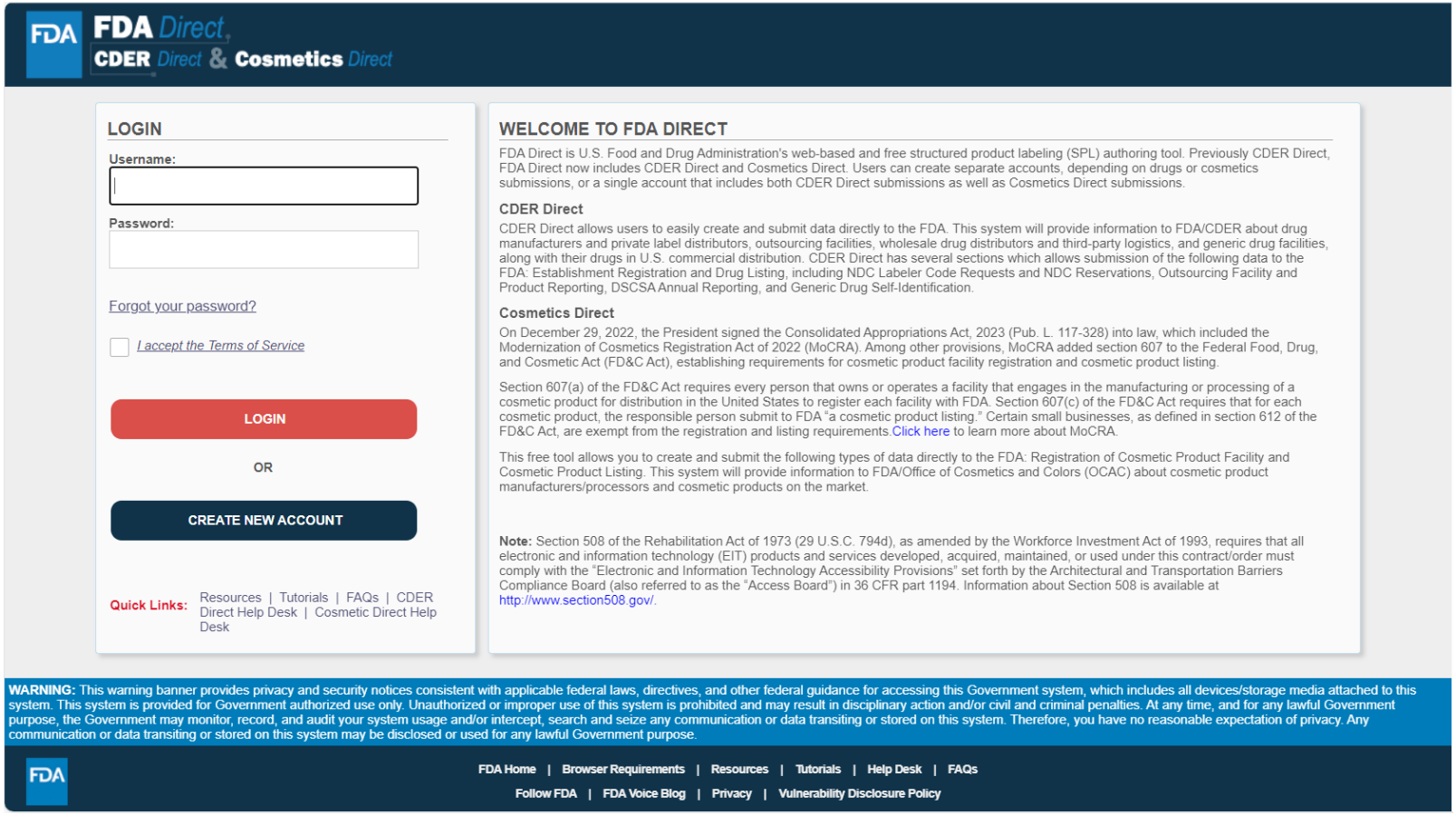
Reference Guide: Blanket No Changes Certification of Product Listing

Welcome to Blanket No Changes Certification of Product Listing in the FDA Direct Portal

This guide provides the essential information on the requirements for certifying drug listings using the Blanket No Changes Certification SPL, applicable only for no changes between October 1 and December 31.

For technical support, email the eDRLS Help Desk at CDERdirect@fda.hhs.gov.



Click here to access the FDA Direct Portal

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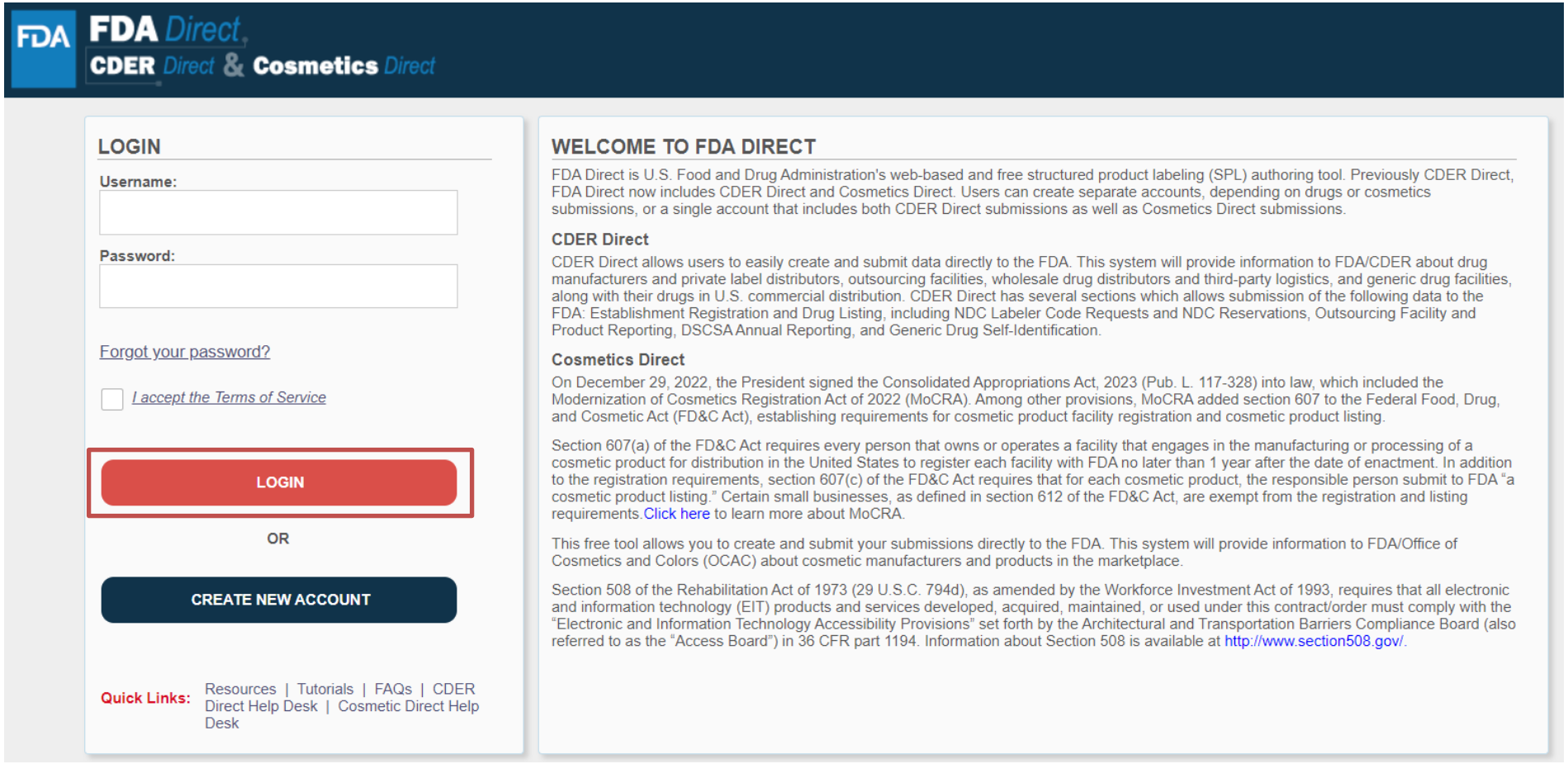
Step 1 Navigate to FDA Direct by accessing: https://direct.fda.gov

Step 2 Enter your login credentials, accept the terms of service, and click **Login**



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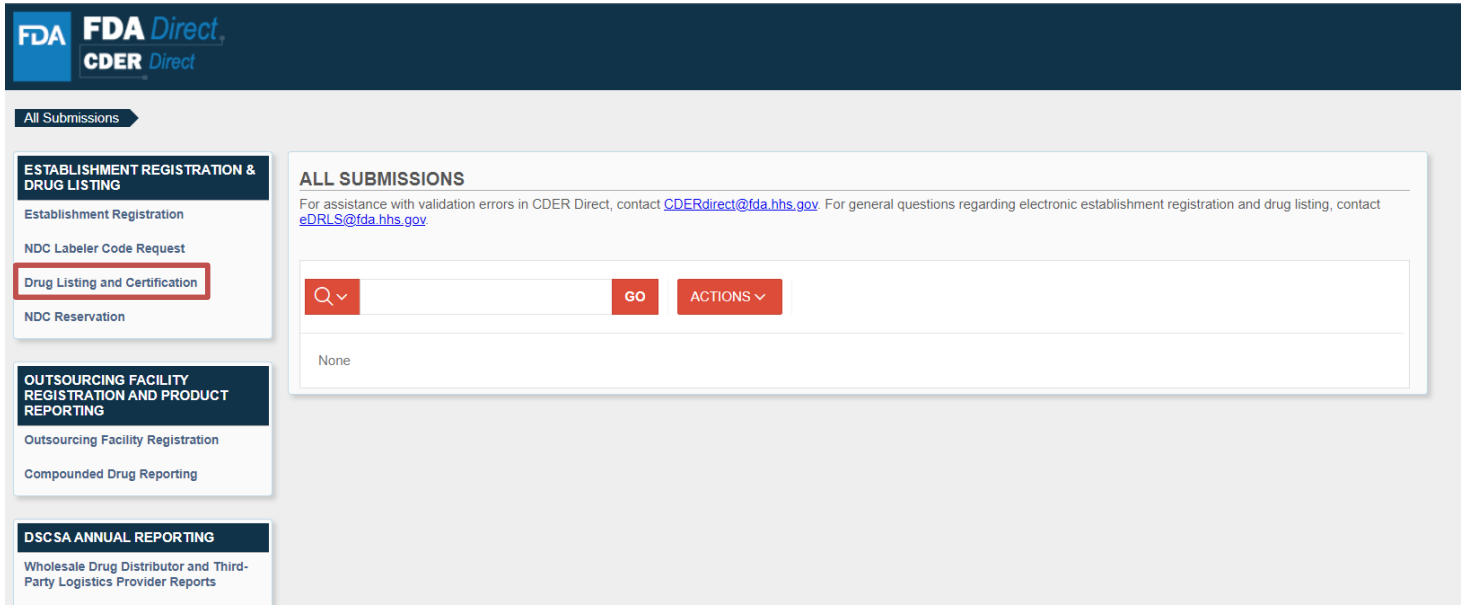
Step 3

Click on **Drug Listing and Certification**

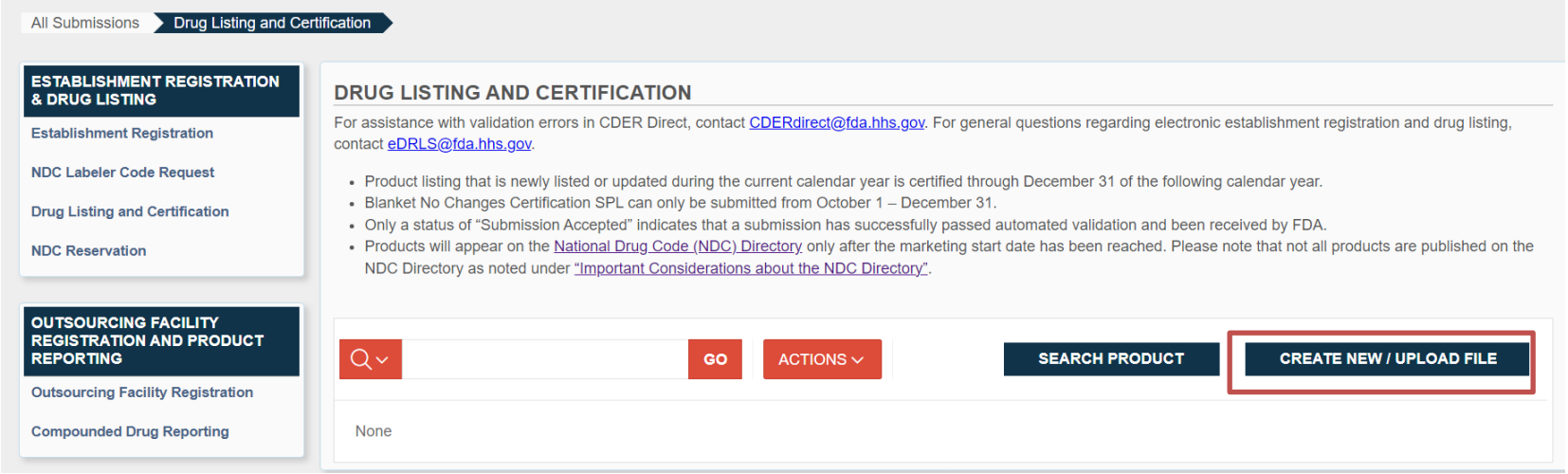


Note:

The Blanket No Changes Certification does not affect Establishment Registration files and cannot be used for establishment registration or to annually renew an establishment registration.

Step 4

Click on **Create New/Upload File**



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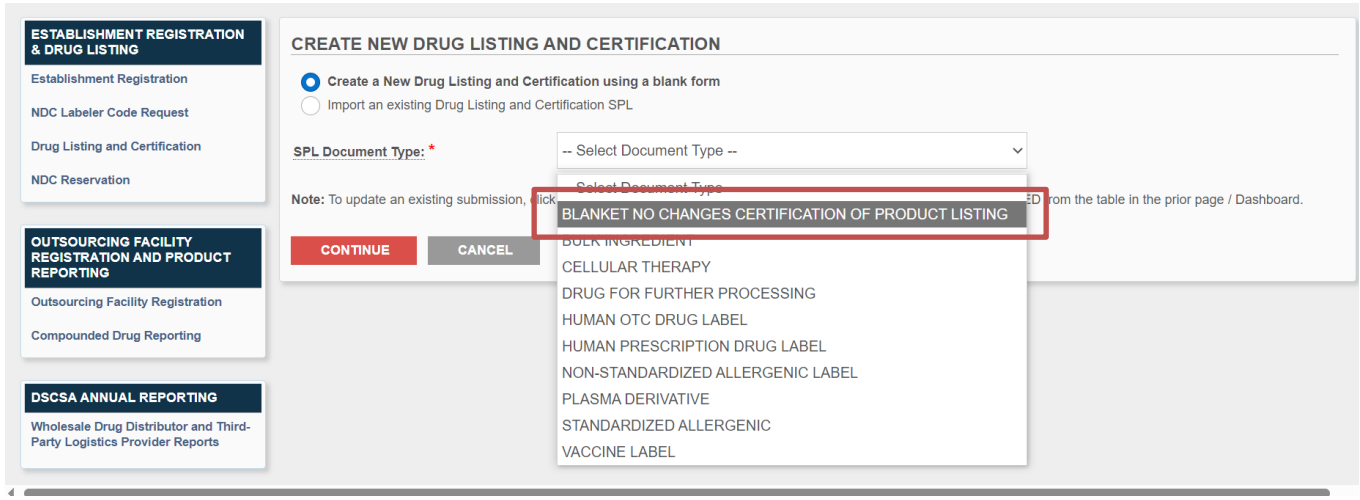
Step 5

Click on **Create a New Drug Listing and Certification using a blank form** and **Select Blanket No Changes Certification of Product Listing** and select **Continue**

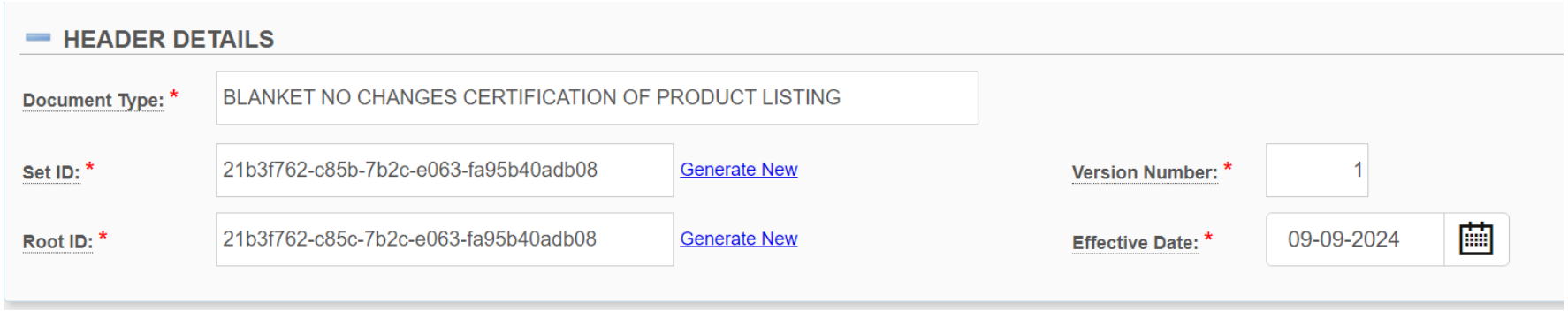
Note: Blanket No Changes Certification of Product Listings can only be submitted between October 1st and December 31st.



Step 6

The information under **Header Details** (Set ID, Root ID, Version Number, Effective Date) will be automatically populated

NOTE: Because this is a single submission every year, you can use the auto generated SET ID and Root ID.



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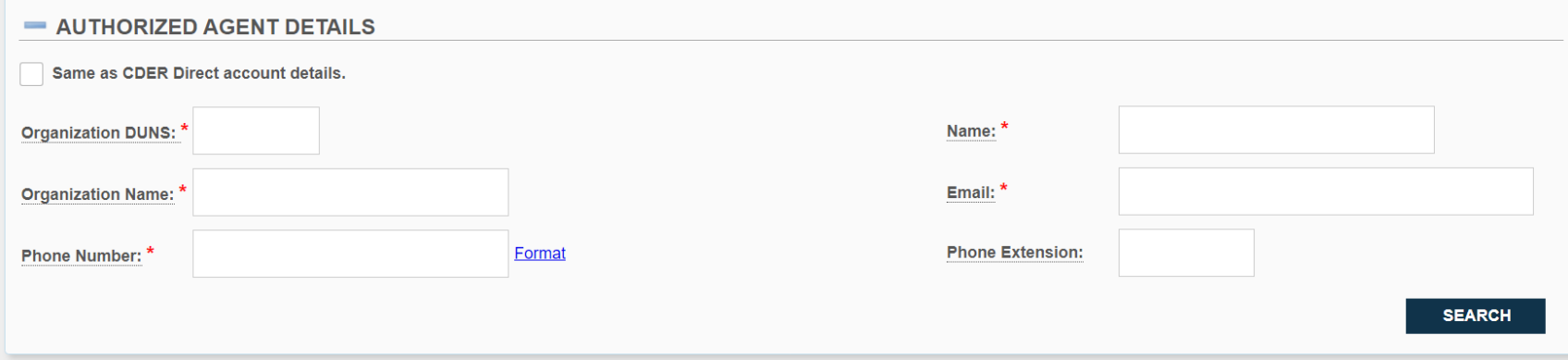
Step 7

Enter the **Authorized Agent Details.** Authorized Agent is generally the same as CDER Direct account owner

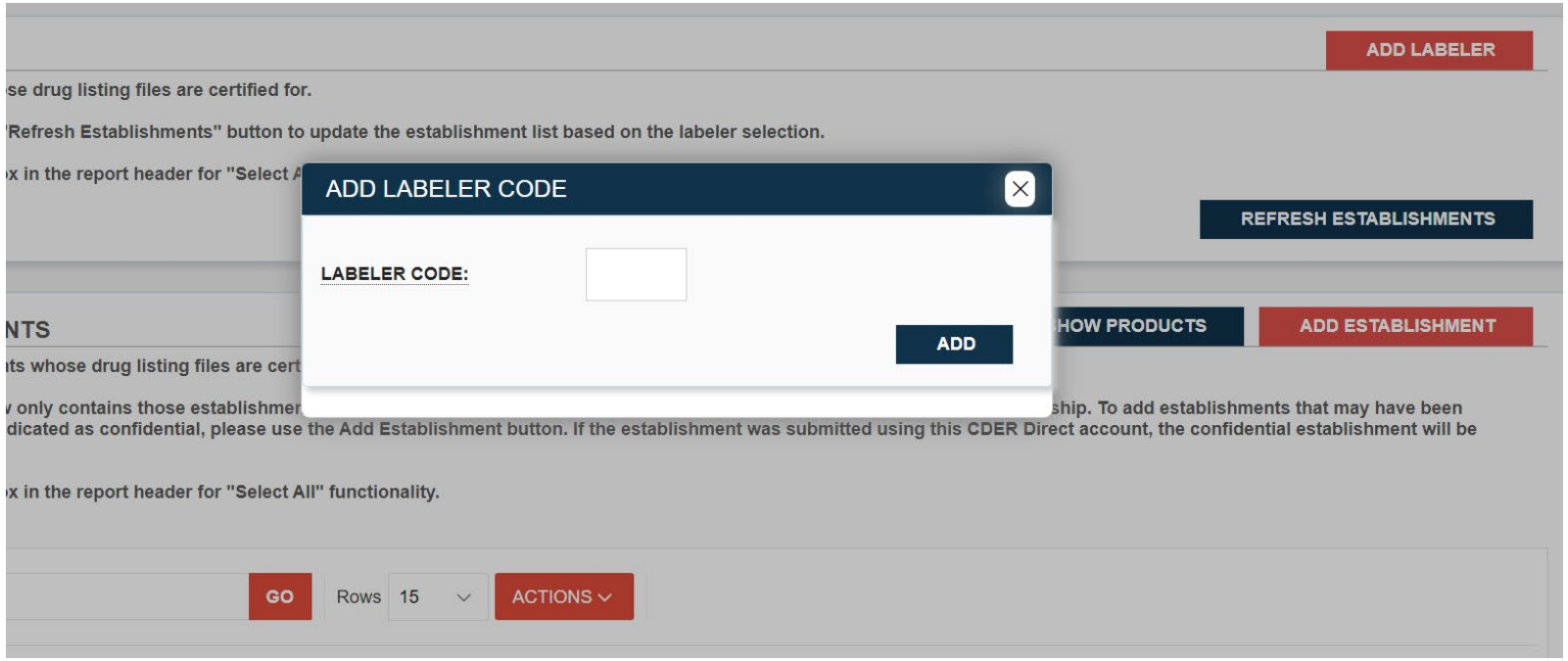


Step 8

Click on **“Add Labeler”** button and enter the labeler code of the product(s) you wish to certify.

Quick Tip!

Clicking on a fieldname that has a dotted underline will bring up Help Text to provide more information as to the type of information being requested



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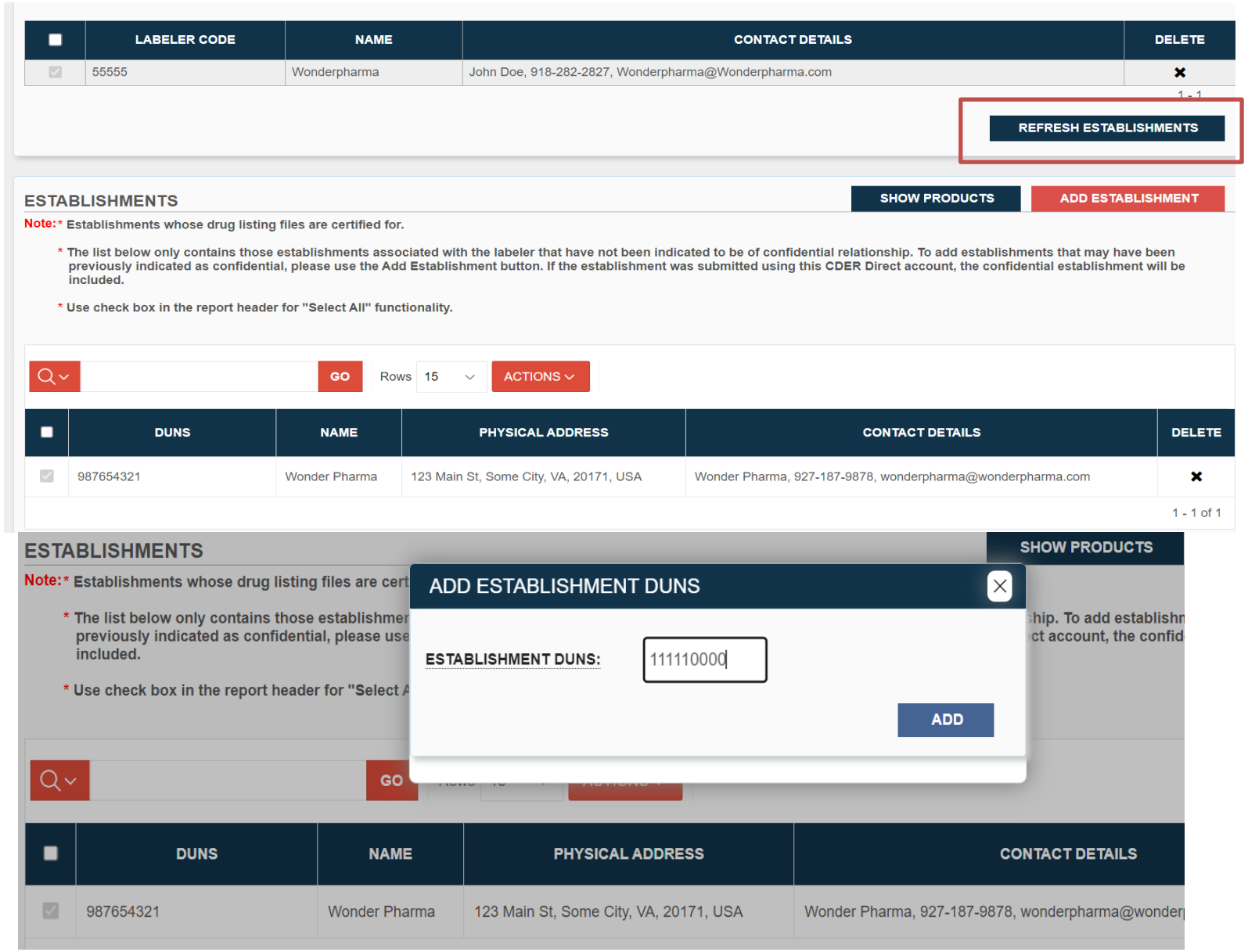
Step 8

“Refresh Establishments” to find all the establishments that are involved with the Labeler(s). products.

Select the **checkbox** to choose all the establishments or just choose specific establishments

Step 9

To add establishments that may have been previously indicated as confidential, please use the **“Add Establishment”** button. If the establishment was submitted using this CDER Direct account, the confidential establishment will be included.



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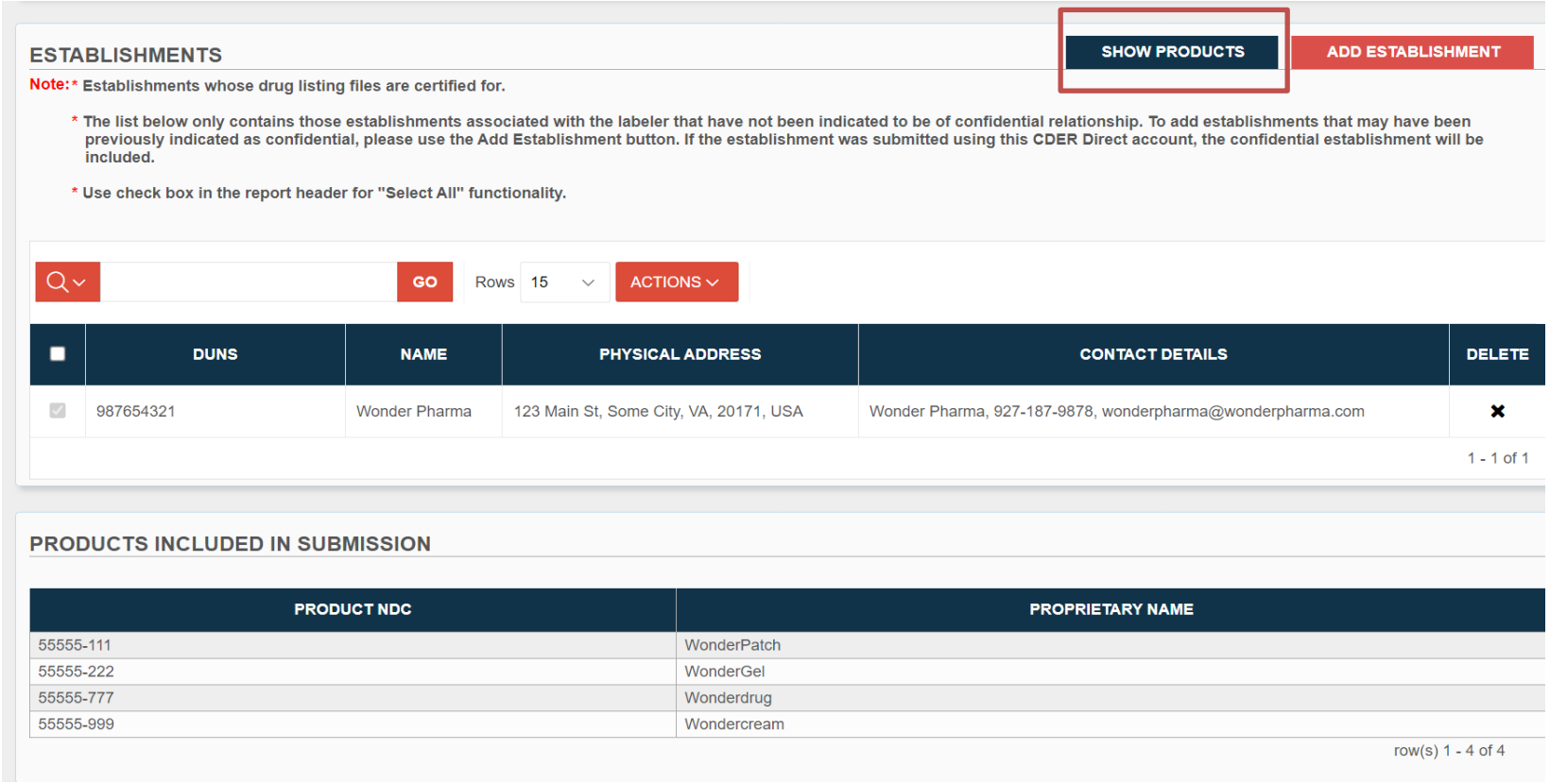
Step 10

Once you have your establishments marked you should select **“Show Products”**. This will result in a list of products where you can choose to certify all or any of the products



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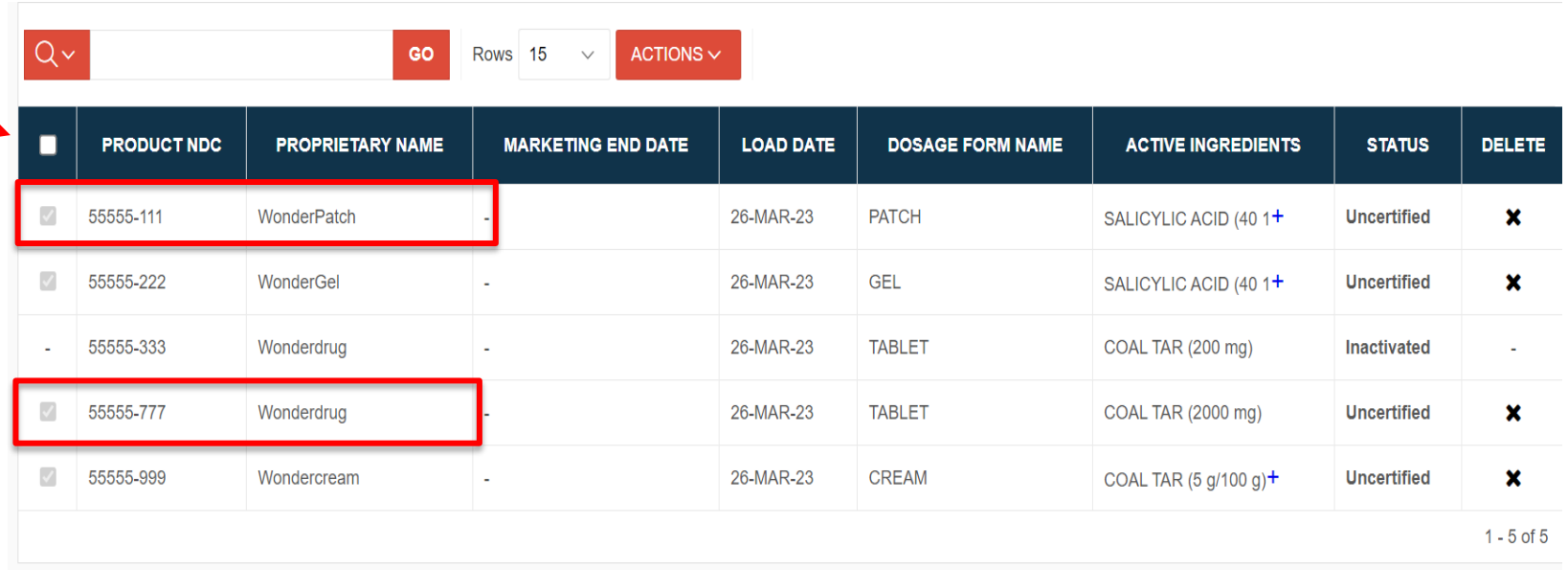
Step 11

Select the checkbox to choose the products you wish to certify. You can select all the products by checking the top



PRODUCT NDC	PROPRIETARY NAME	MARKETING END DATE	LOAD DATE	DOSAGE FORM NAME	ACTIVE INGREDIENTS	STATUS	DELETE
55555-111	WonderPatch	-	26-MAR-23	PATCH	SALICYLIC ACID (40 1+	Uncertified	✖
55555-222	WonderGel	-	26-MAR-23	GEL	SALICYLIC ACID (40 1+	Uncertified	✖
55555-333	Wonderdrug	-	26-MAR-23	TABLET	COAL TAR (200 mg)	Inactivated	-
55555-777	Wonderdrug	-	26-MAR-23	TABLET	COAL TAR (2000 mg)	Uncertified	✖
55555-999	Wondercream	-	26-MAR-23	CREAM	COAL TAR (5 g/100 g)+	Uncertified	✖

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Step 12: After you have selected the products you wish to certify select "**SAVE/UPDATE**"

Note: If you don't find your Product NDC in the list, you can add it using the **"Add Prod NDC"**

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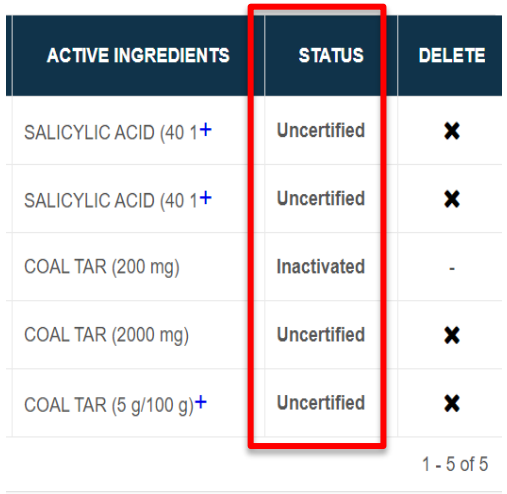
Drug Listing Certification Status Definitions

Certified: This product listing has already been certified. Certification date expires on December 31 of the next calendar year.

- **Uncertified:** This product listing has not been certified for the next calendar year and is available for certification.
- **Pending Compliance Case:** An open listing compliance case exists on this product and the listing data cannot be certified until the case is closed.
- **Completed:** Product is discontinued. The listing data is not available for certification.
- **Current:** The listing data for this product is current because it was either submitted or revised in the current calendar year. No certification is needed.
- **Validation Errors:** The current version of the previously submitted drug/biological product listing file for this NDC or ISBT product item code does not conform to current validation procedures.
- **Inactivated:** The listing data for this product has been inactivated by FDA and cannot be certified.
- **Expired:** The listing data is expired because it was not certified. To change the status to a current listing, submit a new version of the existing listing data



ACTIVE INGREDIENTS	STATUS	DELETE
SALICYLIC ACID (40 1+	Uncertified	✖
SALICYLIC ACID (40 1+	Uncertified	✖
COAL TAR (200 mg)	Inactivated	-
COAL TAR (2000 mg)	Uncertified	✖
COAL TAR (5 g/100 g)+	Uncertified	✖

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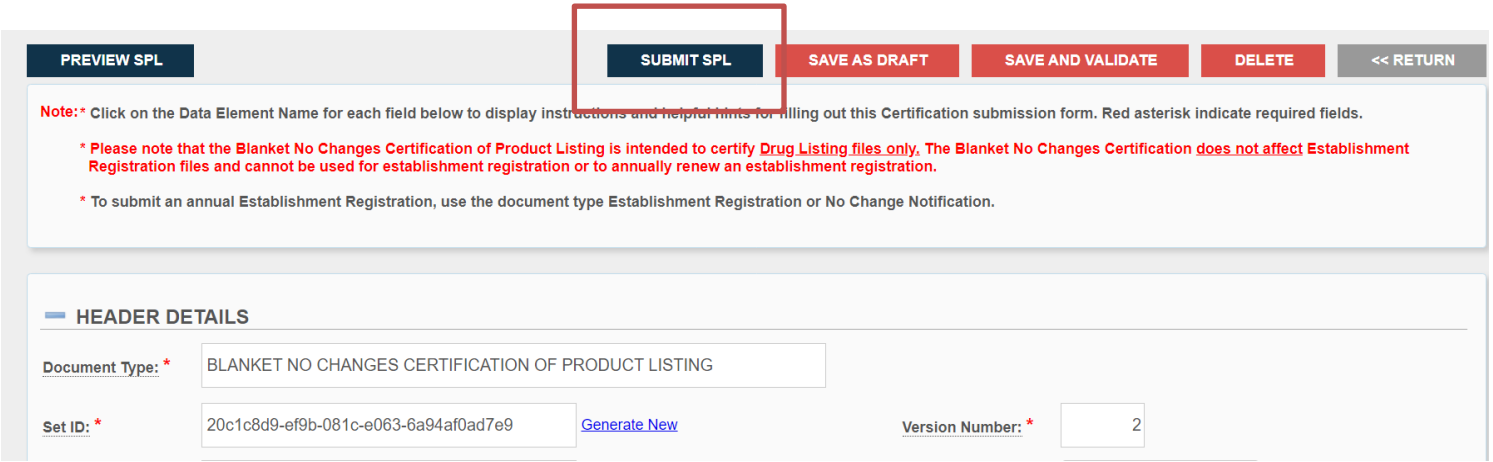
Step 13

Submit SPL



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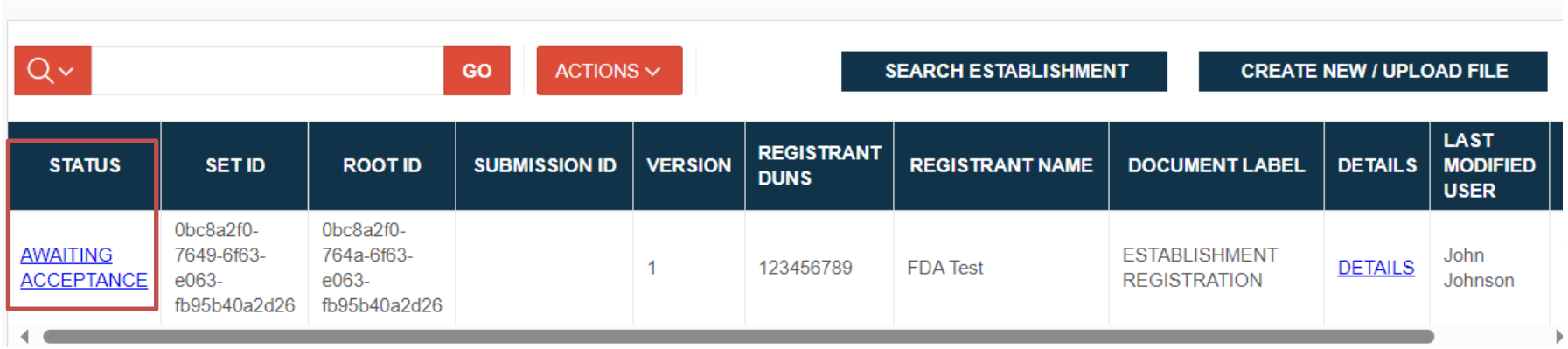
What happens after I click "Submit SPL"?

After clicking on Submit SPL, the submission undergoes an automated, technical validation indicated by the status of "Awaiting Acceptance". This process takes approximately 15 minutes.

If the submission passes technical validation, the status will change to "Submission Accepted".

If the submission fails technical validation, the status will change to "Submission Failed". Click on **Submission Failed** to view and correct the errors identified. Then click on **Submit SPL** to resubmit.



Uploading a Product Listing SPL File

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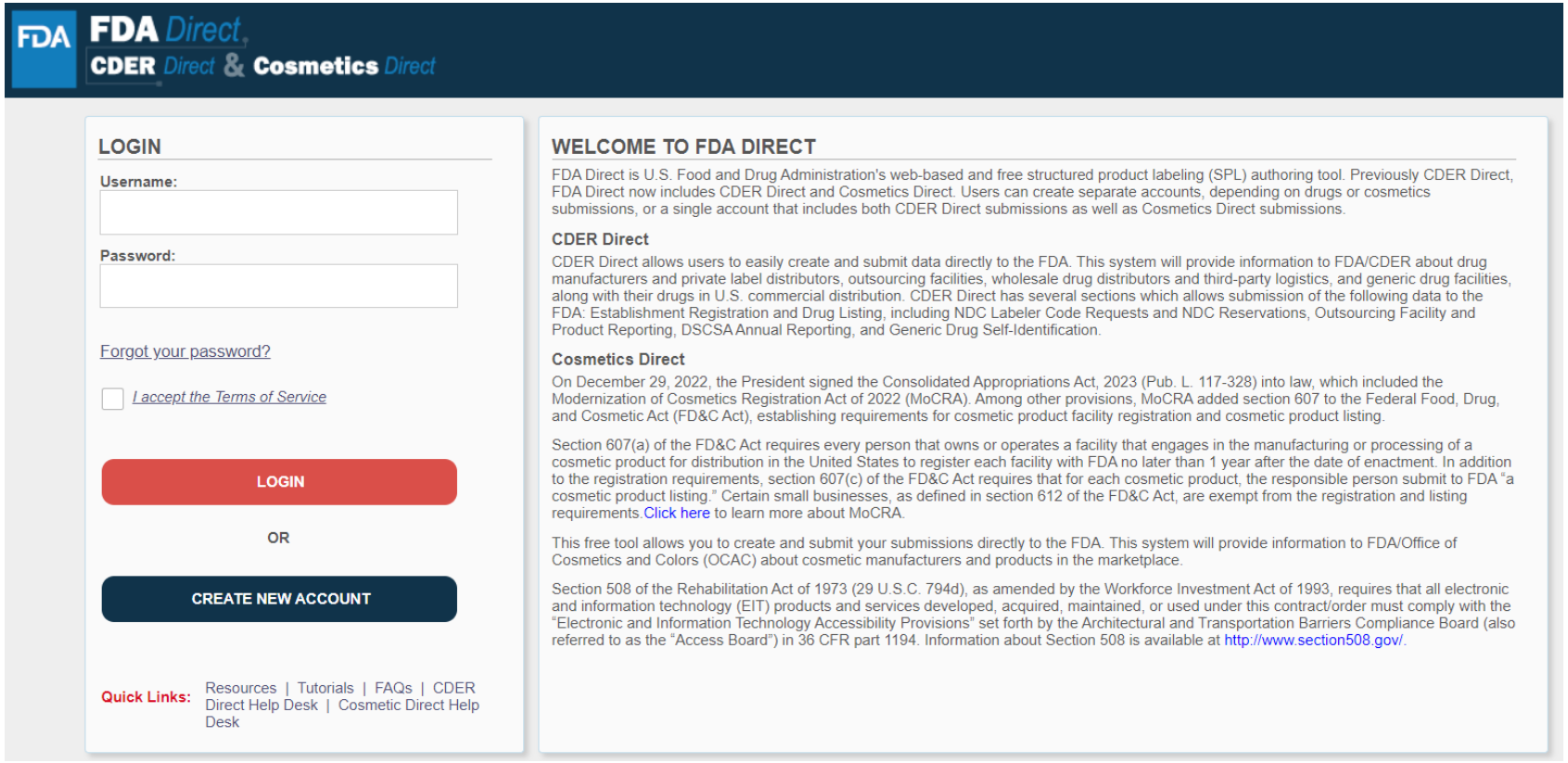
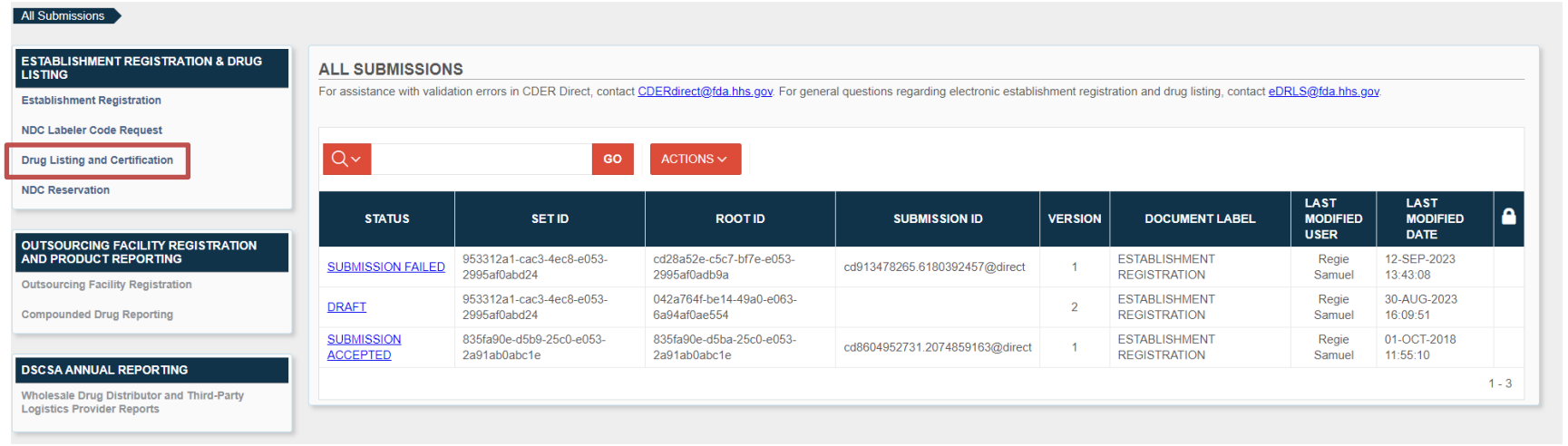


Uploading a Product Listing SPL File

Step 3

After logging in, click on **Drug Listing and Certification** from the navigation pane on the left

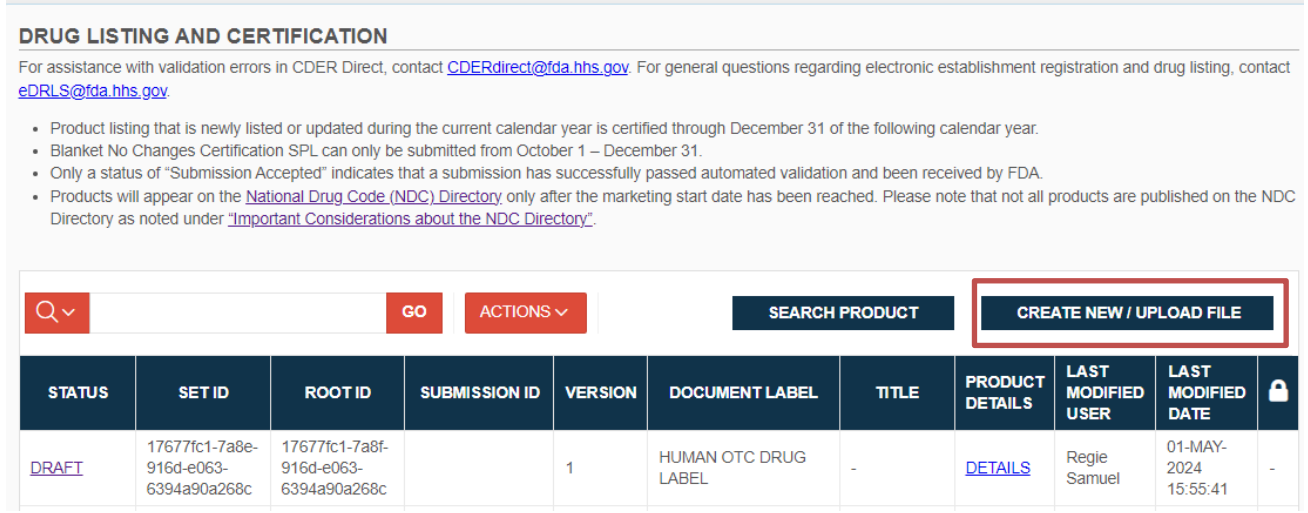


Note:

If you choose to update a blanket no changes certification with the same SET ID, remember to include all NDCs from the previous version or else they will be replaced by the new version.

Step 4

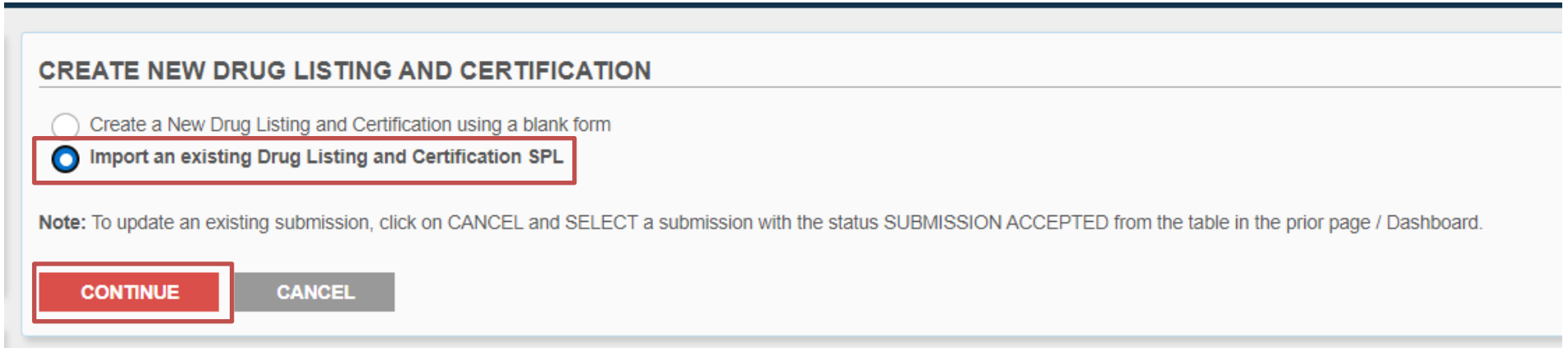
Click on **Create New/Upload File**



Uploading a Product Listing SPL File

Step 5

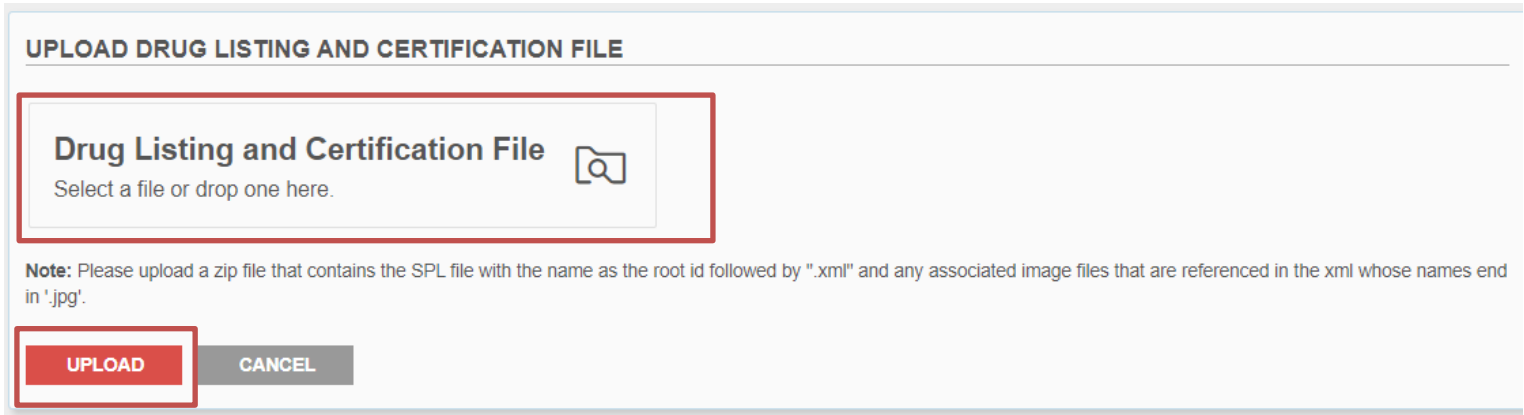
Click on **Import an existing Drug Listing and Certification SPL** and then **Continue**



Step 6

Click on **Drug Listing and Certification File**

Locate and select the Establishment Registration ZIP file to upload into CDER Direct and click on **Upload**



For assistance with errors received in CDER Direct, contact **CDERdirect@fda.hhs.gov.**