COVID-19 Transition Policy for Devices, Final Guidances
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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 COVID-19 Transition Plans for Devices. Now it's hard to believe that we initiated our COVID policies over three years ago at the beginning of the pandemic. And we're here now to review FDA's finalized plans for a return to normal operations.

As you'll learn more today, the overarching COVID device transition policy is actually outlined in two separate guidances, one for products issued emergency use authorizations or EUAs related to COVID and the other for products that fall within the enforcement policies, issued during this public health emergency. And as we'll discuss, we've issued various impactful device specific guidances along the way.

The COVID-19 transition guidances have recently been finalized. As a result, we're holding this webinar to provide you with an opportunity to learn more about these efforts and how to incorporate them into your current and future regulatory activities.

Due to the anticipated high interest in this topic, we've expanded today's webinar to 90 minutes so we can present all of the key highlights of the guidances and answer as many of your questions. Now, for those specifically interested in learning more about COVID tests development and validation, we're holding a dedicated virtual Town Hall for you next Wednesday on April 26 at our usual time of 12:05 PM. Now I'll mention this special session again at the end of today's program.

So a few quick notes for today-- first, please make sure that you've joined us through the Zoom app and not through a web browser. This will help avoid any technical issues. And second, the intended audience for this webinar is industry. Members of media are encouraged to consult with FDA's Office of Media Affairs for any questions you may have.

All right, now, it's my pleasure to introduce you to our FDA presenters for today's program, Dr. Kathryn Drzewiecki, Policy Advisor in CDRH's Office of Policy and Melissa View, Regulatory Policy Analyst, also from the Office of Policy. We'll hear from our presenters and then come back around for a discussion and field your questions. Dr. Drzewiecki will begin remarks today. Once again, thank you all for joining us. And let's hear from Kathryn.

Kathryn Drzewiecki: Thanks, Elias. FDA has issued our two final guidances for our COVID-19 transition plans for devices. These are titled, Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the COVID-19 Public Health Emergency, which we'll referred to in this webinar as the Enforcement Policies Transition Guidance, and the Transition Plan for Medical Devices Issued Emergency Use Authorizations related to COVID-19, which we referred to in this webinar as the EUA Transition Guidance. These guidances will be collectively referenced throughout the webinar as the COVID-19 transition guidances.

We will cover three main areas during this webinar. First, we'll provide an overview of the background related to the COVID-19 public health emergency declarations that relate to the COVID 19 transition guidances. Next, we'll provide a summary of the comments we received on the draft of these guidances and the resulting changes to the guidances during finalization. Last, we'll provide an overview of the COVID-19 transition guidances, including the scope, transition plan, and proposed frames for FDA and stakeholder actions.

We'll start by covering a little bit of background on the COVID-19 public health emergency declarations as it relates to the guidances.

On January 31, 2020, HHS issued a declaration of a public health emergency or PHE related to COVID-19 under Section 319 of the Public Health Service or PHS Act. The section at 319 PHE declaration related to COVID-19 was most recently renewed on February 11, 2023 and is anticipated to expire on May 11, 2023. In addition, there have been three separate device-related EUA declarations, including one each for certain in vitro diagnostics, respiratory protective devices, and devices including alternative products used as devices. Importantly the determination and declarations under Section 564 of the Federal Food, Drug, and Cosmetic or FD&C Act remain in effect, despite the expiration of the section 319 PHE declaration.

Over the course of the pandemic, FDA has authorized the emergency use of over 950 medical devices to help diagnose, treat, or prevent COVID-19. An EUA for a medical device remains in effect for the duration of the relevant EUA declaration, unless the EUA is revoked by FDA because the criteria for issuance of the EUA are no longer met or revocation of the EUA is appropriate to protect public health or safety.

FDA also issued 28 guidance documents describing enforcement policies related to medical devices to support the COVID-19 response.

In contrast to the EUAs we just discussed, the enforcement policy guidances are time bound by the section 319 PHE declaration related to COVID-19. In particular, the guidances in List 1 in the scope of the enforcement policies transition guidance originally stated that they were intended to remain in effect only for the duration of the section 319 PHE declaration related to COVID-19. Now, the guidances in List 1 are intended to continue in effect for 180 days after the expiration of the section 319 PHE declaration related to COVID-19. The List 1 guidances will no longer be in effect after November 7, 2023.

Now, we'll provide a quick recap of the PHE and EUA declarations, authority, and history as it relates to COVID-19. As I previously mentioned, on January 31, 2020, HHS issued a declaration of a PHE related to COVID-19 under Section 319 of the PHS Act. On January 22, 2021, HHS sent a letter to the state governors, stating that HHS would provide 60 days notice prior to the expiration of the PHE declaration related to COVID-19 so that government, agencies, and all stakeholders could plan for the transition. On January 30 of this year, President Biden informed Congress that he intends to end the PHE related to COVID-19 on May 11, 2023. The end of the section 319 declaration related to COVID-19 signals the start of the transition period for devices within the scope of the enforcement policies transition guidance.

Separately on February 4th, 2020, HHS determined that there is a public health emergency that has significant potential to affect national security or the health and security of United States citizens living abroad. And that involves the SARS-CoV-2 virus that causes COVID-19.

On the basis of such determination, HHS declared on that same day that circumstances exist, justifying the authorization of emergency use of certain in vitro diagnostics for detection or diagnosis of the SARS-CoV-2 virus that causes COVID-19 under Section 564 of the FD&C Act.

On March 2 and March 24th, 2020, HHS declared that circumstances exist, justifying the authorization of emergency use of personal respiratory protective devices and of devices, including alternative products used as devices.

On March 15, 2023, HHS amended the February 4, 2020 determination and determined that there is a significant potential for a public health emergency that has significant potential to affect national security or the health and security of United States citizens living abroad. And that involves COVID-19. This amended determination did not impact existing EUA declarations for devices or other medical products.

At this time, FDA does not have any information to share about the timeline for terminating the device-related EUA declarations. As explained further in the EUA transition guidance, HHS intends to publish the advanced notice of termination of each device-related EUA declaration in the Federal Register 180 days before the date on which the EUA declaration is terminated. This advanced notice of termination signals the start of the transition period for devices within the scope of the EUA transition guidance.

Importantly, a determination under Section 319 of the PHS act does not enable FDA to issue EUA. The EUA declaration made under Section 564 of the FD&C Act is distinct from and is not dependent on the PHE declaration under Section 319 of the PHS Act. Therefore, even after the anticipated expiration of the COVID-19 PHE declaration on May 11, EUAs remain in effect. Further, EUAs remain in effect for the duration of the relevant EUA declaration unless revoked by FDA based on the statutory criteria for revocation.

FDA has developed the COVID-19 transition guidances to help stakeholders prepare for the upcoming transition after the expiration of the PHE declaration related to COVID-19 and for the future termination of the device related EUA declarations. In the guidances and in this webinar, we'll address a few important questions. We'll cover why we've issued these guidances now. We'll also cover actions we recommend stakeholders take if they plan or do not plan to distribute their devices after the transition period and the COVID-19 device enforcement policies are no longer in effect, or after the termination of the device EUA declarations related to COVID-19. Finally, we'll cover some important milestones during the transition process that we believe stakeholders should be aware of.

Given the magnitude of the COVID-19 pandemic, we recognize that it will take time for all stakeholders, manufacturers, health care distributors, health care facilities, health care providers, patients, consumers, and others, including FDA, to adjust from policies adopted and operations implemented to the new normal operations. There are also unique considerations for the COVID-19 pandemic, including the number of enforcement policies that EUA has issued to help make a variety of devices available to help diagnose, prevent, or treat COVID-19.

There was also manufacturing of devices by non-traditional manufacturers to help address supply issues and distribution and use of capital or reusable equipment that fall within enforcement policies or authorized under an EUA. With the issuance of the COVID-19 transition guidances, FDA is hoping to help

facilitate an orderly and transparent transition to normal operations. These recommendations will help ensure that devices meet applicable requirements after the transition period, when the enforcement policies are no longer in effect, or after termination of the device-related EUA declarations. Importantly, FDA believes these recommendations will help avoid disruptions in device supply so that the health care community continues to have access to important devices for diagnosis, prevention, and treatment of COVID-19.

Next, we'll provide a summary of comments received on the draft guidances and changes made to the resulting final guidances.

We received a total of 42 comments in both dockets for the COVID-19 transition draft guidances. Many of those comments submitted contained comments on both guidances. We received some requests for clarification on terms, including what labeling would be considered publicly available and what devices would be considered already distributed.

There are many requests for us to include references to the possible use of real-world evidence and marketing submissions, including reference to our guidance on this topic. We also received feedback on unique device identification implementation. Finally, we received comments requesting that stakeholders such as distributors and others should be made aware of manufacturers' transition plans.

As it pertains to the enforcement policies transition guidance, we receive requests for timeline variances and extensions for specific enforcement policies in List 1. For the EUA transition guidance, we received many comments requesting that we remove the recommendation for interim labeling for the time between when the EUA has terminated and is no longer in effect and FDA's final action on the manufacturers' marketing submission. We also receive comments requesting clarification regarding in vitro diagnostics as it relates to the Clinical Laboratory Improvement Amendments or CLIA, dual 510(k) CLIA waiver, and de novo waiver submissions and laboratory developed tests or LDTs.

We incorporated this feedback in finalizing the COVID-19 transition guidances. We revised the labeling recommendations and both guidances in response to stakeholder feedback. We clarified our recommendations regarding publicly available labeling, instead stating that either a physical copy or an electronic copy of updated labeling can be provided as further described in those guidances.

We removed the recommendation for interim labeling in the EUA transition guidance as requested by comments. In both COVID-19 transition guidances, we state that while the device is under FDA review, FDA does not intend to object to devices not complying with labeling requirements if devices continue to be labeled as previously authorized under the EUA or as described in the relevant List 1 guidance.

We also incorporated stakeholder feedback in providing clarity on many additional topics, such as for the purposes of these guidances, what devices are considered to be already distributed.

Given that many manufacturers may have obtained data as a result of device use throughout the COVID-19 pandemic, we also added reference to the use of real world data and that it may be submitted in support of a marketing submission, which is consistent with our guidance on this topic.

For in vitro diagnostics, we included information requested by comments, including information on CLIA, dual submissions, and LDT.

We also included new recommendations regarding collaboration with all stakeholders in transition planning, whether the manufacturer intends to continue to distribute the device or not.

Finally, many of the examples were updated, and more detail was provided to further clarify the recommendations in the guidances.

Next, I'll turn it over to Melissa to talk about the structure, scope, content, and time frames of the COVID-19 transition guidances.

Melissa View: Thanks, Kathryn. The structure of the COVID-19 transition guidances is generally the same, consisting of an introduction, background, scope, guiding principles, the transition plan, and examples to show how the transition process could work for manufacturers of different device types. One key difference is that for the enforcement policies transition guidance, the expiration of the section 319 PHE is the implementation date for the transition period or the beginning of the transition period. In the EUA transition guidance, the advanced notice of termination of the relevant EUA declaration is the beginning of the transition period. And the termination of the EUA declarations under Section 564 of the FD&C Act occurs at the end of the transition period. We'll talk more about how this may affect the transition process in the coming slides.

Now we're going to talk about the scope of each guidance, starting with the Enforcement Policies Transition Guidance. The Enforcement Policies Transition Guidance applies to devices that fall within the enforcement policies included in List 1. You can look at the final guidance and the appendix in slides 34 and 35 for a complete list. From draft to final, we added two guidances, including the enforcement policy for viral transport media during the COVID-19 PHE and the enforcement policy for face shields surgical masks and respirators during the COVID-19 PHE.

As you can see at the bottom of the screen, there are several guidances that are not within scope of the Enforcement Policies Transition Guidance. They include the policy for COVID-19 tests and policy for evaluating the impact of viral mutations on COVID-19 tests, consistent with the draft guidance. Additionally, FDA removed the following guidances from List 1. We removed the enforcement policy for the quality standards of the Mammography Quality Standards Act during the COVID-19 PHE, the enforcement policy for noninvasive remote monitoring devices used to support patient monitoring during the COVID-19 PHE, the enforcement policy for clinical electronic thermometers during the COVID-19 PHE, and the enforcement policy for face masks and barrier face coverings during the COVID-19 PHE. For the last three guidances, stakeholders can continue to follow the recommendations of these guidances, as these guidances have been revised to continue in effect until November 7 of this year while FDA revises and replaces these guidances with successor policies.

The EUA Transition Guidance applies to devices issued EUAs under Section 564 of the FD&C Act on the basis of an EUA declaration related to COVID-19. It does not apply to devices with EUAs that have been revoked by FDA for good manufacturing practice deviations under Section 564a of the FD&C Act.

Now we're going to talk about the guiding principles that underline these COVID transition guidances. In developing these transition guidances, we followed several guiding principles, some derived from existing policies and are widely known. And others are the key to understanding the specific approach set forth in these guidances.

First, these guidances are intended to help facilitate continued patient, consumer, and health care provider access to devices needed in the prevention, treatment, and diagnosis of COVID-19.

The second guiding principle is that the FDA believes the policies and recommendations in the guidances will help ensure an orderly and transparent transition for devices that fall within the scope of the COVID-19 transition guidances. FDA's policies and recommendations in these guidances are consistent with the agency's statutory mission to both protect and promote the public health.

The third guiding principle is that the FDA's policies and recommendations follow a risk-based approach with considerations of the 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 another version of the device is FDA cleared or approved.

The fourth guiding principle is that as always, FDA will make a case-by-case decision regarding the enforcement of legal requirements in response to particular circumstances and questions that arise regarding a specific device or device type. This includes revising or revoking an EUA, requesting a firm initiate or recall, pursuing an enforcement action. Or we may revise the enforcement policies and recommendations in the guidances.

As you can see on this slide, the transition plan is generally aligned across both guidances. We'll discuss the transition timeline as described in EUA Transition Guidance first. As previously mentioned, when the relevant EUA declaration related to COVID-19 is terminated, the corresponding EUAs will cease to be in effect. The advance notice of termination of the relevant EUA declaration will be published in the Federal Register 180 days before the date on which the EUA declaration is terminated. This will allow for a 180-day transition. For the purposes of this guidance, FDA refers to the date on which the EUA is terminated as the EUA termination date.

For devices within scope of the Enforcement Policies Transition Guidance, the transition timeline is also 180 days. The implementation date is the date on which the section 319 PHE declaration expires, which is May 11 of this year. The transition period will end 180 days later. After the 180 day transition period ends, the guidances of List 1 will no longer be in effect.

As mentioned previously, the transition plan is generally aligned between the guidances. We broke the transition timeline down into four sections on this slide for clarity. We'll talk in more detail about each of these stages on the coming slides.

The 180-day transition begins with either the advanced notice of termination for the device EUA declaration related to COVID-19 or the expiration of the public health emergency declaration related to COVID-19. 90 days after the implementation date, 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 device after the transition period. 180 days after the start of the transition, FDA expects manufacturers to comply with all applicable legal requirements. 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 legal 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 the requirements for manufacturers who do not intend to distribute beyond the transition period.

If a manufacturer does not intend to continue to distribute their device after the EUA termination date or end of Phase 2, FDA generally does not intend to object to the disposition and use of already distributed devices, meaning those devices distributed before the end of the 180-day transition period as follows.

For single use, non-life supporting, non-life-sustaining devices such as face masks, they may be used by their end user prior to the product expiration date. Reusable non-life supporting, non-life-sustaining devices such as infusion pumps, may be used by their end user if they are either restored by the manufacturer to an FDA cleared or approved version of the device or if they have a physical and/or electronic copy of updated labeling that accurately describes the product features and state that the product lacks FDA clearance, approval, or authorization. Reusable life supporting life sustaining devices such as ventilators may be used if they are restored by the manufacturer to the FDA cleared or approved version of the device.

If such devices are not restored, a physical and/or electronic copy of updated labeling that accurately describes the product features and the device lacks FDA clearance, approval, or authorization should be provided, and such devices are not to be used. Separately, manufacturers may also voluntarily withdraw their devices from the market. If a manufacturer chooses to voluntarily withdraw their device from the market, FDA recommends doing so before the end of the transition period. For all device categories listed here, manufacturers should be aware of any applicable legal requirements for the device. Manufacturers 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 period begins on the implementation date or the date of that advanced notice of termination. At the beginning of the transition period, if not already doing so, manufacturers should follow adverse event report requirements under 21 CFR Part 803. Manufacturers should also continue to submit all adverse event reports. Manufacturers should be preparing marketing submissions if they intend to continue distributing after the transition period.

Ninety days after the transition period begins for devices that fall within scope of the applicable enforcement policies, manufacturers should follow corrections and removal requirements under 21 CFR Part 806 and quality system requirements under 21 CFR 820. Additionally, 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 under 21 CFR 807 subparts B through D if they haven't already done so. FDA requests that manufacturers of certain reusable life supporting, or life sustaining devices submit a notification of intent to FDA. We'll discuss this more in the next slide.

Let's go into more detail about the notification of intent as part of the transition plan. The information will assist the agency in resource planning for marketing submission review and providing support to manufacturers. FDA request manufacturers of certain reusable life supporting or life sustaining devices with product codes listed in the COVID-19 transition guidances submit a notification of intent. These

product codes generally pertain to ventilators, ventilator accessories, anesthesia gas machines, and other respiratory devices.

We request that this information be submitted to the document control center as soon as possible for devices issued EUAs or before the start of Phase 2 for devices within scope of the Enforcement Policies Transition Guidance. The cover letter of the notification of intent should reference any FDA submission numbers. The submission should include model numbers for the devices, information about the future plan to submit a marketing submission or to discontinue distribution for store or label or other efforts to mitigate risks for distributed devices.

180 days after the start of the transition period, the relevant EUA declaration terminates or the guidances in List 1 will no longer be in effect. At this time, manufacturers must comply with the applicable legal requirements for the device and for the manufacturer. We expect manufacturers who intend to continue to distribute their device after the relevant EUA declaration terminates or the relevant list when guidance is no longer in effect, to submit a marketing submission and have it accepted by FDA before the EUA termination date or start of Phase 3. The marketing submission should include a transition implementation plan, which we'll discuss more on the next slide. For those manufacturers that have a marketing submission that was submitted and accepted by FDA before the EUA termination date or the start of Phase 3 and for which FDA has not yet taken final action on the marketing submission, FDA does not intend to object to the continued distribution of the device while the marketing submission is under review.

FDA requests that any marketing submission for devices within scope of the COVID-19 transition guidances include a transition implementation plan and the cover letter of the marketing submission. It is important for the cover letter to include whether the device is authorized under an EUA or distributed as described in a List 1 guidance and any EUA request or related premarket submission numbers. The transition implementation plan should include the estimated number of devices in US distribution, an explanation of the manufacturers plans for addressing already distributed devices in the event of a positive or negative decision, including 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 after the EUA termination date or start of Phase 3 to have any applicable marketing submission submitted and accepted by FDA. Additionally, FDA expects manufacturers to have completed any steps necessary to transition into compliance with all applicable legal requirements not discussed in the COVID-19 transition guidances. FDA expects distribution to cease 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.

Now I'll turn it back over to Kathryn to discuss engagement with FDA on this topic and a few hypothetical examples to illustrate the transition process for impacted devices.

Kathryn Drzewiecki: Thanks, Melissa. Generally, FDA believes that the COVID-19 transition guidances cover many situations. And the recommendations, actions, and time frames included in the guidances apply. However, there may be certain scenarios that are not specifically addressed. If desired, manufacturers can initiate discussions with FDA through the Q-Submission program. The Q-Submission could be used to provide input on a transition implementation plan to address a specific scenario, study

designs for a novel device, or how to utilize real world evidence gained through use of the device during the COVID-19 pandemic in the marketing submission, for example.

Manufacturers should submit any pre-submissions with the understanding that legal requirements still apply to the device and manufacturer at the end of the transition period. So if the manufacturers intent is to continue to distribute its device after the transition period, we encourage the manufacturer to work toward and we intend to help facilitate acceptance of a marketing submission before the end of the transition period.

The COVID-19 transition guidances include a number of hypothetical examples to illustrate the transition process. Generally, we recommend reviewing the guidances for the recommended actions for manufacturers throughout the transition period. At a high level, we'll go through two examples, one from each of the guidances.

First up is an example from the Enforcement Policies Transition Guidance. In this example, we'll discuss a new telethermographic system that is not FDA cleared but was distributed during the COVID-19 pandemic and falls within the enforcement policy for telethermographic systems. After May 11 when the declaration expires, manufacturers continue to comply with requirements that were not addressed in the enforcement policy, regardless of whether the manufacturer intends to distribute the device beyond the transition period.

Next, for a manufacturer who intends to distribute the device beyond the transition period, the manufacturer registers and lists before the start of Phase 2, which begins on August 9th. That manufacturer also submits a marketing submission, including a transition implementation plan, which is accepted by FDA by the end of Phase 2 or by November 7th.

For a manufacturer who does not intend to distribute the device beyond the transition period, the manufacturer ceases distribution during Phase 2. Both manufacturers continue to comply with requirements that were not addressed in the enforcement policy, including adverse event reporting.

After November 7th, the enforcement policy guidance is no longer in effect, and the transition period ends. For a manufacturer who intends to distribute the device beyond the transition period, since the manufacturer has submitted a marketing submission and it was accepted by FDA, FDA does not intend to object to the continued distribution of the device until FDA takes a final action. The manufacturer complies with all legal requirements for the device and manufacturer. In a scenario where the manufacturer receives a not substantially equivalent or NSC decision after FDA's review, the manufacturer ceases distribution of the device and the manufacturer and FDA engage to address already distributed devices.

For a manufacturer who does not intend to continue to distribute the device beyond the transition period, in this example, the manufacturer ceased distribution during Phase 2. The manufacturer opts to leave already distributed devices in the field and provides electronic copies of updated labeling, which includes the product features and that the product is not FDA cleared, approved, or authorized. The manufacturer continues to report adverse events.

The second example we'll go through is from the EUA Transition Guidance. This example is for a continuous ventilator that was authorized under the umbrella EUA for ventilators. At this time, the dates

for the advanced notice of termination for the device-related EUA declarations are unknown. In this scenario, the hypothetical advanced notice of termination for the relevant EUA declaration is published in the Federal Register on July 1st, which is the start of the transition period for those devices within the scope of the umbrella EUA. Until the EUA declaration is terminated, manufacturers must continue to comply with requirements in the EUAs conditions of authorization.

Within 90 days, because the ventilator is a reusable, life supporting, life sustaining device, the manufacturer submits a notification of intent to FDA to inform FDA whether it intends to pursue marketing authorization. In this scenario, for a manufacturer that intends to distribute the device beyond the EUA termination date, the manufacturer submits a notification of intent to FDA on August 1st. The notification of intent includes that the manufacturer intends to pursue marketing authorization. By the EUA termination date on January 1st, the manufacturer submits a marketing submission, including a transition implementation plan, which is accepted by FDA.

For a manufacturer that does not intend to distribute the device beyond the EUA termination date, the manufacturer submits a notification of intent to FDA, also on August 1st. The notification of intent includes that the manufacturer does not intend to pursue marketing authorization. It also includes the manufacturers plans to address already distributed devices.

On 1st of the next year, the relevant EUA declaration is terminated. And the umbrella EUA is no longer in effect. For a manufacturer that intends to distribute the device beyond the EUA termination date, since that manufacturer has submitted a marketing submission and it was accepted by FDA, FDA does not intend to object to the continued distribution of device until FDA takes a final action. The manufacturer complies with all legal requirements for the device and manufacturer.

In a scenario where the manufacturer receives a positive decision after FDA's review, the manufacturer continues to distribute their cleared device. And FDA and the manufacturer engage on the transition implementation plan to address already distributed devices, including any updates to labeling and components.

For a manufacturer who does not intend to distribute the device beyond the EUA termination date, the manufacturer ceases distribution and engages with stakeholders to determine those that express an interest in keeping the devices.

However, already distributed devices are not used. And the future use of the device would be subject to the regulatory requirements of any future authorization, including marketing authorization or EUA. The manufacturer provides electronic copies of updated labeling, which includes the product features and that the product is not FDA cleared, approved, or authorized. The manufacturer continues to report adverse events.

As we mentioned earlier in this presentation, for your later reference, we've included in these webinar slides, an Appendix. It contains the guidances and List 1 of the Enforcement Policies Transition Guidance.

To summarize, FDA has finalized our COVID-19 transition guidances. Incorporating public feedback and comment, these guidances will help with the transition process for devices that fall within certain enforcement policies issued during the COVID-19 PHE or devices issued EUAs. The COVID-19 transition guidances are generally aligned and identify various actions and milestones to guide FDA and

stakeholders through the transition. I'll note that for devices that fall within certain enforcement policies issued during the COVID-19 PHE, based on the recommendations and the Enforcement Policies Transition Guidance, the transition period begins on May 11, 2023 when the COVID 19 PHE declaration ends.

At this time, the transition period for devices issued EUAs has not started as the advanced notice of termination has not been issued for any device EUA declaration related to COVID-19. That being said, for manufacturers that intend to continue to distribute their devices beyond the transition period when the relevant COVID-19 enforcement policies are no longer in effect or after termination of the relevant EUA declaration, FDA recommends working on your marketing submissions now.

Thanks for your attention to today's presentation, and now I'll turn the program back over to Elias.

Elias Mallis: Thank you, Kathryn. And also, thank you, Melissa. Thank you both for your overview of the COVID-19 transition policy for medical devices. Let's now transition to the interactive question and answer segment of our program, where you, our audience get to ask your questions to our panel. But first, I'd like to introduce several additional panelists who will join our team in answering your questions, Dr. Jacqueline Gertz, Policy Analyst for the Clinical and Scientific Policy staff, and Dr. Ryan Ortega, Policy Analyst for the Regulatory Policy and Combination Product staff. Now both Jackie and Ryan join us from CDRH's super office, which many of you may know as the Office of Product Evaluation and Quality or OPEC. Hello panelists. Thanks for joining us.

So let's now review how we'll manage this segment. To ask a question, please select the Raise Hand icon, which should appear on the bottom of your Zoom screen. I'll announce your name and give you permission to talk. When prompted, please select the blue button to unmute your line and then ask your question.

A few tips about questions-- number one, please limit yourself to one question please, and try to keep it as short as possible. And number two, we appreciate that many of you may have a very specific question involving your exact device or scenario. Please note that we may not be able to answer very specific questions like that. But we'll try to frame a broader response based on the final guidances.

So after you've asked your question, I ask that you lower your hand in the Zoom app and mute yourself again. If you have more questions, no problem at all. Just go ahead and raise your hand again. And we'll come back to you if we have time.

Now, as we wait to get to some of your questions, let's welcome our newest panelist with a few questions that we've gotten over the past few weeks about the COVID transition policies. So Jackie, I'll start with you. First, let me welcome you to our panel and thank you for joining us again this year. You presented it at our program about a year ago, hard to believe it's been a year since the transition started. So our first question to you-- will there be a shortage of devices on the market once the COVID-19 public health emergency expires or EUA declarations terminate?

Jacqueline Gertz: Thanks for the question, Elias. So we put out the transition guidances to help manufacturers and FDA both to have an orderly transition process. With that in mind, we hope that there are no shortages of devices. If there are any, we will be keeping an eye on it, working with our

industry partners, as well as our other government partners, to help mitigate those shortages. And we will have communications available on our website related to any potential shortages.

Elias Mallis: Thank you Jackie, and again, welcome. All right, Ryan, let's welcome you to our panel. Again, thanks for joining us. Here's the question for you-- I haven't yet received FDA clearance for my device. What happens if I want to continue distributing my device after the relevant COVID-19 enforcement policy and a List 1 guidance is no longer in effect or after the termination of the relevant device EUA declaration related to COVID-19.

Ryan Ortega: Yeah, hi. Thanks, Elias. And good afternoon, everyone, or good morning or good evening, depending on where you're listening in from.

We've received this sort of question in a couple of different venues. So it definitely seems like it's of general interest to folks who are wanting to continue manufacturing after the transition periods. And so there's a couple of points that I'd like to emphasize that we're hoping everyone will keep in mind. So if a manufacturer would like to continue distributing their device after either the enforcement policy that's relevant to their devices no longer in effect or after the relevant device EUA declaration has been terminated, we are really strongly recommending that manufacturers should promptly start preparing their marketing submission and have it accepted by their FDA review team before the enforcement policy is no longer in effect or before the EUA termination date, whichever is applicable. As we outlined in the transition guidances, we don't intend to object to continued distribution of devices that are within the scope of each COVID transition guidance when the manufacturer has submitted a marketing submission to us and it's accepted for review before the end of the transition period or before the relevant EUA terminates and we haven't taken a final action on that marketing submission. One thing to note, though, is that if a manufacturer receives a negative decision on such a marketing submission, we expect the manufacturer to discontinue distribution of their device and continue to comply with any applicable legal requirements for their device, for example, adverse event reporting. Otherwise, we may take action as appropriate for any devices that aren't in compliance with the requirements for their device type. But I'll also direct people to Section 5 in each of the transition guidances, where these plans are outlined in greater detail.

Elias Mallis: Ryan, thank you so much for your response, and welcome to our panelists. Now we'll get to our questions. We have a lot of hands raised, so we're going to try to get through as many of them in our time allotted. Again, just a reminder that for COVID test development and validation questions, we're going to try to handle most of those questions next Wednesday at our usual Town Hall.

So with that, let's get started Richard, I'm going to start with you. I'm unmuting your line. Please go ahead and share your question with our panelists.

Richard Montagna: Well, thank you. This is Richard Montagna from Rayonix. My question pertains to the use of what you refer to as real world data. As a result of the interactions we previously had with FDA in a pre-submission, we are currently engaged in nationwide studies to gain --to obtain the appropriate data for a marketing submission. But if we were to choose to use pre-existing data, so-called real world data, I guess you're calling it, the current study, our device is being tested against comparator devices. If we were to use pre-existing real world data, we obviously have access to millions of test results but they would have been run just on our assay. And there would be no comparator data

to try to establish sensitivity and specificity. So am I understanding it correctly that such data could be used. And how will we deal with the lack of comparator data? Thank you.

Elias Mallis: Richard, thank you for your question. I know you made reference to assays. So there might be an in vitro diagnostic aspect to your specific device type. For a response, I'll turn it over to Ryan to give an answer for us.

Ryan Ortega: Yeah, thanks Elias. I can say that in general, we are interested in exploring the ways that real world evidence and real world data can be used to support the transition from an EUA or an enforcement policy to a marketing submission. I know it sounds like you've got some specific questions for your specific case. And while we can't address specific cases here, what I can say is that we generally would recommend that if you've got these sort of specific questions, to engage with the review division for your device, which in this case is in our IVD group.

Our Q-Submission submission process-- I think you mentioned that you've already had some interactions. I think continue Q-Submission interactions to hammer out the specifics of how you might use the real-world evidence that you've collected during your experience with your device could be used to support or to continue to support your work on your marketing submission.

Richard Montagna: OK, thank you very much.

Ryan Ortega: You're welcome.

Elias Mallis: Thank you, Richard, for the question. Thank you, Ryan, for the response. We'll keep going with our Q&A here. Hur, I'm going to unmute your line. Please go ahead and unmute yourself and ask your question.

Hur Koser: Good afternoon. thank you for your opportunity. This is Dr. Hur Koser. You mentioned that next Wednesday, there would be another seminar, but for the sake of safety, I just wanted to ask as generalized of a questions as I might. For diagnostic tests that are multiplex tests that might be starting a clinical study already, at this point, how does the transition plan apply to those tests? Thank you.

Elias Mallis: Thank you for that question. I'm going to suggest that I think for that particular question, this is really a classic good question for our Town Hall. So what I'd like to suggest is that we refer to next week for that so Dr. Tim Stenzel and Toby Lowe and Dr. Kristian Roth can provide a response. So again, my apologies for that. I think we'd like to have those experts feel that specific questions related to COVID test and regulation.

Hur Koser: Sounds good, thank you.

Elias Mallis: All right, thank you so much. Thanks for joining us. Karl, I'm going to proceed with you. I'm unmuting your line again. Please unmute yourself and ask your question.

Karl Enters: Thank you very much. This is Karl Enters from GENETWORx. This is an IVD question as well. Clearly in the transition guidance, FDA indicated that they would be treating LDTs with the same enforcement discretion as other LDTs. Our plan is to move forward with LDTs into the future as the tests

have improved, and they're not EUAed currently. Are we free to do the LDT testing on point of care at March 11 or is there a date at which that becomes accessible?

Elias Mallis: Karl again, thank you for that question. I'm going to probably give the same answer as I gave before. We'd like to answer that question next week so that the entire in vitro diagnostic community can hear the same response. So we appreciate the question. And we'll make a note of that for next week, and we'll provide a response then.

Kathryn Drzewiecki: Karl, this is Kathryn. I'll just mention that May 11 is the end of the PHE declaration for COVID-19. But the EUA declarations for in vitro diagnostics, for respiratory protective devices, for ventilators, all of the EUA declarations are still in effect after that date. So I just wanted to make that one distinction related to the May 11 date. And I think that the IVD Town Hall would be a great place for that question.

Karl Enters: That's good. Thanks, Kathryn, appreciate it.

Elias Mallis: Karl, thank you for the question, and Kathryn, thank you for jumping in with the clarification. Let's continue with our Q&A. Ling, I am unmuting your line next. Thank you for joining us. Please share your question with our panel.

Ling Koh: Hi, this is Ling calling from BD. Thanks for taking my question. It's also about IVDs. And I hope it's the right forum for this. Otherwise, I can ask next week.

So CMS previously announced an end-to-provider discretionary use once the PHE ends and that they will start enforcing on-label adherence for SARS-CoV-2 antigen tests, which includes the serial testing revisions that were effective on November 1st last year. So I had a couple of questions about how clinicians can adhere to those zero testing requirements as we move into a post-PHE era. Should I ask this question today, or would you like me to save that for next week?

Elias Mallis: So my apologies, I think we would like to have you address these questions next week with the IVD community.

Ling Koh: OK, all right, no problem. Thank you.

Elias Mallis: OK, thank you for joining us today. Marnie, I'm going to unmute your line. We welcome your next question for our panel.

Marnie Curbow: Hi there. Thanks so much. During the transition period, will amendments to current EUAs be allowed?

Elias Mallis: That's a very great question. Can you clarify that you have an existing EUA on the books, if you will, and you wish to modify the device?

Marnie Curbow: Yes, sir.

Elias Mallis: OK, Jackie, I'd like to ask you to answer this question.

Jacqueline Gertz: Yeah, no problem. So we are still reviewing amendments to EUAs, even after the advanced notice of termination is publicized and the transition period has started. Of course, we do want to encourage you to consider submitting a traditional marketing submission that will allow you to market beyond the end of the EUA declaration. So I would say that that is really the most important thing, is to get your regular traditional submissions in as soon as possible. But we will still be reviewing amendments.

Marnie Curbow: Thank you.

Elias Mallis: Jackie, thank you for the response. And Marnie, thank you for your question. Meghan, I'm going to unmute your line next. Welcome to our panel, and please share your question.

Meghan Peck: Hi, can you hear me?

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

Meghan Peck: Thank you for having us. So I just had a quick question. I'm from the Connecticut Primary Care Association. And we are advising our members on what to do with these single-use disposable masks, any of them that they may have that are included in the annex that you had provided. I think I heard today to obviously use those up first if we can use them prior to the 11th. After that, any stock, what could be a recommendation as to what to do with them? Do we just throw them away?

Elias Mallis: Thank you for your question. This forum is primarily for industry to help guide on how we will implement the regulation of these products moving forward. You're speaking to us as more of an end user. And that's a great question.

Let's start with Jackie for a response, because it sounds like you're really talking a little bit about shortages and potential shortages.

Jacqueline Gertz: Yeah, so the transition guidance is both have a section that is outlined for what to do with devices where they don't intend to transition to a normal marketing pathway. And in that case, it says for disposable devices like surgical masks, that users should use up what their stock that's currently available or until expiration, I believe. Let me see exactly. It says, yep, may be used by the end user prior to the product expiration date.

Meghan Peck: Oh, even better, perfect. So we was worried about waste. But thank you so much, appreciate it.

Jacqueline Gertz: Yeah, and of course, if the manufacturer chooses to submit a marketing authorization and continue distributing, then I mean, you would still want to use them up and not until beyond expiration date. So in that case, it's similar. But you would obviously have the opportunity to purchase more.

Meghan Peck: Fantastic, thank you so much.

Elias Mallis: Meghan, thank you for the question. Jackie, thank you for the response. Let's continue with Ximena. I am unmuting your line. Thank you for joining us, and please join us with your question.

Ximena Semensato: Hi this is Ximena Semensato with Baxter Health Care. Thanks for taking my question. I'm not sure if this is the right panel to ask this, but I was wondering if the same principles of the transition policy can be applied to drug products.

Elias Mallis: So I would say this is a specific webinar for medical devices. So I don't think we probably would be in position to provide responses for anything outside of CDRH regulation, including drugs.

Kathryn Drzewiecki: This is Kathryn. I'll just chime in. This is a CDRH device-specific guidance. And so I would encourage you to talk to CDER about their transition policies.

Ximena Semensato: OK, thank you.

Elias Mallis: Thank you for the question. Kathryn, thanks for jumping in. Let's continue with Michelle. Michelle, you're up next. Thanks for joining us, and share your question.

Michelle Rubin: Hello, thank you so much. Can you hear me?

Elias Mallis: Yes, you sound great.

Michelle Rubin: Perfect, thank you. I have a question related to the enforcement policy process that you explained with the phases. If a marketing submission is submitted actually prior to even Phase 1, even before really the PHE ending, but the sponsor still intends to distribute during the review of that premarket submission, does FDA still recommend that the sponsor follow the steps outlined in Phase 2 and Phase 3. So for example, registering and listing even while the submission is under review? Or does FDA recommend since the submission is under review, even prior to the ending of the PHE that the sponsor follow the more traditional path of actually waiting once the 510(k) is cleared to actually register and list?

Elias Mallis: Michelle, thank you for that question. I think we'll look for Ryan for a response.

Ryan Ortega: Yeah, thank you, Elias. And thank you for that question. I think even if sponsors are able to get their marketing submissions in before the transition period starts, which first of all, great. I think that would be a great goal to shoot for. We are still thinking that it would be appropriate to follow the steps that are outlined in the transition plan. And also, just to be sure at this point is clear, even if the submission comes in and is accepted for review before the start of those transition periods, it is still able to take advantage of the enforcement policy that we've laid out in these guidances, where the manufacturer may continue to market while that submission is under review.

Michelle Rubin: Fantastic, thank you so much.

Ryan Ortega: You're welcome.

Elias Mallis: Thank you, Michelle, thank you, Ryan. Ben, you're up next with your question. Thanks for joining us.

Ben Hornsey: Hi, can you hear me OK?

Elias Mallis: Yes, you sound great. Thank you.

Ben Hornsey: Awesome. I was wondering if you could please clarify why some enforcement policy guidances are not included in List 1 of the transition guidance and what transition FDA expects for those particular devices that fall into those guidances?

Elias Mallis: Ben, thank you for your question involving List 1. Melissa, let's have you provide a response to our audience.

Melissa View: Thanks for that question. So in considering the changes to the final guidance, we looked at the comments we received. We also wanted to align the transition policies where possible. And so you can look to if the COVID-19 guidance is under the omnibus, you can look to that to see when that guidance may end. Or you can look at the guidance itself.

Ben Hornsey: Am I allowed to ask just one follow-up question?

Elias Mallis: Ben, go ahead if it's short. Go ahead, please.

Ben Hornsey: It'll be short. The specific guidance that I'm looking at does state at the very top that it will no longer be in effect as of November 7th. Is that to assume that all of the phased transition deadlines would still apply, working up to that date, meaning a 510 K submission should be accepted by that date for those particular devices?

Melissa View: Are you-- Oh sorry, go for it, Kathryn.

Kathryn Drzewiecki: Oh, thanks. Ben, I was just going to ask, which guidance are you talking about? That would be helpful.

Ben Hornsey: The non-invasive remote monitoring devices.

Kathryn Drzewiecki: So Melissa, the non-invasive remote monitoring guidance is in the guidance documents related to the COVID-19 Federal Register notice. And that guidance, if we take a look at, I think it's slide 16, is not in the scope of the transition policy. And so we're intending to issue a successor policy. Does that help?

Ben Hornsey: So between now and November 7th, there should be a new guidance that is released speaking to updated policy?

Kathryn Drzewiecki: Melissa, Ryan, others, did I miss anything? But yes, that's correct.

Melissa View: That's correct. Thanks Kathryn.

Ben Hornsey: Thank you,

Elias Mallis: Ben, thanks for joining us. Thanks for your question. Don, we'll go to you next. Thank you for joining us, and please share your question with our panel.

Don Kafader: Yes, thank you for taking my question. With respect to a product that has an EUA and for those EUAs, most of the requirements for good manufacturing practices, including quality system regulations and design controls were waived. What would you suggest for transitioning to a marketing application, where now those elements will apply and they weren't followed during the development of the product, let's say three years ago?

Elias Mallis: Don, thank you for that question. I'll send this one over to Jackie for a response.

Jacqueline Gertz: Hi, Don. I was wondering-- so at the end of the transition period for an EUA device, quality system would be required. Are you asking how to implement a quality system?

Don Kafader: No, not at all. Specifically with respect to the design control requirements in the quality system regulation that require the product development to follow a specific set of procedures.

Jacqueline Gertz: I see. OK, can you email the CDRH non-diagnostic inbox mailbox, and I can get an answer to your question? Do we have that email somewhere?

Elias Mallis: I would say for simplicity, I don't have it off the top of my head. Don, feel free to email our division. And we can then forward it off to Jackie. So you can email us DICE@fda.hhs.gov. Make reference to this webinar, and then we'll route that question to Jackie's team.

Don Kafader: This should apply to in vitro diagnostics, as well as other products that have an EUA that didn't necessarily follow the design control process during the EUA period.

Jacqueline Gertz: Right, is your device specifically a diagnostic?

Don Kafader: It could apply to that. But it could apply to any device that is going to seek a marketing application that was developed without consideration of those requirements.

Jacqueline Gertz: Right, OK, thank you.

Elias Mallis: Thank you, Don. And my only suggestion is if you do submit your question, be specific with your scenario. And then the team will be able to try to provide a response.

Don Kafader: OK, thank you.

Elias Mallis: All right, thank you. Laura, we'll continue with you. Thanks for joining us. And please share your question.

Laura Fredrick: Great, thank you. For manufacturers that do not intend to continue distributing ventilators, if the device were to malfunction during phase 1, one can it be replaced or can it be repaired?

Elias Mallis: Thank you for that question, Laura. Now are you speaking as a manufacturer of that product?

Laura Fredrick: Yes.

Elias Mallis: You are. OK. So I think for that question, if you have not described the device iterations within that product, it may be appropriate to submit a Q-Submission and submit that question to the team responsible for that device type. And they'll provide a detailed response, based on the specific modifications you're looking to make.

Laura Fredrick: OK. All right, thank you.

Elias Mallis: All right, thank you, Laura. Thanks for joining us. Tim, we'll go to you next. Thank you for joining us, and let's have your question.

Tim Coulter: Thank you. Yes, Tim Coulter here. A question on the timeline for a marketing submission to be accepted-- I understand once the submission is accepted, you can continue to distribute your product after November. But how long should we anticipate from the time a submission was sent in to the time when an acceptance might come back?

Elias Mallis: That is a great question. Ryan, I'd like to turn that question over to you.

Ryan Ortega: Yeah, thank you. I appreciate the question. So we are planning to follow our normal RTA timelines when we are considering acceptance for each submission. I will say, it's our intent to do whatever we can to work with sponsors who are submitting applications to ensure that we're getting complete submissions and that we're providing feedback as appropriate to help our sponsors understand what a complete submission looks like and how it impacts their timeline. But again, this is just I think, further underscores that we are really urging and strongly recommending that folks who want to keep marketing not cut it close with respect to getting in their marketing submissions. Get them in as soon as possible. That way, the process could account for any potential hiccups, particularly during that acceptance review phase. So thank you. I think that's a really good question.

Tim Coulter: Good, thank you.

Elias Mallis: Thank you, Ryan. And Tim, thank you for your question. Let's continue with Allen. Allen, I've unmuted your line. Thanks for joining us, and we welcome your question to our panel.

Allen Chun: Yes, thank you. Just a quick question-- could you comment on what FDA plan is for those devices that are currently under EUA submission review post-May 11th?

Elias Mallis: So just to clarify, you've submitted an EUA, it is still under review. And you wish to know what will happen after May 11 for that product.

Allen Chun: That's correct.

Elias Mallis: OK, Kathryn, I'll turn this one over to you for response.

Kathryn Drzewiecki: Yeah, thanks, Allen, thanks, Elias. So Allen, the PHE declaration that is set to expire on May 11 is separate from our authority for EUA declarations. And so as Jackie mentioned earlier in the Q and A, we will still be reviewing EUA requests as long as the EUA declarations are in place. But we do

recommend pursuing traditional marketing submissions at this time, rather than an EUA if you can. And so that's what we can say. And many manufacturers have been doing so and have already obtained clearance or approval. So we encourage you to go the pathway of traditional marketing authorization when possible.

Allen Chun: OK, great. Thank you.

Elias Mallis: Allen, thank you for the question. Kathryn, thank you for the response. Gaby, you're up next. I've unmuted your line, thanks for joining us. Please share your question.

Gaby Orr: Hi, thanks for giving this opportunity. So we have surgical masks, and we have got EUA under product code QKR. And so the PHE is getting over on May 11, and we have 180 days until we make the transition period of 180 days, which is ending on November 7th. So after November 7th, are we able to sell those masks without any pre-market submission?

Elias Mallis: Gaby, thank you for the question. Kathryn, let's go back to you to have a follow-up, perhaps related to the prior question as well.

Kathryn Drzewiecki: Yeah, thanks. As we just stated, the PHE end on May 11 does not impact EUAs. And so, you had mentioned it was an EUA for a surgical mask, correct?

Gaby Orr: Under product code QKR-- so in the guidance document, the surgical masks are under different product codes. But the product code that we have registered, QKR, was not mentioned in the guidance. So now, yeah, it's a bit confusing for us. Does it follow this? I'm thinking it does not.

Kathryn Drzewiecki: I'll just say, if it's an EUA for a surgical mask, that the EUAs remain in effect even after the expiration of the public health emergency declaration on May 11. The advanced notice of termination for respiratory protective devices has not issued. Jackie, would you mind also jumping in? Because I know that there's masks that can be issued or masks that can be marketed under both EUA and enforcement policies.

Jacqueline Gertz: Yeah, that's right. So masks can be marketed under both EUAs and enforcement policies. I mean Kathryn just outlined what would happen for the EUA products. They'll stay in place until the EUA declaration ends, which we don't yet have a date for that. So in terms of the enforcement policies, I believe the transition guidance does apply. The enforcement policy transition guidance does apply to the surgical mask enforcement policy. So if at the end of the transition period, those guidances will end. And you will not be able to continue to market your surgical mask under the enforcement policy unless you have a marketing submission under review.

Gaby Orr: So the enforcement policy is different than the guidance that we reviewed in this slides, right?

Jacqueline Gertz: So in the transition guidance that was discussed in this slide, there were two transition guidances discussed, one for EUAs and one for enforcement policies. The enforcement policy guidance discussed today outlines a procedure for how manufacturers should transition their guidances from being marketed under the enforcement policy to our normal marketing pathways. In that guidance, it includes a small section that says basically, if you have a marketing submission under review, then you can continue to market your device as long as it is under FDA review.

Gaby Orr: OK, thank you.

Elias Mallis: Gaby, thank you for the question. Thank you for the responses, Jackie and Kathryn. Meredith, you're up next with your question. Thanks for joining us.

Meredith Pyne: Hi, thank you. Apologies if I missed this, but I was just wondering if companies are able to use their own EUA submissions as a predicate for a 510(k) submission?

Elias Mallis: Meredith, that's a great question. I like to turn that over to Ryan for a response.

Ryan Ortega: Yeah, thank you. And so in order for a device to serve as a legally marketed predicate, we would not allow for an EUA-authorized device to be the predicate. That would, I think, generally would be another previously cleared legally marketed device.

Elias Mallis: Thank you. Thank you, Ryan, for that response. And Meredith, I'll just add some of this has taken place during the IVD Town Halls. If your product is indeed new, then one approach we have been taking is to have you pursue the de novo pathway. So then, your product would be the first on the market of its device type, et cetera. And then after that, it would serve as a predicate for other devices that would come under 510(k).

So thank you for your question. Stacey, we'll move on to you next. Thanks for joining us. And let's hear your question for our panel.

Stacey Drakousis: Yes, thank you so much for having us. Does the FDA intend to assist manufacturers with their transitioning EUA marketing authorization applications by prioritizing those application reviews?

Elias Mallis: Thank you for that question. I do want to ask a clarification. Can you give us the general description of the device type?

Stacey Drakousis: Yes, IVD.

Elias Mallis: I did want to ask that on purpose, because if-- have you attended our Town Halls that have been—

Stacey Drakousis: Yes.

Elias Mallis You may have heard Dr. Stenzel refer to some of the prioritization efforts that have taken place. So what I'd like to do is defer that particular question to next week so that he and the other panelists can give a response for that product area.

Stacey Drakousis: Thank you.

Elias Mallis: All right, Stacy, thanks for joining us. All right, Tammy, you are up next. Thank you for joining us. Please share your question with our panel.

Tammy Carrea: I think my question may have already been answered in part. But my basic question is if a sponsor has an EUA that is currently in process or under review at this time, will FDA complete the review of that EUA application and provide feedback, even in the form of an AI request, if the submission review is not completed by May 11th? What would be the timeline to ensure that a sponsor gets closure on an EUA application, in light of the new deadlines and dates?

Elias Mallis: Tammy, thank you for that question. Actually, it's a great question we haven't heard yet. Jackie, may I ask you to provide a response?

Jacqueline Gertz: Sure, no problem. So just as a reminder, the end of the public health emergency will not affect EUAs. So the May 11 and November 7th dates will have no impact on the EUAs. In terms of when the EUA transition does start at a later date, any EUAs that are under review at the end of the transition period will be deprioritized.

In terms of getting feedback, if just feedback is your goal, then I recommend you submit Q-sub, rather than an EUA. You will be able to ask direct questions and receive much more clear feedback based through the Q-Submission program. That's really the best way, if what you want is feedback, that's our pathway.

If you are trying to seek an EUA authorization, then the EUA obviously, would be the path. However, I would encourage you to keep in mind that once the advanced notice of termination goes out, that that means that we only have 180 days until the end of the EUAs. So instead of submitting an EUA, I would strongly recommend that you submit a marketing submission. That will allow you to continue to market beyond the end of the EUA period.

Tammy Carrea: May I follow up with something on that?

Elias Mallis: Yes, Tammy, a very brief follow up.

Tammy Carrea: Yes, so in the instance of a device that is not like one of the listed devices, like in other words, a novel device that would under all circumstances, have to pursue a de novo application, do the same dates and deadlines-- and I know that you mentioned the deadlines on May 11 and November 7th. Those make sense. But because those types of devices that are say new or novel already or regardless, will they be impacted any differently by that deadline, by those deadlines?

Jacqueline Gertz: No, they won't. But as outlined in the transition guidances, we do intend to work with manufacturers to be able to get their marketing submissions in a timely way before the end of the transition period. But in order to do that, we need manufacturers to work with us as well and bring in their questions through the Q-sub pathway as soon as possible, submit their marketing authorizations as soon as they possibly can in order to make sure that they have something accepted by the end of the transition period. And just one more time, I want to reiterate that the end of the public health emergency does not affect the EUAs. So the May 11 dates and the November 7th date are not relevant for EUAs, only for the enforcement policies.

Tammy Carrea: Great, thank you.

Elias Mallis: Tammy, thank you for joining us. Jackie, thank you for the response. Just a quick time check-- we have time for a few more questions that can be pretty short. But we're going to try to get through as many as we can. We've already gone through so much with our fine panel. So having said that, Dr. John, you are next. Thanks for joining us, and please share your question.

Dr. John, we can't hear you if you're speaking. I will try to prompt you to unmute yourself.

John: I'm sorry, I apologize. Thank you. Can you hear me?

Elias Mallis: You're loud and clear. Thanks for joining us.

John: I appreciate it. Thank you. We're a manufacturer of biotransport media, falls under List 1 of the PHE. And assuming that we have a positive decision after submission of our marketing submission and the transition plan, how long does our company or companies like ours have to continue to manufacture and distribute until we have our 510(k)? We're trying to get a gauge of a timeline here, post-positive decision by the FDA that will allow us to continue to manufacture and distribute. Of course, as usual these devices are traditionally manufactured and distributed under a 510(k). Thank you.

Elias Mallis: Thank you for the question. Jackie, we'll look to you for a response.

Jacqueline Gertz: Yeah, so as outlined in the transition guidances, there is an enforcement policy that's included there that says that if you have a marketing submission that has been accepted by FDA before the end of the transition period, that you can continue to market your device until you receive your final decision. So that would mean that you can continue to market as long as your device is under review. So that would include on hold. It would not include a deleted decision or NSE, for example. And then, did that answer your question? Or was your question slightly different?

John: So it was slightly different. And I understand there's a 180-day transition period. So if we receive a positive decision, meaning that we can continue to manufacture, are you stating that you will not be able to continue to manufacture after 180 days without a 510(k)?

Jacqueline Gertz: Without a submission that has been accepted.

John: OK, so the question is-- I'm sorry if I'm not being clear. The question is if the submission is accepted and we receive a positive decision, that you'll allow us to continue to manufacture and distribute, how long do we have to continue to manufacture and distribute post that positive decision?

Jacqueline Gertz: So before the enforcement policies are withdrawn, we intend to work with manufacturers to develop a timeline that would work for everybody. So that's something that we will be discussing as the marketing submissions are authorized. After the end of the transition period, those guidances are withdrawn. And the flexibility is not as readily available. Do any of the other panelists have any thoughts they'd like to share?

Ryan Ortega: I can maybe provide one more point. If you receive a positive decision to your submission when it's under review, then let's say it's a 510(k) cleared device and you get 510(k) clearance, then you can just continue to market under the 510(k) clearance, rather than marketing under the enforcement policy.

John: Understood, thank you for that clarification.

Elias Mallis: Dr. John, thank you for your question. And thank you panelists for providing a response. We're almost out of time now. So what I'd like to do is turn the floor back over to Kathryn to give some final thoughts for our audience on this very important topic. Kathryn, the floor is yours.

Kathryn Drzewiecki: Thanks, Elias. And thank you everyone for joining today and for all of your questions. We just want to put in one final plug, which I'm sure you all expect, which is for all manufacturers, whether you have devices distributed under enforcement policies or issued EUAs, FDA believes that you should get started on your marketing submissions. And as many of you have already today, if you have transition-related questions that are specific to your device, you should come in with a Q-Submission as soon as possible and in parallel, continue work on your marketing submission. And thank you again, all, for joining us today.

Elias Mallis: Thank you, Kathryn. Thank you for the final word there. And thank you, our audience today, for joining us for all of your great questions. This will now conclude today's CDRH webinar. I'd like to thank our FDA panel on this discussion as we begin our efforts to implement our various COVID-19 transition policies. Dr. Kathryn Drzewiecki and Melissa View, thank you so much for your presentations. Doctors Jackie Gertz and Ryan Ortega, thanks for joining us as our expert panelists. Also, my thanks to you, our audience, for all of your great participation and questions today.

A recording of today's webinar presentation and transcript will be posted to CDRH Learn in hopefully, a few weeks. Please visit CDRH Learn at the link shown on this slide. This topic will be placed under the section Specialty Technical Topics and the subsection COVID-19 transition policy. We're placing it as the first topic in this section so it'll be really easy to find. Here's a screenshot of where you can find this webinar.

And again, for additional questions about today's program, please email us at DICE@fda.hhs.gov. That email address is listed on this slide as well.

We also encourage you to join us for a future CDRH webinar. A listing of upcoming and past events is listed here on the next slide. And again, if you are interested in learning more about our COVID-19 transition policies that are specific to test, development, and validation, and we had quite a few of those questions today, please, please join us next week. We're having a special session just for you on April 26 at our special time, at 12:05 to 1:00 PM. Please join us for this virtual Town Hall.

Once again, this is Elias Mallis. Thanks so much for joining us today. Take care. Thank you for all of your work on COVID, and we'll see you next time.

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