

# **CDER Direct Labeler Code Request**

**[direct.fda.gov](https://direct.fda.gov)**

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# 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 - When

- Labeler Code Request must be submitted when going into commercial distribution
- 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 – How to Request



- **Step 1** – Submit a **NDC Labeler Code Request Document** if you are requesting a labeler code. Leave the NDC Labeler Code field blank
- **Step 2** - FDA will evaluate the request and may contact the request if any clarification is needed.
- **Step 3** – FDA will email the contact person on the request with the assigned number.
- **Step 4** - To complete the process, submit an updated labeler code form SPL with the newly assigned number filled in.



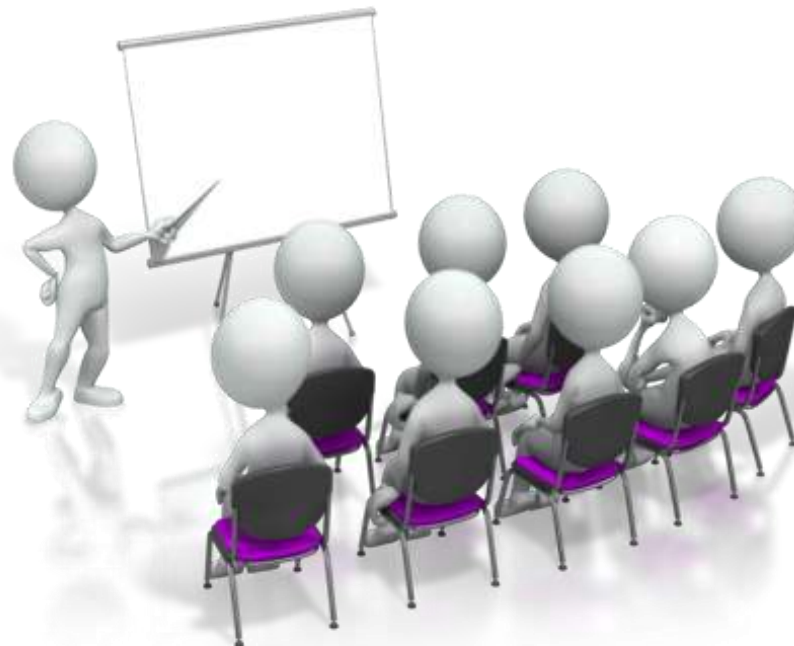
# Labeler Code: How to Inactivate/Reactivate

- **Step 1** – Submit an **NDC Labeler Code Inactivation** if you are inactivating your labeler code.
- **Step 2** – To reactivate your labeler code, submit a NDC Labeler Code request with the labeler code number and use the original SET ID you used to inactivate the labeler code .
- **Step 3** – To reactivate a labeler code that has been automatically inactivated by FDA, you will need to send us the proposed label information to [edrls@fda.hhs.gov](mailto:edrls@fda.hhs.gov)

# LIVE DEMO

Log on to CDER Direct:

[direct.fda.gov](http://direct.fda.gov)





# What happens after a listing has been submitted through CDER Direct

- Email sent to firm with submission status
- Status
  - Submission awaiting acceptance
  - Submission accepted
  - Submission failed





# Labeler Code – Helpful Hints

## Set ID:

- 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.

## Process Time:

- It normally takes 7-10 business days to process a labeler code.

# Questions?

[CDErdirect@fda.hhs.gov](mailto:CDErdirect@fda.hhs.gov)

eDRLS Helpdesk: [edrls@fda.hhs.gov](mailto:edrls@fda.hhs.gov)

