FDA Webinar Series:
Respirators for Health Care Personnel Use during COVID-19 Pandemic

Moderator: Irene Aihie
June 23, 2020
12:00:00 PM ET

Coordinator: Welcome and thank you for standing by. At this time all participants will be on listen-only, until the question and answer session of today's conference. At that time, you may press star 1 to ask a question. Today's conference is being recorded. If you have any objections, please disconnect at this time. I'm now turning the meeting over to your host, Miss Irene Aihie, please begin.

Irene Aihie: Thank you. Hello and welcome to today's FDA webinars. I am Irene Aihie of CDRH's Office of Communication and Education. Welcome to the second CDRH webinar in a series on the topic of importing respirators for health care personnel use during the COVID-19 pandemic.

Today, we will be joined by experts from FDA Center for Devices and Radiological Health and the Office of Regulatory Affairs and colleagues from the Occupational Safety and Health Administration and National Institute of Occupational Safety and Health. During this webinar, FD's ORA will speak about importation respirators and collaborative efforts regarding sampling and testing of international respirators.

In addition, CDC NIOSH will describe its respirators testing, including the modified filtration efficiency testing they perform as part of their international respirator assessment. Following the presentation, we will open the lines for your questions related to the information provided during the presentation.

Now I'll give you Doctor Suzanne Schwartz, Acting Director of CDRH's Office of Strategic Partnership Technology Innovation.

Dr. Suzanne Schwartz: Thank you very much, Irene. Let's turn to the next slide, please. As Irene mentioned, today is the second session in our biweekly webinar series on PPE, where we're continuing our discussion on respirators for use by healthcare personnel during the COVID-19 pandemic response.

In our launch event two weeks ago, FDA, CDC NIOSH and OSHA provided a broad overview of respirators in health care that would serve as the foundation upon which we would then devote subsequent sessions for a deeper dive.

As a refresh. I mentioned last time that the presence of significant national shortages of respirators through the height of the pandemic, with rapidly increasing numbers of COVID-19 cases and inadequate supplies to protect healthcare personnel, serves as an important backdrop to further contextualize why FDA issued three respirator EUAs..

We underscored that this is illustrative of FDA's constant attention and monitoring of the evolving needs of healthcare personnel - that is balancing the supply-related concerns with the necessity to ensure that product made available to our healthcare workforce is indeed, providing adequate respiratory protection.

I'm therefore most pleased to welcome our two speakers from across FDA and

CDC NIOSH, whose exemplary and coordinated efforts are emblematic of federal government working in collaboration to address these challenges of meeting adequate respiratory supply with ensuring proper performance.

We will first hear from John Verbeten, Acting Deputy Director of the Office of Enforcement and Import Operations in the FDA's Office of Regulatory Affairs, or ORA. John will then hand this session, over to John Powers, who is the Branch Chief of the Evaluation and Testing Branch within NIOSH National Personal Protective Technology Testing Laboratory, or NNPPTTL.

Next slide, please.

Upon John Powers conclusion of his presentation, he will turn it back to me and we will ask the operator to open the line for questions.

With that, I'd like to introduce John Verbeten, the floor is yours.

Next slide.

John Verbeten: Thank you and good afternoon. I appreciate the opportunity to speak before this particular webinar today. And I do want to speak a bit to what FDA - what FDA is doing in collaboration with CDC NIOSH when it comes to the respirator sampling under the COVID-19 pandemic.

We can go to the next slide, please.

First, I wanted to speak just a little bit about my organization. I'm part of the Office of Enforcement and Import Operations, which are one of nine offices that fall under the Office of Regulatory Affairs. ORA has over 5000 personnel, in more than 200 locations who work every day in public health

protection. We are, we are predominantly an operational organization. We perform both civil and criminal investigations and inspections, analyze samples and inspect imports at all of the ports of entry.

We're broken into three main from sub-offices. The Office of Human and Animal Foods Operations, Office of Medical Products and Tobacco Operations. And of course, the Office of Enforcement and Import Operations.

We have contracts and cooperative agreements with many state partners to perform inspections under FDA's authority. And most of this activity takes place as part of the food program.

Next slide, please.

We have great partnerships with the different product area centers, which we have to do in order to fulfill our obligations. Most notably and we'll speak to the things we are working on in conjunction with the Center for Devices and Radiological Health. But as you can see, we work with all the different product areas, all the different product areas in our regulatory programs.

Next slide.

And our main function here us just supporting FDA core business functions. Obviously with an eye towards safety and efficacy of the products we regulate through different areas of the product lifecycle from premarket reviews, overall product safety and compliance, and our consumer and patient safety areas.

Within the Office of Regulatory Affairs, we conduct inspections encompassing all the products regulated by FDA. We conduct sample

collections and analysis of both products on the import side and that are produced domestically, and we have our own laboratory capacity.

We spend (and my personal bread and butter), we conduct a number of import product reviews covering over 45 million discrete shipments of FDA regulated products imported in the US in the last fiscal year; reviewing those imports and ensuring the safety and compliance of those products as they're imported; conducting investigations into consumer complaints, responding to emergencies such as foodborne outbreaks, following up on recall situations, and of course, our Office of Criminal Investigations, investigating suspected criminal violations related to FDA regulated products.

Next slide, please.

That's a little just a quick obviously snapshot of ORA and some of the things that we do. Of course, we're here to talk to speak specifically about the FDA sampling of respirators during COVID-19 and our collaboration with CDC NIOSH.

Our sampling, that's been going on in this area is in direct support of FDA emergency use authorizations. We're looking specifically in this program at the non-NIOSH approved respirators that are being imported from China and with the focus on ensuring these products meet the expected 95% filtration efficiency level.

The way that the process works is that samples are collected by FDA and then they are tested by CDC NIOSH; CDC NIOSH having the capacity and the ability to conduct this type of analysis and having the historical knowledge and capabilities for during this type of analysis.

And specifically speaking to the emergency use for authorization covering non-NIOSH approved respirators manufactured in China, any lot or shipment of respirators not meeting that 95% filtration efficiency level cannot be distributed as respirators.

Now we began this program during our regular activities, or I supposed regular is not the proper term to talk about what we're doing under COVID. But during our activities and our collaboration with CDC NIOSH and as part of as mentioned earlier, ongoing coverage of respirators under the emergency use authorization.

We did notice that through CDC NIOSH testing there were products that were not meeting the stated efficiency specifications and this caused concern and led us to moving forward with this particular program in collaboration with CDC NIOSH.

Next slide, please.

For those of you who were in attendance at the webinar from two weeks ago, some this will look familiar as it was covered there. There are the three current respirator emergency use authorizations we spell out here. The one that was specifically going to be focusing on in our discussions today are the non-NIOSH approved disposable filtering facepiece respirators manufactured in China, the third one on this list.

Next slide, please.

Again, this is repeat information from the webinar from a couple of weeks ago, but it lays out the criteria for using the emergency use authorization specifically for non-NIOSH approved respirators from China.

And with our efforts with CDC NIOSH, what we've been doing is working to ensure again that the products that are being imported and intended for import for use as respirators meet these criteria specifically again; that 95% filtration efficiency level.

Next slide, please.

So, when it comes to the emergency use authorization for the non-NIOSH approved respirators from China, there were a certain number of manufacturers and their products, their models that were authorized under the Appendix A but where an adjustment to the emergency use authorization were no longer listed on the Appendix A, but were eligible to be placed back on the Appendix A if they met certain criteria.

There needed to be a submission of information to FDA within 45 days of that adjustment on May 7, so that date would have just recently past, 45 days from May 7 is June 21. Those submissions of certain information has to be made to FDA for (unintelligible).

And in addition to that, they need to arrange for FDA sampling of the products so that FDA can get that sample, submitted to CDC NIOSH for their analysis. Now as of yesterday June 22, there have been 42 Chinese firms authorized and added to the appendix A through these criteria.

Next slide, please.

So, as I mentioned just now the manufacturing needed to arrange with FDA for FDA to collect the sample size is 30 respirators. I'm bringing this up a couple of them just to point out for folks that are intent was to arrange for this

kind sampling with the manufacturer of the respirators, as opposed to US Agent or the importer of the products.

We did this to give us a better assurance that the product we were having analyzed by CDC NIOSH was a legitimate product from the manufacturer, and to avoid any questions about the source of the products that we were sampling.

As I mentioned, sample sizes, 30 respirators, which we would collect randomly across all lots in the particular shipment of that respirator model. FDA and CDC had discussions on this and wanted to make sure that we provided a statistically significant sample in support of any results that may be found.

Once FDA collected those samples are submitted to CDC NIOSH for analysis according to their standard test procedures. John Powers is going to speak more to the CDC NIOSH process for that and again the goal here is to assess the filtration efficiency so we can be determine applicability for that emergency use authorization.

Next slide, please.

So, after the sampling by FDA and submission to CDC NIOSH, CDC NIOSH goes through their testing protocol and provides back their analytical results. CDC provided those back directly to FDA and CDC also publishes those results online for all to see. There's a link to that page here on the slide.

For those models that are tested and found to, you know, meet or exceed a 95% filtration efficiency presumed all other criteria for emergencies use authorization are met, then the product may be included in the Appendix A

under the criterion three. Products that do not meet the 95% filtration efficiency will not be included in the appendix A under that criterion three, and those products cannot be distributed as respirators. They can't be used for those purposes as they do not meet the criteria in the emergency use authorization, and would either have to have a different use for it or, you know, within the import process may ultimately be refused admission by FDA and have to be exported or destroyed.

Next slide.

So, the non-NIOSH approved filter and facepiece respirators manufactured in China that meet the criteria under the emergency use authorization can be used and are acceptable for use as respirators in health care settings pursuant to the applicable recommendations.

The products that do not meet the criteria for eligibility under the EUA, may be eligible for authorization as a face mask for use as source control, presuming that they meet criteria for eligibility under the face mask emergency use authorization. But again, they're not eligible for use as respirators, and in our process of dealing with those products, we need to make sure that the products are not marketed or labeled in a way that either explicitly or implicitly indicates that they're for use as respirators. Again, they may be other uses for those products outside of respirators. But those need to be worked through and ensure that you meet the applicable criteria for those other uses.

Now that the 45-day window has closed for these submissions from inclusion on Appendix A, we will continue to do some level of surveillance sampling just ensure that products being imported for use as respirators do meet that 95% filtration efficiency, the processes will remain the same. Those results

will be identified online for anyone who has a need to review those.

Next slide, please

And so that is obviously a quick overview of the sampling that's being done in conjunction to CBC NIOSH. I will now pass or to my new friend, John Powers, CDC NIOSH to take over from here.

John Powers: Thanks, John. Next slide, please.

So, as John and Suzanne have already indicated. My name is John Powers, and I am the Branch Chief for the Evaluation and Testing Branch at the National Personal Protective Technology Laboratory.

I'll give a brief overview of NPPTL, and where we lie in the federal organizational structure. I'll then discuss our conventional respirator testing as well as the international respirator testing we have been conducting for the past three months, and then I'll go into some of the results of the International respirator assessments we've been conducting.

Next slide.

So, as Suzanne already indicated, NTPTL is part of NIOSH. NIOSH is part of the Centers for Disease Control and Prevention, which lies within the Department of Health and Human Services.

Next slide, please.

So, NIOSH has several divisions and laboratories across the US. The Office of the Director has staff in Washington DC and Atlanta, Georgia. NPPTL has

offices in Pittsburgh, Pennsylvania, and Morgantown, West Virginia, and other locations include Cincinnati, Ohio; Denver, Colorado; Spokane, Washington; and Anchorage, Alaska.

Next slide.

NPPTL has three branches, the Conformity Verification and Standards Development Branch is primarily responsible for executing the respirator approval program. This branch also develops consensus standards and develops policy.

The Research Branch conducts studies related to PPE, including respiratory protection and protective clothing and ensembles. This branch also conducts human performance and surveillance studies, as well as investigating workplace interventions, and conducting outreach.

My branch, Evaluation and Testing, or ETB, conducts all pre-approval and post-approval testing for the respirator approval program. We also are responsible for all post-market activities including product audits, site audits, and product investigations. We also support the Research Branch with testing the protective clothing, including isolation gowns and firefighter protective ensembles.

Next slide.

So, before COVID-19, our branch operations were primarily focused on the respirator approval program and post-market activities. As part of the approval program, we evaluate filtering facepiece respirators, Elastomeric half-facepiece respirators, full-facepiece respirators, self-contained breathing apparatus, and closed-circuit escape respirators. And this slide just shows

some examples of different types of respirators.

Next slide.

I want to describe our conventional respirator testing operations with regard to N95 filtering facepiece respirators, which are commonly referred to as FFRs. There are three standard test procedures that are performed on N95 FFRs. STP-0003, which checks the exhalation resistance. STP-0007, which checks inhalation resistance, and STP-0059, which checks the filter efficiency level against solid particulates.

I'm not going to get into the details about the requirements for STP-0059, but I've listed the primary requirements of the test procedure, including preconditioning, flow rates, particle size, and aerosol concentration. It should be noted that 20 samples are tested, and all 20 must pass this test.

Next slide, please.

So, when the COVID-19 pandemic reached the US, I don't think anyone anticipated the PPE shortage that was upon us. Once the normal supply chains and stockpiles were depleted, something had to be done to address the shortage.

Next slide, please.

NPPTL has worked with the international standards organization, and had knowledge of international standards that were similar to the US respirator requirements found in 42 CFR Part 84. 3M’s personal safety division issued a technical bulletin showing how other international standards compared to the requirements of 42 CFR 84. This slide shows part of the table included in the

3M technical bulletin. As you can see, for the most part, the international standards shown, have similar requirements to 42 CFR 84.

Next slide.

To address the shortage, strategies were developed to optimize the supply of N95 respirators. Three strategies were developed including a conventional capacity, a contingency capacity, and a crisis capacity. The crisis capacity strategy includes the use of respirators approved under standards used in other countries that are similar to NIOSH-approved respirators.

Next slide, please.

So, what seemed like overnight, the US market was flooded with masks and respirators from China. So, we started seeing KN95s, GB2626, EN149, GB19083. We saw products that have no markings on them. We also started seeing packages in Chinese and Korean questions were being asked, what does all this mean and how do I know what I have will protect me.

Next slide.

So, to help workers answer these questions, NPPTL created the international respirator assessments, a test plan was created as well as an online form. Through the online form, users could submit products for evaluation.

This slide shows the requirements that were incorporated into the test plan, which we refer to as the modified version of STP-0059. The differences between the standard STP and the modified STP are shown in red.

As the assessments progressed over time. We made adjustments regarding the

sample size. So, as John already indicated, for our support to the FDA, regarding the emergency use authorization, we developed a sample size of 30. This sample size is based on the statistical probability of finding poor performing products among a shipment of good performing products.

Another adjustment was made, involving investigations that were being conducted by FDA criminal investigators, FBI agents, and US Postal Inspectors. In these cases we may test more than 10, depending on the specific request of the agency conducting the investigation.

We have also made adjustments to what we accept for assessment. For the past few weeks, we have committed to only testing products that were directly related to the FDA Emergency Use Authorizations. We also accept products from other state and federal government agencies, regardless of the status of the EUA.

Next slide, please.

So now we'll go into some of the International respirator results that you've seen. As of June 17th, we have completed 282 International respirator assessments. This slide shows the distribution of completed assessments by international standard. Over half of the assessments are for products claiming to meet GB2626, which is the Chinese standard for respiratory protective equipment, non-powered air-purifying particle respirators.

The next highest percentage of products, have claims that they meet GB2626 and EN149. EN149 is the European standard for respiratory protective devices, filtering half masks to protect against particles, requirements, testing, and marking. The next highest group of products claim to meet EN149 only. Combined EN149 and GB2626 comprise 84% of all the products that have

been evaluated.

Next slide, please.

The slide shows the assessment results by international standard. Products that claim to meet EN149 or GB2626 have similar results, with ~40% having filter efficiencies equal to or greater than 95%. While 60% of the products have filter efficiencies less than 95%.

Products claiming to meet EN149 and GB2626 only have 15% with filter efficiencies equal to or greater than 95%. While 85% of those products are less than 95%.

Of the 14 products we evaluated that claimed to meet GB19083, 13 or 93% of them have filter efficiencies equal to or greater than 95% while only one of the products was below 95%.
Overall, all of the products are averaging approximately 40% with filter efficiencies equal to or greater than 95% and 60% that are less than 95%.

Next slide, please.

NIOSH recommends that you purchase respirators with a traditional head strap design. 91% of the FFRs we've evaluated have ear loops. OSHA regulation 1910.134 requires employers to develop and implement a respiratory protection program when respirators are necessary to protect the health of the employees, or whenever respirators are required by the employer. The regulation provides information on the proper selection of respirators, medical evaluation of employees, and training to name a few.

The regulation also provides guidance on fit test procedures. Appendix A of this regulation contains the fit test procedures which includes eight exercises that must be performed during the fit test. During the COVID-19 national emergency, OSHA issued a memorandum temporarily suspending the annual fit test requirement as long as the employees continue to use the same model, style and size respirator, that the initial fit test was conducted for.

If a different respirator is issued to the employee, the initial fit test requirement still exists, and should be conducted by the employer. This would include switching from a respirator with head straps to a respirator with ear loops.
Preliminary NIOSH assessments indicate that it is difficult to achieve an adequate fit when wearing respirators with ear loops. Several agencies have attempted a fit test with ear loop designs and have anecdotally told us that they cannot get a passing fit factor.

NIOSH strongly recommends that users do not purchase a respirator with ear loops without first conducting a fit test with multiple people with varied facial structures following requirements of your respirator protection program.

So (John) already had this same link on his slide, but it's here as well. So this link provides the results of the assessments.

When you go to this link the assessment results are shown in alphabetical order by manufacturer name. And also we have added a separate table at this link, for manufacturers that have notified us that the products we evaluated were not theirs and may be counterfeit. These have been moved to the separate table on the results page.

Next slide, please.

So I'm going to end my portion of today's webinar by pointing out some additional resources available on our Web site. So every effort should be made to purchase NIOSH approved respirators. There are numerous manufacturers that make NIOSH approved respirators, including several from other countries. The NIOSH certified equipment list is searchable using many different terms.

For example, you can select N95, hit the search button and every manufacturer that makes a NIOSH approved N95 will be returned. Another resource you can check is the respirator user notices. This page contains notices regarding voluntary rescissions of NIOSH approvals. The page also shows an example of what a properly labeled filter facepiece respirator should look like, including required information.

A final resource I would like to mention is our Web page on counterfeit respirators and misrepresentation of the NIOSH approval. When we receive a notification of potential counterfeit products or products that are misusing the NIOSH approval, we always contact the manufacturer to have them verify and validate the information that we have received.

Recently we have received several requests directly from manufacturers that have been added to this page. We always provide pictures to aid users in spotting these products.
So this concludes my portion of the presentation. And I will now turn the webinar back over to Suzanne.

(Suzanne Schwartz): Thank you. Thank you, to both John Powers and John Verbeten, on your very informative talks. At this point, we've concluded the formal presentation portion of the webinar. We'd like now to open it up for moderated Q&A. And

we also have several subject matter experts from across the three agencies, who are standing by for assistance and support with respect to different questions. Operator, may we have the first question, please?

Coordinator: Thank you. We'll now begin the question and answer session. If you would like to ask a question, please press star 1. You will be prompted to record your name. Please be sure to unmute your phone. Once again, if you would like to ask a question, please press star 1. We'll pause for just a moment to allow those questions to start coming through. (Andrew), please check your mute button. The next question comes from (Albert). Your line is open, (Albert).

Albert: Hi. So I understand most of this pertains to products made in China. We make our masks in Hong Kong and I was wondering if that's - this relates and applies to what we make. And also if so, how do we submit our products for assessment?

Suzanne Schwartz: Thank you for that question. So let me, first of all, ask if any of our representatives from NIOSH want to take that question with regards to testing? So hearing none, so this is Suzanne Schwartz, FDA. What I recommend is given the manufacturing site is in Hong Kong, that you reach out to FDA with a separate request for an emergency authorization that would include information about your respirator and the testing that has been done on it as well as whether you have at present any certification such as the CE mark), so that we can evaluate that.

(Albert): Okay. Thank you. I sent it to CDRH-nonDiagnosticEUA-Templates@FDA.HHS.gov. Is that the correct email?

(Suzanne Schwartz): That is the correct email. That would require however, an evaluation that is separate from the umbrella EUA for products manufactured in China.

(Albert): Okay. Got it. So I should just wait for the response there then?

(Suzanne Schwartz): Yes.

(Albert): Thank you. That's all. Thank you.

Coordinator: Our next question comes from Peter. Your line is open.

(Peter): Yes. Thank you for the presentation. I had a question from the last presenter whose bar slide showed the results of the different respirators. And I was unclear if the percentages that were illustrated like let's say one of them was 60%. Was that the average filter efficiency that you actually found instead of the 95% or is that the percentage of respirators that failed or were below 95%?

John Powers: That's correct. That's the percentage of those that were below the 95% for efficiency.

(Peter): Do you have any information about how far below 95% they were?

John Powers: Some of them go as low as 4% or 5%. All the results that are posted on the Web page...

(Peter): Okay, thank you.

John Powers: In the table, you can quickly see the maximums and minimums that we recorded as part of the assessment.

(Peter): Okay, great. Thank you.

Coordinator: The next question comes from Aaron. Your line is open.

Aaron: Hi there. This is Aaron from Open Standard Respirators. My question is a little bit unique in terms of the model here. We're currently developing a respirator that multiple manufacturers are going to produce. Some of them are actual medical name respiratorss and then some potentially for non-medical use.

And when my question comes into effect here is understanding within the NIOSH certification process, does that happen and have to be fully linked to an explicit manufacturer? Or if we are licensing our device for production by multiple manufacturers, could the NIOSH certification be rooted to the device rather than tied to the specific manufacturer?

(Jeff Peterson): So this is Jeff Peterson from NIOSH. Essentially we approve the respirator device as well as the system under which it's manufactured. So the approval holder must be the one that actually controls the design and intellectual property of the design. The approval holder could have multiple manufacturing types under the same approval; however, the approval holder must demonstrate that effective controls over each manufacturing site are present within the quality system.

Aaron: Does that have to follow through typical GMP and typical device manufacturing quality system practices? And so the NIOSH certification would have to be to the manufacturer? So if multiple manufacturers are making it, multiple manufacturers would have to be NIOSH certified then?

(Jeff Peterson): No. We don't tie the certification to the manufacturing sites. It's to the product and the approval holder. So the approval holder has to retain the control over all of the sites that manufacture. So there are alternate ways that folks can

achieve that. So I don't want to get into a lot of detail here, but maybe, you know, certainly you can reach out after this call and we can have a further discussion.

Aaron: Excellent. Thank you.

Coordinator: And next we'll go to Andrew. Your line is open.

(Andrew): Good afternoon. Thank you for taking my call. And frankly, thank you for hosting these weekly conference calls on a variety of subjects. They've been very helpful. I wasn't sure from the discussion though in this call, as far as the timings of manufacture N95 devices was concerned, regarding whether there would be a sampling that would be required as a prerequisite to be included on the FDA's white list.

In the guidance, it doesn't indicate that. But based on this discussion I wasn't sure whether that requirement might be added here or whether they would simply - whether FDA would simply rely on post-market or post-market sampling to establish the, you know, the quality of the devices.

Suzanne Schwartz: Thank you for that. This is Suzanne Schwartz, FDA. It's certainly been a complex picture because the EUA that FDA authorized, FDA issued for product manufacturing in China, has undergone several revisions. So let me clarify that with respect to the assessments that you heard today, the assessments that have been performed together - between FDA collection of 30 samples of products from the manufacturer and submission to NIOSH for testing - has been specifically targeted at those manufacturers and those products that were originally listed on Appendix A based upon one of the criteria, it was criterion 3 if you went back historically and looked at the original EUA that we issued on April 3rd.

That was a criterion based upon test reports. When we revised that original China EUA, the EUA of April 3rd, (and we revised it on May 7th), we removed from the Appendix those manufacturers who were authorized as a result of Criterion 3.

But we put in the condition - the condition that we've been hearing about today, which is an opportunity for those manufactures to demonstrate through NIOSH testing of meeting adequate filtration efficiency performance and ability to get onto the Appendix A and get authorized under the revised Criterion.

So what does that mean as far as going forward? I think what we did hear is that there was a specific window, a 45-day window that we had stated in the May 7th EUA, and we are now officially past that window for those products that were originally listed, under criterion 3. That being said, products that have come in through imports in China that are authorized, will continue to undergo random sampling and surveillance so that we can monitor consistency and reproducibility, in the performance over time.

And then secondly, there is an opportunity for manufacturers in China to continue to be authorized but it would not be under this criterion of joint testing. It would be either by having - by being a NIOSH approval holder already, or alternatively, by having or obtaining the CE mark or NMPA certification. I would point you to the June 6th EUA revision that specifies that. And we certainly can explain further offline, if you have further questions.

(Andrew): No. Thank you. That was incredibly helpful. I appreciate it very much.

Coordinator: Next, we'll go to (Skip Siddington). Your line is open.

(Skip Siddington): Yes. Thank you. I'm from Kaiser Permanente and thank you for these informational sessions. But more importantly, thank you for the continued support with the EAUs. They're vitally important. Without them, I'm not sure we'd be as successful as we've been in this site. So I hope there's no thought of relaxing those or pulling those back.

But my question is we're conserving as many parts of medical-grade N95s as we have in our inventory. But as more and more N95 industrial use or industrial type N95s come available, we're still a little confused on that. Is it safe to say that an industrial N95 would do the same job as medical-grade N95 and we don't have to worry about, you know, efficiencies and effectiveness? We used them during the last pandemic and the issue was then answered with we could not get a good fit test success rate.

We had 70%, 80% failure that had to do with I guess the sizing of the mask. So other than that, is there any other difference that we need to be concerned about in terms of the industrial versus medical-grade N95s? Thank you.

Suzanne Schwartz: This is Suzanne Schwartz, FDA. I'll start off answering the question. I'm also going to turn it to our colleagues at NIOSH to further expand on the answer. And with regard to even the fit aspects, we have our colleagues from OSHA on the phone, who also might weigh in here.

During the context of this public health emergency, the emergency authorizations provide the authorization for all NIOSH approved respirators that are on the CEL list. And the vast majority of those are industrial respirators.

If one were needing to use a respirator in an aerosol-generating procedure or an operating room, then both FDA and CDC NIOSH have provided recommendations in order to provide additional protection for that fluid barrier, that fluid resistance. But with respect to the pandemic, at present your NIOSH approved or FDA cleared respirators, are the place where you would start.

And beyond that availability, the other authorized respirators that FDA has issued starting with the import EUA and then subsequent to that, the China - the products manufactured in China EUA, would be an approach towards obtaining adequate coverage of performance and protection. Maryann or Jeff, is there anything that you want to add specifically, with regard to this questioner's concern around industrial respirators?

(Jeff): Sure. This is (Jeff) from NIOSH. So I think that the biggest thing to realize as (Suzanne) said, in terms of respiratory protection that's provided to the user, is that all products meet the relevant standards. So there are things like fit and such that aren't evaluated as part of the approval process because OSHA does have the requirement to do fit testing on a regular basis as we move forward.

So selections that are made for industrial types of repirators that are N95s with or without valves, should and will offer the same level of respiratory protection. This is a concern with a splash or fluid resistance. They can still always be used with additional PPE such as face shields that would provide the additional fluid protection that would be needed. So I guess with that I'll let (Andy) from OSHA speak about this topic.

(Andy Levinson): Thanks, (Jeff). This is (Andy Levinson), Deputy Director at OSHA Standards and Guidance. I think what (Suzanne) and (Jeff) said is 100% correct. And the only thing that I would say on fit is most of the manufacturers are using

similar face forms for multiple classes of respirators.

So the fit issues are not dependent on whether it's a surgical N95 or a regular N95. The fit issues are going to be dependent upon the make, model, size and style of respirator. And, you know, you could have a poor fitting surgical respirator just as easily as you can have a poor fitting regular respirator, which is why it's important to do fit testing.

(Skip Siddington): I got it. Thank you for that. But - so it sounds like there's an equivalency. So industrial N95 is the same as a medical N95?

(Andy Levinson): Yes. From a filtration perspective, yes. OSHA would say that either one of those would be entirely appropriate and allowed under OSHA's respiratory protection standards. The only time that you would consider a surgical N95 is if you needed enhanced splash, splatter, spray protection from body fluids.

(Skip Siddington): Got it. Thank you very much.

Maryann D'Alessandro: And (Suzanne), can I also add that we have the hospital respiratory protection toolkit that also provides a good amount of resources for respirator program administrators. And there's a nice chart on page 6 of that resource that provides a nice explanation of the differences. This is a joint publication between NIOSH and OSHA that was published in 2015. It's the Hospital Respiratory Protection Program Toolkit. Thank you.

Suzanne Schwartz: Thank you.

Coordinator: Our next question comes from (June Benata). Your line is open.

(June Benata): We applied last - or the manufacturer applied from China on June 19th and

will there be like a chance to qualify on the criteria number 3, for all of us, our team, to be included in Appendix A? But before that, we also did like an inhouse checking whether the filtration efficiency happened or are qualified or the blood splash test was also adopted by a US-based company. So this also - we just want to know if there's a chance that we still could qualify for Appendix A.

Suzanne Schwartz: This is Suzanne Schwartz from FDA. I did not hear the beginning of your question clearly. Let me repeat to you and see if I understood this correctly. Did you say that you applied already or that you submitted on June 19th, a request for a EUA to FDA? And your question is whether you can be eligible for that EUA under criterion 3? Is that correct?

(June Benata): That's correct.

Suzanne Schwartz: Okay. So the only way you would have been eligible under Criterion 3 as a manufacturer, is if you had previously been listed on Appendix A from the original April 3rd EUA. If you were not, and therefore you were not removed from Appendix A, you can still be eligible for the EUA but it would not be through Criterion 3. It would have to be through Criterion 1 or 2.

And so my recommendation - our recommendation at FDA - would be that if you have all your testing done, to proceed with an attempt to obtain the appropriate certification from either an NMPA or the CE marking and then once you've obtained that, to submit that information to the FDA.

(June Benata): Okay, thank you.

Coordinator: I'd now like to turn the call back over to our host, Irene Aihie.

Irene Aihie: Hi there. Before I close out, Suzanne, do you have any closing remarks that you would like to share with the group?

Suzanne Schwartz: Okay, great. Thank you, Irene. Yes. On behalf of FDA, I first want to acknowledge our speakers, John Powers from NIOSH (NPPTL) and John Verbeten from FDA's Office of Regulatory Affairs, for providing us with a glimpse into what has been an outstanding collaborative effort in which they've been engaged so that, together, we are able to meet our common vision and mission of protecting the public health.

I also want to thank and recognize all of the subject matter experts who joined us today from across our respective agencies, OSHA as well as CDC NIOSH, and FDA, in support of the Q&A session. Thank you to everybody who tuned into this webinar. The next session is slated to take place in two weeks, on Tuesday, July 7th at Noon Eastern. Announcement of topics will be forthcoming.

And please do not hesitate to share with us topics of interest that you'd like to hear more about on respirators. I'd like to now turn the session back to Irene, who will close it out.

Irene Aihie: Thank you, Suzanne. This is Irene Aihie and we appreciate your participation and thoughtful questions. Today's presentation and transcript will be made available on the CDRH's main Web page at www.FDA.gov/Training/CDRHLearn by Wednesday, July 1st.

If you do 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/CDRHWebinar, immediately following the conclusion of today's live webinar. Again, thank you for participating. This concludes today's webinar.

Coordinator: Once again, thank you for participating. You may now disconnect.

END