

**FDA Webinar: Enforcement Policy for Personal Protective Equipment (PPE) During
COVID-19: Immediately in Effect Guidance**

**Moderator: Irene Aihie
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3:00 pm ET**

Coordinator: Thank you for standing by. At this time all participants are in a listen-only mode. During the question and answer session please press Star 1. Today's conference is being recorded if you have any objections you may disconnect at this time. I would like to turn the meeting over to Irene Aihie. Thank you, you may begin.

Irene Aihie: Hello and welcome to today's FDA Webinar. I am Irene Aihie of CDRH Office of Communication and Education. The FDA issued two immediately in effect guidances on enforcement policy for personal protective equipment during COVID-19.

The first enforcement policy for facemask and respirators during the coronavirus disease public health emergency which was revised on April 2, 2020 and the second enforcement policy for gowns, other apparel and gloves during the coronavirus disease public health emergency which was released on March 30, 2020.

Today Dr. Cynthia Chang, Director of the Division of Infection Control and Plastic Surgery Devices in the Office of Surgical and Infection Control Devices here in CDRH will present an overview of the guidance documents. She is joined by other members of CDRH. Following the presentation we will open the lines for your questions related to information provided during the presentation. Now I give you Cynthia.

Dr. Cynthia Chang: Good afternoon. I want to first thank you for tuning in during this public health emergency to assist with availability of PPE. We want to provide a high-level overview of how FDA is providing guidance to everyone who is pitching in to help.

Now I know some of you may not be familiar with FDA regulations and the terminology may be new to you. If you don't get all the nuances during the presentation or if you have a special situation that needs our input you can always email us at the addresses listed in this presentation so that we can address your specific question.

So with that let me begin by first walking through our agenda for today. We will begin with the introduction, objectives, and background for the Webinar and then we'll move into policies for the specific devices listed here. We'll then provide links to additional resources and open the lines up for questions.

Next slide please. So the purpose of today's discussion is to describe FDA's enforcement policies for face masks, respirators, gowns and gloves during the COVID-19 public health emergency. Additionally we will describe FDA's emergency use authorizations or EUAs for personal protective equipment products or PPE and for decontamination systems for N95 respirators and facemasks.

Next slide. And to put this all in context medical PPE are regulated by the FDA including surgical gowns, gloves, facemask and respirators. Currently FDA recognizes that the COVID-19 public health emergency presents significant challenges to the availability of PPE for healthcare personnel. And consequently FDA has authorized the emergency use of certain PPE as well as issued guidance on enforcement policies that together establish maximum regulatory flexibility while at the same time ensuring safety and availability of these devices. In the rest of the talk we'll cover the details of these policies.

Next slide please. The first set of policies pertain to facemasks and respirators. Next slide. We issued a guidance on our enforcement policy for facemasks and respirators during the COVID-19 public health emergency which may be found at the link. There are several categories of devices. The guidance explains that they may be marketed without prior FDA review and with discretion for certain other FDA requirements for the duration of the national emergency.

Next slide. This guidance covers our policies for the following range of devices: facemasks, face shields and N95 respirators not intended for medical purpose; facemasks intended for a medical purpose that are not intended to provide liquid barrier protection; face shields intended for a medical purpose; surgical masks intended to provide liquid barrier protection; and alternatives when FDA-cleared or NIOSH-approved N95 respirators are not available.

Next slide please.

One of the most important parts of the guidance is the definitions section as there are a variety of terms used in different settings. However, for FDA's regulatory purposes, do pay close attention to the definitions and descriptions for these product types in the guidance, and I'll quickly go over them now as well.

In the guidance when we discussed facemasks, we refer to a mask with or without a face shield that covers the user's nose and mouth. They may or may not meet fluid barrier or filtration efficiency performance levels.

N95 respirators are also discussed.

These are a specific type of filtering faced piece respirator that covers the user's nose and mouth and offers protection from particulates which are filtered out at greater than or equal to 95% of airborne particles. While many N95 respirators are used in construction or industrial applications, when indicated for use in a healthcare setting, they are regulated by FDA.

Next slide please. I also want to point out two more definitions. A face shield is a device used to protect the user's eyes and face from fluids and splashes. It is generally situated at the crown of the head and constructed with plastic. In the last definition is for surgical masks which cover the nose and mouth. 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.

Next slide please. Now that the terminology is clear, I'll briefly describe our policy for the duration of the national emergency. The FDA does not intend to object to distribution and use, including importation, of the devices listed below without compliance with certain regulatory requirements including 510(k), registration and listing, and quality system regulation requirements.

This applies as long as the device are tested and labeled consistent with the corresponding sections of the guidance for face shields for a medical purpose,

facemasks for a medical purpose without liquid barrier claims and surgical masks that are intended to provide liquid barrier protection.

Next slide please. Let me also point out a section in the guidance addressing alternatives when FDA cleared or NIOSH approved N95 respirators are not available. The section explains that when FDA cleared or NIOSH approved N95 respirators are not available the FDA does not intend to object to the distribution including importation and use of respirators that are identified in the CDC recommendations at this link. Note that the FDA recommends that importers take appropriate steps to verify the authenticity of the products they import.

Next slide please. Now let's turn to the topic of EUAs for facemasks, surgical masks and N95 respirators. Next slide. So what is an emergency use authorization or EUA? It's a vehicle by which FDA may achieve maximum regulatory flexibility while assuring the safety and availability of these products and devices. FDA evaluation of performance, safety and labeling is conducted, and once authorized, the EUA allows devices that are not FDA cleared or approved to be marketed in the US. The EUA can waive quality system requirements and is in effect for the duration of the national emergency.

Next slide. Note that FDA has authorized several EUAs for respirators, including N95 respirators, which are linked on this slide. The authorization letters provide detailed information for what is needed for eligible respirators to be authorized in each category. Next slide please. For EUA requests for novel masks or respirators please check first whether your mask may fall under one of the categories described previously.

If so, FDA review may not be needed for you to market your devices as long as you follow the recommendations in the appropriate section. If there are specific features of your device that fall outside these recommendations, then you may contact FDA to request an EUA.

You should include general information about your device, the labeling information on any marketing authorizations in other countries, information on manufacturing quality systems and a description of any testing conducted. You should send this request to the email listed here for FDA review.

And as I mentioned before, if you have a special situation that needs our input on any of the topics in this presentation you can always email us at the addresses listed in this presentation so we can address your specific question.

Next slide please. Now I will turn it over to Dr. Jon Weeks to discuss EUA's for decontamination of facemasks and respirators and he will be joined by Dr. Clarence Murray for any questions at the end. Dr. Weeks?

Dr. Jon Weeks: Thank you Cynthia next slide please. Today we'll be providing additional information regarding the requirements of Section 6A of this guidance. Please submit inquiries to the email address on the screen.

We encourage you to reach out to us early in developing your EUA to help us understand your decontamination process and how those will be implemented regardless of whether you have all the information at this time. While the information that I will describe is specific to N95 respirators, similar information may be important for surgical masks and surgical respirators.

Next slide please. In the guidance we include a list of items and questions for you to consider which will help us to better understand your process. We will

work with you to develop your EUA to address these items. In order for us to understand your proposed decontamination system and process we request that you provide a summary including the following.

The method of decontamination, the critical parameters including concentration, temperature time, relative humidity and any other parameters which are required to impart microbial killing as well as any and all information regarding chemical indicators, biological indicators, dosimeters, et cetera. which are used to ensure the critical parameters are met.

Please also include in your summary any materials for filters and straps or soils which are not compatible with your proposed decontamination process. Please provide evidence regarding the ability to reduce bio burden on the respirator. This should include any information on viricidal, mycobactericidal and sporicidal activity.

While COVID-19 is of utmost importance during this pandemic we are also concerned about the transmission of other pathogenic microbes if respirators are reused between multiple users. For example methods which only demonstrate viricidal activity could allow for inadvertent transmission of other microbes. So it is important that respirators which have been decontaminated in this way are only used by a single user.

In addition to information about the decontamination process and system we will also need information regarding the chain of custody. The chain of custody is important to understand whether safety precautions took place to reduce the risk of transmission of COVID-19 through individuals handling respirators from healthcare facilities to the site of decontamination and returned to the user.

It is also important to ensure that decontaminated respirators will not be contaminated prior to returning to the user. For methods which only demonstrate viricidal activity this is exceedingly important as a proper chain of custody will help to ensure that respirators are returned only to the same user to help reduce inadvertent transmission of other types of pathogenic microorganisms present in healthcare facilities.

While it is important that the proposed method of decontamination demonstrates effective microbial killing it is equally important to ensure that the decontamination process will not alter the respirator in any way to compromise the barrier protection. As part of this analysis it is important to ensure the materials of both filters and straps are compatible with the proposed mechanism of decontamination.

The filter performance is an essential part of material compatibility. Your analysis should include filtration efficiency and breathability for N95 respirators. Your surgical masks and surgical N95 respirators should also include liquid barrier testing. Please refer to the appropriate standardized test methods for these.

Band integrity is important to ensure proper fit of the respirators so please consider whether the straps maintain their integrity through repeated decontamination cycles. Additionally please describe whether the decontamination process will deform the respirators as this will prevent appropriate fit testing.

If the proposed method includes chemical means of decontamination such as ethylene oxide, vaporized hydrogen peroxide or others please include information regarding the residuals left after decontamination. Please include

an assessment and confirm the residuals will be insignificant to cause health hazard or deleterious effect to the user.

Please ensure that markings placed onto the respirators for labeling are indelible through the proposed number of decontamination cycles. In your submission please clearly state the number of times respirators can be decontaminated through your process. If you have plans to increase this number in the future based on additional testing please discuss with us the additional testing you have planned.

Finally we will need information on labeling to ensure users and decontamination personnel have important information regarding the proposed decontamination system and process. FDA will work interactively with sponsors of EUAs to develop appropriate labeling to include for decontaminated respirators.

This labeling will include a fact sheet and instructions for healthcare personnel and personnel performing decontamination. Again we encourage you to reach out to us early regardless of whether you have all the information at this time.

Next slide please. I will now introduce Dr. BiFeng Qian to discuss information on gowns and gloves. BiFeng.

Dr. (BiFeng Qian): Thank you Dr. Weeks. Good afternoon my name is BiFeng Qian. I'm a scientific reviewer in FDA's CDRH and subject matter expert in personal protective equipment review. I will give a high-level overview of the FDA's immediately in effect guidance for gowns, other apparel, and the gloves.

Next slide please. The enforcement of policy for gowns, other apparel, and gloves during the COVID-19 public health emergency has been posted on the FDA Web site. This guidance is to address some urgent public health concerns and help to expand the availability of gowns, other apparel, and gloves for use by the general public and by healthcare professionals in healthcare settings during the COVID-19 pandemic. This policy is to remain in effect for the duration of the public health emergency related to COVID-19.

Next slide please. Gowns and other apparel are products intended to protect the user from the transfer of materials in the user's environment. The FDA regulated gowns and other apparel to which the policy in this guidance applies are listed in Table 1 of the FDA's immediately in effect guidance. Please note that this guidance does not apply to surgical gowns that have a barrier protection Level 4 claim.

Next slide please. Based on the liquid barrier protection level, the gowns and the other apparel can be categorized as no barrier protection, minimal to low barrier protection that is a Level 1 or Level 2 protection per PB70 standard or equivalent, and moderate to high barrier protection that is Level 3 or higher protection per PB70 standard or equivalent.

Next slide please. FDA does not intend to object to distribution and the use, including importation, of these gowns and other surgical apparel, without compliance with certain regulatory requirements including 510(k) premarket notification and the registration and listing regulation requirements, etc., for the duration of the COVID-19 public health emergency. FDA believes that such devices will not create an undue risk when their testing and/or labeling are consistent with the enforcement policy.

Next slide please. In the next few minutes I will give a high-level overview of the enforcement policy for the gloves. Next slide please. Medical gloves include patient examination gloves and surgeons' gloves. Patient examination glove is a disposable device intended for a medical purpose that is worn on examiner's hand or finger to prevent contamination between patient and examiner.

A patient examination glove can be either sterile or nonsterile. Surgical glove is a device intended to be worn on the hands of operational personnel room personnel to protect a surgical wound from contamination. A surgeon's glove must be used sterile.

Next slide please. In addition to patient examination gloves and surgeon's gloves, - there are also gloves that are not intended for a medical purpose such as a glove for housekeeping. These gloves that are not intended for a medical purpose are not medical devices. The FDA regulated medical gloves to which the policy in this guidance applies are listed in Table 2 of this guidance. The policy for medical gloves is intended to remain in effect for the duration of COVID-19 public health emergency.

Next slide please. The non-medical gloves are not intended for use in the diagnosis, cure, mitigation, treatment or prevention of diseases. They are not labeled or intended for use by a healthcare professional or in a healthcare facility or environment, and do not include any drugs, biologics, or antimicrobial or antiviral agents. For these non-medical devices, FDA's device marketing authorization is not required.

Next slide please. FDA does not intend to object to distribution and use of both patient examination gloves and Surgeon's gloves without compliance with certain regulatory requirements including 510(k) premarket notification, registration and listing regulation requirements, etc., for the duration of the COVID-19 public health emergency. FDA believes that these gloves will not

create an undue risk in light of the public health emergency when the gloves are tested and labeled consistent with the enforcement policy.

Next slide please. These are the FDA website resources regarding FDA's policies and guidance for Personal Protective Equipment during the COVID-19 pandemic. Next slide please. More resources. Next slide please. The list of the FDA regulated gowns and other apparel, their regulations and product codes.

Next slide please. The list of the FDA regulated medical gloves, their regulations and the product codes, including the patient examination gloves and the surgeon's gloves. Next slide please.

So the key message that FDA wants to deliver in today's Webinar is that we would like to give the device manufacturers the maximum flexibility so that we may increase availability of these PPE devices to our frontline personnel and in meanwhile these devices will not create an undue risk in light of the public health emergency as long as these PPE devices are tested and labeled consistent with enforcement policy. Now I will give the time to our audience for questions.

Irene Aihie: Operator we we'll now take questions from participants.

Dr. Cynthia Chang: While we're waiting for questions - this is Cynthia Chang, perhaps we'll start off with a common question. So one common question is about personal protective equipment that is not made in the US and whether it may be used and imported. And so the answer to that is FDA recognizes that there is a critical need right now for healthcare personnel who need personal protective equipment.

And FDA is committed to collaborating with manufacturers to make sure that these products can be made available. The purpose of our guidances is to actually allow maximum availability and regulatory flexibility for these products including those outside of the US and to all allow importation as long as you follow the recommendations for your specific device.

And if you look at a lot of the resources and the links provided in our presentation today you will be able to find a lot of helpful information for your specific question. And if you're not able to find that specific answer, you are always welcome to email us for any questions including import specific questions.

Coordinator: I'll begin our question and answer session. If you would like to ask a question please press Star 1 from your phone and speak your name clearly when prompted. Our first question comes from (Delon). Your line is now open. Our next question comes from the line is now open. Our next question comes from (Kayla Owens). Your line is now open.

(Kayla Owens): Hi. So my question is if an importer is wanting to bring in products like gloves, face shields or facemasks that are not intended for a medical purpose does FDA even need to be flagged at entry or upon importation?

Dr. Cynthia Chang: Hi. This is Cynthia Chang. Thank you for your question. So as we discussed in the presentation there are various products that are not medical devices and the way to tell if they are not medical devices is whether they are or not intended for a medical purpose. And so if the products are not intended for a medical purpose then they are not regulated by FDA.

(Kayla Owens): So FDA doesn't need to be flagged?

Dr. Cynthia Chang: Right, as a medical device.

(Kayla Owens): Okay.

Coordinator: Again if you wish to ask a question please press Star 1 from your phone, submit one question. Our next question.

Irene Aihie: Operator, can you repeat that? Your line is going in and out?

Coordinator: (Terry) the line is now open.

(Terry): Yes, I emailed FDA this morning and haven't received a response back. If we have a letter from the governor of Florida to import some gloves is that - could that be under the emergency intended use code?

Dr. Cynthia Chang: Hi. This is Cynthia Chang and I will start with addressing your question. So thank you for your patience. We recognize that we are getting a lot of questions and so we do try to get to them as quickly as possible.

Now if your gloves are labeled as indicated in the guidance, you know, for a patient exam glove or, you know, a similar intended use then they would be covered by that section of the guidance and the FDA regulatory requirements are, you know, relaxed during this public health emergency. And so...

(Terry): But what's the intended use code? Is it the...

Dr. Cynthia Chang: So...

(Terry): ...emergency use intended use code? Is it the medical device intended use code?

Dr. Cynthia Chang: So is this a question about imports, the imports intended use code. So if you have a question about imports, we do have, you know, a specific group that addresses imports questions but we also do have a Customs and Border Protection Web site and bulletin that addresses import and intended use codes for those products...

((Crosstalk))

(Terry): But it's not actually...

Dr. Cynthia Chang: ...that are under enforcement discretion per the guidance. And so we can provide that to you or you may look on our Web site for that.

(Terry): Well like I said, I...

((Crosstalk))

(Terry): ...emailed you this morning but I haven't received an answer yet. How long is it taking to get an answer on emails?

Dr. Cynthia Chang: So we are doing our best to answer the questions as quickly as possible. For - I can provide information about our import Customs and Border Protection import bulletin. So for those importers who have products that are regulated by FDA as a device that are not authorized by an EUA but where an enforcement discretion policy has been published in guidance the importer should transmit intended use code 081.006 for enforcement discretion per final guidance and the appropriate FDA product code.

(Terry): And would that letter from the governor be under that intended use code?
Would that be...

Dr. Cynthia Chang: You may certainly include any additional documentation that you think would be helpful at the time of entry.

(Terry): So using that intended use code some of the normal requirements would be required correct, like the LST?

Dr. Cynthia Chang: So I think, you know, we do want to be as helpful as possible. I think for your specific situation it's a little bit difficult to address the specific questions here. But in general there is enforcement discretion per final guidance for a number of products that are described in the guidances and as long as you follow the recommendations in those guidances you should be able to get the information about how to enter your importation documentation. And I will be following up by email. Okay, thank you.

(Terry): Thank you.

Coordinator: Our next question comes from (unintelligible). Your line is now open.

Irene Aihie: Operator your line is – your connection is hard to hear. Can you repeat that please?

Coordinator: Our next question comes from (George Karlia). Your line is now open.

(George Karlia): Can you hear me?

Irene Aihie: Yes, we can hear you.

(George Karlia): Okay sorry. I have several questions. I'm a consumer. The first question I have got is it possible in these presentations that you might be able to put more details of the differences in the gown levels and the glove levels? I have concerns that people might try to sell me stuff that's not up to spec and might just put N95 or say the full level gowns? Is there any way you can put more details in the presentation? That's one of my questions.

The other one is I am concerned about how vendors demonstrate to the public that their level of their statements are consistent. What should we look for when we buy these products and how do I report fraud if I should come across them trying to sell me...

Irene Aihie: Excuse me sir?

(George Karlia): ...fraudulent goods?

Irene Aihie: Hi.

(George Karlia): Yes?

Irene Aihie: This Webinar is actually for manufacturers and industry and we're only – we're trying to limit our questions to one question per person. We do want to answer your question. Could you send that does your questions to the following email address? That is dice@fda.hhs.gov. That's our division of industry and consumer education and they can help you out with your question.

(George Karlia): All right, thank you.

Irene Aihie: You're welcome. Next caller please. Operator are you there?

Coordinator: I – oh yes.

Irene Aihie: We'll take our next caller please.

Coordinator: Our next question comes from (Suzanne Freeman). Your line is now open.

(Suzanne Freeman): Hi. Thanks for the useful presentation. I just had a follow-up question. I think you've addressed part of it already on the import issues. But I just wanted to clarify when it said that we should be using the enforcement discretion per final guidance code for imports and then the proper FDA code does that mean that the manufacturer even though registration and listing is technically waived during the pandemic would put the code that would be applicable that included in the guidance for the FDA device code?

Dr. Cynthia Chang: Yes, this is Cynthia Chang. Thank you for the question. Yes in terms of the product code that would be the appropriate FDA product code as listed in the tables for each of the guidances that we discussed today.

(Suzanne Freeman): Okay great. Thank you so much.

Coordinator: Our next question comes from (Bryce Noden). Your line is now open.

(Bryce Noden): Hi there. My question relates to the two different EAUs for KN95 or N95 sorry, equivalent respirators because the first EUA on 3/28 didn't necessarily preclude the use or importation of Chinese manufactured respirators if they met the CE or EN149–2001 specification/compliance for example.

But then the Chinese EUA came out on the second and provides different requirements for how you might request authorization under the EUA. But

then in emails that I received from the FDA it says if I'm receiving masks made in China, they can be ones that are listed on the CDC page which are very generic. They're not listing specific manufacturers.

They're listing whether they met the CE guidelines or the EN-149-2001 guidelines or they can be listed on Appendix a. If they're not made in China, they can be listed in the EUA letter or in Exhibit 1. So can I import masks that meet those let's say CE qualifications or the EN 149-2001 qualifications without getting permission directly from the FDA or do they have to be listed on Exhibit 1 or Appendix A?

Dr. Cynthia Chang: Hello this is Cynthia Chang. Thank you for that question and we appreciate that there are a lot of different documents out there. So I think your understanding is correct that there are several different options. So in the guidance for masks and respirators in Section 5,F we do have a section on alternatives.

An alternative is when the FDA cleared or NIOSH approved N95 respirators are not available. And so for the duration of the public health emergency these respirators are listed on the CDC's Web site in terms of those that would be acceptable alternatives which were evaluated on a method similar to the NIOSH approved respirators.

They do not need prior submission of a 510(k) and certain other regulatory requirements as listed in that section are relaxed. However it is also possible for you to request an EUA under the appropriate EUA authorization. So if it is a product that is manufactured in China you would use the EUA letter that was issued on April 3 and provide the information that is listed in that letter. I hope that that addresses your question.

(Bryce Noden): It does help a bit but when the response I get from FDA says that I can import these masks if they're listed on the CDC page so that does not involve any interaction with the FDA at all or they're listed on Appendix A. The only reason they would be listed on Appendix A is if I do interact with the FDA and send all that information that you've asked for in the EUA.

So it seems like there are two ways to import them. One I don't have to tell you anything and the other I have to send you a bunch of information and have the manufacturer create an English-language Web site for this mask and send you all the information and then you put it on Appendix A or if they meet one of the requirements on the CDC page I don't have to tell you anything. That's the confusion.

Dr. Cynthia Chang: Right so our goal is to, you know, maximize the availability of products and so we understand that the most expedient way to get important products into the country is, as long as you, you know, follow the recommendations in our guidance and if there's respirators that are listed on the CDC Web site, they may be imported during the public health emergency without notifying FDA. That is correct.

If you do wish to, you know, have the additional authorization from FDA that is an option. And so we're providing multiple avenues for these products to be made available. But I understand that it is potentially, you know, confusing as it's not our typical process to have multiple avenues. But during this time of need and because of the shortages we are providing multiple alternatives.

(Bryce Noden): That's great. So I understand that if the masks I'm importing meet those CDC page qualifications that they can be imported without being listed on Exhibit 1 or Appendix A. That's great.

Dr. Cynthia Chang: Yes.

(Bryce Noden): (Unintelligible).

Coordinator: Please remember to only ask one question. Our next question comes from (Jeremy Schwartz). Your line is now open.

(Jeremy Schwartz): Hi. Are you able to hear me?

Woman: Yes.

Irene Aihie: Yes, we can hear you.

(Jeremy Schwartz): Hi. I'm planning to manufacture domestically PPE masks. I worked in China for over seven years in manufacturing of products very similar and I'm somewhat of a subject matter expert. My question is in creating a new product here in the United States using the same PPE materials rolls of the fabric, et cetera, going through the straps is there a – I listened to the whole thing and there was a lot of information.

Is there a specific process of sending you our product to be tested or do I just email you what we've created send video evidence, et cetera, documentation? Can you better clarify what we need to do in order to be approved to market and sell these products?

Dr. Cynthia Chang: So this is Cynthia Chang. I'll start off. Thank you very much for, you know, looking into all the different avenues for making these products available in the time of need. We would first advise you to, you know, look at the appropriate guidance depending on which PPE product type you're intending to make.

And if your product - if your device or your PPE - if it falls under the categories where a, you know, 510(k) is waived where that's not necessary then FDA does not actually need to review the information for you to market. And so that is, you know, one of the regulatory flexibilities that we're putting in place now because of the critical shortage that we are experiencing.

So as long as you make sure that you test your product according to the recommendations that we list in that particular section for each particular product and as long as you, you know, provide labeling that is in alignment with the recommendations just so that people understand, you know, the testing and the quality of the product and that people understand what the product is intended to do, then for many of these categories prior FDA review and clearance is not needed.

((Crosstalk))

(Jeremy Schwartz): Okay, that's excellent. And I can follow-up through dice@fdad.hhs.gov correct with someone...

Dr. Cynthia Chang: Yes.

(Jeremy Schwartz): ...just in case?

Dr. Cynthia Chang: Yes.

(Jeremy Schwartz): Okay. Thank you so much.

Dr. Cynthia Chang: Thank you.

Coordinator: Our next question comes from (Matthew Gholston). Your line is now open.

(Matthew Gholston): Yes, on the KN95 mask they have respiratory sanitizers they devised with 3M what have you. Would those be sufficient to kill enough microbes if people used those respirator wipes to sanitize their own personal masks or would that be inefficient in your opinion?

Dr. Cynthia Chang: So this is Cynthia Chang. I think that that is a question that falls under our decontamination category for N95 masks. And so I'll turn it over to my colleague Dr. Clarence Murray and Dr. Jon Weeks to address that question.

(Matthew Gholston): Thank you.

Dr. Clarence Murray: Hi this is Dr. Murray. Could you please repeat the question?

(Matthew Gholston): 3M makes these like the wipies (sic), the respirator mask sanitizers where it's non-alcohol like where you could rub it on to like N95 mask or other types of mask. I'm not sure if those wipes would be sufficient to kill enough microbes on the mask without using different methods like the hydrogen peroxide spray what have you.

But I was just curious if those would be sufficient for civilians to reuse whatever mask they had to wipe down with those disinfectant wipes that are authorized for cleaning respirator masks?

Dr. Clarence Murray: So thank you for the question. I would say that in the literature - in papers that have been published in the literature would give you a better sense of ways to decontaminate the respirators.

(Matthew Gholston): Right.

Dr. Clarence Murray: And so there are some information that has been circulating around and around. I wouldn't necessarily recommend alcohol or things like that because there is the possibility of destroying the filter functionality...

(Matthew Gholston): Right.

Dr. Clarence Murray: ...of the respirator. And so I think there's been some strategies to use the respirator for intended use and things of that nature. And so I would recommend that before putting any kind of chemical on the respirator before so that you wouldn't destroy the filter of the respirator.

(Matthew Gholston): I appreciate that. All these wipes are nonalcoholic designed to clean the respirator mask but I'm just not clear on their efficiency what microbes they will kill to what percentage without on the mask. I know it won't harm the mask because they're designed for it but as far as the potency of the killing the microbes that I'm uncertain of but maybe that's too difficult of a question because it would depend on the product for manufacturer, I guess.

Dr. Clarence Murray: So this is Dr. Murray. It would. And so without having any further information than what was described it's challenging to give you a full response. But I think using the strategy that could prolong the use of your respirator so that you would not lose the filtering efficiency of the respirator would be the better strategy to use to prolong the use of the respirator.

(Matthew Gholston): I appreciate it. Thank you.

Coordinator: Our next question comes...

((Crosstalk))

Coordinator: ...from (Patricia Peters). Your line is now open.

(Patricia Peters): Yes hi. I was just wondering if you're going to make this Webinar available to the public so that we can when you were saying click on the different Web sites and see the different things you were referring to that we'd be able to then capture that. It was hard...

Irene Aihie: Yes ma'am.

(Patricia Peters): ...just listening.

Irene Aihie: Yes. The Webinar transcript and recording will be made available on [FDA.gov/training/cdrhlearn](https://www.fda.gov/training/cdrhlearn).

(Patricia Peters): Okay, that's great. Thank you so much.

Irene Aihie: You're welcome.

Coordinator: Our next question comes from (Jordan Piper). Your line is now open.

(Jordan Piper): Hi. Actually the - both my questions just got answered so I'm going to let it open up for somebody else. Thank you.

Coordinator: Our next question comes from (Oresh Doshi). Your line is now open.

(Oresh Doshi): Hi. My company actually makes handbags out of China but in the last few weeks I have been getting a lot of emails from people looking to market masks to me. I wanted to bring some masks here to provide to the public because we started to hear that certain counties like Riverside County in

Southern California have has now required that its residents were masks outside.

My question is, is am I allowed to import these masks if I haven't previously done so? And also if the masks are surgical or KN95 can I offer them to the public?

Dr. Cynthia Chang: So this is Cynthia Chang. I'll address the question. So the first question is about whether masks can be imported and offered to the general public. So I think if you look at our facemask and respirator guidance, we do have a section which is Section 5.C for facemasks intended for medical purpose not intended to provide liquid barrier protection.

So for facemasks intended for medical purpose not intended to provide liquid barrier protection let, you know, as long as you meet the labeling recommendations in that section then you may bring those in and you do not need additional FDA review.

(Oresh Doshi): Okay, so does that mean – is there any sort of license that's normally needed by an importer of these types of devices?

Dr. Cynthia Chang: So typically there are various regulatory requirements. And those are listed in that section. But during the public health emergency FDA is not necessarily requiring those. So those requirements are not necessarily needed to be met during this time so that you may import those products.

(Oresh Doshi): So if it's...

Dr. Cynthia Chang: Does that...

(Oresh Doshi): ...meant not to – so if it's meant not to be a liquid barrier like just for people to walk around wearing so that they can minimize their chances of infecting people or being infected I - so I don't need to have that sort of license. Is there a specific code for that?

Dr. Cynthia Chang: Yes. So again that's addressed in Section 5C of the safe mask guidance. And then we do have a Customs and Border Protection bulletin that addresses various import codes that can be used.

And so for products that are addressed under our guidances you can, you know, address the correct product code as indicated in the guidance document. And then you may transmit the intended use code as 081.006. And if you have any problems finding that document please send us an email and we'll point you to it.

(Oresh Doshi): Okay and if by chance some hospitals wanted these, am I allowed to then as someone who has not previously imported medical devices give them to hospitals?

Dr. Cynthia Chang: Right, so as long as it's clearly labeled in terms of, you know, what the product is, and what testing has or has not been conducted. I would again refer you to the appropriate section of the guidance for what that labeling should say in terms of what recommendations should be in there. Then you may market them to hospitals or to the general public.

(Oresh Doshi): Okay, and just I am sorry for the - all these questions but just to understand like so is it called if for someone who has a normal license to be able to import these items is that called registration?

Dr. Cynthia Chang: So let me be clear that my comments were regarding medical device manufacturer registration and listing. I think that import registrations or licenses are outside the scope of this particular Webinar. However you may send us your question via email and will get it to the right group to be able to answer that.

(Oresh Doshi): So (doc) I'm sorry then. For my first question though was am I allowed to import those? And I thought you said yes but now you're saying that the import registration would be different?

Dr. Cynthia Chang: The import registration is outside the scope of this Webinar. So we are just talking about here the FDA regulatory requirements. And so with that I would recommend that any follow-up questions be sent via email and we could open it up to the next question.

(Oresh Doshi): Okay, which email is that?

Irene Aihie: That email...

((Crosstalk))

Irene Aihie: ...that is dice@fda.hhs.gov. We'll take our next caller.

Coordinator: Our next question comes from (Mariah Perkins). Your line is now open.

(Mariah Perkins): Hello, can you hear me?

Irene Aihie: Yes, we can.

(Mariah Perkins): Okay awesome. My - I have a couple of different questions another one had kind of already been addressed but I'm trying to find them here. Okay, regarding the manufacturing if we're importing non-like medical use masks is there a certain market requirement that we need to include on the packing list like just maybe the words that say not for medical use or how would we put that - how would we put the marketing requirement for nonmedical use devices?

Dr. Cynthia Chang: So this is Cynthia Chang. We do not necessarily have, you know, requirements for what would be required for something that's not for medical use but you could look in our guidance on facemask and respirators. We do have a section, Section 5.B that talks about facemasks, face shields and respirators that are not intended for medical purpose. And we give a little bit more detail there about what sorts of information would be considered as to whether they're intended for medical purpose or not.

(Mariah Perkins) Okay, that's what I (unintelligible).

Coordinator: Our last question comes from (Sal Estino). Your line is now open.

(Sal Estino): Hi. Yes, I was - I'm a custom broker and we have several importers interested in importing liquid hand sanitizers and wipes and also some KN95 mask for medical use. Do they need to have an FDA registration number for medical devices and does the sanitizers require the FDA 510(k) import numbers?

Dr. Cynthia Chang: This is Cynthia Chang. I can address that. So hand sanitizer's and wipes I believe are outside of the scope of today's Webinar. I think that hand sanitizers are not medical devices. They may be regulated by our Center for Drug Evaluation and Research but they are outside the scope of today's

Webinar. However regarding the KN95 these respirators can be used and they can be brought in during the pandemic.

We do have as I mentioned previously Section 5.F of our mask and respirator guidance. So we talk about, you know, alternatives when FDA cleared or NIOSH approved N95s are not available. If those KN95s are listed on the CDC's Web site then they may be brought in without prior FDA review.

We just note that FDA cannot confirm the authenticity necessarily of those respirators if we are not reviewing them. So we recommend that importers take appropriate steps to verify the authenticity of the products that you're importing.

(Sal Estino): I see. Okay, and can I – well then, my last question is regarding like gowns...

Coordinator: Hello. We will now turn the call over to Irene Aihie.

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 Learning Web page at www.fda.gov/training/cdrhlearn by Monday, April 13. If you have additional questions about today's presentation please use the contact information provided at the end of the slide presentation. If you send your questions to dice@fda.hhs.gov that is D-I-C-E.fda.hhs.gov.

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 in this concludes today's Webinar.

Coordinator: Thank you for your participation in today's conference. You may disconnect at this time.

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