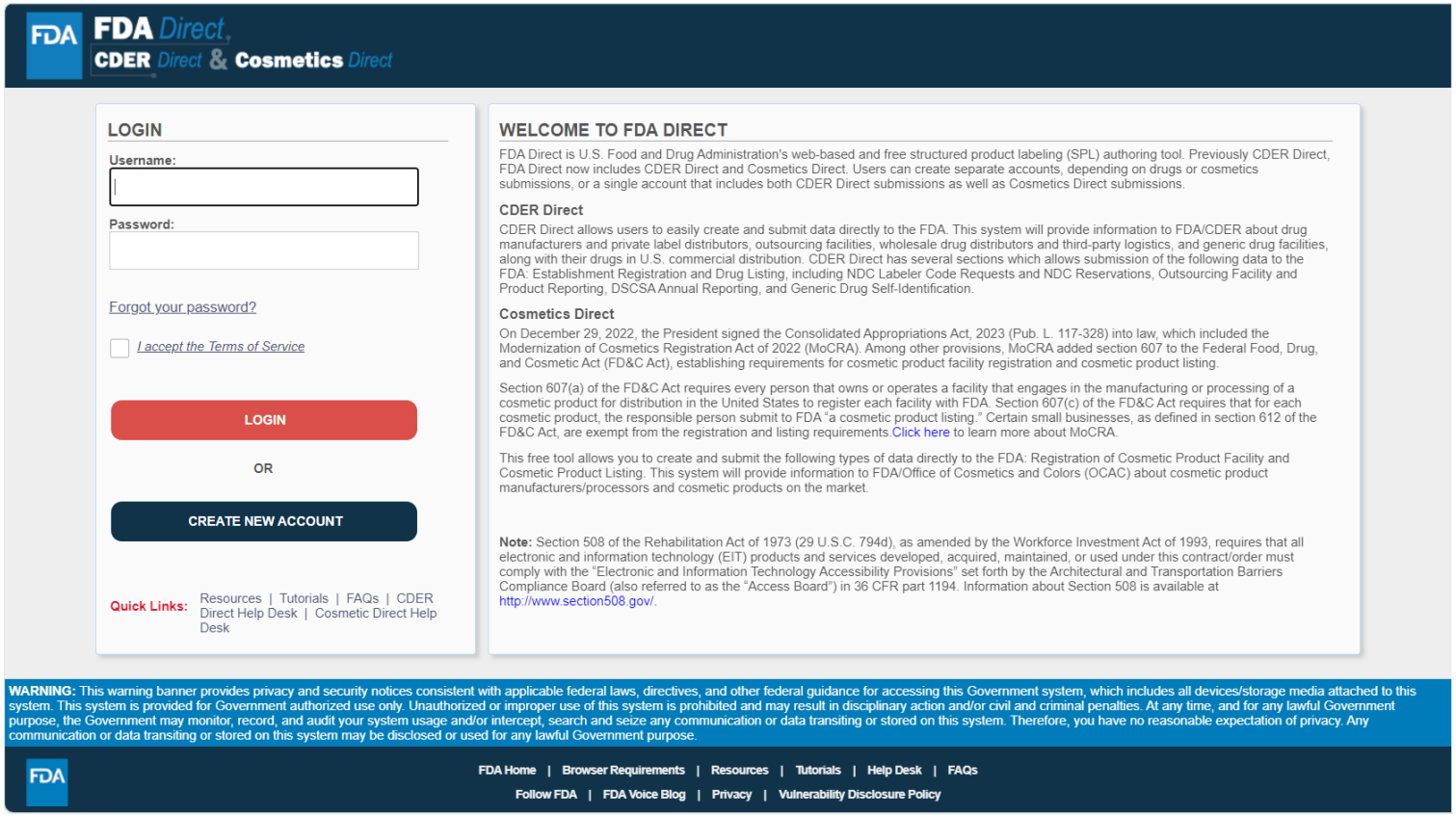
Reference Guide:
NDC Labeler Code Request

Welcome to the NDC Labeler Code Request section of the FDA Direct Portal

This guide provides essential information for requesting a labeler code, confirming a labeler code assignment, or updating labeler code details, and inactivating a labeler code through FDA Direct.

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



Click here to access the FDA Direct Portal

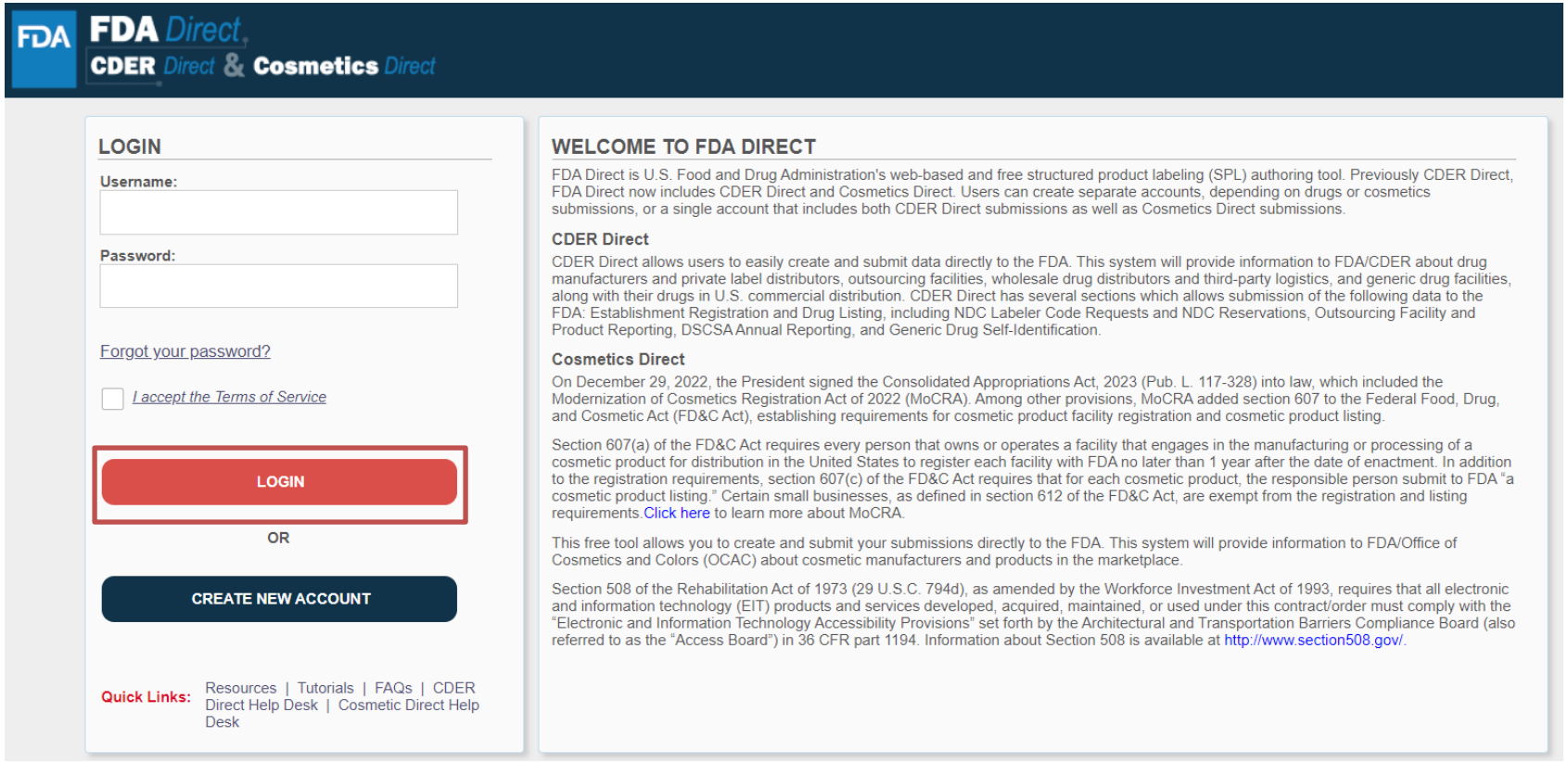
Table of Contents

Requesting a Labeler Code

Requesting a Labeler Code

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

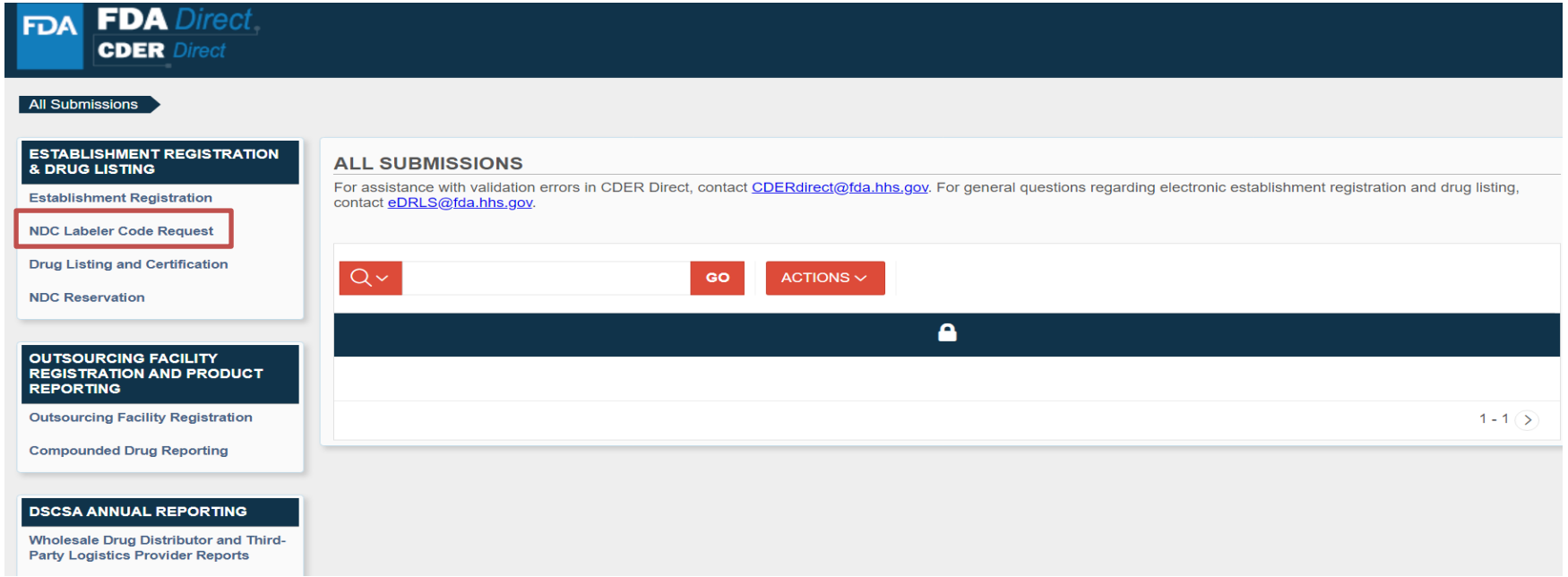
Step 2 Enter your login credentials, accept the terms of service, and click **Login**



Requesting a Labeler Code

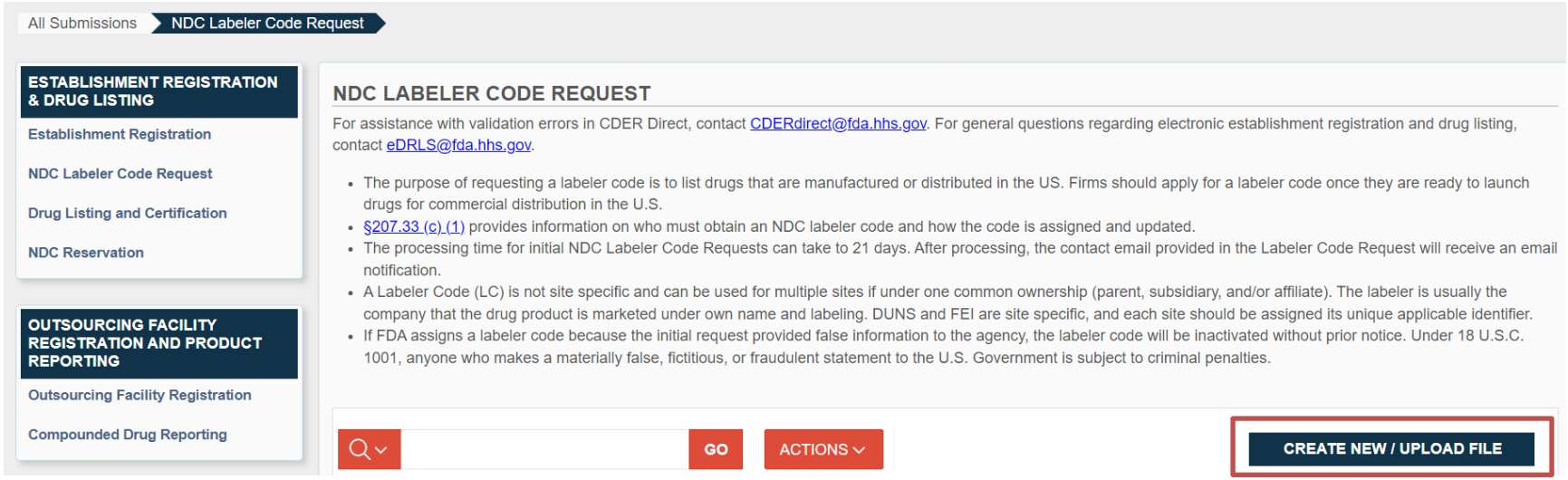
Step 3

Click on **NDC Labeler Code Request**



Step 4

Click on **Create New/Upload File**



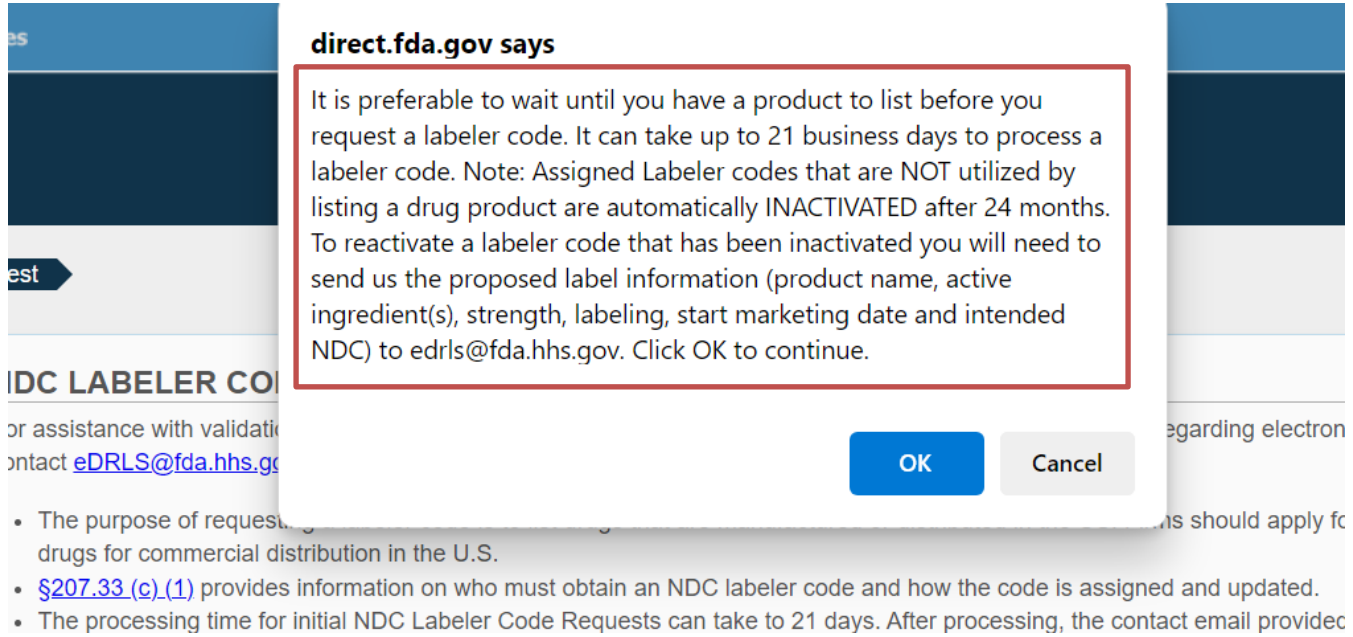
Requesting a Labeler Code

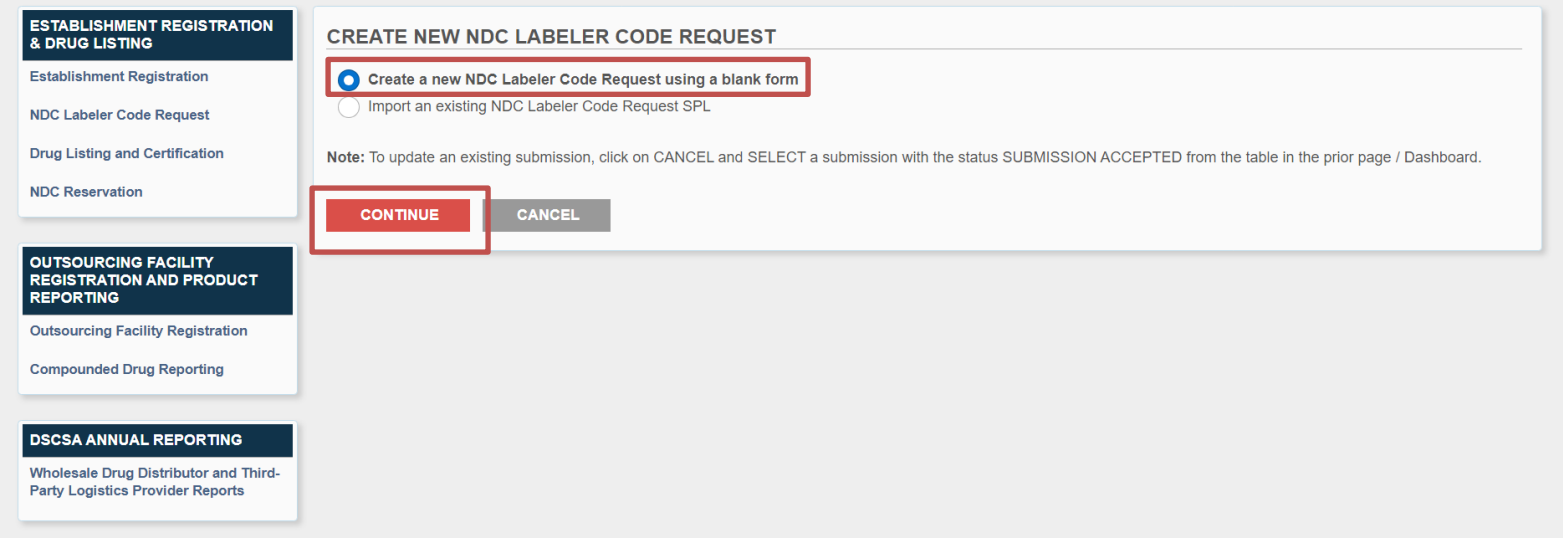
Important Guidelines for Labeler Codes

1. Purpose of Labeler Codes: Labeler codes are exclusively for generating National Drug Code (NDC) numbers for drug products.
2. When to Apply: You only need to apply for a labeler code if you are listing drugs with the FDA.
3. Code Deactivation: If your labeler code is not linked to any NDCs listed with the FDA for two years, it will be deactivated.
4. Multiple Facilities: If your company owns multiple manufacturing facilities, you do not need a separate labeler code for each one. One labeler code per company is sufficient as it identifies the company, not the manufacturing sites.

Step 5

Click on **Create a new NDC Labeler Code Request using a blank form** and then click **Continue**

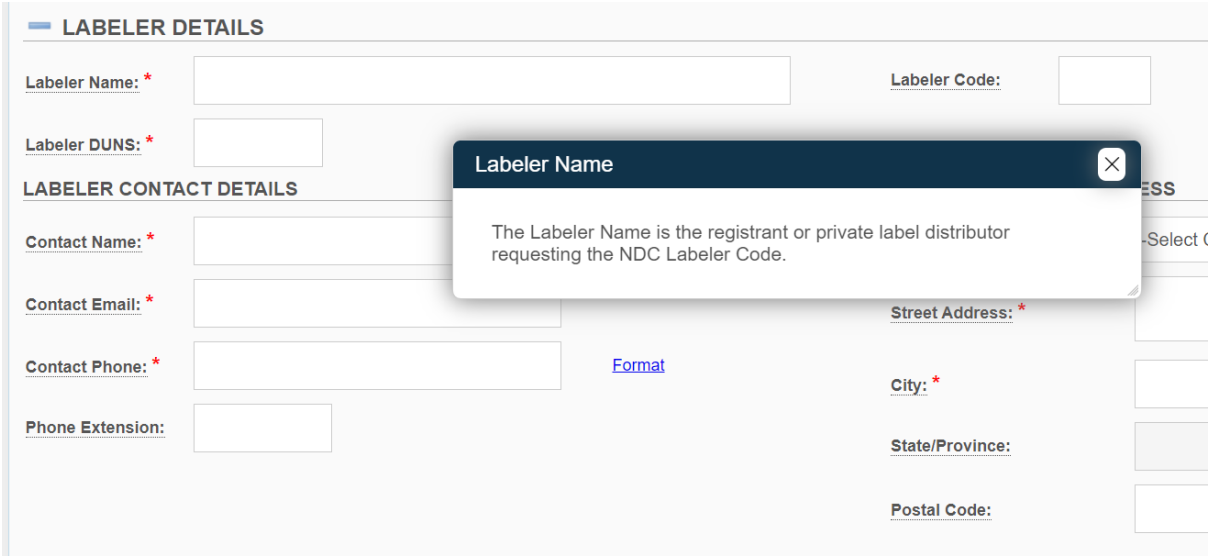




Requesting a Labeler Code

Quick Tip!

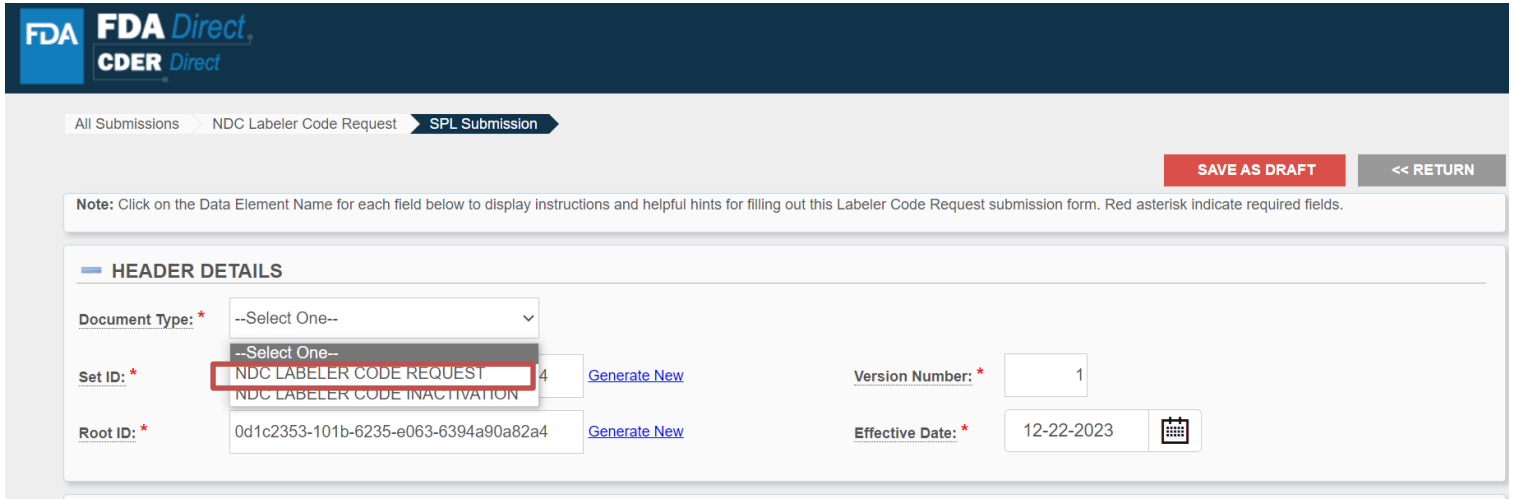
Clicking on a field name with a dotted underline will display Help Text, offering additional information about the type of data being requested



Step 6

In the Document Type drop-down menu, select **NDC Labeler Code Request**

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

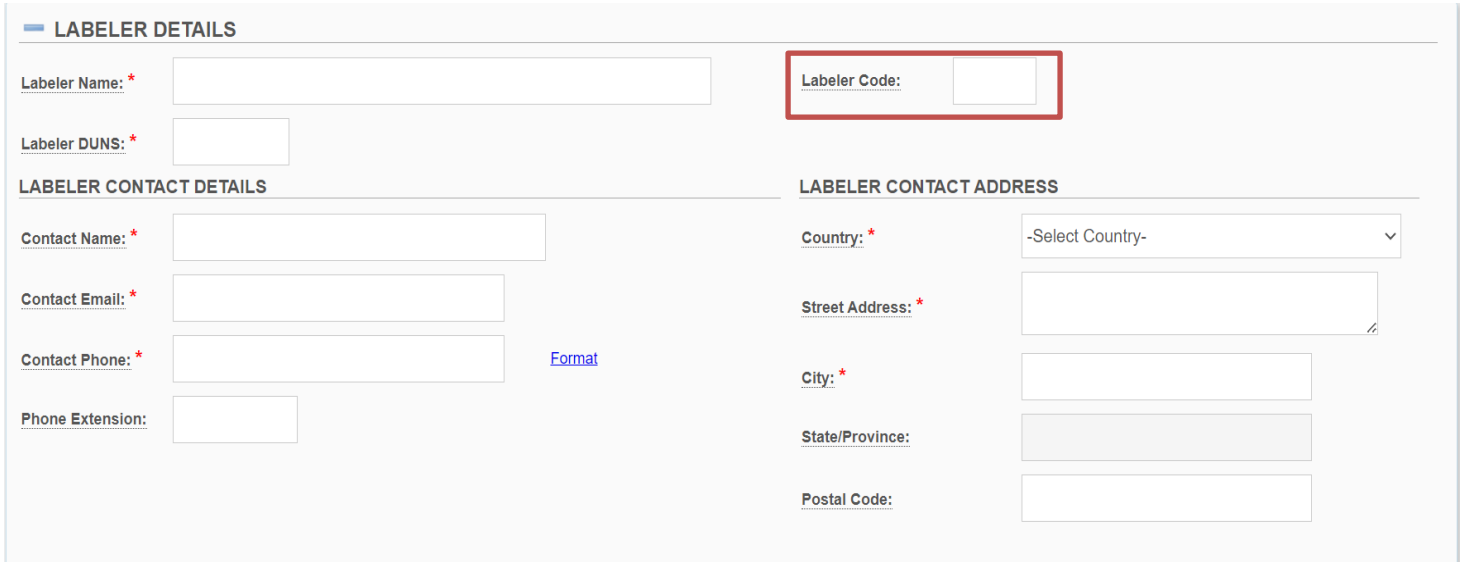


Requesting a Labeler Code

Step 7

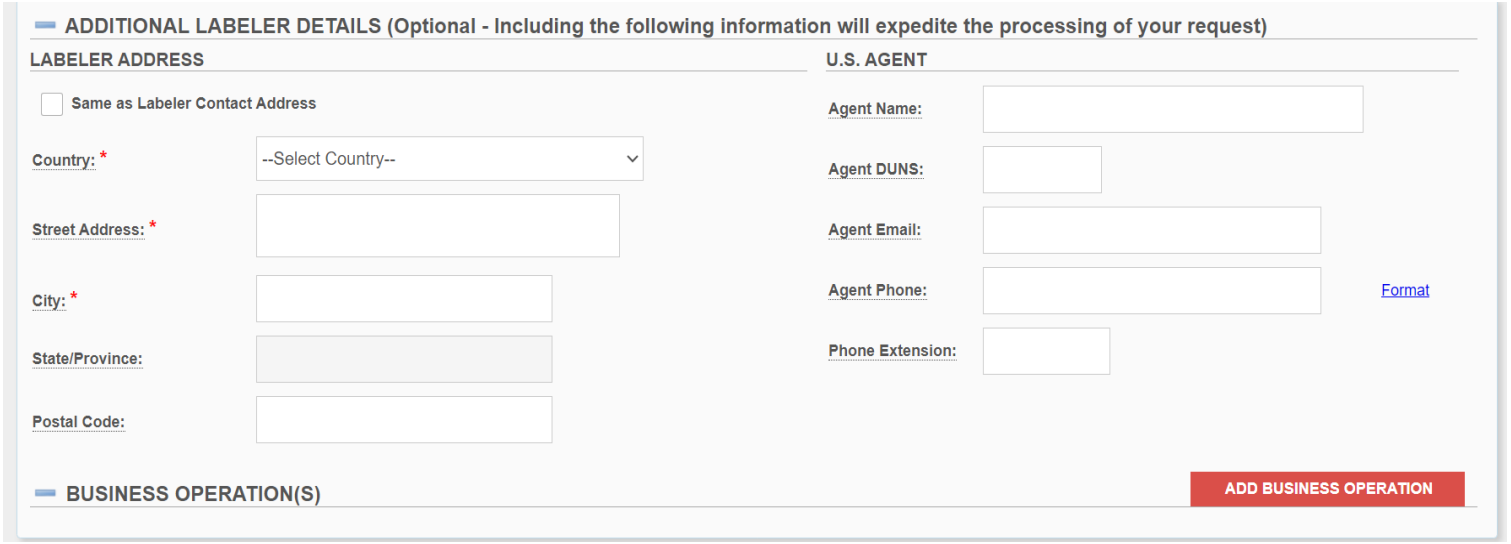
Enter the information for Labeler Details

NOTE: If you are requesting a labeler code, leave this field blank



Step 8

Providing the Additional Labeler Details will expedite the processing of your request



Requesting a Labeler Code

Step 9

Click on **Add Business Operation** to indicate the business operations of the firm requesting the labeler code

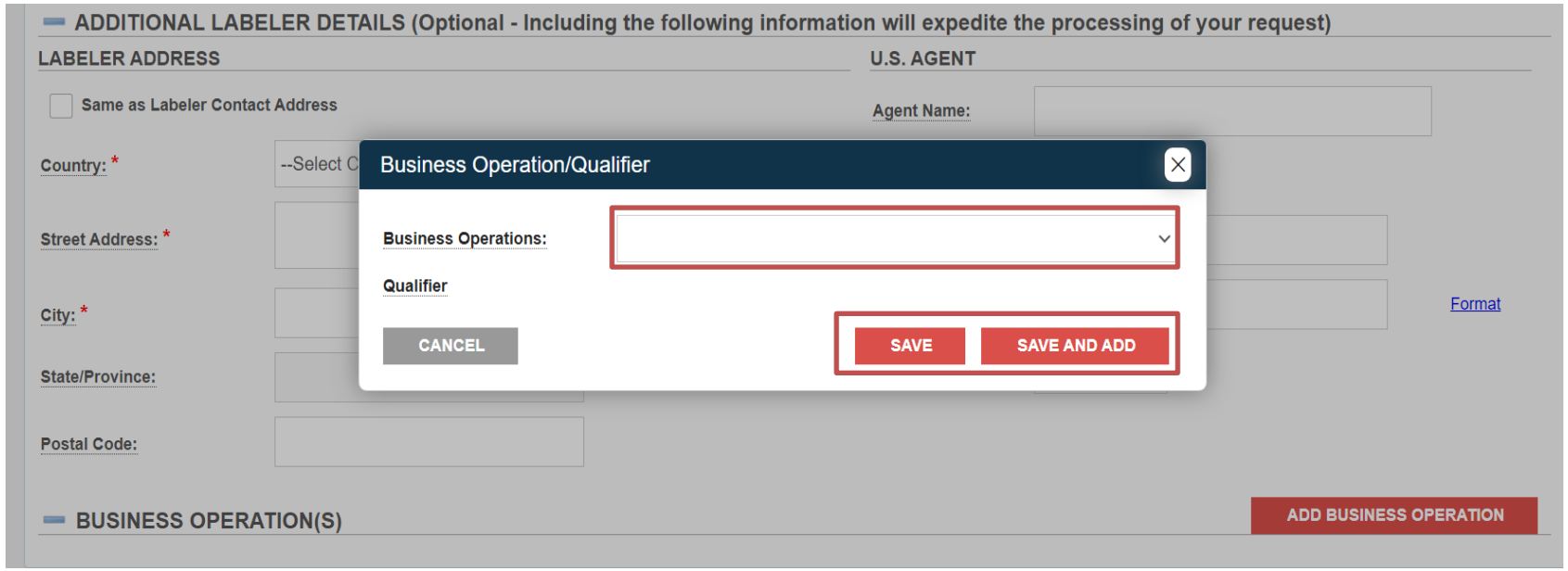
Step 10

Select the Business Operation(s) and associated Qualifier(s) performed by the labeler

Click **Save and Add** to quickly choose multiple business operations

Click **Save** once completed

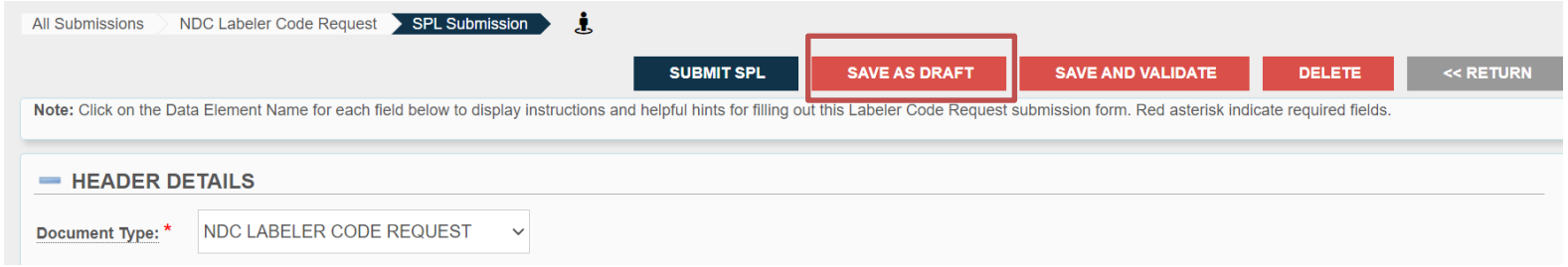
NOTE: Qualifier is required for all Business Operations except for Analysis, API Manufacture, and SIP Foreign Seller



Requesting a Labeler Code

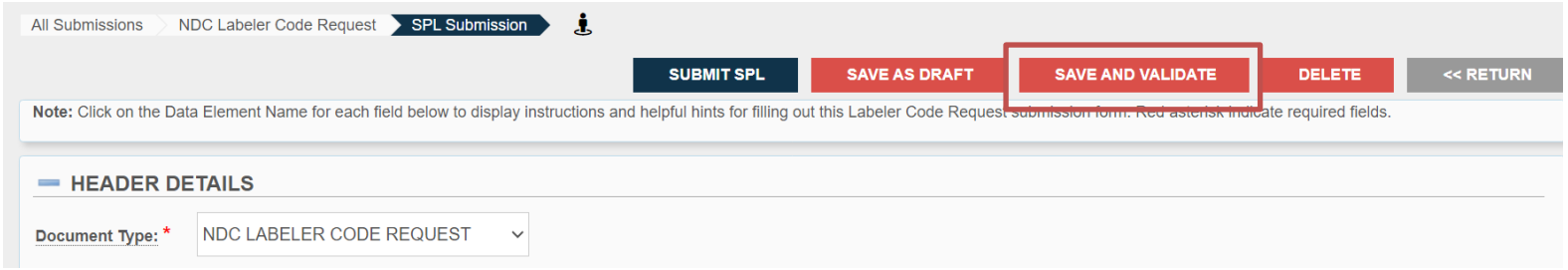
Step 11a

If you need to enter more data, click **Save as Draft** to save your progress and complete your submission at a later time



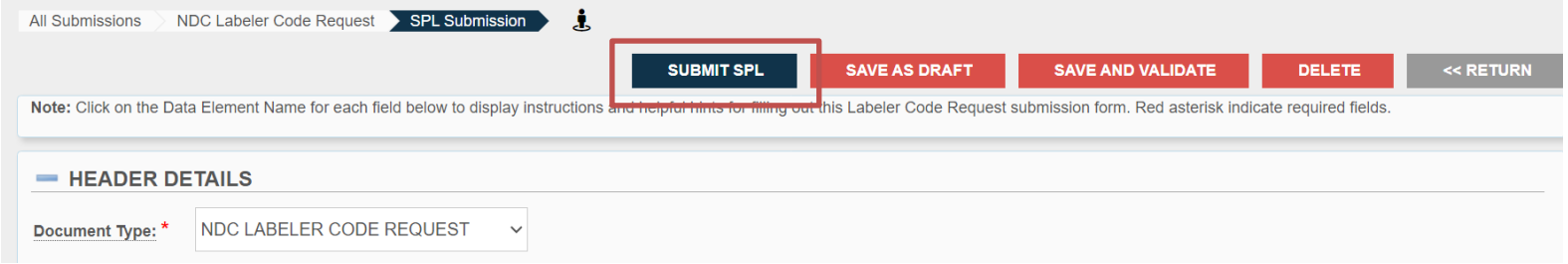
Step 11b

To ensure your submission will pass validation prior to sending it to the FDA, click **Save and Validate**



Step 11c

If completed, click on **Submit SPL** to submit to FDA



Requesting a Labeler Code

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.

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LABELER DUNS	LABELER NAME
AWAITING ACCEPTANCE	59fce009-d61b-4590-e053-2991aa0a83bc	ae2e15e9-1705-296d-e053-2995a90a1b95	cd6045197328.3568207491@direct	2	NDC LABELER CODE REQUEST	987654321	Drug Name

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LABELER DUNS	LABELER NAME
SUBMISSION ACCEPTED	5ac5274b-8bf5-0730-e053-2a91aa0aae64	5ac5274b-8bf6-0730-e053-2a91aa0aae64	cd392145786.6719058342@direct	1	NDC LABELER CODE REQUEST	987654321	Drug Company

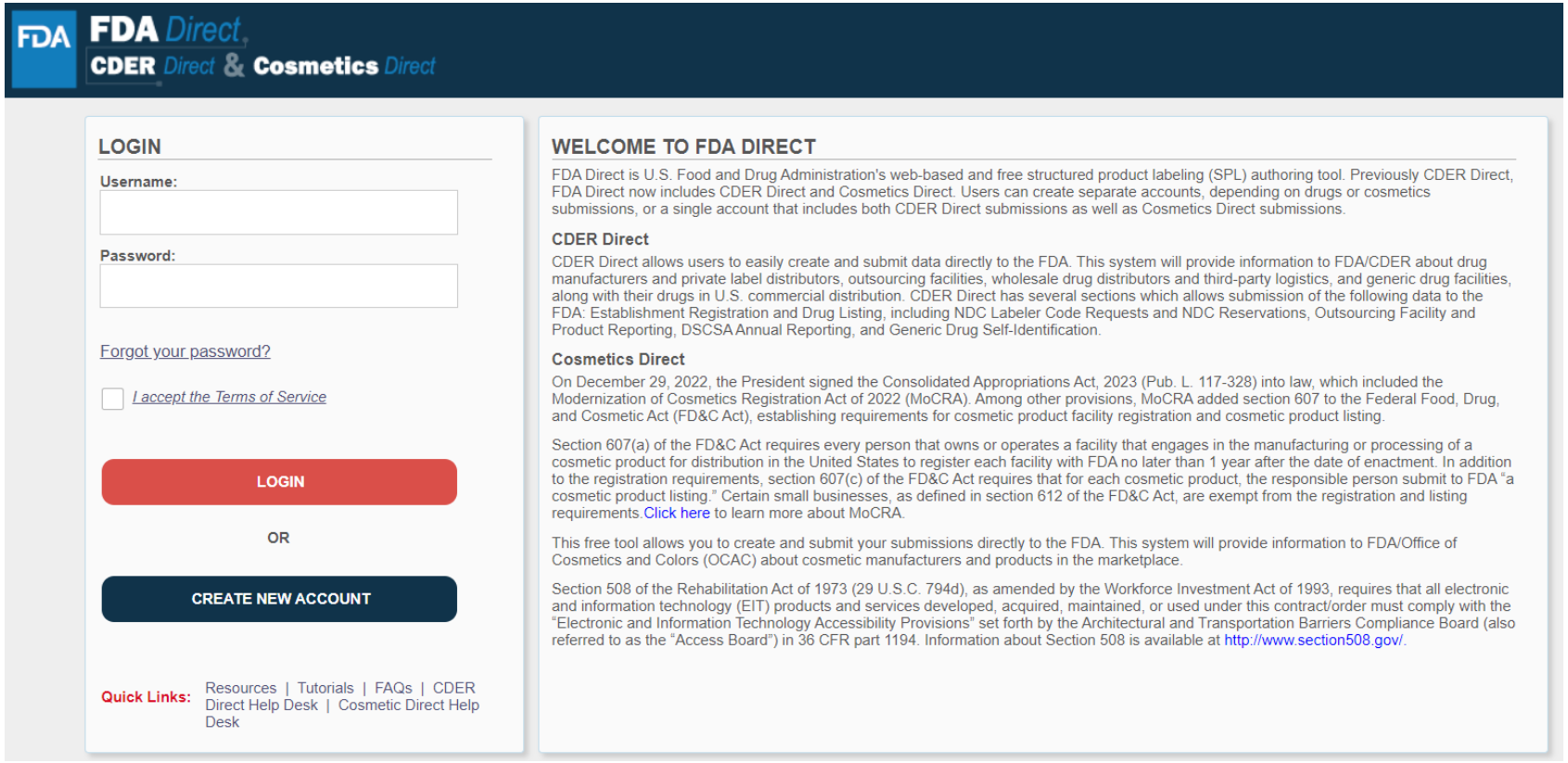
STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LABELER DUNS	LABELER NAME
SUBMISSION FAILED	59ca9536-c241-333c-e053-2991aa0a1038	59ca9536-c242-333c-e053-2991aa0a1038	cd8702419653.5094317862@direct	1	NDC LABELER CODE REQUEST	987654321	Drug Name

Confirming or Updating Labeler Code Details

Confirming or Updating Labeler Code Details

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

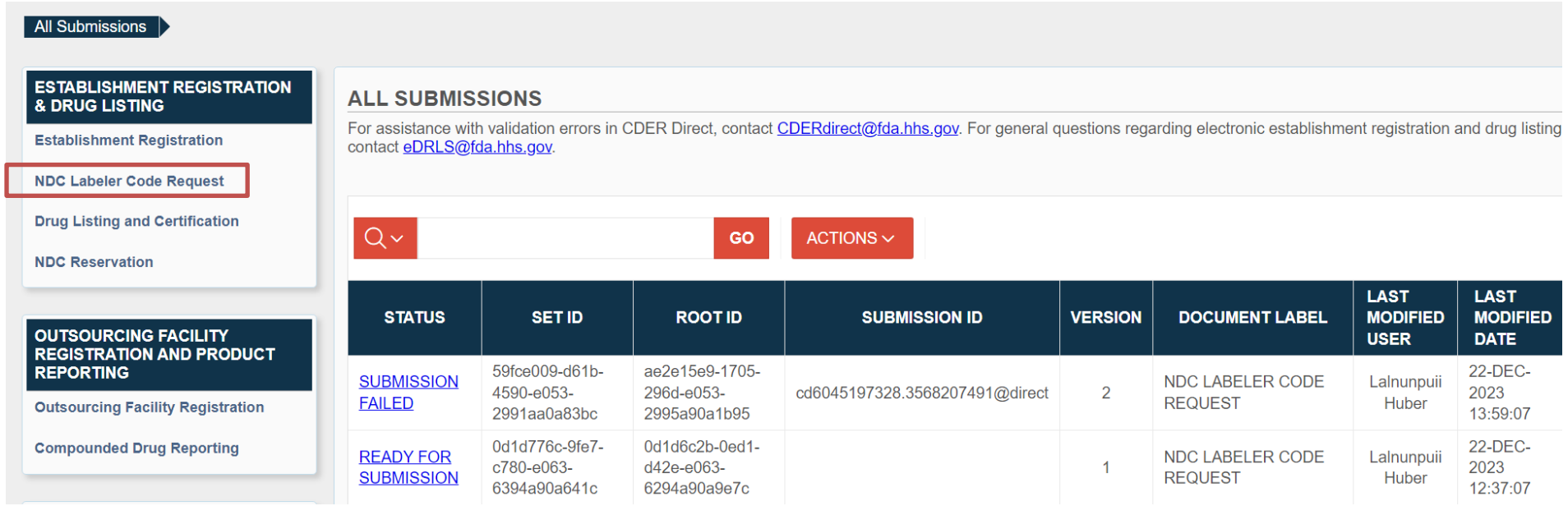
Step 2 Enter your login credentials, accept the terms of service, and click **Login**



Confirming or Updating Labeler Code Details

Step 3

Click on **NDC Labeler Code Request**



Step 4

Click on **Submission Accepted** for the most recently accepted NDC Labeler Code Request to confirm or update

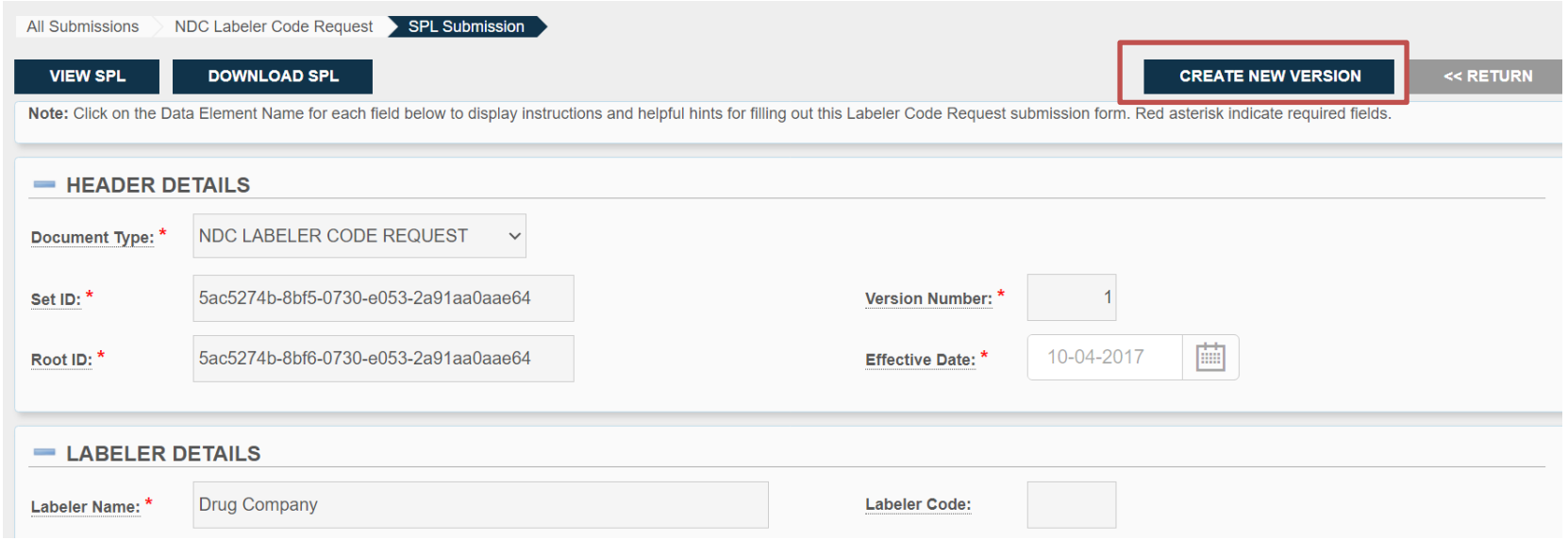
STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LABELER DUNS	LABELER NAME
SUBMISSION ACCEPTED	5ac5274b-8bf5-0730-e053-2a91aa0aae64	5ac5274b-8bf6-0730-e053-2a91aa0aae64	cd392145786.6719058342@direct	1	NDC LABELER CODE REQUEST	987654321	Drug Company

Confirming or Updating Labeler Code Details

Step 5

Click on **Create New Version**, unlocking the SPL to review it and make any updates

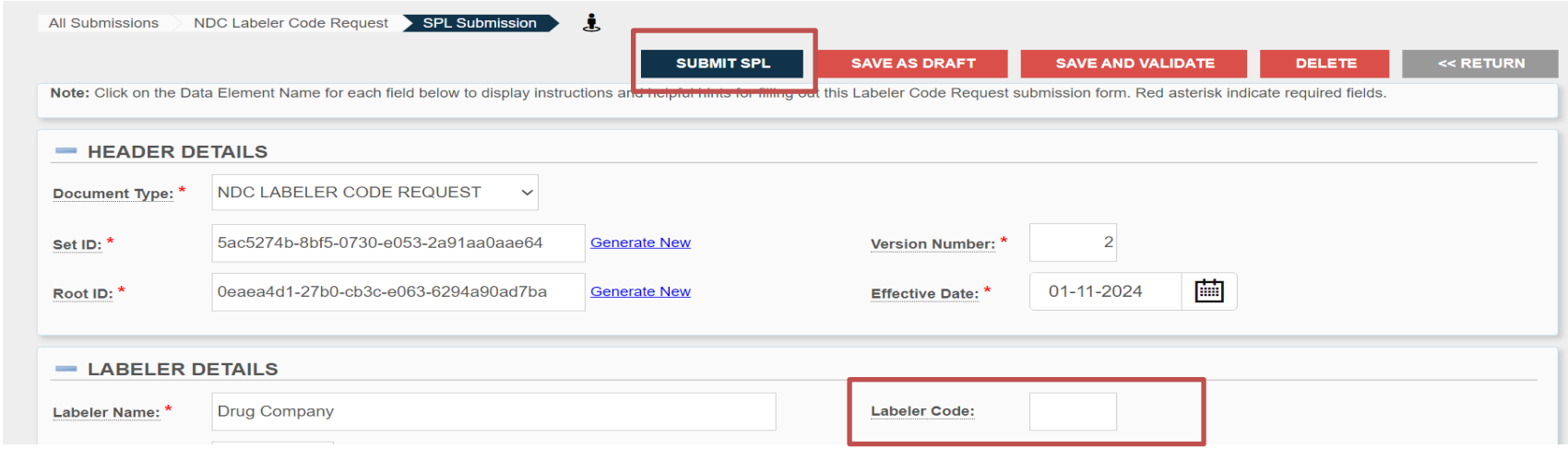
NOTE: After clicking **Create New Version**, the Header Details section will be automatically updated with the correct information with no need to edit it



Step 6

Review the information in the SPL and make any required updates, such as contact information or business operations. If confirming the assignment, enter the assigned Labeler Code

When finished, click on **Submit SPL**



Confirming or Updating Labeler Code Details

What happens after I click "Submit SPL"?

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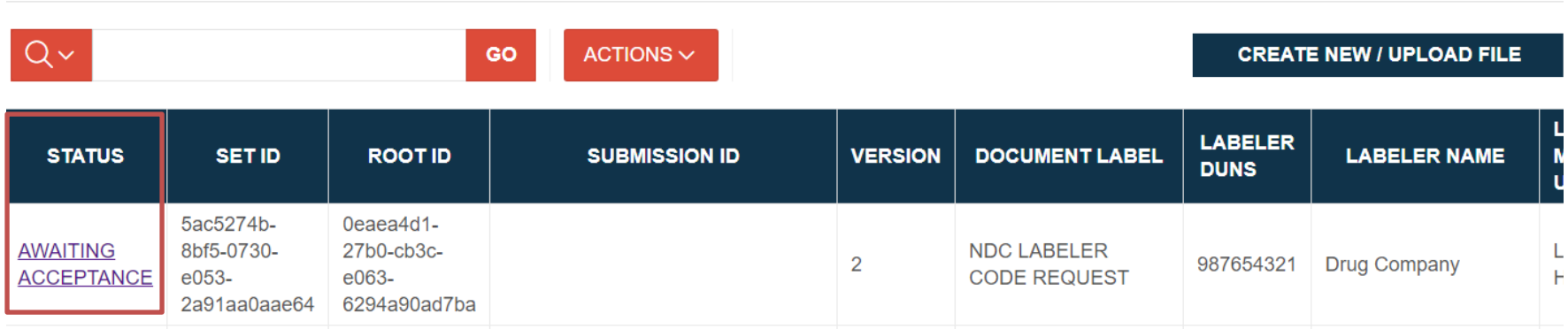

NDC Labeler Code Inactivation

NDC Labeler Code Inactivation

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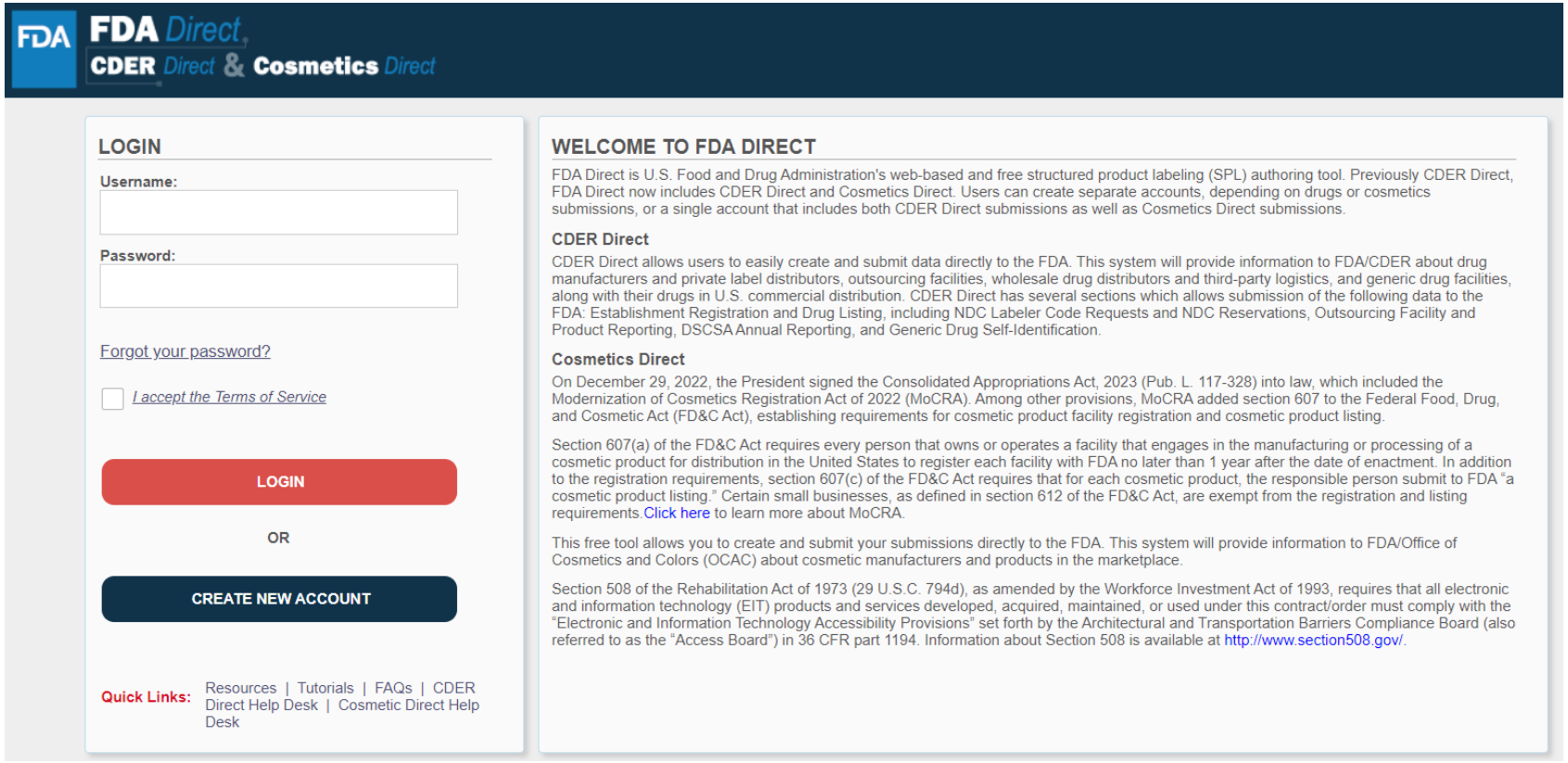
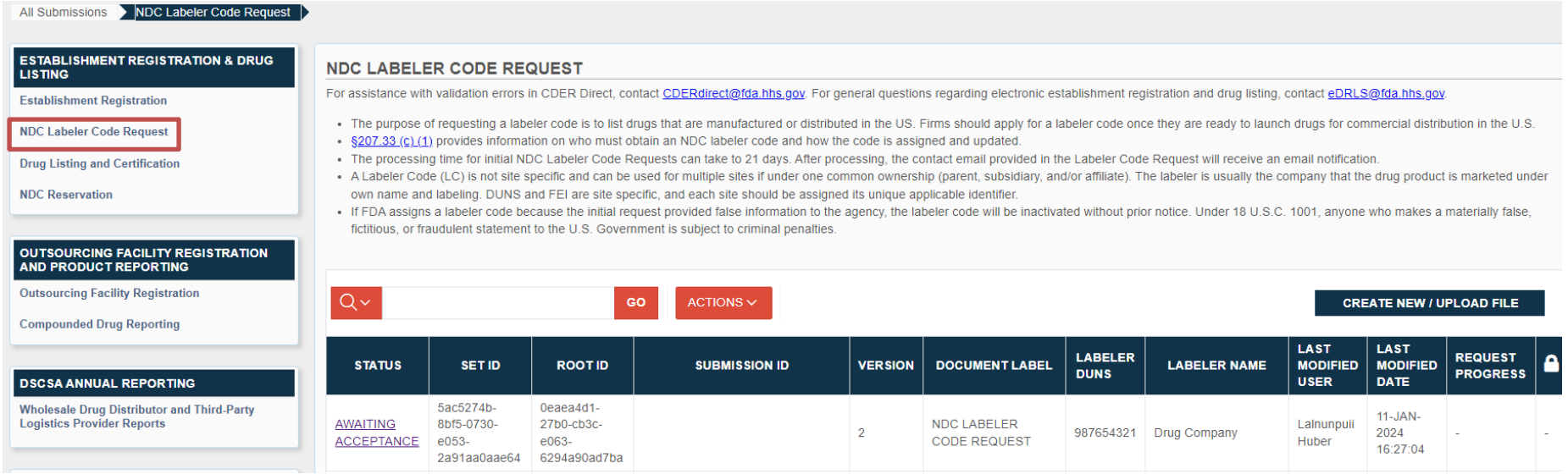


NDC Labeler Code Inactivation

Step 3

Click on **NDC Labeler Code Request**



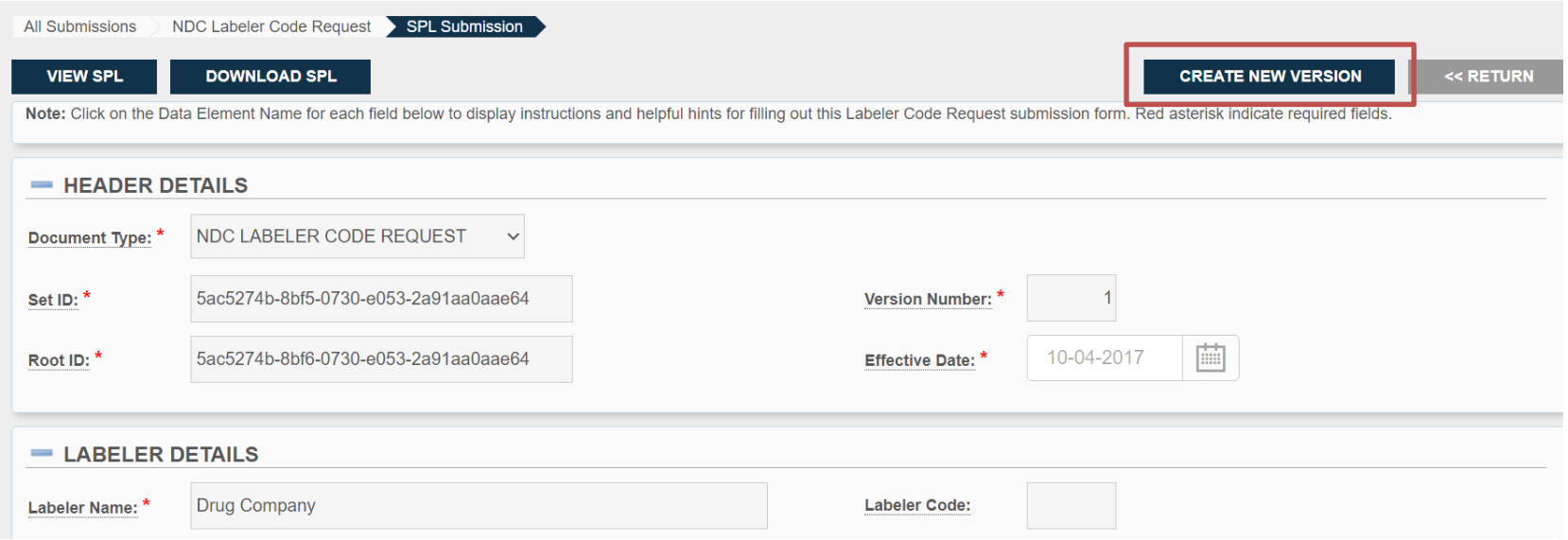
Step 4

Click on **Submission Accepted** for the most recently accepted NDC Labeler Code Request containing the Labeler Code to inactivate

NDC Labeler Code Inactivation

Step 5

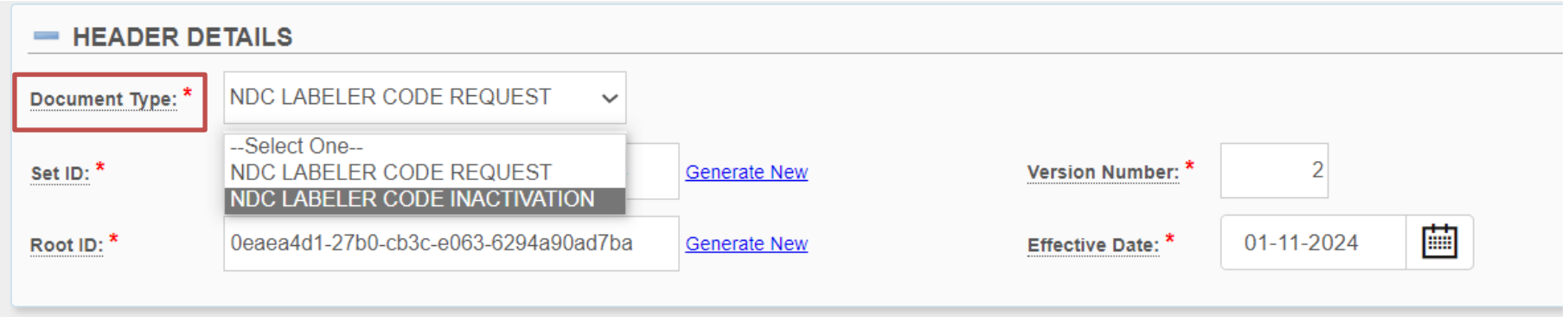
Click on **Create New Version**, unlocking the SPL to review it and make any updates



NDC Labeler Code Inactivation

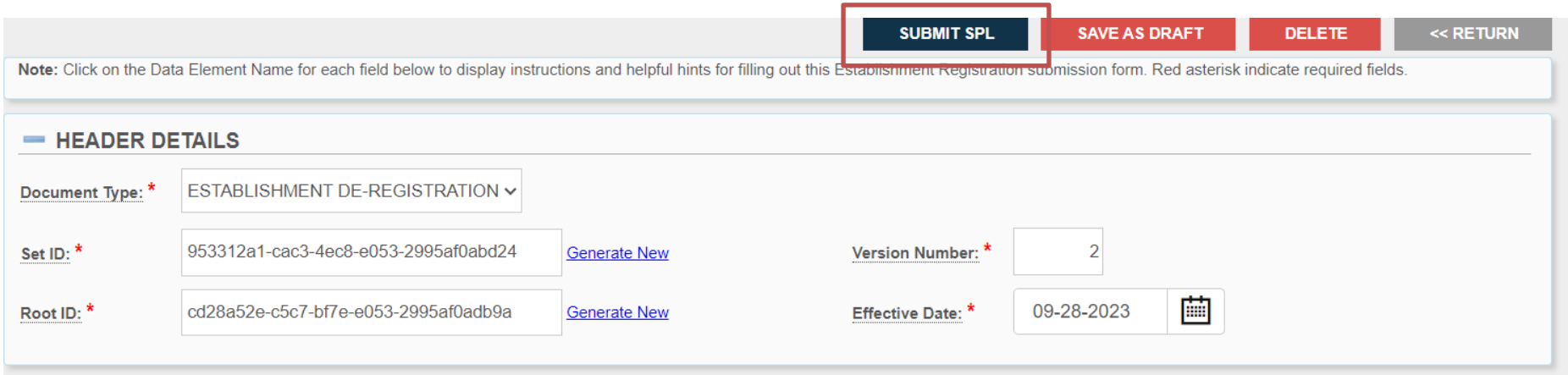
Step 6

To inactivate the labeler code, change the Document Type to **NDC Labeler Code Inactivation**



Step 7

Click on **Submit SPL**



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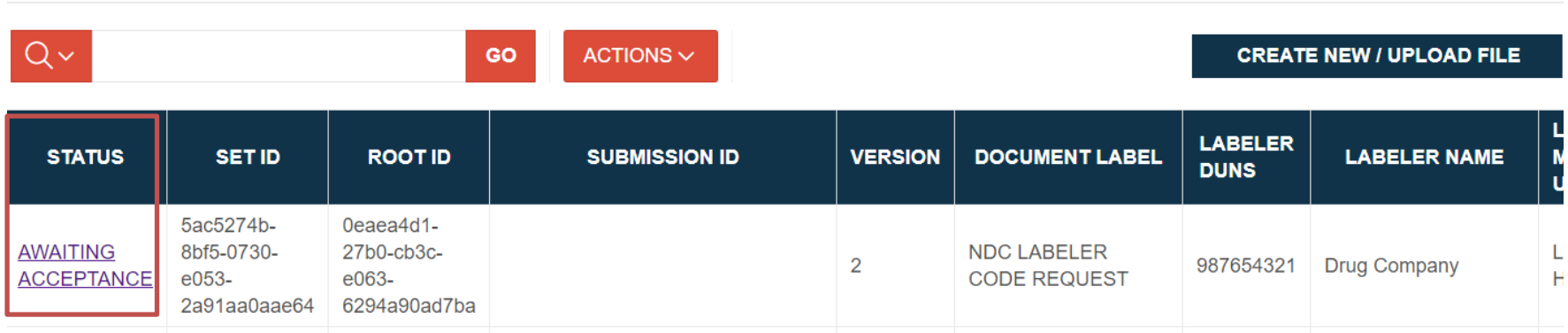

Uploading a Labeler Code Request SPL File

Uploading a Labeler Code Request SPL File

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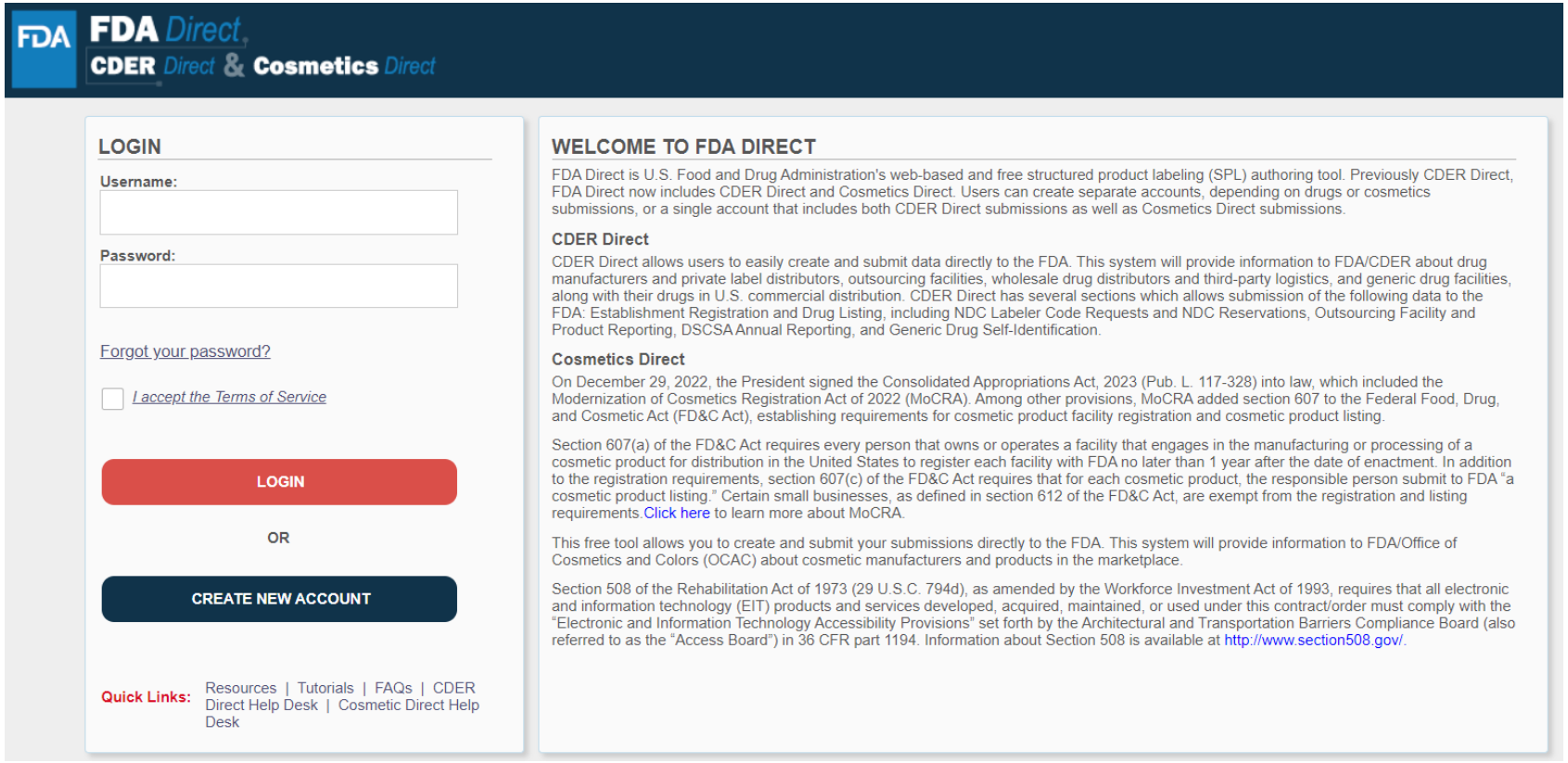
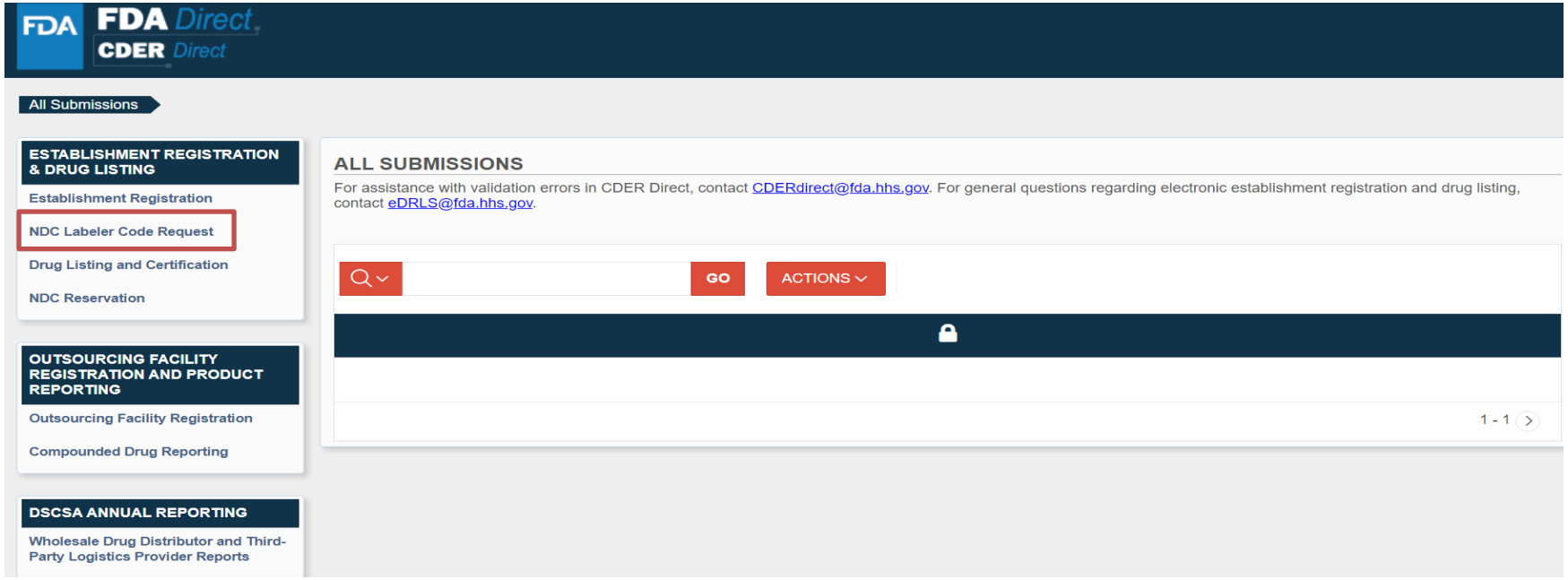


Uploading a Labeler Code Request SPL File

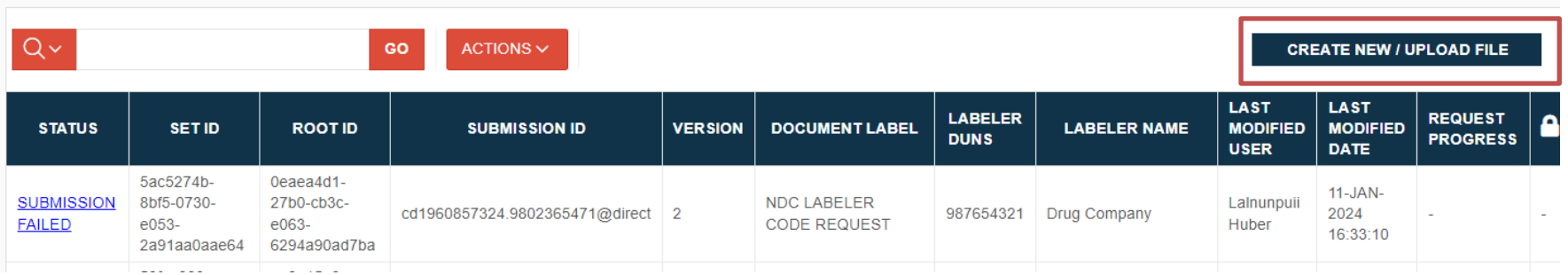
Step 3

Click on **NDC Labeler Code Request**



Step 4

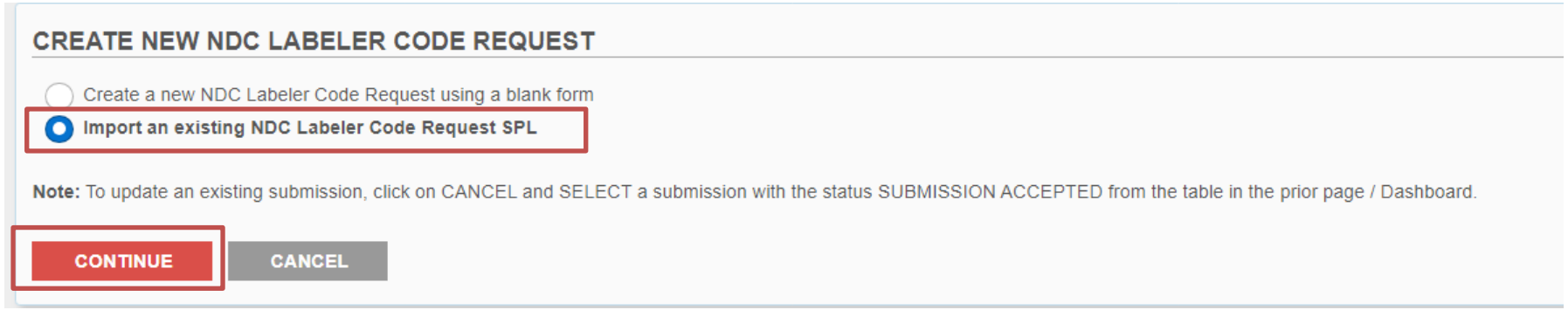
Click on
Create New / Upload File



Uploading a Labeler Code Request SPL File

Step 5

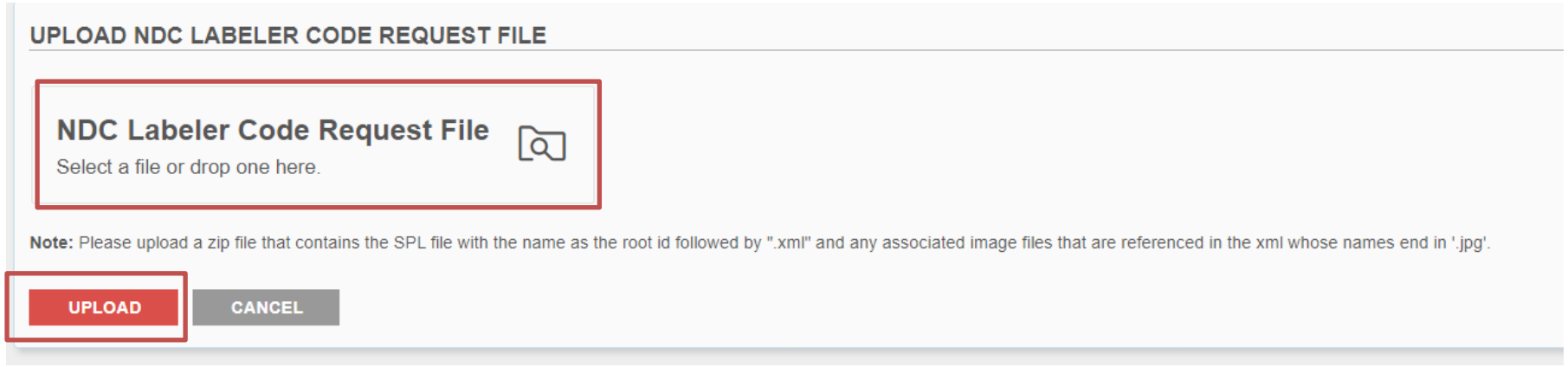
Click on **Import an existing NDC Labeler Code Request SPL** and then **Continue**



Step 6

Click on **NDC Labeler Code Request File**

Locate and select the Labeler Code Request ZIP file to upload into CDER Direct and click **Upload**



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