Establishment Registration & Labeler Code Request

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Overview

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Who Must Register?

- With certain exemptions, any establishment engaged in the manufacture, repacking, relabeling, or salvaging of a drug product for commercial distribution in the U.S. is required to register with FDA *(refer to eDRLS Toolkit for more information).*

- Most exemptions are listed on the eDRLS website.

When to Register?

- Registration is required within 5 days of introducing product into commercial distribution.

Tips Regarding Registration

- Since Private Label Distributors do not manufacture, they should not register.
- Used for inspections and imports
- You can find all currently registered Establishments on the Drug Establishments Current Registration Site (DECRS)
  - Link to DECRS Website
- A Product Listing SPL will fail validation if the Establishment is not registered

Updating Your Establishment Registration

- Annual registration renewal to be submitted between Oct. 1 and Dec. 31
- Expedited updates to be provided within 30 days of a change
  - Closing or selling an establishment
  - Changing an establishment's name or physical address
  - Changing the name, mailing address, telephone number, or email address of the official contact or the United States agent.

Types of Establishment Registration SPLs

Establishment Registration SPL

- New Establishment Registration or an update to an existing Establishment Registration

No Change Notification SPL

- Easily re-register without any updates to the previously submitted Establishment Registration

De-Registration SPL

- De-register because the firm is no longer manufacturing drug products for commercial distribution in the US

Out of Business SPL

- Firm is no longer in business

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on
CDER Direct

Tips for Establishment Registration

- Ensure that the Establishment information you enter (company name and address) exactly matches what is in the DUNS record.
- Ensure that all email addresses are valid and accurate as future FDA correspondence will be sent to the email addresses provided.
- Multiple Establishments can be registered using one Establishment Registration SPL.
- If your Establishment Registration SPL is grayed out and you are unable to edit a field, click on “Create New Version” to edit the SPL.

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 *(refer to eDRLS Toolkit for more information)*.
- 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.

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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**

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Questions?

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Thank You for Registering!

Contact Us:

eDRLS@fda.hhs.gov