

# Reference Guide: NDC Labeler Code Request

FDA

## 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](mailto:CDERdirect@fda.hhs.gov).

**WELCOME TO FDA DIRECT**

FDA Direct is U.S. Food and Drug Administration's web-based and free structured product labeling (SPL) authoring tool. Previously CDER Direct, FDA Direct now includes CDER Direct and Cosmetics Direct. Users can create separate accounts, depending on drugs or cosmetics submissions, or a single account that includes both CDER Direct submissions as well as Cosmetics Direct submissions.

**CDER Direct**

CDER Direct allows users to easily create and submit data directly to the FDA. This system will provide information to FDA/CDER about drug manufacturers and private label distributors, outsourcing facilities, wholesale drug distributors and third-party logistics, and generic drug facilities, along with their drugs in U.S. commercial distribution. CDER Direct has several sections which allows submission of the following data to the FDA: Establishment Registration and Drug Listing, including NDC Labeler Code Requests and NDC Reservations, Outsourcing Facility and Product Reporting, DSCSA Annual Reporting, and Generic Drug Self-Identification.

**Cosmetics Direct**

On December 29, 2022, the President signed the Consolidated Appropriations Act, 2023 (Pub. L. 117-328) into law, which included the Modernization of Cosmetics Registration Act of 2022 (MoCRA). Among other provisions, MoCRA added section 607 to the Federal Food, Drug, and Cosmetic Act (FD&C Act), establishing requirements for cosmetic product facility registration and cosmetic product listing.

Section 607(a) of the FD&C Act requires every person that owns or operates a facility that engages in the manufacturing or processing of a cosmetic product for distribution in the United States to register each facility with FDA. Section 607(c) of the FD&C Act requires that for each cosmetic product, the responsible person submit to FDA a cosmetic product listing. Certain small businesses, as defined in section 612 of the FD&C Act, are exempt from the registration and listing requirements. [Click here](#) to learn more about MoCRA.

This free tool allows you to create and submit the following types of data directly to the FDA: Registration of Cosmetic Product Facility and Cosmetic Product Listing. This system will provide information to FDA/Office of Cosmetics and Colors (OCAC) about cosmetic product manufacturers/processors and cosmetic products on the market.

**Note:** Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1993, requires that all electronic and information technology (EIT) products and services developed, acquired, maintained, or used under this contract/order must comply with the "Electronic and Information Technology Accessibility Provisions" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194. Information about Section 508 is available at <http://www.section508.gov/>.

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Click [here](#) to access the FDA Direct Portal

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## 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**

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This free tool allows you to create and submit your submissions directly to the FDA. This system will provide information to FDA/Office of Cosmetics and Colors (OCAC) about cosmetic manufacturers and products in the marketplace.

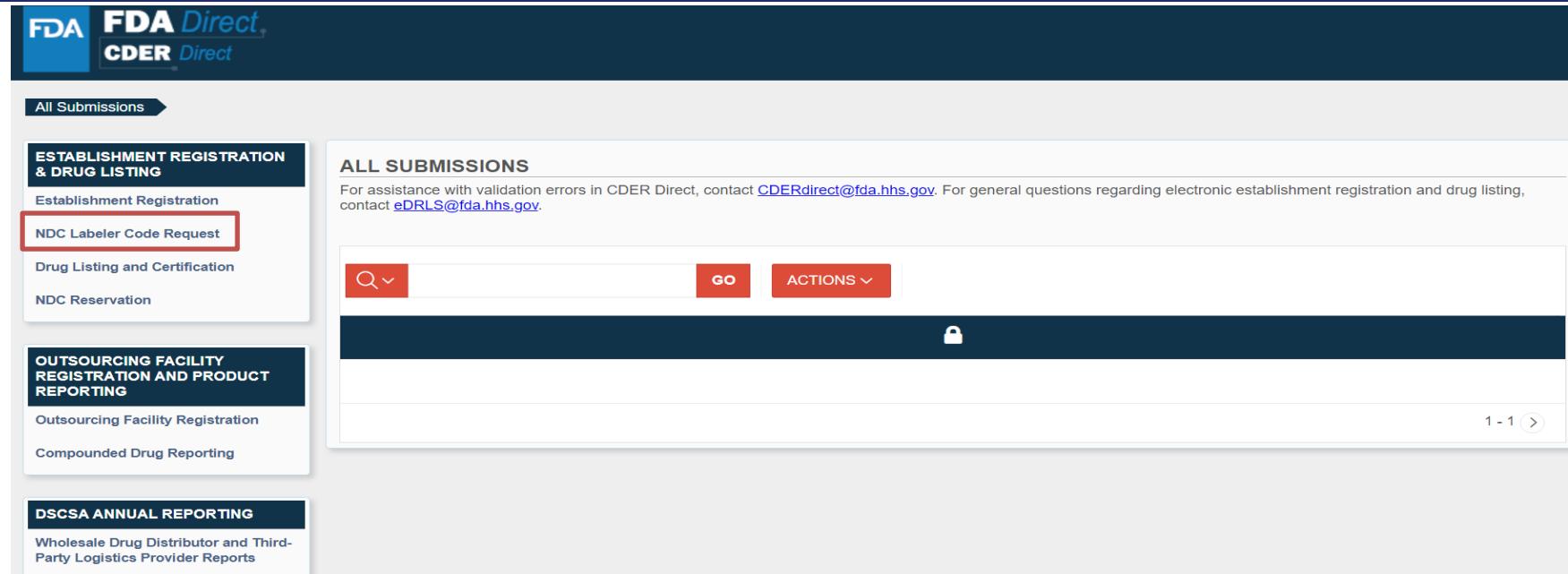
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# Requesting a Labeler Code

## Step 3

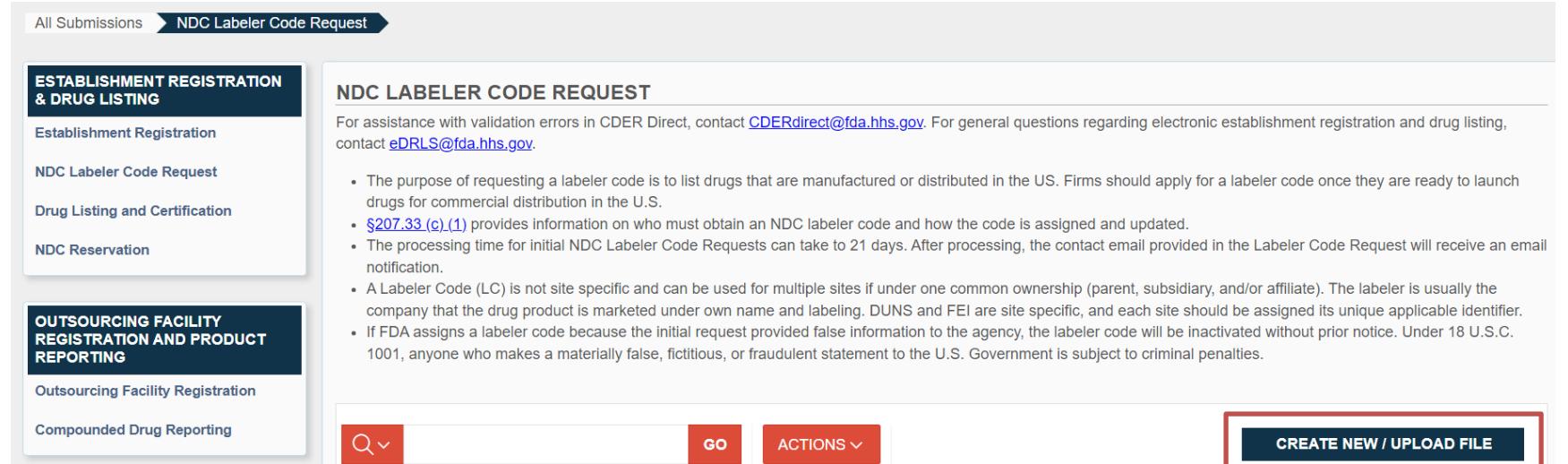
Click on **NDC Labeler Code Request**



The screenshot shows the 'All Submissions' section of the FDA Direct CDER Direct interface. On the left, there are three main categories: 'ESTABLISHMENT REGISTRATION & DRUG LISTING', 'OUTSOURCING FACILITY REGISTRATION AND PRODUCT REPORTING', and 'DSCSA ANNUAL REPORTING'. Under 'ESTABLISHMENT REGISTRATION & DRUG LISTING', the 'NDC Labeler Code Request' option is highlighted with a red box. The 'OUTSOURCING FACILITY REGISTRATION AND PRODUCT REPORTING' category includes 'Outsourcing Facility Registration' and 'Compounded Drug Reporting'. The 'DSCSA ANNUAL REPORTING' category includes 'Wholesale Drug Distributor and Third-Party Logistics Provider Reports'. On the right, the 'ALL SUBMISSIONS' section displays a search bar with 'Q', a 'GO' button, and an 'ACTIONS' dropdown. Below the search bar is a dark header bar with a lock icon. The main content area is currently empty, showing a '1 - 1' status.

## Step 4

Click on **Create New/Upload File**



The screenshot shows the 'NDC Labeler Code Request' page. The left sidebar lists the same categories as the previous screen: 'ESTABLISHMENT REGISTRATION & DRUG LISTING', 'OUTSOURCING FACILITY REGISTRATION AND PRODUCT REPORTING', and 'DSCSA ANNUAL REPORTING'. The 'ESTABLISHMENT REGISTRATION & DRUG LISTING' category includes 'Establishment Registration', 'NDC Labeler Code Request' (which is the current page), 'Drug Listing and Certification', and 'NDC Reservation'. The 'OUTSOURCING FACILITY REGISTRATION AND PRODUCT REPORTING' category includes 'Outsourcing Facility Registration' and 'Compounded Drug Reporting'. The main content area is titled 'NDC LABELER CODE REQUEST' and contains a paragraph of text about assistance for validation errors and contact information. At the bottom right, a 'CREATE NEW / UPLOAD FILE' button is highlighted with a red box.

# 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**

**direct.fda.gov says**

It is preferable to wait until you have a product to list before you request a labeler code. It can take up to 21 business days to process a labeler code. Note: Assigned Labeler codes that are NOT utilized by listing a drug product are automatically INACTIVATED after 24 months. To reactivate a labeler code that has been inactivated you will need to send us the proposed label information (product name, active ingredient(s), strength, labeling, start marketing date and intended NDC) to [edrls@fda.hhs.gov](mailto:edrls@fda.hhs.gov). Click OK to continue.

OK
Cancel

ESTABLISHMENT REGISTRATION & DRUG LISTING
CREATE NEW NDC LABELER CODE REQUEST

Create a new NDC Labeler Code Request using a blank form
 Import an existing NDC Labeler Code Request SPL

**Note:** To update an existing submission, click on CANCEL and SELECT a submission with the status SUBMISSION ACCEPTED from the table in the prior page / Dashboard.

CONTINUE
CANCEL

OUTSOURCING FACILITY REGISTRATION AND PRODUCT REPORTING
DSCSA ANNUAL REPORTING

Outsourcing Facility Registration
Wholesale Drug Distributor and Third-Party Logistics Provider Reports

# 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

The screenshot shows a portion of the 'LABELER DETAILS' section of the form. The 'Labeler Name' field is highlighted with a dotted underline, and a tooltip box is overlaid on the page. The tooltip contains the text: 'The Labeler Name is the registrant or private label distributor requesting the NDC Labeler Code.' Other fields visible in the background include 'Labeler DUNS', 'Labeler Code', 'Contact Name', 'Contact Email', 'Contact Phone', 'Phone Extension', 'Street Address', 'City', 'State/Province', and 'Postal Code'.

## 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

The screenshot shows the 'SPL Submission' section of the FDA Direct website. The 'Document Type' dropdown menu is open, showing two options: '--Select One--' and 'NDC LABELER CODE REQUEST'. The 'NDC LABELER CODE REQUEST' option is highlighted with a red box. Other fields in the header details section include 'Set ID' (containing 'NDC LABELER CODE REQUEST'), 'Root ID' (containing '0d1c2353-101b-6235-e063-6394a90a82a4'), 'Version Number' (set to '1'), and 'Effective Date' (set to '12-22-2023'). Buttons for 'SAVE AS DRAFT' and '<< RETURN' are visible in the top right corner.

# Requesting a Labeler Code

## Step 7

Enter the information for Labeler Details

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

**LABELER DETAILS**

Labeler Name: \*

Labeler Code:

Labeler DUNS: \*

**LABELER CONTACT DETAILS**

Contact Name: \*

Contact Email: \*

Contact Phone: \*  [Format](#)

Phone Extension:

**LABELER CONTACT ADDRESS**

Country: \*  -Select Country- [▼](#)

Street Address: \*

City: \*

State/Province:

Postal Code:

## Step 8

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

**ADDITIONAL LABELER DETAILS (Optional - Including the following information will expedite the processing of your request)**

**LABELER ADDRESS**

Same as Labeler Contact Address

Country: \*  --Select Country-- [▼](#)

Street Address: \*

City: \*

State/Province:

Postal Code:

**U.S. AGENT**

Agent Name:

Agent DUNS:

Agent Email:

Agent Phone:  [Format](#)

Phone Extension:

**BUSINESS OPERATION(S)**

**ADD BUSINESS OPERATION**

# Requesting a Labeler Code

## Step 9

Click on **Add Business**

**Operation** to indicate the business operations of the firm requesting the labeler code

— BUSINESS OPERATION(S)

**ADD BUSINESS OPERATION**

## 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

— ADDITIONAL LABELER DETAILS (Optional - Including the following information will expedite the processing of your request)

LABELER ADDRESS

Same as Labeler Contact Address

Country: \*  --Select C

Street Address: \*

City: \*

State/Province:

Postal Code:

U.S. AGENT

Agent Name:

Business Operation/Qualifier

Business Operations:

Qualifier:

**CANCEL** **SAVE** **SAVE AND ADD**

Format

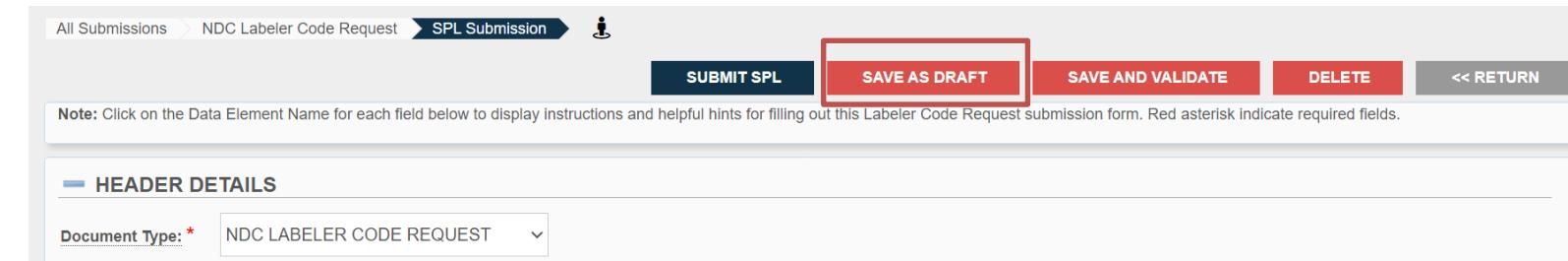
— BUSINESS OPERATION(S)

**ADD BUSINESS OPERATION**

# 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



All Submissions > NDC Labeler Code Request > SPL Submission

**SUBMIT SPL** **SAVE AS DRAFT** **SAVE AND VALIDATE** **DELETE** **<< RETURN**

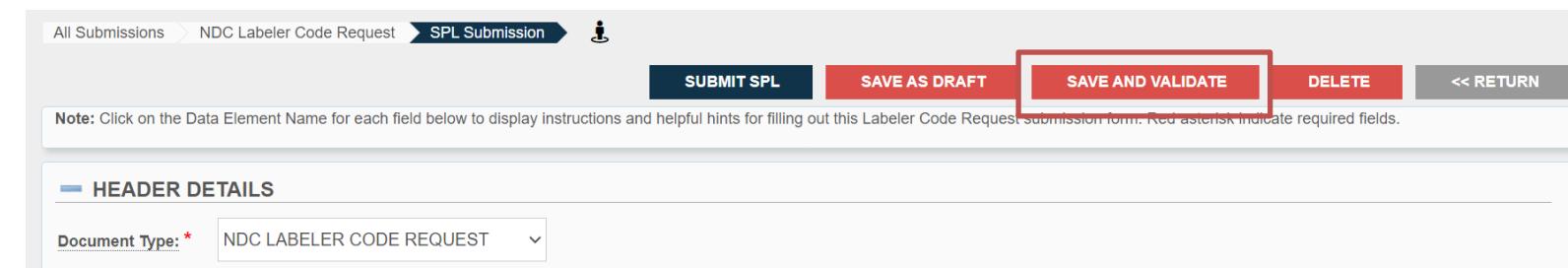
Note: Click on the Data Element Name for each field below to display instructions and helpful hints for filling out this Labeler Code Request submission form. Red asterisk indicate required fields.

**HEADER DETAILS**

Document Type: \* NDC LABELER CODE REQUEST

## Step 11b

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



All Submissions > NDC Labeler Code Request > SPL Submission

**SUBMIT SPL** **SAVE AS DRAFT** **SAVE AND VALIDATE** **DELETE** **<< RETURN**

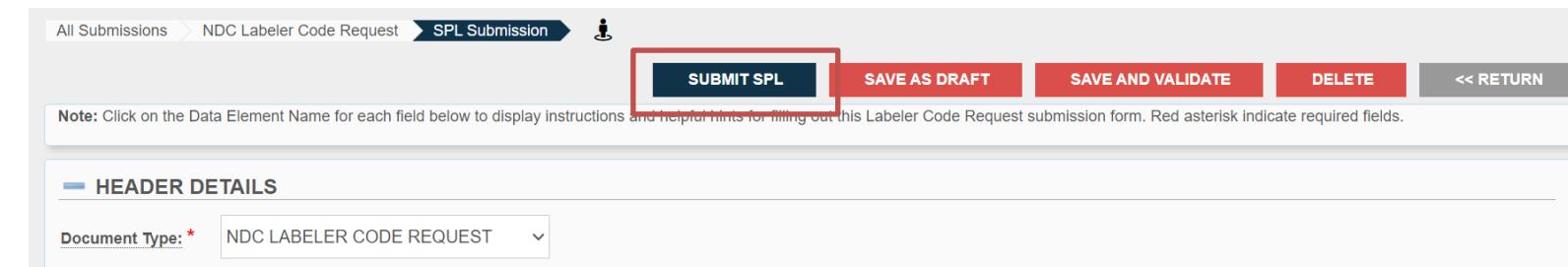
Note: Click on the Data Element Name for each field below to display instructions and helpful hints for filling out this Labeler Code Request submission form. Red asterisk indicate required fields.

**HEADER DETAILS**

Document Type: \* NDC LABELER CODE REQUEST

## Step 11c

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



All Submissions > NDC Labeler Code Request > SPL Submission

**SUBMIT SPL** **SAVE AS DRAFT** **SAVE AND VALIDATE** **DELETE** **<< RETURN**

Note: Click on the Data Element Name for each field below to display instructions and helpful hints for filling out this Labeler Code Request submission form. Red asterisk indicate required fields.

**HEADER DETAILS**

Document Type: \* NDC LABELER CODE REQUEST

# 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

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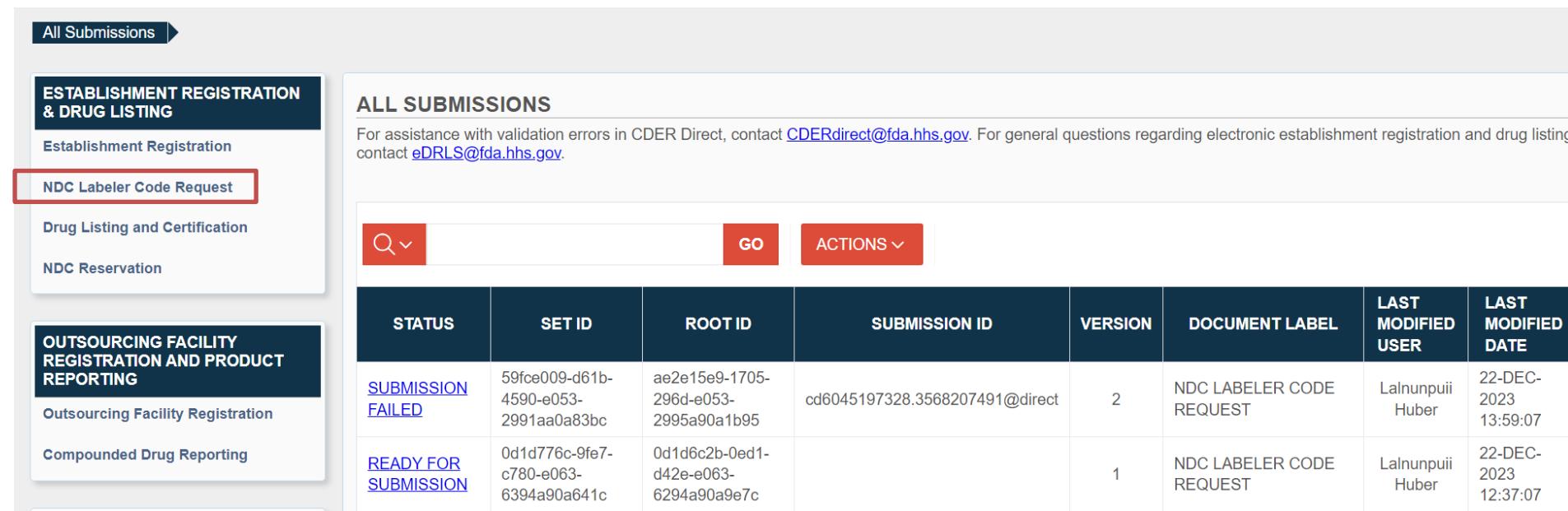
**CREATE NEW ACCOUNT**

**Quick Links:** [Resources](#) | [Tutorials](#) | [FAQs](#) | [CDER Direct Help Desk](#) | [Cosmetic Direct Help Desk](#)

# Confirming or Updating Labeler Code Details

## Step 3

Click on **NDC Labeler Code Request**



All Submissions

**ESTABLISHMENT REGISTRATION & DRUG LISTING**

Establishment Registration

**NDC Labeler Code Request**

Drug Listing and Certification

NDC Reservation

**OUTSOURCING FACILITY REGISTRATION AND PRODUCT REPORTING**

Outsourcing Facility Registration

Compounded Drug Reporting

**ALL SUBMISSIONS**

For assistance with validation errors in CDER Direct, contact [CDERdirect@fda.hhs.gov](mailto:CDERdirect@fda.hhs.gov). For general questions regarding electronic establishment registration and drug listing contact [eDRLS@fda.hhs.gov](mailto:eDRLS@fda.hhs.gov).

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE
<a href="#">SUBMISSION FAILED</a>	59fce009-d61b-4590-e053-2991aa0a83bc	ae2e15e9-1705-296d-e053-2995a90a1b95	cd6045197328.3568207491@direct	2	NDC LABELER CODE REQUEST	Lalnunpuii Huber	22-DEC-2023 13:59:07
<a href="#">READY FOR SUBMISSION</a>	0d1d776c-9fe7-c780-e063-6394a90a641c	0d1d6c2b-0ed1-d42e-e063-6294a90a9e7c		1	NDC LABELER CODE REQUEST	Lalnunpuii Huber	22-DEC-2023 12:37:07

## Step 4

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

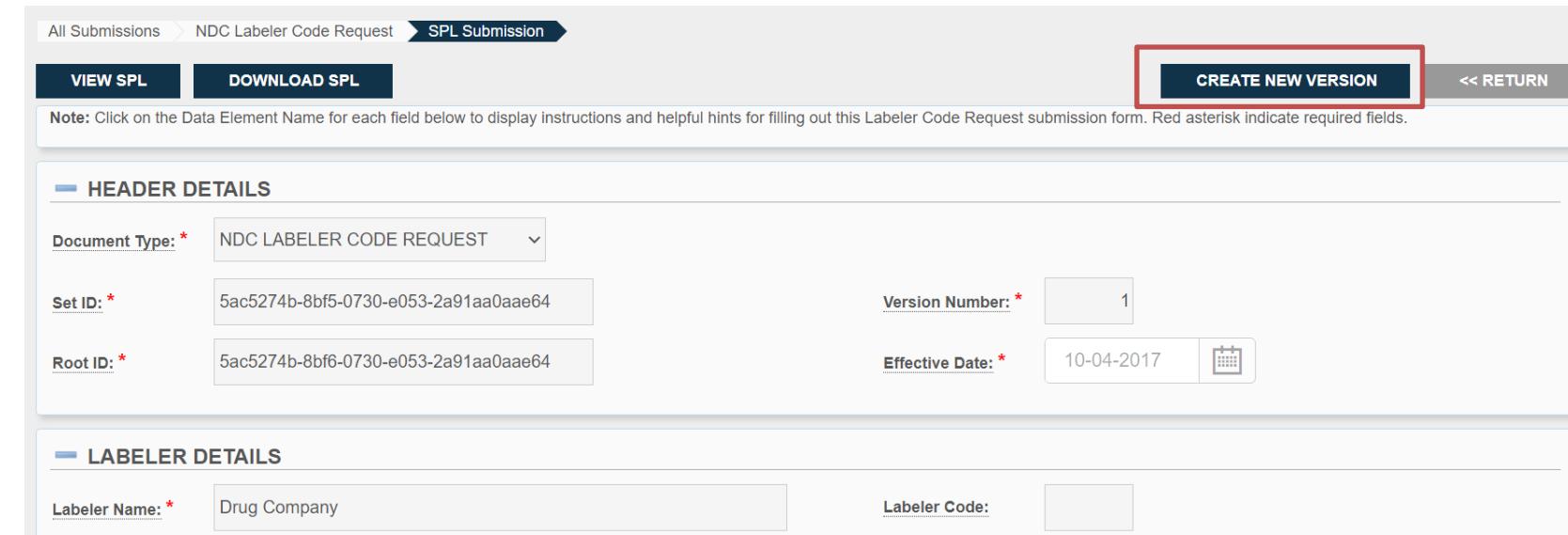


STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LABELER DUNS	LABELER NAME
<a href="#">SUBMISSION ACCEPTED</a>	5ac5274b-8bf5-0730-e053-2a91aa0aae64	5ac5274b-8bf6-0730-e053-2a91aa0aae64	cd392145786.6719058342@direct	1	NDC LABELER CODE REQUEST	987654321	Drug Company

## 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



All Submissions > NDC Labeler Code Request > SPL Submission

**CREATE NEW VERSION**

**HEADER DETAILS**

Document Type: \* NDC LABELER CODE REQUEST

Set ID: \* 5ac5274b-8bf5-0730-e053-2a91aa0aae64

Root ID: \* 5ac5274b-8bf6-0730-e053-2a91aa0aae64

Version Number: \* 1

Effective Date: \* 10-04-2017

**LABELER DETAILS**

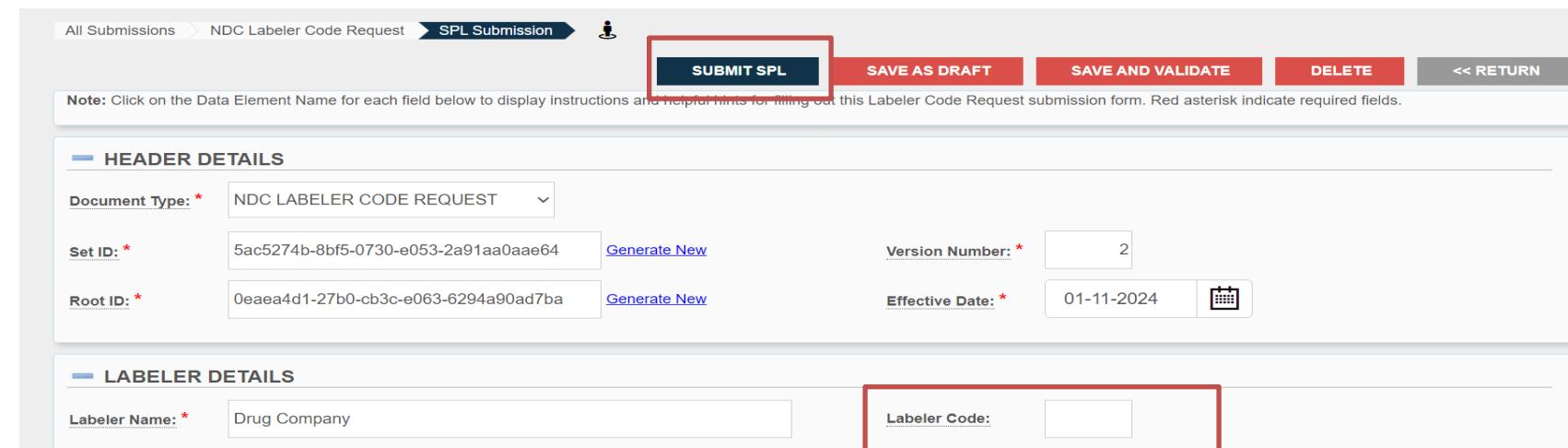
Labeler Name: \* Drug Company

Labeler Code: [empty]

## 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**



All Submissions > NDC Labeler Code Request > SPL Submission

**SUBMIT SPL**

**HEADER DETAILS**

Document Type: \* NDC LABELER CODE REQUEST

Set ID: \* 5ac5274b-8bf5-0730-e053-2a91aa0aae64 [Generate New](#)

Root ID: \* 0eaea4d1-27b0-cb3c-e063-6294a90ad7ba [Generate New](#)

Version Number: \* 2

Effective Date: \* 01-11-2024

**LABELER DETAILS**

Labeler Name: \* Drug Company

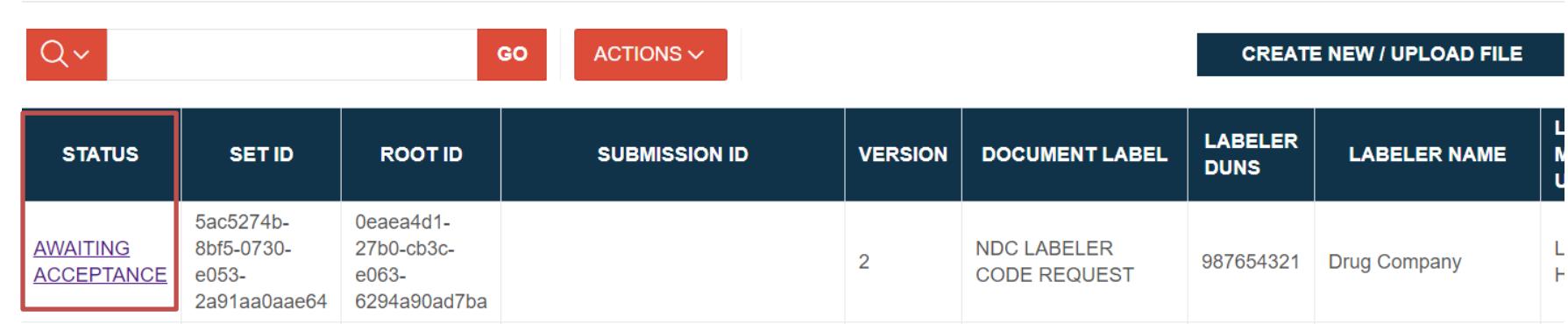
Labeler Code: [empty]

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“Submit SPL”?**

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The screenshot shows a table with columns: STATUS, SET ID, ROOT ID, SUBMISSION ID, VERSION, DOCUMENT LABEL, LABELER DUNS, LABELER NAME, and LNU. The first row is highlighted with a red border around the STATUS column, which contains the text "AWAITING ACCEPTANCE".

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LABELER DUNS	LABELER NAME	LNU
AWAITING ACCEPTANCE	5ac5274b-8bf5-0730-e053-2a91aa0aae64	0eaea4d1-27b0-cb3c-e063-6294a90ad7ba		2	NDC LABELER CODE REQUEST	987654321	Drug Company	LH

# NDC Labeler Code Inactivation

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Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1993, requires that all electronic and information technology (EIT) products and services developed, acquired, maintained, or used under this contract/order must comply with the "Electronic and Information Technology Accessibility Provisions" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194. Information about Section 508 is available at <http://www.section508.gov/>.

**CREATE NEW ACCOUNT**

**Quick Links:** [Resources](#) | [Tutorials](#) | [FAQs](#) | [CDER Direct Help Desk](#) | [Cosmetic Direct Help Desk](#)

**Step 3**

**Click on NDC Labeler Code Request**

All Submissions > NDC Labeler Code Request

**ESTABLISHMENT REGISTRATION & DRUG LISTING**

- Establishment Registration
- NDC Labeler Code Request**
- Drug Listing and Certification
- NDC Reservation

**OUTSOURCING FACILITY REGISTRATION AND PRODUCT REPORTING**

- Outsourcing Facility Registration
- Compounded Drug Reporting

**DSCSA ANNUAL REPORTING**

- Wholesale Drug Distributor and Third-Party Logistics Provider Reports

**NDC LABELER CODE REQUEST**

For assistance with validation errors in CDER Direct, contact [CDERdirect@fda.hhs.gov](mailto:CDERdirect@fda.hhs.gov). For general questions regarding electronic establishment registration and drug listing, contact [eDRLS@fda.hhs.gov](mailto:eDRLS@fda.hhs.gov).

- The purpose of requesting a labeler code is to list drugs that are manufactured or distributed in the US. Firms should apply for a labeler code once they are ready to launch drugs for commercial distribution in the U.S.
- [§207.33\(c\)\(1\)](#) provides information on who must obtain an NDC labeler code and how the code is assigned and updated.
- The processing time for initial NDC Labeler Code Requests can take to 21 days. After processing, the contact email provided in the Labeler Code Request will receive an email notification.
- A Labeler Code (LC) is not site specific and can be used for multiple sites if under one common ownership (parent, subsidiary, and/or affiliate). The labeler is usually the company that the drug product is marketed under own name and labeling. DUNS and FEI are site specific, and each site should be assigned its unique applicable identifier.
- If FDA assigns a labeler code because the initial request provided false information to the agency, the labeler code will be inactivated without prior notice. Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

**CREATE NEW / UPLOAD FILE**

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LABELER DUNS	LABELER NAME	LAST MODIFIED USER	LAST MODIFIED DATE	REQUEST PROGRESS	LOCK
AWAITING ACCEPTANCE	5ac5274b-8bf5-0730-e053-2a91aa0aae64	0eaea4d1-2700-cb3c-e063-6294a90ad7ba		2	NDC LABELER CODE REQUEST	987654321	Drug Company	Lalnunpui Huber	11-JAN-2024 16:27:04	-	-

**Step 4**

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

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LABELER DUNS	LABELER NAME	LAST MODIFIED USER	LAST MODIFIED DATE	REQUEST PROGRESS	LOCK
<a href="#">SUBMISSION ACCEPTED</a>	5ac5274b-8bf5-0730-e053-2a91aa0aae64	5ac5274b-8bf6-0730-e053-2a91aa0aae64	cd392145786.6719058342@direct	1	NDC LABELER CODE REQUEST	987654321	Drug Company	Lalnunpui Huber	05-OCT-2017 00:04:27	-	-

**Step 5**

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

All Submissions > NDC Labeler Code Request > SPL Submission

**VIEW SPL** **DOWNLOAD SPL** **CREATE NEW VERSION** **<< RETURN**

Note: Click on the Data Element Name for each field below to display instructions and helpful hints for filling out this Labeler Code Request submission form. Red asterisk indicate required fields.

**HEADER DETAILS**

Document Type: \* NDC LABELER CODE REQUEST

Set ID: \* 5ac5274b-8bf5-0730-e053-2a91aa0aae64

Root ID: \* 5ac5274b-8bf6-0730-e053-2a91aa0aae64

Version Number: \* 1

Effective Date: \* 10-04-2017

**LABELER DETAILS**

Labeler Name: \* Drug Company

Labeler Code:

# NDC Labeler Code Inactivation

## Step 6

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

**HEADER DETAILS**

Document Type: *	NDC LABELER CODE REQUEST
Set ID: *	--Select One--
	NDC LABELER CODE REQUEST
	NDC LABELER CODE INACTIVATION
Root ID: *	0eaea4d1-27b0-cb3c-e063-6294a90ad7ba
	<a href="#">Generate New</a>
	<a href="#">Generate New</a>
Version Number: *	2
Effective Date: *	01-11-2024
	<a href="#">Calendar</a>

## Step 7

Click on **Submit SPL**

**Note:** Click on the Data Element Name for each field below to display instructions and helpful hints for filling out this Establishment Registration submission form. Red asterisk indicate required fields.

**HEADER DETAILS**

Document Type: *	ESTABLISHMENT DE-REGISTRATION
Set ID: *	953312a1-cac3-4ec8-e053-2995af0abd24
	<a href="#">Generate New</a>
Root ID: *	cd28a52e-c5c7-bf7e-e053-2995af0adb9a
	<a href="#">Generate New</a>
Version Number: *	2
Effective Date: *	09-28-2023
	<a href="#">Calendar</a>

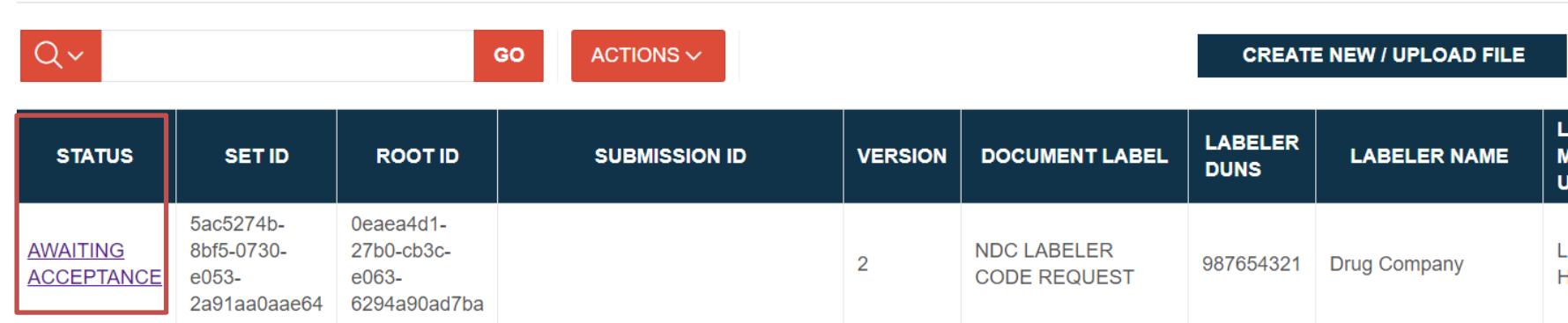
**SUBMIT SPL** **SAVE AS DRAFT** **DELETE** **<< RETURN**

**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 validation 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	LABELER ID
AWAITING ACCEPTANCE	5ac5274b-8bf5-0730-e053-2a91aa0aae64	0eaea4d1-27b0-cb3c-e063-6294a90ad7ba		2	NDC LABELER CODE REQUEST	987654321	Drug Company	LH

Uploading a Labeler Code Request SPL File

**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**

**LOGIN**

Username:

Password:

[Forgot your password?](#)

[I accept the Terms of Service](#)

**LOGIN**

OR

**CREATE NEW ACCOUNT**

**WELCOME TO FDA DIRECT**

FDA Direct is U.S. Food and Drug Administration's web-based and free structured product labeling (SPL) authoring tool. Previously CDER Direct, FDA Direct now includes CDER Direct and Cosmetics Direct. Users can create separate accounts, depending on drugs or cosmetics submissions, or a single account that includes both CDER Direct submissions as well as Cosmetics Direct submissions.

**CDER Direct**

CDER Direct allows users to easily create and submit data directly to the FDA. This system will provide information to FDA/CDER about drug manufacturers and private label distributors, outsourcing facilities, wholesale drug distributors and third-party logistics, and generic drug facilities, along with their drugs in U.S. commercial distribution. CDER Direct has several sections which allows submission of the following data to the FDA: Establishment Registration and Drug Listing, including NDC Labeler Code Requests and NDC Reservations, Outsourcing Facility and Product Reporting, DSCSA Annual Reporting, and Generic Drug Self-Identification.

**Cosmetics Direct**

On December 29, 2022, the President signed the Consolidated Appropriations Act, 2023 (Pub. L. 117-328) into law, which included the Modernization of Cosmetic Registration Act of 2022 (MoCRA). Among other provisions, MoCRA added section 607 to the Federal Food, Drug, and Cosmetic Act (FD&C Act), establishing requirements for cosmetic product facility registration and cosmetic product listing.

Section 607(a) of the FD&C Act requires every person that owns or operates a facility that engages in the manufacturing or processing of a cosmetic product for distribution in the United States to register each facility with FDA no later than 1 year after the date of enactment. In addition to the registration requirements, section 607(c) of the FD&C Act requires that for each cosmetic product, the responsible person submit to FDA "a cosmetic product listing." Certain small businesses, as defined in section 612 of the FD&C Act, are exempt from the registration and listing requirements. [Click here](#) to learn more about MoCRA.

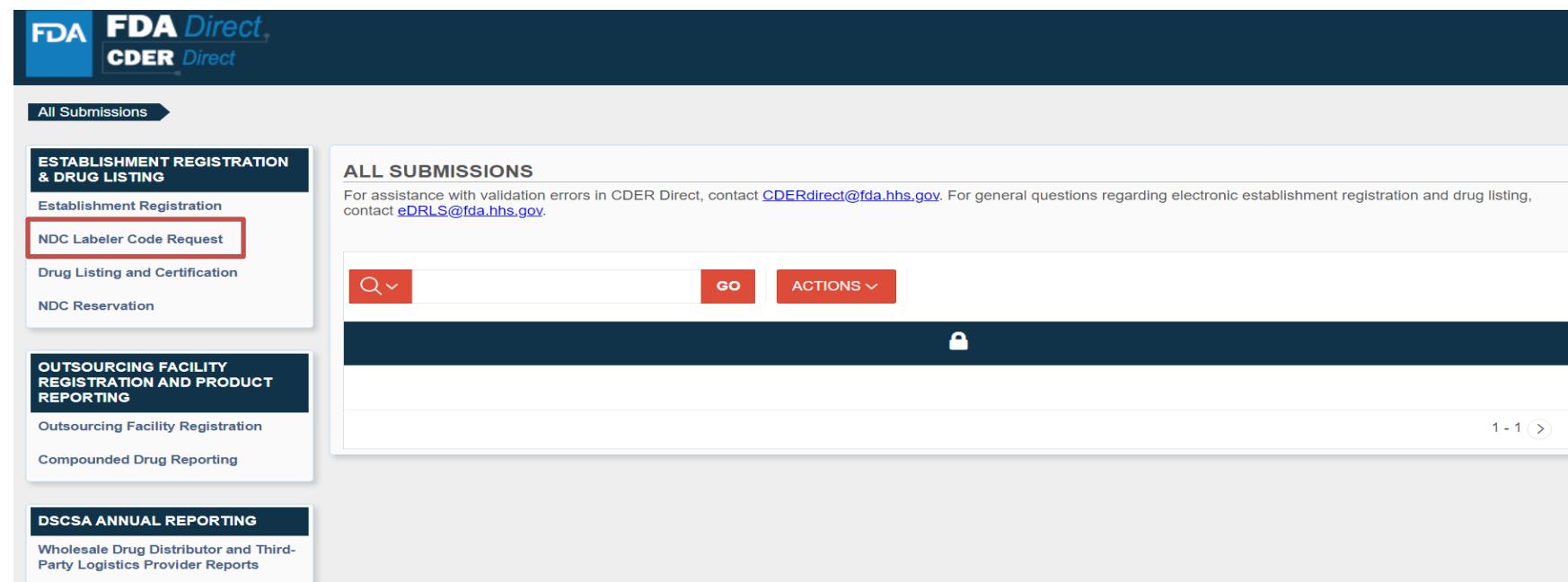
This free tool allows you to create and submit your submissions directly to the FDA. This system will provide information to FDA/Office of Cosmetics and Colors (OCAC) about cosmetic manufacturers and products in the marketplace.

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## Step 3

Click on NDC Labeler Code Request



All Submissions

ESTABLISHMENT REGISTRATION & DRUG LISTING

Establishment Registration

**NDC Labeler Code Request**

Drug Listing and Certification

NDC Reservation

OUTSOURCING FACILITY REGISTRATION AND PRODUCT REPORTING

Outsourcing Facility Registration

Compounded Drug Reporting

DSCSA ANNUAL REPORTING

Wholesale Drug Distributor and Third-Party Logistics Provider Reports

ALL SUBMISSIONS

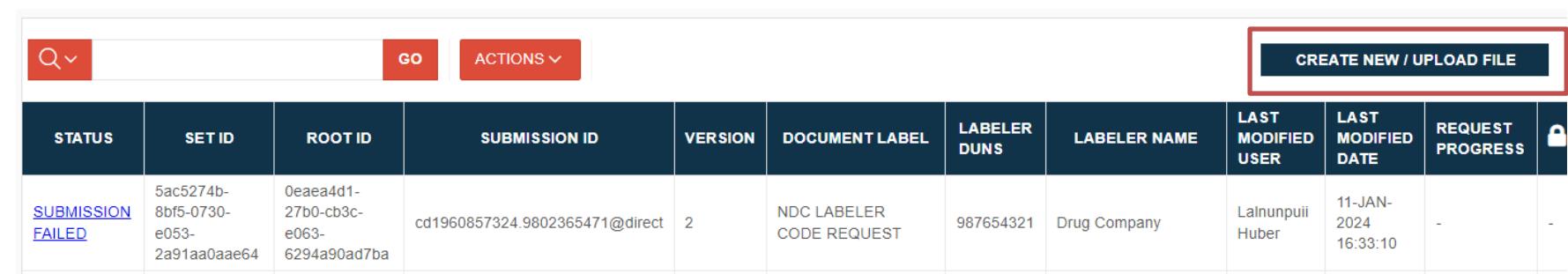
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1 - 1 >

## Step 4

Click on Create New / Upload File



Q v GO ACTIONS v

CREATE NEW / UPLOAD FILE

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LABELER DUNS	LABELER NAME	LAST MODIFIED USER	LAST MODIFIED DATE	REQUEST PROGRESS	LOCK
SUBMISSION FAILED	5ac5274b-8bf5-0730-e053-2a91aa0aae64	0eaea4d1-27b0-cb3c-e063-6294a90ad7ba	cd1960857324.9802365471@direct	2	NDC LABELER CODE REQUEST	987654321	Drug Company	Lainunpuii Huber	11-JAN-2024 16:33:10	-	-

## Step 5

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

**CREATE NEW NDC LABELER CODE REQUEST**

Create a new NDC Labeler Code Request using a blank form  
 Import an existing NDC Labeler Code Request SPL

**Note:** To update an existing submission, click on CANCEL and SELECT a submission with the status SUBMISSION ACCEPTED from the table in the prior page / Dashboard.

**CONTINUE** **CANCEL**

## 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**

**UPLOAD NDC LABELER CODE REQUEST FILE**

**NDC Labeler Code Request File**   
Select a file or drop one here.

**Note:** Please upload a zip file that contains the SPL file with the name as the root id followed by ".xml" and any associated image files that are referenced in the xml whose names end in '.jpg'.

**UPLOAD** **CANCEL**

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