Labeler Code Inactivation and Reactivation

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September 28, 2023

Learning Objectives

- Understand the Labeler Code Verification, Inactivation, and Reactivation process.
- Differentiate between FDA and Industry-initiated Labeler Code Inactivation.
- Learn the steps to reactivate an FDA initiated labeler code.

Labeler Code

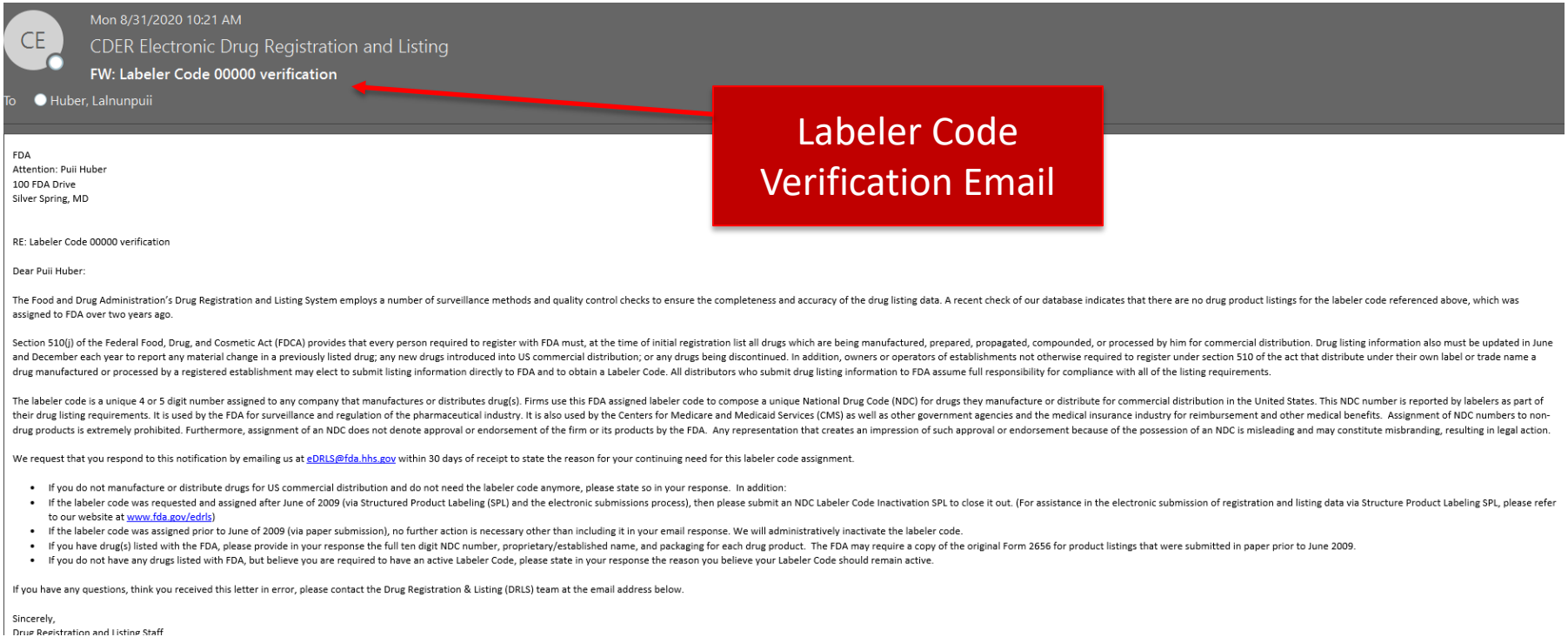
- **Purpose of Labeler Code Request:** To list drugs manufactured or distributed in the United States.
- **Do I need to apply for a Labeler Code?**: If your company does not have any drugs requiring FDA listing, you may not need to apply for a labeler code.
- **Inactivation of Labeler Codes:**
  - Labeler 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.

Labeler Code - Verification

Prior to FDA-Initiated Labeler Code Inactivation for LCs not Used in any Drug Listings

- An email will be sent to the contact email associated with the labeler code assignment.
- **Notification:** Labeler code inactivation will be initiated in 30 days from the date of the email.
- **Action required:** To avoid inactivation, either list a product associated with the labeler code or provide a valid reason for not having any products listed.

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

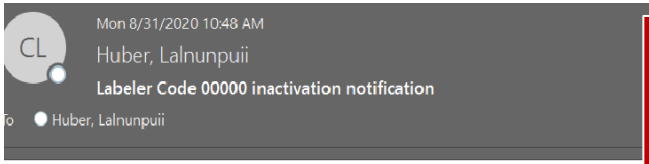
Verification Email Response

If you receive the inactivation notification, please respond within 30 days by emailing us at eDRLS@fda.hhs.gov.

- State the reason for your continued need for the labeler code.
- If you no longer require the labeler code because you don't manufacture or distribute drugs for US commercial distribution, state so in your response and proceed with inactivating your labeler code.

Note: Timely and accurate responses are essential to maintain an active labeler code.

Labeler Code Inactivation Notification



- Labeler codes that have no products listed for two years are sent a 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 a labeler code that is inactivated by FDA.
- To reactivate, send a request with the following information to edrls@fda.hhs.gov for review and approval:
  1. Drug product name
  2. Active ingredient(s)
  3. Strength
  4. Drug labeling
  5. Anticipated start marketing date of the drug
  6. Proposed NDC for each drug

Industry-Initiated Labeler Code Inactivation

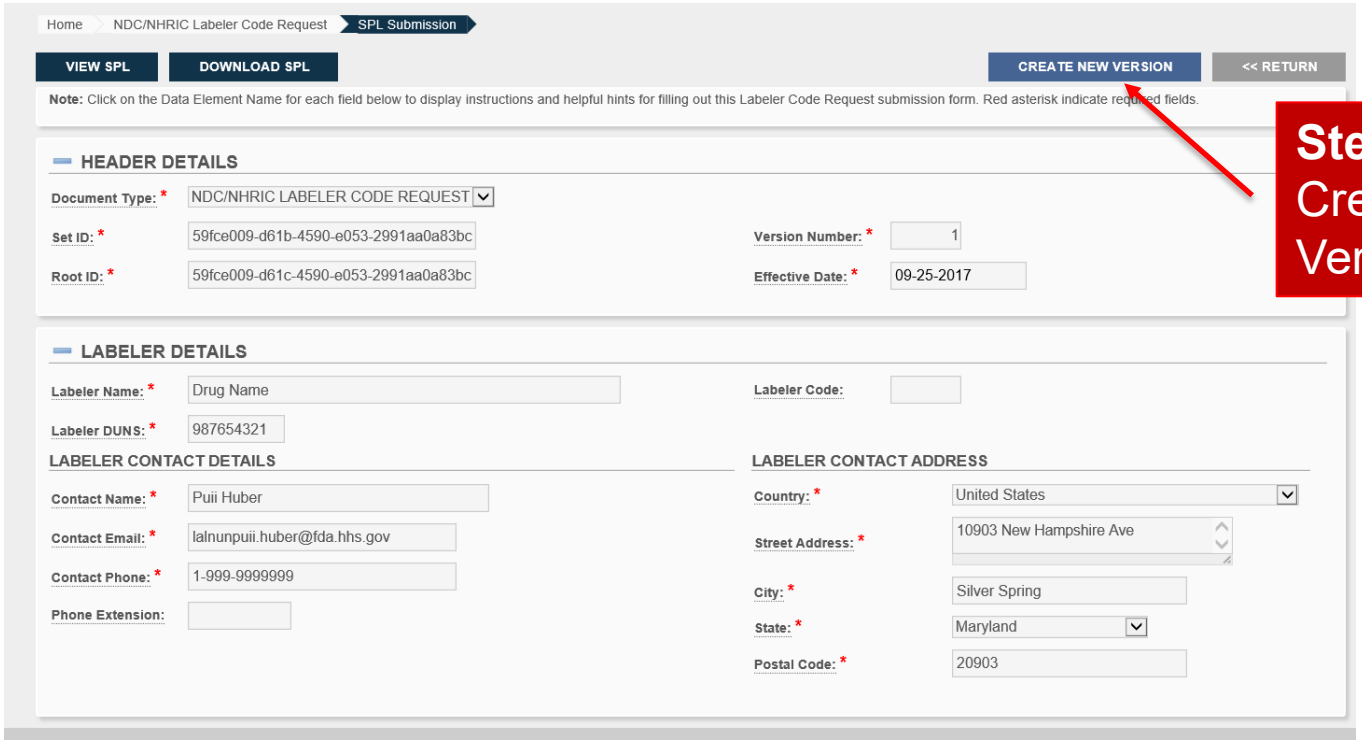
- Labeler code is no longer needed due to:
  - Out of business/ change in business

  - Mergers/ acquisitions

  - Application for a drug in development did not get approved by FDA

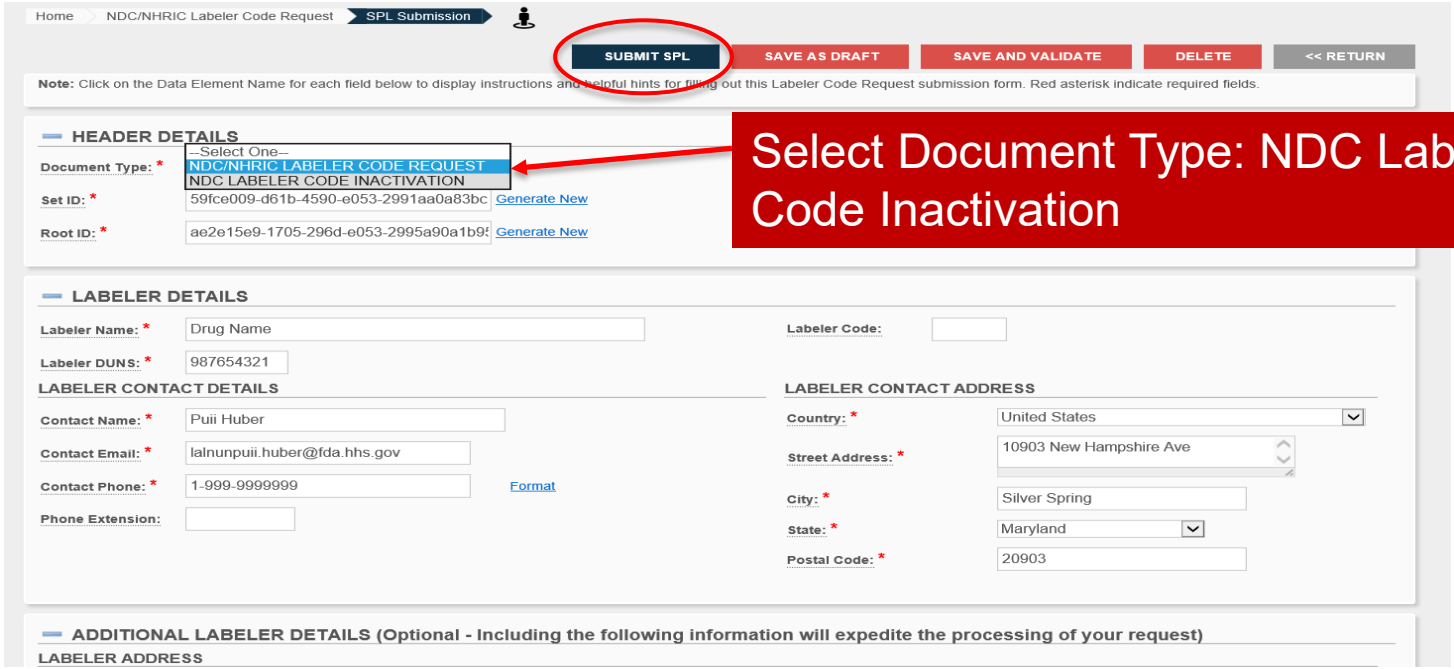
Labeler Code – How to Inactivate

Step 1: **Open the previously submitted and accepted Labeler Code Request**



Labeler Code – How to Inactivate

- **Step 3** – Select Document type and Submit SPL



Labeler Code – How to Reactivate

- Industry-initiated inactivation:
  - Reactivate using the same SET ID
  - Industry can only reactivate the same labeler code it had inactivated in the past

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

Who has the authority to reactivate an industry-initiated inactivated labeler code?

A) FDA

B) Industry

C) Both A and B

D) Regulatory agencies

Summary

- Labeler codes without listed drugs are automatically inactivated after 24 months.
- Before inactivation, a notification email is sent, and a 30-day response window is provided.
- To inactivate a labeler code, submit a NDC Labeler Code Inactivation SPL.
- For FDA-initiated inactivation, contact eDRLS@fda.hhs.gov for reactivation.

Thank you for your attention and engagement!

Questions?

Contact Us:
eDRLS@fda.hhs.gov