

# CDER Direct Labeler Code Request Demo

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Office of Unapproved Drugs & Labeling Compliance

OC | CDER | US FDA

eDRLS Using CDER Direct 2024 – September 12, 2024



# Learning Objectives



- **Identify** the purpose and use of labeler codes
- **Demonstrate** the process of submitting a labeler code request
- **Complete** a labeler code assignment
- **Update** labeler contact or address information
- **Inactivate** a labeler code as necessary

# Labeler Code

The first segment of the NDC is the labeler code and currently consists of 4 or 5 digits.



# Labeler Code – General Info



- **Purpose of labeler code request:** To list drugs manufactured or distributed in the United States.
- **Do I need to apply for a labeler code?:** If your company does not have any drugs requiring FDA listing, you may not need to apply for a labeler code.
- **Inactivation of labeler codes:**
  - Labeler codes without any listed drugs will be automatically INACTIVATED after 24 months.
  - Labeler codes not assigned by FDA, or obtained by providing false information to FDA, may be inactivated without prior notice.
  - Firms may inactivate their FDA-assigned labeler code.

# Labeler Code Document Types

1. NDC Labeler Code Request
2. NDC Labeler Code Inactivation

**HEADER DETAILS**

**Document Type:** \* NDC LABELER CODE REQUEST

**Set ID:** \*   
NDC LABELER CODE REQUEST   
NDC LABELER CODE INACTIVATION

**Root ID:** \* 209ad82d-b40b-28a0-e063-6294a90a864a

# Live Demo of CDER 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 Label 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/>.

# Requesting a Labeler Code



U.S. Department of Health & Human Services | Welcome POINROBER-DALNON-01

**FDA** *FDA Direct*  
**CDER** *Direct & Cosmetics 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
- GENERIC DRUG SELF-IDENTIFICATION**
  - Generic Facility GDUFA Self-Identification

### ALL SUBMISSIONS

For assistance with drug related validation errors please contact [CDERDirect@fda.hhs.gov](mailto:CDERDirect@fda.hhs.gov) and for cosmetic related validation errors please contact [CosmeticsDirect@fda.hhs.gov](mailto:CosmeticsDirect@fda.hhs.gov).  
For general questions regarding electronic establishment registration and drug listing, contact [eDRLS@fda.hhs.gov](mailto:eDRLS@fda.hhs.gov). For general questions regarding electronic registration and listing of cosmetic product facilities, contact [eRLC@fda.hhs.gov](mailto:eRLC@fda.hhs.gov).

Q

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE	
<a href="#">DRAFT</a>	20a110c2-bbd7-6471-e063-6294a90a0293	20a110cc-8c07-96f5-e063-6294a90ab87a		7	HUMAN OTC DRUG LABEL	Lainunpull Huber	26-AUG-2024 21:21:52	

1 - 1 >

# Requesting a Labeler Code



**— LABELER DETAILS**

Labeler Name: \*  Labeler Code:

Labeler DUNS: \*

**LABELER CONTACT DETAILS**

Contact Name: \*

Contact Email: \*

Contact Phone: \*  [Format](#)

Phone Extension:

**LABELER CONTACT ADDRESS**

Country: \*

Street Address: \*

City: \*

State: \*

Postal Code: \*

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

**LABELER ADDRESS**

Same as Labeler Contact Address

Country: \*

Street Address: \*

**U.S. AGENT**

Agent Name:

Agent DUNS:

Agent Email:



# Requesting a Labeler Code



Contact Name: \* Puii Huber Country: \* United States

Contact Email: \* puii@fda.gov Street Address: \* 10903 New Hampshire Ave

Contact Phone: \* 1-333-333-3333 [Format](#) City: \* Silver Spring

Phone Extension: Phone Extension: State: \* Maryland

Postal Code: \* 20903

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

**LABELER ADDRESS**

Same as Labeler Contact Address

Country: \* United States

Street Address: \* 10903 New Hampshire Ave

City: \* Silver Spring

State: \* Maryland

Postal Code: \* 20903

**— BUSINESS OPERATION(S)** [ADD BUSINESS OPERATION](#)

EDIT	DELETE	BUSINESS OPERATION	QUALIFIER
		MANUFACTURE	* MANUFACTURES HUMAN PRESCRIPTION DRUG PRODUCTS

# Requesting a Labeler Code



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: \* NDC LABELER CODE REQUEST

Set ID: \* 20ab53d1-82b8-45c6-e063-6294a90a413a [Generate New](#) Version Number: \* 1

Root ID: \* 20ab53d1-82b9-45c6-e063-6294a90a413a [Generate New](#) Effective Date: \* 08-27-2024

**LABELER DETAILS**

Labeler Name: \* FDA Drug Company Labeler Code:

Labeler DUNS: \* 987654321

**LABELER CONTACT DETAILS**

Contact Name: \* Pull Huber

Contact Email: \* pull@fda.gov

Contact Phone: \* 1-333-333-3333 [Format](#)

Phone Extension:

**LABELER CONTACT ADDRESS**

Country: \* United States

Street Address: \* 10903 New Hampshire Ave

City: \* Silver Spring

State: \* Maryland

# Labeler Code - Assigned



**FDA will send an email to the contact email on the request with the assigned number.**

eDRLS - Electronic Drug Registration & Listing System

Current Date: 31-August-2023

Labeler DUNS: 000000000

Labeler Name: A1 Drug Company

Labeler Code Assigned: 00000



The Food and Drug Administration (FDA) has assigned the above Labeler Code to your firm. The number cannot be used until you have confirmed the assignment. Please revise and resubmit your Labeler Code Request SPL to include the assigned number above to complete the process. To do this, open the previous Labeler Code Request SPL file and fill in the new information (your assigned Labeler Code) without changing the other existing information. Fill in a new root id and new version number with the original set id and the appropriate effective time.

For CDER Direct Users: Open the previously submitted and accepted Labeler Code Request, click Create New Version, enter the Labeler Code assigned in the field for "Labeler Code", and Submit SPL.

This Labeler Code should be used to create the NDC (National Drug Code) assigned to all drugs you manufacture or distribute for U.S. commercial distribution. The assignment of NDC is extensively discussed in Title 21 of Code of Federal Regulations (CFR) 207.35. The NDC for each drug must be submitted as part of drug listing information submitted to FDA. Per 21 CFR Part 207, owners or operators of an establishment entering into the manufacture or processing of a drug or drugs shall drug list, every drug in their commercial distribution within 5 days after the beginning of operation. Labeler Codes are assigned by FDA and may be inactivated at any time upon violation of the Federal Food, Drug and Cosmetic Act.

# Confirm Labeler Code Assignment



additional validation and processing. Check the status of your submission after a few minutes by refreshing the page or logging back into the system. You will also receive an email notification.

## 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 US.
- [§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 at. The labeler code is 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 statement to the Government is subject to criminal penalties.

Q

STATUS = 'SUBMISSION ACCEPTED'

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LABELER DUNS	LABELER NAME	LAST MODIFIED USER
<a href="#">SUBMISSION ACCEPTED</a>	5ac5274b-8bf5-0730-e053-2a91aa0aae64	5ac5274b-8bf5-0730-e053-2a91aa0aae64	cd392145786.6719058342@direct	1	NDC LABELER CODE REQUEST	987654321	Drug Company	Lainunpui Huber
<a href="#">SUBMISSION ACCEPTED</a>	59fce009-d61b-4500-e053-2991aa0a83bc	59fce009-d61c-4500-e053-2991aa0a83bc	cd8320549617.8506321497@direct	1	NDC LABELER CODE REQUEST	987654321	Drug Name	Lainunpui Huber

# Labeler Code Request Rejections



- Why would a labeler code request get rejected?
  - Requesting firm is not required to register and list
  - The product they manufacture or distribute is not a drug
  - Requesting firm is already assigned a labeler code

# Industry-Initiated Labeler Code Inactivation



Labeler code is no longer needed due to:

- Out of business/change in business
- Mergers/acquisitions
- Application for a drug in development did not get approved by FDA

# Labeler Code – How to Inactivate



## LOGIN

Username:

Password:

[Forgot your password?](#)

[I accept the Terms of Service](#)

LOGIN

OR

CREATE NEW ACCOUNT

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Direct

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STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LABELER DUNS	LABELER NAME	LAST MODIFIED USER
<a href="#">SUBMISSION ACCEPTED</a>	5ac5274b-8bf5-0730-e053-2a91aa0aae64	5ac5274b-8bf5-0730-e053-2a91aa0aae64	cd392145786.6719058342@direct	1	NDC LABELER CODE REQUEST	987654321	Drug Company	Lainunpui Huber
<a href="#">SUBMISSION ACCEPTED</a>	59fce009-d61b-4590-e053-2991aa0a83bc	59fce009-d61c-4590-e053-2991aa0a83bc	cd8320549617.8506321497@direct	1	NDC LABELER CODE REQUEST	987654321	Drug Name	Lainunpui Huber



# Labeler Code – How to Reactivate



- Industry-initiated inactivation :

The screenshot displays the 'PREVIEW SPL' form in the CDERSBIA system. At the top, a green notification bar states 'SPL has been successfully cloned'. Below this, a breadcrumb trail shows 'All Submissions > NDC Labeler Code Request > SPL Submission'. The form includes navigation buttons: 'PREVIEW SPL', 'SUBMIT SPL', 'SAVE AS DRAFT', 'DELETE', and '<< RETURN'. A note indicates that red asterisks denote required fields. The 'HEADER DETAILS' section contains the following information:

Field	Value	Action
Document Type *	NDC LABELER CODE INACTIVATION	
Set ID *	5ac5274b-8bf5-0730-e053-2a91aa0aae64	<a href="#">Generate New</a>
Version Number *	2	
Root ID *	20ac158b-a19e-cd3c-e063-6394a90a0c49	<a href="#">Generate New</a>
Effective Date *	08-27-2024	

# Summary

- Labeler Code SPL should be submitted when drugs are ready to be launched for U.S. commercial distribution.
- To complete the labeler code process, inactivate a labeler code or update the labeler code assignment
  - Use the original Set ID Root that was used to request the labeler code.

# Summary



- Labeler codes without listed drugs are automatically inactivated after 24 months.
- To inactivate a labeler code, submit a NDC Labeler Code Inactivation SPL.

# Challenge Question 1



What happens if a labeler code does not have any products listed for two years?

- a) It will be automatically reactivated by the FDA.
- b) It will be permanently inactivated by the FDA.
- c) It will receive a notification 30 days prior to inactivation.
- d) It will be transferred to a different regulatory agency.

# Challenge Question 2



A labeler code is a component of the National Drug Code (NDC) used to identify the manufacturer or distributor of a drug product. What does the labeler code represent in the NDC?

- a) The dosage form of the drug
- b) The specific product formulation
- c) The package size and type
- d) The manufacturer or distributor of the drug

# Challenge Question 3



Which of the following is a reason why a labeler code request might be rejected?

- a) The requesting firm is required to register and list.
- b) The product they manufacture or distribute is classified as a drug.
- c) The requesting firm is not required to register and list.
- d) The requesting firm has not been assigned a labeler code.

# Questions?

[eDRLS@fda.hhs.gov](mailto:eDRLS@fda.hhs.gov)





**U.S. FOOD & DRUG**  
ADMINISTRATION