

**Draft Guidances on Transition Plans for COVID-19 Related Medical Devices
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Moderator: Elias Mallis

Elias Mallis: Hello, and welcome to today's CDRH webinar. This is Elias Mallis, Director of the Division of Industry and Consumer Education in CDRH's Office of Communication and Education. And I'll be your moderator for today's program.

Our topic today features FDA's proposed COVID Transition Policy for Medical Devices. Now, it's hard to believe that we initiated our policies around this time almost two years ago. And we appreciate that these new policies represent an important milestone in the FDA's response to COVID. As you'll learn more today, the overarching COVID device transition policy is actually outlined in two separate draft guidances. One for products directly regulated under an Emergency Use Authorization, or EUA, and the other for those products that fall within the enforcement policies issued during this public health emergency.

These draft guidances are currently open for public comment. As a result, we're holding this webinar to provide you with an opportunity to learn more about the efforts and to answer your questions as you consider providing us with your feedback. Due to the anticipated high interest in this important policy, we've expanded today's webinar to 90 minutes so we can present all of the key highlights of these guidances and answer as many of your questions, which we're sure you have.

So it's my esteemed pleasure to introduce you to your FDA panel for our discussion on the COVID transition policy: Dr. Jacqueline Gertz, Policy Analyst in the Office of Product Evaluation and Quality or OPEQ; Dr. Joshua Silverstein, Policy Analyst in OPEQ's Regulation, Policy, and Guidance Staff; Eli Tomar, Associate Director in the Office of Policy.

On behalf of the panel, Jacquie will provide an overview of the draft guidances and then we'll be joined by Josh and Eli for your question and answer session right after.

Thanks for joining us today. And now, let's hear from Jacquie.

Jacquie Gertz: Thanks so much, Elias. Good afternoon, everyone. I'm so glad you could join us. Today, we would like to share with you some information about the COVID-19 transition plan for medical devices.

The COVID-19 transition policy for devices is proposed in two draft guidances. These are titled the Transition Plan for Medical Devices Issued Emergency Use Authorizations, or EUAs, During the COVID-19 Public Health Emergency, and the Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the COVID-19 Public Health Emergency. These guidances will be collectively referenced throughout the presentation as the transition guidances. We may also refer to them as the EUA transition guidance and the guidance transition guidance individually.

We would like to cover three main areas during this presentation. The first is to describe the background of the COVID-19 public health emergency relating to the transition guidances. Second will be a review of the transition guidances including the scope and proposed timeframes for FDA and stakeholder actions. Third will be to identify how to submit comments to the public docket.

We'll start off today by covering a little bit of background on the guidances.

There are several questions addressed by the guidance that we would like to cover. Why is the FDA issuing these draft guidances now while the COVID-19 pandemic is still ongoing? What are the actions I should take if I do or do not plan to distribute my devices after the relevant EUA declaration is terminated or the public health emergency expires? What are the important milestones that I should know about during the transition process?

We would like to remind everyone that draft guidances, such as the transition guidances, are not for implementation. Also, we welcome your comments on these guidances, and we'll discuss more about how to provide comments later.

On January 31, 2020, the Department of Health and Human Services issued a declaration of a public health emergency related to COVID-19. This Public Health Emergency, or PHE, was most recently renewed on January 14, 2022. In addition, there have been three separate EUA declarations relevant to the device transition policy, including one each for in vitro diagnostics, respiratory protective devices, and for devices, including alternative products used as devices.

FDA has and continues to authorize the emergency use of medical devices under Section 564 of the Federal Food, Drug, and Cosmetic Act, known as the FD&C Act. An EUA issued will remain in effect for the duration of the relevant emergency use declaration unless FDA chooses to revoke the EUA, applying the statutory criteria for revocation, such as the criteria for issuance are no longer met, or revocation is appropriate to protect public health or safety.

An EUA declaration under Section 564 of the FD&C Act is distinct from and is not dependent on the declaration of a public health emergency. Therefore, an EUA may remain in effect beyond the duration of the declared public health emergency.

CDRH has issued more than 900 EUAs and continues to review requests for and issue new EUAs. During this COVID-19 public health emergency, CDRH issued 28 guidance documents describing enforcement policies to support the COVID-19 response. In contrast to the EUAs we just discussed, the enforcement policies and guidances state that they are intended to remain in effect only for the duration of the COVID-19 public health emergency.

Given the magnitude of the COVID-19 public health emergency, FDA recognizes that continued flexibility while still providing necessary oversight will be appropriate to facilitate an orderly and transparent transition back to normal operations. Further, FDA is taking into account that the manufacture, distribution, and use of devices in the context of the COVID-19 PHE raises unique considerations. These unique considerations include, for example, the manufacturing of devices by non-traditional manufacturers to address supply issues and the distribution and use of capital or reusable equipment that fall within enforcement policies or authorized under an EUA.

FDA developed these guidances to describe a transition plan to help avoid disruption in device supply and ensure that devices that fall within enforcement policies or authorized under an EUA meet applicable FD&C Act requirements when the enforcement policies are no longer in effect or after termination of the relevant COVID-19 EUA declaration, if their manufacturers wish to continue distributing them.

FDA issued these draft guidances now while the COVID-19 PHE is ongoing in order to obtain feedback from all interested stakeholders before we finalize and implement the transition policies.

Next, we'll talk about the scope and time frames for the transition guidances.

The proposed transition plan is outlined in two companion guidances. Together, we'll refer to these guidances as the transition guidances. One guidance, the guidance transition guidance, covers a proposed transition for devices that fall within the enforcement policies and guidances identified in list one of the guidance transition guidance. The second guidance covers a proposed transition for devices that were issued EUAs on the basis of a COVID-19 EUA declaration.

The structure of the transition guidances is generally the same, consisting of an introduction, background, scope, guiding principles, and the transition plan, followed by examples to show how the transition could work for manufacturers of different device types. One key difference is that we contemplate the 319 public health emergency ending at the beginning of the transition period, whereas the 564 EUA declarations are proposed to be terminated at the end of the transition period with advance notice from the Secretary of HHS. We'll talk more about how this may affect the transition process in the coming slides.

The transition guidances apply to the devices with EUAs that were issued on the basis of a COVID-19 EUA declaration. It does not apply to devices with EUAs that have already been revoked by FDA or 564A, good manufacturing practice deviations. The guidance transition guidance applies to devices that fall within the enforcement policies listed in the guidance under list one.

Please note that FDA may add or remove guidances as appropriate. In particular, FDA intends to remove guidances from the list if they are withdrawn. The policy for diagnostic tests for COVID-19 guidance is outside the scope of these transition guidances. While we won't be covering fact-specific questions during this webinar, we encourage you to attend future virtual town halls for COVID-19 test development and validation as we get closer to transitioning.

In developing these transition guidances, several guiding principles were followed, some derived from existing policies, and are widely known, and others are key to understanding the specific approach set forth in this guidance. Thus, anyone using this guidance should bear in mind the following guiding principles-- first, that these guidances are intended to help facilitate continued patient, consumer, and healthcare provider access to devices needed in the prevention, treatment, and diagnosis of COVID-19.

The second guiding principle is that FDA believes an orderly and transparent transition is appropriate for devices that fall within the scope of the transition guidances. FDA's policies and recommendations in these transition guidances are consistent with the agency's statutory mission to both protect and promote the public health.

The third guiding principle is the FDA's policies and recommendations follow a risk-based approach with consideration of differences in the intended use and regulatory history of devices, including whether the device is life supporting, or life sustaining, capital, or reusable equipment, a single-use device, and whether the device has previously been FDA cleared or approved.

The fourth guiding principle is that if the agency deems appropriate, FDA may, at any time, take action regarding a specific device or device type, including revocation or revision of an EUA, withdrawal or revision of an enforcement policy, or enforcement action.

The proposed transition plan is generally aligned across both guidances. We'll discuss the process for EUA devices first.

As previously mentioned, when the relevant EUA declaration is terminated, the corresponding EUA authorizations will cease to be in effect. The intention is that the advance notice of termination of the relevant EUA device declaration will be published in the Federal Register 180 days before the day on which the EUA declaration is terminated. This would allow for a 180-day transition. For the purpose of this guidance, FDA refers to the date on which an EUA is terminated as the EUA termination date.

The enforcement policy device transition process is proposed to also be 180 days. The implementation date would be the date that COVID-19 public health emergency declaration expires, or a different date, as we will explain in a moment. The transition period would end 180 days later, on the date that the enforcement policy guidances listed in the guidance are withdrawn.

In the event that the public health emergency ends before the guidance transition guidance is finalized, FDA would not immediately withdraw the guidances that include enforcement policies. Instead, FDA would announce in the Federal Register, in conjunction with the final guidance, an implementation date that is at least 45 days after the finalization of the guidance. There would still be a 180-day transition period before the enforcement policy guidances would be withdrawn.

The transition timeline is broken down into four sections in this slide for clarity. We'll talk in more detail about each of these on the coming slides. The first is the beginning of the 180-day transition through the advance notice of termination for EUA devices, or the expiration of the public health emergency for enforcement policy devices, or the alternative date discussed in the last slide.

90 days later, FDA recommends that manufacturers submit a notification of intent for certain life-supporting or life-sustaining devices regarding whether or not they intend to submit a marketing submission to continue distributing their product after the end of the transition period.

180 days after the start of the transition, FDA expects manufacturers to comply with all of the statutory and regulatory requirements that are applicable to the devices. After the end of the transition period, FDA may take action, as appropriate, to protect the public health for any devices that are not in compliance with the statutory and regulatory requirements for that device type.

Before we talk about how to transition, if you intend to distribute beyond the transition period, we would like to discuss FDA's proposed approach for manufacturers who do not intend to distribute beyond the transition period. If a manufacturer does not intend to continue to distribute its device after the EUA termination date, or withdrawal of the enforcement policy guidances, FDA generally does not intend to request market removal for devices that were distributed before the end of the 180-day transition period as follows-- single-use non-life-supporting, or non-life-sustaining devices, for example, face masks, remain distributed and consumed by the end user.

Reusable non-life-supporting, or non-life-sustaining devices, for example, non-invasive remote patient monitoring devices, or infusion pumps, remain distributed and used by their end user. Such devices

should either be restored by the manufacturer to the previously FDA-cleared, or approved, version of the device, or have publicly available labeling that accurately describes the product features and regulatory status.

Reusable life-supporting, life-sustaining devices that were distributed before the withdrawal of the relevant guidances remain distributed. Such devices should either be restored by the manufacturer to the previously FDA-cleared, or approved, version of the device, or have both publicly available and a physical copy of labeling that accurately describes the product features and regulatory status.

In vitro diagnostic devices may remain distributed and used for no more than two years beyond the EUA termination date, or until the expiration date, whichever is less.

For all the device categories listed here, manufacturers should be aware of any applicable statutory and regulatory requirements for their device, such as adverse event reporting under 21 CFR Part 803, and are expected to comply with such requirements for the duration in which they are applicable, which may extend beyond the cessation of distribution.

As mentioned previously, the transition begins on the implementation date, or date of advance notice, of termination. If not already doing so, manufacturers should follow adverse event reporting requirements under 21 CFR Part 803. Manufacturers should also continue to submit all adverse event reports. Manufacturers that intend to continue distribution of their devices beyond the end of the transition period should begin preparation of the applicable marketing submission.

For devices that fall within the enforcement policies, manufacturers should submit reports of corrections and removals under 21 CFR Part 806 and follow registration and listing requirements as applicable. Manufacturers that intend to continue to distribute their devices after the transition period should also register their establishments and list their devices, or update existing registration and listing information, if they have not already done so.

Within 90 days from the beginning of the transition period, FDA requests that manufacturers of certain reusable life-supporting or life-sustaining devices submit to FDA information about whether or not they intend to submit a marketing submission. We will talk about the notification of intent in the next slide.

We mentioned the notification of intent briefly on the last slide, but we wanted to go into more detail about this aspect of the proposed transition plan. This information will assist the agency in resource planning for marketing submission review and providing increased support to manufacturers. The notification of intent should be submitted for reusable life-supporting or life-sustaining devices with product codes listed in table 1 of the transition guidances.

These product codes generally pertain to ventilators, ventilator accessories, anesthesia gas machines, and other respiratory devices. This is a proposed list of product codes. The final guidance will identify the product codes for which FDA is requesting this information.

FDA requests that this information be submitted to the Document Control Center within 90 days after the transition period begins. The cover letter should reference any FDA submission numbers. In addition to the relevant FDA submission numbers, these submissions should include model numbers for the devices, information about the future plan to submit a marketing submission, or discontinue distribution, restore, free label, or other efforts to mitigate risks of the distributed devices.

Under the draft guidance, 180 days after the start of the transition period, the EUA declarations would be terminated, and the enforcement policies withdrawn. At this time, manufacturers must comply with the relevant statutory and regulatory requirements for this device.

If a manufacturer has not followed steps to allow distribution of the device beyond the end of the transition period, distribution should cease. If a manufacturer intends to continue marketing their device, the relevant marketing submission would need to have already been submitted and accepted by FDA. The marketing submission should include a transition implementation plan, which we will discuss more on the next slide.

The transition guidances include an enforcement policy for devices with a marketing submission under review by FDA. It states that FDA does not intend to object to the continued distribution of devices within the scope of these guidances after the EUA termination date or withdrawal of the enforcement policy, where the manufacturer has submitted a marketing submission to FDA and had it accepted by FDA before the start of phase 3, and FDA has not taken a final action on the marketing submission.

This enforcement policy only applies to the requirement to obtain FDA marketing authorization. It does not apply to other applicable statutory and regulatory requirements such as registration and listing, quality system requirements, and reports of corrections and removals required.

FDA requests that any marketing submission for devices that are transitioning include information that addresses the manufacturer's plans for devices already distributed in the case of a positive decision or a negative decision on the marketing submission, specifically, the estimated number of devices in US distribution, an explanation of the manufacturer's plans for addressing already distributed product in the event of a positive or a negative decision. This would include a notification to stakeholders of the regulatory status and a process and timeline to restore, or relabel, the device as needed.

Before the end of the transition period, FDA expects manufacturers who intend to continue to distribute their device have completed any steps necessary to transition into compliance with all FD&C Act requirements applicable to their devices. FDA expects that distribution will cease if a required marketing submission is not accepted by the end of the 180-day transition period, if FDA issues a negative decision on a marketing submission, or if a marketing submission is withdrawn, or the manufacturer fails to provide a complete response to a request for additional information.

FDA understands that there may be scenarios that are not specifically addressed in the transition guidances as proposed. In certain circumstances, manufacturers may wish to initiate discussions with the agency through the Q-Submission Program, to develop a plan to address their specific scenario if it is not discussed in the guidances.

Manufacturers should submit any pre-submissions with the understanding that the statutory and regulatory requirements still apply at the end of the transition period. Therefore, if the manufacturer's intent is to continue to distribute its device after the transition period, FDA encourages the manufacturer to work toward, and FDA intends to help facilitate acceptance of a marketing submission before the end of the transition period.

The transition guidances include a number of hypothetical examples to illustrate the transition outlined in the transition guidances. We want to go through two of the examples here.

For the first example, we'll discuss a new telethermographic system that was not 510(k) cleared and falls within the enforcement policy for telethermographic systems. In this example, the implementation date is hypothetically set at July 1. Note that FDA did not propose any actual date to start the transition period.

At this time, all manufacturers should continue to comply with the requirements that were not addressed in the enforcement policy guidances, regardless of whether they intend to distribute their devices beyond the COVID-19 public health emergency. Within 90 days, a manufacturer who intends to distribute beyond the PHE registers and lists, and submits a marketing submission, which is accepted by the agency.

Meanwhile, a manufacturer who does not intend to distribute beyond the PHE ceases distribution during phase 2 and notifies users of the regulatory status, and continues to report adverse events. At the end of the 180-day transition period, the enforcement policy guidance is withdrawn.

The manufacturer who intends to distribute beyond the PHE has already submitted a marketing submission, and it has been accepted. Therefore, FDA does not intend to object to continued distribution until FDA takes a final action. The manufacturer receives an NSE decision after review and ceases distribution. FDA and the manufacturer engage to address already distributed devices.

The manufacturer who does not intend to distribute beyond the PHE has not submitted a marketing submission. This manufacturer leaves previously distributed devices in the field and makes revised labeling publicly available, sends notices to users, and continues to report adverse events.

The second example we'll go through is for a continuous ventilator that was authorized under the umbrella EUA for ventilators. Similar to the last example, the hypothetical start of the transition period is set as July 1. At this time, the advance notice of termination for the relevant EUA declaration is published in the Federal Register. Within 90 days, the manufacturer should submit a notification of intent to inform FDA that it does not intend to pursue a marketing authorization. They do this on August 1.

At the end of the transition period, in this case, January 1, the relevant EUA declaration is terminated, and the umbrella EUA is no longer in effect. The manufacturer ceases distribution of the device. FDA does not intend to object if the manufacturer develops a plan for the already distributed product to remain distributed. The future use of the device would be subject to the regulatory requirements of any future authorization, including marketing authorization or EUA.

As we previously mentioned, we welcome comments from all interested stakeholders on the draft guidances. Though we understand time is of the essence in issuing final policies, it was very important to FDA to issue these guidances, in draft form, to have the opportunity for public comment to inform the final transition policies.

While you may comment on any guidance at any time, we request that you please submit comments on the draft guidances before March 23 of 2022, to ensure that FDA considers your comment before we work on the final guidance. There are two separate dockets for the transition guidances, and the links are included on this slide, as well as links to the guidances. Again, we request that comments be submitted by March 23 of this year.

To summarize this webinar, FDA has proposed a transition plan for devices issued EUAs or that fall within enforcement policies during the COVID-19 PHE. FDA invites stakeholder feedback now while the COVID-19 PHE is ongoing.

The transition guidances propose actions and milestones to support FDA and stakeholders through a transparent and orderly transition, and FDA requests stakeholder feedback by March 23 of 2022.

Thank you so much for your attention to today's presentation. I'll hand it back over to Elias for questions.

Elias Mallis: Thank you, Jacquie, so much. That was really amazing, what an incredible overview. You covered such a lot of ground in walking us through these two draft guidances.

So I'm really excited now to get started with our interactive question-and-answer segment of our program. This is a chance for you, our audience, to ask our illustrious panel your questions about these policies. So once again, joining Jacquie on the discussion panel are Joshua Silverstein of OPEQ and Eli Tomar of the Office of Policy.

So let's run down how we'll manage this segment. To ask a question, please click the Raise Hand button-- this should appear on the bottom of your Zoom screen-- and click it if you have a question you want to ask us. I'll then announce your name, one-by-one, and invite you to ask your question. You should get a prompt on your Zoom screen to allow you to speak. Please click this, and then go ahead and ask your question.

Now a few tips about questions, please limit yourself to one question only. Try to keep the question as short and focused as possible. And then the second point, we really appreciate that many of you have a lot of specific questions involving a particular device scenario. We recognize you have specific questions for yourself as you plan ahead. Just please be advised, and note, that we may not be able to answer such specific questions at this webinar, but we'll try to frame a broader response based on what's proposed in the guidance.

Again, remember, this is your chance to better understand, get clarity on what we're proposing in these draft guidances. So you could try to frame your question with that in mind. So once you've asked your question, please mute yourself again. And if you have more than one question, no problem, just go ahead and raise your hand again, and we'll get to you-- as many of you as we can during our Q&A segment. I already see a lot of hands getting raised.

So now as we wait to get to some of your questions, let's welcome our newest panelists with a few questions that we've gotten over the past few weeks about the two draft guidances.

So first, Josh, let me welcome you to our panel. Thank you for joining us today. So I'd like to ask you our first question, which is, does FDA expect both guidances to follow the same general timeline, that is, the same 180-day transition period?

Josh Silverstein: Thanks so much, Elias. In general, FDA intends for similar devices to transition along the same general timeline to the extent feasible and appropriate. FDA will consider many factors in the decision to begin the transition period, including the status of the COVID-19 pandemic, whether

adequate supply of the product is available and whether sufficient notice has been given to all interested stakeholders.

Elias Mallis: All right, thank you, Josh. Alright, let's welcome Eli to our panel. So Eli, our next question goes to you.

Does FDA expect all EUAs to be subject to the same Advanced Notice of Termination, or ANT, and timeline?

Eli Tomar: Sure, thanks for the question, Elias. You know, I think in general, I'd start where Josh did, that the general intent is for similar devices to transition along the same timeline to the extent feasible for the factors and reasons that Josh set forth there.

On the EUA side, it's worth noting that there are three distinct COVID-19 EUA declarations that apply to devices, one for IVDs, In Vitro Diagnostics, one for respiratory protective devices, and another one for other devices, or products used as devices during the public health emergency.

I would refer you to the footnote 9 in the EUA transition guidance for more specific information on these declarations, including hyperlinks to each of them. The HHS Secretary may or may not terminate all of these declarations at the same time, depending on the status of the pandemic and the need-- the ongoing need for different types of these devices.

Elias Mallis: Alright, thank you, Eli, and thank you for joining us on the panel.

Alright, let's get to your questions now. Again, raise your hands if you'd like to speak with our panel. Karl, I'm going to go to you first and allow you to speak with our panel. So please go ahead and ask your question.

Karl Enters: Hi, it's Karl Winters from GENETWORx. My question is simple, are you guys, through this period of comment and prior to the 180-day window, accepting new EUAs under the present rule making?

Elias Mallis: That is a great question. Josh, can we send that one to you to answer?

Josh Silverstein: Sure, I'm happy to answer the question. So right now, the two draft guidances are out for public comment, and the public comment period is open until March 23. So FDA is accepting comments on these two draft guidances and will continue to accept them for review for another month. In terms of your question about EUAs, as long as a relevant EUA declaration is in place, FDA is authorized to issue EUAs.

Karl Enters: Thanks much, that helps.

Elias Mallis: Alright, thank you, Karl, for the question. Thanks for joining us.

Let's continue. Michelle, I'm going to unmute you next. Please go ahead and ask your question of our panel.

Michelle Rubin-Onur: Hi, can you hear me?

Elias Mallis: You sound great, thank you. Thank you for joining us.

Michelle Rubin-Onur: Thank you so much for the webinar. My question is related to this idea of continued flexibility. If a sponsor can't submit a pre-market submission before the enforcement policies are withdrawn, due to, for example, an ongoing clinical trial, given the low-nature risk of these devices, is there a path to stay on the market for a short period of time and then submit a pre-market submission?

Elias Mallis: Michelle, thank you for that question. Josh, I think we're going to call your number again to answer.

Josh Silverstein: Sure. In the end, we understand that there are unique circumstances that may be present for your particular device. The agency is willing to discuss those unique considerations that you may have on a device-specific basis. But categorically, it is our intention, once we finalize these two guidances-- is to follow this general transition framework.

Elias Mallis: Thank you, Josh. Michelle, does that answer your question?

I think we may have lost Michelle. Alright, Josh, thank you for that.

Michelle Rubin-Onur: Thank you.

Elias Mallis: Oh sorry. Thank you so much for joining us. Thank you for the question. Let's keep going. Jody, I'm going to unmute you next. Please go ahead and ask your question of our panel.

Go ahead and join us, Jodie, if you're free. Alright, I don't hear any audio.

Jody Schulz: Hi there, can you hear me now?

Elias Mallis: You're loud and clear now. Excellent.

Jody Schulz: All right, thank you. I had some microphone problems.

Elias Mallis: No worries.

Jody Schulz: Thank you for your patience. All right, so my question is around the requirement of a transition plan, as noted in the transition plan for EUA guidance document. The question is, is a manufacturer required to submit a transition plan, and is there a timeline recommended for that, and in what fashion should you do that, either a 510(k), or a pre-sub, or any of the above?

Elias Mallis: Thank you for that question. Jacquie, welcome back to our panel, great presentation. I think we'll toss this question over to you to address.

Jacquie Gertz: Hi, yeah. So a transition implementation plan should be submitted with your application to continue marketing. And I believe there was a second part of your question about the timeline, so that should be done before the end of the transition period. Josh, do you have anything else to add?

Josh Silverstein: The only other thing that I would say is that this is an FDA recommendation, and we think that we're doing this to have consistent communications with all manufacturers in sort of a transparent way. And so to the extent possible that we can have all products, especially those that are similar in nature, getting the same information from all manufacturers is going to help FDA, and all other stakeholders as well, have an orderly transition.

Jacquie Gertz: I would also add just one more thing to my response, is that this is a draft guidance, and it's not yet for implementation.

Elias Mallis: Thank you both. And to that point, to Jody, if you had any opinion about this approach, or feedback, this is where we encourage you to submit your comments to the appropriate docket, so that way we can make sure that your perspective is incorporated, once you understand what our proposal is for the two draft guidances. Thank you for the question.

Jody Schulz: Thank you.

Elias Mallis: Thank you. So we'll keep going. Erika, you are next. I'm going to unmute you. Please go ahead and ask your question of our panel.

Erika Bladholm: Hi, can you hear me?

Elias Mallis: You're great. Thanks for joining us.

Erika Bladholm: Yeah, thank you. My question is, will the De Novo, or 510(k) guidance documents for serology tests be issued prior to the announcement of the EUA terminations, and will these include intended use of the COVID assays for vaccinated patients, or just continue to be limited to naturally infected patients?

Elias Mallis: Erika thank you for that question. Eli, I think we'll call upon you to provide a response.

Eli Tomar: Sure. Unfortunately, this is probably not going to be a very satisfactory response, but I think that question is probably best addressed in another venue. We have an ongoing series of virtual town halls with our in vitro diagnostic experts within the center, and I unfortunately think those questions are probably going to be beyond the scope of this webinar and better addressed there.

Erika Bladholm: OK, thank you.

Elias Mallis: Thank you, Eli. And just to plug, the next webinar, town hall, is actually tomorrow at 12:15. So if you'd like to join us for that, we will definitely cover things related to IVDs.

Thank you for that question. We'll keep going. Laura, you are next to join our panel with your question, thank you.

Laura: Hello, can you hear me?

Elias Mallis: You sound great.

Laura: Oh great, thank you. Hello. My question is specific to a device distributed under enforcement policy, and I'm just a bit curious about transition timeline. So after a device should receive pre-market authorization, it would take time for the manufacturer to implement that newly 510(k) cleared labeling on their device, which was previously distributed under the enforcement policy.

So I'm curious, does FDA have a timeline that they would allow a manufacturer to transition to that newly 510(k) cleared labeling? And then once that labeling has been implemented, how long can that enforcement policy labeled device continue to be distributed, as the manufacturer's kind of device inventory is being turned over?

Elias Mallis: Laura, thanks for that question about enforcement policies, very important here. Josh, we'll send it over to you to address.

Josh Silverstein: Yeah, thanks so much for the question. So ultimately, the enforcement policies will be withdrawn at the end of our transition period, and then sort of transition to whether your device has a marketing submission that's under review, and so we do have labeling recommendations for under review. If you do have questions or comments that are related to the labeling after you receive, say, a positive decision and commercialization, that's certainly a comment that we would welcome to the docket if it wasn't clear in the draft guidance document. But your scenario is not explicitly addressed in that draft guidance, so we would appreciate seeing that to the docket.

Laura: OK, thank you.

Elias Mallis: Thank you, Josh, and, Laura, thank you for joining this panel. Franziska, I am-- I'm meeting you next. Please go ahead and ask your question.

Franziska Moeckel: Great. Thank you so much. I did not see a footnote in any of the draft guidance documents pertaining to laboratory-developed tests that receive an emergency use authorization, so I was wondering, if post-EUA revocation, if they fall again under FDA-enforcement discretion?

Elias Mallis: Thank you for that question. Eli, I think back to you for an IVD or LDT question.

Eli Tomar: Yeah. Unfortunately, again, that's-- I appreciate the question. It's not something we're going to be able to address in the context of this webinar, which is really trying to elucidate and clarify the policy set forth in the draft guidance. So I would recommend that be saved for the virtual town hall series on IVDs, or if there's a more specific question, to reach out to FDA directly.

Franziska Moeckel: I appreciate it. Thank you.

Elias Mallis: Thank you for joining us. Dan Kuehner. I'm unmuting you next. Welcome to our panel, and we'd love to have your question.

Dan Kuehner: Good morning. Can you hear me?

Elias Mallis: You sound great.

Dan Kuehner: Thanks. So in slide 18 of Jacquie's presentation about the 90-day notification of intent, it says for certain LS/LS devices, does that apply also to EUA IVDs?

Elias Mallis: Thank you for sharing that question. I think we have a couple of people who want to join and answer. I would say let's go with Josh first.

Josh Silverstein: So the notification of intent applies for the procodes that are in each respective guidance document. And so if that procode is not included, it would not-- we would not be requesting a notification of intent.

Ultimately, as you already noted in the slide deck, the final guidances would identify the specific procodes for which FDA is requesting a notification intent. So if you believe that some life-supporting, or sustaining, devices should be included on that list, that is something that would be helpful to be submitted to the public docket.

Dan Kuehner: OK, thank you.

Elias Mallis: All right, thank you for the question, Dan. Geoff, you are next. We're going to unmute. Please share your question for our panel.

Geoff Marcek: Hello. Thanks to the panel. One question would-- is FDA potentially going to consider accepting any post-market data from devices that have been distributed under the EUA, as part of the 510(k) process?

Elias Mallis: Thank you for that question. We'll send it back to Josh to provide a response. Josh?

Josh Silverstein: As we begin to shift toward conventional marketing authorization, we are, and will continue to communicate with manufacturers about the evidence that may be available to support such authorization, including real-world evidence. You know, given the heterogeneity of devices that are addressed by these two guidance documents, we can't necessarily go into the details of it within this webinar, but we do encourage you to reach out to CDRH as appropriate, if you have questions about specific devices and the evidence that you may have generated during the pandemic.

Elias Mallis: Thank you, Josh. Geoff, did that answer your question for us?

Geoff Marcek: Yeah, thank you.

Elias Mallis: All right, thanks for joining the webinar today. Erika, we'll go to you with your question for our panel.

Erika Bladholm: They already asked my question. Sorry, I think I forgot to put my hand down.

Elias Mallis: Oh, no worries. Do you have another question since we have you here?

Erika Bladholm: No, that's it.

Elias Mallis: OK, no worries. Thanks so much again. Allyson, let's go to you next, for your question for the panel.

Allyson Mullen: Hi. My question has to do with FDA's guidance on the effects of the COVID-19 public health emergency on formal meetings in user-fee applications. I'm wondering if that will remain in place during the transition period, such that sponsors will have automatically 360 days to respond to requests for additional information, versus the standard 180?

Elias Mallis: Thank you for that question. We think that's probably a little bit out of scope of this particular topic. May we ask you to write that question up and send it to my division, DICE@fda.hhs.gov. Please go ahead and submit that question, and then we'll take a look at it and provide an individualized response to you about this.

Allyson Mullen: Will do. Thank you.

Elias Mallis: Alright, thank you so much. Also, on the last slide, if you stayed to the end, we'll repeat the email address so you can refer to that there as well. Alright? Thank you, we'll keep going.

Mike, I'm going to unmute next to join the panel and ask your question.

Mike Schiller: Thank you. Can you hear me OK?

Elias Mallis: You sound great. Thanks.

Mike Schiller: Perfect. This may be out of scope for you guys. Let me know. This is coming from a provider perspective. So when the transition periods begin, and actually terminate, if a hospital has product on their shelf still, I'm guessing they're no longer able to use that within the patient care setting. Is that correct?

Elias Mallis: Thank you for that question. There was a little bit of discussion in the guidance about what we do with product that's already on the shelves and stocks. But for that particular question, I'll turn it over to Eli for your thoughts in response as well.

Eli Tomar: Sure. Thanks, Elias, and Mike, thanks for the question. I think, as a threshold matter, I would refer you to each of the guidances depending on whether you're considering devices that had EUA specifically, or also devices that were distributed pursuant to enforcement policies. But in either case, we do have a policy around allowing specific products that have already been distributed commercially to remain distributed, in some cases, with revised labeling or restoration.

Some of the guidances will provide more specificity around this. I might invite my colleague, Josh Silverstein, to provide a little bit more substance. But at this point, again, to be a bit of a broken record, it's a draft guidance, so if you have concerns with the policies that we've proposed regarding products remaining distributed commercially after the end of the 180-day transition period, we would absolutely welcome provider perspective regarding those proposals.

Josh, I don't know if you would want to add or clarify anything there.

Josh Silverstein: No, I think unless Mike has a follow-up question, I think you covered it.

Mike Schiller: No, I'm good. Thank you so much for that. I appreciate it.

Elias Mallis: Thank you, Mike, for joining, and thanks for the responses, Eli and Josh.

All right, let's keep going. Richard, you're going to be next to ask your question for our panel. Welcome.

Richard Montagna: Thank you. With 900 EUAs already issued, I would assume that FDA is likely to get a large number of marketing submissions during the transition period. So therefore, given the workload that FDA has kind of already endured during the public health emergency, and the fact that FDA found it necessary to prioritize review of EUAs, do you anticipate that FDA will prioritize review of incoming marketing submissions, or will they be simply reviewed on a first come, first serve basis? Thanks.

Elias Mallis: Thank you for that question, and for that one we'll turn back to Jacquie for your thoughts and response.

Jacquie Gertz: Yeah, great question. I think I'm actually going to hand it over to Josh to answer that.

Josh Silverstein: Yeah, thanks for the question, Richard. Ultimately, many of our reviewing divisions have seen extremely large increases in workload during the pandemic, and we've certainly put out a lot of statements that are related to how we're prioritizing work. And I would look to those statements in the future, and also our most recent statements about how CDRH is going to be prioritizing the submissions that we have in-house.

Elias Mallis: Thank you, Josh. And thank you, Richard, for the question. Thanks for joining us. Gabe, we'll go to you next for your question for us.

Gabe Kadoo: Yes, hello, can you hear me?

Elias Mallis: You sound great. Thanks.

Gabe Kadoo: My question is regarding the pathway to full submission. For IVDs, with the first person to submit need to submit as a De Novo or 510(k)?

Elias Mallis: That is an excellent question. We'll turn that over to Eli for your thoughts and response.

Eli Tomar: Sure. You know I think at some level this is probably going to be a fact-specific question that it may be most appropriate to reach out to our Office of RPG within Josh and Jacquie's office in OPEQ, for specific guidance or to the review division, as applicable, OHT7 regarding an IVD device. There may be submissions in the interim period that would change the answer on that.

But I think as a general matter, if it's a specific question regarding the pathway for an IVD, In Vitro Diagnostic Device, we would encourage you to reach out to our subject matter experts, either in the town hall setting or individually, with regard to clarity. But certainly, I don't think that this policy speaks to whether which type of submission would be appropriate. So while I don't want to discourage comments to the docket, I think we would want to give you a more targeted response to that question, rather than referring you to our docket on the draft guidance.

Elias Mallis: Thank you, Eli. Gabe, does that answer your question, or respond to your question?

Gabe Kadoo: Yeah, that was a good response.

Elias Mallis: OK. I will add that in the IVD town halls that we've talked about, typically there are updates, programmatic updates, involving IVDs, LDTs, as they relate to COVID. And there are at least some initial De Novos that have been reviewed and processed through OHT7 during COVID. So there is certainly some precedent, but as we all know, it all depends on the specific device and intended use. That's the rate limiting factor for determining whether there is a predicate that exists for a product, or whether it's new enough, novel enough, and warranted De Novo.

All right, let's keep going. Nancy, you are next to join our panel. Thank you for joining us and let's hear your question.

Nancy LeMaster: Thank you. In looking at your timeline for the various steps for manufacturers, where in that timeline do you expect manufacturers to be communicating their intent to either seek full approval or discontinue manufacturing a device to hospitals, healthcare providers, to their customers?

Elias Mallis: Nancy, thank you for that question. Jacquie, let's send it back to you, to discuss the timeline.

Jacquie Gertz: Hey Nancy, great question. So we would expect a notification of intent for the product codes that are listed in the table, and the guidance, which is, we mentioned previously, are primarily ventilator and other respiratory-type devices. So we would expect that a notification of intent would be submitted within the first 90 days of the transitioning period.

Nancy LeMaster: Thank you.

Jacquie Gertz: Did that answer your question?

Nancy LeMaster: Yes.

Jacquie Gertz: OK. And if you-- you could presumably communicate this to customers at any time, or before or soon after submitting the notification of intent. But ultimately, it's a business decision.

Elias Mallis: Thank you, Jacquie, and Nancy, thank you so much for your question.

Let's keep going. And thank you all for your hands raised and having it be such an interactive session with you. Again, we appreciate these questions that will hopefully help you better understand what we propose in these two draft guidances.

So what that, we'll keep going to our next question. Ellen, you are next up to ask your question for our panel.

Alright, Ellen, can you join us? Ellen, if you can, can you unmute yourself and ask your question?

Alright, we'll try to go back to you. I'm sorry about that. Judith, let's go to you next. Please go ahead and unmute yourself and ask your question to our panel.

Judith Meritz: Yes. My question, and maybe anyone could clarify, if you have a ventilator, for example, that falls under a policy within the enforcement policy, but of course, they also applied for an EUA, and were granted one, how do the two policies overlap?

Elias Mallis: Judith, thank you for that question. Josh, let's turn to you.

Josh Silverstein: What I can say to you is that the specific facts of your case will certainly be really important. But just in general, an enforcement policy is a guidance document where an EUA sets binding requirements that are applicable to your device. And so my best suggestion is to start with the conditions of authorization that are relevant in your EUA authorization letter, which is likely under the umbrella EUA. But if there are specific questions that you have that are related to transitioning, when both an enforcement policy and an EUA are applicable to your device type, we're certainly willing to discuss it directly with you.

Elias Mallis: Josh, thank you for that response. Judith, did that answer your question?

Judith Meritz: Yes, I think so. Thank you.

Elias Mallis: Thank you for joining us. Paul, let's go to you next. Thanks for joining us and let's have your question for the panel.

Paul Jung: Hi, I wonder what will happen to the products under review for EUA, once the EUA declaration is terminated. Will FDA stop reviewing applications that were already submitted? Thank you.

Elias Mallis: Paul, thank you for that question. For that, let's turn to Josh.

Eli Tomar: Hi Elias, this is Eli, I can actually jump in on that one, if that works. So thanks for the question. You know as a threshold matter, I do think that's probably beyond the scope of the draft guidances, but what I can say is if you look at section 564 of the FD&C Act, the declarations made by the Secretary of the Emergency Circumstances under subsection (b) of that section are a prerequisite to us issuing any EUAs. So once those declarations have been terminated, FDA will not be in a position to issue EUAs.

And so submissions, I can't speak for review divisions, and how this would get communicated publicly at this juncture, but those submissions would probably not be able to be-- well, they would not be able to be authorized as EUAs in the current form. Happy to clarify, but that's sort of a general answer. I do think it's a little bit beyond the scope of what we're trying to capture today, but I hope that's clear.

Paul Jung: OK. Thank you very much.

Eli Tomar: And Josh, I don't know if you would want to add anything there as well.

Josh Silverstein: Yeah, as a practical matter, assuming that the information has already been submitted, and is in FDA records, just like any other pre-market submission, you are more than welcome to reference the location of that, so you could provide an EUA number so that you don't have to submit duplicate information. That's sort of a general policy. I don't know if it would apply to your specific case, but that does happen pretty often from a review perspective.

Paul Jung: Thank you very much for the answers.

Elias Mallis: Alright, thank you. Thank you, all. Thank you, Paul, for joining us and your question. And MHANNA1, let's go to you next with your question for our panel.

MHANNA1: Thank you. Thanks for the webinar today. I believe my question was raised in part already by Richard, but with the high number of IVDs currently commercialized, 180 days to review and accept the submissions seems very optimistic. Does FDA have a plan to resource and prioritize the reviews, or is it a first in, first out approach?

Elias Mallis: Thank you for that question. And yes, we've discussed that briefly earlier. The one thing I will throw in is, if you have suggestions, or feedback, or questions specifically about our plans, we encourage you to provide your recommendations to the docket, provide that comment. That will at least allow us to better understand your perspective and thoughts.

And with that in mind, Eli, I think you wanted to add also a response?

Eli Tomar: Sure. Yeah, thanks for the question. You know I think it's an important point to flag for us here, and as Elias mentioned, having comments to the docket on this topic will be very helpful to us. I just can't get into the resource questions at this point, which are a bit speculative, but the 180-day period is really the period by which device makers, manufacturers should be sort of starting to phase in a return-to-normal operations, preparing a submission, engaging in the Q-Submission process as appropriate.

And so we certainly don't have an expectation that manufacturers should wait until day 180 to submit the marketing authorization to us. Pre-market submissions should really come in as soon as they're ready, and as soon as the questions are resolved. That 180-day timeline doesn't apply to FDA's review of the submission. So once a submission has been received and has been accepted by FDA, the enforcement policies described in this guidance, as currently proposed, would apply until FDA reaches a final decision, whenever that is, presumptively, or potentially, after day 180.

So those are MDUFA decisions. And so the resource questions, and things of that nature, are probably beyond the scope of what we can get into today, but I just wanted to clarify that the 180 days is really the timeline for the submission, and not the timeline for FDA's review, in case that was ambiguous. I don't know if Josh, or Jacquie, have anything to add or clarify there.

Josh Silverstein: The only thing that I would add-- this is Josh, sorry-- is that that's one of the reasons why we put this guidance out in draft guidance and request comment, because we could start the conversation about transition. And the guidance actually talks a little bit about manufacturers starting to plan for their transition, irrespective of whether FDA is implementing this guidance document. And so that's just something to keep in mind as we start reviewing comments, and you think about your transition plan in a post-pandemic world, hopefully.

MHANNA1: Thank you for that, appreciate it.

Elias Mallis: Thank you, all, and thank you for joining the panel. Michelle, you are next to join the panel with your question for us.

Michelle Lott: Hello. Thank you for the presentation. My question is around the registration and listing requirements, and it's kind of two parts. The first part is, for the registration and listing, typically when you conduct a listing, you have to have the associated cleared submission number. And so if you have to conduct the listing in advance of having your review complete, what product codes does the FDA anticipate you should conduct that listing number with, or that listing with?

And then secondly, what are the quality system expectations that a company has in place when they complete that registration listing? Because typically, it means that you're telling the FDA, hey, here are the type of devices I'm making, and I have a full quality management system to support those.

Elias Mallis: Michelle, thank you for the excellent questions. Josh, can we turn to you for your thoughts and response?

Josh Silverstein: Yeah. Thanks for the question, Michelle. And so one can register and list without a marketing submission number. We have the information on our website under how to register and list. In the guidance document, we proposed phasing in registration and listing to help manufacturers prepare for transitioning their products, and give the agency visibility to potential trends. And if you, or other stakeholders, find this approach to be confusing or pose other challenges, we certainly welcome public comments on this topic to the docket.

And you also had a question, I'm sorry, about 820, and I didn't catch the end of it. Was it effectively the same question, but applicable, to 820?

Michelle Lott: Yeah, what are the quality system expectations when companies complete said registration?

Josh Silverstein: So again, depending on when you're actually conducting this-- and I'm sorry, is this under the enforcement policy, or is this talking about EUAs?

Michelle Lott: Well, it's under the phase 2, where you suggested—

Josh Silverstein: OK.

Michelle Lott: Yeah. The registration listing in advance of them turning in the submission.

Josh Silverstein: Sure. Yeah. So in the end, we have tried, to the extent possible, to have sort of a re-phasing in of requirements, but if you take a look at the guidance as proposed, sort of once a product receives marketing authorization is ultimately the date on which we would expect manufacturers to comply with all applicable requirements. Hopefully that helps a little bit.

Elias Mallis: Josh, thank you for that reply. Michelle, did that answer your question?

Michelle Lott: To a point. I'll follow up with some comments to the register.

Elias Mallis: OK. Thank you so much and thank you for joining us today. Allyson, let's go to you with your question.

Allyson Mullen: Hi. Hopefully you all can answer this one. So on slide 16 of the presentation, it talked about the ability to distribute devices during, or after, the transition period. Does this apply to devices anywhere in the distribution chain beyond the manufacturer, for example through third party distributors, or only devices that have already gone into the hands of end users? There was some mention in the guidance of ability to be used by end users, but the supply chain didn't seem to be clearly identified.

Elias Mallis: Great question. This will be very important as we roll this out. Jacquie, can we ask you for a response?

Jacquie Gertz: Sure. Great question. So in general, we meant that such devices have been commercially distributed in interstate commerce. But if you have specific scenarios that may be addressed in the draft guidances, we would welcome your comments to the docket to help further clarify this point.

Elias Mallis: Jacquie, thank you for that. Allyson, did that answer your question?

Allyson Mullen: Sort of. So as long as they've taken a step into commercial distribution, they can continue through the supply chain, am I understanding that?

Jacquie Gertz: I believe that's correct, but I'm going to ask Eli and Josh to chime in and make sure.

Eli Tomar: This is Eli. I think as a general matter-- and I'm frantically turning through my guidance, because I think this is discussed in a little bit more detail in one of the footnotes that I don't have in front of me, but if others do, they can point to it. But as a general matter, in devising the draft guidances, we were focused on distribution, as we think this is sort of the most impactful from a public health standpoint. And from a practical matter, you know enforcement policies are legally organized around the concept of introducing a product into interstate distribution.

So when it has left the manufacturer's control, and is in the supply chain outside of their control, I think that is generally where we intend for the current proposals relating to distribution and products remaining distributed-- that's sort of the trigger point, I think, from our perspective. But if you think that's not sufficiently clear in the guidance and in the footnotes, I think we would be happy to take that feedback back and potentially consider how we can clarify that further in the final guidance.

Allyson Mullen: That's great. Thank you, and I'll double check the footnotes.

Elias Mallis: Thank you, Eli. Thank you, Allyson, for joining us. Richard, let's go back to you with your second question for our panel.

Richard Montagna: Thanks for giving me an opportunity for a second question. If an IVD manufacturer currently has an EUA for a COVID test, but then during the transition period submits a marketing submission for an expanded respiratory panel that would include detection of SARS-CoV-2 as well as other respiratory viruses, would that qualify the manufacturer to keep the original COVID-only test on the market while the marketing submission for the expanded panel is under review?

Eli Tomar: You know I think that sort gets into a fact-specific inquiry that would probably be hard to address in the context of the guidance. I don't think that that necessarily flows intuitively from the draft guidance and probably not something we could even address in the final guidance, so I would encourage

specific outreach to our relevant division. You might want to send to CDRH-EUA-templates@fda.hhs.gov with regard to the question about the current EUA.

With regard to submission of a conventional marketing authorization, not an EUA, I think reaching out to our OHT7, or within OPEQ, and can be referred directly, is probably the best way to get you the right answer on that question.

Richard Montagna: Well, we actually did submit to the docket a comment kind of related to this, but thank you very much. I appreciate your help.

Eli Tomar: Sure.

Elias Mallis: Thank you, Eli. Thank you, Richard, for the question. We appreciate the timing issue is very important. We have a couple of questions left, or hands raised, so we're going to try to get through those and actually wind down this Q&A segment in a few minutes.

So with that, Bryan, you are next to ask your question for our panel.

Bryan: Yes. So many questions regarding the requirement that manufacturers should submit an assessment, or a risk assessment, even though there's a negative outcome after the-- submitting the marketing authorization. Did that assessment-- where exactly do we-- where exactly does the FDA require that assessment to be submitted? Is it during the notice of intent to manufacture the device, or during the actual pre-market submission?

Elias Mallis: Thank you for that question, and we'll turn it over to Josh for your thoughts and response.

Josh Silverstein: Thanks for the question. So the first thing that I wanted to start off with is that this is a draft guidance document, and it's also-- so it's out for public comment. It's not for implementation at this time. The second item is that it's a guidance, so it does not have binding effect. So it is a recommendation within a marketing submission that is required that manufacturers submit a transition implementation plan.

In terms of the focus on a negative decision, again, kind of related to a question that we had at the beginning of the Q&A session, this is really to help guide and have consistent manufacturer-FDA interactions during marketing submission review. And so it's our goal to have a framework by which we can give to our reviewing divisions to help them implement a consistent approach so that we're sort of all singing the same song. So thank you.

Bryan: Thank you.

Elias Mallis: Thank you for the question, Bryan. Dan, we'll go back to you, and you get the last question for our discussion today.

Dan Kuehner: Hi. Thanks again for a shot at a second question. So my question is just about sequence and timing, and here, I'm talking about the context of an already EUA-approved IVD test. So let's define day 0 as the day that the emergency is revoked in the Federal Register, and then we're on the 180-day clock.

If we have an EUA application for another product already submitted, either at day negative-something, before day 0, or even after day 0-- because I heard an earlier answer saying that it may still be possible to accept those after day 0-- if it's kind of in the pipeline with FDA already, once the 180-day clock starts, do we need to convert that to being a full 510(k), or can we still let it ride as an EUA application?

Elias Mallis: Thank you, Dan. Eli, let's turn it to you for your thoughts.

Eli Tomar: Sure. I just want to start by maybe clarifying some of the timelines, in case that would be helpful. So as currently proposed in the draft guidance, the intent would be for the Secretary of HHS to publish an advance notice of termination for the relevant device EUA declaration. So there's one specific to IVD that was published in 2020, and when that EUA declaration is terminated, or when that advance notice of termination is published, with an intent that that would be an 180-day timeline, that would start the clock.

There's nothing that prohibits FDA, by statute, from continuing to issue EUAs at that time to grant the request for an EUA. However, that is given the timeline by which those EUAs will no longer have effect. So I think as a general matter, it would probably not make the most sense for a manufacturer that wants to continue marketing the product to submit an EUA, or to pursue an EUA, after the day 0, as you described it. This is obviously unrelated to, and potentially a separate timeline from the public health emergency declaration under Section 319 of the Public Health Services Act.

So there's nothing that prevents or prohibits FDA from granting an EUA authorization after that day 0, but that would be the timeline in which we would be urging and encouraging manufacturers to shift from an EUA that they currently are marketing a device under to submitting the permanent marketing-- I'm sorry, permanent is the wrong word, but a conventional marketing authorization, such as a 510(k) or De Novo, as appropriate, during that window. So I hope that clarifies the timeline, if not, it might make sense to clarify. But Josh or Jacquie, I don't know if you want to add any nuance there.

Josh Silverstein: Thanks, Eli. From a review perspective, we don't currently have sort of a conversion process from an EUA to, let's say, a 510(k). I mean there are also some differences between those submissions beyond their underlying statutory framework. For example, EUAs are not subject to user fees, whereas 510(k)s are.

And so there's not a seamless process that we have in place right now, or in our experience from past emergencies, where we can have sort of this administrative conversion that's sort of like the click of a button. So one would presumably need to submit a 510(k), if that was the appropriate marketing submission, through the traditional process by which that happens.

Dan Kuehner: OK. I guess I'm just wondering if EUAs are in the works when that day comes. Will they be orphaned, if they're not done yet, or if they still have a shot? Thank you for your reply. I'll follow up with comments in the docket.

Elias Mallis: Alright, thank you for joining us, Dan, and thank you for our panel for answering all these questions.

Let's turn it back to Jacquie for your final thoughts for our audience today.

Jacquie Gertz: Thanks for all the great questions, everybody. We really appreciated it, and we really, in particular, look forward to your comments in the docket. And the docket will be closing on March 23, so please try to get your questions in before that.

Elias Mallis: Thank you, Jacquie. Thank you, everyone, for joining us today. And with that, this concludes today's CDRH webinar. I'd like to thank our panelists, Dr.'s Jacquie Gertz and Josh Silverstein, and Eli Tomar for this great discussion on an important topic, high impact for all of us as we deal with the COVID transition policy for devices.

Our thanks to you, the audience, for joining us today and all your great questions. There's a lot of material to cover. We appreciate this, gives us things to think about as we finalize these policies.

A recording of today's webinar presentation and transcript will be posted to CDRH Learn in a few weeks. Please visit CDRH Learn at the link shown on the slide here. And the topic will be placed under a specialty technical topics. We've actually created a new COVID category, so take a look at it from there, so it's easy for you to find. For additional questions about today's presentation, please email us at DICE@fda.hhs.gov.

We appreciate all of your feedback about the CDRH webinar program series, and we encourage you to complete a brief survey which you may find at the link shown on this slide.

This is Elias Mallis. Thanks again for your vital contributions during the COVID-19 public health emergency, and thank you for joining us today. Take care, and we'll see you next time.

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