

Establishment Registration

Troy Cu

and

Regie Samuel

Overview

- Who Must Register
- When to Register
- Registration Updates
- Tips Regarding Registration
- Types of Establishment Registration SPLs
- Live Demo
- Tips for CDER Direct Establishment Registration
- Questions

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.
- Most exemptions are listed on the [eDRLS website](#).

When to Register?

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

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.

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

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



LIVE DEMO

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.

Questions?

Contact Us:

eDRLS@fda.hhs.gov

Thank You for Registering!