FDA Webinar Series-
FDA's Regulation of Face Masks and Surgical Masks During the COVID-19 Pandemic

Moderator: Irene Aihie
August 4, 2020
12:00 pm ET

Coordinator: Welcome and thank you all for standing by. At this time, all participants will be in a listen-only mode until the question and answer portion of today's conference. During the question and answer portion, if you do have a question, you may use Star 1 on your phone or the WebEx Q&A box. Today's conference is being recorded. If you have any objections, you may disconnect at this time. I would now like to turn the call over to 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. Welcome to the 5th CDRH webinar in our respirator webinar series. Today's webinar will expand the scope of this series to discuss face masks and surgical masks.

Today, representatives from the FDA will share information and answer questions related to face masks and surgical masks. The discussion will include the FDA's Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency and relevant emergency use authorizations (EUAs).

Following a few opening remarks, we will open the line for your questions related to information provided during today's discussion. Colleagues from OSHA will join us to assist with the Q&A.

Now, I give you Dr. Suzanne Schwartz, Acting Director of CDRH's Office of Strategic Partnerships and Technology Innovation.

Suzanne Schwartz: Thank you and welcome everyone - as Irene mentioned, this is the fifth session in our biweekly Webinar series on PPE. Today's discussion will focus on how FDA regulates face masks and surgical masks, the guidance we've issued on this topic, as well as the applicable emergency use authorization during the COVID-19 response.

At our prior session on July 21st, we changed things up a bit by holding the entire session as a Town Hall after some frequently asked questions to kick things off from both FDA and CDC NIOSH. Today, I'm pleased to introduce Dr. Cynthia Chang, Director of CDRH's Division of Infection Control and Plastic Surgery Devices within the Office of Surgical and Infection Control Devices.

Dr. Chang will start us off by providing an important high-level overview on face masks and surgical masks emphasizing how they are different from respirators. And after her opening remarks, we'll then move to the same format as the last session beginning with frequently asked questions that FDA has accrued over the past months. And then we will turn to the operator for live Q and A.

Due to a longstanding competing commitment, our CDC NIOSH colleagues are unfortunately unable to attend today and they'll be missed. I am pleased however that we are joined by our partners and colleagues from OSHA on the

line with us and they will be available to field questions relevant to OSHA's mission, role and responsibilities. So at this time, I'd like to turn the webinar over to Dr. Cynthia Chang.

Cynthia Chang: Good afternoon and thank you Suzanne - these are the things that I am going to go over. First, FDA's enforcement policies for face masks and surgical masks described in a guidance document on the next slide, and second, FDA's emergency use Authorization for Face Masks. The guidance was issued on March 25th, 2020 to increase the supply of face masks, surgical masks and similar devices.

The EUA was issued on April 18th, 2020 for face masks. We have in the past received questions on why we have issued both an enforcement policy as well as an EUA for face masks. So I will touch on how these two documents are complementary.

Before I go into the details, I want to emphasize that face masks and surgical masks and respirators are different devices that should not be confused. Both face masks and surgical masks are loose-fitting products. All respirators have a tight fit to the face. So face masks and surgical masks are not respiratory protection devices. Surgical masks are a barrier that provides fluid protection and respirators are respiratory protection devices.

Now let's dive into the policies for face masks and surgical masks. First, what is a face mask? There are many products marketed in the United States as face masks that offer a range of protection against potential health hazards. Some face masks are not intended for a medical purpose and are not medical devices. These might be for use in construction and other industrial applications.

They do not have medical claims and are not intended to slow the spread of the

virus. They are not the focus of our discussion today. Let's move onto face masks for a medical purpose that are medical devices.

There are two categories of these masks that are medical devices. The first category is face masks intended for a medical purpose that are not intended to provide liquid barrier protection. This type of face masks -- as defined by FDA and CDC -- refers to a mask with or without a face shield that covers the user's face and mouth and may or may not meet fluid barrier or filtration efficiency performance levels. This category includes cross face coverings intended to reduce the spread of the virus.

According to our enforcement policy -- face masks intended for medical purpose that are not intended to provide liquid barrier protection -- may be marketed without prior FDA review and with discussion for certain other FDA requirements for the duration of the national emergency.

This means the FDA does not intend to object to distribution and use including importation of these devices without compliance with certain regulatory requirements including 510(K), registration and listing, and quality system regulation requirements. This applies as long as the devices are labeled consistent with the recommendations in our guidance.

Specifically -- face masks under the enforcement policy -- would not create an undue risk where the product includes labeling but accurately describes the product as a face mask and includes a list of the body-contacting materials which does not include any drugs or biologics. The labeling includes recommendations that would reduce the risk of use such as recommendations against use in any surgical setting or use in a clinical setting.

For this kind of face mask, certain claims are not included under our

Enforcement Policy. These include claims that the product is a surgical mask, respirator or N95, claims that the product is antimicrobial or antiviral, claims that it prevents infection or claims regarding particular filtration.

These claims need FDA review prior to marketing because they fall outside the recommendations in our guidance. I also want to highlight that if the product contains an antimicrobial -- even if you do not make antimicrobial claims -- you also need FDA review prior to marketing.

A second category of devices is surgical masks. These masks are medical devices and are intended to provide liquid barrier protection. They cover the nose and mouth and provide a physical barrier to fluids and particular material. The key for surgical masks is fluid-resistance testing as it is important to have liquid barrier protection during surgery. They are also characterized for flammability.

The guidance explains that surgical masks may be marketed without prior FDA review and with discussion for certain other FDA requirements for the duration of the national emergency. This means the FDA does not intend to object to distribution and use including importation of these devices without compliance with certain regulatory requirements including 510(K), registration and listing, and quality system regulation requirements. This applies as once the devices are tested and labeled consistent with the guidance.

For surgical masks, they should meet fluid-resistance testing consistent with the ASTM Standard F1862. And they should address flammability, either through testing or labeling. The guidance also recommends the labeling for a surgical mask should describe the product as a surgical mask. And it should include a list of the body contacting materials.

Certain claims are not included under our enforcement policy. These include claims that the product is a respirator or N95, claims that the product is antimicrobial or antiviral, claims that it prevents infection or claims regarding particulate filtration.

These claims need FDA review prior to marketing because they fall outside the recommendations in our guidance for a surgical mask. Again, if the product contains an antimicrobial, even if there are no antimicrobial claims, you also need FDA review prior to marketing.

There is also an emergency use authorization or EUA for face masks intended for a medical purpose but are not intended to provide liquid barrier protection. To be covered under the EUA, the manufacturer and distributors should meet the requirements listed in the EUA and follow the conditions of the authorization. There are more requirements in the EUA conditions than in the recommendations listed in the guidance document.

Specifically, authorized face masks must meet several labeling requirements listed in the EUA. They are consistent with the recommendations and the guidance but there are two more specific requirements in the EUA. Namely, the face mask should not be labeled as a respiratory protective device and therefore should not be used for particulate filtration and the product should not be labeled for use in high-risk aerosol-generating procedures.

If you have a face mask that meets the appropriate requirements and recommendations, it is up to you as a manufacturer whether you wish to market the device under the enforcement policy or under the EUA.

So how do these policies work to increase the supply of face masks during the pandemic? In some cases, devices may be distributed as face masks if they meet

the appropriate recommendations, even if they are originally intended as different kinds of devices. Specifically, surgical masks and respirators were being imported into the US to increase supply.

While these devices did not meet our expectations for use as either a surgical mask or a respirator, they did meet the criteria of being a face mask. Rather than sending these shipments back or destroying these shipments, the option was given for manufacturers to relabel these materials as face masks being very clear that it was not a surgical mask or a respirator.

There are no claims that a product is antimicrobial or antiviral. There were no claims that it prevents infection and no claims regarding particulate filtration. Now with that overview, I would like to turn it over to Dr. Suzanne Schwartz to go over some FAQs.

Suzanne Schwartz: Thanks so very much Cynthia for your overview of face masks and surgical masks. We are now going to switch over to that townhall portion of our session and I will begin with sharing some frequently asked questions of FDA. And this will also help further amplify and further underscore some of what you just heard from Dr. Chang.

So the first question, what requirements do I need to market my surgical masks? Well, if you meet the requirements in our Enforcement Policy about surgical masks including the liquid barrier testing and labeling recommendations, you may market during the public health emergency without a 510(K) submission and other requirements.

If however, you have additional claims, have an antimicrobial in your device or otherwise go beyond to the recommendations, then an additional FDA review is needed. You may also seek 510(K) clearance for your mask through our

510(K) process which will last beyond the end of the public health emergency.

Next question - Can I put the ASTM level rating on the labeling for my surgical masks even though under the Enforcement Policy, filtration claims should not be made? And the answer is no. Referencing the ASTM standard for particulate filtration is a filtration claim.

The third question - how do I get my mask tested, certified and approved by the FDA for use in the United States? So the answer is, first off, the FDA does not approve surgical masks. Typically, 510(K) clearance is needed to market a surgical mask. However, we currently have the Enforcement Policy in place to increase the availability of masks.

And once again, under the enforcement policy, 510(K) clearance is not needed as long as you meet the liquid barrier testing recommendations and follow the labeling recommendations in our guidance document. You would need to conduct the testing or arrange to have the testing done. FDA does not conduct testing.

Another question - do I need an EUA for a surgical mask? If so, what does an EUA confer? Well as we've gone over in this session, you do not need an EUA for a surgical mask. What an EUA would confer is through the PREP Act, it may provide liability protection for products that are inclusive under the EUA.

What is the minimum testing needed for a 510(K)? And for that we would refer you to our guidance on this topic entitled Surgical Masks, Premarket Notification, 510(K) Submissions.

I'm going to do one more question, but I think that at this time -- Operator if you could start to line up calls that are coming in -- that would be very, very helpful.

Coordinator: Absolutely - for those of you on the phone, if you would like to ask a question, please unmute your phone, hit Star 1, and record your name clearly when prompted. Again, that's Star 1 to ask a question and Star 2 to withdraw your question. One moment to see if we have questions.

Suzanne Schwartz: Thank you

Coordinator: And our first question is from Gene Harpel. Your line is open. Hi Gene, can you check the mute feature on your phone?

Okay, we have a question from (Keisha Jones). Your line is open.

Keisha Jones: Hi, good afternoon - yes, I have a question about the labeling and some of the import requirements. Because as a large health system -- trying to get masks -- as we know there is a shortage of certain rated masks. The suppliers are telling us that the customs process is very difficult.

And when they are asking questions, they are being given information that for masks that have fluid resistance, they need to labeled as surgical masks and they need a 510(K).

Can you help with that because there is a lot of, I think, interpretation confusion going on right now? In our world, surgical masks aren't necessarily or fluid-rated masks aren't necessarily surgical. We use them for procedures as well. So those are sort of medical-use masks with fluid resistance. So can you help us do that because that custom process has become very antagonizing for our suppliers trying to provide us products?

Deniz Mackey: I can take that question. My name is Deniz Mackey and I can answer that

question. Per FDA guidance documents and enforcement policy, the FDA does not intend to object to the distribution of use of the face masks that you are referring to. Just at the time of entry, importers have certain requirements they need to transmit.

In this case, it would be Intended Use Code 081.006 and certain affirmations and compliance are not required such as registration and listing. So if you have any specific examples of issues where a shipment is being held -- whether it's by customs or by FDA -- you can always send us an email at CDRHimport@FDA.hhs.gov and then we can certainly assist.

Keisha Jones: Okay thank you - and we have but we always get a response about respirators instead of face masks are - if (unintelligible) send an email. I think I've sent an email or asked (unintelligible) to send it on our behalf. So just some clarity on that. I' think even to the custom's responses would be helpful because it's not consistent. I just want to bring that to your attention but we have sent several emails and we get the Enforcement Policy and/or we get responses about respirators.

And we're like, no, we're not talking about respirators. We're talking about face masks with fluid protection, you know, how does that work? And even though the 510(K) is exempt -- customs on both sides-- have confusion.

And so we have to somehow address that because we are in a state of emergency, and right now it's not working. I just want to bring that to your attention. Even our suppliers in the US, our suppliers are having difficulty getting products into the - across our borders from China, specifically from China.

Deniz Mackey: Okay absolutely - yes, there is that very unique difference with the respirators

versus face masks and I understand that there may be some confusion. So we'll continue to conduct outreach to customs brokers to educate them on the differences, and we have a website that touches on the import requirements.

We'll ensure our messages that are going across are clear and answer the question. But if you do send an email today or tomorrow to CDRHimport@FDA.hhs.gov, we can try to answer accordingly.

Keisha Jones: Okay perfect. And what was that code again because I think I'm going to send an email just so we can (unintelligible).

Deniz Mackey: Absolutely.

Keisha Jones: It was 81...

Deniz Mackey: So for the ones that fall under Enforcement Policy, it's 081.006. And the reason that we say that is because certain affirmations of compliance; meaning the importer requirements that we would expect for a regular entry, you know, pre-COVID when we had different requirements that weren't weighed such as registration listing, it would allow the entry to come in with only the necessary information.

Keisha Jones: I appreciate that.

Deniz Mackey: Absolutely.

Coordinator: Thank you - next we have Mr. (Bostonbau), your line is open. Can you check the mute feature on your phone? Thank you - next we have (Gina Rios). Your line is open.

Gina Rios: Yes, hi, good afternoon - I was just wondering what the turnaround time for is EUA at the moment? We submitted all our documentation back on June 20th and we've been emailing practically every single date and we have not heard back from the FDA yet. So if you can kind of just walk me through of how long the process is taking at this time, I would appreciate it.

Suzanne Schwartz: Thank you for the question - this is Suzanne. So I'll start off with an answer of, you know, how long it takes for an EUA to be processed depends on a whole host of factors, including how complete the submission is upon its receipt. If this is specific for a surgical mask, and I - we didn't talk about what, you know, the product is.

But if you're asking regarding a surgical mask, you note that an EUA is not needed to market as long as you're following the recommendations in the Enforcement Policy Guidance Document. And I will ask OHT4 if there is any further information that you would like to add as well?

Binita Ashar: This is Binita Ashar. I think that Suzanne characterized it very well. A lot of the submissions that we received are variable in nature based on their completeness. The technology may be novel which also requires further evaluation by experts across the center.

So each situation is very unique and it's difficult to explain exactly the circumstances around each individual manufacturer. But we do commit to communicating regularly to each of the manufacturers. So if you have not received feedback or communication, then I would encourage you to reach out to your point of contact to understand what the status of the application is.

Gina Rios: For (unintelligible) -- I apologize, I didn't mention that at the beginning. And all we have that was provided to us to submit information and we just continue

sending emails out. Like I said, we're doing it daily because we have not received any feedback.

Suzanne Schwartz: I'm so sorry - it was not easy for me to hear what you said at the very beginning of your follow-up.

Gina Ross The product - yes, it's for respirators. It's not surgical masks.

Suzanne Schwartz: Okay well so there is a point of contact for respirators as well. I think that part of this we need to understand whether these are imported from outside the country or are these related to respirators manufactured in the United States?

Gina Rios: No, these are going to be imported. They're manufactured in China.

Suzanne Schwartz: Okay - what I would recommend is if you can reach back out to the email address for the EUA request pertaining to respirators manufactured in China, we do have folks on the line right now amongst our Subject Matter Experts who will, you know, make sure to address this if you indicate in the email that you asked this question on the webinar on today's date. That will be very helpful.

Gina Rios: Okay we'll go ahead and send another email today and stating that we did request information on the webinar. Like I said, any information is helpful. We've been emailing every single day and we haven't got any feedback as of yet. And it's been, you know, quite some time. So I'll go ahead and do that - thank you.

Suzanne Schwartz: Sure - I'm going to add a question that came in through our web chat as well, and this question will be addressed to our ORP folks to respond. The question comes from Maria Griffen. What are the guidelines for importing face masks and repackaging them in the USA? Is this allowed or will there be issues at

customs?

Deniz Mackey: So, I can answer that question. So as long as the customs requirements are met, the specific intended use codes are provided and it meets the guidelines of the Enforcement Policy, there shouldn't be any issues. And there are no repackaging guidelines, you just need to make sure that they're following the guidelines that were provided as recommendations through the guidance document.

Suzanne Schwartz: Thank you - can we have the next question, please?

Coordinator: Absolutely - we have (Gary Tisnick) - your line is open.

Gary Tisnick: Hello - I have my...

Coordinator: We can hear you.

Gary Tisnick: Okay great, yes thank you - so my question is I think it's sort of in alinement with that last question with (unintelligible) but more. So along (unintelligible) sort of a (unintelligible). I think some of the challenges that we would see as an importer or distributor of products come in from foreign forces is that the label criteria as outlined in the EUAs (unintelligible) Enforcement Policy may not be fully completed.

So since there's -- to my understanding -- there is an exception or exemptions related that's applicable to manufacturers as long as they fill the criteria, would those be able -- those exceptions or exemptions-- be extended to importers or distributed to help fulfill the labeling criteria and where to get these types of products to market?

Suzanne Schwartz: Thank you - I'm going to ask Deniz if she can address this question as well.

Deniz Mackey: I think I just want to make sure I understand it. We're saying if a product doesn't meet the labeling requirements upon entry that an importer can recondition the products - is that the question? Can I just make sure I understand the question?

Man 1: All right...

((Crosstalk))

Deniz Mackey: There is a process for reconditioning so long as that reconditioning process takes place by a responsible party within a certain amount of time, we would look at what should be reconditioned and the proposal to meet certain requirements or recommendations, and it's usually that labeling type information.

Reconditioning could apply for anything, like respirators being reconditioned to be face masks, and then we would allow it in. But there are certain steps that would need to be taken to accomplish that reconditioning process and meet the labeling criteria and enforcement policy or the EUA.

Suzanne Schwartz: I think part of the question was whether the importer of record is allowed, is permitted, to provide that type of labeling change or reconditioning, or whether this needs to be performed by the manufacturer?

Deniz Mackey: So, it could be the importer; absolutely. It could be the importer; yes. That's allowable.

Man 1: Okay. Thank you very much.

Coordinator: Thank you. Next, we have Anne Waterhouse. Your line is open.

Anne Waterhouse: Hi, yes. My question has to do with shelf life. And with this being emergency use, are we given a year of shelf life just automatically off without having a whole lot of data or any real-world data? And if we wanted to go further with that, would we have to put in an application, obviously, to get any more than one year? Or is there another parameter that's put around that, and we don't, or are not required to label with any shelf life, to begin with?

Suzanne Schwartz: So, OHT-4, can you please address the shelf life question?

Dr Binita Ashar: Hi. I'm going to have Dr. Chang start, and then I and others will chime in. This is Dr. Ashar.

Dr Cynthia Chang: Hi, this is Cynthia Chang. Thank you for the question about what type of shelf life is allowable under the enforcement policy.

So, our enforcement policy as described in the Guidance does not directly, you know, provide any information on shelf life. So, what I would say is that the shelf life should really be supported by the information that (unintelligible), you know, that's really up to the manufacturer to demonstrate that in general, and you know, it should be justified based on testing and appropriate scientific rationale.

And I'll turn over to my other colleagues to see if there are any additional items that they want to add.

Dr Binita Ashar: Hi. This is Binita Ashar. I think that that's accurate. The one thing that I can suggest is to consider submitting a 510(k) for your surgical mask so that you may be able to continue marketing your device after the pandemic.

And in addition, one point to note is that our team is working very quickly to prioritize PPE submissions that are coming in through 510(k). So, hopefully, that expedites the process and is helpful to you.

Coordinator: Thank you. Next, we have Shandra Pauley. Your line is open.

Shandra Pauley: Hey, good afternoon, everyone. Thank you for accepting my question. I have a question regarding the PFE claims. So, if a manufacturer has a surgical mask that was cleared by the FDA with a particulate filtration claim, and the manufacturer has conducted testing to update the existing claim, to align with the ASTMS 2299 test method, does the FDA object to the manufacturer marketing the product with the updated PFE claim?

Suzanne Schwartz: Dr. Chang, or Dr. Ashar, would you like to take that?

Dr Cynthia Chang: Hi, this is Cynthia Chang. I can start.

So, our enforcement policy as described in the Guidance for surgical masks, you know, describes that to be covered by that enforcement policy, particulate filtration claims should not be made (unintelligible). PFE claims really are a particulate filtration claim. I think to the, you know, covered by that Guidance document, those claims should not be (a part of that).

So, if you do have a device that (unintelligible), recommend that you go through a different route to update the labeling. I would also turn to my colleagues to see if they have anything to add.

Dr Binita Ashar: Hi, yes, this is Binita Ashar. I would — you know, so the good news is that you have a cleared 510(k). And I think possibly Captain Claverie or Dr. Murray

might have any additional remarks regarding claims under 510(k) clearance that are typically permitted.

Captain Liz Claverie: Hi. This is Liz Claverie. Thank you so much, Dr. Ashar, Dr. Chang, and thank you for the question. My additional comment and recommendation to you would be to actually send us a pre-submission stating the type of testing that you had cleared in your 510(k). Please reference your 510(k) in the Q-sub.

And then, mention to us the testing, the validation testing that you had performed with the new standard that's in place, and ask us in that pre-submission whatever question you may have as relates to labeling, or whether you would need to come in with the new 510(k) and we'll give you further guidance through that format.

Shandra Pauley: Thank you very much. I really appreciate your time and advice. I'll be reaching out shortly.

Captain Liz Claverie: Great. Thank you, sir.

Coordinator: Thank you. Next, we have (Audrey Swerdgeon). Your line is open.

(Audrey Swerdgeon): Yes. I understand that the antimicrobial masks are not covered under the current umbrella EUA or the enforcement policy. If a manufacturer wishes to market an antimicrobial mask during the COVID-19 pandemic, (unintelligible) they can submit a request for an EUA under the, using the non-IBD template? Is that correct?

Suzanne Schwartz: Dr. Chang, Dr. Ashar, would you like to address or defer to OHT-4 colleagues?

Dr Binita Ashar: I think that's absolutely correct. You would submit an EUA, or a pre-EUA submission to FDA.

Now, you would, to be authorized, need to meet the criteria on in our EUA Guidance, so I would ensure that you have justification that those criteria are met. I don't know if others have any more to add.

Dr Cynthia Chang: This is Cynthia Chang. I agree that the pre-EUA pathway is certainly something that you could pursue for your antimicrobial-containing mask. The other option would be another pre-marketing submission (510)(k) which again would last beyond the end of the Public Health Emergency.

Audrey Swerdgeon: Okay. Thank you. I think the intent was actually to do both, but to try to get it on the market sooner under the EUA, then follow up with the 510(k).

So, I just want to clarify. When you referenced meeting the criteria in the EUA Guidance, you mean the general guidance that's not specific to face masks?

Dr Cynthia Chang: Yes. That's correct. I'm sorry for not being more clear. Thank you.

(Audrey Swerdgeon): All right. Thank you.

Coordinator: Thank you. Next, we have Dr. Scott Noren. Your line is open. Dr. Noren, your line is open. Can you check the mute feature on your phone?

Next, we have Eberhard Link. Your line is open.

Eberhard Link: Hello. Can you hear me?

Coordinator: Yes.

Eberhard Link: Can you hear me?

Coordinator: We can hear you.

Suzanne: We can hear you.

Coordinator: Mr. Link, we can hear you.

John Cheng, your line is open.

John Cheng: Hi, this is John Cheng from (P-Zero) USA. My question is we're about to begin manufacturing in Los Angeles, and I understand that surgical mask labeling requirement as it pertains to the imports, in terms of having done the testing for (unintelligible) penetration, we're able to achieve the same level as the ASTM Level 2, and I understand we can't put that ASTM Level 2 claim. How do we include that information?

And the fact in question is are we able to — we've done testing for the bacterial penetration as well, and are able to achieve that 95%. Are we able to include that information as part of our packaging label?

Suzanne Schwartz: Drs. Chang or Ashar, can you take this question, please?

Dr Cynthia Chang: Hi. This is Cynthia Chang. So, thank you for the question. Under our enforcement policies for surgical masks, you know, if you have done the testing to provide, you know, the fluid-resistant barrier claim support, then you do not need a specific submission to FDA.

However, in terms of the labeling, you should not be including claims regarding

particulate filtration or bacterial filtration or, you know, these other claims. If you want to make those additional claims, then a 510(k) might be an appropriate option at this point. You know, to the — in terms of just being covered by the enforcement policy as described by the Guidance documents. We're asking that you follow the recommendations that are listed there regarding the labeling restrictions. And I'll turn...

((Crosstalk))

Dr Cynthia Chang: Oh, go ahead.

John Cheng: Go ahead, please. I just have a follow-up question after any other responses.

Dr Binita Ashar: This is Binita Ashar. I think clarity is important. So, you sound like your device potentially meets some of the surgical mask criteria, so you would need to submit a 510(k) for clearance related to that. Or meet all of the expectations in the enforcement policy related to surgical masks.

Or, if you don't meet all of those criteria for the surgical masks, then you can see if you meet all the criteria for a face mask. But you can't make claims that are, you know, for a face mask but actually try to step into demonstrating that you have greater capabilities than your average face mask.

John Cheng: Understood and I appreciate the feedback. We do intend to start our — pursuing our 510(k) process. We're just trying to figure out what's available for us on the labeling side.

The follow-up question is if we're sourcing our main materials stateside, but some of the components from Asia, are we able to claim a made-in-the-USA product since we are manufacturing — the equipment is in Los Angeles, and

we're finishing the products here. Is there any issue about making a claim of made in the USA?

Suzanne: Oh, I'm going to refer that question to ORP. I'm not even certain that we — FDA — would be in a position to answer that. But let's let the subject matter expert weigh in here.

Sean Boyd: Yes, hi, Suzanne. This is Sean Boyd. I don't believe FDA regulates what may be claimed as made in the USA or not. I don't know what federal agency would weigh in on that question. Maybe the Federal Trade Commission. I think we'd have to do some additional research to point you in the right direction to figure out who would be able to answer that question.

John Cheng: Okay. I appreciate the feedback. And would there be a person I could email to do a follow-up after the conversation?

Suzanne: Absolutely. Rather than a person, if you can go ahead and email — Sean, do you have a general mailbox for inquiries around imports that we could apply for this?

Sean Boyd: We do have one regarding imports. We could ask Deniz and crew to monitor for that question.

Deniz: CDRHimport@fda.hhs.gov. And we'll take a look at it.

Suzanne: And we'll do some homework.

((Crosstalk))

Suzanne: We'll do some homework for you in terms of which Agency within the

government would be able to provide a response to your question.

John Cheng: Thank you very much. You all have been very helpful this morning.

Suzanne: Thank you.

Sean Boyd: Actually, Suzanne, just to follow up on that real quick, a Google search indicates that it is regulated by the Federal Trade Commission, so we'll look further to find a specific contact for that.

John Cheng: Great. Thank you.

((Crosstalk))

Coordinator: Thank you. Next, we have Alia Eves. Your line is open.

Alia Eves: Hello, good afternoon. First, I want to say thank you to CDRH for this Webinar series; in particular Suzanne, Jessica, Cynthia, Binita, Liz and Sean. You have been incredibly helpful and clarifying during this rapidly-evolving regulatory environment.

My question is about if a face mask enters the commercial market under the EUA and then it subsequently gets 510(k) clearance, what post-market actions does the manufacturer or the initial importer have to do? Is it going to create any sort of confusion when you have the same product that one is labeled with filtration claims and the other is not? So, what responsibility would the manufacturer or initial importer have to correct any sort of discrepancy?

And then I have a follow-up question after I hear your answer.

Suzanne: Thank you for that question. That is a great question in terms of realistically, what will likely occur in the future. I am going to direct that question to either Deniz or Sean, if you have any thoughts, considerations at this time that we could share. Certainly, areas of transition are ones that we are working on at present. But you know, to the extent that we have information that would be helpful, we're happy to share that.

Deniz: Sure. I can answer that question. If it is coming in and now we have a 510(k), it should go through the quote/unquote normal entry process, meaning, it should use — the intended use code 081.001. And that will flag it for that 510(k) data element to be transmitted during import entry review.

So, if it is under the EUA, of course, or the enforcement policy, it's a different intended use code and the transmittal information is different than what it would be for a device that had a 510(k) as you're referring to. That should come in through the regular 0-8-1.0-0-1 intended use code.

Alia Eves: So, that brings me to my follow-up question. I noted that there was the same product that was being distributed by two large commercial distributors, and the exact same product had completely different promotional labeling.

One included the filtration claim, and the other did not. Now, I don't know if that was just — one was just inappropriately labeled, or perhaps it initially entered the commercial market under an EUA, and that's how it was being marketed by the one distributor, and then another large distributor had the filtration claims which they, you know, the (that) may have had a 510(k) at that point. I don't know. But clearly that creates confusion for consumers.

Deniz: Right. And during import entry process, we do look at the labeling, resources permitting of course, and we flag and detain those shipments and then give the

option for export out of the country, but for — so I don't know if that is helpful or not. But we do make sure to detain and refuse those products that are not meeting the requirements, and especially for ones where we don't have a 510(k) so they're not allowed to enter the United States.

Dr Binita Ashar: And this is Binita Ashar. It sounds like this might be an allegation. You know, something that you're questioning. And so what you could do is you could submit the information that you're questioning to CDRHDeviceAllegations@FDA.HHS.gov
And our Website, Describing Allegations, talks about how we look into such matters.

Alia Eves: Thank you. I'm wondering is there a responsibility once the products are on the market to give any sort of recall or post-market action to correct the labeling? Or that may be something that's still under consideration.

So, the product that's on the market under the EUA is the lawfully on the market, but once you have that 510(k) you can make different claims. So, essentially, you could have the same product with two different sets of claims. Is there going to be — is it CDRH's expectation at this point that the manufacturer cure that discrepancy?

Suzanne: So, another really important question, and this is something that we are going to have to take a further deeper look at. I don't think that we are at this very moment in time positioned to answer that question and whether it's a hypothetical or in a real situation, but something, you know, as we work through that process of transitioning out of the Public Health Emergency where there's going to be products that are in those categories, what the policy will be of the FDA of CDRH with respect to, you know, proper labeling or, if appropriate, recall, or how we will go about that. And we will certainly be

transparent in communicating that with sufficient advance notice.

Alia Eves: Great. Thank you so much.

Coordinator: Thank you. And our last question comes from Naveen Agarwal. Your line is open.

Naveen Agarwal: Yes. Thank you very much. I appreciate your taking my question, and I also appreciate the transparency and candid advice from these Webinars.

I'm setting up an operation to import face masks from Germany, and we want to market it for both general public use and health care professionals as a source control, (again, in some countries) tend to policy and EUA. We also are planning to register with the FDA under quote/unquote (QKR).

So, my question is whether that's allowed under the EUA or the policy, or do we need to file any other submissions with the FDA?

Suzanne: Right. Dr. Chang, Dr. Ashar, would you like to address that question with regard to the face mask EUA and whether there is a necessity for registration and listing or whether that's problematic? I think that that is what the questioner is asking.

Dr Cynthia Chang: Hi. This is Cynthia Chang. I can start. So, thank you for the question. You may have seen in the EUA that states that the requirements under 21-CFR, Part 807 regarding registration and listing do not apply to products authorized under an EUA, but you know, there's nothing to prevent you from doing so, as far as I understand. And so, you know, that's certainly up to you. And I can also check with my colleagues to confirm or see if there are any additional thoughts.

Dr Binita Ashar: Hi, this is Binita. That's my understanding as well.

Naveen Agarwal: Okay. Thank you. I understand that and certainly it's our decision. So, we are fine with that.

One follow-up on that is I heard that whether you market under an EUA or under the policy is the decision that we can make on our own. You don't have a specific recommendation, but if we decided to market under an EUA, would we have to then complete all the paperwork using an EUA template, or will the current face mask EUA cover that?

Dr Cynthia Chang: So, this is Cynthia Chang. To be covered under the face mask EUA, if you go through it carefully, actually, all you have to do is make sure that you meet the requirements that are listed in the EUA, and you must also follow the conditions of authorization.

However, you do not have to (unintelligible) anything to FDA to be authorized under the face mask EUA. You know, there may be other EUAs that are different, but for this particular face mask EUA, you do not have to submit anything to FDA. You just have to follow the requirements.

Naveen Agarwal: Thank you; I appreciate it.

Suzanne: All right. Well, that was our last question. So, on behalf of FDA, I first want to recognize all of the subject matter experts who joined us today in support of the Q&A session — from OSHA as well who were on stand by for any questions. And thank you to all of you who've joined, who've tuned in to listen to this session.

The next one is slated to take place in two weeks August 18th at Noon Eastern.

Announcement of topics will be forthcoming. As always, please don't hesitate to share with us topics of interest that you'd like to hear more about. And last now, I'll turn the session back to Irene who will close it out for us.

Irene Aihie: Thank you. This is Irene Aihie. We appreciate your participation and thoughtful questions. Today's presentation and transcript will be made available on the CDRH Web page at www.fda.gov/training/cdrhlearned by Wednesday, August 12th.

If you have additional questions about today's presentation, please use the contact information provided at the end of the slide presentation. As always, we appreciate your feedback. Following the conclusion of today's Webinar, please complete a short, 13-question survey about your FDA CDRH Webinar experience. The survey can be found at www.fda.gov/cdrhwebinar immediately following the conclusion of today's live Webinar. Again, thank you for participating and this concludes today's Webinar.

Coordinator: Thank you for participating in today's conference. You may disconnect your line and enjoy the rest of your day.

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