Labeler Code Request

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Drug Registration and Listing Staff
FDA/CDER/Office of Compliance

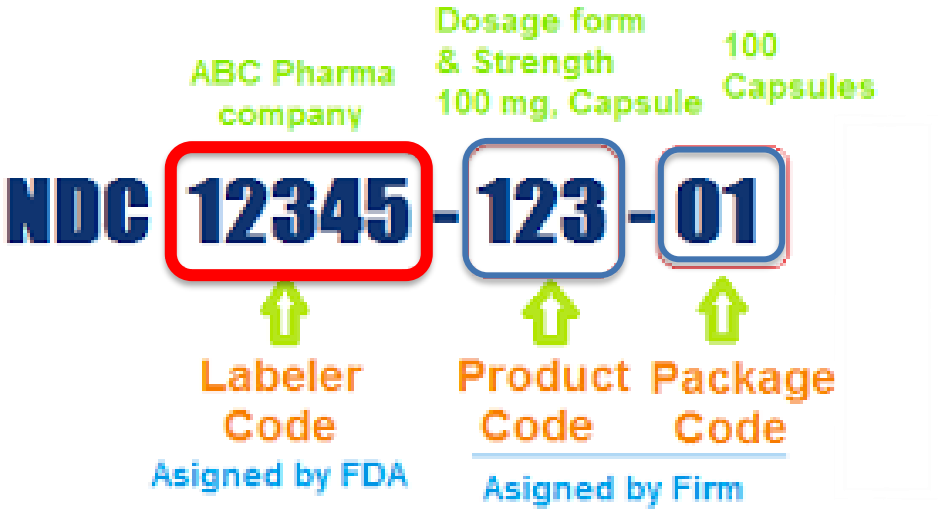
Electronic Drug Registration and Listing Using CDER DIRECT
October 13, 2021

Overview

- Labeler Code Request Process – Who, When, How
  - Update Labeler Code
  - Labeler Code Rejections
  - Live Demo
- Labeler Code Inactivation Process
  - FDA-initiated inactivation
  - Industry-initiated inactivation
  - Live Demo

Labeler Code

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



Labeler Code - Who

§207.33 (c) (1) provides information on who must obtain an NDC labeler code and how the code is assigned and updated.

- Each person who engages in manufacturing, repacking, relabeling, or private label distribution of a drug subject to listing under this part must apply for an NDC labeler code

Labeler Code - When

- Labeler Code Request must be requested before a drug listing must be submitted, which is 5 days within going into commercial distribution.
  - Labeler Code Request must be submitted and completed prior to drug listings.
- If you do not have to list any drugs with FDA, you do not need to apply for a labeler code .
- Labeler codes that are NOT utilized by listing a drug product are automatically INACTIVATED after 24 months.

When should a 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.

Labeler Code – Rejections

- If you are not required to list drugs
- If you already have a LC assigned
    - A second one may be granted if first labeler code is running out of available NDCs

- 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)

Labeler code Document Types

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

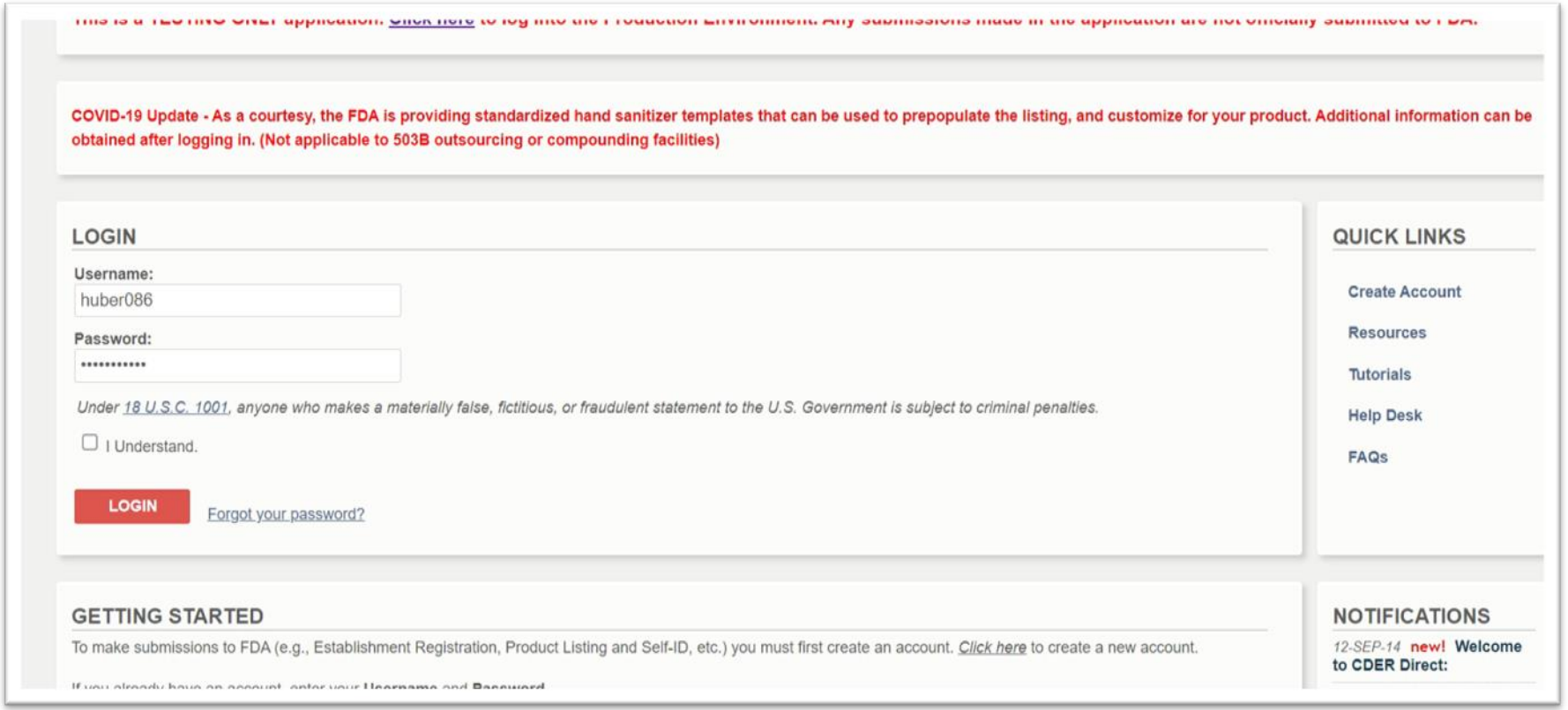
Labeler Code - How

- Live Demo of CDER Direct

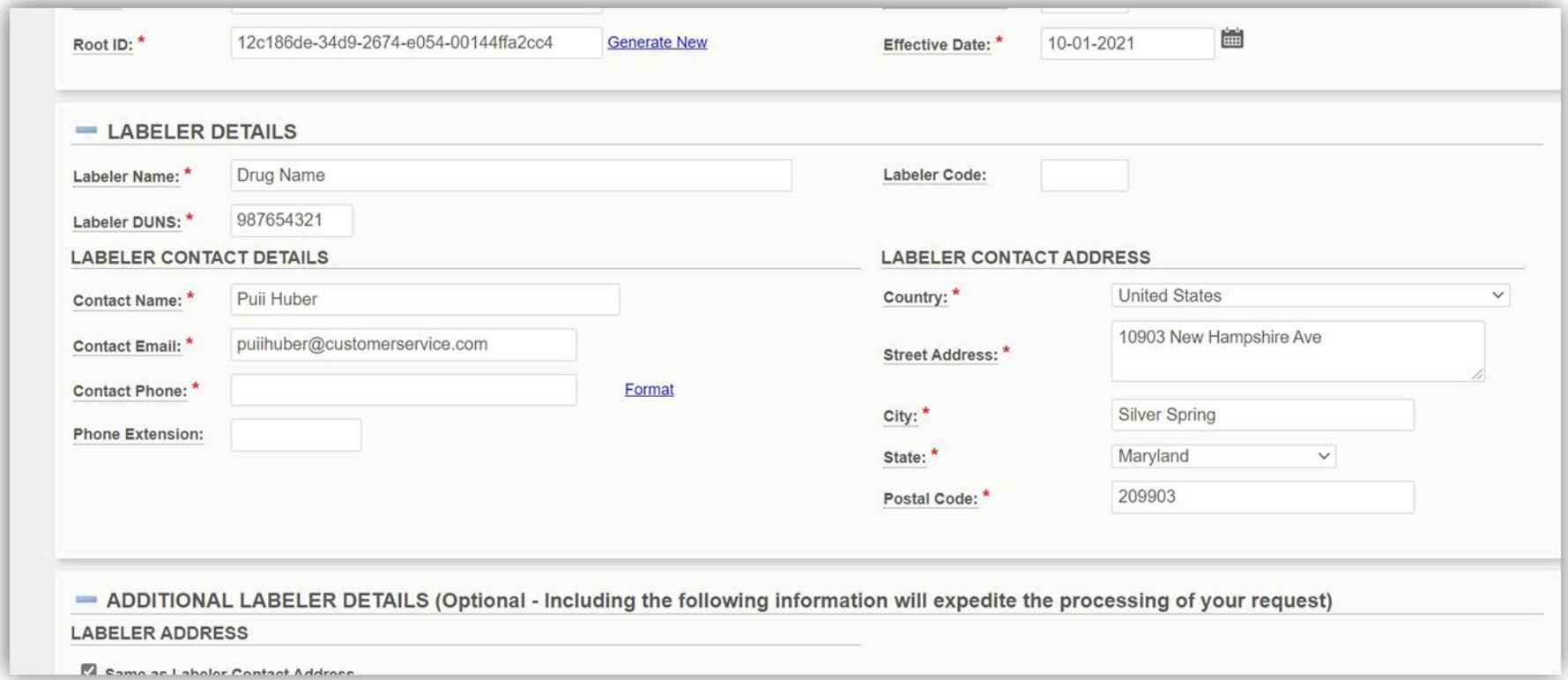
https://direct.fda.gov

  - Requesting a labeler code
  - Completing a labeler code process
  - Updating Labeler Contact or address

Requesting a Labeler Code



Enter Labeler Details



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: 08-Oct-2021
Labeler DUNS: 000000000
Labeler Name: A1 Drug Company
Labeler Code Assigned: 00000

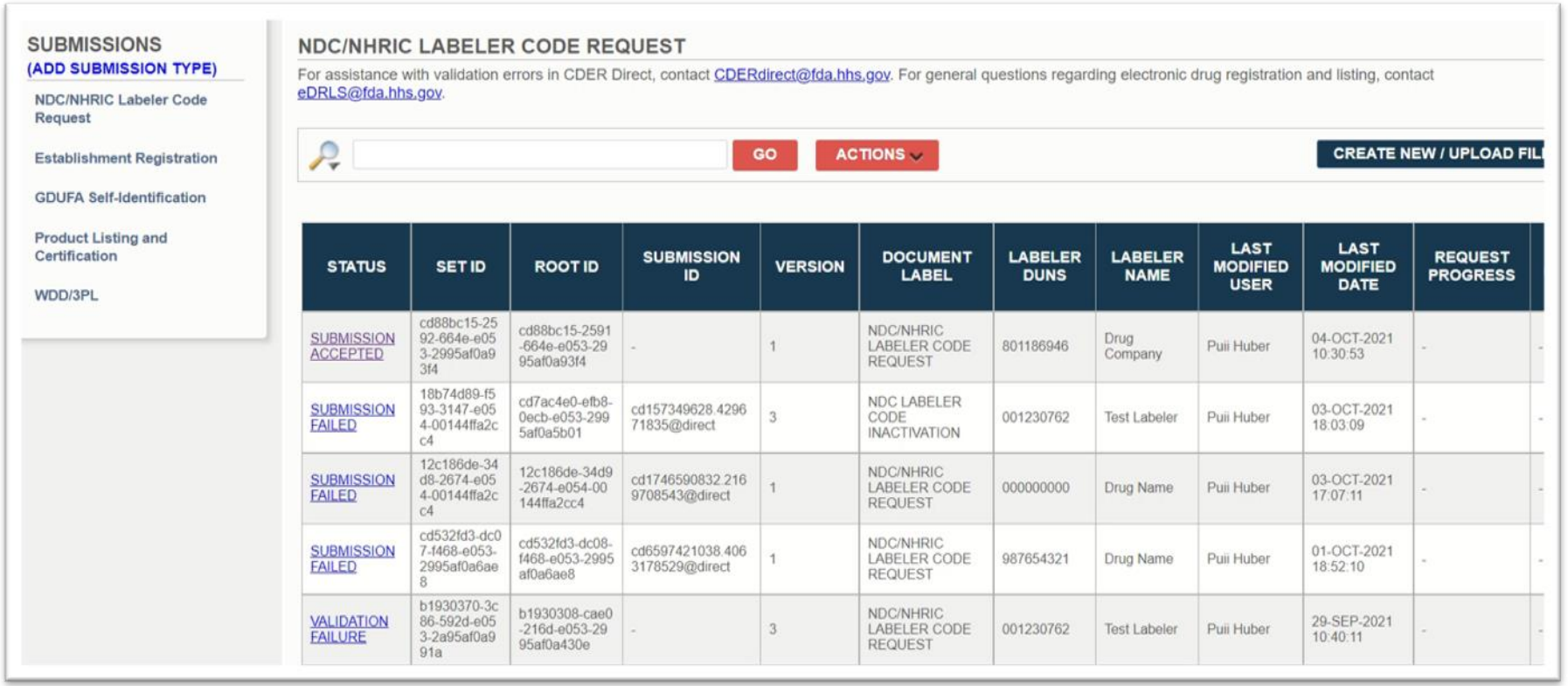
The Food and Drug Administration (FDA) has assigned the above Labeler Code to your firm. The number cannot be used until you have confirmed the assignment. Please revise and resubmit your Labeler Code Request SPL to include the assigned number above to complete the process. To do this, open the previous 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).

Confirm Labeler Code Assignment



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 FIL

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LABELER DUNS	LABELER NAME	LAST MODIFIED USER	LAST MODIFIED DATE	REQUEST PROGRESS
SUBMISSION ACCEPTED	cd88bc15-2592-664e-e053-2995af0a93f4	cd88bc15-2591-664e-e053-2995af0a93f4	-	1	NDC/NHRIC LABELER CODE REQUEST	801186946	Drug Company	Puii Huber	04-OCT-2021 10:30:53	-
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SUBMISSION FAILED	cd532fd3-dc07-f468-e053-2995af0a6ae8	cd532fd3-dc08-f468-e053-2995af0a6ae8	cd6597421038.4063178529@direct	1	NDC/NHRIC LABELER CODE REQUEST	987654321	Drug Name	Puii Huber	01-OCT-2021 18:52:10	-
VALIDATION FAILURE	b1930370-3c86-592d-e053-2a95af0a991a	b1930308-cae0-216d-e053-2995af0a430e	-	3	NDC/NHRIC LABELER CODE REQUEST	001230762	Test Labeler	Puii Huber	29-SEP-2021 10:40:11	-

Labeler Code – Inactivation Process

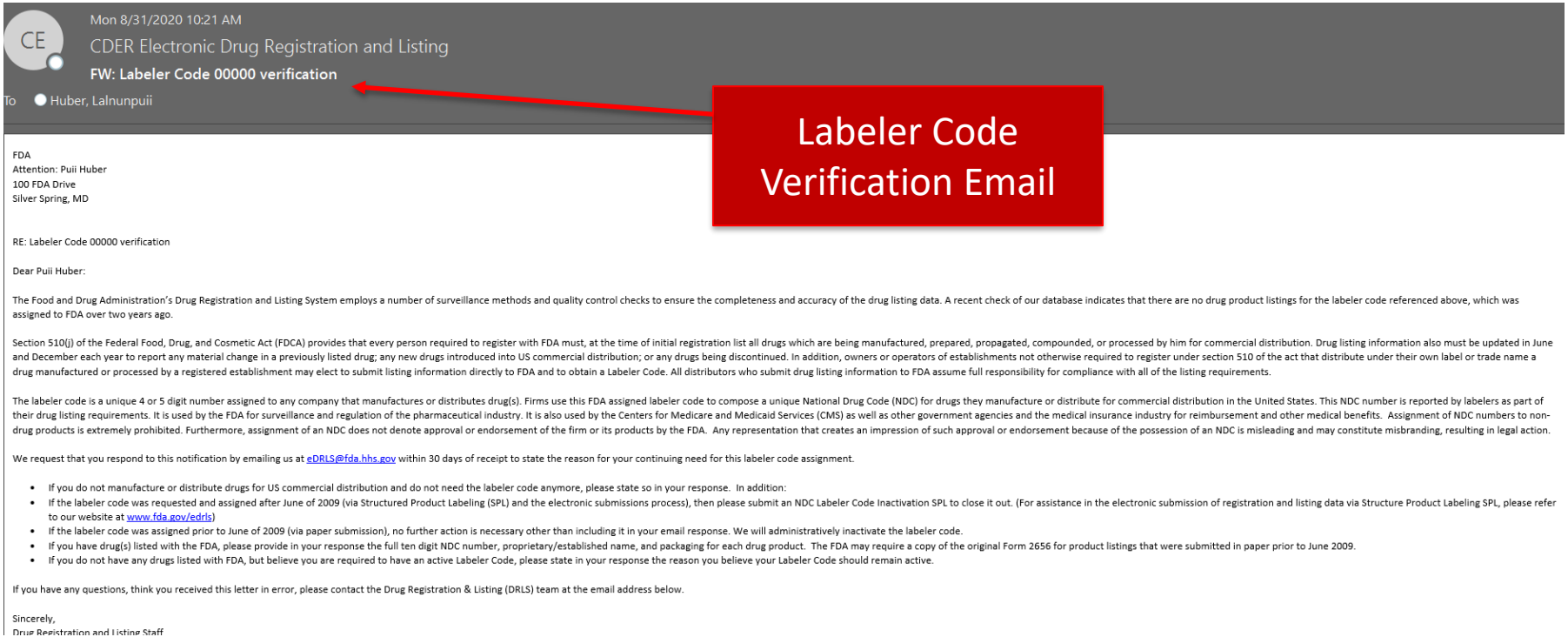
- FDA-initiated inactivation
- Industry-initiated inactivation

Labeler Code - Verification

- Prior to FDA Initiated labeler code inactivation

  - An email is sent to the contact email associated with the labeler code assignment, announcing that in **30 days the labeler code will be inactivated** unless the company lists a product or provides a valid reason for remaining active.

Labeler Code – Verification Email



Mon 8/31/2020 10:21 AM

CDER Electronic Drug Registration and Listing

FW: Labeler Code 00000 verification

To Huber, Lalnunpuii

Labeler Code Verification Email

FDA
Attention: Puii Huber
100 FDA Drive
Silver Spring, MD

RE: Labeler Code 00000 verification

Dear Puii Huber:

The Food and Drug Administration's Drug Registration and Listing System employs a number of surveillance methods and quality control checks to ensure the completeness and accuracy of the drug listing data. A recent check of our database indicates that there are no drug product listings for the labeler code referenced above, which was assigned to FDA over two years ago.

Section 510(j) of the Federal Food, Drug, and Cosmetic Act (FDCA) provides that every person required to register with FDA must, at the time of initial registration list all drugs which are being manufactured, prepared, propagated, compounded, or processed by him for commercial distribution. Drug listing information also must be updated in June and December each year to report any material change in a previously listed drug; any new drugs introduced into US commercial distribution; or any drugs being discontinued. In addition, owners or operators of establishments not otherwise required to register under section 510 of the act that distribute under their own label or trade name a drug manufactured or processed by a registered establishment may elect to submit listing information directly to FDA and to obtain a Labeler Code. All distributors who submit drug listing information to FDA assume full responsibility for compliance with all of the listing requirements.

The labeler code is a unique 4 or 5 digit number assigned to any company that manufactures or distributes drug(s). Firms use this FDA assigned labeler code to compose a unique National Drug Code (NDC) for drugs they manufacture or distribute for commercial distribution in the United States. This NDC number is reported by labelers as part of their drug listing requirements. It is used by the FDA for surveillance and regulation of the pharmaceutical industry. It is also used by the Centers for Medicare and Medicaid Services (CMS) as well as other government agencies and the medical insurance industry for reimbursement and other medical benefits. Assignment of NDC numbers to non-drug products is extremely prohibited. Furthermore, assignment of an NDC does not denote approval or endorsement of the firm or its products by the FDA. Any representation that creates an impression of such approval or endorsement because of the possession of an NDC is misleading and may constitute misbranding, resulting in legal action.

We request that you respond to this notification by emailing us at eDRLS@fda.hhs.gov within 30 days of receipt to state the reason for your continuing need for this labeler code assignment.

- If you do not manufacture or distribute drugs for US commercial distribution and do not need the labeler code anymore, please state so in your response. In addition:
- If the labeler code was requested and assigned after June of 2009 (via Structured Product Labeling (SPL) and the electronic submissions process), then please submit an NDC Labeler Code Inactivation SPL to close it out. (For assistance in the electronic submission of registration and listing data via Structure Product Labeling SPL, please refer to our website at www.fda.gov/edrls)
- If the labeler code was assigned prior to June of 2009 (via paper submission), no further action is necessary other than including it in your email response. We will administratively inactivate the labeler code.
- If you have drug(s) listed with the FDA, please provide in your response the full ten digit NDC number, proprietary/established name, and packaging for each drug product. The FDA may require a copy of the original Form 2656 for product listings that were submitted in paper prior to June 2009.
- If you do not have any drugs listed with FDA, but believe you are required to have an active Labeler Code, please state in your response the reason you believe your Labeler Code should remain active.

If you have any questions, think you received this letter in error, please contact the Drug Registration & Listing (DRLS) team at the email address below.

Sincerely,
Drug Registration and Listing Staff

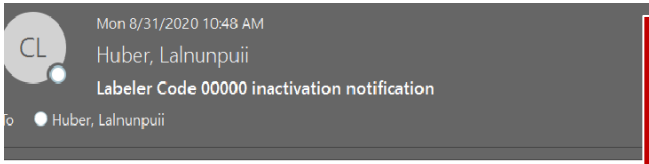
Verification Email Response

We request that you respond to this notification by emailing us at eDRLS@fda.hhs.gov within 30 days of receipt to state the reason for your continued need for this labeler code.

- If you do not manufacture or distribute drugs for US commercial distribution and do not need the labeler code anymore, please state so in your response.

- If you do not have any drugs listed with FDA, but believe you need to have an active labeler code, please state in your response the reason you believe your labeler code should remain active.

Labeler Code Inactivation Notification



Labeler codes that have no products listed for two years are sent notification 30 days prior to inactivation. If there is no response to the notification then your labeler code is inactivated.

FDA
Attention: Puii Huber
FDA Drive

Silver Spring, MD

RE: Labeler Code 00000 inactivation notification

Dear Janine Ellenberger:

This is an FDA automatically generated email to notify you that Labeler Code 00000 assigned previously by FDA to Puii is now inactivated.

Labeler codes that have no products listed for two years are sent notification 30 days prior to inactivation. If there is no response to the notification then your labeler code is inactivated. This Labeler Code cannot be used for NDC assignment to drugs or drug listing with FDA. If you have a drug or drugs that you are about to enter in US commercial distribution, please provide us with details for each drug in an email. We request information on product name, active ingredient(s), strength, labeling, start marketing date and intended NDC for each drug in order for us to determine if the labeler code should be reactivated. For more information visit: www.fda.gov/edrls

If you think you received this letter in error, please contact the Drug Registration & Listing (DRLS) team at the email address below.

Sincerely,
Drug Registration and Listing Staff
FDA/CDER/Office of Compliance
edrls@fda.hhs.gov

Labeler Code – How to Reactivate

For FDA-initiated inactivation:

Only FDA is able to reactivate the labeler code

Send a request with the following information to edrls@fda.hhs.gov:

- Product name
- Active ingredient(s)
- Strength
- Labeling
- Anticipated start marketing date of the drug
- Intended NDC for each drug

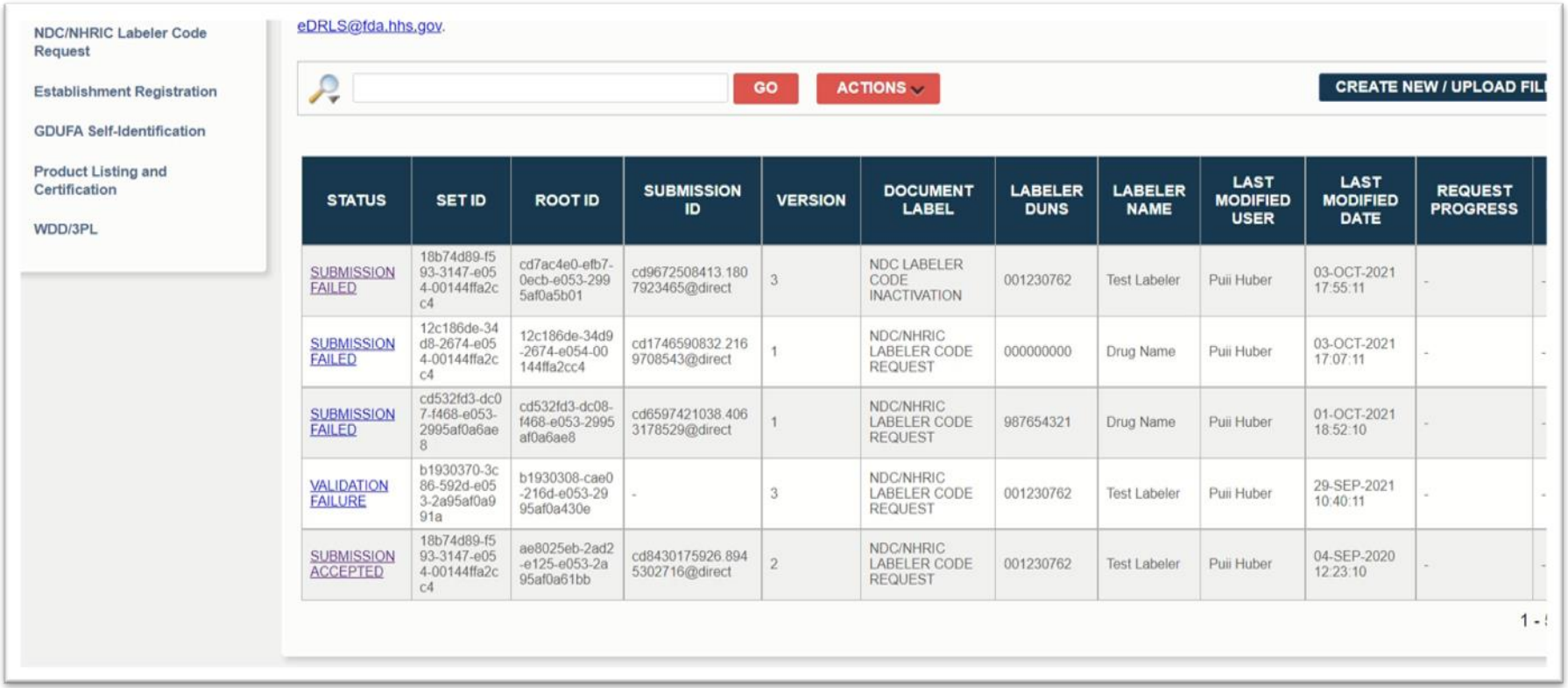
Industry-Initiated labeler code Inactivation

- Labeler code is no longer needed:
  - Out of business/ change in business
  - Mergers/ acquisitions
  - Application for a drug in development did not get approved by FDA

https://direct.fda.gov

- Live Demo of CDER Direct
  - How to Inactivate
  - How to Reactivate

How to Inactivate a Labeler Code



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SUBMISSION FAILED	12c186de-34d8-2674-e054-00144ffa2cc4	12c186de-34d9-2674-e054-00144ffa2cc4	cd1746590832.2169708543@direct	1	NDC/NHRIC LABELER CODE REQUEST	000000000	Drug Name	Puii Huber	03-OCT-2021 17:07:11	-
SUBMISSION FAILED	cd532fd3-dc07-f468-e053-2995af0a6ae8	cd532fd3-dc08-f468-e053-2995af0a6ae8	cd6597421038.4063178529@direct	1	NDC/NHRIC LABELER CODE REQUEST	987654321	Drug Name	Puii Huber	01-OCT-2021 18:52:10	-
VALIDATION FAILURE	b1930370-3c86-592d-e053-2a95af0a991a	b1930308-cae0-216d-e053-2995af0a430e	-	3	NDC/NHRIC LABELER CODE REQUEST	001230762	Test Labeler	Puii Huber	29-SEP-2021 10:40:11	-
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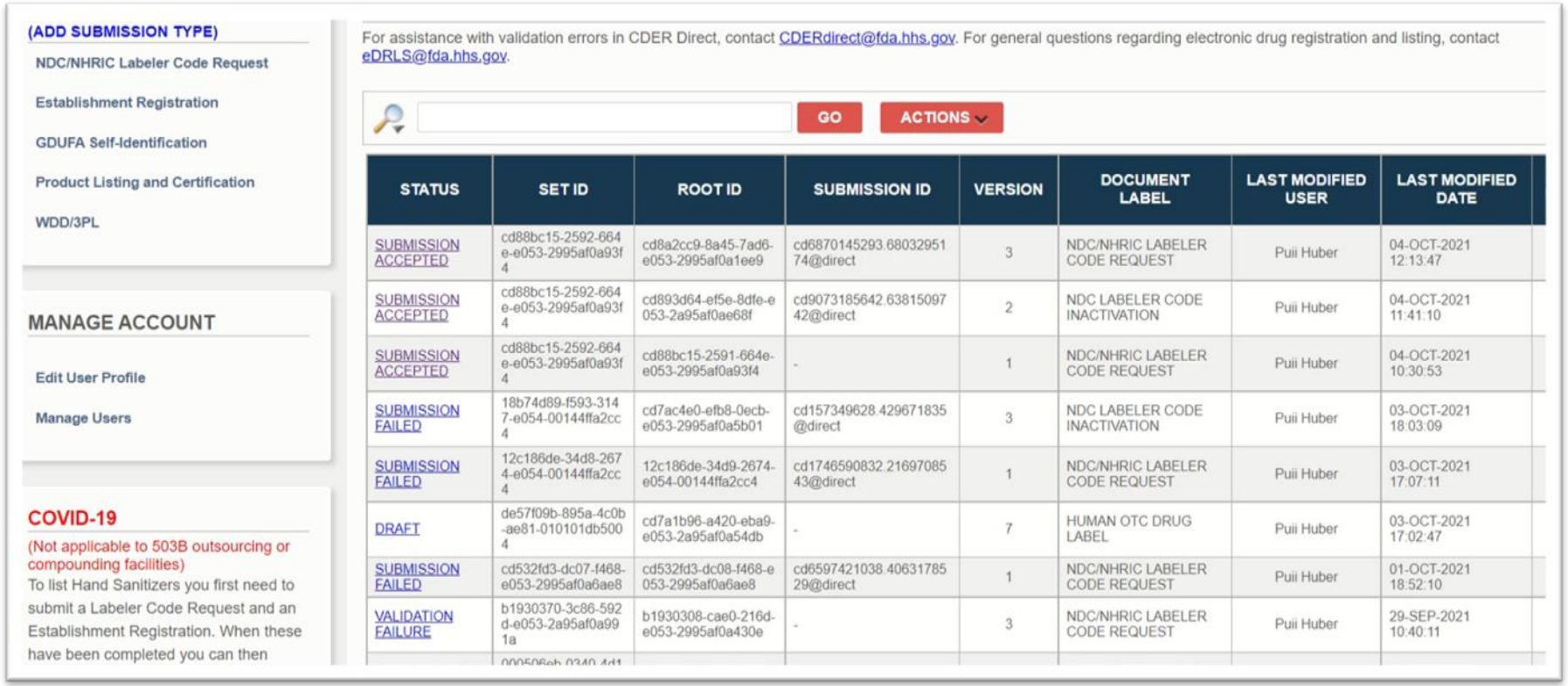
How to Reactivate a Labeler Code



(ADD SUBMISSION TYPE)

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

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 have been completed you can then

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

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE
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DRAFT	de57f09b-895a-4c0b-ae81-010101db5004	cd7a1b96-a420-eba9-e053-2a95af0a54db	-	7	HUMAN OTC DRUG LABEL	Puii Huber	03-OCT-2021 17:02:47
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VALIDATION FAILURE	b1930370-3c86-592d-e053-2a95af0a991a	b1930308-cae0-216d-e053-2995af0a430e	-	3	NDC/NHRIC LABELER CODE REQUEST	Puii Huber	29-SEP-2021 10:40:11

Summary

- Labeler Code Request should only be submitted when drugs are ready to be launched for US 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.
- To Reactivate a labeler code inactivated by the FDA, email eDRLS@fda.hhs.gov

Questions?

Contact Us:

eDRLS@fda.hhs.gov