Registration & Listing Requirements for In Vitro Diagnostic Products (IVDs), Including Laboratory Developed Tests (LDTs)
December 3, 2024

Moderator: CDR Kim Piermatteo

CDR Kim Piermatteo: Hello and thanks for joining us for today's CDRH Webinar. This is CDR Kim Piermatteo of the United States Public Health Service and I serve as the Education Program Administrator in the Division of Industry and Consumer Education within CDRH. I'll be your moderator for today's webinar.

We are holding today's webinar for laboratory manufacturers and other interested parties to provide information on how to comply with registration and listing requirements for IVDs, including LDTs.

I now have the pleasure of introducing today's presenter, Kimberly Kopecki, Senior Policy Advisor within CDRH's Office of the Center Director. We'll begin with a presentation from Kim and then address previously emailed questions about today's topic.

Before I turn it over to Kim, I'd like to provide two administrative reminders. First, please make sure you've joined us through the Zoom app, and not through a web browser to avoid technical issues. And second, the intended audience for this webinar is industry. Trade press reporters are encouraged to consult with the CDRH Trade Press Team at cdrhtradepress@fda.hhs.gov. And members of national media may consult with FDA's Office of Media Affairs at FDAOMA@fda.hhs.gov.

Thank you all again for joining us, I'll now turn it over to Kim.

Kimberly Kopecki: Thank you, Kim, for the introduction. And thank you to all the participants who have joined the webinar today regarding Establishment Registration & Device Listing Requirements for In Vitro Diagnostic Products or IVDs, Including Laboratory Developed Tests or LDTs.

Today we are going to review portions of the phaseout policy outlined in the preamble to the LDT Final Rule, identify which establishments need to register, explain how user fees for establishment registration are paid, and discuss the process for registering an establishment and listing medical devices.

As outlined in the preamble to the LDT Final Rule, FDA is phasing out its general enforcement discretion approach for LDTs in stages. The second stage under this phaseout policy begins May 6, 2026, when FDA will expect compliance with establishment registration and device listing requirements, among other things, for IVDs offered as LDTs. In today's webinar, we will be providing information on the registration and listing process and how you can meet those stage 2 requirements.

Compliance with registration and listing requirements will have substantial public health value. The collection of this information provides FDA with the location of device establishments and all devices manufactured at those establishments. Knowledge of the location where devices are manufactured allows for effective planning, coordinating, and scheduling of inspections, ensuring that FDA has visibility into the operations and practices at different manufacturing facilities. In addition, compliance with listing requirements will give FDA better information about the universe of IVDs on the market. With greater listing information, FDA can better protect the public through more comprehensive remediation

efforts, among other things. FDA's publicly accessible registration and listing database also gives the public greater knowledge of IVD manufacturers and the range of IVDs on the market, which will benefit patients and providers who seek to better understand the different testing options that are available and the source and location of those testing options. Right now, there is no reliable inventory of IVDs offered as LDTs on the market. More comprehensive information will do a great service to the public and improve patient care.

So how do you know if you need to register your establishment? Registration and listing requirements apply to any person who is engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for human use, subject to certain exemptions listed in the Federal Food, Drug, and Cosmetic Act and under FDA's regulations. Under FDA's regulations regarding establishment registration, an establishment is a place of business or other entity under one management at one general physical location that performs activities on products subject to FDA regulation. For example, a laboratory that manufactures and offers IVDs as LDTs would register as an establishment.

With the phaseout of the general enforcement discretion approach for LDTs, manufacturers of IVDs offered as LDTs generally will be expected to comply with registration and listing requirements in the same way as other medical device manufacturers.

FDA considers one general physical location, also referred to as one geographic location, to include separate buildings within close proximity, if the activities being performed in them are closely related to the same business enterprise, under the supervision of the same local management, and are capable of being inspected at the same time. These must be operating under the same quality management system to be considered a single geographic location for the purposes of establishment registration.

Close proximity is defined as within a campus setting and within three miles or less driving distance of each other. Additionally, the buildings must be within the same state and the same U.S. judicial district court area. These definitions are outlined in the FDA wide establishment inventory procedure, linked on this slide.

To the extent a laboratory has multiple sites in different physical locations, each of these sites would need to be registered separately, unless they meet the attributes listed here to be considered one geographic location. The registered establishment is responsible for compliance with all applicable regulatory requirements for the devices listed under that establishment.

However, as described in the preamble to the LDT Final Rule, FDA intends to generally not enforce registration and listing requirements for certain categories of IVDs, including 1976 Type LDTs, certain Human Leukocyte Antigen (HLA) Tests for Transplantation, Forensic Tests, Department of Defense and Veterans Health Administration LDTs, and Public Health Surveillance Tests. For additional information, please refer to the preamble to the LDT Final Rule.

As described in the preamble to the LDT Final Rule, FDA expects compliance with registration and listing requirements by May 6, 2026, which is the beginning of Stage 2 of the phaseout policy for IVDs offered as LDTs. The phaseout policy applies to IVDs that are manufactured and offered as LDTs by laboratories that are certified under the Clinical Laboratory Improvement Amendments of 1988 or CLIA and that meet the regulatory requirements under CLIA to perform high complexity testing, and used within such

laboratories, even if those IVDs do not fall within FDA's traditional understanding of an LDT because they are not designed, manufactured, and used within a single laboratory.

If an establishment does not have any devices under commercial distribution as of May 6, 2026, but subsequently places a device into commercial distribution, the establishment must register and list within 30 days of an establishment beginning an activity or putting a device into commercial distribution. As discussed in the preamble to the LDT Final Rule, commercial distribution means on the market. Tests manufactured and performed in a laboratory are considered to be commercially distributed.

Establishments must also register annually, between October 1 – December 31 of each year. An establishment is also required to provide updates within 30 days for changes made to information listed in 21 CFR 807.25(b). Please see 21 CFR 807.22 for additional information on when to file updates.

Initial establishment registration requires the creation of new accounts, and therefore involves more steps than the annual registration. We'll walk through each process in this webinar.

First, we will go through the steps required for initial, or first time, registration. First, for each establishment, an individual must create an account and pay the registration user fee in the Device Facility User Fee or DFUF website. After you create the account and submit the order, you will receive an email with your Payment Identification Number or PIN and instructions explaining how to pay. After your payment is processed, you will receive another email with your Payment Confirmation Number or PCN and next steps.

The next step is to create an account with the FDA Unified Registration and Listing System, referred to in this presentation as FURLS, which also includes the Device Registration and Listing Module, or DRLM. This system houses registration and listing information.

At step 3, the contact person provides necessary information for their establishment. At step 4 they create the device listing. The establishment can list one or more devices at this time. Additional devices may also be added through the account at a later time. At step 5, they review and certify that the information is correct and submit their PIN and PCN to complete the registration. We will review each of these steps in more detail in the following slides.

There is a user fee associated with initial and annual registration of medical device establishments. The registration fee changes from year to year and is announced in the Federal Register prior to the fiscal year beginning that October. The fees are set based on Medical Device User Fee or MDUFA agreements between FDA and industry. The current MDUFA program runs through fiscal year 2027. FDA anticipates a new program will be negotiated and authorized for subsequent years.

In order to register an establishment, one must first create an account in the DFUF website so that they can pay the user fee. If you have never paid a user fee, click the New User link and follow prompts to create your account. Once you have created your account, you will login and follow the prompts to pay the Establishment Registration User Fee for the current fiscal year. You will receive a PIN which starts with 50 and has 5 more digits. After your payment has been cleared, you will receive a payment confirmation number via email. You can pay the fee through credit card, electronic payment, mailed paper check, or wire transfer. We will review these steps in the next few slides.

This slide shows screenshots of the DFUF website, where you will create an account and pay the annual establishment registration user fee. On the main site you will select new user and then you will be prompted to enter your business name, address, and Data Universal Numbering System or DUNS number, if available. If your company can be located by the DUNS number, the business user registration page will be auto populated. If you do not have a DUNS number, or it cannot be located, you will select I am a new Organization and enter the required Business Information fields. After completing the required information, select Submit, where you will receive the confirmation of your registration with the user fee system, as shown on the next slide.

After you have set up your account, you can login at the confirmation screen shown here, or at the main user fee website page. Once you are logged in, you will see the User Fee Website main page. Click on Go under the annual registration option for Fiscal Year 2024 MDUFA Registration, as shown in the screenshot on this slide. Click continue on the next slide, then you will see a page where you can add your registration to your cart for payment. You can pay for multiple facilities by adjusting the quantity.

Once you follow the prompts on the screen and confirm billing information, you will select submit order. Next, a new page will appear which will contain your PIN number and payment instructions. From there, you can either create another order, or choose to make your payment. If you pay by credit card or electronic payment, it will take two to three days to process the payment. If you pay by check or wire transfer, please write your PIN on the check or wire transfer. It can take seven to ten days to process payments made by this method. Once the payment is processed, you will receive a Payment Confirmation Number or PCN.

If you pay for more than one establishment at the same time, then each order will have the same PIN but there will be a separate PCN for each establishment which starts with the two digits of the Fiscal Year you are making the payment for.

Once you have paid the fee and have your PIN and PCN, you are ready for your initial registration, meaning you are ready to register the establishment for the first time. All registration and listing information is submitted electronically using the FDA Unified Registration and Listing System, or FURLS, which contains the Device Registration and Listing Module, or DRLM. This system houses establishment registration and device listing information.

You will be required to create an account in FURLS. The first account you create is the Owner or Operator Account. You will be assigned an Owner Operator Account ID. If the owner operator contact person will also be the official correspondent, no account other than the owner operator account will be required. If the owner operator contact person and the official correspondent will be two different people, you will need to create a sub-account under the owner operator account for the official correspondent. If a sub-account is created, the official correspondent will have a separate Account ID and password.

The owner operator account allows the owner operator contact person to make more changes to the registrations under this account than can other types of users. An owner operator can register one or many establishments under their account. You can only have one owner operator contact person. However, you may have a separate official correspondent for each registration under the owner operator account.

FDA offers many resources linked here to walk through step-by-step instructions for registering an establishment in FURLS. These resources can also be found on the Device Registration and Listing Homepage.

This slide shows screenshots of the FURLS DRLM system. From the main webpage, click on create new account, then choose the Device Registration and Listing Module box. Follow the prompts and enter the required information. Once your account is successfully created, a confirmation screen will appear which will give you your account ID. Once you have created your account, you will need to login using your newly created login information to continue with registration and listing.

Once you have an account and are logged in to FURLS DRLM, you will create your initial registration. To do so, you will need to provide additional information on your facility. For example, if the official correspondent is different than the owner operator, you will need to provide the contact information for the official correspondent.

This slide shows screenshots of the FURLS DRLM system. Once you are logged in, from the DRLM home page, click on Register a New Medical Device Facility and provide the requested facility information, and then hit next. Again, you can enter in your DUNS number, if available, which will prepopulate this form. Once complete, this will register your establishment.

During the initial registration process, you will be automatically prompted to create one or more associated device listings. You will be asked if you have a premarket submission number. If you are listing an IVD offered as an LDT and do not have a premarket submission number because under the phaseout policy described in the preamble to the LDT Final Rule, FDA does not expect compliance with premarket review requirements until stage 4 or stage 5 of the phaseout policy, or because the IVD falls within a targeted enforcement discretion policy as described in the preamble to the final rule, select yes and enter 2177 in the Premarket Submission Number field. A list of policy specific product codes will be displayed. Per 21 CFR 807.22(a), if you put a new device onto the market after your initial registration and listing, you must go back into your account and add the new device listing within 30 days of an establishment beginning an activity or putting a device into commercial distribution.

To support implementation of the policies described in the preamble to the LDT Final Rule, we have created policy-specific product codes for manufacturers to use for IVDs offered as LDTs that are subject to the policies described in the preamble. These product codes were created to differentiate the different compliance expectations for IVDs under each targeted enforcement discretion policy described in the preamble, and those that are subject to the phaseout policy but not subject to a targeted enforcement discretion policy. This will help manufacturers indicate if they are offering their IVD under one of the targeted enforcement discretion policies and to help FDA to be consistent with expectations for each IVD.

Because there is currently no reliable inventory of IVDs offered as LDTs on the market, FDA has not made device specific product codes for IVDs offered as LDTs and is not expecting you to choose a device-specific product code when listing your device. However, you are welcome to utilize device specific product codes if they are applicable to your device, in addition to these policy-specific product codes. Please reach out to the Registration & Listing Helpdesk for assistance in listing device specific product codes.

Here we provide the remaining LDT product codes. Note that all of these product codes are identical to those described in our recent webinar on MDR requirements for IVDs.

For each device, you must also provide proprietary or brand names under which the device is marketed. However, an establishment may mark their proprietary or brand name as confidential so it will not publicly display in the public registration and listing database.

Each successfully created listing generates a unique listing number. All registered establishments under the same owner or operator can share the same device listing, instead of having to separately list the same device for more than one establishment. Follow the remaining prompts and review the added device listings, as shown here.

After entering the appropriate information, you will be required to review all the registration and listing information you've entered. During review and confirmation of the information provided, you will need to enter your PIN and PCN number. Once you enter Submit, your owner operator number will appear in the text of the registration confirmation message. The official correspondent will also receive a confirmation email.

After completing this step, your registration and listing information will be forwarded to the Office of Inspection and Investigation, or OII, formerly known as ORA, for assignment of the FDA Establishment Identifier, or FEI, Number. This number is utilized as the medical device registration number and is used by FDA to track inspections and payments. It may take up to 90 days for the Registration or FEI Number to be assigned. If an FEI number was assigned during the eMDR set up process, this FEI Number will be assigned to your registration by OII. When the Registration or FEI Number is assigned to your registration, an email will be sent to the official correspondent.

This slide shows a screenshot of the FURLS DRLM website where you will review the registration and listing information you entered. After reviewing this information, check the box next to certification statement and enter your PIN and PCN and hit submit. After you submit your registration, your owner operator number as well as your device listing number will appear in the text of the registration and confirmation message. The confirmation screen also contains the date your registration expires, all documented facility registration information that you entered during registration, and the fee amount.

Establishments must pay a registration user fee each fiscal year and complete the annual registration between October 1 and December 31 of each year.

First You must pay the annual registration user fee for the fiscal year. This will provide you with a new PIN and PCN for the fiscal year. You must have a separate PIN PCN combination to complete the annual registration for each registered establishment. Next you must log in to FURLS DRLM using your Account ID and password and complete the annual registration for each of your registered establishments. You can edit registration information, deactivate establishments, and edit device listing information during the annual registration process. For example, if you stop marketing a particular device or modified a previously listed device in a way that changes one or more listing element. Finally, you will be asked to review and certify the information you entered and to input your PIN and PCN.

This slide shows a screenshot of the DFUF website where you pay your annual registration fee for the Fiscal Year. You must first login to your Device Facility User Fee website account. When you are at the main user fee website, click on go next to the MDUFA annual establishment registration description. Follow prompts to complete payment for the fiscal year. You will then receive your new PIN and PCN for the fiscal year.

This slide shows a screenshot of the FURLS website where you complete annual registration. Log into your existing FURLS account and select the device registration and listing module.

From the DRLM home page, click on Annual Registration. Follow the prompts within FURLS DRLM to complete annual registration for your establishment, including review and updates, as necessary, to your registration and listing information.

If an establishment no longer performs activities that require registration, the establishment's registration may be deactivated at this time. Instructions explaining how to deactivate a registration can be found on the Registration and Listing website.

Once you have made any necessary changes to your registration and listing information and check the box next to the certification statement, click submit. Then enter your PIN and PCN numbers and submit to complete the annual registration.

For additional information and help in registering your establishment or listing your device, please utilize the following FDA resources. For questions regarding user fees, please reach out to the User Fee Helpdesk. For general information about the registration and listing process or assistance with entering your registration and listing information into FURLS DRLM, please email the CDRH Registration and Listing Helpdesk. For policy or specific questions about requirements for IVDs offered as LDTs, please email the LDT Mailbox. Please note that general questions to the LDT mailbox are being answered in a public manner, such as through guidance, webinars, and website FAQs in the interest of fairness, efficiency, and transparency.

In summary, all establishments that manufacture IVDs, including laboratory developed tests, are generally required to pay the annual registration user fee and register and list the IVDs they manufacture, subject to the targeted enforcement discretion policies outlined in the LDT final rule.

FDA expects compliance with registration and listing requirements for most IVDs offered as LDTs by stage 2 of the phaseout policy described in the preamble to the LDT Final Rule, which begins on May 6, 2026. If a firm owns or operates more than one establishment, the firm can create the registration for each laboratory under its owner operator account. Each device needs its own listing, so if each establishment is manufacturing its own test system, each test system should be listed separately.

Compliance with registration and listing requirements will provide FDA and the public with basic information on the landscape of IVDs offered as LDTs which will benefit patients and providers who seek to better understand the different tests that are available and the source and location of those test options.

The next webinar will occur in February 2025. Please stay tuned in the new year for additional details.

The following slides provide references and resources as mentioned in today's webinar.

This concludes today's webinar regarding Establishment Registration & Device Listing Requirements for In Vitro Diagnostic Products, Including Laboratory Developed Tests. We hope this material was helpful in providing information and resources on how to register your medical device establishments, and list associated IVDs.

Thank you again for attending today's webinar, I will now turn it back to Kim Piermatteo.

CDR Kim Piermatteo: Thank you for that presentation, Kim. We will now transition to address some previously submitted questions related to today's topic. For this segment, I'll read a question aloud and then Kim will provide a response. We will not be taking live questions during today's webinar, therefore, please refrain from raising your hand in Zoom.

Kim let's get started. Our first question is, when will I need an FDA Establishment Identifier, or FEI, number?

Kimberly Kopecki: Thanks Kim. Manufacturers will use an FEI number when they register their establishment and list a device, or when they submit a medical device report, or a correction or removal report. Manufacturers can request an FEI number before submitting an MDR or correction and removal report by contacting feiportal@fda.hhs.gov. Manufacturers will receive an FEI number, if they don't already have one, when they register their establishment.

CDR Kim Piermatteo: Thanks Kim. Okay, so for our next question that question is, what information do I need to apply for an FEI number?

Kimberly Kopecki: Thanks Kim. So you can request an FEI number as noted in the last answer by providing various information to feiportal@fda.hhs.gov. And a list of the information you can provide for the FEI number includes the legal name of the firm being registered; whether you are representing the firm as an Agent or third party; any alternate firm names, including those used for doing business as purposes; the physical address of the firm being registered; the designated mailing address for the firm being registered; the name and contact information of the designated contact person at the facility being registered; a comprehensive list of activities conducted at this specific location for example manufacturing of IVD offered as an LDT; any registration numbers associated with other FDA Centers, if applicable; any former names the firm was known by; and finally any previous addresses linked to the firm.

CDR Kim Piermatteo: Thanks Kim. So for our next question that is, will establishments that manufacturer IVDs offered as LDTs be assigned an FEI number based on their CLIA number?

Kimberly Kopecki: Great question, no, so an FEI number is distinct from a CLIA number, and establishments that manufacture IVDs offered as LDTs will be designated an FEI number following standard FDA procedures. These procedures are not based on CLIA numbers. The registration and listing requirements applicable to IVDs offered as LDTs are the same as those applicable to other IVDs and other devices; FDA did not establish any new registration and listing requirements as part of the LDT rulemaking.

CDR Kim Piermatteo: Thanks Kim. Good pointes. Our next question is, if an entity comprises multiple laboratories that function under the same quality management system and use the same policies and procedures, how does FDA define an establishment for the purpose of registration?

Kimberly Kopecki: Thanks Kim. Again another great question that we've gotten quite a bit. FDA's regulations define establishment in the registration context as a place of business under one management at one general physical location at which a device is manufactured, assembled, or otherwise processed. So one general physical location also referred to as one geographic location includes separate buildings, and could include multiple laboratories, within close proximity if the activities in them are closely related to the same business enterprise, and also under the supervision of the same local management, and are capable of being inspected at the same time.

So all of these locations must be operating under the same quality management system to be considered a single geographic location for the purposes of establishment registration. As noted in the webinar, FDA considers close proximity to be within a campus setting, within three miles driving distance of each other, and within the same state and the same U.S. judicial district court area. To the extent a laboratory manufacturer has multiple labs in different physical locations, each of these labs must be registered separately, unless they meet the attributes listed here. The registered establishment is responsible for compliance with all applicable regulatory requirements for the devices listed under that establishment.

CDR Kim Piermatteo: Great, thanks Kim. Our next question is, if our organization has multiple laboratories that each need an FEI number, can we submit that information all together for example in one spreadsheet or do we need to request each FEI number in an individual email for each laboratory?

Kimberly Kopecki: Thanks Kim. So first the organization needs to determine whether each multiple labs need their own FEI number and if the organization has determined that multiple labs each need their own FEI number, you can submit that information altogether in a spreadsheet or in a single email or whatever would work best for that establishment.

CDR Kim Piermatteo: Okay, thanks for that. Our next question is, is there or will there be a repository for all laboratory establishments registered and LDTs listed with the FDA?

Kimberly Kopecki: Yes, so the FDA maintains a database of establishment registrations and device listings, which lists the medical device manufacturers registered with the FDA and medical devices listed with the FDA, on its website. As described in the preamble to the LDT final rule, the FDA generally expects manufacturers of IVDs offered as LDTs to comply with establishment registration and device listing requirements by May 6, 2026. So once a laboratory manufacturer registers its establishment and lists its devices, the registration and listing information will appear in the FDA's database of establishment registrations and device listings, as it does for all other medical devices. As discussed in the preamble to the LDT final rule, FDA's registration and listing requirements applicable to IVDs offered as LDTs are the same as those applicable to other IVDs and other devices. So FDA did not establish any new registration and listing requirements as part of LDT rulemaking.

CDR Kim Piermatteo: Thanks for that clarification Kim. Our next question is, what is the annual cost for establishment registration?

Kimberly Kopecki: Thanks Kim. Great question. A registration fee is required upon initial registration and annually thereafter for each establishment that requires establishment registration. The annual registration user fee for each fiscal year is provided on the CDRH registration and listing website. The annual registration fee is announced in the Federal Register prior to the fiscal year beginning that October. The fees are set based on Medical Device User Fee or MDUFA agreements between FDA and industry. The current MDUFA program runs through fiscal year 2027. FDA does anticipate a new program will be negotiated and authorized for subsequent years.

CDR Kim Piermatteo: Thanks for that Kim. Okay so we have a couple more questions for today. The next question I have for you is, how does a laboratory comply with MDR requirements before compliance with registration and listing?

Kimberly Kopecki: Sure, so for manufacturers of IVDs offered as LDTs, FDA generally expects compliance with MDR requirements by May 6, 2025, and compliance with establishment registration and device listing requirements by May 6, 2026. So if a laboratory has an MDR to submit to the FDA for their IVD offered as an LDT prior to registration of the associated establishment, and does not already have an FEI number then the laboratory should request an FEI number from FDA. So as noted in previous responses, an FEI number can be requested by emailing feiportal@fda.hhs.gov. And we do want to note there is no fee associated with assignment of an FEI number. And for additional information on MDR requirements please refer to FDA's webinar on MDR reporting for additional information.

CDR Kim Piermatteo: Thanks Kim. Moving on to our next question, that is, how do we list a device that has not been submitted for premarket review to FDA?

Kimberly Kopecki: Thanks Kim. Another great question. So if you do not have a premarket submission number because, under the phaseout policy described in the preamble to the LDT Final Rule, FDA does not expect compliance with premarket review requirements until stage 4 or 5, or because the IVD falls within a targeted enforcement discretion policy then you will enter 2177 into the Premarket Submission Number field when listing the device in the FURLS DRLM database. FURLS DRLM will then display a list of product codes specific to enforcement discretion policies described in the preamble to the LDT Final Rule. Please then select the product code applicable to the policy under which you are marketing your IVD.

CDR Kim Piermatteo: Thanks for that clarification, Kim. Good instructions there. Okay so for our final question for today, that question is, does a laboratory have to register and list their test system if the test system utilizes FDA authorized components such as reagents, instruments, etc.?

Kimberly Kopecki: Yes, so if the test system is an IVD offered as an LDT. For example, a laboratory manufacturing a test system that includes FDA cleared or approved components for an intended use that is not in accordance with the labeled intended use of the FDA cleared or approved components they would be expected to register and list the test system.

So if a laboratory offers a test system that is legally marketed by another manufacturer for clinical use and offers that test system in accordance with the test system's labeled intended use and without other modification, the laboratory is not acting as a manufacturer of that test system and is not subject to FDA's registration requirements or labeling or other requirements. However, when a laboratory manufactures its own test system even if all components of that system, such as assay kits and supplies,

are purchased from other vendors or manufacturers, for example, components, including reagents labeled as analyte specific reagents, or instruments labeled for Research Use Only, then that laboratory is responsible for meeting applicable requirements, including establishment registration and device listing requirements, consistent with FDA's expectations for compliance as described in the phaseout policy described in the preamble to the LDT final rule.

CDR Kim Piermatteo: Great. That will wrap up our previously submitted questions for today. I'd like to thank everyone who submitted questions in advance of today's webinar, as well as to Kim and her team for developing responses to these questions and presenting them today.

At this time, I'll now turn it back over to Kim for her final remarks on today's topic. Kim.

Kimberly Kopecki: Thanks Kim. So as noted in the presentation today, knowledge of the location where devices are manufactured allows for effective planning, coordinating, and scheduling of inspections. It also gives FDA better information about the universe of IVDs on the market and provides publicly accessible information on the IVDs on the market which will in turn benefit both patients and providers. So we hope this information was helpful for today and we thank you for joining the webinar. I'll now turn it back to Kim.

CDR Kim Piermatteo: Thanks again Kim. For your information printable slides of today's presentation are currently available on the CDRH events webpage for this webinar, as well as on CDRH Learn at the link provided on this slide under the section titled "In Vitro Diagnostics."

A recording of today's webinar and a transcript will be posted to the webinar webpage and CDRH Learn within the following week. A screen shot of where in CDRH Learn you can find these materials has been provided on this slide.

If you have additional questions about today's webinar, feel free to reach out to us in DICE at DICE@fda.hhs.gov.

And lastly, as Kim mentioned previously, we are planning to hold our next IVD related webinar at a date to be determined in February 2025. Once this date has been confirmed, you will be able to find information on how to attend this webinar and any of our upcoming webinars on our CDRH Events page at www.fda.gov/CDRHEvents.

Thank you all again for joining us. Have a great rest of your calendar year 2025! This now concludes today's CDRH Webinar.

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