

Labeler Code Requests

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CDER | US FDA



Learning Objectives

- Labeler Code – Describe **Who** needs a labeler code and **When** should a firm get a labeler code.
- Describe the steps required to obtain a Labeler Code.
- Describe why it is important to confirm the Labeler Code.

What is the Labeler Code process?



- A manufacturer or private label distributor requests a labeler code
- The FDA will process and send an email with the assigned labeler code number and confirmation instructions
- The firm sends a “Confirmation” labeler code request SPL:
 - Same SETID
 - Different ROOT ID
 - Version number 1 higher than the last submission
 - Fill in the assigned labeler code
- Once the Confirmation SPL has been *accepted* by *the system* you may begin listing drug products



Who needs a Labeler Code?

- A labeler code is required by firms wishing to sell a drug product in the United States.
- Both Manufacturers and Private Label Distributors (PLD) require a labeler code and both must list their products.
- A product made by a contract manufacturer (CMO) and distributed by a PLD must be listed by both organizations though in different categories.
- Only drug products sold to consumers are listed on the NDC Directory. The CMO listings are for FDA internal purposes.

The Labeler Code and the NDC

How are they related?





Labeler Code – When?


- A Labeler Code Request must be submitted and completed prior to listing a drug product.
- If you do not have to list any drugs with FDA, you do not have a need for a labeler code.

How many Labeler Codes do I need?



- Companies do not need a labeler code for each site.
- DUNS and FEI are site-specific and labeler codes are company-specific.
- If a firm runs out of NDC numbers, an additional labeler code can be assigned. Email us before you apply for a second labeler code.

How to Request a Labeler Code

**CDER Direct**
Electronic Submissions Portal

Home

SUBMISSIONS
[\(ADD SUBMISSION TYPE\)](#)
NDC/NHRC Labeler Code Request
Establishment Registration
GDUFA Self-identification
Product Listing and Certification
WDOGFL

MANAGE ACCOUNT
Edit User Profile
Manage Users

COVID-19
(Not applicable to 503B outsourcing or compounding facilities.)
To list Hand Sanitizers you first need to submit a Labeler Code Request and an Establishment Registration. When these

ALL SUBMISSIONS
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	
SUBMISSION FAILED	afe59fa-3712-5026-e05-3-2995afe5c8	8b13636f-dbc5-5d7b-e05-3-2a95afe5c5	cd4535567881.301785662@direct	2	NDC/NHRC LABELER CODE REQUEST	Don Duggan	24-SEP-2020 13:55:10	
SUBMISSION ACCEPTED	afe59fa-3712-5026-e05-3-2995afe5c8	afe59fa-3712-5026-e05-3-2995afe5c5	cd2467188359.708152543@direct	1	NDC/NHRC LABELER CODE REQUEST	Don Duggan	22-SEP-2020 16:03:11	
SUBMISSION ACCEPTED	afe59fa-3712-5026-e05-3-2995afe5c8	afe59fa-3712-5026-e05-3-2995afe5c5	cd6583071924.123886475@direct	1	NDC/NHRC LABELER CODE REQUEST	Don Duggan	22-SEP-2020 15:58:12	
DRAFT	3b670a1e-4b10-24f1-e05-4-901448ba759	3b670a1e-4b10-24f1-e05-4-901448ba759	-	1	ESTABLISHMENT REGISTRATION	Don Duggan	02-SEP-2016 09:17:33	
SUBMISSION ACCEPTED	3b790a1e-d958-4138-e054-001448ba7cc4	3b790a1e-d958-4138-e054-001448ba7cc4	cd6239914795.8026145837@direct	1	NDC/NHRC LABELER CODE REQUEST	Don Duggan	02-SEP-2016 09:16:12	

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Contact Help Desk

<https://direct.preprod.fda.gov/apex/f?p=100:30:5291795286235::NO::>

Click on Create New

U.S. Department of Health & Human Services

FDA **CDER Direct**
Electronic Submissions Portal

Home > NDC/NHRC Labeler Code Request

SUBMISSIONS
[\(ADD SUBMISSION TYPE\)](#)
NDC/NHRC Labeler Code Request
Establishment Registration
GDUFA Self-Identification
Product Listing and Certificates
WADGRL

NDC/NHRC LABELER CODE REQUEST
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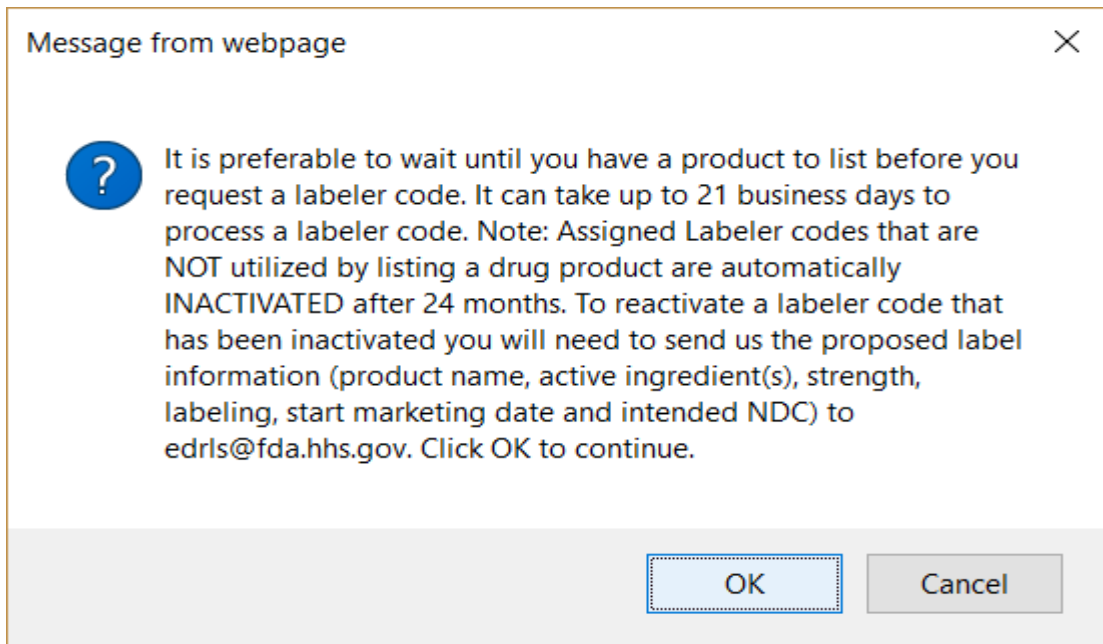
GO ACTIONS CREATE NEW / UPLOAD FILE

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LABELER DUNS	LABELER NAME	LAST MODIFIED USER	LAST MODIFIED DATE	REQUEST PROGRESS	
QWMT	609A7085-1e6d-4096-a632-0a36a6971a3	609A7085-1e6d-4096-a632-0a36a6971a3	-	1	NDC/NHRC LABELER CODE REQUEST	MAAA5555	Wander Drug	Don Duggan	28-SEP-2020 14:06:36	-	-
SUBMISSION CANCELED	61e6b516-3702-a053-2993-fa1fa1a1d	601833d7-d0d8-5d75-a053-2a0fa1d3a1255	cd433557581303783624@fda.hhs.gov	2	NDC/NHRC LABELER CODE REQUEST	MAAA5555	Wander Drug Imports	Don Duggan	24-SEP-2020 12:56:10	-	-
SUBMISSION ACCEPTED	61e6b516-3702-a053-2993-fa1fa1a1d	61e6b516-3702-a053-2993-fa1fa1a1d	cd4671003337081328475@fda.hhs.gov	1	NDC/NHRC LABELER CODE REQUEST	MAAA5555	Wander Drug Imports	Don Duggan	22-SEP-2020 16:03:11	Assigned Contributor Based on (1563)	-
SUBMISSION ACCEPTED	61e6b516-3702-a053-2993-fa1fa1a1d	61e6b516-3702-a053-2993-fa1fa1a1d	cd4636715241575636477@fda.hhs.gov	1	NDC/NHRC LABELER CODE REQUEST	U3M6U789	Wander Drug LLC	Don Duggan	22-SEP-2020 15:58:12	-	-
SUBMISSION SUCCEEDED	267735e9-4896-4159-a054-30144967e0c4	267735e9-4896-4159-a054-30144967e0c4	cd0235014705800C145037@fda.hhs.gov	1	NDC/NHRC LABELER CODE REQUEST	11111111	PDA	Don Duggan	20-SEP-2020 09:18:12	7	-

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Contact Help Desk

Click OK



Select the radio button to create a new Labeler Code

A screenshot of the CDER Direct Electronic Submissions Portal. The header is dark blue with the FDA logo and the text "CDER Direct Electronic Submissions Portal". On the left, a sidebar lists "SUBMISSIONS" with links: "(ADD SUBMISSION TYPE)", "NDC/NHRC Labeler Code Request", "Establishment Registration", "GDUFA Self-Identification", "Product Listing and Certification", and "WDO/3PL". The main content area is titled "CREATE NEW NDC/NHRC LABELER CODE" and contains two radio buttons: "Create a new NDC/NHRC Labeler Code Request using a blank form" (which is selected) and "Import an existing NDC/NHRC Labeler Code Request SPL". Below the radio buttons is a "Note" about updating existing submissions. At the bottom are "CONTINUE" and "CANCEL" buttons.

FDA CDER Direct
Electronic Submissions Portal

SUBMISSIONS
[\(ADD SUBMISSION TYPE\)](#)
NDC/NHRC Labeler Code Request
Establishment Registration
GDUFA Self-Identification
Product Listing and Certification
WDO/3PL

CREATE NEW NDC/NHRC LABELER CODE

☒ Create a new NDC/NHRC Labeler Code Request using a blank form
☐ Import an existing NDC/NHRC Labeler Code Request SPL

Note: To update an existing submission, click on Cancel and select a submission with the status SUBMISSION ACCEPTED from the table in the prior page / Dashboard.

CONTINUE **CANCEL**

Fill in your data



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/NHRC LABELER CODE REQUEST

Set ID: * aed6cec8-294d-5d8e-e053-2995a90a381: [Generate New](#)

Version Number: * 1

Root ID: * aed6cec8-294e-5d8e-e053-2995a90a381: [Generate New](#)

Effective Date: * 09-08-2020

LABELER DETAILS

Labeler Name: * A1 Drugs

Labeler Code: *

Labeler DUNS: * 111222333

LABELER CONTACT DETAILS

Contact Name: * Don Duggan

Contact Email: * Donovan.Duggan@a1drug.com

Contact Phone: * 1-301-555-1212

Phone Extension: *

[Format](#)

LABELER CONTACT ADDRESS

Country: * United States

Street Address: * 111 Main Street

City: * Springfield

State: * Maryland

Postal Code: * 20903

Contact Help Desk

Fill in the Additional Information

- Step 2 – Fill out the additional information in CDERDirect
 - Labeler's Physical Address
 - US Agent if your firm is foreign to the USA

LABELER ADDRESS
☐ Same as Labeler Contact Address

Country: * --Select Country--

Street Address: *

City: *

State/Province:

Postal Code:

U.S. AGENT

Agent Name:

Agent DUNS:

Agent Email:

Agent Phone: [Format](#)

Phone Extension:

BUSINESS OPERATION(S)

+	BUSINESS OPERATION	QUALIFIER
✖	MANUFACTURE ▼	--Select One-- ▼

Choose your business operation and qualifier



— 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: *

City: *

State/Province:

Postal Code:

U.S. AGENT

Agent Name:

Agent OUNS:

Agent Email:

Agent Phone: [Email](#)

Phone Extension:

BUSINESS OPERATION(S)

BUSINESS OPERATION	QUALIFIER
<input checked="" type="checkbox"/> DISTRIBUTES DRUG PRODUCTS UNDER OWN PRIVATE L.F.	<input type="text" value="-Select One-"/> DISTRIBUTES HUMAN OVER-THE-COUNTER DRUG PRODUCTS DISTRIBUTES HUMAN PRESCRIPTION DRUG PRODUCTS

LABELER ADDRESS

☐ Same as Labeler Contact Address

Country: *

Street Address: *

City: *

State/Province:

Postal Code:

U.S. AGENT

Agent Name:

Agent OUNS:

Agent Email:

Agent Phone: [Email](#)

Phone Extension:

BUSINESS OPERATION(S)

BUSINESS OPERATION	QUALIFIER
<input checked="" type="checkbox"/> MANUFACTURE	<input type="text" value="-Select One-"/> MANUFACTURES HUMAN OVER-THE-COUNTER DRUG PRODUCTS MANUFACTURES HUMAN PRESCRIPTION DRUG PRODUCTS

Additional Information



FDA will evaluate the request and may contact the firm if any clarification is needed

- 1) Name of the firm requesting a new labeler code - *FDA Company*
- 2) Address and DUNS of firm requesting labeler code - *101 FDA Drive*
- 3) Drug business type of labeler (e.g. manufacturer, distributor, contract manufacturer, repacker, relabeler, analytical lab, etc)-*Distributor*
- 4) Type of drug product(s) (Rx or OTC, also Human or Vet)-*OTC-Human*
- 5) US agent information (if firm is located outside of the United States of America)-*N/A*

(edrls@fda.hhs.gov).

Save, Validate and Click SUBMIT



FDA CDER Direct
Electronic Submissions Portal

Home NDC/NHRC 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: * NDC/NHRC LABELER CODE REQUEST

Set ID: * b0643085-1eef-d58e-e053-2a95af0a91a3 [Generate New](#) Version Number: * 1

Root ID: * b0643085-1eef-d58e-e053-2a95af0a91a3 [Generate New](#) Effective Date: * 09-28-2020

LABELER DETAILS

Labeler Name: * Wonder Drug Labeler Code: *

Note: Request Progress is real time

[Home](#) [NDC/NHRC Labeler Code Request](#)

SUBMISSIONS

[\(ADD SUBMISSION TYPE\)](#)
[NDC/NHRC Labeler Code Request](#)
[Establishment Registration](#)
[GDUFA Self-Identification](#)
[Product Listing and Certification](#)
[WDD/3PL](#)

NDC/NHRC LABELER CODE REQUEST

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STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LABELER DUNS	LABELER NAME	LAST MODIFIED USER	LAST MODIFIED DATE	REQUEST PROGRESS	
DRAFT	b0643085-1eef-458e-e053-2a95af0a91a3	b0643085-1eef-d58e-e053-2a95af0a91a3	-	1	NDC/NHRC LABELER CODE REQUEST	555555555	Wonder Drug	Don Duggan	28-SEP-2020 14:00:38	-	-
SUBMISSION FAILED	afed50fa-3712-5026-e053-2995af0a5c8	b01393ef-dbd5-d7b-e053-2a95af0a6255	cd2493567081.3017895624@direct	2	NDC/NHRC LABELER CODE REQUEST	555555555	Wonder Drug Importers	Don Duggan	24-SEP-2020 13:55:10	-	-
SUBMISSION ACCEPTED	afed50fa-3712-5026-e053-2995af0a5c8	afed50ed-9af3-48fb-e053-2995af0a0c56	cd2467108359.7081526439@direct	1	NDC/NHRC LABELER CODE REQUEST	555555555	Wonder Drug Importers	Don Duggan	22-SEP-2020 16:03:11	Assigned, Confirmation Required(1561)	-
SUBMISSION ACCEPTED	afed50ed-5af1-48fb-e053-2995af0a0c56	afed50fa-3711-5f26-e053-2995af0a5c8	cd5583071924.1238064759@direct	1	NDC/NHRC LABELER CODE REQUEST	123456789	Wonder Drug LLC	Don Duggan	22-SEP-2020 15:58:12	-	-
SUBMISSION ACCEPTED	36798ade-d85b-4130-e054-00144fa2cc4	36798ade-d86c-4130-e054-00144fa2cc4	cd8235914706.0026145937@direct	1	NDC/NHRC LABELER CODE REQUEST	111111111	FDA	Don Duggan	02-SEP-2016 09:16:12	-	-

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Confirm the Labeler Code

To complete the process, submit an updated labeler code form SPL with the newly assigned number filled in.

HEADER DETAILS	
Document Type: *	NDC/NHRC LABELER CODE REQUEST <input type="button" value="v"/>
Set ID: *	771c9a4c-cb83-3c05-e053-2a91ab0a54ea Generate New
Root ID: *	93dbd9d1-f5bb-ca7e-e053-2995af0a9eb6 Generate New
Version Number: *	2
Effective Date: *	10-01-2019 <input type="button" value="Calendar"/>

LABELER DETAILS	
Labeler Name: *	FDA Company
Labeler DUNS: *	123456789
Labeler Code:	12345

LABELER CONTACT DETAILS	
Contact Name: *	Puii Huber
Contact Email: *	puii@email.com
Contact Phone: *	1-999-999-9999 Format
Phone Extension:	

LABELER CONTACT ADDRESS	
Country: *	United States <input type="button" value="v"/>
Street Address: *	101 FDA Drive <input type="button" value="v"/>
City: *	Silver Spring
State: *	Maryland <input type="button" value="v"/>
Postal Code: *	20903



Email Sent

eDRLS - Electronic Drug Registration & Listing System

Current Date: 03-AUG-2020

Labeler DUNS: 111222333

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 (edrils@fda.hhs.gov).

Rejections

- If you are not required to list drugs
- If you already have a LC assigned
- Invalid contact information
- If your labeler code was automatically inactivated
- If your Information does not match D&B data
- If you are a veterinarian drug manufacturer or distributor
 - Submit an NDC Labeler Code Request-Animal Drug (LOINC Code-72871-7)



When should labeler code information be updated?

- Information must be updated within 30 calendar days after any change:
 - Physical address, email and other information
- Per § 207.33(c)(2)
- FDA uses this information for official communication regarding the listing.

Mergers & Acquisitions



Merger & Acquisitions are different in each case based on business decisions and contractual agreements.

Company A and B are Merging and they are changing their name to Company C. In addition, they have decided to keep company A's Labeler Code.

- **Company A :**

- ✓ Update their Labeler Code Information to include the new name and any other updates.
- ✓ Drug listing must be updated to include the new Labeler name.

- **Company B :**

- ✓ Discontinue all drug listings associated to their old labeler code
- ✓ Relist the listings under Company C's Labeler Code
- ✓ Labeler Code must be inactivated.



Do's and Don't's



- Do know what your Dun and Bradstreet data before you apply for a labeler code – it must match exactly
- Do doublecheck your data in the SPL form (for all SPL's you submit)
- Do confirm your labeler code
- Do contact the eDRLS Helpdesk with Questions
- Don't use outdated phone numbers or email addresses



Challenge Question #1

Labeler Code Information including the name, physical address, email address and other contact information must be updated within:

- A. 60 days
- B. 90 days
- C. 30 days
- D. Every June and December

Challenge Question #2

The Physical address must match the Duns & Bradstreet record exactly? True or False

- True

Why?

- The FDA validates the address you provide with the D&B record.

Challenge Question 3

If a company has three locations, how many labeler codes do they need?

- a) One labeler code
- b) Two labeler codes
- c) Three labeler codes (one for each site)

Resources

- For questions on the electronic registration and listing requirements send an inquiry to eDRLS@fda.hhs.gov

If you have submitted your electronic registration through the ESG and have questions on the status of your submission, please contact the SPL Coordinator at SPL@fda.hhs.gov

[Electronic Drug Registration and Listing Instruction](#)

[Points of Contact for Drug Registration and Listing](#)

