

# CDER Direct Labeler Code Request Demo

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Drug Registration and Listing Branch

FDA/CDER/OU DLC

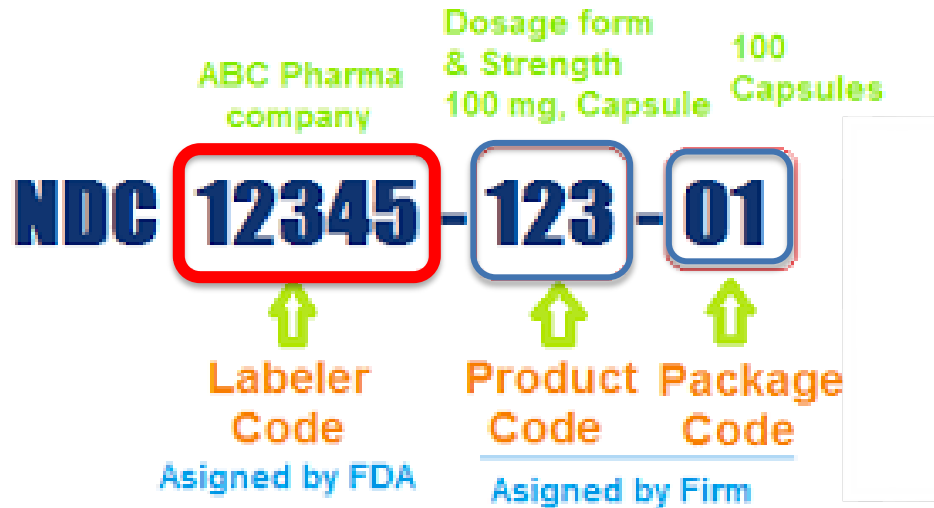


# Learning Objectives

- 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

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

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



GO

ACTIONS

| STATUS                              | SET ID                               | ROOT ID                              | SUBMISSION ID                  | VERSION | DOCUMENT LABEL  | LAST MODIFIED USER | LAST MODIFIED DATE   |  |
|-------------------------------------|--------------------------------------|--------------------------------------|--------------------------------|---------|---|--------------------|----------------------|--|
| <a href="#">DRAFT</a>               | 05d52a4b-6a66-0828-e063-6b94af0ae673 | 05d52a4b-6a67-0828-e063-6b94af0ae673 |                                | 1       | NDC LABELER CODE REQUEST  | Soo Jin Park       | 20-SEP-2023 21:12:50 |  |
| <a href="#">SUBMISSION FAILED</a>   | 84312c4a-d284-bbfc-e053-2995af0a28b9 | 05d34713-2d99-c411-e063-6a94af0ac297 | cd8726503491.6493527801@direct | 3       | NDC LABELER CODE REQUEST  | Soo Jin Park       | 20-SEP-2023 20:11:08 |  |
| <a href="#">SUBMISSION ACCEPTED</a> | 84312c4a-d284-bbfc-e053-2995af0a28b9 | 05cb4e85-a2f7-3929-e063-6b94af0adfc5 | cd4378569120.9572306184@direct | 2       | NDC LABELER CODE REQUEST  | Soo Jin Park       | 20-SEP-2023 09:33:09 |  |
| <a href="#">VALIDATION FAILURE</a>  | 05ca5a78-12d0-73b5-e063-6a94af0ad25f | 05ca5a78-12d1-73b5-e063-6a94af0ad25f |                                | 1       | NDC LABELER CODE REQUEST  | Soo Jin Park       | 20-SEP-2023 09:06:08 |  |
| <a href="#">DRAFT</a>               | 6fb6319d-ec40-7d31-e053-2a91ab0a239d | 6fb6319d-ec41-7d31-e053-2a91ab0a239d |                                | 1       | HUMAN COMPOUNDED DRUG LABEL   | Soo Jin Park       | 28-JUN-2018 11:16:32 |  |
| <a href="#">DRAFT</a>               | 6debe8fd-c10f-1d24-e053-2991ab0a02f2 | 6debe8fd-c110-1d24-e053-2991ab0a02f2 |                                | 1       | HUMAN OTC DRUG LABEL <span style="color:red">NDC RESERVATION</span> | Soo Jin Park       | 05-JUN-2018 16:29:45 |  |
| <a href="#">DRAFT</a>               | 6dd26d63-f490-530b-e053-2991ab0a960f | 6de92115-a9b0-2f45-e053-2991ab0a26f7 |                                | 2       | BULK INGREDIENT <span style="color:red">NDC RESERVATION</span>      | Soo Jin Park       | 05-JUN-2018 13:34:33 |  |
| <a href="#">DRAFT</a>               | 6dd26d63-f492-530b-e053-2991ab0a960f | 6de92115-a9af-2f45-e053-2991ab0a26f7 |                                | 2       | BULK INGREDIENT <span style="color:red">NDC RESERVATION</span>      | Soo Jin Park       | 05-JUN-2018 13:34:07 |  |
| <a href="#">SUBMISSION ACCEPTED</a> | 6dd26d63-f490-530b-e053-2991ab0a960f | 6dd26d63-f48f-530b-e053-2991ab0a960f | cd5146028739.352189764@direct  | 1       | BULK INGREDIENT <span style="color:red">NDC RESERVATION</span>      | Soo Jin Park       | 04-JUN-2018 11:00:12 |  |
| <a href="#">SUBMISSION ACCEPTED</a> | 6dd26d63-f492-530b-e053-2991ab0a960f | 6dd26d63-f491-530b-e053-2991ab0a960f | cd7548201936.7326518409@direct | 1       | BULK INGREDIENT <span style="color:red">NDC RESERVATION</span>      | Soo Jin Park       | 04-JUN-2018 10:57:12 |  |
| <a href="#">SUBMISSION ACCEPTED</a> | 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 |  |
| <a href="#">SUBMISSION</a>          | 6d097ad3-d71a-64b9                   | 6d097ad3-d71a-64b9                   | cd8749032516                   |         | BULK  |                    | 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 DETAILS**

Document Type: \* NDC LABELER CODE REQUEST

Set ID: \* 05d52a4b-6a66-0828-e063-6b94af0ae673 [Generate New](#)

Version Number: \* 1

Root ID: \* 05d52a4b-6a67-0828-e063-6b94af0ae673 [Generate New](#)

Effective Date: \* 09-20-2023 

**LABELER DETAILS**

Labeler Name: \* WonderPharma

Labeler Code:

Labeler DUNS: \* 123456789

**LABELER CONTACT DETAILS**

Contact Name: \* John Doe

Contact Email: \* Wonderpharma@Wonderpharma.com

Contact Phone: \* 555-876-5309 [Format](#)

Phone Extension:

**LABELER CONTACT ADDRESS**

Country: \* United States

Street Address: \* 123 Main St

City: \* Herndon

State: \* Virginia

Postal Code: \* 20171



**SUBMISSIONS**  
[\(ADD SUBMISSION TYPE\)](#)

- NDC Labeler Code Request
- Establishment Registration
- GOUGA Self-Identification
- Product Listing and Certification
- NDC Reservation

**NDC LABELER CODE REQUEST**

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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> | 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 | -                | - |
| <a href="#">SUBMISSION FAILED</a>   | 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 | -                | - |
| <a href="#">SUBMISSION ACCEPTED</a> | 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 | -                | - |
| <a href="#">VALIDATION FAILURE</a>  | 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 | -                | - |

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# 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 ([edrIs@fda.hhs.gov](mailto:edrIs@fda.hhs.gov)).

## SUBMISSIONS

[\(ADD SUBMISSION TYPE\)](#)

NDC Labeler Code Request

Establishment Registration

GDUFA Self-Identification

Product Listing and Certification

NDC Reservation

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| <a href="#">DRAFT</a>               | 6debe8fd-c10f-1d24-e053-2991ab0a02f2 | 6debe8fd-c110-1d24-e053-2991ab0a02f2 |                                | 1       | HUMAN OTC DRUG LABEL <b>NDC RESERVATION</b> | Soo Jin Park       | 05-JUN-2018 16:29:45 |  |
| <a href="#">DRAFT</a>               | 6dd26d63-f490-530b-e053-2991ab0a960f | 6de92115-a9b0-2f45-e053-2991ab0a26f7 |                                | 2       | BULK INGREDIENT <b>NDC RESERVATION</b>      | Soo Jin Park       | 05-JUN-2018 13:34:33 |  |
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| <a href="#">SUBMISSION ACCEPTED</a> | 6d987ed3-d21d-6db8-e053-2a91ab0adc46 | 6d987ed3-d21c-6db8-e053-2a91ab0adc46 | cd8749032516.4805312697@direct | 2       | BULK INGREDIENT <b>NDC RESERVATION</b>      | 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](mailto:eDRLS@fda.hhs.gov)