

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

The screenshot shows the FDA Direct portal login page. The header features the FDA logo and the text "FDA Direct, CDER Direct & Cosmetics Direct". The main content area is divided into two columns. The left column contains a "LOGIN" section with fields for "Username:" and "Password:", a "Forgot your password?" link, a checkbox for "I accept the Terms of Service", and two buttons: "LOGIN" (red) and "CREATE NEW ACCOUNT" (dark blue). Below these is a "Quick Links" section with links to Resources, Tutorials, FAQs, CDER Direct Help Desk, and Cosmetic Direct Help Desk. The right column contains a "WELCOME TO FDA DIRECT" section with a paragraph about FDA Direct, sections for "CDER Direct" and "Cosmetics Direct" explaining their purposes, and a "Note" about Section 508 of the Rehabilitation Act. A blue warning banner at the bottom of the main content area provides privacy and security notices. The footer contains navigation links for FDA Home, Browser Requirements, Resources, Tutorials, Help Desk, FAQs, Follow FDA, FDA Voice Blog, Privacy, and Vulnerability Disclosure Policy.

**FDA Direct, CDER Direct & Cosmetics Direct**

**LOGIN**

Username:

Password:

[Forgot your password?](#)

☐ [I accept the Terms of Service](#)

**LOGIN**

OR

**CREATE NEW ACCOUNT**

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

**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/>.

**WARNING:** This warning banner provides privacy and security notices consistent with applicable federal laws, directives, and other federal guidance for accessing this Government system, which includes all devices/storage media attached to this system. This system is provided for Government authorized use only. Unauthorized or improper use of this system is prohibited and may result in disciplinary action and/or civil and criminal penalties. At any time, and for any lawful Government purpose, the Government may monitor, record, and audit your system usage and/or intercept, search and seize any communication or data transiting or stored on this system. Therefore, you have no reasonable expectation of privacy. Any communication or data transiting or stored on this system may be disclosed or used for any lawful Government purpose.

**FDA** [Home](#) | [Browser Requirements](#) | [Resources](#) | [Tutorials](#) | [Help Desk](#) | [FAQs](#)  
[Follow FDA](#) | [FDA Voice Blog](#) | [Privacy](#) | [Vulnerability Disclosure Policy](#)


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

Requesting a Labeler Code	<a href="#"><u>3</u></a>
Confirming or Updating Labeler Code Details	<a href="#"><u>12</u></a>
NDC Labeler Code Inactivation	<a href="#"><u>17</u></a>
Uploading a Labeler Code Request SPL File	<a href="#"><u>23</u></a>
Assistance with Errors	<a href="#"><u>27</u></a>

## 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**



FDA Direct

CDER Direct & Cosmetics Direct

LOGIN

Username:

Password:

[Forgot your password?](#)

☐ [I accept the Terms of Service](#)

LOGIN

OR

CREATE NEW ACCOUNT

Quick Links:

[Resources](#) | [Tutorials](#) | [FAQs](#) | [CDER Direct Help Desk](#) | [Cosmetic Direct Help Desk](#)

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 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 (OCC) about cosmetic manufacturers and products in the marketplace.

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/>.

# Requesting a Labeler Code



Step 3

Click on **NDC Labeler Code Request**

FDA

FDA Direct  
CDER Direct

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

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).

Q

GO

ACTIONS

1 - 1

Step 4

Click on **Create New/Upload File**

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

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.

Q

GO

ACTIONS

**CREATE NEW / UPLOAD FILE**

## 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**

es

est

**IDC LABELER CO**

or assistance with validation  
contact [edrls@fda.hhs.gov](mailto:edrls@fda.hhs.gov)

- The purpose of request...
- 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 providec

**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**

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

**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

### 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

— LABELER DETAILS

Labeler Name: \*

Labeler Code:

Labeler DUNS: \*

LABELER CONTACT DETAILS

Contact Name: \*

Contact Email: \*

Contact Phone: \*

Phone Extension:

Street Address: \*

City: \*

State/Province:

Postal Code:

Format

Labeler Name

×

The Labeler Name is the registrant or private label distributor requesting the NDC Labeler 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

FDA

FDA Direct

CDER Direct

All Submissions

NDC Labeler Code Request

SPL Submission

SAVE AS DRAFT

<< 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: \*

--Select One--

--Select One--

NDC LABELER CODE REQUEST

NDC LABELER CODE INACTIVATION

Set ID: \*

0d1c2353-101b-6235-e063-6394a90a82a4

Version Number: \*

1

Effective Date: \*

12-22-2023

Generate New

Generate New

## 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 DUNS: \*

Labeler Code:

LABELER CONTACT DETAILS

Contact Name: \*

Contact Email: \*

Contact Phone: \*

Phone Extension:

[Format](#)

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:

Phone Extension:

[Format](#)

— BUSINESS OPERATION(S)

ADD BUSINESS OPERATION



### 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:

Format

Business Operation/Qualifier

Business Operations:

Qualifier

CANCEL

SAVE

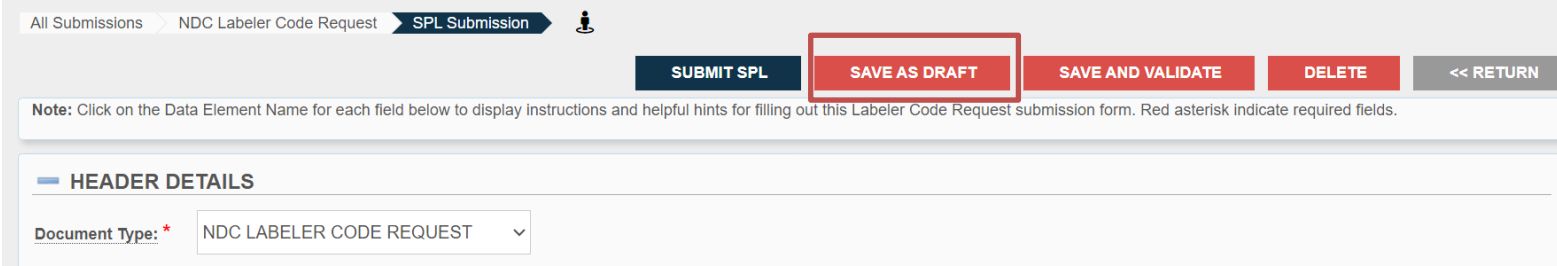
SAVE AND ADD

BUSINESS OPERATION(S)

ADD BUSINESS OPERATION

### Step 11a

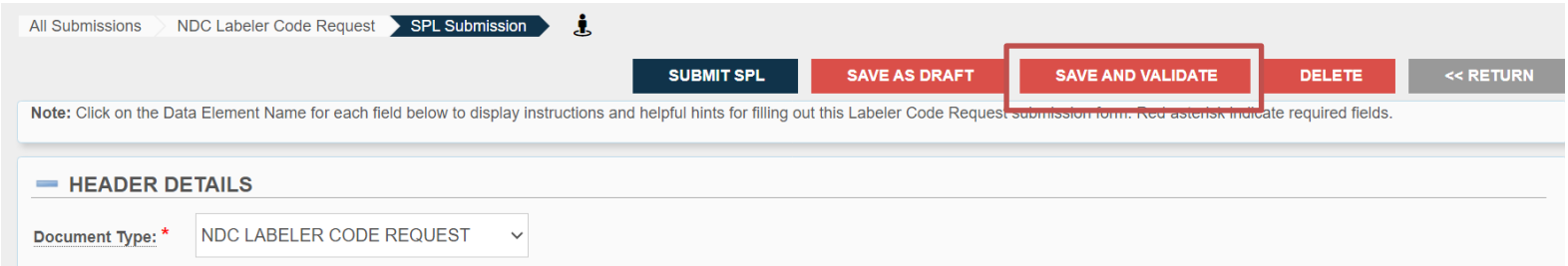
If you need to enter more data, click **Save as Draft** to save your progress and complete your submission at a later time



The screenshot shows the 'SPL Submission' form. At the top, there are navigation links: 'All Submissions', 'NDC Labeler Code Request', and 'SPL Submission'. Below these are five buttons: 'SUBMIT SPL', 'SAVE AS DRAFT', 'SAVE AND VALIDATE', 'DELETE', and '<< RETURN'. The 'SAVE AS DRAFT' button is highlighted with a red box. Below the buttons is a note: '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.' Below the note is a section titled 'HEADER DETAILS' with a dropdown menu for 'Document Type' set to 'NDC LABELER CODE REQUEST'.

### Step 11b

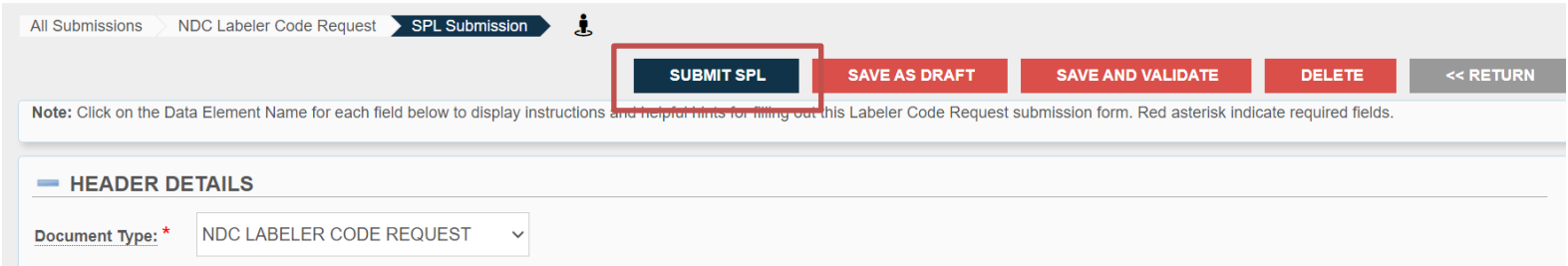
To ensure your submission will pass validation prior to sending it to the FDA, click **Save and Validate**



The screenshot shows the 'SPL Submission' form. At the top, there are navigation links: 'All Submissions', 'NDC Labeler Code Request', and 'SPL Submission'. Below these are five buttons: 'SUBMIT SPL', 'SAVE AS DRAFT', 'SAVE AND VALIDATE', 'DELETE', and '<< RETURN'. The 'SAVE AND VALIDATE' button is highlighted with a red box. Below the buttons is a note: '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.' Below the note is a section titled 'HEADER DETAILS' with a dropdown menu for 'Document Type' set to 'NDC LABELER CODE REQUEST'.

### Step 11c

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



The screenshot shows the 'SPL Submission' form. At the top, there are navigation links: 'All Submissions', 'NDC Labeler Code Request', and 'SPL Submission'. Below these are five buttons: 'SUBMIT SPL', 'SAVE AS DRAFT', 'SAVE AND VALIDATE', 'DELETE', and '<< RETURN'. The 'SUBMIT SPL' button is highlighted with a red box. Below the buttons is a note: '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.' Below the note is a section titled 'HEADER DETAILS' with a dropdown menu for 'Document Type' set to 'NDC LABELER CODE REQUEST'.

### 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
<a href="#">AWAITING ACCEPTANCE</a>	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
<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

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LABELER DUNS	LABELER NAME
<a href="#">SUBMISSION FAILED</a>	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**



**FDA Direct**  
CDER Direct & Cosmetics Direct

**LOGIN**

Username:

Password:

[Forgot your password?](#)

☐ [I accept the Terms of Service](#)

**LOGIN**

OR

**CREATE NEW ACCOUNT**

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

**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 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 (OCC) about cosmetic manufacturers and products in the marketplace.  
  
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/>.

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).

Q

GO

ACTIONS

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	LaInunpuui 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	LaInunpuui 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

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:

### 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

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

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:

## 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.


Q	GO	ACTIONS	CREATE NEW / UPLOAD FILE					
STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LABELER DUNS	LABELER NAME	
<a href="#">AWAITING ACCEPTANCE</a>	5ac5274b-8bf5-0730-e053-2a91aa0aae64	0eaea4d1-27b0-cb3c-e063-6294a90ad7ba		2	NDC LABELER CODE REQUEST	987654321	Drug Company	L



## NDC Labeler Code Inactivation

**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**



FDA Direct

CDER Direct & Cosmetics Direct

LOGIN

Username:

Password:

[Forgot your password?](#)

☐ [I accept the Terms of Service](#)

LOGIN

OR

CREATE NEW ACCOUNT

Quick Links:

Resources | Tutorials | FAQs | CDER Direct Help Desk | Cosmetic Direct Help Desk

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 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 (OCC) about cosmetic manufacturers and products in the marketplace.

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/>.

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.

Q

GO

ACTIONS

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	
<a href="#">AWAITING ACCEPTANCE</a>	5ac5274b-8bf5-0730-e053-2a91aa0aae64	0eaea4d1-27b0-cb3c-e063-6294a90ad7ba		2	NDC LABELER CODE REQUEST	987654321	Drug Company	Lalnunpuui 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	
<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	Lalnunpuui 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 SubmissionsNDC Labeler Code RequestSPL 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

Version Number: \*1

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

Effective Date: \*10-04-2017

LABELER DETAILS

Labeler Name: \*Drug Company

Labeler Code:

Step 6

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

—

HEADER DETAILS

Document Type: \*

NDC LABELER CODE REQUEST

--Select One--

NDC LABELER CODE REQUESTNDC LABELER CODE INACTIVATION

Set ID: \*

0eaea4d1-27b0-cb3c-e063-6294a90ad7ba

[Generate New](#)

Root ID: \*

0eaea4d1-27b0-cb3c-e063-6294a90ad7ba

[Generate New](#)

Version Number: \*

2

Effective Date: \*

01-11-2024

Step 7

Click on **Submit SPL**

SUBMIT SPL

SAVE AS DRAFT

DELETE

<< RETURN

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

[Generate New](#)

Root ID: \*

cd28a52e-c5c7-bf7e-e053-2995af0adb9a

[Generate New](#)

Version Number: \*

2

Effective Date: \*

09-28-2023

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.

<div><div>Q</div></div>		<div>GO</div>		<div>ACTIONS</div>		<div>CREATE NEW / UPLOAD FILE</div>		
STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LABELER DUNS	LABELER NAME	L M U
<div>AWAITING ACCEPTANCE</div>	5ac5274b-8bf5-0730-e053-2a91aa0aae64	0eaea4d1-27b0-cb3c-e063-6294a90ad7ba		2	NDC LABELER CODE REQUEST	987654321	Drug Company	L H

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**

FDA

FDA Direct  
CDER Direct & Cosmetics Direct

LOGIN

Username:

Password:

[Forgot your password?](#)

☐ [I accept the Terms of Service](#)

LOGIN

OR

CREATE NEW ACCOUNT

Quick Links:

Resources | Tutorials | FAQs | CDER Direct Help Desk | Cosmetic Direct Help Desk

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 allow 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 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.  
  
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/>.



Step 3

Click on **NDC Labeler Code Request**

FDA

FDA Direct  
CDER Direct

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

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).

Q

GO

ACTIONS

1 - 1

Step 4

Click on **Create New / Upload File**

Q

GO

ACTIONS

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	
<a href="#">SUBMISSION FAILED</a>	5ac5274b-8bf5-0730-e053-2a91aa0aae64	0eaea4d1-27b0-cb3c-e063-6294a90ad7ba	cd1960857324.9802365471@direct	2	NDC LABELER CODE REQUEST	987654321	Drug Company	Lainunpuil 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](mailto:CDERdirect@fda.hhs.gov)**.