

## **FDA FDA's Surgical Masks Umbrella EUA**

**Moderator: Irene Aihie**  
**August 18, 2020**  
**12:00 pm ET**

**Coordinator:** Welcome and thank you for standing by. At this time all participants are in a listen-only mode until the question and answer session of today's call. At that time if you would like to ask a question please press star 1. Today's conference is being recorded. If you have any objections you may disconnect at this time. I would now like to turn the meeting over to Miss Irene Aihie. Thank you. 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 6th CDRH webinar in our respirator webinar series. On August 5, 2020, the FDA issued a Surgical Masks Umbrella Emergency Use Authorization in response to concerns relating to insufficient supply and availability of disposable, single-use surgical masks.

Today, representatives from the FDA will share information and answer questions related to the umbrella EUA.

Following a few opening remarks, we will open the line for your questions related to information provided during today's discussion.

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

Dr. Suzanne Schwartz: Thank you and welcome everyone. As Irene mentioned this is the sixth session in our biweekly Webinar series on PPE. At our last Webinar on August 4, Dr. Cynthia Chang, the Director of CDRH's Division of Infection Control and Plastic Surgery Devices in the Office of Surgical and Infection Control Devices provided a high-level overview on face masks and surgical masks emphasizing how they are different from respirators.

Her discussion focused on how FDA regulates face masks and surgical masks. She covered the immediately in effect enforcement policy guidance we've issued on this topic as well as the emergency use authorization for face masks during the COVID-19 response.

In the intervening time since then, FDA has issued an umbrella EUA for surgical masks. We anticipate that many of you may have questions regarding this latest EUA and we'd like to be able to address those. Therefore today I'm pleased to introduce Dr. Binita Ashar, Director of the Office of Surgical and Infection Control Devices also known as OHT-4 within CDRH's Office of Product Evaluation and Quality or OPEQ who will speak about this new EUA for surgical masks.

After her remarks we'll then move to the same format as the last session beginning with frequently asked questions that FDA has accrued and then we'll turn to the operator for live Q&A.

I'm pleased that we are joined today by our federal partners and colleagues who are on the line with us from OSHA and they are available to field questions

relevant to their respective mission, roles and responsibilities at this time. I'd like to turn the Webinar over to Dr. Binita Ashar. Binita?

Dr. Binita Ashar: Great thank you Suzanne. Hello everyone. In order to explain the new umbrella EUA for surgical masks, my remarks provide a high-level comparison of authorized surgical masks, surgical masks that are under FDA's enforcement policy and FDA cleared surgical masks.

Before I start, I want to emphasize that face masks and surgical masks and respirators are different devices. Both face masks and surgical masks are loose fitting products in contrast to respirators which have a tight fit to the face and provide respiratory protection. While face masks are not personal protective equipment for protecting the wearer, they do serve as source control.

Surgical masks are personal protective equipment, serve as source control and as a barrier device that provides fluid protection. Remember that because of their loose fit surgical masks do not reliably block very small particles in the air that may be transmitted by coughs, sneezes or certain medical procedures. So surgical masks are not recommended for the use in aerosol generating procedures and any clinical conditions where there is significant risk of infection through inhalation exposure. Under those conditions a filtering facepiece respirator such as an N95 respirator with a tight fit to provide respiratory protection is recommended.

So on August 5, FDA issued an umbrella EUA for surgical masks for use by healthcare personnel in healthcare settings. So what do healthcare personnel need to know about the emergency use of authorized surgical masks? Here is a list of things. The surgical masks covered under this umbrella EUA are single use disposable surgical masks only.

Authorized surgical masks meet the fluid barrier, flammability and particulate filtration efficiency performance requirement set forth in the EUA. They do not pose significant risks concerning breathability and biocompatibility. They may be effective in blocking respiratory droplets and large particles. They do not include drugs, biologics, nanoparticles, anti-microbial/antiviral agents. They are not FDA cleared devices.

They are not indicated for anti-microbial or antiviral protection infection protection, infection reduction, or effective viral filtration. They are not intended to replace the need for FDA cleared surgical masks, or FDA cleared or authorized respirators. Healthcare personnel should review the authorized surgical mask labeling prior to use and follow the instructions for use.

Okay so what should manufacturers, healthcare personnel, hospitals and any other stakeholders know about how surgical masks are regulated? There are three ways to market a surgical mask during this public health emergency. There is the enforcement policy for surgical masks during the COVID-19 public health emergency, there is the new umbrella EUA for surgical masks during the COVID-19 public health emergency, or they can be marketed as a 510(k) cleared surgical mask which can be marketed regardless of whether or not there is a public health emergency.

I am now going to briefly describe the requirements for each of these three ways for a surgical mask getting to market. First surgical masks marketed under the enforcement policy. The guidance describing the surgical mask enforcement policy explains that surgical masks may be marketed without prior FDA review and with discretion for certain other FDA requirements for the duration of the national emergency.

This means the FDA does not intend to object to the 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 tested and labeled consistent with the guidance.

For surgical masks they should meet the 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 be describe the product as a surgical mask and include a list of the body contacting materials.

The following claims are not included under our enforcement policy. The product is a respirator or N95, claims that the product is anti-microbial or antiviral, claims that it prevents infection, or claims regarding particulate filtration. These claims need FDA review prior to marketing because they fall outside of the recommendations in our guidance for a surgical mask during a public health emergency. Again if the product contains an antimicrobial, even if there are no antimicrobial claims, FDA review is required prior to marketing.

Okay so now I'm going to move on to surgical masks marketed under the umbrella EUA. Authorized surgical masks in general must meet the labeling requirements listed in the enforcement policy that I just described. Plus there are several more testing labeling and regulatory requirements in the EUA that I will briefly go over here.

Okay so in addition to excluding surgical masks including drug biologics, nanoparticles or antiviral, antimicrobial agents, the EUA also excludes surgical masks that have 510(k) clearance and excludes surgical masks manufactured in China. In addition to fluid resistance requirements the EUA requires that the surgical mask meets certain performance criteria with respect to flammability

testing, particulate filtration efficiency, airflow resistance and biocompatibility.

There are additional labeling requirements associated with the umbrella EUA including describing the product as a disposable single use not to replace FDA cleared surgical masks or authorized respirators, not recommended for aerosol generating procedures and not including statements that would create undue risk such as infection prevention or viral filtration efficiency. Authorized products must be accompanied by the required labeling and the fact sheet for healthcare personnel which can be found on FDA's Web site.

Manufacturers may request the inclusion of a surgical mask model in Appendix A of the umbrella EUA by submitting a request to FDA. Manufacturers may email FDA with the subject line, "Surgical mask EUA" to [cdhr-nondiagnosticeua-template@fda.hhs.gov](mailto:cdhr-nondiagnosticeua-template@fda.hhs.gov) and include the information outlined in the EUA. This will allow FDA to confirm that the surgical mask meets the criteria and other requirements described in the EUA.

The letter of authorization for surgical mask lists several conditions of authorization specifically for manufacturers such as providing all labelling in English, complying with adverse event reporting under 21 CFR 803 and notifying FDA of any authorized distributors or importers of the authorized surgical masks for example. The letter of authorization for surgical masks lists several conditions of authorizations for distributors and authorized importers such as ensuring compliance with mask labeling available, recordkeeping and when requested submitting lots of authorized surgical masks for testing by FDA for example.

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

authorized and listed in Appendix A of the umbrella EUA for a surgical mask it is important for you to follow all of the listed conditions of authorization.

Okay so now I'm going to talk about FDA cleared surgical masks. FDA cleared surgical masks have demonstrated substantial equivalence to a legally marketed predicate device and current performance testing expectations include fluid penetration, flammability, breathability, particulate filtration efficiency and biocompatibility. Unlike surgical masks authorized under the EUA, 510(k) cleared surgical masks are all tested for airflow resistance even if a mask has fewer than four layers, and tested for bacterial filtration efficiency.

The biocompatibility assessments are conducted on the final finished masks and not only on the raw materials used. In some cases these surgical masks may have undergone additional testing based on materials or other features. Unlike surgical masks under the enforcement policy or that has been authorized, cleared surgical masks must adhere to applicable device regulations and current good manufacturing practice requirements including the quality system requirements under 21 CFR Part 820 with respect the design, manufacture, packaging, labeling, storage and distribution. That concludes my remarks. Thank you very much for your attention. And with that overview I would like to turn it over to Dr. Suzanne Schwartz to go over some frequently asked questions.

Dr. Suzanne Schwartz: Thanks so much Binita for that really great discussion on FDA's recently issued surgical mask umbrella EUA and how it fits within the context of FDA's holistic regulatory approach to surgical masks. We're going to switch over to the town hall portion of our session and I'll kick it off with sharing some frequently asked questions of FDA. But before I get started, I also wanted to mention that in addition to OSHA, we have representation from NIOSH on the call line as well in case there are any questions that NIOSH is best positioned to

address.

So let's start off with the following. "Will there be a product code for surgical masks authorized under the EUA? Will there be a specific product code for surgical masks authorized under the umbrella EUA that are imported?" The answer is there will be a product code for surgical masks authorized under this EUA which will apply to both surgical masks manufactured in the US and surgical masks that are imported. The product code is still in development.

The next question which further underscores what Dr. Ashar went over just a short moment ago, the EUA includes a waiver for quality systems regulation only but the enforcement policy indicates that we would not object to the distribution and use of surgical masks without compliance with certain regulatory requirements if they do not create an undue risk in light of the public health emergency as indicated in the guidance. "Is this guidance still in effect and does it apply to surgical masks authorized under the EUA?"

The answer is the surgical mask EUA does not impact the FDA's enforcement policy guidance for surgical masks. The enforcement policy for face masks and respirators during the coronavirus disease public health emergency is still in effect. The EUA and the enforcement policy set forth in the guidance set out two different ways for manufacturers to distribute surgical masks during the COVID-19 pandemic.

One more question before we turn to the live operator facilitated Q&A. "Can surgical masks still be marketed, distributed, used and/or imported without being included under the EUA due to the already issued enforcement policy?" And the answer is yes, for the manufacture of surgical masks that do not create an undue risk in light of the public health emergency as described in the enforcement policy guidance. FDA does not intend to object to their

distribution and use without compliance with the regulatory requirements listed in the guidance and authorization under the EUA is not required. And with that I'd like to turn to the operator if you can provide to us our first call?

Coordinator: Yes ma'am, thank you. If you would like to ask a question over the phones please press Star 1 and record your first and last name. To withdraw your question you may press Star 2. Once again to ask a question please press Star 1 and record your first and last name. Our first question is from (Michelle MacDonald). Your line is open.

(Michelle MacDonald): Hi, good morning. This is really good information but there seems to be a little confusion with the general public use masks which often look like surgical masks. And those currently seem to fall under the product code QKR which has enforcement discretion and does not make any claims for filtration or any of those other requirements for the surgical grade masks.

Is there any change coming regarding those that are - were - that we're supplying or purchasing for the retail outlets that you know for like home use and that? How did those particular mask QKR for general public use, how are they being impacted under the EUA way or other FDA enforcement activities?

Dr. Suzanne Schwartz: So thank you for that question. Dr. Ashar, do you want to take that one?

Dr. Binita Ashar: Sure. This Binita Ashar. I can start and I can have my colleagues chime in. So I'm not entirely sure of what the confusion is so I might need some more details around that. But just to give you the general framework there is an enforcement policy in place for face masks as well as an umbrella EUA for face masks.

And so just like with surgical masks, a manufacturer can choose to market

under the enforcement policy or under the umbrella EUA. They would simply need to adhere to the guidance if it was under the enforcement policy or the conditions of authorization if it was under the umbrella EUA.

Now I think what you're getting at and this is where I need clarification is that perhaps there is some confusion in the marketplace on what is a face mask and what is a surgical mask. Is that what you're referring to or is that the concern?

(Michelle MacDonald): It is. That is the question because we do have a supplier. The general-purpose ones I'd buy, you buy, we only go to the stores. But then some of our, you know, healthcare organizations are also looking to expand the utilization of masks for their, you know, nonsurgical, you know, like they've got a janitor in a hospital. They want to use these masks that have that minimal protection but they're not FDA classified devices. And that's why I was seeking that clarification.

FDA does have some non-classified devices or not classified which seem to be low risk. And I believe the QKR existed prior to the COVID outbreak as a way of discriminating between a medical device and a non-medical device and I think that's what I'm looking at. I want to continue to sell these non-medical grade because people are going to continue to use personal protection post-COVID. That's what I'm trying to distinguish. They don't label any of the requirements as a medical device.

We just want to make sure we're not going to have some surprise that our general-purpose masks that whether I'm purchasing them or supplying them will be terminated as a result of the COVID. So I just want to make sure that the FDA has already acknowledged that even prior to COVID people were buying these masks and FDA said these aren't regulated masks because they're there just for disposable personal use.

Dr. Binita Ashar: Right so, you know, you're - FDA is aware that, you know, after the pandemic ends and these policies go away with the pandemic that there is going to need to be a transition plan. And so there is some effort underway to understand what that transition plan is going to be.

And the second part of the issue is a little bit of the education on what the difference is between a face mask and a surgical mask. And so that's why we have our Web site with the information available that there. That's why we're happy that we have good attendance at these Webinars to help disseminate information. And we'll continue doing everything that we can to educate on our end and appreciate, you know, everything that you're doing as well. I don't know if others on the line from FDA have additional thoughts.

Cynthia Chang: Hi. This is Cynthia Chang. I think the question brings up an important topic which is the challenge in distinguishing between the different terms and the different types of products. So I would really encourage you and others on the line who have similar questions to take a closer look at our enforcement policy guidance documents because in that guidance document we lay out on the distinctions between masks that are not intended for a medical purpose and are not regulated as devices.

And we make a distinction between those as well as between face masks that are intended for a medical purpose and between those and surgical masks. And so the regulatory policies are different for each of those different categories.  
Thank you.

Dr. Suzanne Schwartz: Thank you. Can we have the next question please?

Coordinator: Thank you. Our next question is from (Jack Finanapi). Your line is open.

(Jack Finanapi): Hello. Thank you, guys, for taking all of our questions, been very helpful so far. I have two questions. My company's manufacturing face - surgical masks and N95s in New York and we're looking to see if - we were having trouble finding out if you need a clearing for, you know, NIOSH or, you know, any other - any of the regulatory measures that you guys are putting forth. There's been trouble finding that.

And the second thing is last Webinar you guys said that we cannot promote our filtration and like ASTM levels or meeting those requirements. But now with the surgical masks are we allowed to if we meet those requirements on early warning?

Dr. Suzanne Schwartz: So thank you for the question. I'm going to split the question into two because it really does need to go to two different parties.

(Jack Finanapi): Yes, yes, okay, thank you.

Dr. Suzanne Schwartz: So I think with respect to your first question regarding manufacturing of respirators and I believe that you also stated that you're a domestic manufacturer...

(Jack Finanapi): Yes.

Dr. Suzanne Schwartz: ...with regard to what that process is. We do have our NIOSH colleagues on the line. I'm wondering if Jeff or (John), someone could address what this manufacturer should be doing in terms of going through the approval process for the respirators? We'll start with that part.

Jeff Peterson: Sure. This is this is Jeff Peterson from NIOSH. So, you know, currently we

have no requirement that respirators need to be produced or manufactured in a clean room environment. And I think that's consistent with FDA requirements as well for surgical masks. But certainly the requirements that we have or that need to be met are the requirements that are listed in the regulation (42 CFR 84).

So you would be need to demonstrate that you can manufacture a product that can meet the particular filtration and breathing resistance requirements and then have a applicable quality system that ensures consistency in manufacturing so that we understand that the products coming off the production line are consistent and continue to meet the relevant requirements.

(Jack Finanapi): Thank you.

Dr. Suzanne Schwartz: Thanks. And then for the second part of that question you asked with regard to the claim, the filtration claims on the surgical mask. Since you're testing to certain claims can you label the product with the claims being met if I understood correctly? Is that okay?

(Jack Finanapi): Yes just to explain, so on the last Webinar I think we were told that we're not supposed to put what, you know, BSE and PSE we meet on our labeling through the EUA. But now with the surgical mask if we're meeting those requirements through testing are you allowed to say it's a surgical mask level one, level two, level three, or do we have to take that off when it comes to surgical mask?

Dr. Suzanne Schwartz: Right so I'm going to turn this over to Dr. Chang. I do want to - I do think though that this question came in two weeks ago I'm remembering, I think it might have been though in the context of the enforcement policy for which we would have said, you know, that you could not list those specific claims on

it. But that is where the distinction probably lies. Cynthia maybe you can provide further clarity around that?

Dr. Cynthia Chang: Yes, hello. This is Cynthia Chang. Thank you for the question. So with the enforcement policy there are some different labeling recommendations compared to what is required in the EUA for surgical masks. So that is also reflecting the difference in the testing that we're looking at.

And so for the EUA we are allowing certain claims regarding filtration and the other testing that has been conducted as long as they're meeting the requirements that are laid out in the scope and the conditions of authorization. And so if you are interested in pursuing that pathway, we will be evaluating the testing and the labeling that you provide to work with you to make sure that anything that is submitted to us is appropriately meeting the conditions of authorization and the scope of the authorization.

Man 1: Okay, all right, thank you. We had submitted the testing I think already so thank you for your help.

Dr. Cynthia Chang: Thank you.

Suzanne: To our next question, please.

Coordinator: Thank you. Our next question is from (John Doen) your line is open.

(John Doen): Thank you guys very much FDA and it's good to have Jeff Peterson on from NIOSH. We had a couple of quick questions. One of our - we've been doing this since 2006, 2008. We do have our 510(K)-pre-market clearance and notification on our next air medical. And the question came up are we, you know, how do we qualify for the CDC listing? Is there a special requirement? A

couple of these customers have said well you're not on the CDC list. Is that a separate designation?

Dr. Suzanne Schwartz: Thank you for the question. Let me ask a clarifying question back. We're talking about respirators N-95 correct?

(John Doen): Correct.

Dr. Suzanne Schwartz: Okay. And did you indicate that you already have a 510(K) clearance in place for the respirators?

(John Doen): Correct.

Dr. Suzanne Schwartz: All right. It should actually be on the NIOSH Certified Equipment List - the CEL if that's the case. I will let Jeff address this question - Jeff Peterson. But because we work closely in the area of N-95 respirators between FDA and NIOSH, those respirators that have certainly gone through the FDA clearance process already should be on the NIOSH equipment list.

(John Doen): Is that the same as the CDC list? For some reason they keep asking about a CDC cleared list and I wasn't sure the distinction.

(Jeff Peterson): So this is (Jeff). If you have an N-95 respirator that is approved by NIOSH or parent agency CDC and there seems to be some perception that there is another meaning to that term which is not true. So if your products are NIOSH approved and listed on the CEL and have that FDA clearance they should be good to go as a surgical N-95 type device.

(John Doen): Okay.

(Jeff Peterson): There is no other CDC list other than the CEL.

(John Doen): Interest, okay. Well I appreciate that answer. And if we wanted to follow up and get a reusable test for 14, 28 or 60 days do we refile that with the FDA or would NIOSH?

(Jeff Peterson): So for a filter and safety?

(John Doen): The reusability aspect.

(Jeff Peterson): But I was going to clarify the question. So, you know, I'm assuming that the products that you've alluded to have clearance on and approval for are filtering facepieces not elastomeric types correct?

(John Doen): Correct.

(Jeff Peterson): So Suzanne or (Jonisha) those questions are probably more for you.

Suzanne Schwartz: Yes. So I'm going to turn to Binita to address a question with regard to reusability of the filtering face piece respirators and perhaps that's what we need to talk about. I guess, you know, decontamination as opposed to labeling for reusability.

Binita Ashar: Sure this is Binita Ashar from FDA's OHT4. If you're looking to have your respirator authorized for its decontamination that would come to FDA. So there is an FDA - the CDC NIOSH MOU where this is not addressed. This kind of trips that. So this would come to FDA for review.

(John Doen): Okay. Can we get an expedited review so we can market it or it the normal process?

Binita Ashar: We're prioritizing all personal protective equipment submissions so we would do whatever we could to move it along quickly.

(John Doen): Okay. So where would we apply it the MOU? That would be under the - which Web site would we find that information?

Binita Ashar: So it sounds like you would need to request - you would need to submit a pre-EUA to get emergency use authorization to be able to have your single-use respirator authorized for decontamination. So do others from FDA have a EUA mailbox to suggest?

Suzanne: So Binita this is Suzanne. Just a point of clarity that I think that it might be helpful to elicit a little bit more information from the questioner. All of the respirators that are on the NIOSH CEL that have - that are really under the FDA NIOSH EUA that because they are authorized, they are also authorized for the allowance of decontamination by an authorized decontaminated system.

So I'm not sure if -- and this goes back to the question of whether there is something very new or specific about the design of your current device that you're wishing to make claims as to its reusability - - as opposed to undergoing decontamination by a system or a modality that the agency has given a decontamination EUA to. If you could maybe clarify that for us a little bit that'd be helpful.

(John Doen): Yes. These are particulate N-95 respirator masks with a silver copper permanently embedded feature which has been done for over 10 years. So that's where I would - it's because it's firmly embedded and we've done substantial tests independently, we wanted to make sure that we did it the proper way and maybe go through the EUA way process. Just so that if we make any claims it's,

you know, in coordination with any clearance factors we might need.

Suzanne: All right. That provides a lot more helpful information too. I'm going to turn this back to OHT4 for Dr. (Chang) who may be able to provide a little bit more insight in terms of what you would do as a next step.

Dr. (Cynthia Chang): Hello this is (Cynthia Chang). So thanks for that clarification. It sounds, like, you have an anti-microbial containing respirator from what I'm hearing. You have a few options. You could submit a 510(K) for your respirator, or if you think that it meets the criteria for an emergency use authorization you could also submit a pre-EUA to us. You could submit it to the CDRH non-diagnostic EUA template mailbox which is found on our Web site as well as in our EUA letters of authorization. And we would work with you to see what kind of information is provided and what's needed to move that forward.

(John Doen): Excellent. Well thank you so much.

Suzanne: Thank you. Next question please.

Coordinator: Our next question is from (Jamie Fosco) your line is open. Once again (Jamie Fosco) your line is open. Okay due to no response we can move forward. Our next question is from (Jessica Kinzer) your line is now open.

Woman 2: Thank you and good morning. From the perspective of the health system looking to procure surgical masks, I have a two-part question. One, in regards to the pre-510(K) process and the product and registry listing databases, could you just briefly summarize the lifecycle for that and how are those two related?

And then if looking at those databases I come across something that says enforcement discretion, how do I get more information regarding what that FDA enforcement discretion was and could I expect the vendors or manufacturers to have a letter from the FDA explaining that?

Suzanne: Okay thank you some really good questions in there. So to start with I'm going to turn to OHT4 - Drs. Ashar, Dr. Chang might you be able to start us off? Alright can you recap the question for us please?

Woman 3: Sure, sorry about that. It's a two-part question. One is in looking at that 510(K) pre-market process and the product and registration database, what's the lifecycle for those or how are those two related? And then when I'm looking in those databases the second part is and I come across something that has not been cleared because of discretion -- FDA discretion or enforcement discretion -- how do I find out more information about what that enforcement discretion is and can I expect that the vendor or the manufacturer will have a letter from the FDA about what that is?

Suzanne: Thanks for repeating those questions. I'm going to ask Deniz Mackey if she could begin by addressing the first question with respect to the process around applying and registration and listing et cetera.

Deniz Mackey: Absolutely. As you all have known during this pandemic, we're seeing a lot of changes. And so a lot of these enforcement policies and EUAs that have been posted in the recent months have allowed firms to come in without the registration and listing requirement under 21 CFR Part 807.

So firms are still able to register and list. And I've seen many firms have continued to register and list. What they do is use that enforcement flag. So they

are able to make that registration happen. As, you know, it's a self-registration process. Otherwise it would require the need for the 510(K), etc.

So there is a difference from the registration listing database than the 510(K) database. And that's where you would have that information on products that we do have the 510(K) and the PMA. So hopefully that answers that question.

Woman 2: Yes, thank you.

Suzanne: Right and then the second question was with regard to the enforcement discretion. And Deniz or Sean maybe elaborate a little bit further. What does that actually mean to a healthcare provider? Somebody who is looking to, you know, purchase products and wants a little bit better understanding as to what a manufacturer's obligation is. I think your question specifically was would the manufacturer have such a letter from the FDA stating that they were granted enforcement discretion as well.

Woman 2: Correct.

Deniz Mackey : Sure I can go ahead and take that question. So I'm looking at the registration list and database and I see that that enforcement flag is there. That just means that the firm has voluntarily registered their product that they don't have a 510(K) for and they're using either one of the enforcement policies or the EUAs as authorized to come in. But that's really all that means.

So they may have that letter of authorization through an EUA but it could also fall under enforcement if they're just trying to follow the enforcement policy, they're just voluntarily registering without that 510(K) number. So hopefully that clarifies things further.

Woman 2: Thank you.

Deniz Mackey: Go ahead.

Woman 2: Oh I just wanted to summarize and make sure I understood. So basically, they the companies do not have to do a product and registration listing but they can. And if they go that route but say their product comes in under an EUA, then that enforcement discretion flag will be on the product and listing. But it doesn't have a negative connotation or anything like that.

Deniz Mackey: Right, that's correct. So it could be either the EUA option or it could be the enforcement policy but you're right.

Woman 2: Thank you so much.

Coordinator: Thank you. Our next question is from (Erin Wagner) your line is open.

Erin Wagner Thank you. I think my question was answered previously but I just wanted to confirm that if you're marketing surgical masks under the enforcement policy you cannot put ASTM Level 1, 2 or 3 for fluid barrier protection and filtration efficiency but if you're marketing under the EUA you can. Can you please confirm that?

Suzanne: So OHT4s Dr. (Chang) do you want to just confirm that being the case?

Dr. (Cynthia Chang): Yes this is (Cynthia Chang). It is correct that under the enforcement policy you're not to make any of these claims. Under the EUA certain claims related to what testing has been evaluated in the EUA may be made. And we will work with you on exactly what is on the labeling and making sure that it does indeed meet the scope and conditions of the authorization.

Erin Wagner        Okay. And under the EUA then the interpretation or the intent is if you're manufacturing in China you either - you have to go the 510(K) route if you want to put claims on your masks?

Dr. (Cynthia Chang): So...

Erin Wagner        The level basically.

Dr. (Cynthia Chang): The surgical masks manufactured in China are not under the scope of the surgical mask EUA. So we would at this point recommend either the 510(K) pathway or the enforcement policy pathway. I should note that viral filtration claims are not, you know, covered by the testing that is listed in the EUA.

Erin Wagner        Understood. Thank you.

Suzanne:            Next question please.

Coordinator:        Thank you. Our next question is from (Ruthanne Rapp) your line is open.

(Ruthanne Rapp): Hello. Thank you so much for this webinar. All of these PPE webinars have been very helpful. I just had a question with regards to the umbrella EUA for surgical masks. I understand that 21 CFR 820 requirements have been waived under the EUA. But in alignment with the enforcement discretion policy facility registration and device listing requirements have been waived if you're going that enforcement discretion policy route.

Would that apply to surgical masks under the EUA? Is registration and listing waived for surgical masks under the EUA?

Suzanne: Okay sorry about that. It took me a moment to get off of mute. I'm sorry.  
(Deniz) can you address that?

Deniz Mackey: Sure, you're right. In the enforcement policy and several other documents it had clearly stated that there is a waiver for the 21 CFR Part 807. For this particular umbrella surgical mask EUA I didn't see that. But that doesn't mean it is not. It is waived. It's just not annotated within the EUA.

(Ruthanne Rapp): Great, thank you.

Suzanne: One last question please.

Coordinator: Thank you. Our last question is from (Howard Sherman) your line is open.

(Howard Sherman): Thank you so much. Just to be super clear. Up until August 5 we were manufacturing Level 3 surgical masks under the EUA where we had all the proper lab tests that justified that listing on our packaging. When we received the letter on August 5 we stopped - submitted to get on the Appendix A for that approval. Is that appropriate or is there a path for us to continue to still sell Level 3s prior to get notified whether we're on the appendix or not?

Dr. Suzanne Schwartz: So the surgical masks EUA was first issued on August 5. There was no prior surgical mask EUA. Let me clarify that first. And Dr. (Chang) do you want to provide now for further specificity around what happens beyond August if someone - a manufacturer desires to include under that EUA?

Dr. (Cynthia Chang): Yes. So if you have been marketing under the enforcement policy and you meet the recommendations under the enforcement policy for a surgical mask, then it's really your choice as to whether you want to continue following the

enforcement policy or if you wish to, you know, go the EUA route.

So the EUA for surgical masks is an additional option. We have not changed the enforcement policy for surgical masks. If you wish to follow under the EUA surgical mask you may submit your request to us using the template that is on our Web site and making sure that you have provided all of the information that is outlined in the surgical mask EUA. Does that help clarify your question?

(Howard Sherman): Yes you did. We submitted about 10 days ago. Do you know what it is really within 24 hours? Do you know what the timing is for a response?

Dr. (Cynthia Chang): So we do have a large volume of requests and we are working to respond as quickly as possible. If you have not received a response I'd say within a week or two please check back with us so that we can make sure that we get to your request. Thank you for your patience.

Howard Sherman: Thank you.

Suzanne: All right, well thank you. And on behalf of FDA I would like to recognize all of the subject matter experts who joined us today from CDC, NIOSH, from OSHA and FDA in support of this Q&A session. Thank you to everybody who has tuned in. The next session is scheduled to take place in two weeks which brings us to Tuesday, September 1 at noon Eastern. The announcements of topics will be forthcoming. So please do not hesitate as well to share with us any topics of interest that you'd like to hear more about. I'd like to now turn the session back to (Irene) who will close it out for us today.

Irene Aihie: Thank you Suzanne. This is Irene Aihie. And we appreciate your participation and thoughtful questions. Today's presentation and transcripts will be made available on the CDRH learn Web page at [www.fds.gov/training/cdrhlearn](http://www.fds.gov/training/cdrhlearn) by

Wednesday, August 26.

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 do 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](http://www.fda.gov/cdrhwebinar) webinar immediately following the conclusion of today's live webinar. Again thank you for participating and this concludes today's webinar.

Coordinator: Thank you for your participation. This now concludes today's conference. All lines may disconnect at this time.

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