

Labeler Code Inactivation

Lalnunpuii Huber
Technical Information Specialist
Drug Registration and Listing Staff
FDA/CDER/OC/OPRO



Overview

- Labeler code Inactivation process
 - FDA-initiated inactivation
 - Industry-initiated inactivation
- How to inactivate a labeler code
- How to reactivate a labeler code
- Challenge Questions

Labeler Code



The purpose of requesting a labeler code is to list “drugs” that are manufactured or distributed in the US.

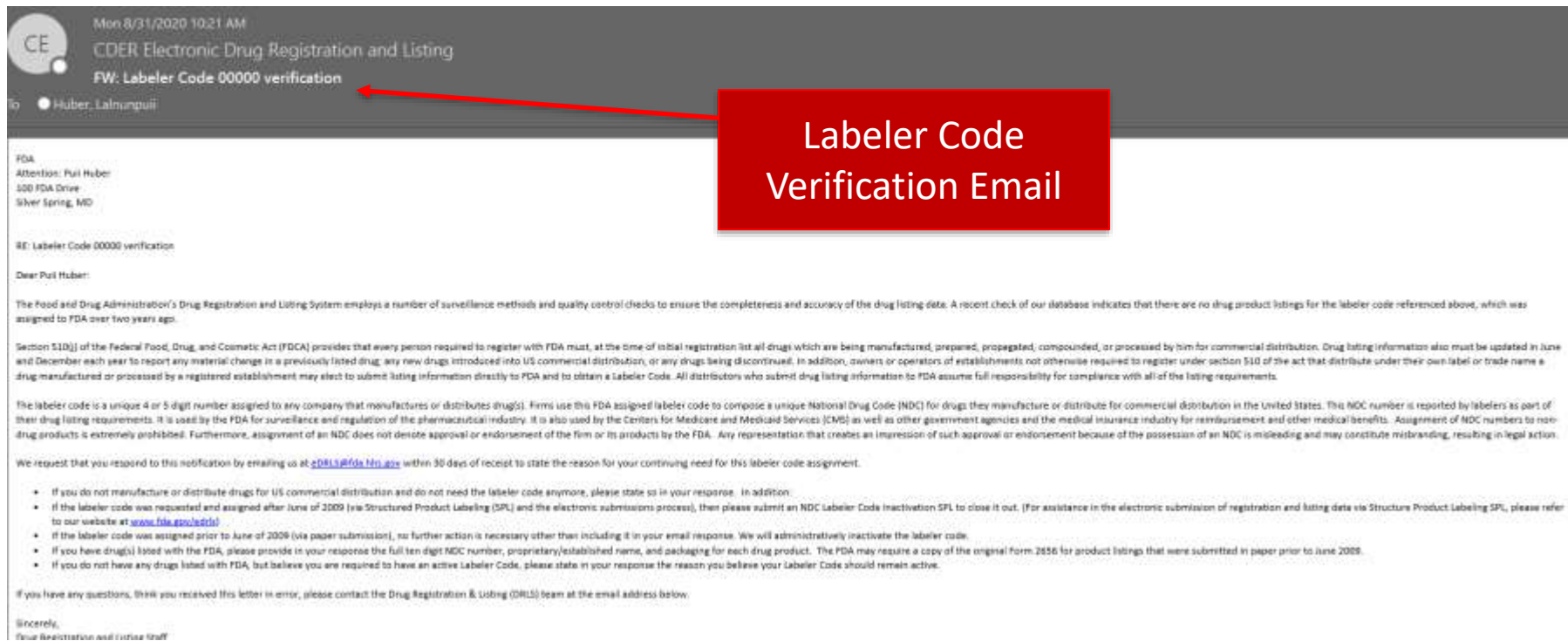
- If you do not have to list any drugs with FDA, most likely you do not need to apply for a labeler code .
- Labeler codes that do not have any drugs listed are automatically INACTIVATED after 24 months.

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.

Labeler Code – Verification Email



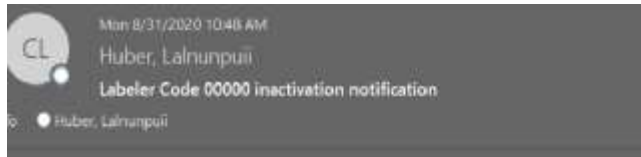


Verification Email Response

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



FDA
Attention: Puui 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 Puui 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 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.

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

Labeler Code – How to Inactivate



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

Home NDC/NHRC Labeler Code Request SPL Submission

VIEW SPL DOWNLOAD SPL CREATE NEW VERSION << 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: * 59fce009-d61b-4590-a053-2981aa0a83bc

Root ID: * 59fce009-d61c-4590-a053-2991aa0a83bc

Version Number: * 1

Effective Date: * 09-25-2017

LABELER DETAILS

Labeler Name: * Drug Name

Labeler DUNS: * 987654321

Label Code: *

LABELER CONTACT DETAILS

Contact Name: * Puli Huber

Contact Email: * lahunpuli.huber@fda.hhs.gov

Contact Phone: * 1-999-9999999

Phone Extension: *

LABELER CONTACT ADDRESS

Country: * United States ▼

Street Address: * 10903 New Hampshire Ave

City: * Silver Spring

State: * Maryland ▼

Postal Code: * 20903

Step 2: Click
Create New
Version

Labeler Code – How to Inactivate



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

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: * --Select One--
NDC/NHRC LABELER CODE REQUEST
NDC LABELER CODE INACTIVATION

Set ID: * 58fca009-d61b-4590-a053-2991aa0a83bc [Generate Now](#)

Root ID: * aa2e15a9-1705-298d-a053-2995a90a1b0f [Generate Now](#)

LABELER DETAILS

Labeler Name: * Drug Name

Labeler DUNs: * 987054321

LABELER CONTACT DETAILS

Contact Name: * Pui Huber

Contact Email: * lahnunpui.huber@fda.hhs.gov

Contact Phone: * 1-800-0999009 [Format](#)

Phone Extension: *

LABELER CONTACT ADDRESS

Country: * United States

Street Address: * 10903 New Hampshire Ave

City: * Silver Spring

State: * Maryland

Postal Code: * 20903

ADDITIONAL LABELER DETAILS (Optional - Including the following information will expedite the processing of your request)

LABELER ADDRESS

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

Labeler code verification email must be responded within

- a) 60 days
- b) 90 days
- c) 30 days
- d) Every June and December

Challenge Question 2



Labeler codes that do not have any NDCs listed are automatically INACTIVATED after

- a) 12 months
- b) 6 months
- c) 24 months.

Summary



- Labeler codes that do not have any drugs listed are automatically INACTIVATED after 24 months.
- Before Inactivation, an email is sent to the labeler contact to respond within 30 days
- To Inactivate a labeler code: Submit a Labeler Code Inactivation
- To Reactivate a labeler code inactivated by the FDA, email eDRLS@fda.hhs.gov



Questions?

Contact Us:
eDRLS@fda.hhs.gov