CDER *Direct*
Electronic Submissions Portal

direct.fda.gov

Drug Facility Registration

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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

Why CDER Direct?

- More data entry form style of interface
- Help text for each required field will be provided
- Stores SPL submissions within individual account
- Offers submission status on SPL
- It will *not* replace Xforms.

Who are CDER Direct users?

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

Available SPL Formats

- 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

FAQs

- What is the annual registration fee?
  - For most drug facilities, there is no registration fee. For 503B Human Drug Compounding Outsourcing Facilities, please refer to the guidance *Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the FD&C Act* for more information.
  - Payment of fees **cannot** be made through CDER Direct. An invoice will be sent to the registrant upon review of the registration submission.

FAQs

- When do drug facilities need to register?
  - After initial registration, facilities must register **annually**, between **October 1 and December 31** of each year, to continue to be registered facilities.

FAQs

- How can I update information included in my registration?
  - In order to update any existing registration information, open the previous establishment registration SPL file and fill in the new information **without** changing the other existing information.
  - Fill in a **new** root id and **new** version number with the **original** setId and the appropriate effective time.

FAQs

- Is there a list of registered facilities?
  - A list of currently registered facilities can be found on our Drug Establishments Current Registration Site (DECRS) at: http://www.fda.gov/Drugs/InformationOnDrugs/ucm135778.htm

For more information

Log on to CDER Direct: direct.fda.gov

Compatible with:

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

Help Desk: CDERdirect@fda.hhs.gov

eDRLS Helpdesk: edrls@fda.hhs.gov