CDER Direct Labeler Code Request Demo

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OC | CDER | US FDA

eDRLS Using CDER Direct 2024 – September 12, 2024

Learning Objectives

- **Identify** the purpose and use of labeler codes
- **Demonstrate** the process of submitting a labeler code request
- **Complete** a labeler code assignment
- **Update** labeler contact or address information
- **Inactivate** a labeler code as necessary

Labeler Code

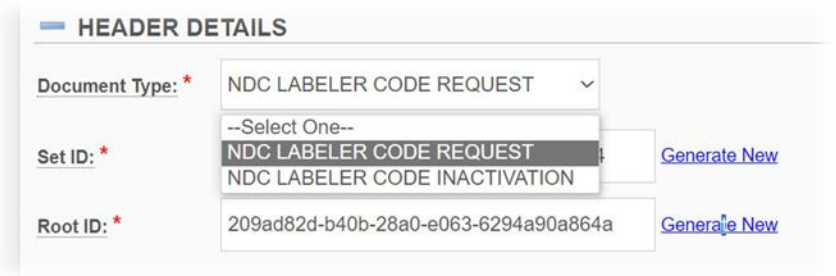
The first segment of the NDC is the labeler code and currently consists of 4 or 5 digits.

Labeler Code – General Info

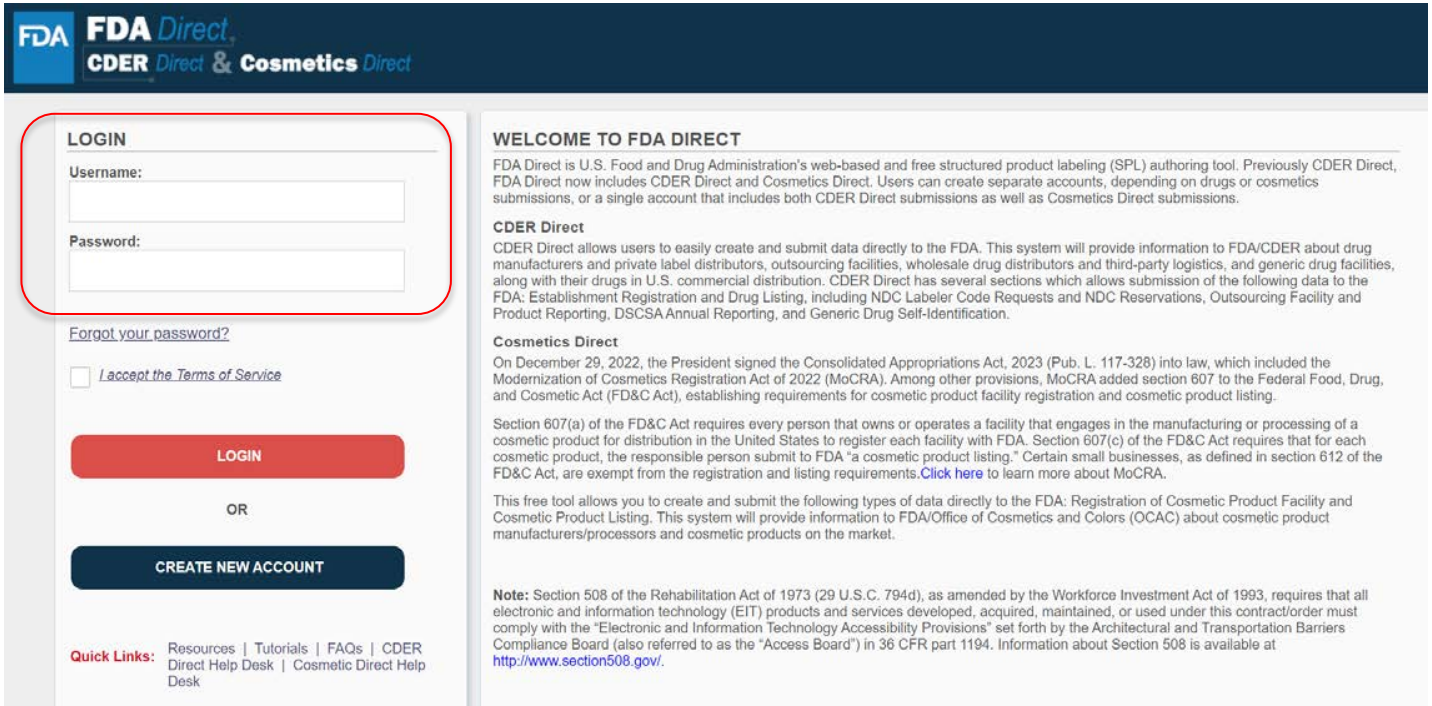
- **Purpose of labeler code request:** To list drugs manufactured or distributed in the United States.
- **Do I need to apply for a labeler code?**: If your company does not have any drugs requiring FDA listing, you may not need to apply for a labeler code.
- **Inactivation of labeler codes:**
  - Labeler codes without any listed drugs will be automatically INACTIVATED after 24 months.
  - Labeler codes not assigned by FDA, or obtained by providing false information to FDA, may be inactivated without prior notice.
  - Firms may inactivate their FDA-assigned labeler code.

Labeler Code Document Types

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

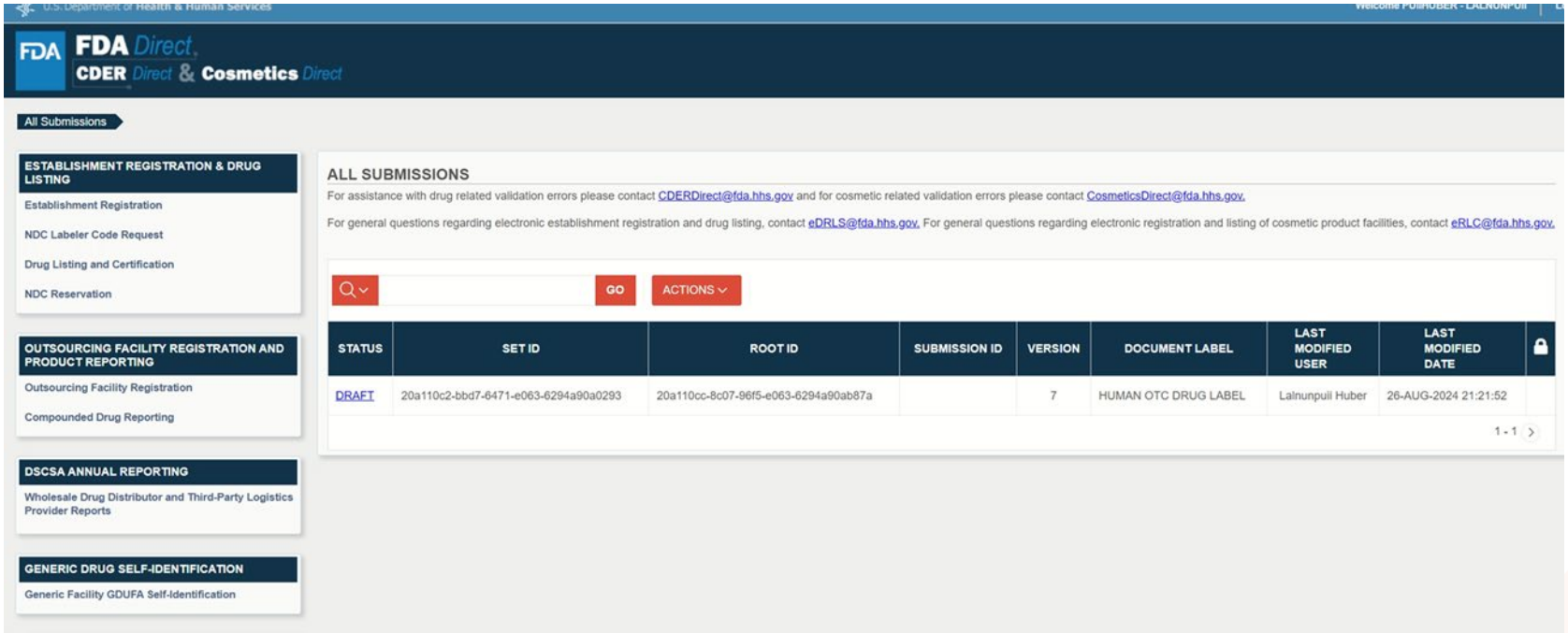


Live Demo of CDER Direct

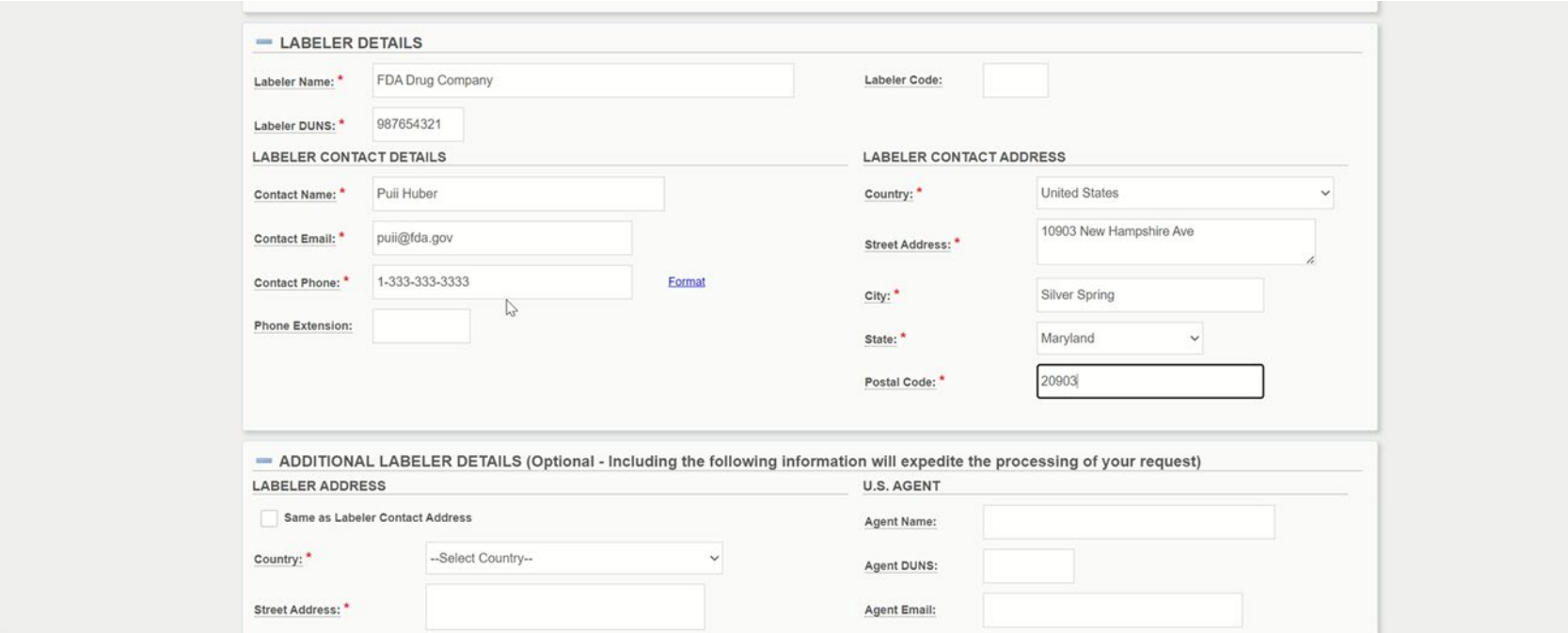


https://direct.fda.gov

Requesting a Labeler Code



Requesting a Labeler Code



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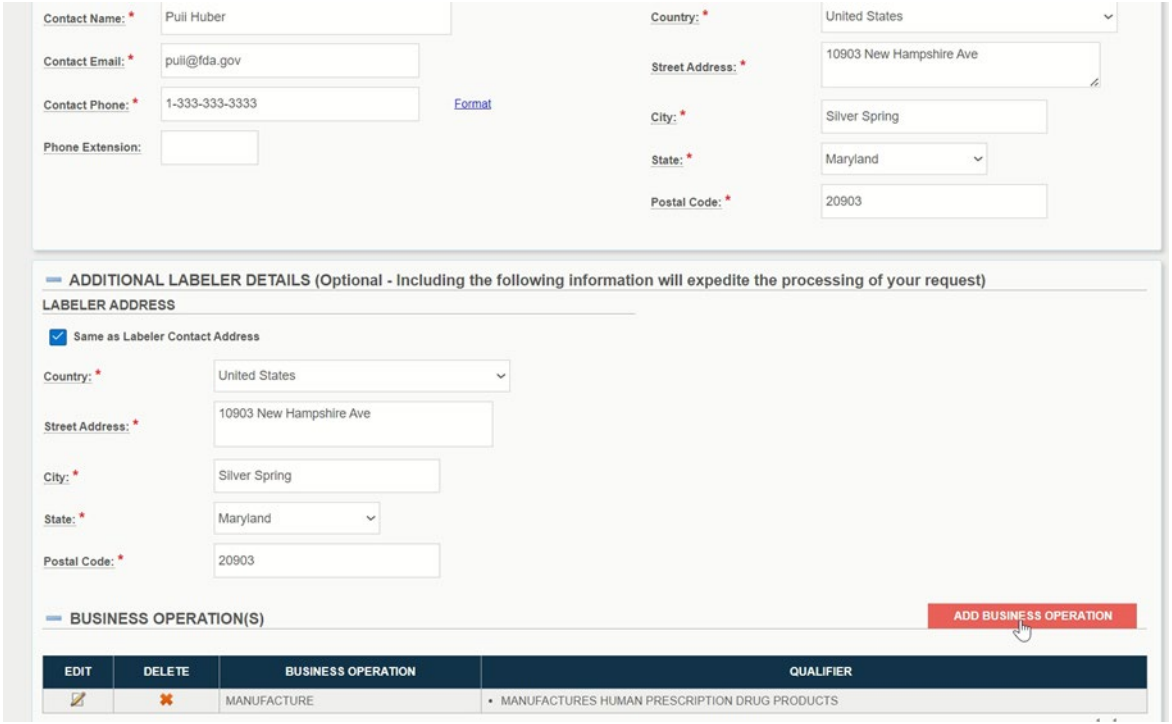

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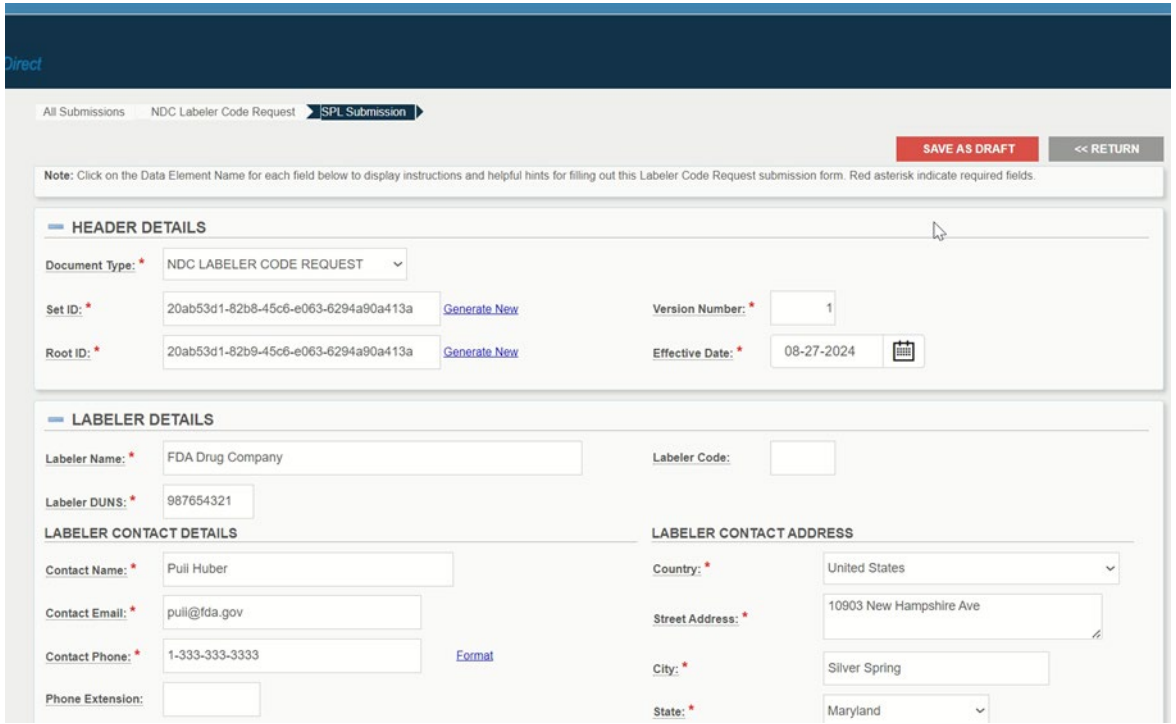


Labeler Code - Assigned

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

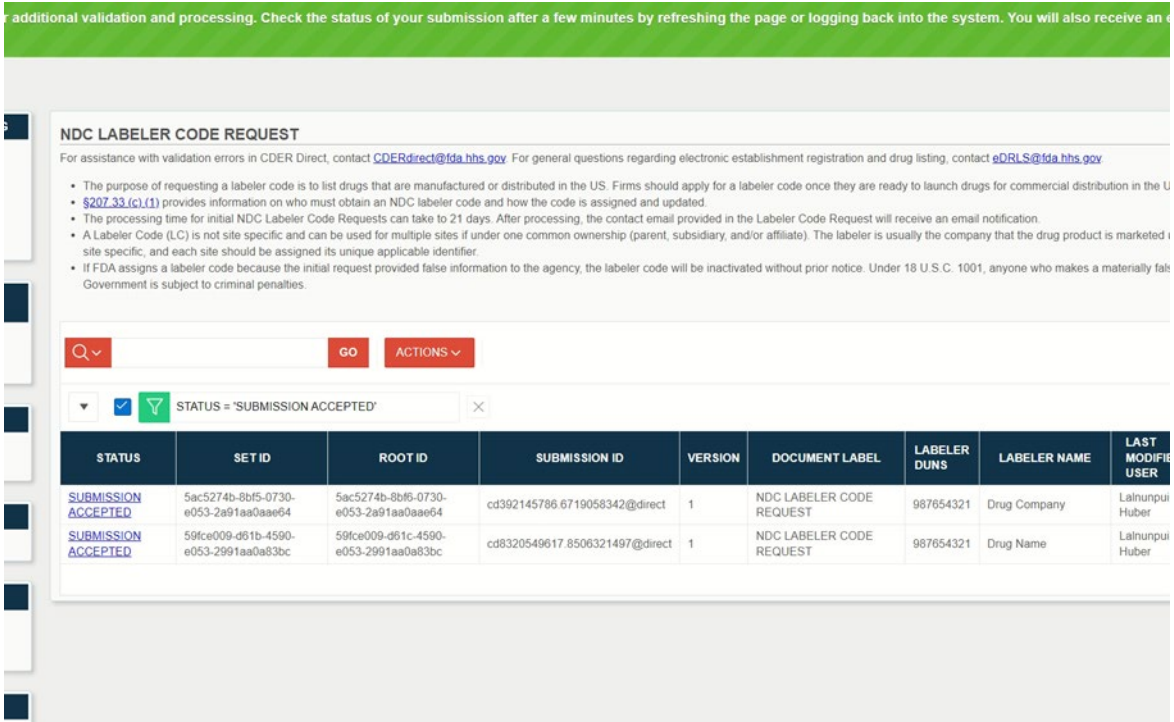
Labeler Code Assigned: 00000

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, for 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.

Confirm Labeler Code Assignment



Labeler Code Request Rejections

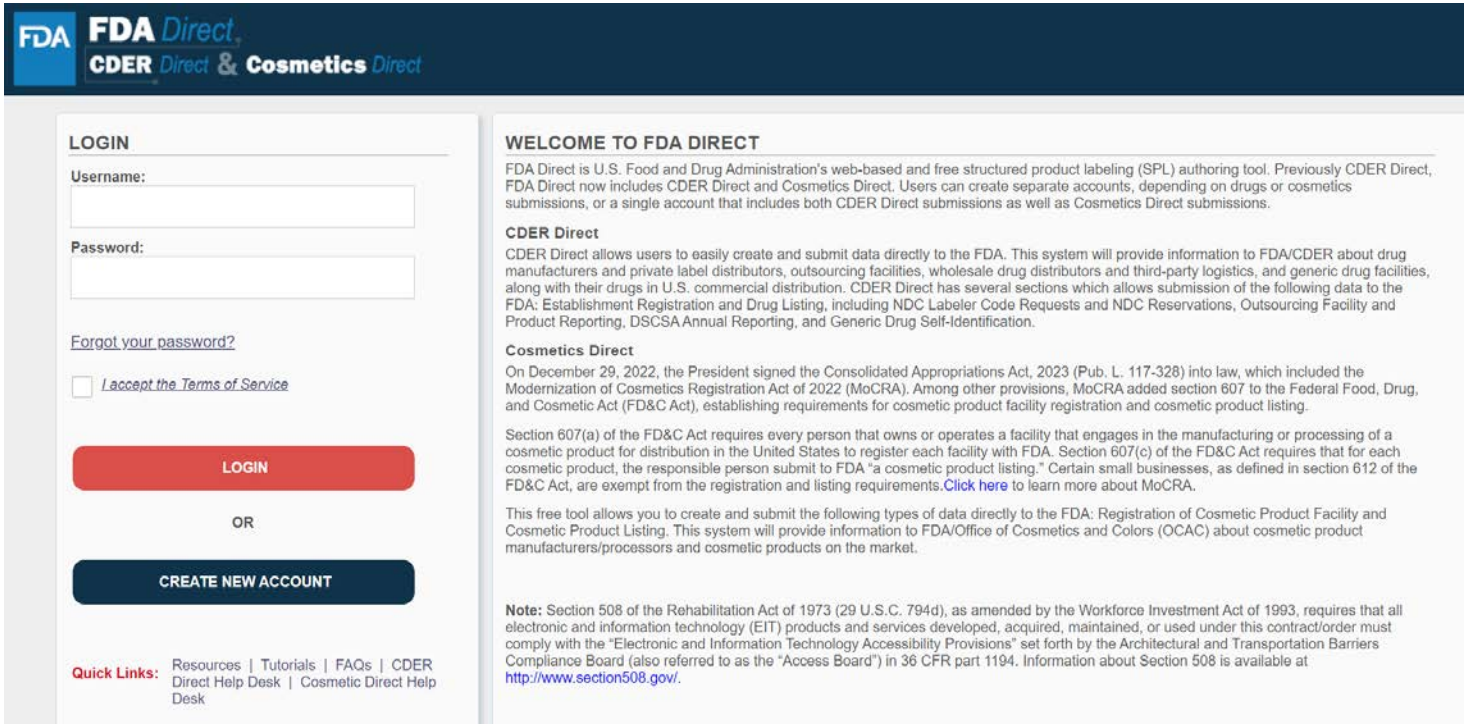
- Why would a labeler code request get rejected?
  - Requesting firm is not required to register and list
  - The product they manufacture or distribute is not a drug
  - Requesting firm is already assigned a labeler code

Industry-Initiated Labeler Code Inactivation

Labeler code is no longer needed due to:

- Out of business/change in business
- Mergers/acquisitions
- Application for a drug in development did not get approved by FDA

Labeler Code – How to Inactivate



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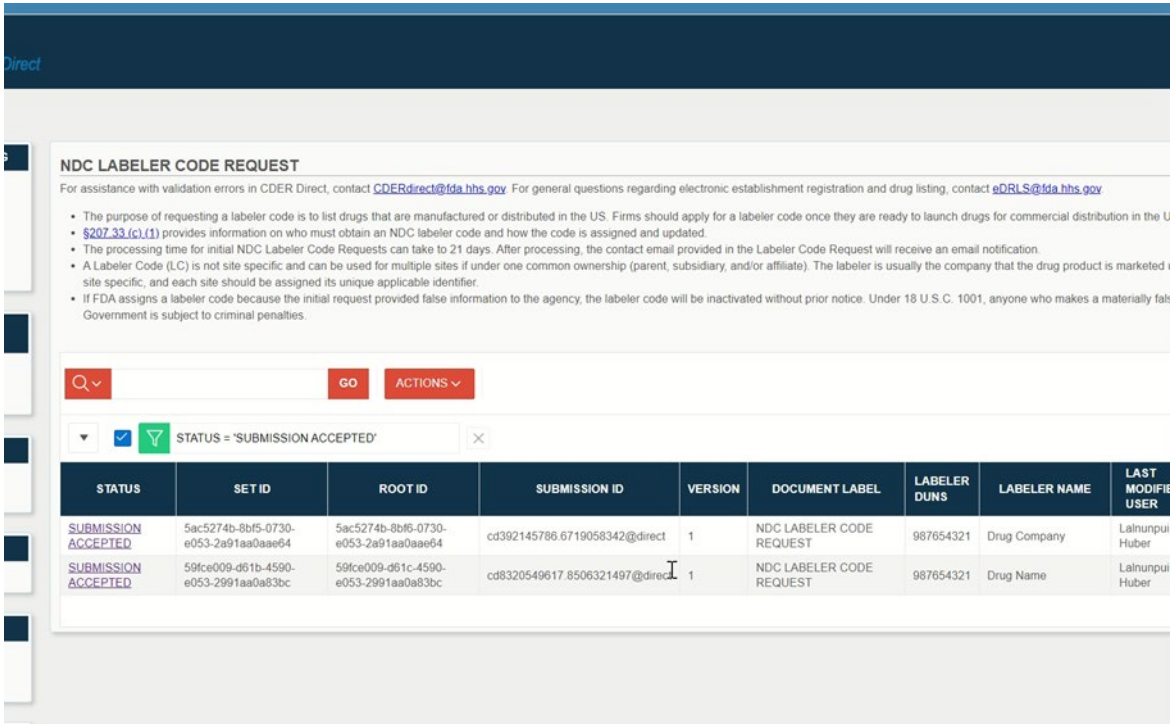
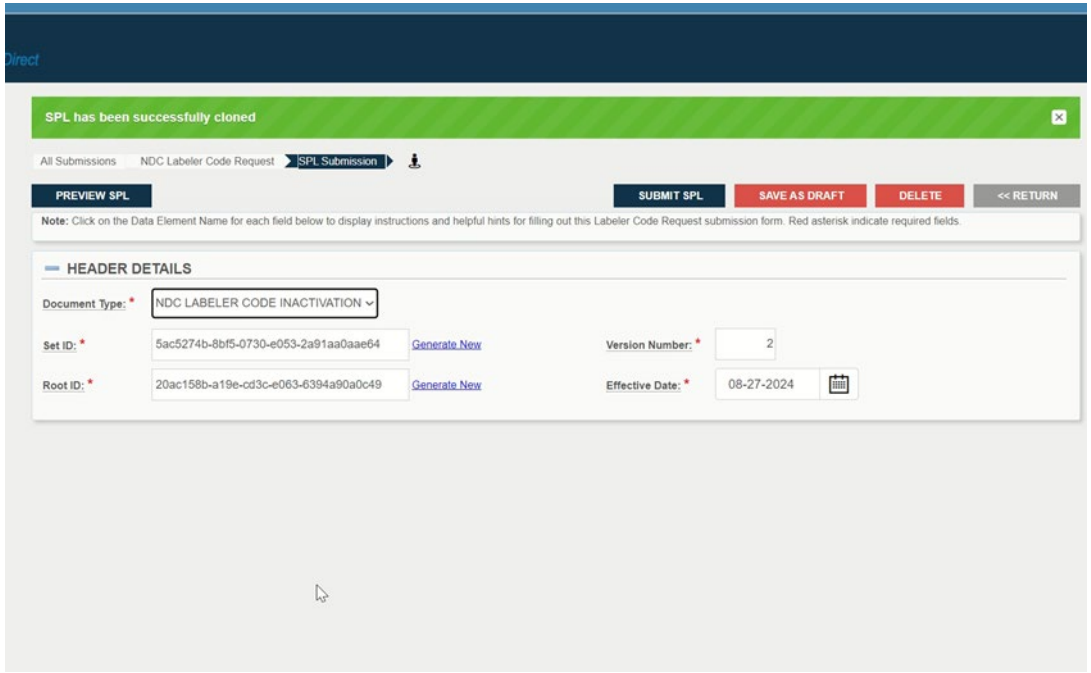
Labeler Code – How to Inactivate



Labeler Code – How to Reactivate

- Industry-initiated inactivation :



Summary

- Labeler Code SPL should be submitted when drugs are ready to be launched for U.S. commercial distribution.
- 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.

Summary

- Labeler codes without listed drugs are automatically inactivated after 24 months.
- To inactivate a labeler code, submit a NDC Labeler Code Inactivation SPL.

Challenge Question 1

What happens if a labeler code does not have any products listed for two years?

a) It will be automatically reactivated by the FDA.

b) It will be permanently inactivated by the FDA.

c) It will receive a notification 30 days prior to inactivation.

d) It will be transferred to a different regulatory agency.

Challenge Question 2

A labeler code is a component of the National Drug Code (NDC) used to identify the manufacturer or distributor of a drug product. What does the labeler code represent in the NDC?

a) The dosage form of the drug

b) The specific product formulation

c) The package size and type

d) The manufacturer or distributor of the drug

Challenge Question 3

Which of the following is a reason why a labeler code request might be rejected?

a) The requesting firm is required to register and list.

b) The product they manufacture or distribute is classified as a drug.

c) The requesting firm is not required to register and list.

d) The requesting firm has not been assigned a labeler code.

U.S. FOOD & DRUG ADMINISTRATION

Questions?

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