direct.fda.gov

510 Product Listing

- **Part I**
  - What is CDER Direct?
  - Why CDER Direct?
  - CDER Direct Users
  - Available SPL Forms
- **Part II**
  - **LIVE** demonstration
- **Part III**
  - FAQs
  - Additional information

CDER Direct: direct.fda.gov

What is CDER Direct?

- A web based tool for electronic registration and listing
- Allows you to create and send SPL submissions
- It offers:
  - User friendly web-based data entry forms
  - Create, review and edit SPLs
  - Directly submit to FDA for internal processing
    - No SSL certificates needed
    - No ESG Account needed
  - Perform initial validations and provide the FDA response to the user

CDER Direct: direct.fda.gov

Why CDER Direct?

- More data entry interface
- Help text for each required field
- Stores SPL submissions within your individual account
- Offers submissions status on SPL
- It will *not* replace Xforms.

CDER Direct: direct.fda.gov

Who are CDER Direct users?

- Individuals with the following SPL responsibilities:
  - NDC Labeler Code Requests
  - Establishment Registrations and annual updates
  - GDUFA Facility self-identification
  - Product Listing
  - 503B outsourcing facility
    - Registration
    - Product reporting
  - Wholesale Drug Distributors and Third Party Logistics Providers (WDD/3PL)

Available SPL Forms

- Labeler code Request
- Establishment Registration/Update
- Human Prescription Drug Label
- Human OTC Drug Label
- GDUFA Self ID
- 503B Outsourcing Facility Registration
- 503B Outsourcing Facility Product Reporting
- Future expansion to include other submissions

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FAQs

- Do I need a web trader account with CDER Direct?
  - CDER Direct submissions are directly submitted for internal processing. No Webtrader account is needed
- Is there a fee to use CDER Direct?
  - There are no fees to utilize the FDA's CDER Direct Electronic Submission Portal

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FAQs

- What are the advantages of using SPL?
  - SPL employs accepted data standards and takes advantage of FDA's existing infrastructure. Additionally, SPL provides more efficient quality control of the incoming data
- Is there a fee to register and list?
  - There are no fees associated with electronic labeler code request, registering or listing with FDA or maintaining and updating this information.

FAQs

- What tools are available to create an SPL file?
  - Facilities have the option to choose from multiple SPL authoring tools to create and submit a product listing, including FDA's CDER Direct.

- What is the Java, or system requirement, to use CDER Direct?
  - CDER Direct application was designed for and works best with:
    - *IE 8 or above*
    - *Firefox version 28 or above*
  - Java and/or JavaScript is *not* required for CDER Direct

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FAQs

- Can I import existing registration and listing SPL files into these new forms?
  - Yes, you can import existing SPL and make any changes if needed and submit
- What is a Dashboard and where is it located in CDER direct?
  - The Dashboard contains all the submissions you have made with CDER Direct. It is the opening page upon login.

FAQs

- I have a labeler code that I obtained many years ago, through the paper application. I am now trying to apply through the online system, and I am hoping to get the same number. Can I use this labeler Code?
  - Yes, the firm can use the same code that was assigned via paper format.
  - To activate this labeler code in our electronic system – they **must submit** a Labeler Code Request SPL with the assigned number to confirm the assignment and complete the process.

For More Information

Log on to CDER Direct: direct.fda.gov

Compatible with:

- *IE 8 or above*
- *Firefox version 28 or above*
- *Chrome*

Help Desk: CDERdirect@fda.hhs.gov

eDRLS Helpdesk: edrls@fda.hhs.gov