CDER *Direct*

Electronic Submissions Portal

direct.fda.gov

503B Product Reporting (Compounding)

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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

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 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

CDER Direct: direct.fda.gov

Live Demonstration of CDER Direct

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FAQs

- Why can't product reports be submitted via Excel spreadsheet?
  - It offers limited manipulation because users can include varieties of text formats and abbreviations.
- What can be included in one product report SPL?
  - For a unique drug, one SPL can include:
    - multiple strengths
    - package sizes
    - source NDC numbers

FAQs

- How long does it take to submit a product report SPL?
  - There is a labor cost for creating the initial product report; however, SPL allows previous files to be saved. Therefore, subsequent reports will require much less time to update and submit. We estimate each initial SPL file can take 1 – 2 hours to create and submit.
- Why should I save SPL files I've submitted?
  - FDA recommends saving product report SPL files for future use. This saves the time it takes to recreate all of the product data and provides consistency in product data across reporting periods.

FAQs

- What is required to be included in a product report?
  - The National Drug Code (NDC) number of the final product, if assigned.
  - The active ingredient and strength of active ingredient per unit.
  - The NDC number of the source drug or bulk active ingredient, if available.
  - The source of the active ingredient.
  - The dosage form and route of administration.
  - The package description.
  - The number of individual units produced.

FAQs

- What is FDA's standard for NDC numbers?
  - FDA enforces the standard 10-digit, 3-segmented, hyphenated NDC.
    - xxxxx-xxxx-x
    - xxxxx-xxx-xx
    - xxxx-xxxx-xx
  - A company must use the same configuration above for all of its NDCs

FAQs

- During each reporting period, what timeframe should the report cover?
  - Drug product reports submitted between June 1 and June 30 of each year must report products produced during the previous six month period (December 1 through May 31).
  - Reports submitted between December 1 and December 31 of each year must report drug products produced during the previous six month period (June 1 through November 30).

FAQs

- If I did not compound any drugs during the previous 6-month period, do I have to submit a product report?
  - Yes, submit a single SPL submission stating that no products have been produced. If an individual product was not compounded during a 6 month period while others were, then only submit SPL submissions for the products that were compounded.
- If I submitted a report upon initial registration before June or December, do I still need to submit a product report for the upcoming reporting period?
  - Yes, registered outsourcing facilities must submit a report upon initial registration under section 503B of the FD&C Act and twice each year thereafter, once in June and once in December.

FAQs

- What information from my product report will be published?
  - For drugs compounded at outsourcing facilities, we plan to publish the following data elements:
    - NDC of the final product (if assigned)
    - name of the outsourcing facility
    - dosage form
    - name of the active ingredient
    - strength of the active ingredient per unit
    - package size
    - package type

For More Information

Log on to CDER Direct: direct.fda.gov

Compatible with:

- *IE 8 or above*
- *Firefox version 28 or above*
- *Chrome version 44.0.2403.130*

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eDRLS Helpdesk: edrls@fda.hhs.gov