FDA Webinar Series - Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

Moderator: Irene Aihie
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Coordinator: Good afternoon and thank you for standing by. I'd like to inform all participants that your lines have been placed on a listen-only mode until the question-an- answer session of today's call. Today's call is also being recorded. If anyone has any objections, you may disconnect at this time. I would now like to turn the call over to Ms. 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 Communications and Education. Welcome to the 12th CDRH webinar on our PPE Webinar Series. During this webinar, the FDA will share information about sterilizers, air purifiers and disinfectant devices, including chemical and physical disinfectant devices and ultraviolet disinfecting devices.

Representatives from the FDA and the 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. Cynthia Chang, from CDRH's Office of Surgical and Infection Control Devices.

Dr. Cynthia Chang: Good afternoon, everyone and welcome. As Irene mentioned, this is the 12th session in our bi-weekly webinar series on personal protective equipment or PPE. In prior webinars, we have discussed the regulation of a variety of devices, including PPE, face masks and protective barrier enclosures during the COVID-19 pandemic.

Today we will be expanding the scope of the webinar series to include sterilizers, disinfectant devices and air purifiers. Dr. Christopher Dugard, a biologist in our Office of Surgical and Infection Control Devices, will provide an overview of our guidance, which covers our enforcement policy for sterilizers, disinfectant devices and air purifiers during the COVID-19 public health emergency.

After his presentation, we will turn to the operator for live Q&A. With that, I am pleased to introduce Mr. Chris Dugard.

Mr. Christopher Dugard: Thank you, Dr. Chang and good afternoon, everyone. As Dr. Chang mentioned, my name is Chris Dugard and welcome to this webinar on our enforcement policy for sterilizers, disinfecting devices and air purifiers during the COVID-19 public health emergency.

During the public health emergency, the availability of technologies that help mitigate the transmission of pathogenic microorganisms, have become critical to protect healthcare workers and patients. For this reason, FDA released a guidance back in March, describing our enforcement policies for sterilizers, disinfectants and air purifiers during the public health emergency.

In general, this policy states that FDA does not intend to object to limited modifications to the indications or functionality of either FDA cleared or approved or non-FDA cleared or approved sterilizers, disinfecting devices and air purifiers regarding claims of viricidal effectiveness against SARS-CoV-2, the virus that causes COVID-19.

Sterilizers for use in a healthcare facility, are medical devices that are regulated by FDA and are intended to render reusable medical devices sterile, that is free from viable microorganisms. Sterilizers vary in both construction ranging from small tabletop sterilizers to large sterilizers intended for large loads and modality. For example, steam, ethylene oxide or vaporized hydrogen peroxide.

FDA evaluates and authorizes sterilizers for marketing with specific cycle parameters intended for specific loads. These should also include appropriate accessories such as biological indicators, chemical indicator, wraps, trays, et cetera.

FDA considers chemical physical disinfectant devices to encompass chemical disinfectant solutions used to disinfect medical devices, as well as medical washer disinfectors or automated endoscope reprocessors that utilize chemical disinfectant solutions or physical processes, for example, thermal, to reprocess medical devices.

UV disinfecting devices are devices that use UVA or UVC light to produce a germicidal effect. They are intended to augment disinfection of healthcare environmental services after manual cleaning has been performed. Air purifying devices are intended for medical purposes, to kill pathogens in the air by exposure to UV radiation or remove them through filtration.

Note that some of these products, some of which I will elaborate on later in the discussion, have dual jurisdiction with EPA's Office of Pesticide Programs. The goal of this policy is to help expand the availability and capability of sterilizers, disinfecting devices and air purifiers during this public health emergency.

Note that the policy we will discuss today, will remain in effect only for the duration of the public health emergency. Regarding the scope of this policy, decontamination of PPE or reprocessing of single use devices using these technologies, is outside of the scope. It only applies to those devices that are adhering to their typical intended use.

I would also like to note that none of the devices that are within the scope of this policy, have received an EUA authorization. For any EUA authorization, all of the criteria for an EUA must be met as outlined in the EUA guidance. I encourage you to review the EUA guidance for more information. Despite this, FDA considers these technologies important in protecting patients and healthcare workers from contamination which is the reason we have developed this enforcement policy.

First, I want to provide an overview of the policy in general. During the COVID-19 public health emergency it is necessary to maintain an adequate supply of sterilizers, disinfecting devices and air purifiers that can facilitate rapid turnaround of sterilized or disinfected medical equipment and that help reduce the risk of viral exposure for patients and healthcare providers, to SARS-CoV-2.

FDA believes that certain sterilizers, disinfecting devices, and air purifiers falling within the scope of this guidance, may help reduce the risk of viral exposure based on our current understanding of these devices and SARS-

CoV-2. Scientifically, we have based this policy on the descending order of resistance of microorganisms to germicidal chemicals which is seen here.

Because sterilization processes render devices free from viable microorganisms, including bacterial spores and because disinfection kills most recognized pathogenic microorganisms, it can generally be inferred that sterilization and disinfection should minimize the viability of SARS-CoV-2 on surfaces and in the air and confined spaces since SARS-CoV-2 is an RNA virus enveloped in a lipid bilayer and is considered one of the least resistant microorganisms.

In addition, air purifiers can be designed to filter out virus sized particles. For this reason, FDA does not intend to object to limited modifications to the indications or functionality of either FDA cleared or approved or non-FDA cleared or approved sterilizers, disinfecting devices and air purifiers, when making claims of viricidal effectiveness against SARS-CoV-2.

During the public health emergency, we are providing flexibility on the regulatory requirements outlined in Section 4 of the guidance, provided these devices and/or modifications do not create an undue risk. These requirements include prior submission of a pre-market notification under Section 510(k) of the FD&C Act and 21 CFR 807.81 or submission of a pre-market approval application or PMA supplement, under section 515 of the FD&C Act and 21 CFR 814.39, registration and listing requirements in 21 CFR 807 and unique device identification requirements in 21 CFR 830 and 21 CFR 801.20.

You must still comply with all other applicable regulatory requirements if they are not specifically addressed in the enforcement policy, including but not limited to 21 CFR Parts 820 for quality systems, 806 for reports of

corrections and removals, 803 for medical device reporting, and Part 801 for labeling, except for the sections specifically called out in the guidance.

As an example, this would apply to a manufacturer that is - that previously received 510(k) clearance for a steam sterilizer that is intended for sterilization of medical devices in healthcare settings where the manufacturer would like to include a statement in the labeling that the device is effective in killing SARS-CoV-2 when used in accordance with the validated sterilization processes identified in the labeling.

As another example, this would apply to the manufacturer of a new medical air purifier that has not been approved or cleared, and that is effective in filtering out dust particles and bacteria, where the manufacturer would like to modify the filter mesh size in order to filter out viruses including the SARS-CoV-2 virus.

I want to highlight that any claims of sterilizers, disinfecting devices, or air purifiers that are intended to prevent or reduce the risks of hospital acquired infections or HAIs, or COVID-19, are outside the scope of this policy. If you intend on making these claims, we highly recommend you discuss with the agency, to determine what is needed before proceeding.

I also want to highlight another key phrase of this policy. These devices should not create any undue risk. For example, a device that uses a new technology that has not been well-characterized or a device that is typically intended for a different use that has been repurposed, may create an undue risk and could potentially be outside the scope of this policy.

First, I'd like to go over sterilizers. As described previously, sterilizers for use in a healthcare facility, are medical devices that are regulated by FDA and are

intended to render medical devices sterile, that is free from viable microorganisms. This does not include industrial sterilization where FDA regulates the process but not the sterilizer or facility, as this is considered part of the manufacturing process.

The table shown here lists the various regulations and associated device types and product codes that are within the scope of this policy. Note that this encompasses all healthcare sterilizers which the exception of new modalities that the agency is not familiar with.

A typical sterilization validation involves supporting that the sterilizer can show adequate lethality to a specified populations of the most resistant microorganism. Using the hierarchy of resistance, we can then assume if these sterilizers are lethal to the most resistant microorganism they would also be lethal to SARS-CoV-2.

For this reason, these sterilizers are included in the scope of this policy. Regarding performance, FDA expects that any modifications including changes to the indications or functionality to the sterilizers or to their accessories, be designed, evaluated and validated, in accordance with FDA recognized standards.

Note that manufacturers must document changes to their device and their device master record and change control records and make this information available to FDA if requested, per 21 CFR 820.30 and 21 CFR 820.180. we have listed the typical standards associated with the various modalities FDA is familiar with, in section 4(a) of the guidance.

The typical expectation is that a sterilizer and its cycles be validated to an SAL or sterility assurance level, of 10^-6 in accordance with these standards.

We have also listed some additional helpful documents like the guidance on sterilization and reprocessing, in section 4(c). Regarding labeling, we expect that if there are changes to the indications or functions related to SARS-CoV-2, this be addressed in the labeling and include information on device performance and the potential risks of these changes.

There should also be labeling clearly delineating FDA cleared or approved indications from non-FDA cleared or approved indications. Next, I will discuss chemical and physical disinfectants, the regulations, device types and product codes of which are listed here.

As previously described, FDA considers chemical and physical disinfectant devices to encompass chemical disinfectant solutions, used to disinfect medical devices, as well as medical washer disinfectors or automated endoscope re-processors that utilize chemical disinfectant solutions or physical processes like thermal, to reprocess medical devices.

FDA regulates medical device, washer disinfectant devices, liquid chemical (sterilants) and high level disinfectants. General purpose cleaners and disinfectants such as household products or products which are not specifically for use on medical devices, are regulated by the EPA and are outside the scope of its policy.

As with sterilizers, we have listed commonly used FDA recognized standards to address the performance of chemical and physical disinfectants in the guidance. In addition, we have listed our criteria to support the indicated level of disinfection. That is low, intermediate or high level, which should be clearly indicated on the labeling.

A low level disinfection process is intended to kill vegetative forms of bacteria, some fungi and lipid viruses. This is shown by demonstrating a process can achieve a six (log) reduction of common vegetative microorganisms, including pseudomonas aeruginosa, staphylococcus aureus, E. coli and representatives of the klebsiella (enterobacter) genus.

Intermediate level disinfection is meant to kill all that a low level process would, with the addition of mycobacteria, but not bacterial spores. This is shown with a six (log) reduction of common vegetative microorganisms as well as a three (log) reduction of an appropriate mycobacteria species.

High level disinfection is intended to kill all forms of microbial life with the exception of large numbers of bacterial spores. This is shown with a six (log) reduction of common vegetative microorganisms as well as a six (log) reduction of an appropriate mycobacterium species.

The labeling requirements are similar to the sterilizer requirements, where we expect that if there are changes to the indications or functions related to SARS-CoV-2 this be addressed in the labeling and include information on device performance and of potential risks of these changes. They should also be labeling clearly delineating FDA cleared or approved indications from non-FDA cleared or approved indications.

So while we've grouped UV disinfector devices with chemical and physical disinfectants, there are some key differences I'd like to point out. on this slide you see the regulation for UV devices. As previously described, UV disinfecting devices are devices that use UVA or UVC light to produce a germicidal effect.

They are intended to augment disinfection of healthcare environmental surfaces after manual cleaning has been performed. They have the same requirements as chemical physical disinfectants, in particular our criteria for the claimed level of disinfection.

In addition, FDA recommends that the manufacturer evaluate whether the product controls for time, UV radiation dose and intensity of UV dose. Validation of the cleaning and disinfection procedure that the device augments, should support the claim level of disinfection, be it low, intermediate, or high level.

UV disinfectors also typically produce ozone. Ozone generation should be evaluated to ensure it is below the limit established in 21 CFR 801.415. This states a device will not generate ozone at a level of .05 PPM by volume of air circulating through the device, or cause an accumulation of ozone in excess of .05 PPM by the volume of air in the atmosphere of the enclosed space.

Note that the current limit of ozone exposure for an 8-hour day of industrial workers, is .1 PPM per OSHA's requirements. Regarding labeling, UV disinfectors also have additional requirements. This includes a caution that UV disinfection will reduce the number of pathogens on the device but it will not eliminate them completely.

A statement that the device is an adjunct to currently existing reprocessing practices and not a replacement or modification to such practices; a statement regarding the time, distance and maximum area over which the device has been evaluated for effectiveness; and appropriate UV hazard warning label, identification of the expected UV lamp operational life, and instructions for procedures on replacement of the UV lamp when needed; procedures to follow if the UV lamp malfunctions or fails; a description of the preparation

of equipment or the room for disinfection; a statement that the equipment intended to be disinfected is UV compatible; and identification of the UV dose.

Finally, I would like to discuss air purifiers. The associated regulations are listed here. Performance requirements are listed in Section 4(a) of the guidance and they include demonstration of a four (log) reduction through a combination of capture or destruction of claimed particulates, if intended for use against bacteria. So effectiveness against representative gram positive and gram negative species. If intended for use related to SARS-CoV-2 effectiveness against a representative virus.

If intended for use in areas that have a sterile field or a controlled airflow, a risk assessment to address turbulent airflow and/or potential site contamination. You'll see here we also have a regulation for air purifiers that use UV to kill pathogens. Please note that the same requirements outside of the device being labeled as an adjunct, apply to air purifiers that use UV.

This includes an evaluation of whether the product controls for time, UV radiation dose and intensity of UV dose. Assurance that the ozone generated falls under the level of ozone specified in 21 CFR 801.415 should also be shown.

Air purifiers within the scope of this guidance are those that are intended for medical purposes. Non-medical air purifiers are not within FDA's purview. The term for medical purposes, is kept intentionally general. We will review the claims being made for the device as well as its intended operating environment, to determine if an air purifier is making a medical claim. I will provide some examples.

Simply listing the microorganisms the device is effective against, or the particle sizes it can filter, does not necessarily make the device a medical device. Reduction or prevention of infection from those microorganisms however, is a medical claim. Protection against these microorganisms would also be considered a medical claim.

Providing specific health benefits is considered a medical claim. Regarding this policy, claims of lethality against SARS-CoV-2 which is the pathogenic organism, is an acceptable claim. However, treatment or prevention of COVID-19 which is the disease state, is not an acceptable claim.

As noted earlier, healthcare associated infection claims are outside the scope of this policy. If you are uncertain as to whether a claim you are making is considered a medical claim, we encourage you to reach out to the agency for feedback.

So we are getting to the end of the presentation part of this webinar. Here are some useful resources including the sterility guidance, the reprocessing guidance and liquid chemical sterilant high level disinfectant guidance. I encourage you to review these.

And that concludes my presentation and we will now take questions. And while we're opening the line and you're thinking about your questions, I thought I would get this started with a couple of frequently asked questions. So I know I just went over this in my last slide, but we've received a lot of questions about it, so I think it bears - we often receive a question about what claims constitute a medical claim, especially in the context of air purifiers.

So to reemphasize, examples of nonmedical claims include listing the microorganisms, the device is effective against either by killing the

microorganisms or filtering them. And this also includes listing specific particle sizes the device can filter.

Removal of airborne microorganisms, pollutants, contaminants or pollen. And if it is intended for general use, such as on surfaces and non-healthcare environments, these are all examples of non-medical claims. Examples of medical claims include stating it's for medical purposes; reduction or prevention of infection; prevention of any adverse health effect such as alleviation of allergies, asthma, et cetera; or if it claims to provide any specific health benefits; or if it is for use on another medical device.

And again, in the context of this policy, a claim that the device can kill or filter SARS-CoV-2, which is the virus, is an acceptable claim within the scope of this policy. A claim that the device can treat or prevent COVID-19, the disease state SARS-CoV-2 causes, are not within the scope of this policy.

So we also received quite a few questions about the regulatory requirements, so we've - so the question we receive often is do I need to comply with regulatory requirements that are not listed in the enforcement policy for my device, such as 21 CFR 820 for quality systems, 806 for reports of corrections and removals, 803 for medical device reporting and 801 for labeling?

The answer is yes. If you are marketing a medical device, you must comply with all applicable regulations and requirements. Our enforcement policy identifies the specific areas for which we do not intend to object if you do not comply. However, all other requirements are still in effect.

Now with that, I will pause there and see if we have any questions from the audience.

Irene Aihie: Operator, do we have any questions on the line? Please standby as we wait on our operator. She is gathering participants and their questions now.

Dr. Christopher Dugard: Great. Thank you. Well while we're waiting I can go over one more frequently asked question. So again, this is another topic that I mentioned in my presentation, but it bears repeating. Is my sterilizer, disinfecting device or air purifier that uses a new technology, within the scope of the guidance?

If your device uses a new technology or involves changes to an existing medical device, we highly recommend you reach out to the agency for feedback on whether your device would still be within the scope of the guidance. This goes for any aspect of any device that may be within scope of the policy. If you suspect something may create an undue risk, please reach out to the agency.

Irene Aihie: We will take our first question. Operator, I believe you may still be muted.

Dr. Christopher Dugard: Well I can discuss one more quick question. Another frequent question we receive is can I decontaminate PPE or other single use devices? And the answer is unless the specific device you are working with has received an EUA to do so, then no. Some healthcare sterilizers have received an EUA authorization to decontaminate N95s, but indicating any of the devices that are in the scope of the guidance for decontamination of PPE, requires an EUA.

Please refer to FDA's Web site for those healthcare sterilizer models that have received EUA authorization for decontamination of N95s or other PPE. Unless the device you are working with has EUA authorization, the device should continue to be used as originally indicated.

For example, this means a healthcare sterilizer can continue to sterilize reusable medical equipment and make claims that it is effective at killing SARS-CoV-2. However, the same healthcare sterilizer cannot reprocess single use devices like N95s, surgical gowns, etc.

Irene Aihie: Thanks, Chris. I believe we have (Alison Comioma), who is ready to ask a question. Go ahead, (Alison).

(Alison Comioma): Can you hear me?

Irene Aihie: Yes.

(Alison Comioma): Okay. Hi. Thanks so much for putting this webinar on. I really appreciate it. And Chris, this is excellent information. My question is what sort of documentation - like level of documentation should be prepared to support a device that falls within this guidance document, as we continue to put together the quality system per 21 CFR 820?

I know you said, you know, it is good to have that FDA won't, you know, they're not going to enforce that general control at this time, but yes, what would be acceptable just for our internal purposes?

Dr. Cynthia Chang: Hi. This is Cynthia Chang. So thank you for the question. The question is about the level of documentation that is needed under 21 CFR 820 for making changes in alignment with the guidance. And to answer that question, I would say that our enforcement policy is not making any changes to 21 CFR 820 and the quality system regulation.

So for the purposes of making any changes in accordance with this enforcement policy, you should continue to follow 820 and the quality systems regulation as you would, under normal circumstances. Thank you.

(Alison Comioma): Okay. What I'm - sorry, can I have a quick follow up? Is there - the level of - would an internal memo to make sure that we fulfill each one - the appropriate sections of the guidance document just be an added document that we should have in place?

Dr. Cynthia Chang: So the question is regarding whether a memo to address how each of the items are addressed under 820, if that would be sufficient. And for the purposes of the enforcement policy and our guidance, we do not have any specific recommendations on that. I will turn to my colleagues and ORP and CDRH to see if there is any additional comments on documentation of changes that might be appropriate under 21 CFR 820.

(Cesar Perez): Yes. Good afternoon. This is (Cesar Perez) from the Office of Regulatory Programs. I believe what Cynthia - what you provided is correct. I don't think there's any specific guidance on what type of accommodations you need to provide in - in order to state that you are fulfilling all the requirements in the enforcement policy.

But it would be important to provide that information as part of your regular process. And maintain files or a memorandum potentially, to be able to state that you are fulfilling those requirements. But there isn't any specific. It's up to the (firm) to do that. Thank you.

(Alison Comioma): Okay. Thank you. Thank you, Dr. Chang. I appreciate it.

Dr. Cynthia Chang: Thank you. We could take the next question, please.

Irene Aihie: Okay. We have another caller. Caller, your line is open. I can't see your name because our operator is having some issues on her line. But if your line is open, please go ahead with your question. Caller, or operator, can you hear us? Or are you on mute? Our operator is contacting me and she's saying that she's speaking; but we cannot hear you, Operator. Okay.

I am showing that there are no further questions. Before I close out, Chris or Cynthia, do you have any closing remarks?

Dr. Cynthia Chang: Hi. This is Cynthia Chang. Just to thank all of our audience for dialing into the call today. As we noted, if you do have a question about a specific device or situation, you may feel free to use the email address on the screen now, to send your questions to us. And let me check with Chris, to see if there are any final comments from him.

Irene Aihie: One second, before Chris gets started. Our operator just mentioned that we have a question from someone named (Mike). So I'm going to go ahead and pause there. And (Mike), if your line is open, please proceed with your question.

(Michael Marrow): Hi. This is (Michael Marrow). I hope I'm the open line. So is it - can you guys hear me?

Irene Aihie: Yes. We can hear you, (Mike). Thanks.

(Michael Marrow): Okay, good. Thanks. And thank you for putting on this webinar and thank you, Chris, for the slideshow and examples. They were really helpful. I Have a quick example. If I'm - have a company that has new technology for killing or filtering virus sized particles or specific to SARS-CoV-2 but they

keep their claims in that realm of killing or filtering in non-medical, is an EUA required or is that outside the scope of this guidance? Thanks.

Dr. Christopher Dugard: I can answer that question.

Dr. Cynthia Chang: Hi (Michael). This is - this is Cynthia. Let me just repeat the question and then I'll turn it over to Chris. So the question is about if a device has specific claims and whether that needs an EUA or whether it could be covered under the scope of the guidance.

And let me just remind everyone that in general, we are providing high level comments today and in terms of the specifics of any particular device, you know, that's something that we would advise you to look into the details of our enforcement policy before making a final determination and reaching out to us for any specific issues.

However, in general, let me turn it over to Chris Dugard, to see what comments he has about this question.

Dr. Christopher Dugard: Thank you, Dr. Chang. At a high level, well first you mentioned that it would be a new technology. And as I mentioned in my presentation, we are concerned with devices that might create an undue risk.

And since this is a new technology and, you know, we're speaking generally now, I encourage you for that alone, to reach out to the agency so that we can work with you and determine whether or not that technology does represent or does present any undue risk.

Regarding EUAs, for any device where, you know, it might be outside the scope of this policy or you just think you have a technology that might fit

within the EUA paradigm, again we highly recommend you review the guidance and ensure that the technology that you're trying to support fulfills all of the criteria outlined within that guidance.

Without knowing more about the device, I don't think I can provide too much more feedback. But I do hope that answered some of your question.

(Michael Marrow): Yes. I appreciate that. And I wanted to keep it as general as possible. We'll probably follow up. Thanks a lot.

Dr. Christopher Dugard: Thank you.

Irene Aihie: Okay. It looks like we have no further questions. Chris, I believe I cut you off before you were about to make some closing remarks. Is that still the case?

Dr. Christopher Dugard: Thank you. Yes. I just wanted to thank the audience for attending and we look forward to working with all of you if you have any devices that you'd like to get any feedback on.

Irene Aihie: Thank you so much, Chris. Again, thank you to everyone. This is Irene Aihie. 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, December 16.

If you have additional questions about today's presentation, please use the contact information provided at the end of this live presentation. As always, we appreciate your feedback. Following the conclusion of today's webinar, please complete a short 13-question survey about your FDA CDRH webinar experience.

The survey can be found at www.FDA.gov/CDRHWebinar, immediately following the conclusion of today's live webinar. Again, thank you for participating and this concludes today's webinar.

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