Labeler Code Requests

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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?

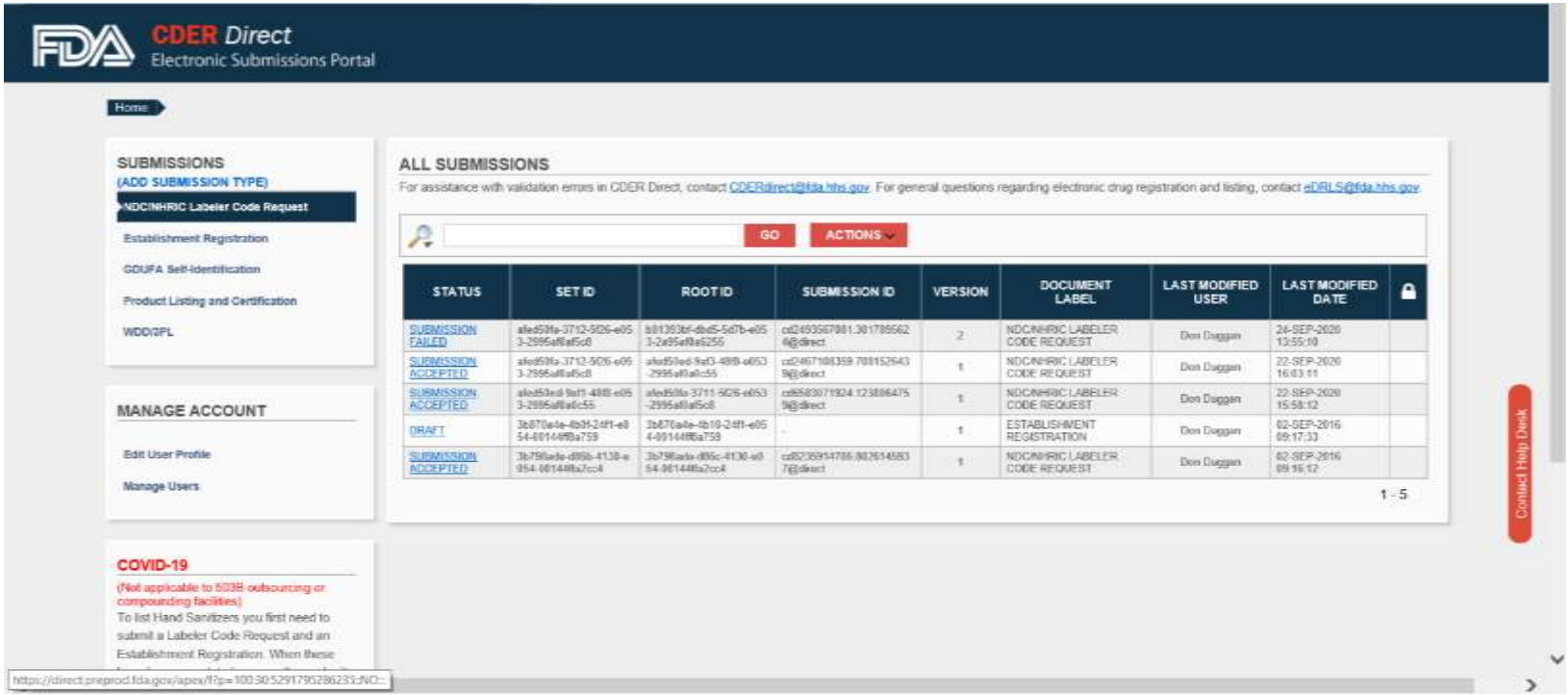
Labeler Code – When?

- 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.

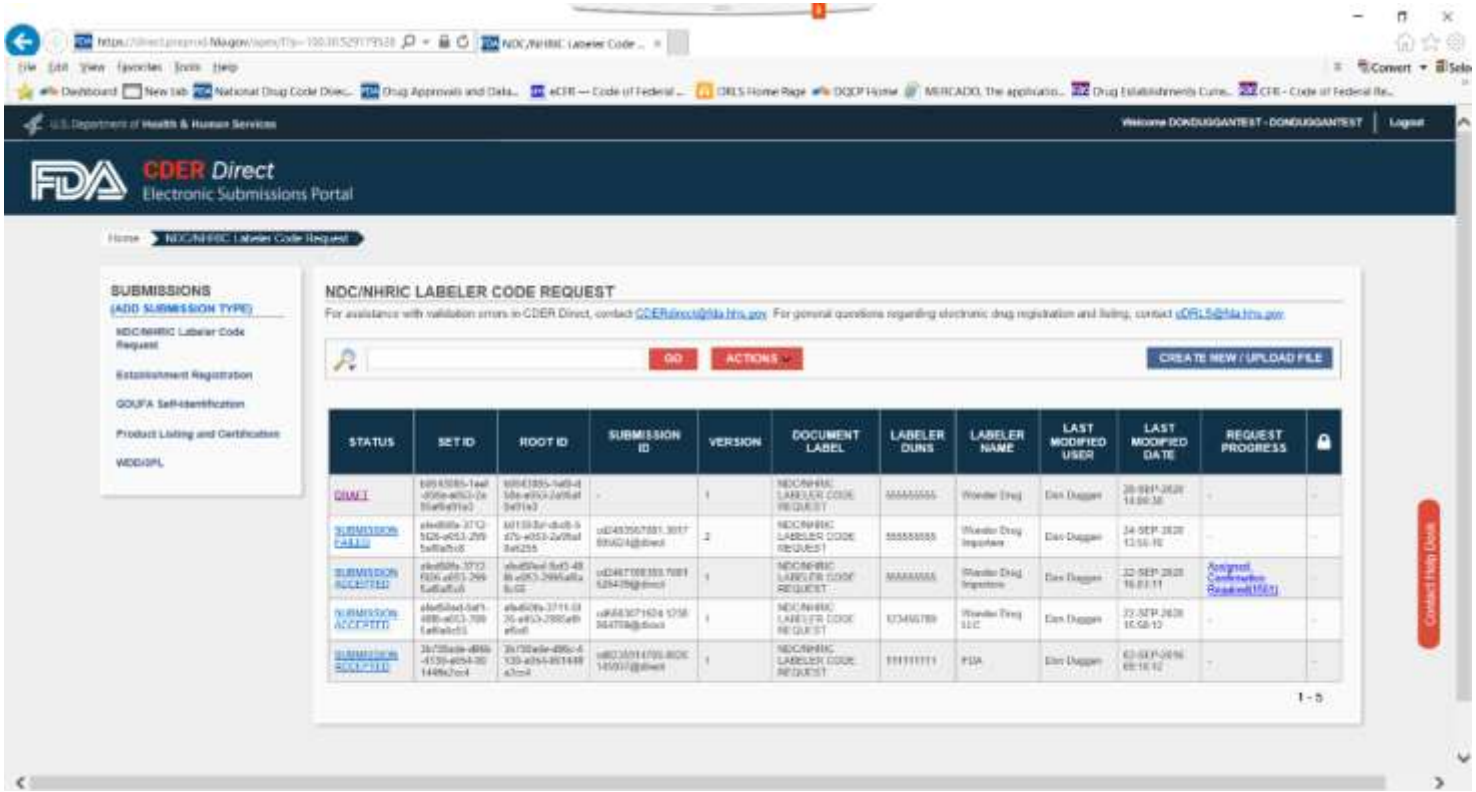
How many Labeler Codes do I need?

- 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.

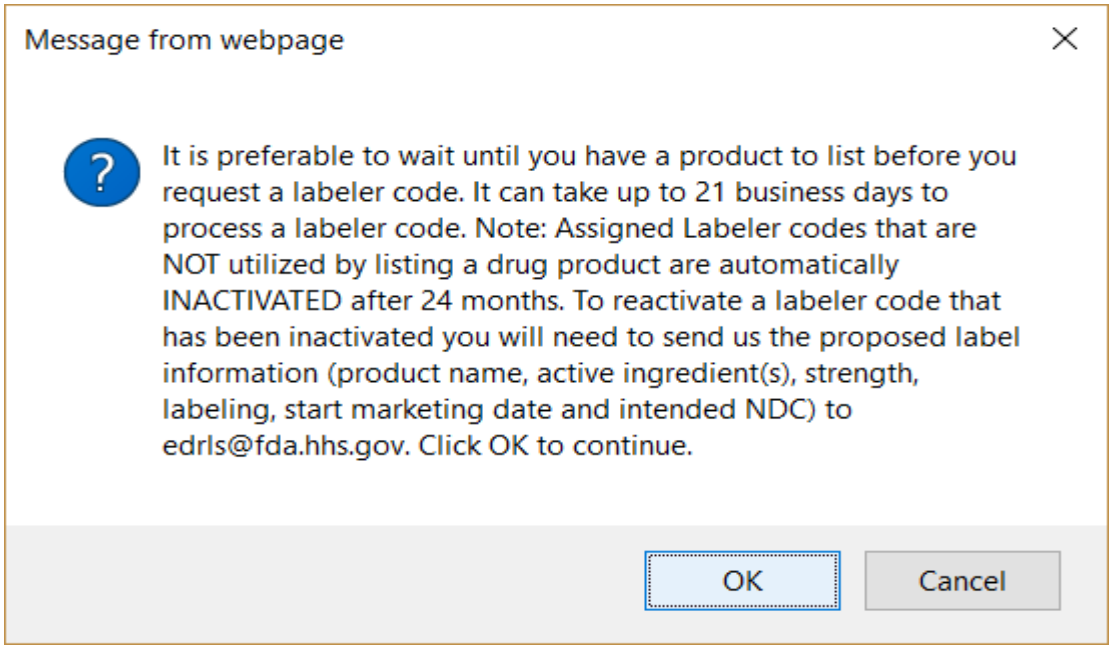
How to Request a Labeler Code



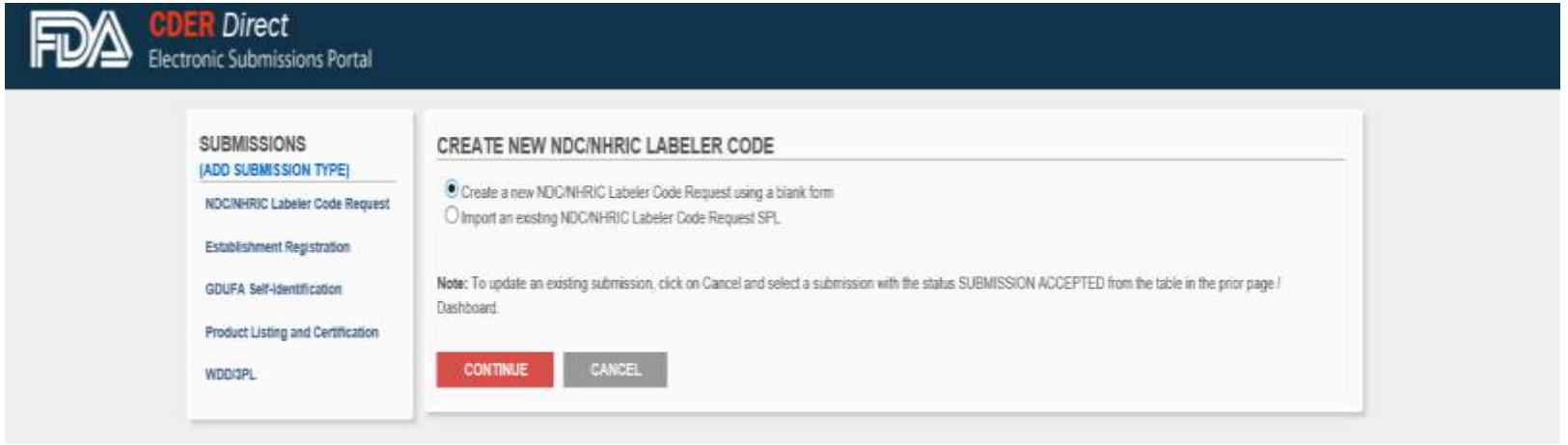
Click on Create New



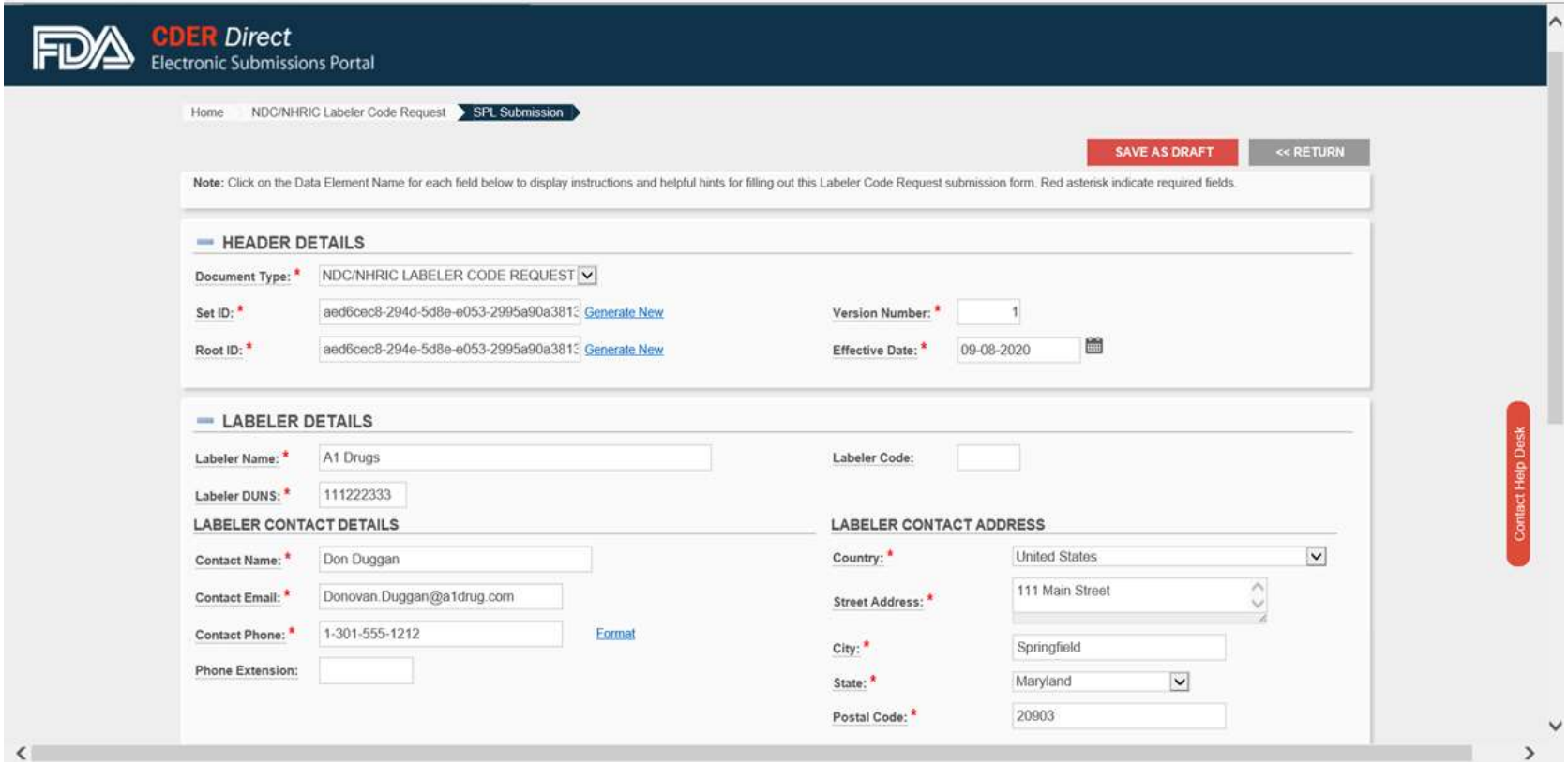
Click OK


Message from webpage
It is preferable to wait until you have a product to list before you request a labeler code. It can take up to 21 business days to process a labeler code. Note: Assigned Labeler codes that are NOT utilized by listing a drug product are automatically INACTIVATED after 24 months. To reactivate a labeler code that has been inactivated you will need to send us the proposed label information (product name, active ingredient(s), strength, labeling, start marketing date and intended NDC) to edrls@fda.hhs.gov. Click OK to continue.
OK
Cancel

Select the radio button to create a new Labeler Code

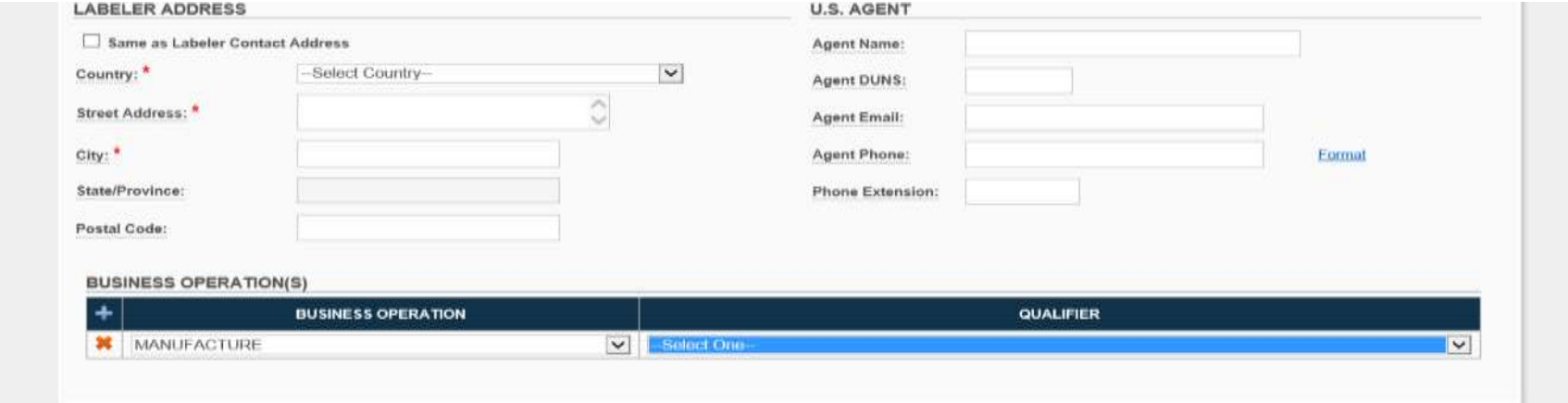


Fill in your data

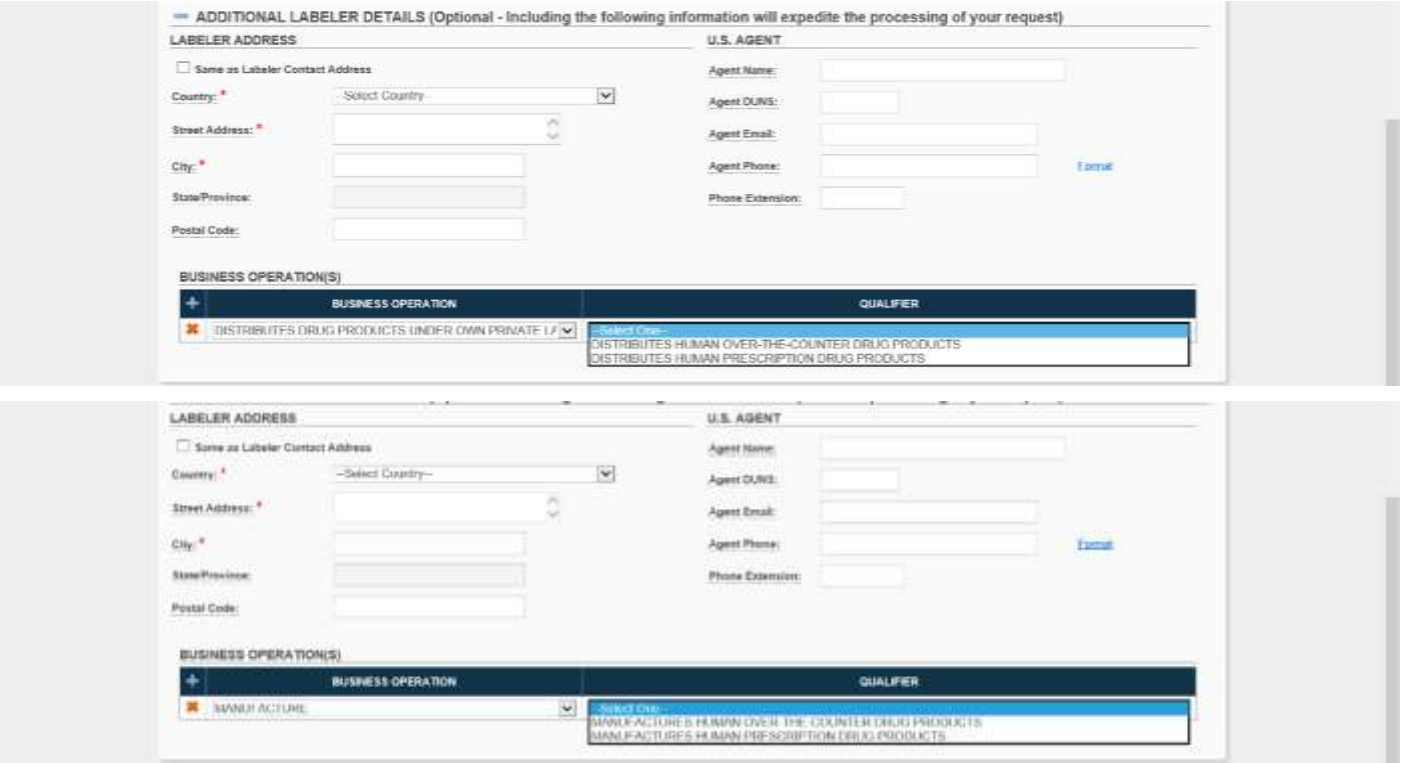


Fill in the Additional Information

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



Choose your business operation and qualifier



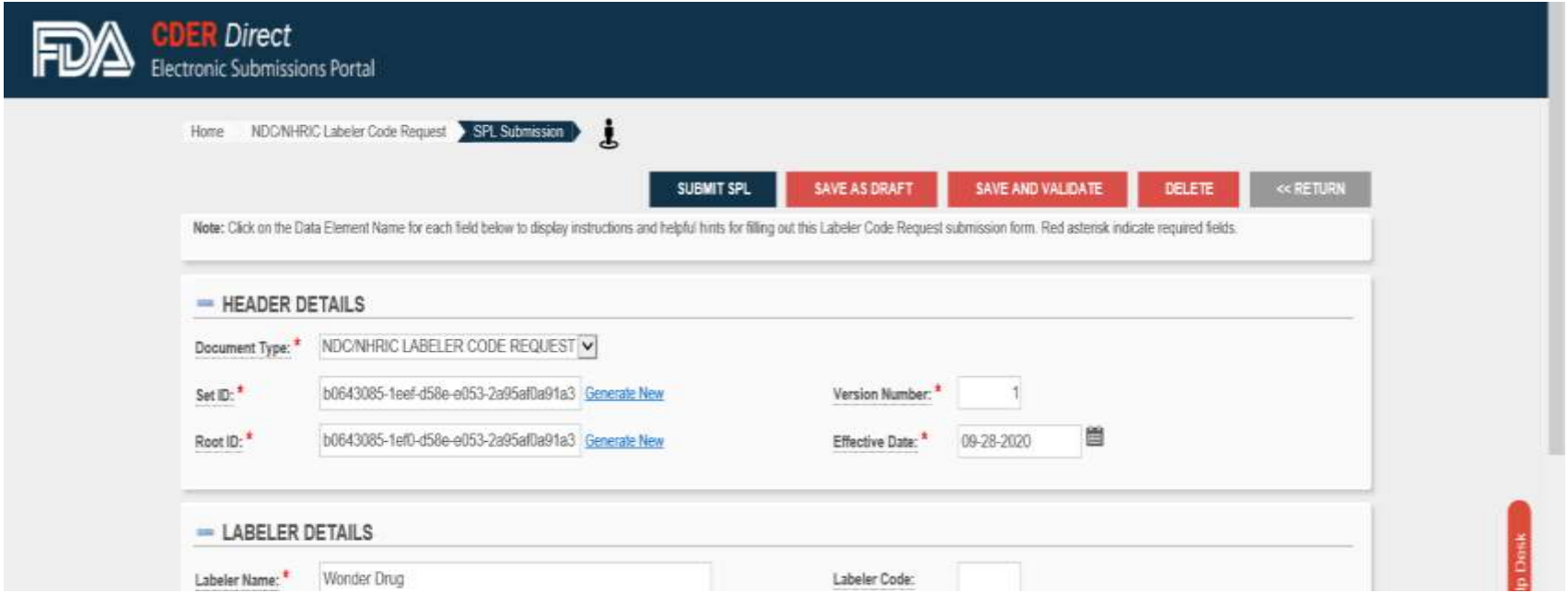
Additional Information

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

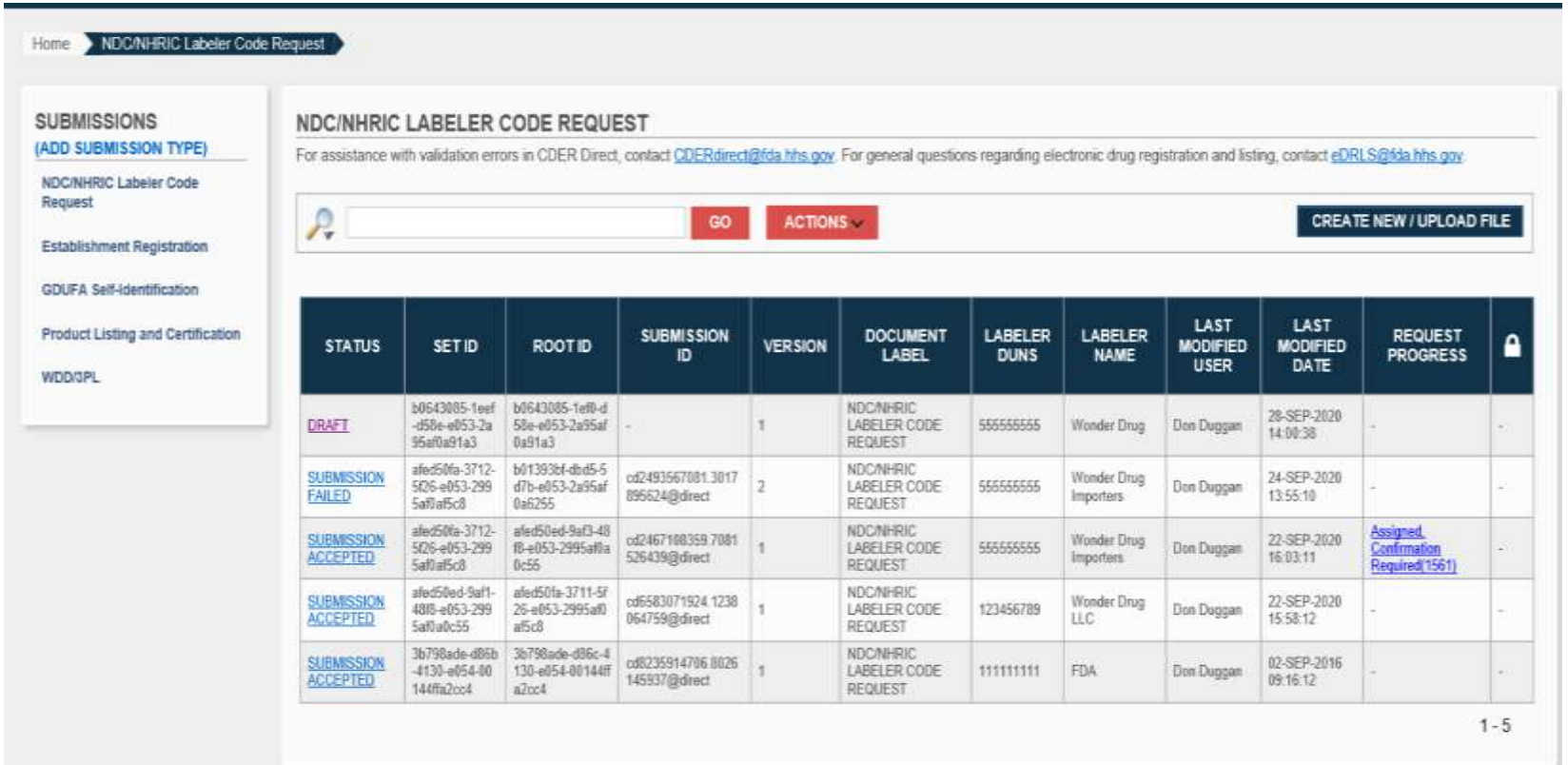
1) Name of the firm requesting a new labeler code - *FDA Company*
2) Address and DUNS of firm requesting labeler code -*101 FDA Drive*
3) Drug business type of labeler (e.g. manufacturer, distributor, contract manufacturer, repacker, relabeler, analytical lab, etc)-*Distributor*
4) Type of drug product(s) (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



Note: Request Progress is real time



Home > NDC/NHRIC Labeler Code Request

SUBMISSIONS
(ADD SUBMISSION TYPE)

- NDC/NHRIC Labeler Code Request
- Establishment Registration
- GDUFA Self-Identification
- Product Listing and Certification
- WDD/3PL

NDC/NHRIC 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.

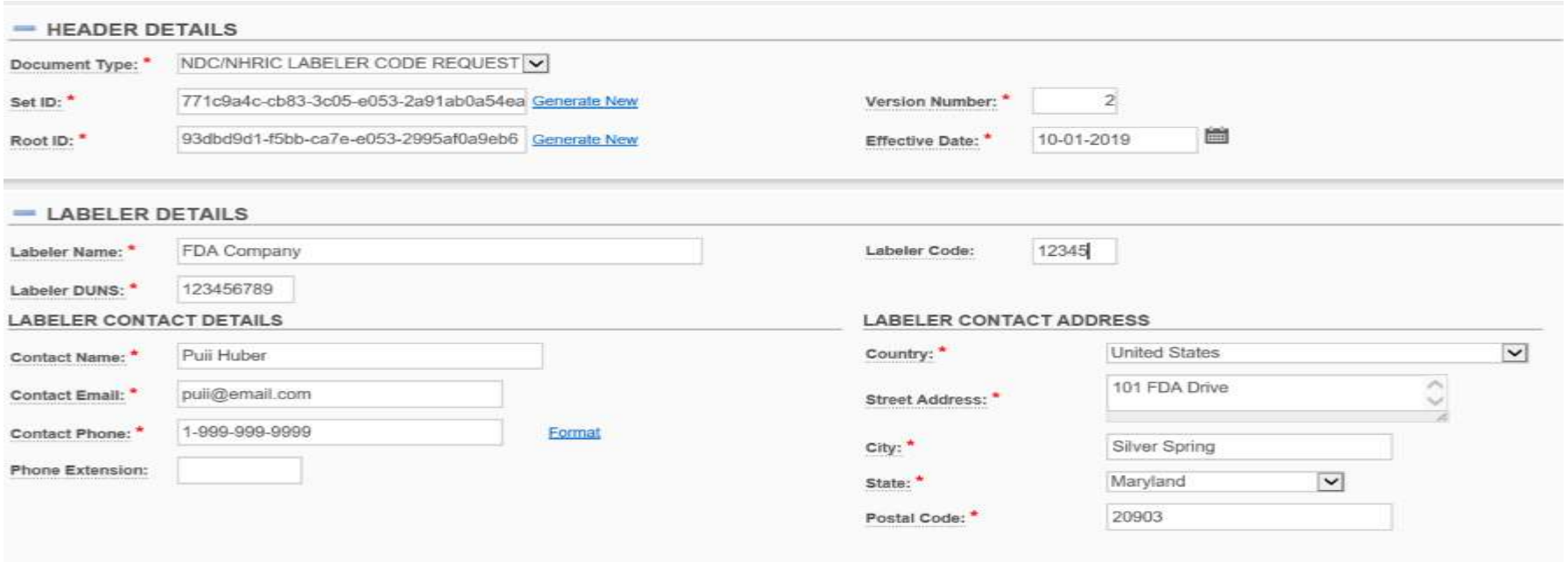
GO | ACTIONS | CREATE NEW / UPLOAD FILE

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LABELER DUNS	LABELER NAME	LAST MODIFIED USER	LAST MODIFIED DATE	REQUEST PROGRESS	
DRAFT	b0643085-1eef-d58e-e053-2a95af0a91a3	b0643085-1ef0-d58e-e053-2a95af0a91a3	-	1	NDC/NHRIC LABELER CODE REQUEST	555555555	Wonder Drug	Don Duggan	28-SEP-2020 14:00:38	-	-
SUBMISSION FAILED	afed50fa-3712-5f26-e053-2995af0af5c8	b01393bf-dbd5-5d7b-e053-2a95af0a6255	cd2493567081.3017895624@direct	2	NDC/NHRIC LABELER CODE REQUEST	555555555	Wonder Drug Importers	Don Duggan	24-SEP-2020 13:55:10	-	-
SUBMISSION ACCEPTED	afed50fa-3712-5f26-e053-2995af0af5c8	afed50ed-9af3-48f8-e053-2995af0a0c55	cd2467108359.7081526439@direct	1	NDC/NHRIC LABELER CODE REQUEST	555555555	Wonder Drug Importers	Don Duggan	22-SEP-2020 16:03:11	Assigned. Confirmation Required(1561)	-
SUBMISSION ACCEPTED	afed50ed-9af1-48f8-e053-2995af0a0c55	afed50fa-3711-5f26-e053-2995af0af5c8	cd6583071924.1238064759@direct	1	NDC/NHRIC LABELER CODE REQUEST	123456789	Wonder Drug LLC	Don Duggan	22-SEP-2020 15:58:12	-	-
SUBMISSION ACCEPTED	3b798ade-d86b-4130-e054-80144ffa2cc4	3b798ade-d86c-4130-e054-80144ffa2cc4	cd8235914706.8026145937@direct	1	NDC/NHRIC LABELER CODE REQUEST	111111111	FDA	Don Duggan	02-SEP-2016 09:16:12	-	-

1 - 5

Confirm the Labeler Code

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



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 (edrls@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 andListing


FDA
U.S. FOOD & DRUG
ADMINISTRATION