This is the regulatory foundation for the pilot program.

Next slide. While we identify the regulatory foundation of ASCA, I'd like to delve further on why the ASCA pilot program was developed. Evidence of conformity to one or more FDA recognized standards is often a thorough and efficient way for a manufacturer to address certain questions of safety and or effectiveness. This is why FDA invests time and personnel into participating in various standards working groups so that the agency may have input in the development of these different medical standards. For manufacturers and FDA to benefit from this efficiency, FDA must have confidence in the Declaration of Conformity or DOC submitted by device manufacturers in their pre-market submission.

This is described in the final guidance document titled “Appropriate Use of Voluntary Consensus Standards and Pre-Market Submissions for Medical Devices”. While the appropriate use guidance document describes the different types of information needed from medical device testing to determine safety and or effectiveness in the DOC, in practice, the reliability of the determination in the DOC varies depending on the specific laboratory performing the testing and the standard being used.

These differences between testing laboratories and how they conduct the testing, in some instances, results in the need for FDA to request additional

information and review supplemental documentation given this variability. Additional FDA review and questions may lead to repeated or revised testing causing delays and or additional costs.

Next slide, please. We establish the why but let us now discuss how the program was developed. As mentioned earlier, the concept of the ASCA Pilot Program emerged from discussions between device manufacturers and FDA resulting in MDUFA IV and FDARA.

FDA then published the Federal Register Notice in May of 2017, requesting comments on a set of questions designed to gain insight regarding the development and overall design of the ASCA Pilot Program. We then took that information and held a public workshop the following year. The workshop took place over two days on May 22 and 23 in 2018.

And we invited testing laboratories, accreditation bodies and device manufacturers to open discussion across these different stakeholders and FDA. Throughout this time and even now, we are collaborating with NIST, the National Institute of Standards and Technology to develop the ASCA Pilot Program using best practices as established by experts in conformity assessment. NIST has helped multiple federal agencies set up conformity assessment programs, ranging from OSHA to GSA. We then published the draft guidance on September 23 of 2019 and hosted a webinar shortly after. We received comments on the draft guidance and have incorporated them into the final guidance documents which were published on September 25, 2020.

Next slide. The ASCA Pilot is a conformity assessment scheme in which ASCA recognized accreditation bodies will accredit testing laboratories using ISO/IEC 17025 and ASCA program specifications.

For those who may be unfamiliar with the standard, ISO/IEC 17025 specifies the general requirements for the competence of testing and calibration laboratories. ASCA will then grant eligible accreditation bodies, what we call ASCA Recognition. ASCA accredited testing laboratories will conduct medical device testing in accordance with ISO/IEC 17025 and the ASCA program specifications. ASCA will then grant eligible testing laboratories what we call ASCA Accreditation. FDA ASCA staff will administer the ASCA program, including managing participation of accreditation bodies and testing laboratories, including suspensions and withdrawals.

Next slide, please. The ASCA Pilot Program capitalizes on the relevance of consensus standards in device development and regulatory review, as well as the existence of a well-established international conformity assessment infrastructure. The ASCA Pilot Program aims to improve efficiency of the pre-market review process by building confidence in the declaration of conformity through the utilization of accredited testing laboratories.

With this increase in confidence, when device manufacturers include test results from an ASCA accredited testing laboratory in a pre-market submission, FDA pre-market review staff are expected to generally accept declarations of conformity that rely on testing from an ASCA accredited testing laboratory without the need for additional questions related to testing methodology. FDA has not previously had a relationship with testing laboratories, but through the ASCA Pilot Program, we hope to change this by opening up a relationship with testing laboratories through accreditation bodies.

Next slide. This is a detailed process flowchart that breaks down the previous slides in smaller steps. Accreditation bodies that are interested in participating in the ASCA pilot apply to FDA for ASCA recognition. FDA grants ASCA

recognition to qualified accreditation bodies. Testing laboratories that are interested in participating in the ASCA pilot, can receive accreditation from ASCA recognized accreditation bodies. FDA will ensure that a list of ASCA recognized accreditation bodies will be made available on the FDA website.

Once laboratories receive accreditation from an ASCA recognized accreditation body, they can apply to FDA for ASCA accreditation. FDA will grant ASCA accreditation to qualify testing laboratories.

Device manufacturers can then select an ASCA accredited testing laboratory from a list posted on FDA's website for device testing. An ASCA accredited testing laboratory conducts device testing and provides information listed in relevant ASCA program specifications including ASCA summary test reports to the device manufacturer. The device manufacturer includes the DOC with ASCA summary test reports in their pre-market submission to FDA. And then FDA pre-market review staff applies pre-market review considerations per the ASCA pilot.

Next slide. Where is the ASCA pilot described? The draft ASCA pilot guidance document was split into three guidance documents for final publication on September 25, 2020. The first guidance is the one being discussed at today's webinar, which is the overview of the ASCA Pilot Program. The following two are standards-specific ASCA pilot guidance documents which are also final.

One is for the basic safety and essential performance of medical electrical equipment, medical electrical systems and laboratory medical equipment. The second is for the biocompatibility testing of medical devices.

The standards specific ASCA pilot guidance documents include a list of the standards and test methods selected for the ASCA pilot, ASCA program specifications for those standards and testing methods, recommended content for pre-market submission containing testing from an ASCA accredited testing laboratory, example declarations of conformity for those standards and test methods and example ASCA summary test reports for those standards and test methods.

Next slide. How does the ASCA pilot leverage existing conformity assessment resources? FDA did not want to reinvent the wheel. Therefore, we maximized the use of existing frameworks and arrangements for the ASCA pilot wherever possible. The first framework we leveraged is the ILAC MRA, or the International Laboratory Accreditation Cooperation Mutual Recognition Agreement. ILAC is an international organization for accreditation bodies that are credit conformity assessment bodies, such as testing laboratories. Accreditation bodies that are signatories to the ILAC MRA are evaluated to ISO/IEC 17011 to demonstrate their competence.

ISO/IEC 17O11 includes specifications for accreditation bodies and is titled Conformity Assessment Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies.

Next slide. So how does ASCA leverage the ILAC MRA? Well in the ASCA Pilot Program, accreditation bodies must have ILAC MRA signatory status in order to qualify for participation. FDA will leverage ILAC MRA policies and procedures by reviewing accreditation body peer evaluation reports and or participating as an observer during these activities. FDA will also leverage 17011 policies and procedures by reviewing testing laboratory assessment reports and or participating as an observer during these activities.

Next slide. The second framework that FDA will leverage is ISO/IEC 17025. This standard contains specifications for laboratories to operate competently and generate valid results. The title of 17025 is General Requirements for the Competence of Testing and Calibration Laboratories. Accreditation bodies that are signatories to the ILAC MRA already accredit testing laboratories to ISO/IEC 17025.

Next slide. In the ASCA pilot, we will leverage this framework by utilizing accreditation bodies to use ISO/IEC 17025 plus ASCA program specifications outlined in the standard specific guidances to accredit testing laboratories. Along the same line, ASCA accredited testing laboratories will conduct testing in accordance with ISO/IEC 17025 and ASCA program specifications.

Next slide. So which FDA recognized consensus standards and test methods are in the ASCA pilot? In accordance with the MDUFA IV commitment letter, the standards and test methods in the ASCA pilot include both cross-cutting or horizontal and device specific or vertical standards. They are of public health significance and have or are able to provide a means for establishing acceptance.

The standards are exclusively listed out in each standard specific guidance document. In terms of the standards chosen for the pilot program. There are no changes from draft guidance to final guidance.

Next slide. For the basic safety and essential performance of medical electrical equipment, medical electrical systems and laboratory medical equipment, the guidance document consists of the IEC 60601/80601 series of standards recognized by FDA at the time of final guidance publication. This includes IEC 60601-1, ICN US adopted collaterals, along with the particulars.

Please refer to the basic safety and essential performance final guidance document for a complete list of eligible standards.

Next slide. For the biocompatibility testing of medical devices, the following is a table of all standards and test methods that are part of the pilot.

Next slide. So how did FDA come up with the ASCA program specifications? Well, ISO/IEC 17025 served as the foundation for ASCA program specification found in the standard specific ASCA pilot guidance documents. The working group that developed the specification consisted of technical experts and personnel from FDA and NIST.

To give you a better idea of how this was established, these three images are excerpts of Section 7.2 of the ISO/IEC 17025 standard, section 7.2 of the ASCA program specifications for the biological evaluation of medical devices and section 7.2 of the ASCA program specifications for the basic safety and essential performance standards family.

As you can see, the technical experts and personnel for each working group went through each section of 17025 and added in additional specifications for the two sets of standards that we believe will help bolster the confidence in the testing of the selected device standards. This slide shows you how each group listed out program specifications for the selection, verification and validation of methods.

Next slide. This chart provides a comprehensive overview of how each of the different stakeholders relate to one another in terms of their roles and responsibilities. I realized that the font size is small but this chart shows the various interactions between the stakeholders that provides a great visualization of these relationships.

Accreditation bodies in the green box, they apply to FDA in the blue box for ASCA recognition. And then FDA ASCA staff grant ASCA recognition to qualified accreditation bodies. The yellow box represents the International Laboratory Accreditation Cooperation, where ILAC develops and maintains the mutual recognition agreement with the accreditation bodies.

Then the testing laboratory in the pink purple box, show that test labs request accreditation from ASCA recognized accreditation bodies, who in turn accredit testing labs to ISO/IEC 17025 and ASCA program specifications. Testing laboratories then apply to FDA for ASCA accreditation and FDA ASCA staff grants ASCA accreditation to qualify testing laboratories.

The next focus is on the device manufacturers in the gray box. They request device testing from ASCA accredited testing labs, who in turn conduct testing in accordance with their scope of ASCA accreditation. Device manufacturers then submit pre-market submissions with testing from ASCA accredited testing labs to FDA, who then review and provide a final decision on the pre-market submission.

The biggest takeaway from this chart is the fact that FDA has a relationship with the accreditation bodies, testing laboratories and device manufacturers.

Next slide. We will now take a deeper dive into the policies and processes for accreditation bodies. The role of an ASCA recognized accreditation body is to accredit testing laboratories using the specifications of ISO/IEC 17025 and ASCA program specifications associated with each FDA recognized consensus standard and test method in their scope of ASCA recognition.

So, what are the qualifications? An accreditation body must have signatory status of testing to ISO/IEC 17025 within the ILAC mutual recognition agreement. They must be based in the United States and they also must agree to the terms of participation.

Next slide. The following slide describes the application process an accreditation body must go through to be granted ASCA recognition. An accreditation body will draft an application for ASCA recognition consistent with Appendix A of the ASCA Pilot Program guidance. The accreditation body then submit the application via email to ASC@fda.hhs.gov. FDA reviews the application within 60 days, FDA will notify the accreditation body of final decision via email, and if applicable, of any issues precluding ASCA recognition.

FDA aims to resolve any issues in an interactive manner during the 60 Day Review. And if ASCA recognition is granted, we will update the FDA website to include the newly recognized accreditation body, the expiration date and scope of ASCA recognition.

If an accreditation body wants to extend its ASCA recognition by adding standards or test methods to their scope, then the same process must be followed.

Next slide. FDA intends to periodically audit accreditation bodies to ensure that they are adequately fulfilling program expectation. We heard your comments regarding audits, so we fleshed this out a bit more.

FDA will use a tiered approach with three levels of audits. Level one audits will leverage the existing arrangement of ILAC peer evaluation by requesting a copy of the most recent ILAC peer re-evaluation report. Such periodic

assessments will ensure adherence to program expectations. Level two audits will ask for a copy of the most recent ILAC peer re-evaluation report, as in level one, but will also participate as an observer during the next scheduled ILAC peer re-evaluation. Level two audits will take place when level one is insufficient. For example, if there are persistent issues with testing laboratories accredited by a particular accreditation body. For level three audits, FDA will initiate on site or remote audit of the accreditation body outside of the ILAC MRA peer evaluation schedule. This will occur when level one and level two audits are insufficient. For example, if there is a public health concern regarding the safety of a device.

Next slide. This next slide focuses on withdrawals and this is also in response to comments received asking for more information. Withdrawal of ASCA recognition cancels the accreditation body's full scope of ASCA recognition and removes them from the ASCA pilot entirely.

So why would it withdraw the appropriate? This will happen when FDA no longer has confidence in the accreditation body's ability to adequately fulfill its role in the ASCA pilot. For example, violation of law or policies outlined in the guidance or other standards specific ASCA pilot guidance, failure to correct nonconformities, failure to adhere to the signed agreement, if there's information materially bearing on safety or effectiveness of a device that reasonably relates to the accreditation body, and withdrawal or suspension of ASCA accreditation for a testing laboratory that was accredited by the accreditation body.

Next slide. FDA will send a withdrawal letter via email to the contact on record for the accreditation body. The letter will include reasons for withdrawals and if appropriate, how these issues may be addressed in the future through new applications to the ASCA pilot program. Accreditation

bodies can also voluntarily request to withdraw from the program by emailing ASCA@fda.hhs.gov. In either case, FDA then notifies ASCA accredited testing laboratories accredited for the ASCA pilot by the now withdrawn accreditation body. If an accreditation body wants to participate again, they must submit a new application.

Next slide. We will now shift gears to the policies and processes for testing laboratories. So, what is their role? ASCA accredited testing laboratories perform testing in accordance with the specifications of ISO/IEC 17025 and the ASCA program specifications associated with each FDA recognized consensus standard and test method in their scope of ASCA accreditation. After testing is complete, ASCA accredited testing laboratories provide the information listed in the relevant ASCA program specifications including an ASCA summary test report to the device manufacturer.

So, what are the qualification? The requested scope of ASCA accreditation must be consistent with the scope of accreditation provided by an ASCA recognized accreditation body. The testing lab has also agreed to the terms of participation in the pilot program.

Next slide. The following slide describes the application process a testing laboratory must go through to be granted ASCA accreditation. A testing laboratory would draft an application for ASCA accreditation, consistent with Appendix B of the ASCA Pilot Program guidance. The testing laboratory then submits the application via email to ASCA@fda.hhs.gov. FDA reviews the application within 60 days.

FDA will notify the testing laboratory of the final decision via email, and if applicable, of any issues precluded ASCA accreditation. FDA aims to resolve any issues in an interactive manner during the 60 Day Review. And if ASCA

accreditation is granted, we will update the FDA website to include the newly accredited testing laboratory, the expiration date and scope of ASCA accreditation. If the testing laboratory wants to extend its accreditation by adding standards or test methods to their scope, then the same process must be followed.

Next slide. FDA intends to periodically audit testing laboratories to ensure that they are adequately fulfilling program expectations. FDA will use a tiered approach with three levels of audits similar to the accreditation body audit scheme. Level one audits will leverage the existing arrangement of assessment by the accreditation body of the testing laboratory, as laid out in ISO/IEC 17011. FDA will request a copy of the most recent assessment report of the testing laboratory. Such periodic assessments will ensure adherence to program expectations.

Level two audits will ask for a copy of the most recent assessment report as in level one, but FDA will also participate as an observer during the next scheduled assessment of the testing laboratory by the accreditation body. Level two audits will take place when level one is insufficient. For example, if there are concerning trends in the testing laboratory's complaint log.

For level three audits, FDA will initiate on site or remote audit of the testing laboratory outside of the assessment schedule stablished by the accreditation body. This will occur when level one and level two audits are insufficient. For example, if there is a public health concern regarding safety or a device.

Next slide. The next several slides will discuss suspension and withdrawals of testing laboratories from the pilot program. FDA considers the magnitude of issues when determining whether suspension or withdrawal is appropriate. As

they must feel confident that such actions are sufficient to maintain confidence in the program.

Why would a testing lab be suspended? This will occur when FDA identifies potential concerns regarding the testing laboratories ability to adequately fulfill its role in the ASCA pilot. For example, if there is an existence of a nonconformity, inadequate completion of training or communication with FDA, information materially bearing on safety or effectiveness of a device that reasonably relates to the testing laboratory, such as a GLP warning letter, or withdrawal of ASCA recognition from the accreditation body that accredited the testing laboratory for the ASCA pilot.

Next slide. FDA will initiate a suspension by sending a letter via email to the contact on record for the testing laboratory. A testing laboratory can also voluntarily request suspension by submitting an email to ASCA@fda.hhs.gov. In either case, FDA will notify the accreditation body that accredited that particular testing laboratory for the ASCA pilot. The testing laboratory can request the suspension to be listed by sending a response to ASCA@fda.hhs.gov addressing the issues and concerns identified.

Next slide. Withdrawal of ASCA accreditation cancels the testing laboratory's full scope of ASCA accreditation and removes them from the ASCA pilot entirely.

Why would FDA withdraw ASCA accreditation? This will happen when FDA no longer has confidence in the testing laboratories ability to adequately fulfill its role in the ASCA pilot. For example, violation of law or policies outlined in this guidance and other standards specific ASCA pilot guidance, failure to correct nonconformity, failure to adhere to signed agreement, information materially bearing on safety or effectiveness of a device that

reasonably relates to the testing laboratory, or withdrawal of ASCA recognition from the accreditation body that accredited the testing laboratory for the ASCA pilot.

Next slide. FDA will initiate a withdrawal by sending a withdrawal letter via email to the contact on record and include the reasons for withdrawal. In turn, the testing laboratory can also voluntarily request to withdraw themselves from the ASCA program by sending an email to ASCA@fda.hhs.gov. In either case, FDA will notify the accreditation body that accredited that particular testing laboratories for the ASCA pilot. If the testing laboratory wants to participate in the program again, they must send in an application.

Next slide. We will now focus on policies and processes for device manufacturers. Device manufacturers may voluntarily choose to use an ASCA accredited testing laboratory to conduct testing included in the pre-market submission. A list of ASCA accredited testing laboratories will be posted on the ASCA FDA website.

Next slide. The ASCA program does not change the fact that device manufacturers are responsible for ensuring that FDA recognized consensus standards are selected and used appropriately. Device manufacturers may still choose to work with a testing laboratory given their expertise in developing the test plan. Considerations for development of a test plan for testing at an ASCA accredited testing laboratory include other relevant FDA guidance documents, such as device type guidance, scientific area guidance or submission type guidance, other FDA recognized consensus standards, such as collateral and particular standards for basic safety and essential performance, the impact of deviations from FDA recognized consensus standard,s and testing outside of testing laboratory scope of ASCA accreditation.

Note that deviations with standards are different from modifications allowed by a standard. Deviations from standards are not allowed in ASCA because we need a declaration of conformity. Please also note that a device manufacturer can always request a Q submission to discuss any details.

Next slide. Device manufacturers are responsible for documenting how the testing supports pre-market authorization even when testing is performed at an ASCA accredited testing laboratory.

The manufacturer will submit a cover letter that includes the following information, clear identification of the term ASCA, name and location of the testing laboratory where testing was conducted, the ASCA testing laboratory identification number, FDA recognized consensus standards and specific test methods used during testing.

The manufacturer will also include a declaration of conformity. This declaration of conformity will include information already expected in a DOC, plus the ASCA accreditation status of the testing laboratory.

In response to your comments, we have included example DOC in the standard specific ASCA pilot guidance documents. Supplemental documentation may be necessary. Again, please review the standard specific ASCA guidance documents. And also, in response to your comments we provided example ASCA Summary Test Reports for you. Note that in some situations FDA may need information beyond ASCA Summary Test report. This is discussed in detail in the standard specific guidance documents.

Next slide. The following slide provides pre-market considerations for FDA staff. The ASCA pilot's conformity assessment scheme provides FDA

increased confidence in the methods used and results reported by ASCA accredited testing laboratories when testing is performed within the testing laboratory scope of ASCA accreditation. This increase in confidence leads to the following FDA review policies. FDA intends to rely on the results from ASCA accredit testing laboratories for the purposes of premarket review, without the need for additional information related to conformance with the standard. FDA does not intend to question the validity of test methods within a testing laboratory scope of ASCA accreditation.

Next slide. However, there will be exceptions to these review policies. FDA will take a deeper dive in the review process and may ask for additional information in the following cases which are: as part of periodic audits, if FDA becomes aware of information that would result in suspension or withdrawal of the testing laboratories ASCA accreditation, if FDA becomes aware of information that will result in withdrawal of the associated accreditation bodies ASCA recognition, if FDA becomes aware of information materially bearing on the study conduct or quality, or if the ASCA summary test report indicates an issue with a testing or device. Please note that this list is not exhaustive.

Next slide. What if ASCA accreditation was suspended at the time of testing? FDA may then need to review additional information and or ask questions to determine whether the test results can be used to support a decision on a pre-market submission. Please note that FDA is only concerned with the status at the time of testing, not the time of pre-market submission receipt or review. FDA intends to carefully consider the issues resulting in suspension, as well as which FDA recognized consensus standards and test methods were subject to the temporary labeling constraints of the suspension.

Next slide. What if ASCA accreditation was withdrawn at the time of testing? FDA will then apply the policies applicable to testing from labs that never received ASCA accreditation. FDA intends to carefully consider the nature and severity of the reasons for withdrawal of ASCA accreditation when determining what if any post market action is needed for closed pre-market submission that included testing results from testing laboratories whose ASCA accreditation has been withdrawn.

FDA will suspend the testing laboratories ASCA accreditation when specific issues are identified that raise potential concerns with the results from that specific laboratory. And FDA will withdraw a testing laboratories ASCA accreditation when FDA no longer believes the premarket review benefits of the ASCA pilot are appropriate for testing conducted at that testing laboratory.

Next slide. We hope that with teamwork across the four different stakeholders, accreditation bodies, testing laboratories, device manufacturers and FDA, we will be able to leverage the existing conformity assessment framework to all of our advantage for efficient utilization of medical device testing.

Next slide. I will now conclude with several important dates and timelines to keep in mind. The slide describes key application dates. FDA intends to publish a list of ASCA recognized accreditation bodies on November 25, 2020. Applications received on or before November 4, 2020 will be considered for publication on this initial list. Applications received after November 4, 2020 will be reviewed in the order received and the list of ASCA recognized accreditation bodies will be updated as appropriate. FDA intends to publish an initial list of ASCA accredited testing laboratories that will be updated throughout the pilot. FDA will update the webpage to include the anticipated publication date for the initial list of ASCA accredited testing

laboratories and the date by which advocates should receive a testing laboratories application in order for the organization to be considered for the initial list.

For more information, you can visit the Web site.

The following two slides provide training and Q&A sessions information for those who want to participate in the pilot program. Accreditation body training session for accreditation body program managers is scheduled on October 29, from 1 pm to 5pm. This will focus on the overview of ASCA pilot policies and processes for accreditation bodies.

Technical ASCA training sessions for accreditation bodies are scheduled from October 30 to November 3 from 1:00 pm to 5:00 pm. These sessions will provide detailed instruction on how to use the ASCA program specification during the accreditation of testing laboratories for the ASCA pilot.

And again, for more information regarding these sessions, including how to sign up, please visit the ASCA website.

Next slide. Testing laboratories will be provided with Q&A sessions. Basic safety and essential performance testing Q&A will be held on November 16, 2020 and biocompatibility testing Q&A will be held on November 23, 2020.

Next slide. The following links are to the 3 final guidance documents, the ASCA webpage, the FDA recognized consensus standards database and appropriate use guidance document. These are resources that will help you understand the ASCA Pilot Program.

Next slide. This concludes the presentation portion of the webinar. We will now take questions over the phone. If you have any questions that we cannot get to or if you have questions later down the road regarding the asker pilot program, please email us at asca@fda.hhs.gov. For more general questions, please submit them (dice) at fda.hhs.gov.

At this time, I'd like to introduce the panel of experts present who will also help answer your questions. I'd like to first introduce Captain Scott Colburn. He is the Director of the Standards and Components Estimate Program at CDRH. Next is Amy Phelps. She is a Conformity Assessment expert from NIST, the National Institute of Standards and Technology. And last but certainly not least, (Erin Cutts), who is a Senior Policy Analyst and team lead of the ASCA program.

Thank you.

Irene Aihie: Operator, we will now take questions.

Coordinator: We will now begin our question and answer session. If you would like to ask your question, press star 1 from your phone, unmute your line and record your first and last name clearly when prompted. If you would like to withdraw your question, you can press star 2. Just a moment as we wait for questions to queue.

Scott Colburn: Good afternoon, this is Scott Colburn. I first want to thank Stacy for doing just an excellent job in conveying a very complex and very long guidance. Very hard to distill down three guidance documents into a 40 minute presentation. But I feel she did an excellent job.

For all of our participants are called in. Also thank you for the time and effort during a very challenging time in our economy and in our public health crisis that we are dealing with. We do want to try to make sure we answer as many questions as we can. And as Stacy mentioned, if we're not able to get to your question or something comes up, please do try to contact the program using the email there.

Do we have any questions currently in the queue right now?

Coordinator: We do. Our first question comes from (Michael Yardsale), your line is now open.

(Michael Yardsale): Good morning and thank you very much for the presentation. Actually, to an extent it's a two part question. I guess the first part and this would be around biocompatibility. So, for many submissions, medical device submissions, there is quite a bit more in vivo, in vitro, as well as chemistry testing performed over and above what is included in this program.

And so, my question is, what is the advantage of participating when during an application review, the FDA would be looking at quite a few other tests that are not included within this program? And then I guess my second question, if it's possible, is, if you are not participating in this, does anything change during the application review process, in terms of review of your test results? Is there more scrutiny placed on laboratories that aren't accredited under this process? Or is there just less scrutiny versus today?

Thank you very much.

Scott Colburn: All right. Thank you, Michael. So, he started off with the tough one, right? I'll do my best & I will admit, I'm not the biocompabiltiy expert. So, if you

don't feel we're hitting it right, I would encourage you to also forward that question on.

First, yes we realized there are several other methods or standards that a manufacturer may be looking to do in developing their test plan to address their particular medical device depending on its intended use with the contact, duration, et cetera that goes into selection of the types of methods that are

necessary based upon the guidance documents or the standards lead you down.

The methods and standards that were selected for the pilot program were done intentionally to try to address common test methods that are seen a crossed a particular type of medical devices but also apply to others that may also need additional testing. And in those cases, you would be kind of doing a little bit of a split and how you would propose the delivery of that information.

The guidance documents themselves have very specific ways of supporting how you address particular methods that are contained in the ASCA pilot. And with that, the coordination with the testing laboratory should you choose to use one that's participating or has ASCA recognition in the pilot, would work with you to fill out those tests report, summary test reports to support the declaration of conformity to those particular methods that are made that that you can include in your submission.

If you have additional testing, you would need to follow the relevant either biocompatibility guidance and or supplemental for how the appropriate use guidance would help direct you using that information to support that in your submission.

To the second part of your question, I'll try to remember but what we are doing and why, you know, what we're doing within the ASCA pilot program as it relates to engagement with the testing laboratories and specifically to the biocompatibility testing laboratories, is we really trying to get behind a confidence window here of understanding their competence to the specific methods and the biocompatibility area is very specific. FDA has put a lot of effort over the years to try to coordinate our expectations for how information should be delivered. Based upon the types of tests being done.

ASCA opened up that door for us to coordinate that more now with not just how accreditation is being looked at from the ISO/IEC 17025 competencies, but also in how that information can be delivered by the testing laboratory to the agency. So, we no longer need to read or evaluate that over and over and each submission, but rather have confidence on it based upon a point in, you know, of understanding when they come in for their ASCA recognition. And from that, that lowers the threshold a little bit of what we need to be looking for and we can be able to rely on the results of tests rather than how it was tested to make a regulatory determination. I hope that helps answer your question a little bit.

(Michael Yardsale): Thank you very much.

Coordinator: Our next question comes from (Sarah Plough), your line is now open.

(Sarah Plough): Thank you. My question is related to if you're using a third party reviewer for your FDAs 510 k submission. Are there any limitations when you're going that route with respect to this program?

Scott Colburn: Good, Stacy.

(Erin Cutts): So, there are no limitations in terms of using third party review program. It would just be ensuring that you adhere to the guidance documents established for the third-party program and also for the ASCA guidance as well. So, the simple answer to that question is no. No limitations.

(Sarah Plough): Okay, thank you.

(Erin Cutts): You're welcome.

Coordinator: Our next question comes from (Tara), your line is now open. (Tara), we'll take your questions, your line is now open. (Tara), would you please check your mute button.

Okay, our next question comes from (Mi Salaam), your line is now open.

(Mi Salaam): Thank you very much. I think that was a very good, excellent presentation. Good job. My question goes in multiple pools. Is ASCA going to have a checklist for the 70 logical. I am an auditor; I am an extensive multi-site. And ideally (unintelligible) have their own checklist.

And also, SPC is affiliated with 17025 and industrial Canada is also affiliated with 17025 and all these they have their checklist to be followed. My question is, is ASCA program going to have their own checklist, 17025? Thank you.

Scott Colburn: Thanks very much. That's a that's a good question. So, we're working that process through the pilot. So, the first stage of this is working with the interested accreditation bodies and we know the accreditation bodies as part of that develop their checklists at that underneath their own organization. So, they will be managing that for each of their applications & each of their

programs as they set that up. And we'll have that as part of their application with us to kind of show how they are using their technical assessors and measuring the competencies to 17025 plus the ASCA specific program specifications that are outlined in the guidance documents, dependent upon the types of scope that testing laboratory is asked for.

The program itself did not develop or will be delivering specific checklists to the ABs. Those will be presented to us, based upon the specifications outlined in the guidance. I hope that helps.

(Mi Salaam): Okay, all right. Thank you.

Coordinator: Our next question comes from (Chris Dodd), your line is now open.

(Chris Dodd): Hi, good morning, everyone. To all the panel, I have a couple of questions. The first one is related to the accreditation body training session. So, this program for training starting with October 29 to November 3, we are in the process of considering submitting our applications to the accreditation body. Is there a way that we could attend this training and because the application might take a little longer? That's my first question.

And the second question is related to I think this pilot program has to start with, it should be in USA. Is it also okay to have an accreditation body or the consultants or the test lab can be outside the US? Or is there any constraints as such?

Scott Colburn: Thank you very much. This is Scott Colburn again. I'll try to tackle that question. And I'll invite other experts if they wish to, of course.

If you are working are part of accreditation body or are a technical assessor that works for one or more accreditation bodies, you can go ahead and submit a request to attend the accreditation body technical assessor training that's taking place in about a month. Or, yes, in the next few weeks, I'm sorry. But the - and we can try to make sure you can get registered into the appropriate sessions. So that that is something that anyone is allowed.

We are asking for accreditation bodies that are interested in applying to be a participant in the program and to obtain recognition in that first wave to have an application in by November 4, which is just the day after the technical assessor training to be a part of that first wave announcement, but there may be an opportunity after that for another accreditation body to join the pilot later on. And again, I just want to stress this as a pilot program. So, we're trying to get a first wave of interested accreditation bodies in.

The need to attend the training that's going to be provided on the 29, 30, and 2, 3 of November, is not a requirement for application and accreditation bodies can submit an application now. But one of the requirements for them to be able to conduct assessments or accreditations to testing labs to the ASCA program specifications is that their technical assessors need to attend relevant training. So, I just want to make sure that is clear.

Regarding the second part of your question, you know, the guidance document specifically asked that the - for purposes of the pilot that we use a US based accreditation body that has an ILAC MRA. So, the accreditation bodies themselves would need to be US based and fit that criteria.

Testing laboratories, however, as long as they are accredited by a participating accreditation body, that is meeting the criteria can be from outside of the US as long as they're following the criteria that is outlined. And I think the

guidance is specific to that. So, there's a limitation on that the same way as there is with an accreditation body.

And I'll just kind of open that up for anyone else if there's more to add to that.

(Erin Cutts): Hi Scott, this is (Erin), I was going to add just a little bit about the application process. So just to I think this was super clear, I just want to just take the risk of being even more clear. We will be making decisions for accreditation body applications on a first come first serve basis after that initial list. So please just get your application in as soon as you can, noting that the November 4, timeline is to be on our initial list. But even if you submit on November 5, we'll be looking at that right away. You just might not make that first list. We will be looking at them first come first serve and updating our Web site as needed throughout the pilot.

(Chris Dodd): Great, thank you. Thank you.

Coordinator: Our next question comes from (Mandy Ambrick), your line is now.

(Mandy Ambrick): Thanks. Thank you very much. I think this is kind of a follow up question to one asked earlier. And that is in reference to the accreditation program, if it's going to be combined in any way with accreditation programs, for example, from CSA and UL, for example, supporting the issuance of an NRTL in the US? Thank you.

Scott Colburn: So that's a great question. And this has been something we've been actually talking about since the thought of the accreditation scheme for conformity assessment, realizing that there are a number of other regulatory jurisdictions that have similar areas and conformity assessment.

This is really, I'll kind of put it in the most simple way, it really it's up to how the accreditation body wants to address us. We are really, we are very cognizant of how OSHA works within their NRTL program but OSHA has a different operating platform and how they kind of act more as the accreditation body in their program. But we have been coordinating with them as well to kind of make sure that we're addressing similar things because we are interested in harmonization. And same thing with things like the FCC, and so forth. So, one of our goals with this is in coordination with the accreditation bodies is making sure that, you know, the program specifications clearly communicate across other regulatory programs. So, they can be, you know, intertwined into each other in a way and not have to be necessarily additive. This is probably something that we will learn a little bit more as we go on. And if you're having more questions about that, I definitely would encourage you to submit that into the program as well. So, we can go a little bit further.

I just asked if there's anyone else on the phone and want to add into that.

No, okay, thank you. Go ahead, next question.

Coordinator: Our next question goes from (Jenin), your line is now open. (Jen), your line is now open. And our next question comes from (Victor Kaczynski), your line is now open.

(Victor Kaczynski): Okay, good afternoon. So, I believe my question was a partially answer. And it was related about what's the requirements for testing laboratories located outside the United States? So, my understanding is, if they are accredited with appropriate scope by a accreditation body, US base and recognized by FDA, that will be sufficient to get recognition for that ASCA program. Is that correct?

Scott Colburn: Yes and thank you for asking a question that you answered. That makes it easier.

(Erin Cutts): The only other thing I'd add is that there's two parts to the test lab. Testing qualificationsfirst the one you mentioned, making sure you have an appropriate scope of accreditation from an ASCA-recognized accredention body. And the second is the signed agreement that we have in the guidance section itself, inside the application. And it just outlines all the things that you would agree to do agree to acknowledge as part of your participation in the program. So that's another part I wanted to point out.

(Victor Kaczynski): Great, thank you so much.

Coordinator: Our next question comes from (Yan Chen), your line is now open.

(Yan Chen): Thank you. I have a question regarding to the testing lab qualification. Let's say if a testing lab received a four eighty three warning letter in the past and still in the middle of resolving the issue. Does that disqualify the lab from attending the ASCA program?

(Erin Cutts): I can try to take that one, and then others can add in.

So we are doing a lot of training, as you heard about the dates, for our accreditation bodies to get trained on the program specifications. And we are relying on those accreditation bodies to truly go out there and look at the things that we think are important. One of the things that we are asking for accreditation bodies to do is to consider other things that -- consider, for example, GLP, and bio kind of issues.

And, you know, how they would look at that sort of information as they're accrediting testing laboratories. So I think it will be important for the accreditation bodies, they're the ones that are going to be making the accreditation decisions. And in using the ASCA program specifications, I think they will be looking at some of the same things that might have been in the 483.

Is that, does anyone want to add to that? Or maybe clarify something I was unclear about?

Scott Colburn: Yes, I think (Erin) kind of hit it well. You know, I think the easiest thing to this, there's always anytime there's a question, I would encourage you to contact us if you've received accreditation from an accreditation body that is participating in the program was received as a recognition and you want me to submit. If there's other things that are dependent upon yourself recognition that you think would be, you know, something that needs to be, you know, brought out, I know, you could always contact us and we can help walk through that as well. We want to be - tried to help make sure we walk through some of these educate type questions.

I think the guidance document itself though, does walk through, you know, what are the things that need to be necessary to demonstrate that you are, you know, someone who is qualified to be a participant, or in this case, receive ASCA accreditation. But if there's any kind of question, feel free to contact the program, and we can try to walk through that question a little bit more in detail.

(Erin Cutts): And I realized I was remiss in not saying another part. So I talked about the role of the accreditation bodies. There's also the test lab application stuff and in particular, for biocompatibility test labs we'll be looking at the procedures,

protocols, those things that are biocompatibility lab is doing. So there's also that part of the review that's needed to get granted ASCA accreditation.

(Yan Chen): Thank you very much.

Coordinator: Our next question comes from (Damien), your line is now open.

(Damien): My questions were answered already. Thanks.

Coordinator: Thank you. And our last question come from (Ross), I believe your line is now open. (Ross) for question, your line is open, please check your mute button. And our next question comes from (Mike McGrew), your line is now open.

(Mike McGrew): Good afternoon, folks, again, have echoed the sentiments from the rest of your listeners, the great presentation now very informative. My question may be more of an outcome of the ASCA pilot program, that is part of it. But I want to get it on the table. One of the elements that I experienced being in the GLP testing world is we are often audited by GMP testing manufacturing related facilities.

And as such, I think there's a mixture of the relevant systems in some of the observations, which leads to a potential muddling of those systems. And so I'm wondering if as an outcome of the ASCA accreditation, would this preclude the need for manufacturers to audit the laboratories?

Scoot Colburn: Hi (Mike) this is Scott Colburn and good to hear from you. I think there might be others that can get a little bit more specific. I don't believe it would preclude this. What we're doing when working with the accreditation bodies is looking to make sure that there's the appropriate procedures in place for you

and how you're addressing GLP and how any types of inspection findings or, you know, things have been addressed as part of the oversight and what they're taking into consideration. But it should be the same requirements and expectations that you're seeing today.

The whole idea of ASCA is not to increase or invent requirements, but to look at how the existing requirements are in place, but consistently applied and communicated across the board, so that way that helps the agency develop consistent approaches and how we can evaluate that information. So at that point, what we can do is make, how we would hope these would be addressed by any lab looking for that scope of accreditation under a specific credibility area.

I hope that, does that answer your question? It's not, I might get someone else.

(Erin Cutts): I was, if you don't mind Scott, I was going to add something in one of your points of communication and making sure we're all on the same page. So within FDA, we are coordinating and working with other folks in FDA, who perform different roles that might be affected by the ASCA program. So we'll be talking with BIMO and the folks who do audits, to understand what they're looking for. We'll be talking with pre-market review staff on what they see in the submissions that come through to really get into a continuous improvement kind of approach for the ASCA program.

So there's going to be some coordination communication amongst the individuals that allows sharing.

(Mike McGrew): Sure, actually, from my experience, anyway, I've always received pretty clear expectations from the FDA is more than manufacturers that I get very mixed

signals from. So it's more of the requirements in the FDA to the manufacturers that if they're using an ASCA accredited laboratory, there's no need for them to be conducting an audit, especially based on their lens, their lens will be different than what the laboratory is operating under.

Scott Colburn: Yes, I make that's a really good question. And I think, you know, really, you know, we can't say that the manufacturer shouldn't be doing, it is up to them and how they manage their own quality system. And you know, I'm sure you understand that, of course, but I think what, you know, what ASCA trying to do in assessing laboratories that are qualified to receive the ASCA accreditation or have been accredited by the ABs is that the procedures that are in place are there to make sure findings are being addressed that, you know, you're here at least getting, you know, GLP, you know, addressed and so forth, by the manufacturer themselves dependent upon, you know, how they're using your test to, you know, get into markets and so forth, may feel the need to do something that's additional.

Look for the purposes of ASCA that isn't an expectation that is in our guidance right now. If I'm understanding your question correctly.

(Mike McGrew): Yes. And that's what I expected. Thanks Scott.

Coordinator: Yes. Our next question comes from (Sarah), your line is now open.

(Sarah): Yes. Hi, thank you so much for the excellent presentation, I actually have a couple of questions. The first is whether the laboratory accreditation is specific to a specific lab location, or whether a laboratory that's part of a larger organization whether an accreditation could be issued to the larger organization that has multiple labs in the US or overseas.

And then my second question is, if you could speak to the process for adding other standards to the ASCA pilot program, please?

(Erin Cutts): Sure, understand, I can take a first stab at that and other folks can add in. So your first question about accreditation to specific test lab locations, we do

need to have an application for each location of the test lab. So it will be location dependent. And you can combine that in one application. If that makes sense. We just need to know exactly what scope is being requested for the different locations. And then if there are procedures and that sort of like differences, especially for biocompatibility, we would need to know the what applies to which location, that sort of thing.

Hopefully answers your first question. And then your second question about expanding to include additional standards. The ASCA program is a pilot program from the MDUFA and in FDARA and it's set to sunset, October 1, 2022.

And after that, after its sunsets, you won't be it won't be a pilot anymore. We won't necessarily have a program -- we're actually in the middle of negotiation discussions to understand what the ASCA pilot program would look like afterwards. So during this current phase - so we're in a pilot phase, we were not intending to include additional standards right away. We want to learn from our experience here first. And we also want to get input from stakeholders like yourself, if we did add additional standards.

And yes, I think that answers your question. Did I miss anything, folks? Anything to add to that?

Scott Colburn: Erin was very well put I, I'll just kind of add that, you know, every negotiation phase, because we're looking into the next stage of negotiations. And as Erin mentioned, we are interested in seeing how the pilot itself runs. And of course, we're always looking, you know, from our side of this, as you know, what would a permanent program look like? And one of those questions that we do consider is, what other types of standards would be

appropriate for such a type of program, of course, we have our recognition program that we've had in place since 1997, which permits the manufacturer to submit a declaration of conformity. But we have 1400 standards in that program right now. And we don't feel that 1400 standards is where we need to go with ASCA either.

But we are interested to learn from stakeholders in areas where they feel that this type of conformity assessment platform, a third party, so to speak, conformity assessment platform, add benefit and value to everything that we're trying to do with the objectives here. Have we spurred in some framework and proving the overall quality of submissions and testing being conducted.

So there will be times to have discussions on this, but to Erin's point, at this time, we're not intending to open up doors for a lot of different platforms for new types of standards to ASCA pilot right now, you know, we're still trying to grasp our hands around just getting the first stage going.

Once that gets going and learn more about our program, we'll probably be able to have other discussions later on how an approach like that could look. What we are most interested in is hearing from our external stakeholders on what that could look like to be of highest value for all the stakeholders that are

involved in this because it does require all of us to work together to understand best practices moving forward.

(Sarah): Great, thank you. Yes, that's perfect. Perfect, perfectly answered my questions. Thank you.

Coordinator: Our next question comes from (Dan Schofield), your line is now open.

(Dan Scofield): Thank you for the presentation was very good. My question is, so I'm part of a medical device manufacturer. And as a part of that organization, we have an accredited test labs in there that the test to the IEC 601 of particular in the collateral standards. My question is what is the benefit to us of going into this type of a program? For instance, I mean, will it shorten our 510 K approval cycle time from 90 days to something less than that? Because I haven't seen any questions from the FDA, when they're doing reviewing our 510 Ks concerning safety or EMC, for that matter? is a part of that, so.

Scott Colburn: That's a great question. And that's a common one we get from the manufacturer or stakeholder is, will this reduce my time to market I asked, you know, the use of standards and the review of testing from standards is a component of review. And so the ASCA program itself does not have as, a primary objective to reduce the 90 day time clock for 510(k)'s. But what we are very interested in is reducing the types of the additional information questions that would put a submission on hold. And, you know, in areas where if we had better understanding or a better appreciation or higher confidence in how testing is conducted to areas, then we feel we are addressing the larger question, which is that total time to market and reduction in burden both from the regulatory side but on our review staff, as well as manufacturers who have to go back and look at how testing is done, do they need to retest? Do they need to deliver testing from a different format?

So really, the benefit should be having a greater assurance that there's some predictability, that we wouldn't be looking to ask questions on how you are tested, we're going to be able to see the results of tests based upon the summary test report that is in the outlined in our guidance documents. To help better illustrate how the information that is contained and how you address say basic safety and central performance areas of the standard per

60601 and how that can easily translate to support to your intended use and other aspects that are important to the reviewer.

You know, every manufacturer has a different experience. And I think part of that is because we see a lot of differentiation and how the information is conveyed in a submission. And, you know, so I can't give a specific answer to your particular, you know, precedents on how you've gone through with premarket submissions.

But we do feel that based upon what we have heard, both from our stakeholders externally and from many interviews with review staff, that the areas that we brought into the pilot are the ones that are most commonly seen with additional information questions and add the highest burden to review staff in terms of having to submit consultations and do a lot of review work where we can lower that burden and have a hopefully a shorter review time cycle going on.

I hope that kind of paints that picture a little bit better for you.

(Dan Scofield): Okay, thank you very much.

Coordinator: Next question comes from (Amanda MacDonald), your line is now open. (Amanda MacDonald), your line is open, please check your mute button.

(Amanda MacDonald): Hi, thank you. I have two questions related to the accreditation (body). The first is under the appendix for the application under the signed agreement, one of the things we have to agree to is to provide ASCA pilot accreditation documentation to the FDA upon request. And could you just elaborate exactly what's covered under that? Would it be specific testing laboratories records that we accredit that you would be looking to see? Or could you just elaborate a little bit more about that?

And then my second question is, are remote assessments of the testing labs going to be accepted for the program?

(Stacy Cho): So I'll take a stab at those questions. The first one in terms of what's requested in that, in the description of accreditation services offered, this would pretty much just be kind of an overview of how the accreditation policies and procedures that you currently provide, or you have to be described.

And this would include whatever documents that the accreditation body deems necessary, for example, checklists or SOPs, work instructions. We didn't want to be limiting in terms of detailing out exactly what type of documentation are needed, but rather, in general, making sure that the documents provided do support an overarching understanding of the accreditation services provided, whether they're the existing accreditation services that a body might be conducting right now or kind of how it's tailored towards the ASCA program.

So I know that that's a very vague response to your question, because you probably wanted something a little bit more specific, but in terms of what it is

that we're going to be reviewing, I think it's more along the lines of does the content substantiate, you know, confidence and understanding the accreditation body and what it provides. So that can come in different shapes and forms. We don't want to be overly limiting. But that's the overarching kind of gist of the documents we'd like to look at.

In terms of your second question. Remote is definitely acceptable, given the climate now, you know, this was something that people were doing prior to the pandemic, but of course right now, we'd like to state that remote is definitely acceptable.

I hope that answers your question. If not, please let me know.

(Amanda MacDonald): Thank you.

Coordinator: And that is it for the question. But now I kind of fall back over your host Irene Aihie.

Irene Aihie: Thank you. This is Irene Aihie. We appreciate your participation and thoughtful questions.

Today's presentation and transcripts will be made available on the CDRHLearn)web page at www.fda.gov/training/cdrhlearn by Friday, October 30th. 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 live webinar, please complete a short 13 question survey about your FDA CDRH webinar experience. The survey can

be found at www.fda.gov/cdrhwebinars immediately following the conclusion of today's live webinar.

Again, it works for participating. This concludes today's webinar.

Scott Colburn: Thank you, everybody.

Coordinator: Thank you for your participation in today's conference. All parties may disconnect at this time. Leaders, please stand by.

END