Recent Automated Validation Rules

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September 28, 2023

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

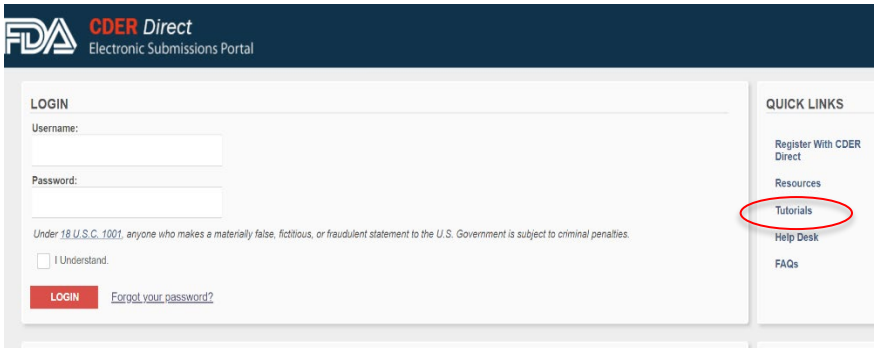
SPL Highlights

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

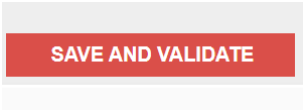
Registration and listing SPL files may be created using FDA SPL authoring tools such as CDER Direct.



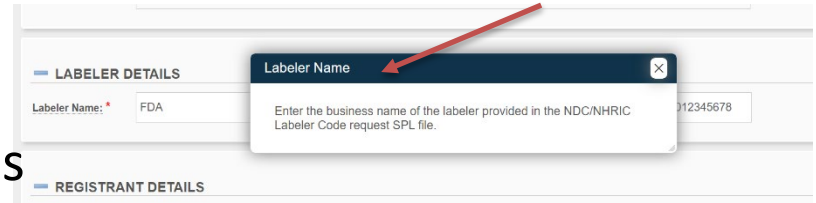
CDER Direct Features:

- User friendly interface

- Realtime validation



- Tutorials
- Helpful hints for filling out the forms



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>
```

What are Validation rules ?

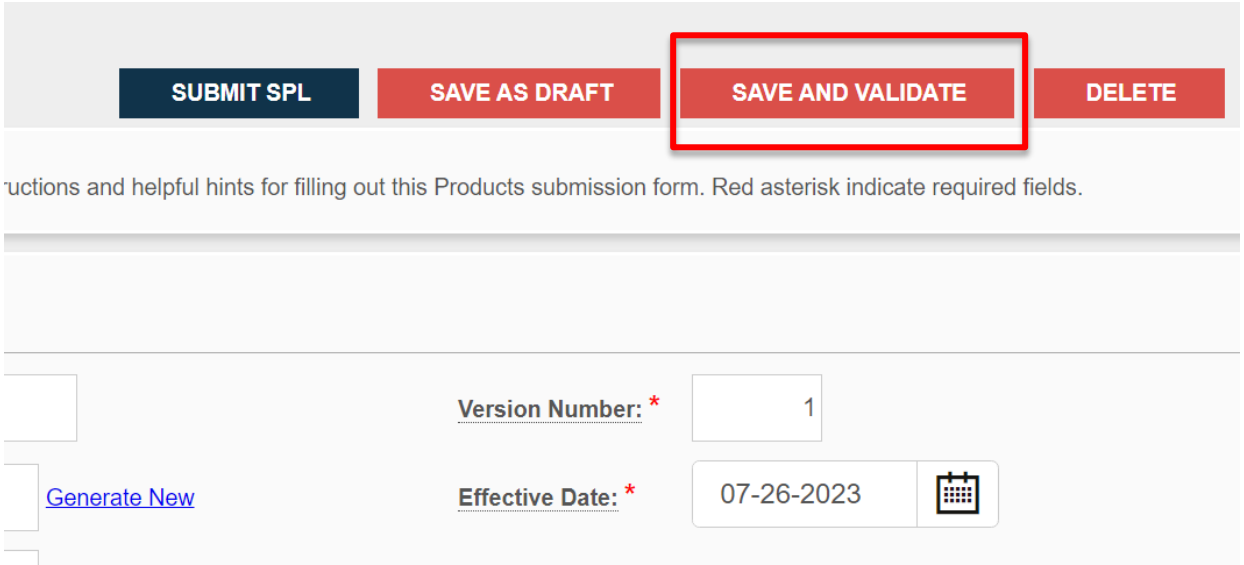
Cross-Field Validation: Confirm consistency and accuracy of data across different fields.

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

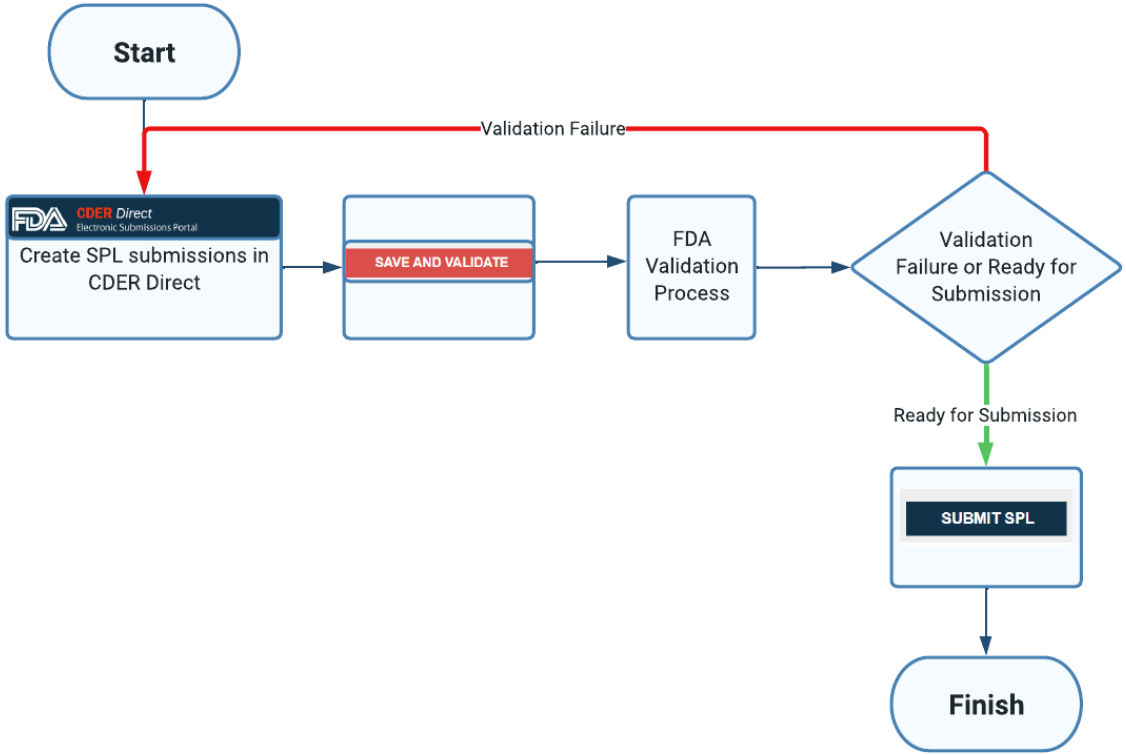
- Structured Product Labeling Resources | FDA
- SPL Implementation Guide with Validation Procedures

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

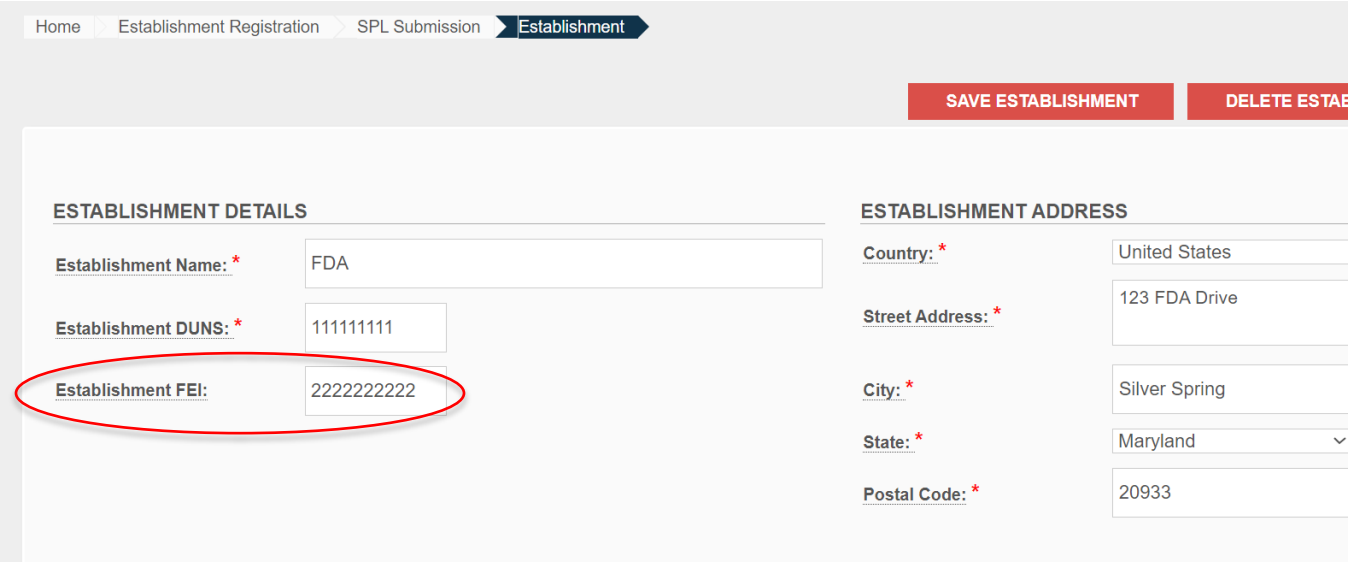


CDER Direct Validation Tool



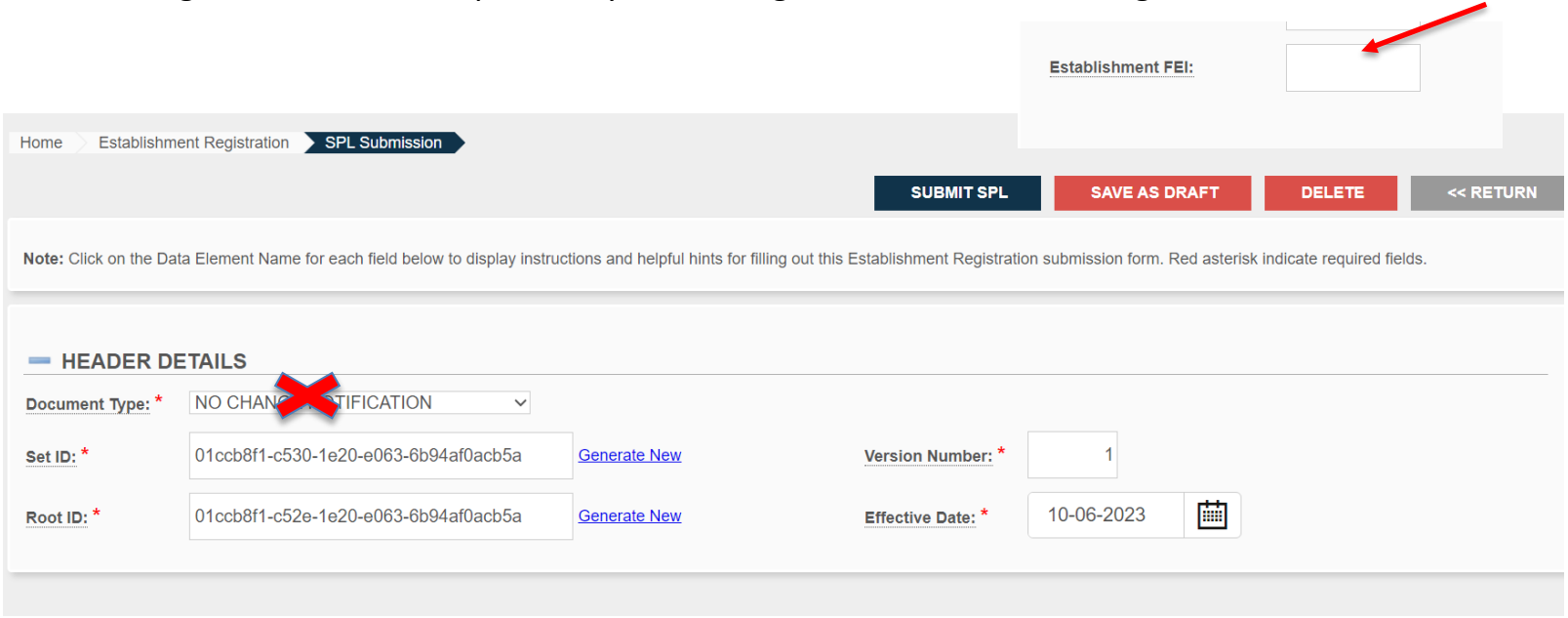
Recent Validation Rules in CDER Direct for Establishment Registration

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.



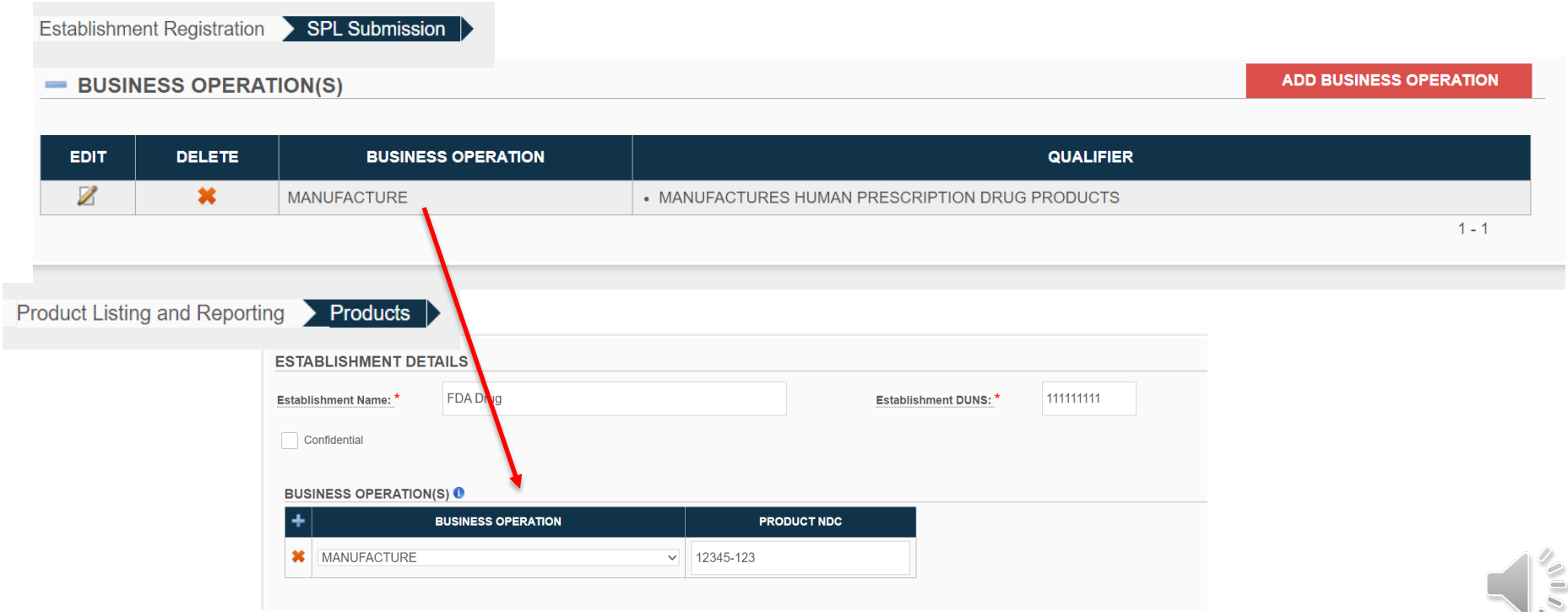
Recent Validation Rules in CDER Direct for Establishment Registration

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



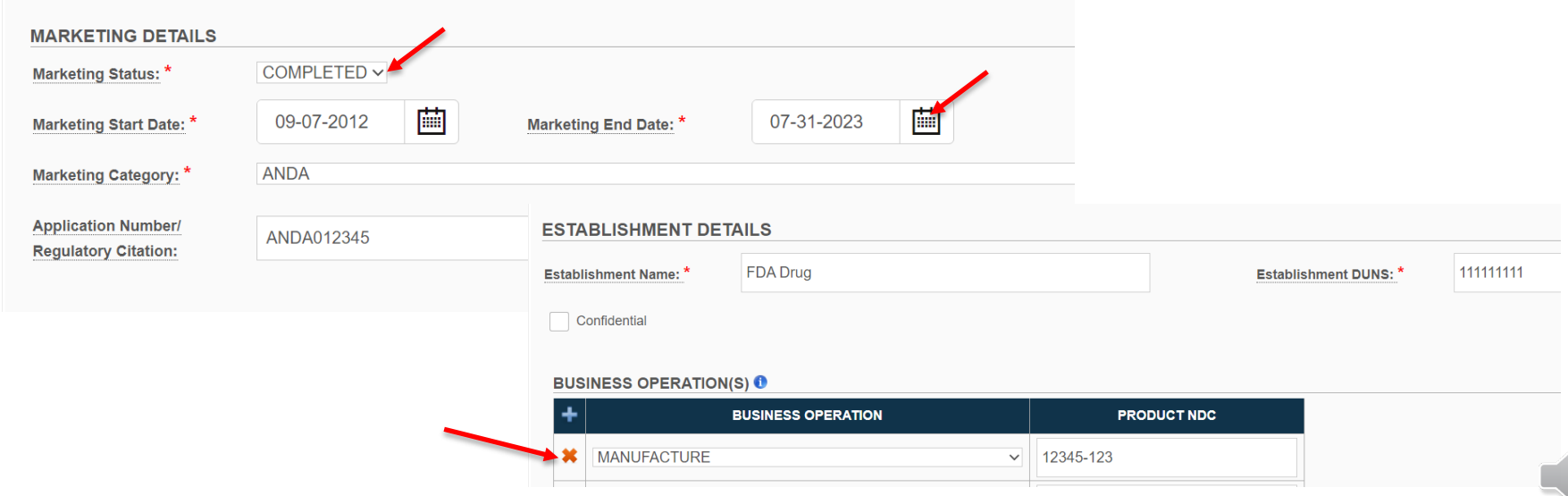
Recent Validation Rules in CDER Direct for Product Listing

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



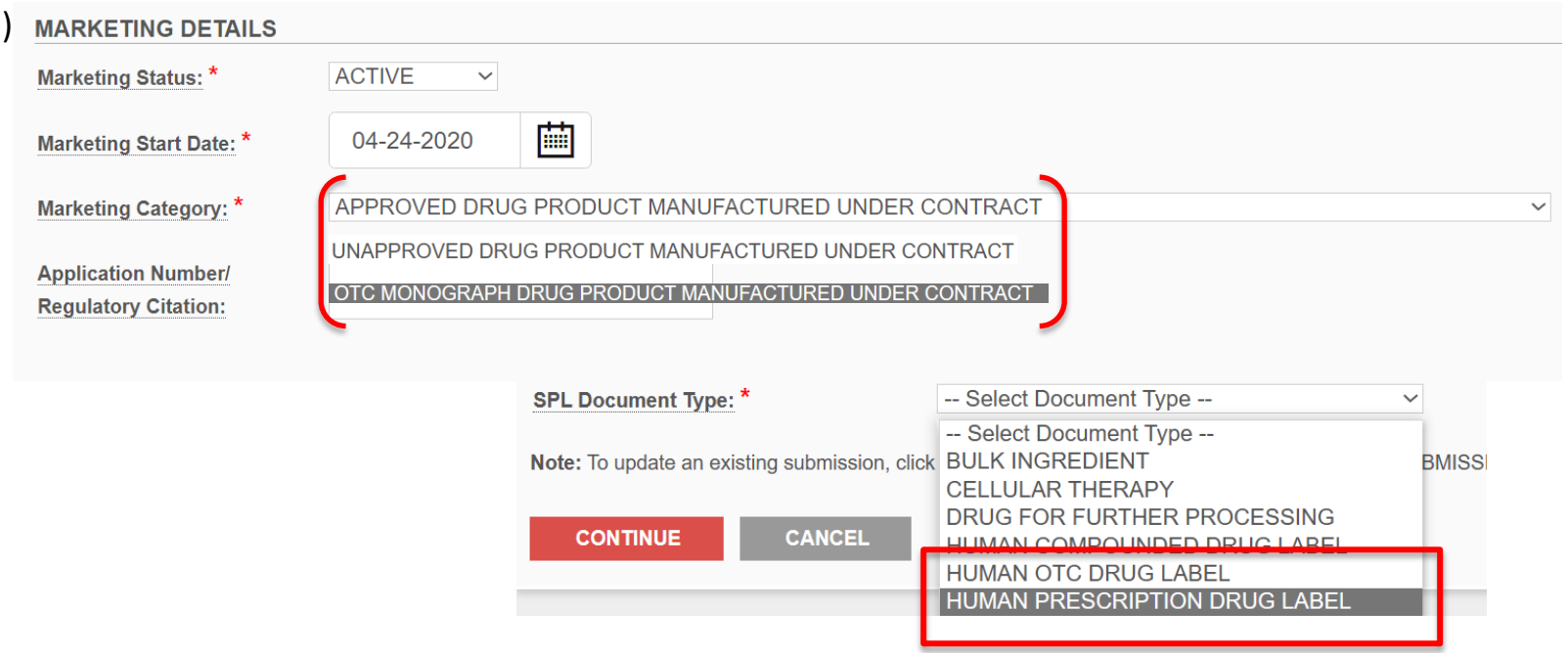
Recent Validation Rules in CDER Direct for Product Listing

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).



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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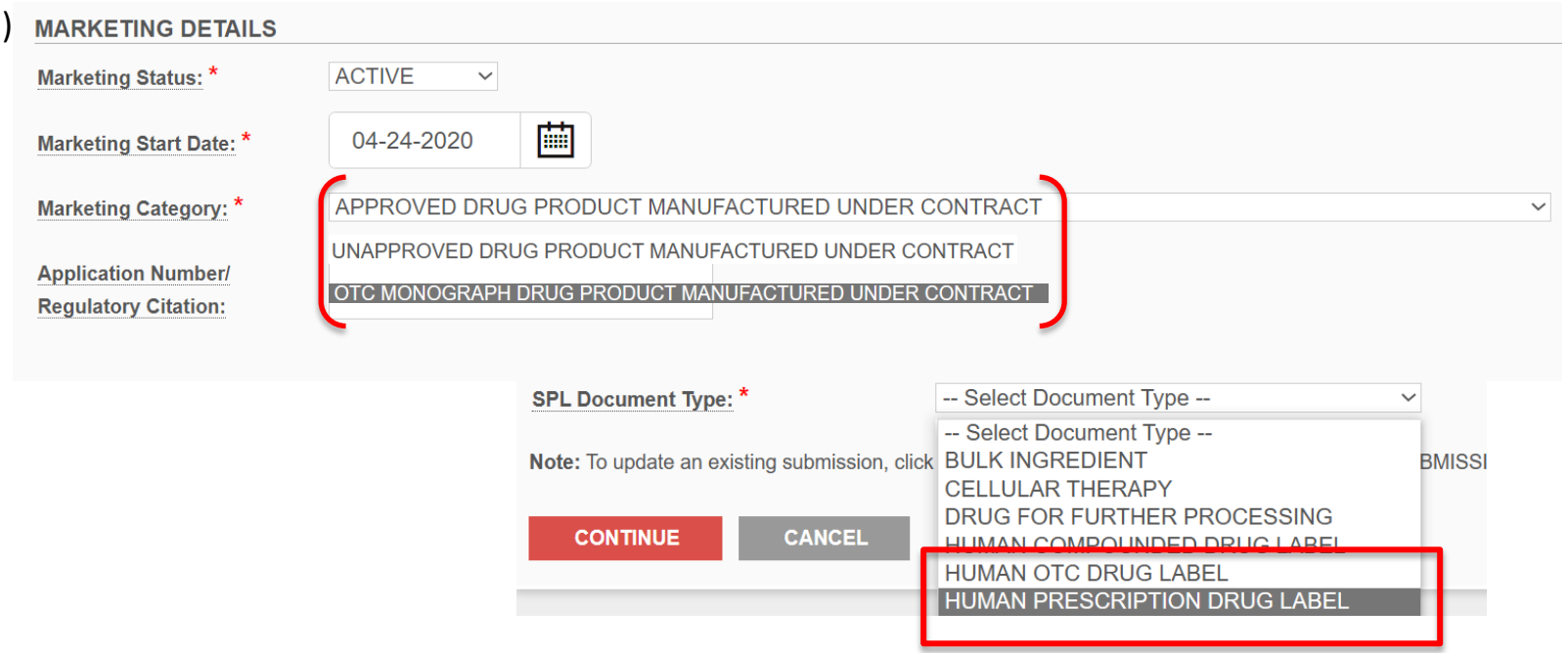
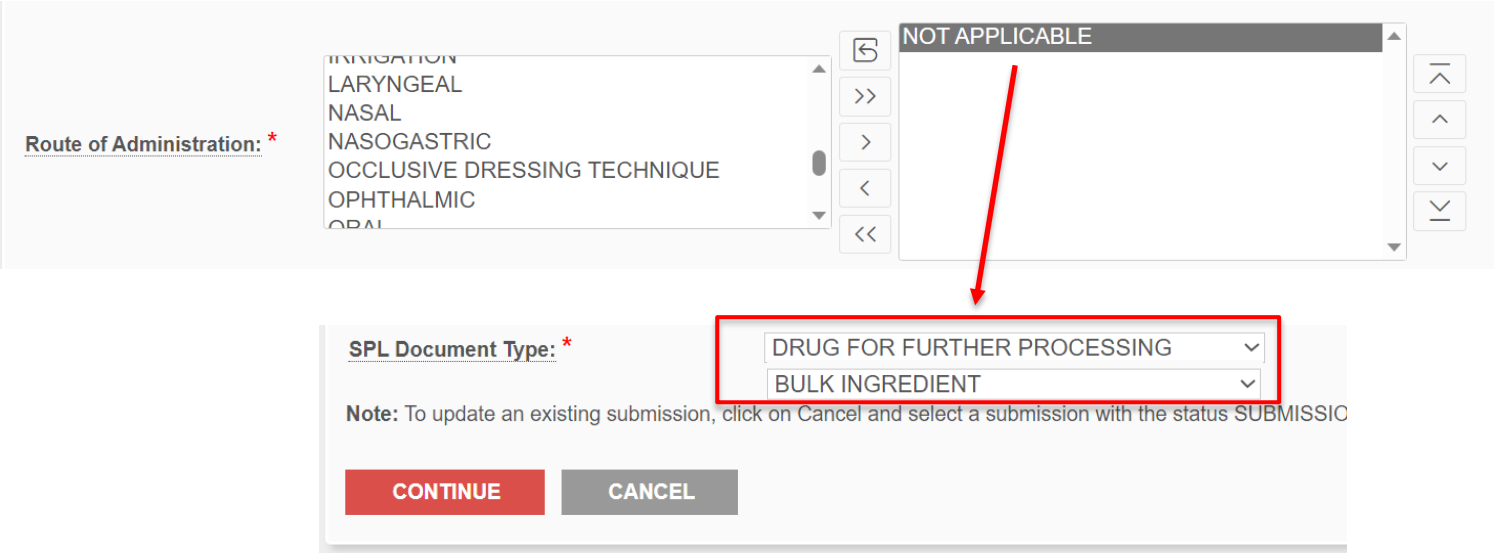


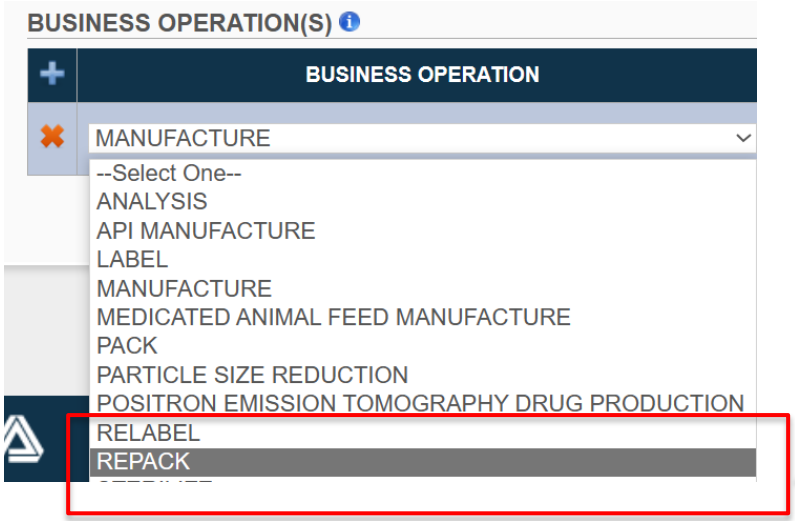
Recent Validation Rules in CDER Direct for Product Listing

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).



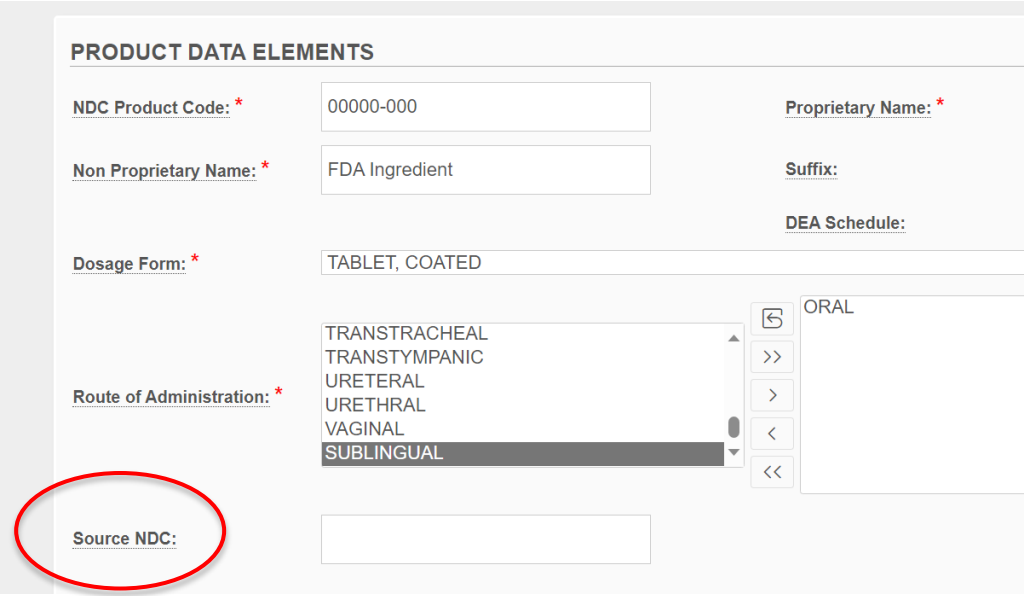
Recent Validation Rules in CDER Direct for Product Listing

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)).



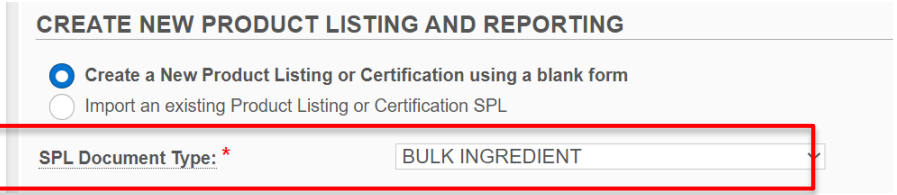
Recent Validation Rules in CDER Direct for Listing

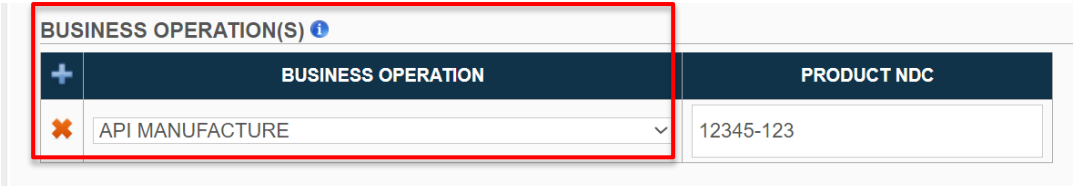
The Source NDC product code is not currently inactivated by an FDA Agency Initiated Compliance Action.



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.

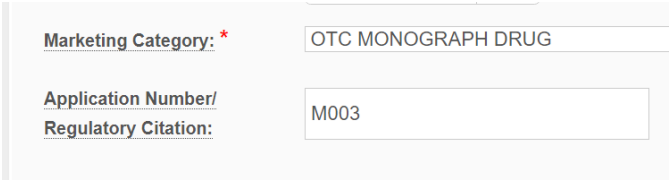


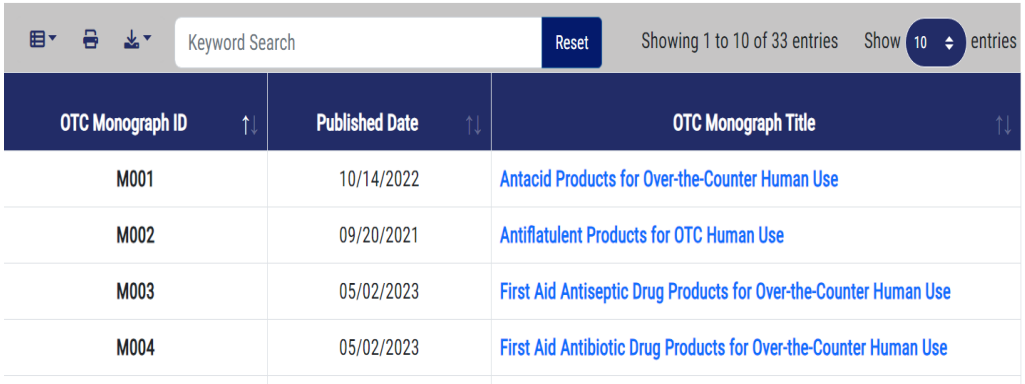


Upcoming in CDER Direct for Listing

- 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

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