

FDA PPE Webinar

Moderator: Anike Freeman

July 13

12:00 pm ET

Hello, everyone. We apologize for the technical difficulties. Please standby. We will be starting momentarily.

Anike Freeman: Good afternoon. Thank you for holding. Welcome to today's FDA webinar. I'm Anike Freeman with the CDRH office of communication and education. Welcome to the 17th and final CDRH webinar in our PPE series. During this webinar the FDA will share information and answer questions about revocation of non-approved respirators and decontamination and bioburden reduction systems. Specifically, the FDA will present information about the June 30, 2021, update. FDA no longer authorizes use of non-NIOSH approved or decontaminated disposable respirators letter to healthcare personnel and facilities. Representative from the FDA, CDC's National Institute for Occupational Safety and Health and the Occupational Safety and Health Administration will be available to answer your questions. Following a few opening remarks, we will open the line for your questions related to information provided during today's discussion. In an effort to ensure we answer as many questions as possible, we ask you use the raise your hand feature in Zoom if you'd like to ask a question during the Q&A. Now I give you Dr. Aftin Ross.

Aftin Ross: Thank you Anike. Good afternoon. My name is Aftin Ross and I am on detail as a senior special advisor for emerging initiatives in CDRH's office of strategic partnerships and technology innovation or OST. I would like to welcome you to the 17th session, and the

final session in our webinar series on personal protective equipment or PPE. We recognize that many of you are on the front lines of care and appreciate your commitment and hard work during the pandemic. Please note that as part of its commitment to protecting and promoting public health, FDA is working diligently to support your efforts by ensuring PPE availability. We greatly appreciate you taking time out of your busy schedules to attend today's webinar. In prior webinars, we discussed the regulation of a variety of devices during the COVID-19 pandemic including filtering facepiece operators and decontamination systems for filtering facepiece respirators including N95 respirators. Please note that we are at a very different place in the pandemic today regarding respirator availability than we were in March and April of 2020. As a result, FDA has revoked the EUAs for non-NIOSH approved disposable respirators and the EUAs for decontamination and bioburden reduction systems. In today's webinar, I will present information about FDA's June 30, 2021 letter to healthcare personnel and facilities which announce these revocations. After the presentation, we will turn to live Q&A. We are joined by our colleagues from NIOSH and OSHA for the question and answer portion of the session. Next slide please.

For today's agenda, I am first going to provide an overview of the letter to healthcare personnel and facilities FDA released late last month announcing the FDA has revoked the EUAs for non-NIOSH approved disposable respirators and the EUAs for decontamination and bioburden reduction systems. We will then provide a resource slide for attendees and then along with our NIOSH , OSHA colleagues answer any questions you may have regarding this topic. Next slide please.

On June 30, 2021, the FDA issued a letter to healthcare personnel and facilities where FDA announced it was revoking the emergency use authorizations for non-NIOSH approved

disposable respirators with the revocation effective July 6, 2021. And the EUAs for decontamination and bioburden reduction systems with the revocation effective June 30, 2021. As of the effective date of the revocations, these devices are no longer authorized for use by healthcare personnel in healthcare settings. This recommendation is in follow-up to the May 27, 2021 letter in which the FDA recommended a transition away from non-NIOSH approved disposable respirators as well as from reusing the contaminated or bioburden reduced disposable respirators. Based on increased domestic supply of respirators approved by the centers for disease control and prevention's National Institute for occupational safety and health or NIOSH, and consistent with CDC's updated recommendations, and in alignment with Occupational Safety and Health administration or OSHA's recently published emergency temporary standard to protect healthcare workers, the FDA believes healthcare facilities should not use crisis capacity strategies any longer. From our engagement with various healthcare facilities, we know that many were no longer using non-NIOSH approved respirators or decontamination or bioburden reduction systems. We are now recommending healthcare personnel and facilities only use FDA cleared or NIOSH approved respirators. Next slide please.

During the public health emergency, one of the ways FDA used its emergency use authorization authority to expand the availability of respirators for healthcare personnel was by issuing the NIOSH approved respirator EUA in March of 2020. Under this EUA, NIOSH-approved air purifying respirators, including disposable respirators and respirators that were designed to be reusable were authorized for use by healthcare personnel. Once a respirator receives NIOSH approval it is automatically authorized under this umbrella EUA until the US Department of Health and Human Services Secretary's declaration that circumstances exist justifying authorization is terminated or the EUA is revoked. From January 2020 through June of 2021,

NIOSH approved over 875 respirator models or configurations with some of these being manufactured by approximately 20 new domestic NIOSH approval holders. To give you further insight into the magnitude of respirators available, I would like to highlight that today there are over 6400 total respirator models or configurations on the NIOSH certified equipment list which meet the NIOSH-approved EUA criteria and thus are FDA authorized. These wide-ranging respirator types include more than 600 FFR models of which there are over 530 N95 FFR models. Over 360 PAPR configurations and over 5500 elastomeric respirator configurations including new elastomeric respirators without an exhalation valve. The availability of elastomerics without an exhalation valve is significant as one of the obstacles limiting the wider use of these reusable respirators in healthcare settings has been the inclusion of exhalation valves as a design feature. It means the respirator cannot provide source control and cannot be used in the operating room because the exhaled air can transmit respiratory secretions, which could transmit infection or contaminate the sterile field. Next slide please.

Our letter had several key recommendations that I would like to highlight which are as follows. First, the use of only FDA cleared or NIOSH approved respirators including N95s and other respirators under the EUA for NIOSH approved air purifying respirators for use in healthcare settings during the COVID-19 public health emergency. Two, transition from wearing disposable respirators for respiratory protection for an extended time to conventional capacity strategies that include wearing a disposable respirator for each patient contact, according to the CDC's recommendations, as appropriate. Next slide please.

FDA's recommendations continue on this slide and are as follows. Consider redistributing current inventory of non-NIOSH approved respirators, such as to non-healthcare settings for nonmedical use, for example, construction. Distribution to other countries in need in

accordance with Federal Food, Drug, and Cosmetic Act export provisions. Also consideration that while it is possible that non-NIOSH approved respirators may be reconditioned for use as source control the FDA does not recommend non-NIOSH approved respirators undergo reconditioning at this time, because there is current sufficient supply of source control medical devices. Next, consider continuing to increase the inventory of available NIOSH approved respirators including N95s and other disposable filtering facepiece respirators , elastomeric respirators including new elastomeric respirators without an exhalation valve that can be used in the operating room. And powered air purifying respirators or PAPRs. Next slide please

Now, I would like to describe several recent actions FDA has taken. On June 30, 2021, the FDA announced the revocation of the following EUAs. The imported non-NIOSH approved disposable filtering facepiece respirators EUA. The non-NIOSH approved disposable filtering facepiece respirators manufactured in China EUA. And decontamination and bioburden reduction system EUAs for personal protective equipment. As of today, all of these revocations are effective and thus these devices are no longer authorized for use by healthcare personnel in healthcare settings. In addition, on June 30, 2021, the FDA withdrew two related decontamination and bioburden reduction guidance documents. Those documents are provided here on this slide. In coordination with these EUA revocations the FDA updated the NIOSH approved EUA such as the scope of the products authorized under this EUA is in alignment with the actions taken on June 30, 2021. Specifically on July 12, 2021, FDA reissued the NIOSH approved EUA to no longer include the use of decontaminated respirators or expired respirators within the scope of authorization. Similarly, the FDA intends to update the guidance document enforcement policy for facemasks and respirators during the coronavirus disease public health emergency to align with these actions. Next slide please.

The FDA actions continue on this slide and are as follows. FDA has been actively monitoring the respirator supply chain throughout the pandemic and will continue to do so as facilities systemically transition away from the most extreme measures of respirator conservation. That is crisis capacity strategies towards contingency and conventional use. Though there is an increase in domestic supply of respirators for healthcare personnel, specifically surgical respirators, these surgical respirators presently remain on FDA's device shortage list as mitigation strategies such as the use of NIOSH-approved industrial respirators are still being employed. Please note that the shortage list reflects the categories of devices that FDA has determined to be in shortage at this time. It will be maintained and updated as the COVID-19 public health emergency evolves. FDA remains committed to being as transparent as possible with our stakeholders. As such, we will continue to keep healthcare personnel and the public informed if new or additional information becomes available. Next slide please.

On this slide, you will find several links for resources that are available to you for further information. The first link is for the updated letter to healthcare personnel and facilities the FDA released June 30 regarding the revocation of non-NIOSH approved disposable respirator EUAs and the decontamination of bioburden reduction EUAs. As I mentioned, earlier in this presentation, FDA has authorized the use, the emergency use of certain FFR's in accordance with CDC recommendations during the public health emergency. The next link can help healthcare facilities identify respirators for use and directly links to NIOSH approved respirators on the NIOSH certified equipment list. The other links on this slide provide helpful resources on the CDC and OSHA websites. With a third link taking you to CDC's N95 respirator optimization strategies and OSHA's emergency temporary standard. Next slide, please.

Please note that any questions you may have after this webinar may be sent via email. Also, a copy of the presentation, transcript, or the webinar recording may be found at the webinar address shown here under the heading, specialty topics and subheadings personal protective equipment. We have now come to the conclusion of our presentation. We will be answering questions that you may have at this time. If my FDA colleagues could please open the line for questions, we would greatly appreciate it. I will give you an opportunity to provide instructions to the attendees with regard to how to ask a question and then we will turn to our colleagues from NIOSH, OSHA and FDA to share comment on the presentation and some frequently asked questions.

Tony Dillon: Hello, everyone. Just some instruction for asking verbal questions. If you look at the bottom of your screen, you will see the option to raise your hands in the middle icon. If you raise your hand, we will then get to you and allow you to speak verbally. Thank you.

Aftin Ross: Thank you. We will pose our first question to our OSHA colleagues. OSHA, could you please comment on your stands regarding the use of non-NIOSH approved respirators and respirator decontamination.

Jennifer Kim: This is Jennifer Kim, acting director of COVID enforcement for OSHA. I would be happy to comment on that. From an enforcement standpoint, we are no longer exercising enforcement discretion of the respiratory protection standard as we had done during the COVID pandemic. This coincides with the FDA notice and the issuance of the OSHA emergency temporary standard for healthcare. For non-healthcare industries, we recently issued a revised interim enforcement response plan for COVID on July 7 and that plan officially

rescinded and archived those enforcement discretion memos. The new interim enforcement response plan is available and OSHA's COVID plays under enforcement and does include a link to the archived memos should you need those for any reference in the future. That is our current stance, and I thank you for the opportunity.

Aftin Ross: Thank you. I am not sure that our NIOSH colleague was able to join us. I will turn to my -- actually, Maryannr and does appear to be on the call. Are we able to elevate bpj5 to a speaker so we can have NIOSH participate in the Q&A ? And while our team works to see if that is possible, I will ask my FDA colleagues a couple of frequently asked questions.

Maryann D'Alessandro: Can you hear me Aftin?

Aftin Ross: We can hear you. Great. We will go ahead then and ask NIOSH a question before I turn to my FDA team members. Could NIOSH comment on your stands regarding the use of non-NIOSH approved respirators and respirator decontamination.

Maryann D'Alessandro: Thank you Aftin. Like FDA and OSHA, NIOSH and CDC do not believe that the non-NIOSH approved respirators and respirator decontamination processes should be used. First healthcare facilities should not be using is crisis capacity strategies at this time and should resume conventional practices. This has been updated in the CDC guidance. We do encourage all purchasers and users to check the NIOSH certified equipment list to identify the NIOSH approved respirators to purchase and use those. Second, the healthcare facility should stop purchasing non-NIOSH approved respirators for use as respiratory protection and consider using any that have been stored for source control where respiratory protection is not needed. Respirators that were previously used and decontaminated should not be stored. We have been hearing that healthcare organizations are using some non-NIOSH

approved respirators as source control devices and this should be encouraged and is acceptable. Third, healthcare facilities should also stop using the decontamination strategies such as UVGI, moist heat and vaporized hydrogen peroxide. Again, since the availability of respirators has returned to conventional levels, there should be no issue in obtaining the NIOSH approved respirators. Again this is because we do not know the long-term stability of the non-NIOSH approved respirators and decontamination methods. Thank you Aftin.

Aftin Ross: I am going to turn to a couple of my FDA colleagues to address a few topics that we've receive questions about since the revocations were issued. My first question is, what does it mean if a firm is registered and listed with the FDA under the real product codes, QKU for non-NIOSH FFRs and QKY for decontamination systems?

Cesar Perez: Good afternoon. This is Commander (CDR) Cesar Perez, I am the division director for division of establishment support within the office of regulatory programs at CDRH. If they have not already done so, firms should deactivate their product's listing in the FDA's Unified registration and listing system also known as FURLS. The firm's official correspondent should follow instructions on how to deactivate a product listing, which is found in the FDA's device registration and listing website. If there are additional questions regarding the products listing and/or there is a need for assistance on the registration and listing process, firms should contact the CDRH registration and listing helpdesk at the website.

Aftin Ross: Thank you Cesar. The next question is, can importers still import non-NIOSH approved FFR's for distribution to healthcare personnel?

Brenda Reihing: This is Brenda Reihing with the division of import operations. The answer to this question is effective July 6, 2021, non-NIOSH approved FFR's are no longer authorized for use by healthcare personnel in a healthcare setting. Any non-NIOSH approved FFRs offered for import on or after the revocation date may not be sold or offered for sale to healthcare personnel for use in the healthcare setting.

Aftin Ross: Thank you, Brenda. We will open it up for audience Q&A. First question, please.

Kevin F: This comes from To Harris, you are now unmuted.

ToHarris: With the N95 masks it seems like you are talking about the ones with valves. Does this is apply to the K95s and N95s the ones without the valves that were imported?

Aftin Ross: Thank you for your question. Let me make sure that I clarify that the revocations that we announced on June 30 and that were effective for decon systems June 30 and for the non-NIOSH approved FFR's including KN95s effective July 6 mean these devices should no longer be used or no longer authorized for use by healthcare personnel in healthcare settings. That means that those products should not be leveraged as respirators in healthcare at this time as they are no longer authorized. Next question please.

Kevin F: Next speaker is Martin Leighton. Martin, you are able to unmute yourself if you click the microphone icon on the bottom left hand corner of your screen.

Martin Leighton: Thank you, thank you. My question is to both FDA and CDC NIOSH NPPTL. Is the MOU between FDA and CDC for the review and clearance of N95 surgical

respirators, FFR surgical respirators has that been implemented and, if not, if you could comment on that and if it has been implemented, comment on that. Thank you.

Aftin Ross: Thank you. I can start and feel free to add on, Maryann. Yes that MOU has been implemented. Just to clarify, surgical N95 respirators are exempt subject to the conditions and limitations of the exemption and the MOU that we have between FDA and CDC highlight what conditions have to be met in order for N95s to be 510(k) exempt which means that if they meet that criteria and they are sufficient for the NIOSH approval and they get that approval, then those devices would not need to come into FDA for review. We have certainly implemented that process during the pandemic and I can certainly let NIOSH speak to that.

Maryann D'Alessandro: Thank you Aftin. As mentioned, the MOU was effective in 2018. From 2018 until the pandemic, there were no surgical N95s approved under the process. However, in 2020 and 2021, I believe we are up to almost 20 new ones that have been approved. How it happens now is that FDA has delegated the authority of the evaluation of the fluid resistance, flammability and biocompatibility components of that approval to NIOSH. Instead of manufacturers having to conduct two parallel processes going to NIOSH for the NIOSH approval and then FDA for the FDA clearance, they come to NIOSH for that surgical N95 approval and it is 510(k) exempt.

Martin Leighton: Thank you.

Aftin Ross: And for everyone's awareness, we did have a webinar on this topic area. I believe it was back in September, 2020. If you go to the same PPE webinar page that you may

have found the information for this webinar, you will also find a recording and transcript from that webinar which speaks to some of this in a little bit greater detail. Next question please.

Kevin F: Next question comes from Charles Shen.

Charles Shen: I have a question to the NIOSH people. I just want to find out what is the current timeline for the NIOSH approval for the N95? We are a manufacturer located in China and the way we applied for the NIOSH N95 I think about nine months ago and we are not making progress and we have reached out to NIOSH. And we were told to be patient and we understand that the priority for NIOSH is for the domestic manufacturers but with this recent FDA policy change, does NIOSH have a timeline now for the international manufacturers like us.

Maryann D'Alessandro: This is Maryann with NIOSH. I can tell you that we still are operating under our prioritization policy and domestic approvals are those that are being processed first. We have identified, I believe, we have 20 international applications that have moved up in the queue right now and those 20 applications will require site qualifications as is part of our process. Right now I do not know if you are one of those 20 or not, but they are moving up in the queue but we are still prioritizing those domestic applications. I cannot give you a timeframe at this point in time.

Aftin Ross: Thank you. Next question please

Kevin F: Next question comes from Gerard Olson.

Gerard Olson: I was wondering if FDA or NIOSH have recommendations on the use or assessment of non-NIOSH FFR's for nonmedical use for the general public. And are there any resources available to determining whether these products have the necessary filtering efficiency?

Aftin Ross: Maryann, would you like to speak to that? I know NIOSH has been involved with some of the BARDA challenge efforts for example.

Maryann D'Alessandro: I can start and then I can go to -- I think OSHA may want to speak on this as well. We have evaluated a number of these products and initially some of these products that were non-NIOSH approved respirators were authorized for use under the OSHA enforcement discretion but now since that has been pulled, I would have to turn to OSHA to respond to the use of those products in other workplaces. They have had variable performance. You can find the results of the testing we have conducted on our website. We had some that performed very well and some that did not and those that performed well along with other evaluation from FDA ended up on the FDA emergency authorization list, which is no longer valid. At this point in time, we are not recommending those for use in the workplace since they are able to -- you are able to find NIOSH approved products.

Jennifer Kim: This is Jennifer from OSHA. Yes, I would agree with that. For non-healthcare industry, we are back to full enforcement of our respiratory protection standard 1910.134, and that does require that respirators be NIOSH approved wherever there is a hazard requiring a respirator. So yes it must be a NIOSH approved respirator for those situations. Thank you.

Aftin Ross: Thank you. Next question please.

Kevin F: Next question comes from Caroline.

Caroline: My question was similar to the one just asked about non-NIOSH approved respirators in other industries. I do see that FDA recommends healthcare facilities redistribute non-NIOSH approved respirators to other industries. Given that that's not allowed from an enforcement perspective from OSHA, does FDA plan to rescind that recommendation?

Aftin Ross: Hi. This is Aftin. I want to make sure that the context for what was put forward is understood. Those are considerations that we were putting forward for consideration by healthcare organizations. It is by no means saying that that is something that healthcare organizations need to do. It just tried to give some insight, some things to think about as they think through what they may want to do with their surplus non-NIOSH approved respirators. Next question please.

Kevin F: Next question comes from Hayden Wilson.

Hayden Wilson: Hi there. I guess this is a question for both OSHA and NIOSH. I understand the revocation of non-NIOSH approved devices. In the event that the public health emergency approvals are rescinded, is there any plan for how those devices will be, I guess, guided to be used or distributed?

Maryann D'Alessandro: This is NIOSH. At this point in time, we are working through what that might look like. At this time we are recommending the public health emergency approvals

come into NIOSH for conventional approval and that you start phasing out the sale of those PHE approvals.

Jennifer Kim: This is OSHA. I have nothing to add to that comment. I would agree with that comment. Thank you.

Aftin Ross: Next question please.

Kevin F: Andres Maldonado

Andres Maldonado: I have a question, I guess, for maybe all three. The recommendation -- part of the recommendations are for respirators to be used only single contact so that the assumption is that they should be disposed of after each patient contact. I want to just make sure that's correct as part of the recommendation. Secondly, are there plans to look at further recommendations moving forward for the use of respirators versus surgical masks in healthcare settings? Any changes that are coming down the line from OSHA or CDC guidelines standpoint?

Aftin Ross: Maryann, did you want to start?

Maryann D'Alessandro: Sure I can start. In the updated CDC guidance, we do recommend that the number of reuses for respirators should be limited to no more than five uses or five donnings per device by each healthcare worker to ensure adequate respiratory performance. Excuse me. Sorry. We also have some studies underway where we are looking at how this recommendation may evolve in the future because we have heard throughout the response that

wearing the same product and going from patient to patient may be a feasible path forward but we do not have the research at this time to make any recommendation other than what we have in our current guidelines. We are confident that our research studies may provide other answers going forward or other inputs what the future guidance should be.

Aftin Ross: To follow-up on what Maryann said, certainly in alignment with CDC recommendations with regard to use practices. We are recommending that facilities start to transition back to more of those conventional use practices with regard to the use of the respirators as the supply certainly has increased to be able to afford more of that as we go forward in the future. Again, I think there may have been a question with regard to a contact versus an encounter and what that means. I don't know if you want to speak to that with regard to what that means for conventional use, Maryann.

Maryann D'Alessandro: For conventional use, the only recommendation we have right now is the five donnings recommendation. The contact and encounters we do not have any recommendation apart from the donning recommendation used by the same healthcare practitioner per device.

Aftin Ross: Thank you, Maryann. Next question please.

Kevin F: Next question comes from Rana.

Rana: Hi my question is to FDA and OSHA and possibly NIOSH as well. If we would like to bring an N95 mask to the general public not necessarily to healthcare worker or any healthcare setting, first, the FDA recommendation for NIOSH approval and five times and not

being able to use it for more than five times still remain even if it is meant for general public use?

Aftin Ross: Good afternoon. First, I just want to clarify and this position has been fairly consistent throughout the public health emergency that generally speaking it is not recommended that the general public needs to wear a respirator as part of the -- as PPE. Certainly there have been a lot of research and studies that have been done throughout the pandemic with regard to using various masks for source control. There are a lot of nuances related with respirators and their fit and fit being very important with regard to how well the respirator does or does not perform. It can be challenging to get that fit right in workplace settings which is part of the reason why OSHA has its various enforcement policies. For that reason as well as thinking about comfort for wearing these products for long periods of time, we do not recommend the use of respirators generally for the general public. I don't know if NIOSH or OSHA would like to speak to that.

Aftin Ross: Aftin this is Maryann with NIOSH. I will provide my perspective. I would agree with what you said up to this point, and also mention we have a national Academy committee on respiratory protection for the general public and contingent workers--

Rana: I'm sorry – I'm losing you– [overlapping speakers]

Maryann D'Alessandro: I'm sorry can you hear me ?

Aftin Ross: I can hear you Maryann.

Maryann D'Alessandro: We have this study that is underway and a report will be delivered to the government February 2022. The committee is continuing to meet through September, I believe, and the report will be finalized and submitted to peer review and then delivered to the government in February. I don't expect any recommendations will change until that report is delivered. And dissected. Thank you.

Aftin Ross: Thank you. Next question please.

Kevin F: Martin Leighton with a follow-up question.

Aftin Ross: Please

Martin Leighton: Thank you. I am going to go back to a previous callers question. I think during the pandemic, the healthcare providers particularly learned a great deal more about the differences between respirators versus surgical masks, and I think we all agree that in a surgical N95 affords a great deal more protection both for the patient and the user, the healthcare provider than a surgical mask. Does the CDC and or FDA anticipate that there may be a change in the standard and the standard of care expected of hospitals and perhaps even JCO in requiring that a surgical N95 be used in surgery and other procedures where the protection is critical? Thank you, that's my question.

Aftin Ross: I will start and if NIOSH or OSHA colleagues want to chime in, feel free to do so. I am not aware of any forthcoming changes to use practice guidance as it relates to the use of surgical respirators in healthcare. I will see whether my NIOSH or OSHA colleagues have anything else they would like to add.

Maryann: This is Maryann. I will start with NIOSH and I will say also, the same as you, Aftin, there are no forthcoming changes. However, I also want to mention that when it comes to respiratory protection, the standard N95 is as protective as a surgical N95. I think what we are looking at now is when a standard N95 may be able to be used in healthcare when the surgical N95 may not be needed. Those are some of the things we are discussing right now.

Jennifer Kim: This is OSHA. I would agree with that. I have nothing else to add and I'm not aware of any forthcoming changes either. Thank you.

Aftin Ross: Thank you Jennifer.

Martin Leighton: I did ask about the difference between a surgical mask and a surgical N95. Not the difference between an N95 and a surgical N95. I am wondering if clarifying that changes any of your responses. Again, a surgical mask is significantly different than an N95 or surgical N95 in terms of the protection it affords and clearly a surgical N95 and N95 provide more protection than a common surgical mask.

Aftin Ross: Yes, no, thank you for the clarification. I did understand your question the first time with regard to a surgical respirator or respirator versus a surgical mask. FDA's answer remains the same and that we are not aware of any changes in use practice or guidance as it relates to those two devices. I will see if my FDA, I'm sorry, CDC or OSHA colleagues want to update anything they said based on the additional clarification.

Maryann D'Alessandro: I would say the same. I don't have anything to add, but I will also state that like you said like the caller said we have learned a lot throughout the pandemic. I believe that going forward we will probably be looking at what the future looks like when it comes to the standard of care and any changes. At this time, there are no changes planned, to my knowledge.

Martin Leighton: Thank you.

Jennifer Kim: This is OSHA. I would also agree with that as well.

Aftin Ross: Thank you. I think we have time if there's one more question otherwise we will have two get ready to close the call.

Kevin F: We have one more question from Donna.

Aftin Ross: Ok. Thank you.

Donna: Good afternoon. Can you hear me?

Aftin Ross: Yes, we can.

Donna: I just want to clarify that I heard the response correctly, so this is in context to previously approved on the FDA list of KN95s in healthcare settings. I believe what I heard going forward as of date of this effective revocation.

Aftin Ross: They are no longer authorized for use in healthcare settings as of the effective date of the revocations.

Donna: Thank you.

Aftin Ross: Thank you very much. We greatly appreciate everyone's active engagement during the webinar today and appreciate you taking time out of what we know are very hectic schedules to participate in the webinar. We hope you found value in the presentation and in the Q&A in particular. Certainly if there are additional questions, we have up on the slide here an opportunity to submit those questions. We certainly tried to get through as many as we could today. We greatly appreciate throughout the pandemic the active participation in our PPE webinars. This will be the last formal webinar within the series but certainly as appropriate if other topics come up and there might be a need to have an ad hoc webinar, we will do that as needed. Thank you again for your time. I will turn it back over to Irene to close this out. I also want to thank our CDC and OSHA colleagues for participating in the Q&A today.

Anike Freeman: Thank you.

Aftin Ross: I'm sorry, it's Anike.

Anike Freeman: No problem. We appreciate your participation. Today's presentation and transcript will be available on the CDRH webpage at www.fda.gov/training/cdrhlearn. If you have questions, use the contact information provided. We appreciate your feedback. Following the conclusion of the webinar, please complete a short, 13 question survey that can be found at www.fda.gov/cdrhwebinar immediately following the webinar. Again thank you for participating, this concludes today's webinar. Recording stopped.

[Event Concluded]