

CDER Direct Labeler Code Request Demo

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Learning Objectives

- Learn to create, complete, and submit NDC NHRIC Labeler Code SPL
- Learn to confirm labeler code assignment

Labeler Code

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





Labeler Code – General Info

- Labeler code is assigned by FDA after a company submits a Labeler Code SPL to request one.
- Labeler code uniquely identifies the company that puts the drug in U.S. commercial distribution under own name and label.
- Labelers are entities that labeler code part of the NDC is assigned to by FDA
 - Labelers may be registered manufacturing facilities, or private label distributors (such as applicants).

Labeler code Document Types



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



Labeler Code - How

- Live Demo of CDER Direct

<https://direct.fda.gov>

- Requesting a labeler code
- Completing a labeler code process
- Updating labeler contact or address
- Confirm labeler code assignment

[Home](#) > [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: *

Set ID: *

[Generate New](#)

Version Number: *

Root ID: *

[Generate New](#)

Effective Date: *



== 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: *

SUBMISSIONS

[\(ADD SUBMISSION TYPE\)](#)[NDC Labeler Code Request](#)[Establishment Registration](#)[GDUFA Self-Identification](#)[Product Listing and Certification](#)[NDC Reservation](#)

NDC LABELER CODE REQUEST

For assistance with validation errors in CDER Direct, contact CDERdirect@fda.hhs.gov. For general questions regarding electronic drug registration and listing, contact cders@fda.hhs.gov.

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LABELER DUNS	LABELER NAME	LAST MODIFIED USER	LAST MODIFIED DATE	REQUEST PROGRESS	
AWAITING ACCEPTANCE	05052a4b-6a66-0828-e063-6b94af0a673	05052a4b-6a67-0828-e063-6b94af0a673	cd972684315-8074651382@direct	1	NDC LABELER CODE REQUEST	123456789	WonderPharma	Soo Jin Park	21-SEP-2023 18:16:59	-	-
SUBMISSION FAILED	04312c4a-d284-b0fc-e053-2965af0a28b9	05d34713-2d99-c411-e063-6a94af0a297	cd8726803491-8493527801@direct	3	NDC LABELER CODE REQUEST	123456789	Wonderpharma	Soo Jin Park	20-SEP-2023 20:11:08	-	-
SUBMISSION ACCEPTED	04312c4a-d284-b0fc-e053-2965af0a28b9	05cb4e05-a2f7-3829-e063-6a94af0a2fc5	cd4378569120-9572306184@direct	2	NDC LABELER CODE REQUEST	123456789	Wonderpharma	Soo Jin Park	20-SEP-2023 09:33:09	-	-
VALIDATION FAILURE	05ca5a78-1280-73b5-e063-6a94af0a25f	05ca5a78-12d1-73b5-e063-6a94af0a25f		1	NDC LABELER CODE REQUEST	987654321	Drug Name	Soo Jin Park	20-SEP-2023 08:06:08	-	-

1 - 4



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 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.

Note that receipt of this letter is not to be construed as Federal Government endorsement or approval of the establishment or its products.

For additional information please visit Drug Registration and Listing System or reply back to this email (edrls@fda.hhs.gov).

SUBMISSIONS

[\(ADD SUBMISSION TYPE\)](#)[NDC Labeler Code Request](#)[Establishment Registration](#)[GDUFA Self-Identification](#)[Product Listing and Certification](#)[NDC Reservation](#)

MANAGE ACCOUNT

[Edit User Profile](#)[Manage Users](#)

ALL SUBMISSIONS

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GO

ACTIONS ▾

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE	
SUBMISSION ACCEPTED	84312c4a-d284-bbfc-e063-2995af0a28b9	05cb4e85-a2f7-3929-e063-6b94af0adfc5	cd4378589120.9572306184@direct	2	NDC LABELER CODE REQUEST	Soo Jin Park	20-SEP-2023 09:33:09	
VALIDATION FAILURE	05ca5a78-12d0-73b5-e063-6a94af0ad25f	05ca5a78-12d1-73b5-e063-6a94af0ad25f		1	NDC LABELER CODE REQUEST	Soo Jin Park	20-SEP-2023 09:06:08	
DRAFT	8fb6319d-ec40-7d31-e053-2a91ab0a239d	8fb6319d-ec41-7d31-e053-2a91ab0a239d		1	HUMAN COMPOUNDED DRUG LABEL	Soo Jin Park	28-JUN-2018 11:16:32	
DRAFT	6debe8fd-c10f-1d24-e053-2991ab0a02f2	6debe8fd-c110-1d24-e053-2991ab0a02f2		1	HUMAN OTC DRUG LABEL NDC RESERVATION	Soo Jin Park	05-JUN-2018 16:29:45	
DRAFT	8dd26d63-f490-530b-e053-2991ab0a960f	8de92115-a9b0-2f45-e053-2991ab0a26f7		2	BULK INGREDIENT NDC RESERVATION	Soo Jin Park	05-JUN-2018 13:34:33	
DRAFT	8dd26d63-f492-530b-e053-2991ab0a960f	8de92115-a9af-2f45-e053-2991ab0a26f7		2	BULK INGREDIENT NDC RESERVATION	Soo Jin Park	05-JUN-2018 13:34:07	
SUBMISSION ACCEPTED	8dd26d63-f490-530b-e053-2991ab0a960f	8dd26d63-f48f-530b-e053-2991ab0a960f	cd5146028739.352189764@direct	1	BULK INGREDIENT NDC RESERVATION	Soo Jin Park	04-JUN-2018 11:00:12	
SUBMISSION ACCEPTED	8dd26d63-f492-530b-e053-2991ab0a960f	8dd26d63-f491-530b-e053-2991ab0a960f	cd7548201936.7326518409@direct	1	BULK INGREDIENT NDC RESERVATION	Soo Jin Park	04-JUN-2018 10:57:12	
SUBMISSION ACCEPTED	6d987ed3-d21d-8db8-e053-2a91ab0adc46	6d98a9ee-d587-9d17-e053-2991ab0a818d	cd5169208374.5982410378@direct	3	BULK INGREDIENT	Soo Jin Park	01-JUN-2018 13:42:10	
SUBMISSION ACCEPTED	6d987ed3-d21d-8db8-e053-2a91ab0adc46	6d987ed3-d21c-8db8-e053-2a91ab0adc46	cd8749032516.4805312697@direct	2	BULK INGREDIENT NDC RESERVATION	Soo Jin Park	01-JUN-2018 13:08:09	

Summary



- Labeler Code SPL should be submitted when drugs are ready to be launched for U.S. commercial distribution.
- Labeler code information must be updated within 30 calendar days after any change
- 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.

Test Your Knowledge



1. Labelers may be registered manufacturing facilities, or private label distributors (such as applicants)
 - A. True
 - B. False

Test Your Knowledge



2. Labeler code information must be updated within how many calendar days after any changes occur?

- A. 14
- B. 90
- C. 30
- D. Never

Questions?

eDRLS@fda.hhs.gov