

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



SAVE AND VALIDATE



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.

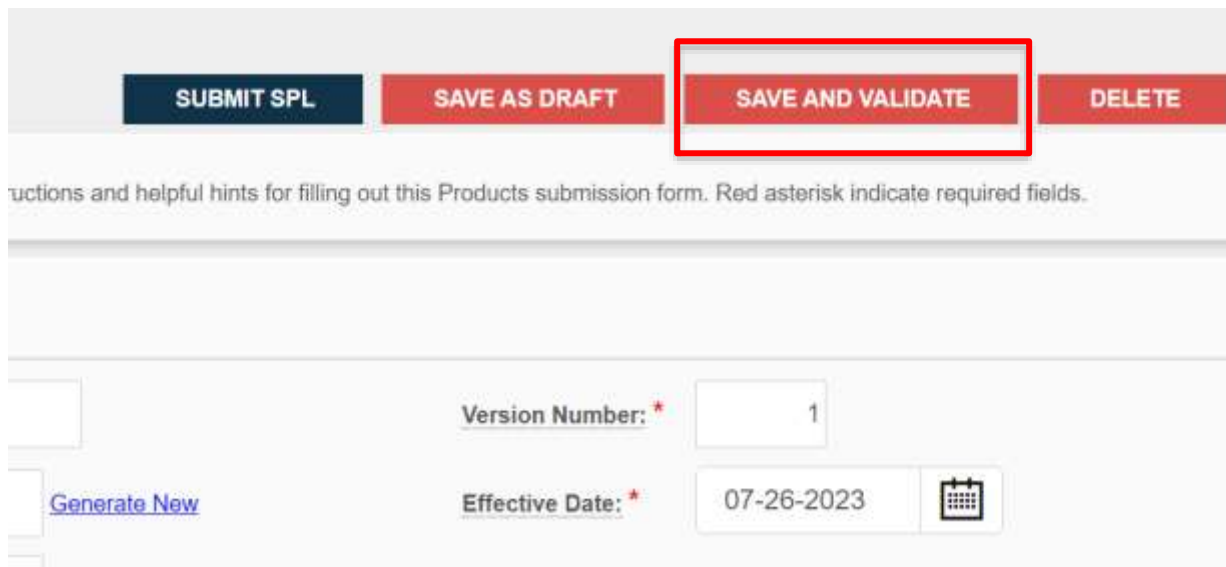
- [Structured Product Labeling Resources | FDA](#)
- [SPL Implementation Guide with Validation Procedures](#)



CDER Direct Validation Tool



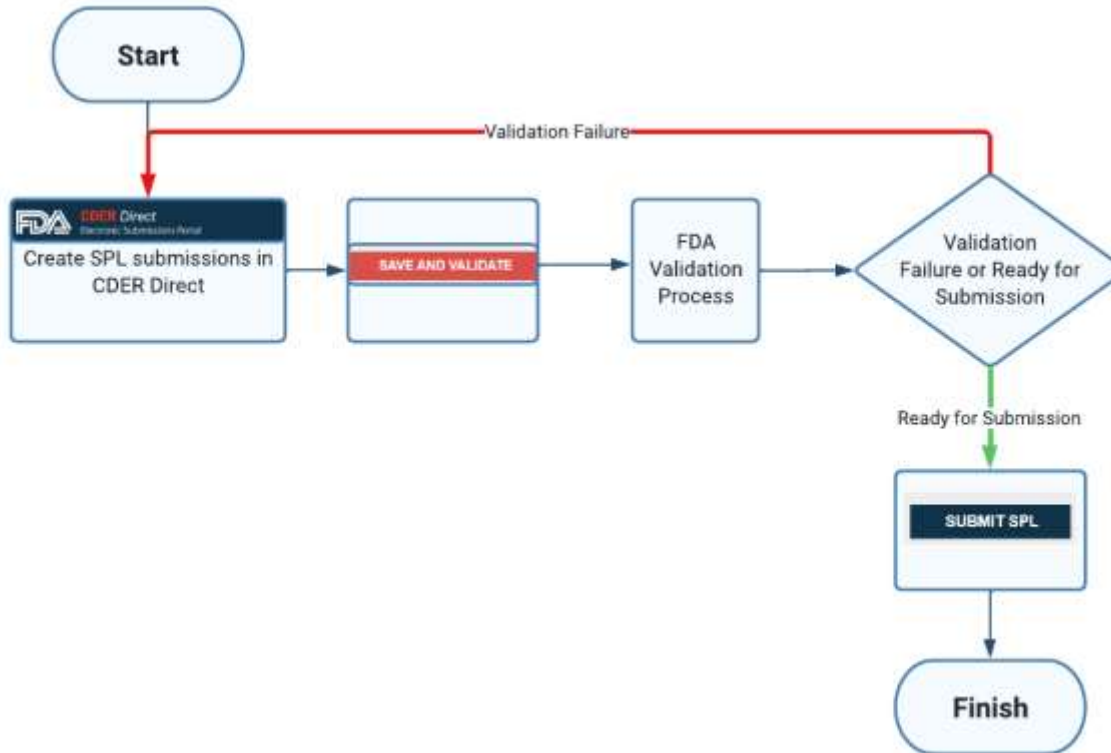
Save and Validate: Ensures SPL content complies with FDA requirements, verifies data accuracy, and allows error identification and correction prior to submission



The screenshot shows the top section of the CDER Direct Validation Tool interface. At the top, there is a horizontal bar with four buttons: "SUBMIT SPL" (dark blue), "SAVE AS DRAFT" (red), "SAVE AND VALIDATE" (red, highlighted with a red border), and "DELETE" (red). Below this bar, there is a line of text: "Instructions and helpful hints for filling out this Products submission form. Red asterisk indicate required fields." Below this text, there is a form section. On the left, there is a "Generate New" link. To the right, there are two fields: "Version Number: *" with a text input containing "1", and "Effective Date: *" with a date input containing "07-26-2023" and a calendar icon.



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.

A screenshot of the CDER Direct web application showing the "Establishment Registration" form. The form is divided into two main sections: "ESTABLISHMENT DETAILS" and "ESTABLISHMENT ADDRESS". In the "ESTABLISHMENT DETAILS" section, the "Establishment FEI:" field is highlighted with a red oval and contains the value "2222222222". Other fields in this section include "Establishment Name:" with the value "FDA" and "Establishment DUNS:" with the value "111111111". The "ESTABLISHMENT ADDRESS" section includes fields for "Country:" (United States), "Street Address:" (123 FDA Drive), "City:" (Silver Spring), "State:" (Maryland), and "Postal Code:" (20933). At the top of the form, there are navigation links: "Home", "Establishment Registration", "SPL Submission", and "Establishment". On the right side, there are two red buttons: "SAVE ESTABLISHMENT" and "DELETE ESTAB".

ESTABLISHMENT DETAILS		ESTABLISHMENT ADDRESS	
Establishment Name:	FDA	Country:	United States
Establishment DUNS:	111111111	Street Address:	123 FDA Drive
Establishment FEI:	2222222222	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](#)

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

Version Number: * 1

Effective Date: * 10-06-2023

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: *

11111111

☐ 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
- OTC MONOGRAPH DRUG PRODUCT MANUFACTURED UNDER CONTRACT**

Application Number/
Regulatory Citation:

SPL Document Type: *

Note: To update an existing submission, click

CONTINUE **CANCEL**

-- 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**

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)

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Marketing Start Date: * 04-24-2020

Marketing Category: *

- APPROVED DRUG PRODUCT MANUFACTURED UNDER CONTRACT
- UNAPPROVED DRUG PRODUCT MANUFACTURED UNDER CONTRACT
- OTC MONOGRAPH DRUG PRODUCT MANUFACTURED UNDER CONTRACT**

Application Number/
Regulatory Citation:

SPL Document Type: *

Note: To update an existing submission, click

CONTINUE **CANCEL**

-- 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**

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).

The screenshot displays two dropdown menus from the CDER Direct interface. The top dropdown, labeled 'Route of Administration: *', contains the following options: LARYNGEAL, NASAL, NASOGASTRIC, OCCLUSIVE DRESSING TECHNIQUE, OPHTHALMIC, and ODAI. The bottom dropdown, labeled 'SPL Document Type: *', contains 'DRUG FOR FURTHER PROCESSING' and 'BULK INGREDIENT'. A red arrow points from the 'NOT APPLICABLE' option in the 'Route of Administration' dropdown to the 'DRUG FOR FURTHER PROCESSING' and 'BULK INGREDIENT' options in the 'SPL Document Type' dropdown. Below the dropdowns, a note states: 'Note: To update an existing submission, click on Cancel and select a submission with the status SUBMISSIO'. At the bottom, there are two buttons: 'CONTINUE' (red) and 'CANCEL' (gray).

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: 12345-123

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: *	00000-000	Proprietary Name: *	
Non Proprietary Name: *	FDA Ingredient	Suffix:	
Dosage Form: *	TABLET, COATED	DEA Schedule:	
Route of Administration: *	<div>TRANSTRACHEAL</div> <div>TRANSTYMPANIC</div> <div>URETERAL</div> <div>URETHRAL</div> <div>VAGINAL</div> <div>SUBLINGUAL</div>	<div>5</div> <div>ORAL</div>	
Source NDC:			

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.](#)

Keyword Search Reset Showing 1 to 10 of 33 entries Show 10 entries		
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: *
OTC MONOGRAPH DRUG

Application Number/
Regulatory Citation:
M003

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:
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