Device Registration and Listing: An Introduction – Part 2

Slide 1
Hello! I'm Elias Mallis, Director of the Division of Industry and Consumer Education in the Center for Devices and Radiological Health, at the U.S. Food and Drug Administration. Welcome to CDRH Learn, FDA's preeminent catalog of multi-media educational modules about medical devices and radiological products! In this module, we're going to focus on one of the most foundational aspects of the medical device regulations: Device Registration and Listing. This is Part 2 of this introduction.

Slide 2
Our introduction has so much information to review, we've divided this into two parts.
We encourage you to watch Part 1 before continuing with this module. In Part 1, we covered the "what," the "why" and the "who"-involved with registration and listing. We defined several terms and principles that we use in Part 2. And importantly, after watching Part 1, you should know if you're required to register and list. If the answer is yes, then you're ready for Part 2. Let's learn how to complete this process.

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In this module, we're going to cover several learning objectives. We'll first list the steps you need to register your establishment. We'll then review the information you need to list your devices. We'll then discuss how you use the electronic systems to register and list – that is, FURLS and DRLM. And we'll get into the details of user fees.

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So, let's start out with a review of the steps to register your establishment. Please make sure to follow these in order.

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The first few steps apply to all establishments, whether you are domestic or foreign. The first step is to pay the annual registration user fee. You can't start the establishment registration process before FDA has received and processed your payment.

The second step is to register your establishment in the FDA Unified Registration and Listing System, more commonly known by its acronym, FURLS. FURLS is the electronic system that the FDA uses for registration and listing. Once in FURLS, you'll then select the Device Registration and Listing Module, or DRLM, to complete the process for registering your establishment.

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In Step 3, you'll now need to provide the necessary information about your establishment. This includes the name of the establishment, the owner operator, and official correspondent. You'll also provide your contact information, establishment website address if you have one, and any trade names used by your establishment.

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Now for this 4th step, if this is your initial registration and you are not an initial importer, you'll need to create at least one device listing. Any device you intend to list must be legally marketed. For the most part, this will mean that the device is either exempt from a premarket submission, or that you've submitted a submission and received marketing authorization on your device from the FDA. For

example, substantial equivalence for a premarket notification or 510(k); approval of a premarket approval, or PMA; approval of a humanitarian device exemption, or HDE, or granting order for a De Novo Classification Request.

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Now at Step 5, you provide all proprietary names under which your device is marketed in the United States. You may mark this information as "confidential" so that the name will not publicly display in the FDA's public registration and listing database.

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These remaining two steps apply only to foreign establishments. In Step 6, you identify all persons you know who import, or offer for import, your product into the United States.

In Step 7, you identify a U.S. Agent who must confirm that they are the U.S. Agent for you as a foreign establishment. Please note that if this is not done, the FDA may place your establishment in a "failed to register" status.

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Now, if you're an initial importer, your sixth and final step is to identify the manufacturer of the device that you're importing. You may either provide the device listing, if known, or provide the manufacturer's name. Note that the manufacturer should already be in FURLS because they should have already registered themselves and identified you as the importer as part of their registration. Note that FDA does not provide device listing information to an importer, so you'll need to get this information from the manufacturer directly.

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Let's now talk a little about the United States Agent, or the U.S. Agent. The U.S. Agent assists the FDA in communicating with a foreign establishment. The foreign establishment grants the U.S. Agent the authority to act as their official correspondent. The Agent will receive official FDA information or documents and will respond to questions from the FDA about devices being imported.

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The U.S. Agent must reside or have a place of business in the United States. Note that the address cannot be a Post Office Box, or P.O. Box. The Agent has no responsibility to report adverse events nor responsibility to submit marketing submissions. Foreign establishments should update any changes to their U.S. Agent in FURLS and DRLM within 10 business days.

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Now that we've reviewed the steps to register, let's go over the information you'll need to list your medical device.

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You'll need your establishment registration number and name. You'll need to identify the activities that are performed at your establishment, such as manufacturing or labeling.

And you'll need to provide some regulatory information about your medical device. If your device is exempt from a premarket submission, or is considered Pre-Amendments, that is, in distribution prior to May 28, 1976, then you'll provide the product code for the device. Otherwise, we'll generally need the

premarket submission number, whether it be a 510(k), PMA, De Novo, or Humanitarian Device Exemption. Examples of those submission numbers are listed here. Please note that you'll list a device only after you have received marketing authorization from FDA.

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We have a few other details involving device listing. Each device listing that you successfully create will generate its own unique listing number. However, all establishments under a given owner operator will share the same listing number.

Note that you cannot create a new device listing in a few situations: (1) for multiple exempt devices with the same product code, except for manufacturers of export only; and (2) for multiple non-exempt devices with the same premarket number, under the same registration.

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All establishments that must register must also list their devices. The only exception is for initial importers, who are not required to list. Foreign establishments must list their device before it may be imported into the United States. The device list sequence is, first, manufacturer or specification developer, and second, contract manufacturer or contract sterilizer. And for combination products, please identify the combination type for your product, for example, "device-biologic" or "device-drug."

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Let's now get into the details of accessing the FURLS and the DRLM systems.

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So what is FURLS? FURLS is an acronym that stands for FDA Unified Registration and Listing System. This is the web-based, online system to electronically submit information to the FDA. A link to FURLS is listed on the bottom of this slide. Once you're in FURLS, you'll select the Device Registration and Listing Module, or DRLM.

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In rare situations, you may request a waiver from completing your registration and listing through the FURLS electronic system. To do so, we prefer that you email your waiver request to the CDRH FURLS Team at the email address listed here. Alternatively, you may send us a letter to the mailing address listed here.

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Please explain why you're not able to electronically submit this information. FDA will then notify you if the waiver to submit electronically is granted. Please note that you're still required to pay the user fee that's due annually.

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We have two FURLS account types: owner/operator and official correspondent (or OC). This is a good place for an important note that the FURLS account is not the same as your user fee account. Make sure to keep these accounts separate from each other, as you'll need each of them.

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An important thing to keep in mind is your FURLS account password. You'll be required to change this password every 90 days and you'll need your current password to make the change. If you've forgotten

your current password, first try to recover it by clicking the "Forgot Password" link on the login home page. You'll need your Account ID as well as the answer to your secret question. If this doesn't work, then please reach out to the CDRH Registration and Listing Help Desk for assistance. The team's email address is listed here. As a gentle reminder, please do not attempt to create a new FURLS account if you've forgotten your password. We'll help you to re-set your password if you have any problems.

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Let's now get to the two account types, first starting with the owner/operator. The owner/operator account is often referred to as the "enterprise" or "primary account." The owner/operator is assigned to the corporation or proprietor directly responsible for the activities of the registered establishment. The owner/operator may create new FURLS sub-accounts and official correspondent accounts. They may also create, update, and deactivate registrations and listings.

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The second type of account is the "official correspondent", and this is the one created by the first one we just reviewed – the "owner/operator". The official correspondent may complete the registration and listing information for any establishment that is under their responsibility. The official correspondent may create new, or update and cancel existing, registrations and listings assigned to them. They may not change any owner/operator or official correspondent information, as this may be done only by the owner/operator.

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This slide shows how an owner/operator may create multiple official correspondent accounts, each of which may be responsible for one or more establishments. Starting from the top left circle, we have the owner/operator. The owner operator here has created an owner operator account and several official correspondent accounts.

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In order to tell what type of account you have, you can log into FURLS and look for "Edit Account Profile" on the Account Management Menu. If you see the "Edit Account Profile" button, then you're signed in as the owner operator.

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Let's conclude our introduction to registration and listing and Part 2 with a review of user fees for establishment registration.

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Most importantly, all establishments that are required to register must pay the establishment registration user fee. There are no waivers, reductions, or exemptions. To pay the user fee, set up or access your user fee account that's on the Device Facility User Fee website, or DFUF. A link to the website is listed at the bottom of this slide.

Remember, the FURLS and user fee accounts are not the same. They have different IDs and passwords, so please make sure to track these carefully and individually.

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After you paid the annual registration user fee, FDA will email you a payment identification number, or PIN. And after your payment has been fully processed, FDA will email you a payment confirmation

number, or PCN. You'll need both the PIN and PCN to complete your FURLS registration, so please keep a record of these items.

After you receive your PCN, you may then register your establishment in FURLS. Please don't attempt to start your registration before you have both the PIN and PCN. You won't be able to save any information that you complete, and you'll need to re-enter everything when you get back into the system.

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The user fee amount usually changes each year and is set by statute. The user fee cycle runs on a fiscal year, so it runs from October 1 of the current year through September 30 of the next year. I encourage you to go to the website listed here to find the user fee for the current fiscal year.

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FDA offers several methods for you to submit your payment. First, you may pay electronically, with a credit card or automated clearing house electronic check. You can also choose to mail a paper check. If you do so, please make sure the check is drawn on a U.S. Bank in U.S. currency. Make the check payable to "Food and Drug Administration" and make sure to include the PIN. And finally, you may pay with a wire transfer. Keep in mind that you'll need to pay any wire transfer fees if you choose this method.

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We've covered a lot of information on the overview of the registration and listing process. If you have any further questions about this process, please email the FDA Team at: reglist@cdrh.fda.gov.
Now if you have any specific policy questions or import detention issues, please email the second email address listed here: Device.Reg@fda.hhs.gov.

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On this slide, we've listed some of the resources that we referenced during this presentation. Please keep this handy in the future.

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As I've mentioned, this is Part 2 of our two-part overview of the Registration and Listing Introduction. Now that you've watched these modules and understand the overall process, you're ready for our other CDRH Learn modules to help you successfully complete your establishment registration and device listing. If this is your initial, or first, registration, please go to our instructional guide on the top link. If this is your annual registration, then go to the bottom link for that CDRH Learn module instead. This is an important process for all establishments, so we're here to guide you through it!

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Let's now recap what we discussed in this module. First, an establishment follows a series of steps to complete the establishment registration. Specific information is needed to complete the device listing, and FURLS is the online electronic system that you'll use to complete this process. FURLS account types are either "owner/operator" or "official correspondent". And finally, establishments use the DFUF user fee system to pay the required annual registration user fee, and then complete establishment registration.

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We in the Division of Industry and Consumer Education provide you with regulatory education in several key formats, so you can choose the most effective way you wish to learn. CDRH Learn consists of over

200 multi-media industry education modules, such as the one that you're watching here. These include videos, webinars, presentations, and various "how to guides." Use your computer, phone, or portable device to click on the link shown here. Now, if you prefer to learn by reading, check out Device Advice! Device Advice consists of several hundred pages of comprehensive regulatory information across the device total product life cycle. And finally, if you have a specific question and wish to ask us directly, I encourage you to call or email us. Our contact information is listed here, and we look forward to speaking with you.

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Let's conclude this module with your call to action. First, learn the steps you'll need to successfully register your establishment and to list your devices. Second, make sure to pay your user fee before you register and list. And finally, use the FDA educational resources to help you complete the initial and annual registration process. We're here to help. Thank you for your attention to the module "Device Registration and Listing, An Introduction, Part 2." Take care and we'll see you next time!

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