

CDER Direct Labeler Code Request Demo

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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



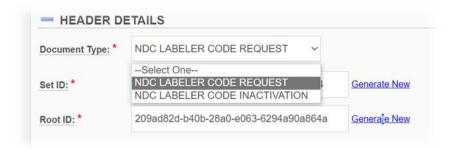
- **Purpose of labeler code request:** To list drugs manufactured or distributed in the United States.
- Do I need to apply for a labeler code?: If your company does not have any drugs requiring FDA listing, you may not need to apply for a labeler code.
- Inactivation of labeler codes:
 - Labeler codes 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.







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



Live Demo of CDER Direct

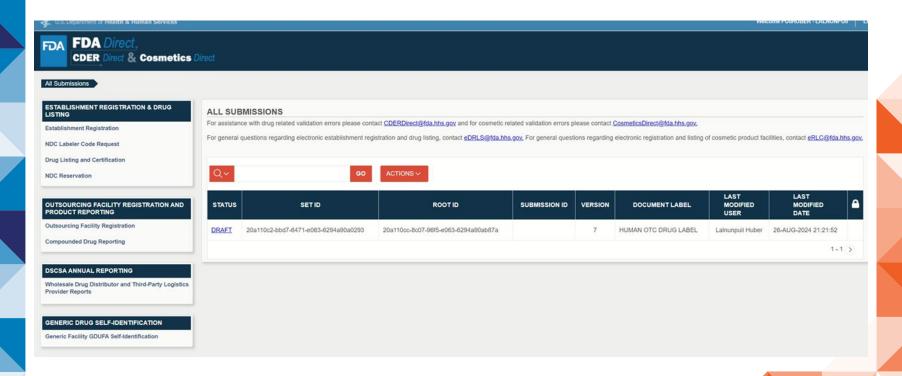


LOGIN	WELCOME TO FDA DIRECT
Jsername:	FDA Direct is U.S. Food and Drug Administration's web-based and free structured product labeling (SPL) authoring tool. Previously CDER Direct FDA Direct now includes CDER Direct and Cosmetics Direct. Users can create separate accounts, depending on drugs or cosmetics submissions, or a single account that includes both CDER Direct submissions as well as Cosmetics Direct submissions.
Password:	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 facilitie 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.
Forgot your password?	Cosmetics Direct
Laccept the Terms of Service	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
LOGIN	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.
OR	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.
CREATE NEW ACCOUNT	
Resources Tutorials FAQs CDER	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 as

https://direct.fda.gov











Labeler Name: *	FDA Drug Company		Labeler Code:		
Labeler DUNS: *	987654321				
LABELER CONT	ACT DETAILS		LABELER CONTACT	ADDRESS	
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:	13		State: *	Maryland	
			Postal Code: *	20903	
— ADDITIONAL LABELER ADDR	AL LABELER DETAILS (Optional	I - Including the following	information will expedite the	processing of your request)	
Same as Labr	eler Contact Address		Agent Name:		
Country: *	Select Country	~	Agent DUNS:		

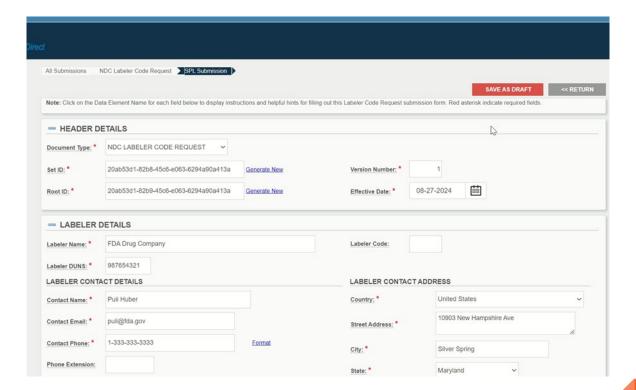




Contact Name: *	Puil Huber		Country: *	United States	~
Contact Email: *	puii@fda.gov		Street Address: *	10903 New Hampshire Ave	
Contact Phone: *	1-333-333-3333	Format	City: *	Silver Spring	
Phone Extension:			State: *	Maryland	
			Postal Code: *	20903	
— ADDITIONAL	AL LABELER DETAILS (Option	nal - Including the following i	nformation will expedite the p	processing of your request)	
	eler Contact Address				
Country: *	United States	V			
Street Address: *	10903 New Hampshire Av	e			
City: *	Silver Spring				
	Silver Spring Maryland	~			
State: *		v			
State: * Postal Code: *	Maryland	~		ADD BUSINESS OF	PERATION
	Maryland 20903			ADD BUSINESS OF	°ERATION



Requesting a Labeler Code



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



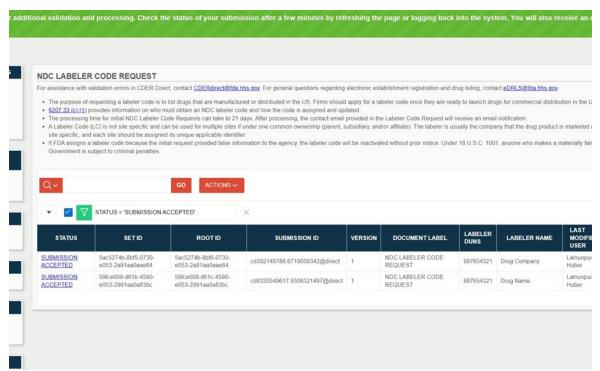
The Food and Drug Administration (FDA) has assigned the above Labeler Code to your firm. The number cannot be used until you have confirmed the assignment. Please revise and resubmit your Labeler Code Request SPL to include the assigned number above to complete the process. To do this, open the previous 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, following into the manufacture or processing of a drug or drugs shall drug list, following into the manufacture or processing of a drug or drugs shall drug list, following into the manufacture or processing of a drug or drugs shall drug list, following into the manufacture or processing of a drug or drugs shall drug list, following into the manufacture or processing of a drug or drugs shall drug list, following into the manufacture or processing of a drug or drugs shall drug list, following into the manufacture or processing of a drug or drugs shall drug list, following into the manufacture or processing of a drug or drugs shall drug list, following into the manufacture or processing of a drug or drugs shall drug list, following into the manufacture or processing of a drug list, following into the manufacture or processing of a drug or drugs shall drug list, following into the manufacture or processing of a drug list, following into the manufacture or processing of a drug or drugs shall drug list, following into the manufacture or processing or drugs shall drug list, following into the manufacture or processing or drugs shall drug list, following into the manufacture or processing or drugs shall drug list, following into the manufacture or processing or drugs shall drug list, following into the manufacture or processing or drugs shall drug list, following into the manufacture or processing or drugs shall drug list, following into the manufacture or processing or drugs shall drug list, following into the manufacture or proce

Confirm Labeler Code Assignment





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

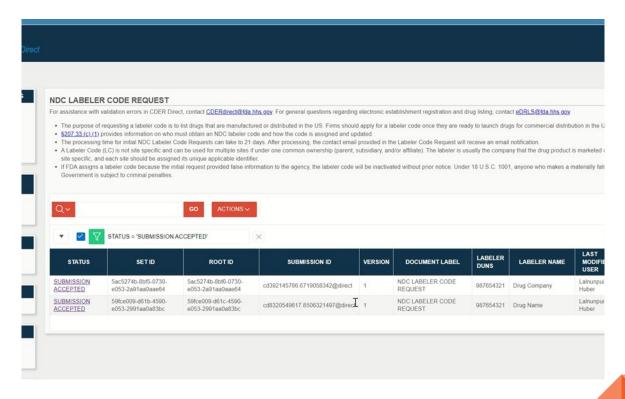


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Labeler Code – How to Inactivate

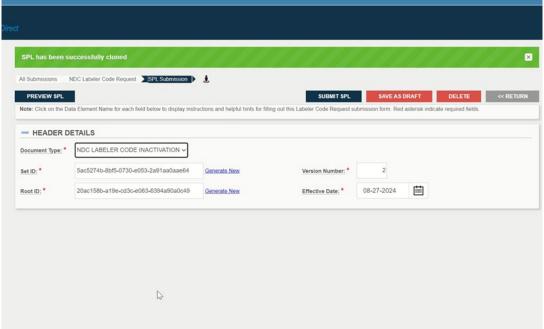




Labeler Code – How to Reactivate



Industry-initiated inactivation :



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.
- It will be permanently inactivated by the FDA.
- 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?

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