

Recent Automated Validation Rules

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Learning Objectives

- Identify SPL benefits and features
- Explain CDER Direct's role in SPL creation and real-time validation
- Recognize the impact of latest validation rule developments
- Describe how to avoid errors with recent validation rules



SPL Highlights



Structured Product Labeling (SPL) is a standardized format approved by Health Level Seven (HL7) and adopted by the FDA, facilitating the efficient exchange of drug product information. Here are some key highlights of SPL:

- Facilitates efficient data exchange
- Streamlines regulatory submissions
- Improves patient safety through consistent data presentation
- Continuously updated for relevance and advancements
- Machine-readable using XML for enhanced interoperability.





Submission Methods



Registration and listing SPL files may be created using FDA SPL authoring tools such as CDER Direct.

CDER Direct Features:

- User friendly interface 
- Realtime validation 
- Tutorials
- Helpful hints for filling out the forms

CDER Direct
Electronic Submissions Portal

LOGIN

Username:

Password:

I Understand.

[LOGIN](#) [Forgot your password?](#)

Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

QUICK LINKS

- [Register With CDER Direct](#)
- [Resources](#)
- [Tutorials](#)
- [Help Desk](#)
- [FAQs](#)

LABELER DETAILS

Labeler Name: * FDA

REGISTRANT DETAILS

Labeler Name

Enter the business name of the labeler provided in the NDC/NHRIC Labeler Code request SPL file.



What are Validation rules ?



Verify Data Standards: Ensure that user-entered data meets specified standards before saving the record.

Syntax and Format Checks: Validate that SPL files adhere to correct XML and format requirements.

```
<performance>
  <actDefinition>
    ...
    <subjectOf>
      <approval>
        <code code="C101886" codeSystem="2.16.840.1.113883.3.26.1.1"
          displayName="manufactures non-generics"/>
      </approval>
    </subjectOf>
  </actDefinition>
</performance>
```



What are Validation rules ?



Cross-Field Validation: Confirm consistency and accuracy of data across different fields.

Reference SPL Implementation Guide: Follow FDA guidelines for technical conformance.

- [Structured Product Labeling Resources | FDA](#)
- [SPL Implementation Guide with Validation Procedures](#)



CDER Direct Validation Tool




Save and Validate: Ensures SPL content complies with FDA requirements, verifies data accuracy, and allows error identification and correction prior to submission

[SUBMIT SPL](#) [SAVE AS DRAFT](#) [SAVE AND VALIDATE](#) [DELETE](#)

Instructions and helpful hints for filling out this Products submission form. Red asterisk indicate required fields.

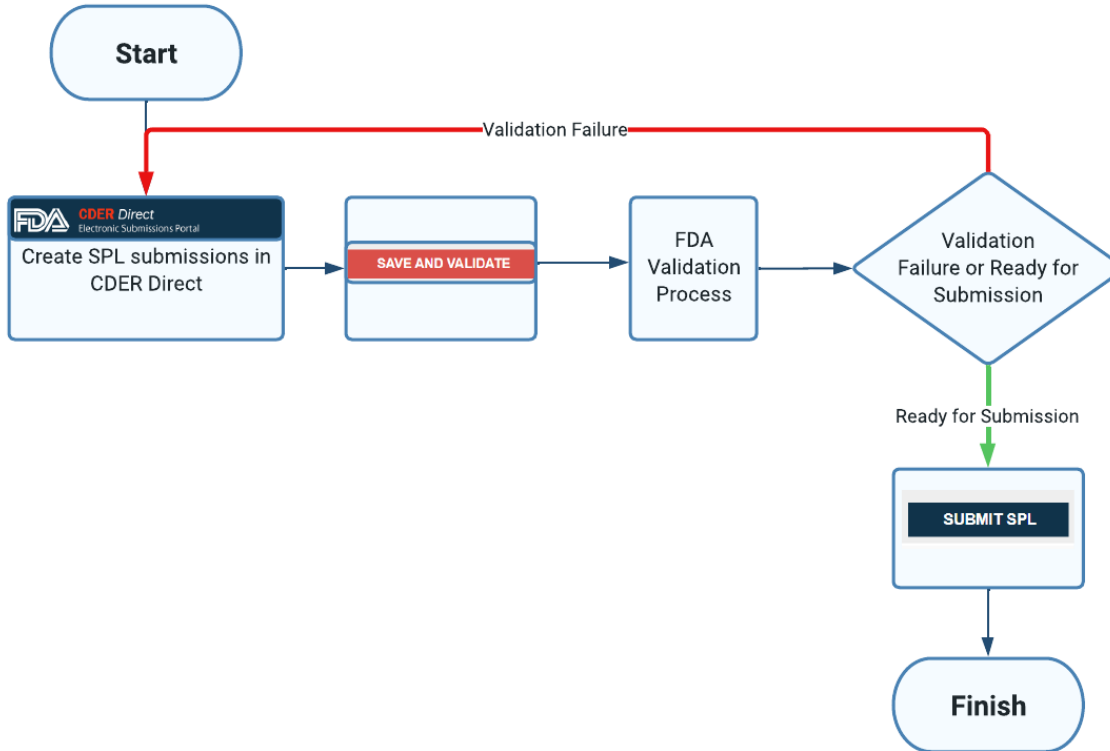
[Generate New](#)

Version Number: *

Effective Date: * 



CDER Direct Validation Tool



Recent Validation Rules in CDER Direct for Establishment Registration



If the document type is Establishment Registration (51725-0) and there is a previously submitted document with the same set id as the one in this file, then there is a second id with the root 2.16.840.1.113883.4.82 (FEI number) for each establishment previously identified by an id (DUNS number) with the root 1.3.6.1.4.1.519.1.

Home Establishment Registration SPL Submission **Establishment**

SAVE ESTABLISHMENT **DELETE ESTAB**

ESTABLISHMENT DETAILS

Establishment Name: * FDA

Establishment DUNS: * 11111111

Establishment FEI: * 22222222

ESTABLISHMENT ADDRESS

Country: * United States

Street Address: * 123 FDA Drive

City: * Silver Spring

State: * Maryland

Postal Code: * 20933



Recent Validation Rules in CDER Direct for Establishment Registration



If the document type is No Change Notification (53410-7) and its most recent Establishment Registration does not have a second id with the root 2.16.840.1.113883.4.82 (FEI number) for each establishment, then the Establishment Registration must be updated by submitting a full Establishment Registration file with FEI numbers

Home > Establishment Registration > SPL Submission

SUBMIT SPL **SAVE AS DRAFT** **DELETE** << RETURN

Note: Click on the Data Element Name for each field below to display instructions and helpful hints for filling out this Establishment Registration submission form. Red asterisk indicate required fields.

HEADER DETAILS

Document Type: * NO CHANGE NOTIFICATION

Set ID: * 01ccb8f1-c530-1e20-e063-6b94af0acb5a [Generate New](#)

Version Number: * 1

Root ID: * 01ccb8f1-c52e-1e20-e063-6b94af0acb5a [Generate New](#)

Effective Date: * 10-06-2023

Establishment FEI:



Recent Validation Rules in CDER Direct for Product Listing



Business operation code matches a business operation code for the establishment with same id in its most recent establishment registration.

Establishment Registration **SPL Submission**

BUSINESS OPERATION(S)

ADD BUSINESS OPERATION

EDIT	DELETE	BUSINESS OPERATION	QUALIFIER
		MANUFACTURE	• MANUFACTURES HUMAN PRESCRIPTION DRUG PRODUCTS

1 - 1

Product Listing and Reporting **Products**

ESTABLISHMENT DETAILS

Establishment Name: *

FDA Drug

Establishment DUNS: *

111111111

Confidential

BUSINESS OPERATION(S)

+	BUSINESS OPERATION	PRODUCT NDC
	MANUFACTURE	12345-123



Recent Validation Rules in CDER Direct for Product Listing




If the marketing status code for any of the products that is or includes a drug is completed and the document type and marketing categories are as follows, then there are one or more establishments.

For document type Bulk Ingredient (53409-9) the marketing category Bulk Ingredient for Human Prescription Compounding (C96793); for document type Human OTC Drug Label (34390-5) the marketing categories OTC Monograph Final (C73603), OTC Monograph Not Final (C73604), OTC Monograph Drug Product Manufactured Under Contract (C132334), Unapproved Drug Other (C73627), Unapproved Drug Homeopathic (C73614), and Unapproved Drug Product Manufactured Under Contract (C132335); for document type Human Prescription Drug Label (34391-3) the marketing categories Approved Drug Product Manufactured Under Contract (C132333), NDA Authorized Generic (C73605), Export Only (C73590), ANDA (C73584), BLA (C73585), IND (C75302), NDA (C73594), Unapproved Drug for Use in Drug Shortage (C101533), Unapproved Homeopathic (C73614), Unapproved Medical Gas (C73613), Unapproved Drug Other (C73627), and Unapproved Drug Product Manufactured Under Contract (C132335); and for the marketing category BLA (C73585) the document types License Blood Intermediates/Paste Label (53407-3), Licensed Minimally Manipulated Cells Label (53408-1), Cellular Therapy (60684-8), Licensed Vaccine Bulk Intermediate Label (53406-5), Non-Standardized Allergenic Label (53405-7), Plasma Derivative (60683-0), Standardized Allergenic (60682-2), and Vaccine Label (53404-0).

MARKETING DETAILS

Marketing Status: *

COMPLETED 

Marketing Start Date: *

09-07-2012



Marketing End Date: *

07-31-2023



Marketing Category: *

ANDA

Application Number/
Regulatory Citation:

ANDA012345

ESTABLISHMENT DETAILS

Establishment Name: *


FDA Drug

Establishment DUNS: *

111111111

Confidential

BUSINESS OPERATION(S)

	BUSINESS OPERATION	PRODUCT NDC
	MANUFACTURE	12345-123



Recent Validation Rules in CDER Direct for Product Listing



If the marketing category is Approved Drug Product Manufactured under Contract (C132333), OTC Monograph Drug Product Manufactured Under Contract (C132334), Unapproved Drug Product Manufactured Under Contract (C132335), then the document type is Human Prescription Drug Label (34391-3) or Human OTC Drug Label (34390-5)

5) MARKETING DETAILS

Marketing Status: *

ACTIVE

Marketing Start Date: *

04-24-2020



Marketing Category: *

APPROVED DRUG PRODUCT MANUFACTURED UNDER CONTRACT

UNAPPROVED DRUG PRODUCT MANUFACTURED UNDER CONTRACT

Application Number/

Regulatory Citation:

OTC MONOGRAPH DRUG PRODUCT MANUFACTURED UNDER CONTRACT

SPL Document Type: *

Note: To update an existing submission, click

-- Select Document Type --

-- Select Document Type --

BULK INGREDIENT

CELLULAR THERAPY

DRUG FOR FURTHER PROCESSING

HUMAN COMPOUNDED DRUG LABEL

HUMAN OTC DRUG LABEL

HUMAN PRESCRIPTION DRUG LABEL

CONTINUE

CANCEL



Recent Validation Rules in CDER Direct for Product Listing



If the marketing category is Approved Drug Product Manufactured under Contract (C132333), OTC Monograph Drug Product Manufactured Under Contract (C132334), Unapproved Drug Product Manufactured Under Contract (C132335), then the document type is Human Prescription Drug Label (34391-3) or Human OTC Drug Label (34390-5)

5) MARKETING DETAILS

Marketing Status: * ACTIVE

Marketing Start Date: * 04-24-2020

Marketing Category: *
UNAPPROVED DRUG PRODUCT MANUFACTURED UNDER CONTRACT
OTC MONOGRAPH DRUG PRODUCT MANUFACTURED UNDER CONTRACT

Application Number/Regulatory Citation:

SPL Document Type: * -- Select Document Type --

Note: To update an existing submission, click



Recent Validation Rules in CDER Direct for Product Listing



The route (of administration) code cannot be "not applicable" (C48623) for document types other than Bulk Ingredient (53409-9), Bulk Ingredient - Animal Drug (81203-2), Licensed Vaccine Bulk Intermediate Label (53406-5), Recombinant Deoxyribonucleic Acid Construct Label (78745-7), or Drug for Further Processing (78744-0).

Route of Administration: *

INJECTION
LARYNGEAL
NASAL
NASOGASTRIC
OCCLUSIVE DRESSING TECHNIQUE
OPHTHALMIC
ORAL

NOT APPLICABLE

SPL Document Type: *

DRUG FOR FURTHER PROCESSING
BULK INGREDIENT

Note: To update an existing submission, click on Cancel and select a submission with the status SUBMISSIO

CONTINUE **CANCEL**

Recent Validation Rules in CDER Direct for Product Listing



If the product has a product source reference (source NDC product code), then one of the operations is Repack (C73606) or Relabel (C73607) except if the SPL file is for Salvaged Drugs (having business operation as salvage (C70827)).

BUSINESS OPERATION(S) ⓘ

+	BUSINESS OPERATION
×	MANUFACTURE
	--Select One--
	ANALYSIS
	API MANUFACTURE
	LABEL
	MANUFACTURE
	MEDICATED ANIMAL FEED MANUFACTURE
	PACK
	PARTICLE SIZE REDUCTION
	POSITRON EMISSION TOMOGRAPHY DRUG PRODUCTION
	RELABEL
	REPACK

Source NDC:



Recent Validation Rules in CDER Direct for Listing



The Source NDC product code is not currently inactivated by an FDA Agency Initiated Compliance Action.

PRODUCT DATA ELEMENTS

NDC Product Code: *	<input type="text" value="00000-000"/>	Proprietary Name: *	
Non Proprietary Name: *	<input type="text" value="FDA Ingredient"/>	Suffix:	
Dosage Form: *	<input type="text" value="TABLET, COATED"/>	DEA Schedule:	
Route of Administration: *	<div style="border: 1px solid gray; padding: 2px;"><p>TRANSTRACHEAL TRANSTYMPANIC URETERAL URETHRAL VAGINAL SUBLINGUAL</p></div>	<div style="border: 1px solid gray; padding: 2px;"><p>ORAL</p></div>	
Source NDC:	<input type="text"/>		



Recent Validation Rules in CDER Direct for Listing



If in a Bulk Ingredient (53409-9) or Bulk ingredient – Animal drug (81203-2) listing there is a product with marketing category Bulk Ingredient (C73626) and without a marketing completion date, then one or more establishments with operation of API manufacture (C82401) are included.

CREATE NEW PRODUCT LISTING AND REPORTING

- Create a New Product Listing or Certification using a blank form
- Import an existing Product Listing or Certification SPL

SPL Document Type: *

BULK INGREDIENT

Marketing Category: *

BULK INGREDIENT

BUSINESS OPERATION(S) ⓘ



BUSINESS OPERATION

PRODUCT NDC



API MANUFACTURE

12345-123





Upcoming in CDER Direct for Listing

- Starting October 1st, new Marketing Category and Monograph Citations will be required for OTC drugs.
- Provide OTC Monograph ID (if applicable) when listing your OTC drug product.
- Examples: Monograph ID - M001.
- For more information, visit

[OTC Monographs FDA.](#)

OTC Monograph ID	Published Date	OTC Monograph Title
M001	10/14/2022	Antacid Products for Over-the-Counter Human Use
M002	09/20/2021	Antiflatulent Products for OTC Human Use
M003	05/02/2023	First Aid Antiseptic Drug Products for Over-the-Counter Human Use
M004	05/02/2023	First Aid Antibiotic Drug Products for Over-the-Counter Human Use

Marketing Category: *

Application Number/
Regulatory Citation:



Challenge Questions

When the SPL document type is 'Bulk Ingredient' and the marketing category is 'bulk ingredient,' which business operation(s) must be associated with one or more establishments?

- A) Analytical Testing
- B) API Manufacture
- C) Packaging
- D) None of the above

Challenge Questions



In a listing submission for a repackager or relabeler, what is the role of the manufacturer's NDC?

- A) It is not required in a repackager's submission.
- B) It is included as the source NDC.
- C) It is provided to the FDA only upon request.
- D) It is used for relabeling purposes.



Summary

- **CDER Direct's Role:** User-friendly interface, real-time validation, tutorials, and guidance.
- **Save and Validate:** Pre-submission error identification and correction.
- **Stay Updated:** Latest rules for error-free submissions
 - [SPL Implementation Guide with Validation Procedures](#)



Thank you for your attention and engagement!

Questions?

Contact Us:
eDRLS@fda.hhs.gov

