



CDER Direct Labeler Code Request Demo

LCDR Soo Jin Park, PharmD., MS

Regulatory Operations Officer
Drug Registration and Listing Branch
FDA/CDER/OUDLC

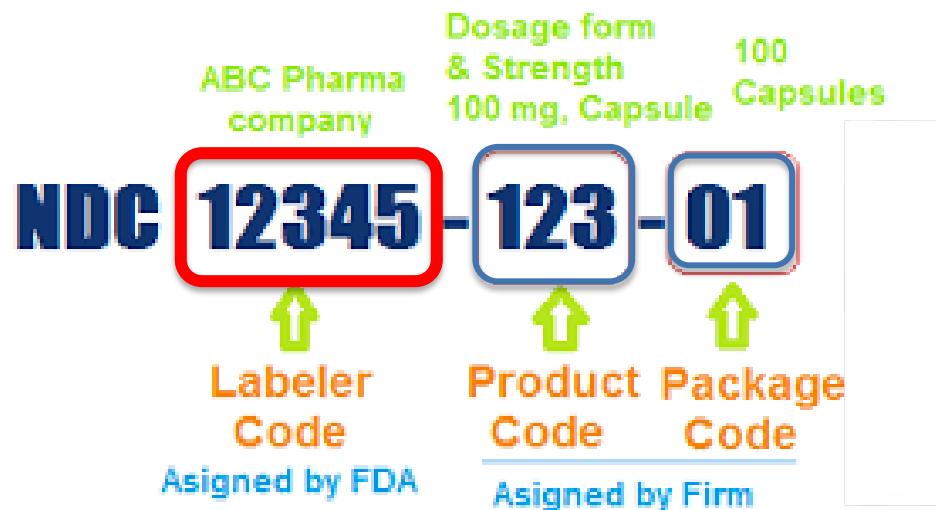
Learning Objectives



- 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

REQUEST



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



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

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE	LOCK
DRAFT	05d52a4b-6a66-0828-e063-6b94af0ae673	05d52a4b-6a67-0828-e063-6b94af0ae673		1	NDC LABELER CODE REQUEST	Soo Jin Park	20-SEP-2023 21:12:50	
SUBMISSION FAILED	84312c4a-d284-bbfc-e053-2995af0a28b9	05d34713-2d99-c411-e063-6a94af0ac297	cd87265034916493527801@direct	3	NDC LABELER CODE REQUEST	Soo Jin Park	20-SEP-2023 20:11:08	
SUBMISSION ACCEPTED	84312c4a-d284-bbfc-e053-2995af0a28b9	05cb4e85-a2f7-3929-e063-6b94af0adfc5	cd43785691209572306184@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	6fb6319d-ec40-7d31-e053-2a91ab0a239d	6fb6319d-ec41-7d31-e053-2a91ab0a239d		1	HUMAN COMPOUNDED DRUG LABEL	Soo Jin Park	28-JUN-2018 11:18:32	
DRAFT	6debe8fd-c10f-1d24-e053-2991ab0a02f2	6debe8fd-c110-1d24-e053-2991ab0a02f2		1	HUMAN OTC DRUG LABEL <small>NDC RESERVATION</small>	Soo Jin Park	05-JUN-2018 16:29:45	
DRAFT	6dd26d63-f490-530b-e053-2991ab0a960f	6de92115-a9b0-2f45-e053-2991ab0a26f7		2	BULK INGREDIENT <small>NDC RESERVATION</small>	Soo Jin Park	05-JUN-2018 13:34:33	
DRAFT	6dd26d63-f492-530b-e053-2991ab0a960f	6de92115-a9af-2f45-e053-2991ab0a26f7		2	BULK INGREDIENT <small>NDC RESERVATION</small>	Soo Jin Park	05-JUN-2018 13:34:07	
SUBMISSION ACCEPTED	6dd26d63-f490-530b-e053-2991ab0a960f	6dd26d63-f48f-530b-e053-2991ab0a960f	cd5146028739352189764@direct	1	BULK INGREDIENT <small>NDC RESERVATION</small>	Soo Jin Park	04-JUN-2018 11:00:12	
SUBMISSION ACCEPTED	6dd26d63-f492-530b-e053-2991ab0a960f	6dd26d63-f491-530b-e053-2991ab0a960f	cd75482019367326518409@direct	1	BULK INGREDIENT <small>NDC RESERVATION</small>	Soo Jin Park	04-JUN-2018 10:57:12	
SUBMISSION ACCEPTED	6d987ed3-d21d-6db8-e053-2a91ab0adc46	6d98a9ee-d587-9d17-e053-2991ab0a818d	cd51692083745982410376@direct	3	BULK INGREDIENT	Soo Jin Park	01-JUN-2018 13:42:10	
SUBMISSION	2A007A02-A71A-8A00	2A007A02-A71A-8A00	cd8749032516		REVIEW		01-JUN-2018	

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 DETAILSDocument Type: * **NDC LABELER CODE REQUEST** 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: * Country: * Contact Email: * Street Address: * Contact Phone: * City: * Phone Extension: State: * Postal Code: * **LABELER CONTACT ADDRESS**

SUBMISSIONS
 (ADD SUBMISSION TYPE)

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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 eDRLS@fda.hhs.gov.

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	LOCK
AWAITING ACCEPTANCE	05d52a4b-6a66-0828-e063-6b94af0ae673	05d52a4b-6a67-0828-e063-6b94af0ae673	cd972684315.8074651392@direct	1	NDC LABELER CODE REQUEST	123456789	WonderPharma	Soo Jin Park	21-SEP-2023 18:16:59	-	-
SUBMISSION FAILED	84312c4a-d284-bbfc-e053-2995af0a28b9	05d34713-2d99-c411-e063-6a94af0ac297	cd8726503491.6493527801@direct	3	NDC LABELER CODE REQUEST	123456789	Wonderpharma	Soo Jin Park	20-SEP-2023 20:11:08	-	-
SUBMISSION ACCEPTED	84312c4a-d284-bbfc-e053-2995af0a28b9	05cb4e85-a2f7-3929-e063-6b94af0adfc5	cd4378569120.9572306184@direct	2	NDC LABELER CODE REQUEST	123456789	Wonderpharma	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	987654321	Drug Name	Soo Jin Park	20-SEP-2023 09:06:08	-	-
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
[**\(ADD SUBMISSION TYPE\)**](#)

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DRAFT	6dd26d63-f492-530b-e053-2991ab0a960f	6de92115-a9af-2f45-e053-2991ab0a26f7		2	BULK INGREDIENT	Soo Jin Park	05-JUN-2018 13:34:07	
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SUBMISSION ACCEPTED	6dd26d63-f492-530b-e053-2991ab0a960f	6dd26d63-f491-530b-e053-2991ab0a960f	cd7548201936.7326518409@direct	1	BULK INGREDIENT	Soo Jin Park	04-JUN-2018 10:57:12	
SUBMISSION ACCEPTED	6d987ed3-d21d-6db8-e053-2a91ab0adc46	6d98a9ee-d587-9d17-e053-2991ab0a818d	cd5169208374.5982410376@direct	3	BULK INGREDIENT	Soo Jin Park	01-JUN-2018 13:42:10	
SUBMISSION ACCEPTED	6d987ed3-d21d-6db8-e053-2a91ab0adc46	6d987ed3-d21c-6db8-e053-2a91ab0adc46	cd8749032516.4805312697@direct	2	BULK INGREDIENT	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, deactivate 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