

**FDA Webinar Series –
Gowns and Other Apparel for Use by Health Care
Personnel in COVID-19 Pandemic**

**Moderator: Irene Aihie
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Coordinator: Welcome and thank you for standing by. At 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 our meeting over to Ms. Irene Aihie. Thank you. You may begin.

Irene Aihie: Thank you. Hello and welcome to today's FDA webinar. I'm Irene Aihie of CDRH's Office of Communication and Education. Welcome to the 8th CDRH webinar in our respirator webinar series. This webinar will expand the scope of the webinar series from respirators and masks to gowns and other apparel. During this webinar, the FDA will present information on both the enforcement policy and the EUA for gowns and other apparel.

And representatives from FDA, Centers for Disease Control and Prevention and Occupational Safety and Health Administration will be available to answer your questions. Following a few opening remarks, we will open the line for your questions related to information provided during today's discussion.

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

Suzanne Schwartz: Thank you and welcome, everyone. As Irene mentioned, this is the eighth session in our bi-weekly webinar series on personal protective equipment or PPE. At our last webinar, on September 1, Colleen Miller, Deputy Chief Conformity Verification and Standards Development Branch from CDC NIOSH's National Personal Protective Technology Laboratory, and (Heidi Sewchok), NIOSH Approval Coordinator, provided an overview of the recently updated NIOSH guidance on surgical respirators.

Today, I'm pleased to introduce Dr. Bifeng Qian, Scientific Reviewer in CDRH's Office of Health Technology Four, or OHT4, Surgical and Infection Control Devices in the Office of Product Evaluation and Quality. She will provide an overview on FDA's enforcement policy and umbrella EUA for gowns and other apparel for use by health care personnel. After Bifeng's presentation, we will return to the operator for live Q&A.

As Irene already mentioned, our federal partners and colleagues from CDC NIOSH and OSHA are presently on the line with us, and they'll be available to field questions relative to their respective mission, roles, and responsibilities. At this time, I'd now like to turn the webinar over to Bifeng.

Bifeng Qian: Thank you, Suzanne. Good afternoon, everyone. I'm going to talk about different type of PPE device today, gowns and other apparel. In response to concerns relating to insufficient supply and availability of gowns and other apparels for use by healthcare personnel as personal protection equipment in health care settings during the COVID -19 pandemic, FDA issued the following two documents.

On March 30, 2020, FDA issued Enforcement Policy Guidance for Gowns, Other Apparel, and Gloves during the COVID-19 Public Health Emergency. On May 22, 2020, FDA issued an umbrella Emergency Use Authorization (or EUA) for gowns and the other apparel. In order to explain these policies, my remarks provide a high-level comparison of the authorized gowns and other apparel, the gowns and other apparel that are under the FDA's enforcement policy, and the FDA-cleared (gowns and other apparel).

Before I start, I want to briefly explain how gowns and other apparel are classified and regulated. Gowns and other apparel are products intended to protect the wearer from the transfer of microorganisms, body fluids and particulate materials in the wearer's environment. Gowns and other apparel can be intended for medical or non-medical purposes. Gowns and other apparel intended for a medical purpose are regulated by FDA under 21 CFR 878.4040 Surgical Apparel and 21 CFR 880.68265 Examination Gown.

Gowns and other apparel that are not intended for a medical purpose are not medical devices. FDA's device marketing authorization is not required for non-medical gowns and other apparel. They are not the focus of our discussion today.

Per the FDA recognized standard ANSI/AAMI PB70, titled "Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities", there are four different levels of barrier protection. Level 1 provides minimal barrier protection. Level 2 is for low barrier protection. Level 3 for moderate barrier protection, and level 4 for high barrier protection. Level 1 and level 2 gowns are class 1 exempt medical devices.

Because they do not provide sufficient barrier protection for surgical settings, they should not be called surgical gowns. Gowns providing moderate or high

level of barrier protection, that is level 3 or level 4, are class 2 medical devices. These gowns may be labeled as surgical gowns, surgical isolation gowns, or surgical togas. A surgical gown is expected to be used by operating room personnel during surgical procedures. Therefore, it must be provided sterile. A surgical isolation gown, if it's sterile, can also be used in surgical settings.

Now let's dive into the FDA's enforcement policies for gowns and other apparel for use by health care personnel during the COVID-19 public health emergency. Next slide, please.

The first question is which gown products and other apparels are covered under the FDA enforcement policy guidance. Next slide, please.

As listed in Table 1 of the FDA guidance, most class 1 exempt gowns and class 2 surgical gowns and other apparel fall under the scope of the FDA enforcement policy guidance.

The next question is which gown products and other apparels are not covered under the FDA enforcement policy guidance. The non-covered gowns and other apparel include those products that contain drugs or biologics, are indicated for level 4 barrier protection, are indicated for antimicrobial or antiviral protection, or are indicated for infection prevention or reduction.

So what are the enforcement policies outlined in this guidance? The enforcement policy divides the gowns and other apparel into two categories based on their liquid barrier protection level. The first category is the non-surgical gowns and minimal to low barrier protection surgical apparel. The second category is the moderate to high barrier protection surgical gowns.

The non-surgical gowns and minimal to low barrier protection surgical apparels are intended to provide level 1 or level 2 barrier protection (or have no barrier protection level claim). These products should be labeled as a gown, a toga or other apparel. They should not be labeled as a surgical gown or surgical toga. The product labeling should identify a list of the body contacting materials which should not include any drugs or biologics.

The product labeling should include information that would reduce the device use risk, for example, not using the device in surgical settings, not using the device in clinical settings where significant exposure to bodily or other fluids may be expected, in clinical settings where level 3 or level 4 barrier protection is warranted, and in the presence of high intensity heat source of flammable gas. The product labeling should not include any claims for antimicrobial or antiviral protection and any claims for infection prevention or reduction.

The second category is the moderate to high barrier protection surgical gowns. The products under this category are surgical gowns, including surgical isolation gowns. These gowns are intended to provide level 3 or higher barrier protection, and they may be used in surgical procedures. To fall under this category, the gown product should meet the requirements for liquid barrier protection level 3 or higher, consistent with AAMI PB70 for the critical zone areas, meet class 1 or class 2 flammability requirements per 16 CFR Part 1610, and be sterile if intended for use in surgical settings.

The product labeling should accurately describe the product's sterility status, sterile or non-sterile, and the sterilization method used, the barrier protection level as level 3, and the flammability classification as class 1 or class 2. The product labeling should identify a list of the body contacting materials.

The product labeling should include adequate information that would reduce sufficiently the risk of device use, for example, a general statement that the

device has not been cleared by the FDA, a recommendation against use when FDA-cleared surgical gowns are available, and a recommendation against any use of non-sterile products in surgical settings. The product labeling should not include any claims for antimicrobial or antiviral protection and any claims for infection prevention or reduction. The product should not be labeled as having AAMI PB70 level 4 liquid barrier protection.

Our guidance explains that FDA does not intend to object to distribution and use (including importation) of these gowns and other apparel without compliance with certain regulatory requirements, including 510(k) premarket notification, registration and listing, etcetera, 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.

Now that I have provided you with an overview of the enforcement policy for gowns and other apparel. In the next few minutes, I will be talking about the umbrella EUA for gowns and other apparel for use by health care personnel as personal protective equipment in health care settings.

You may ask, why do we need an umbrella EUA while the enforcement policy guidance is already in place? The answer is, while we continue to believe that it is important to have the enforcement policy guidance in place as it establishes the maximum regulatory flexibility to help expand the availability of gowns and other apparel, it is the FDA's intention to provide as many appropriate pathways as possible to address the increased demands and PPE shortages during the COVID-19 pandemic.

If we compare to the FDA enforcement policy guidance, which gown products and other apparel are excluded from the scope of the umbrella EUA? This

umbrella EUA is limited to class 1 non-surgical gowns and minimal to low barrier protection surgical apparel (that is level 1 and level 2).

This EUA does not cover any of the class 2 devices, including surgical gowns, patient gowns, surgical isolation gowns, and surgical hoods. This EUA excludes two class 1 devices, surgical suits under the product code FXO and surgical dress under the product code FYE. Lastly, gowns with no barrier protection level claim are also excluded.

The authorized non-surgical gowns and other apparel must meet the labeling requirements listed in the EUA. The labeling requirements are consistent with the labeling recommendations outlined in the enforcement policy guidance, but with a few additional requirements or clarifications.

In addition to drugs and biologics, we emphasize that the authorized non-surgical gowns and other apparel should not include any nanoparticles or antimicrobial/antiviral agents. The product should not be misrepresented as a surgical gown or be labeled as having AAMI PB70 level 3 or level 4 liquid barrier protection. The product labeling should include the intended use of the product, for single use or reuse, with appropriate instructions.

The manufacturers and distributors should follow the conditions of the authorization. Similar to the non-surgical gowns and other apparel intended for minimal to low barrier protection under the enforcement policy guidance, the following regulatory requirements do not apply to the EUA authorized products, including applicable good manufacturing practice requirements, applicable labeling requirements except for those described in the EUA, registration and listing, and Reports of Corrections and Removals.

If you have a gown product or other apparel that meets appropriate requirements listed in the umbrella EUA and the recommendations outlined in

the enforcement policy guidance, it is up to you as the manufacturer whether you wish to market the device under the enforcement policy or under the EUA.

The final question of my presentation is what about if a gown product or other apparel falls outside the scopes of both the enforcement policy guidance and the umbrella EUA?

Our answer is there are additional regulatory pathways that may be applicable to the product including a separate, independent EUA, a 510(k) submission if a predicate device can be identified, or other pathways.

Lastly, I will briefly mention about the FDA cleared gowns and other apparel, as compared to the gowns and other apparel under the EUA or under the FDA's enforcement policy. FDA cleared gowns and other apparels have demonstrated substantial equivalence to a legally marketed predicate device.

As compared to the gowns and other apparel under the enforcement policy or the umbrella EUA, which are more relying on labeling and self-certification, 510(k)-cleared gowns and other apparel have been fully evaluated for physical specifications including liquid barrier performance, mechanical specifications, sterility if applicable, biocompatibility, and any special labeling claims made.

Unlike the gowns and other apparel under the enforcement policy or EUA, 510(k)-cleared gowns and other apparel must adhere to all applicable device regulations and the current good manufacturing practice requirements including the quality system requirements under 21 CFR 820 with respect to the design, manufacture, packaging, , labeling, storage, and distribution.

Please note that while the FDA enforcement policy guidance and the umbrella EUA are intended to remain in effect only for the duration of the public health

emergency related to COVID-19, the 510(k) cleared gowns and other apparels may continue to legally market after the COVID-19 public health emergency. Next slide, please.

Now, with that overview, I would like to turn it over to Dr. Suzanne Schwartz to go over some frequently asked questions.

Suzanne Schwartz: Thank you very much Bifeng for your comprehensive presentation. Rather than going through any frequently asked questions, we're going to actually switch over directly to the town hall portion of our session for live Q&A. Operator, can we have the first question, please?

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 on the phones, please press "star," "1" and record your first and last name. Thank you. Just a few moments for questions.

And our first question is from (Janelle Bentz). Your line is open.

(Janelle Bentz): Hi. Thank you. This is more of a comment, I guess, than a question. But for me at least, the slides were not advancing, so I'm wondering if the deck will be available for review later. It was a bit difficult to follow the presentation without being able to see which slide we were on. We were stuck on resources the whole time.

Suzanne Schwartz: Hi. This is Suzanne Schwartz. There were only a few slides, and we were deliberately on the resource slide for the majority of the presentation. So you weren't missing anything. What I would say is certainly the transcript or the presentation will be available in order to fill in whatever gaps you were not able to follow during the actual audio.

(Janelle Bentz): Fantastic. That will be helpful. Thank you.

Coordinator: Thank you. Our next question's from Jose Chavez. Your line is open.

Jose Chavez: Good morning, everybody. This is Jose Chavez, Premiere Resource. You have a question regarding the, I guess the complementation of the letter of authorization along with the enforcement policy. It looks - it appears on - when it comes to more at the high-level protection surgical apparel, that the enforcement policy covers that and gives sort of a, of a open interpretation to the, I guess, the usage without a formal 510(k) to market notification. But in the gowns and apparel EUA that came out in May, it appears that that class of products specifically state requiring 510(k). Can you please elaborate on that?

Suzanne Schwartz: Sure, I'm going to turn to OHT4 to Bifeng or her colleagues to address that distinction. And that's an important point that warrants some clarification.

Jose Chavez: Thank you.

Suzanne Schwartz: So either Dr. Chang or (Dr. Qian), either one.

Cynthia Chang: Hi. This is Cynthia Chang. So thank you for that question. I think there are a number of different parts to that. So as (Dr. Qian) mentioned in her talk, the enforcement policy guidance and then the EUA authorization do not cover exactly the same devices. So the authorization for the EUA covers a subset of gowns and apparel. The enforcement policy is broader. Now, for all of these devices, we're providing a different pathway than what would normally be expected due to the extreme need that we're facing during the public health emergency.

So there are statements in both the enforcement policy and the EUA that explain under normal circumstances certain of the device product codes require a 510(k) under normal circumstances. However, the enforcement policy and the EUA allow marketing under different circumstances as long as you follow either the recommendations in the policy for the guidance document or if you follow the conditions of authorization for the EUA.

I think there's a question in there about high level barrier protection. I do want to note that level 4 gowns do require a 510(k) to be marketed at this time. They are not covered by the enforcement policy. Level 4 gowns are not covered by the EUA. I hope that addresses your question. And let me must turn to (Dr. Qian) to make sure that I did not miss anything.

Bifeng Qian: Yes, Dr. Chang, what you said is absolutely correct. So with the enforcement policy, and with the umbrella EUA in place, we also have the regular 510(k) pathway. A level 4 device which is not included in both the umbrella EUA and the enforcement policy, can always be reviewed through the 510(k) program. For level 3 gowns, you can choose either 510(k) for premarket review, or you can market it under the enforcement policy, if the testing and labeling are consistent with the enforcement policy outlined in the guidance.

The level 1 and level 2 gowns and minimal to low barrier protection other apparel are 510(k) exempt medical devices. – You may also market the devices under the enforcement policy or umbrella EUA during the COVID-19 public health emergency, if the criteria are met

Jose Chavez: I have a follow up question, if I may?

Bifeng Qian: Sure.

Jose Chavez: Currently, during the pandemic, looking at the 510(k) that were issued during this time frame, there was probably less than six 510(k)s related to surgical gowns that have been approved. As a point of reference, I've submitted EUA's on several other similar products, and the response time has been about a month and a half. Following the 510(k) premarket notification pathway, is the FDA taking any action to sort of expedite that process or is it still the normal timeframe of approximately 90 days?

Suzanne Schwartz: Dr. Chang, do you want to respond to that with respect to the processes that OHT4 has been implementing around both the 510(k) reviews as well as EUAs?

Cynthia Chang: Yes. This is Cynthia Chang. Thank you so much for bringing that up. At this time, because we recognize the need for available PPE, OHT4 within CDRH is expediting the review of 510(k) submissions for PPE submissions. The length of time that it takes often, for any submission, really does depend on the completeness of the submission. However, for complete submissions, we are seeing that they're getting reviewed as swiftly as possible, and we are working to interact as much as possible with those submissions that may have some outstanding questions, as well. And that goes for the 510(k)s and also any EUAs that we're receiving as well. Thank you.

Binita Ashar: Hi. This is Binita Ashar. And if I could add to that, we do appreciate the patience of the individuals that are working with these manufacturers to help bring these products to market. And as Dr. Chang mentioned, we're working to expedite that process as much as possible. We are committed to making sure that we communicate regularly with you regarding the status of your submission.

We cannot make promises, however, related to the duration of time it may take to review an EUA, pre-EUA submission, however. As Dr. Chang

mentioned, it really depends on the completeness. So I don't think that you can expect every submission to take a certain period of time. Some will be much faster; others will take on the order of months. It really depends on the starting place for that technology.

Because, in many ways, these pre-EUAs are breakthrough technologies, and the submitter may be at a very early stage in their development which requires a lot of interaction with the FDA team. But we are, certainly, committed to prioritizing these and committed to communicating with you on the status of your file.

Jose Chavez: Thank you. I appreciate that very much.

Suzanne Schwartz: Can we have next question, please?

Coordinator: Sure. Our next question is from (Matthew Aziz). Your line is open.

(Matthew Aziz): Okay. Thank you for taking my question. I actually have two, if I may. And the first question is for the level 1 and 2 apparel and gowns that are imported, is the foreign firm required to be registered and listed as well as the importer?

Deniz Mackey: I can take that question. So per the enforcement policy for the level 1 and 2 gowns, it ensures that we are okay with firms bringing in these products without meeting 21 CFR Part 807, the registration and listing requirements. And therefore, also, the initial importer requirement, that would not be expected, and they should be able to import these products, as long as it meets the scope and the recommendations outlined in the enforcement policy.

(Matthew Aziz): Okay. Thank you. And the second question is regarding the product entry. In other words, if this level 1 and 2 apparel and gowns are destined for a GMP

lab, as opposed to a health care establishment, how is the FDA able to differentiate at the point of entry in order to determine the level of scrutiny?

Suzanne Schwartz: This is Suzanne. If you don't mind, can you repeat the question again? I, at least, missed the first part of it.

(Matthew Aziz): Absolutely. Yes. I was asking that in a case whereby this apparels and gowns are destined for a GMP lab, as opposed to a health care establishment, what level of scrutiny is placed on the importation by the FDA at a point of entry?

Deniz Mackey: Wait one second here.

Suzanne Schwartz: Okay, so I think that's Deniz who's starting to answer. Let me just also mention an important distinction with regard to the EUA and the enforcement policy. Really, we've scoped that to health care personnel. If you look at the language there, as opposed to GMP labs or other uses outside of the health care setting, health care interactions. I just want to make that clear from the start.

As to how, at the point of entry, there is a screening or distinction made between who the intended customer is, I'm going to turn to our imports folks, and, Deniz, maybe you have an answer for that.

Deniz: Right, I can take this on. So if the product is coming in through the port of entry if it does get detained, we would just need that additional clarification. And what we've said previously is include additional information, et cetera within the paperwork when it's submitted. And it should, hopefully, there should be no other issue.

But if you have encountered issues during imports, usually FDA notice of action will have those contact information for who is dealing with that

particular shipment from one of our five import divisions at ORA. I would recommend reaching out to that person. We also have a mailbox, COVID-19FDAimportinquiries@fda.hhs.gov.

One more thing I will like to add is recently we have posted FAQs for both imports as well as registration and listing pertaining to medical devices during this COVID-19 emergency, and that has a lot of these questions that we have received in previous couple months, and you can certainly always refer to that for any other imports questions, as well as R&L, registration questions you may have.

(Matthew Aziz): Okay. Thank you.

Suzanne Schwartz: Also here it's important in terms of mentioning that - - and I know you state this in the enforcement policy guidance - - that if the particular product, here you're talking about a gown, but it could be a face mask or another form of PPE, is not intended for a medical purpose, we would not consider it a medical device. So that is another important consideration to bear in mind. If it was not intended for a medical purpose, FDA would not be, even at the import site, really weighing in on whether the device, whether the product, undergoes FDA scrutiny or screening.

(Matthew Aziz): Got it. Thank you.

Coordinator: Thank you. Our next question is from (Para Vensouli). Your line is open.

(Para Vensouli): Thank you. Good afternoon. Can you hear me? Hello?

Woman: Yes.

((Crosstalk))

(Para Vensouli): My question is you mentioned isolation gown and surgical gown. There is, in addition, there is a type called surgical isolation gown. Would you please clarify what is it and how can a gown be qualified as a surgical isolation gown as compared to just either isolation gown or surgical gown?

Suzanne Schwartz: Thank you. I'm going to turn to (Dr. Qian). Can you answer that please?

Bifeng Qian: Sure. the major different between an isolation gown and a traditional non-isolation gown is with respect to the critical zone area. The critical zone is the area where direct contact with blood, bodily fluids and other potential infectious material is most likely to occur. An isolation gown has a larger critical zone area than a traditional non-isolation gown.

All areas of an isolation gown except for the binding, cuff, and hem are considered the critical zones of protection and must meet the highest liquid barrier protection level for which the gown is rated. In contrast, critical zones of a traditional, non-isolation gown only cover the front of the body and the forearm portions.

Then, the difference between a surgical isolation gown and a non-surgical isolation gown is with respect to the barrier protection level. The non-surgical isolation gown is for minimal to low barrier protection, level 1 or level 2. The surgical isolation gown is for level 3 or level 4 barrier protection.

In addition, a surgical gown, as compared to a surgical isolation gown, both of which may provide level 3 or level 4 barrier protection, surgical gowns, because they are going to be used in operating room, they must be provided sterile. A surgical isolation gown, if it is going to be used in surgical settings or in sterile environment, it must be provided sterile too. A surgical isolation

gown, if provided non-sterile, can be used in non-surgical settings. Did I answer your question?

(Para Vensouli): Yes. Thank you very much. Appreciate. So I am applying for the 510(k) now, so I need to apply for isolation gown, surgical gown or isolation surgical gown, three different classes, correct?

Bifeng Qian: Yes. an isolation gown, if it is non-surgical, is a 510(k) exempt device. So currently, during the COVID-19 public health emergency, you can either market it under the enforcement policy guidance or under the EUA, provided that the testing and labeling are consistent with the enforcement policy, the EUA requirements are met, and the conditions of the EUA authorization are followed for the isolation gowns. But for surgical gowns or surgical isolation gowns, these are class 2 medical devices. If it is a level 3 gown, you can either market it under the enforcement policy guidance or you can submit a 510(k). But if it is a level 4 gown, you must submit a 510(k) for premarket review prior to marketing.

(Para Vensouli): Great. Thank you very much. I really appreciate it.

Bifeng Qian: Thank you.

Coordinator: Thank you. Our next question is from (Kai Lee). Your line is open.

(Kai Lee): Okay. Great. So this is a follow up to a question that was asked by a previous audience member. So if we market a level 3 surgical gown under the enforcement policy which this product, as Dr. Chang said, isn't included under the EUA, would the product liability protections under the PREP act apply for these level 3 surgical gowns? So it's currently my understanding that prep act product liability only applied to devices that carry some sort of

approval or clearance or authorization by the FDA, like the EUA. Am I understanding that correctly?

Suzanne Schwartz: So, this is Suzanne. I will start, and then I'll turn it over to my colleagues in OHT4. The EUA for gowns does not include the higher risk levels of barrier protection. It excludes level 3 and level 4. The EUA is a vehicle that is used for liability protection. Therefore, your marketing of a level 3 gown, you're marketing it under the enforcement policy guidance, and the enforcement policy does not include the liability protection. I'm going to ask Dr. Chang or Dr. Ashar if there is additional information that you'd like to elaborate or correct, if that wasn't accurate.

Cynthia Chang: Dr. Chang here. Nothing to add.

(Kai Lee): Okay. Great. Thank you.

Coordinator: Thank you. Our next question is from (Sherry Barry). Your line is open.

(Sherry Barry): Yes. Thank you for taking my call. I have a related question to the others. If we're currently marketing level 3 gowns under the enforcement policy that would normally require 510(k) clearance, is the FDA going to provide some, I would call it, a grace period or a notification when you have to move off the enforcement policy to 510(k) to legally market the products that your currently manufacturing?

Susanne Schwartz: Thanks, so OHT4s, Drs. Chang or Ashar, do you want to provide a response to that?

(Binita Ashar): Sure. This is (Binita Ashar). I can start. So I think it's a great question. First and foremost, we appreciate the fact that you're marketing currently under the enforcement policy and would encourage you to submit a 510(k) now so that

when the enforcement policy sunsets after the public health emergency, you are in good position to continue marketing your device.

Now, with respect to when the policy sunsets and how the policy will sunset, the Center is still working out how that will occur. We recognize that some sort of transition period will be necessary, but how that should occur and will occur hasn't necessarily been established yet. So for this reason, we think it would be helpful though, for you to think in the long term as you have been and consider submitting a 510(k) now. It won't - the transition won't happen overnight. We do expect that there would be a transition period.

(Sherry Barry): Okay. Great. Thank you. We are planning on doing that. Just the concern is the time period to get approval for the 510(k), if it did sunset, and the transition period allowed.

(Binita Ashar): Right. I think we're doing our very best to prioritize these 510(k)s, and we will take into account the period of time necessary for review, I think, as we're developing the policies around transition. There's no assurances, of course, but I don't think you should be - we are hoping that your review doesn't necessarily take the full 510(k) review period, provided that you have all of the materials set and ready to go in your submission.

(Sherry Barry): Thank you.

Coordinator: Thank you. Our next question is from (Karen Buschimi). Your line is open.

(Karen Buschimi): Thank you. I have two questions, actually. So first of all, we are, at this point, manufacturing level 1 and level 2 or manufacturing level 1, getting ready to move to level 2, sorry. So our fabric obviously has been tested, and we have that paperwork. For level 1 and level 2, do the gowns need to be lab tested or not necessarily?

Suzanne Schwartz: Do the gowns need to be, I missed that word, lab tested, laboratory tested?

(Karen Buschimi): Yes. Do they need to be sent to the lab for level 1 and level 2 to have the testing done or as long as the fabric's been tested, and we have the paperwork for that that it meets, you know, level 1, level 2, is that appropriate for manufacturing?

Suzanne Schwartz: Got it. Okay. (Dr. Qian), can you provide a response to that, please?

Bifeng Qian: Yes. if you intend to make a claim, a barrier protection level claim, the gowns need to be tested and meet the AAMI PB70 requirements for level 1 and level 2 claim.

(Karen Buschimi): Okay. And, then, I'm still confused listening to the questions and the answers regarding level 3 because I feel like I'm hearing a couple different things. So, level 3, if it is - the level 3 that is not sterile is a surgical isolation gown, is that correct?

Woman: Yes.

(Karen Buschimi): Okay. And does that follow the EUA?

Bifeng Qian: A non-sterile level 3 gown may be a surgical isolation gown. but it needs to meet the isolation gown criteria. That means that all areas of the gown need to be protective. For example, if you have an open back gown, even though it is a level 3, you cannot call it a surgical isolation gown.

(Karen Buschimi): Okay. But can a surgical isolation gown level 3? Does that fall under the EUA, non-sterile?

Bifeng Qian: No. the EUA only covers level 1 and level 2 gowns. It does not cover level 3 gowns.

((Crosstalk))

Bifeng Qian: A Level 3 gown may be covered under the enforcement policy guidance.

(Karen Buschimi): Thank you.

Bifeng Qian: Thank you for your question.

Coordinator: Thank you ...

((Crosstalk))

Suzanne Schwartz: We can take one more question, and then after this last question we'll wrap it up.

Coordinator: Yes, ma'am. Our last question is from (Jim Matthews). Your line is open.

(Jim Matthews): Thank you. My question is around the scope that's outlined in the EUA. It's specific to the surgical apparel for health care professionals. The question is around the guidance and potential expansion of the scope for aseptic manufacturing with respect to drug products. Given the limited amount of PPE across the world and globally, will there be an expansion to that scope for additional guidance there?

Suzanne Schwartz: Let me make sure I understood the question was whether the EUA itself, the scope would be expanded beyond healthcare personnel. Is that correct?

(Jim Matthews): Correct.

Suzanne Schwartz: No. At this time there is no intent to expand the scope of the EUA beyond health care personnel.

(Jim Matthews): Thank you.

Suzanne Schwartz: And that was our last question. And I want to, again, thank all of the subject matter experts who joined us today and our formal presenter Dr. Bifeng Qian for her comprehensive overview of gowns and apparel under both the enforcement policy as well as under the EUA.

The next session will take place in two weeks on Tuesday, September 29 at noon Eastern. The announcement of topics will be forthcoming, and we encourage you to share with us those that might be of interest to you. I'd like to now turn the session back to Irene who will close it out.

Irene Aihie: Thank you, Suzanne. (Unintelligible) We appreciate your participation and thoughtful questions. Today's presentation and transcript will be made available on the CDRH Learn Web page at www.fda.gov/training/CDRHlearn by Wednesday, September 23. If you have additional questions about today's presentation, please use the contact information provided at the end of slide presentation.

As always, we appreciate your feedback. Following the conclusion of today's live webinar, please complete a short 13-question survey about your FDA/CDRH webinar experience. The survey can be found at www.fda.gov/cdrhwebinar, immediately following the conclusion of today's live webinar. Again, thank you for participating, and this concludes today's webinar.

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