Annual Certification of Drug Product Listings

Lalnunpuii Huber
Technical Information Specialist
Drug Registration and Listing Staff
FDA/CDER/Office of Compliance/OPRO

Agenda

- Background
- Who must certify and when?
- What must be certified?
- What will happen if a product is not certified?
- Challenge Questions

Background

In 2016 – 21 CFR 207 was published (August) and implemented (November).

21 CFR 207.57 (b)(2) *For each listed drug, certify that no changes subject to reporting under paragraph (b)(1)(iv) of this section have occurred if no such changes have occurred since the last review and update. If a drug is discontinued and FDA has received the information required under paragraph (b)(1)(ii) of this section, no further certifications are necessary for the discontinued drug. After initial electronic listing, registrants may satisfy the listing update requirement with respect to unchanged listing information by making a single "no changes" certification during the annual registration update under §207.29(b) applicable to all of the registrant's listed drugs for which no changes have been made since the previous annual registration update.*

As a result, there is now an annual requirement to update your listing or certify that no changes have occurred, similar to registration requirements.

Who Must Certify and When?

Since the legal responsibility for submitting product listing lies with the registered establishment, certification of product listing is also the responsibility of the registered establishments. Private label distributors can choose to submit the data directly.

Certification SPL submissions will ONLY be accepted during the annual listing certification period of October through December.

What Must Be Certified?

During the annual listing certification period - October 1st – December 31st, every active listing on file that has not been updated within the current calendar year must be certified that no changes have occurred in order to remain active for the following year.

When to Use the Blanket No Changes Certification

- ONLY when ALL the data on a listing SPL is still current:
  - Listing information contained in a Product Listing SPL is fully accurate, including establishment information
  - Quickly certify many drug products for a firm

What Happens to an Uncertified Product?

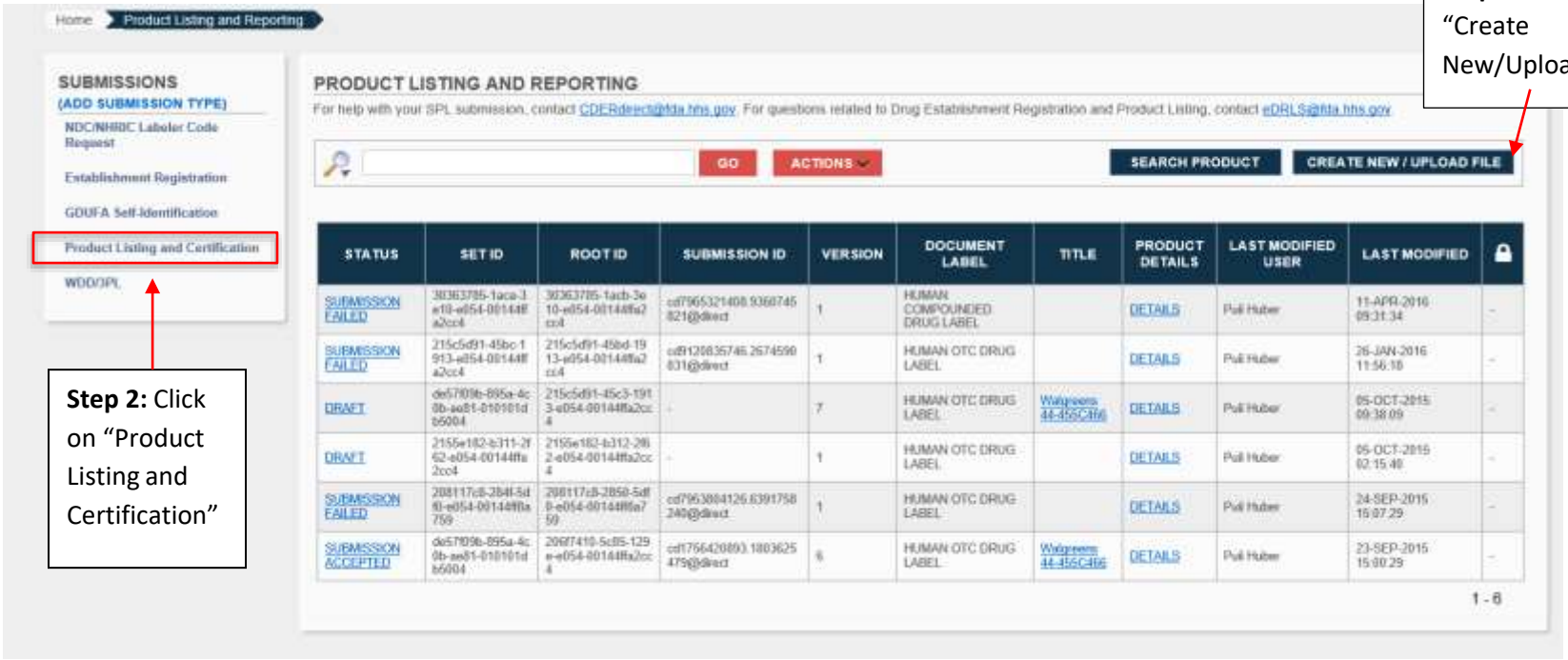
Any NDC product code which has not been updated during the calendar year, or certified during the October to December registration renew period **will be considered expired** on January 1st of the following year.

All expired listings will be removed/notated in the NDC Directory and Unfinished Drug download files.

The only way to reinstate an expired listing is to submit an updated product listing SPL (with same SETID as previous version)

How to Certify?

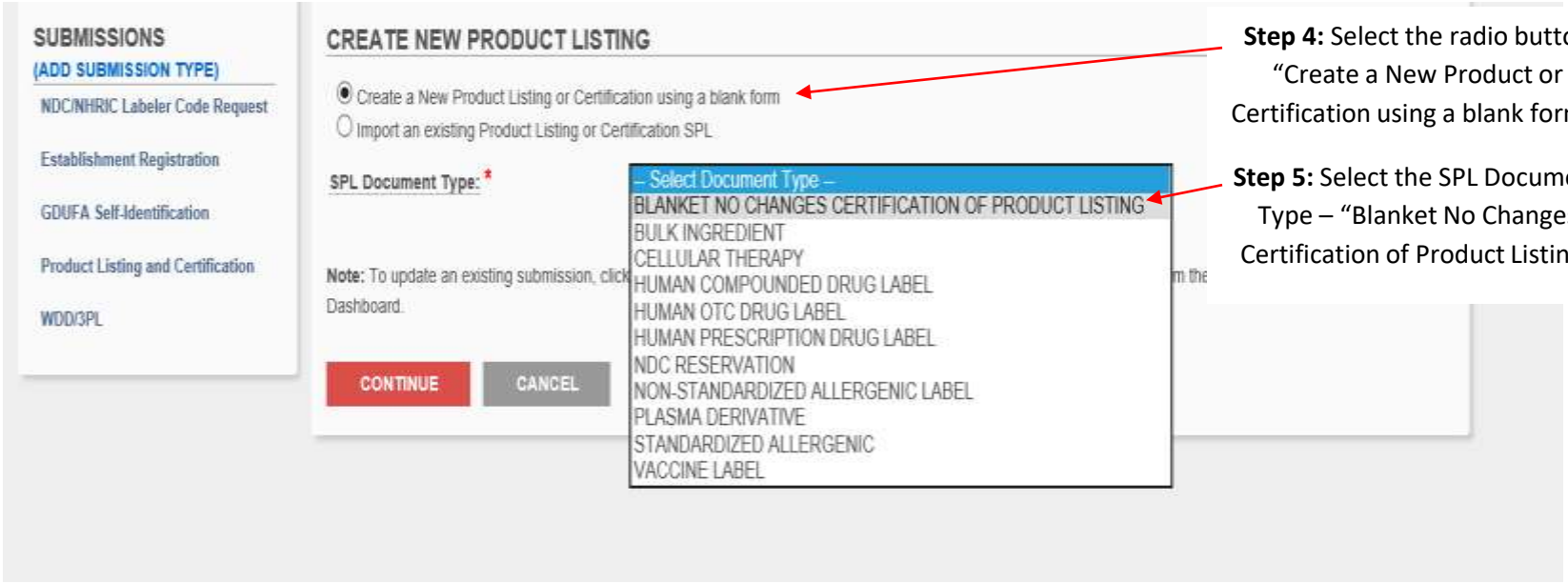
Step 1: Log into your CDER Direct Account



Step 2: Click on "Product Listing and Certification"

Step 3: Click on "Create New/Upload File"

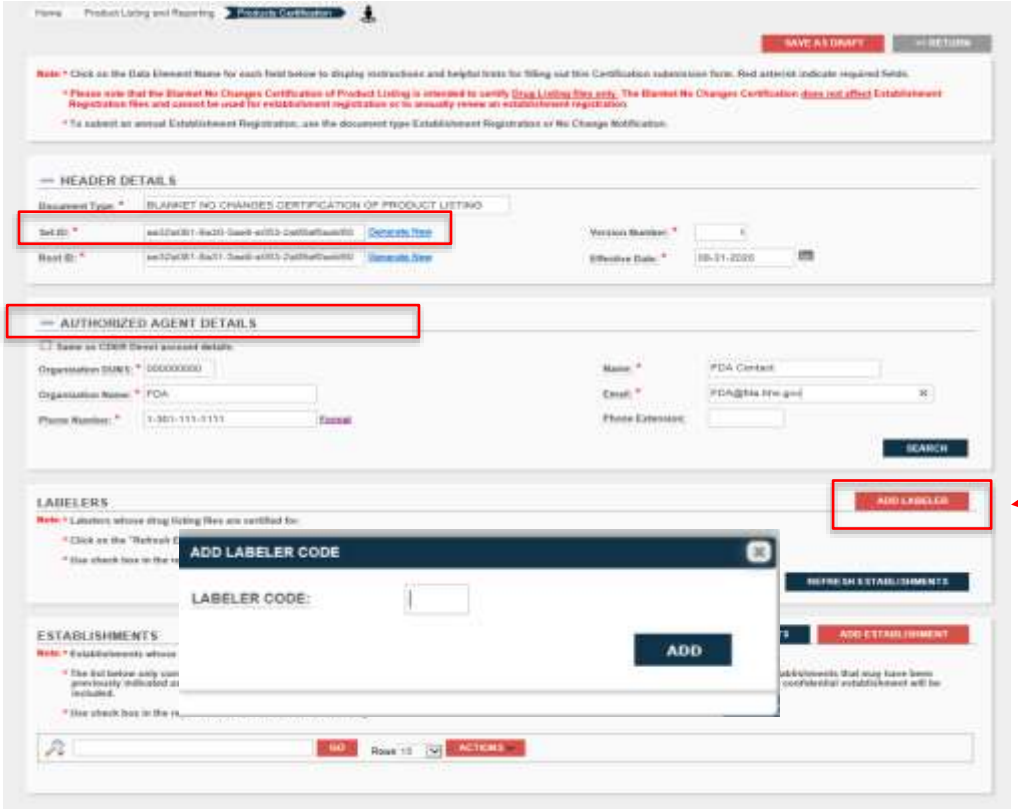
How to Certify?



Step 4: Select the radio button "Create a New Product or Certification using a blank form".

Step 5: Select the SPL Document Type – "Blanket No Changes Certification of Product Listing"

How to Certify?

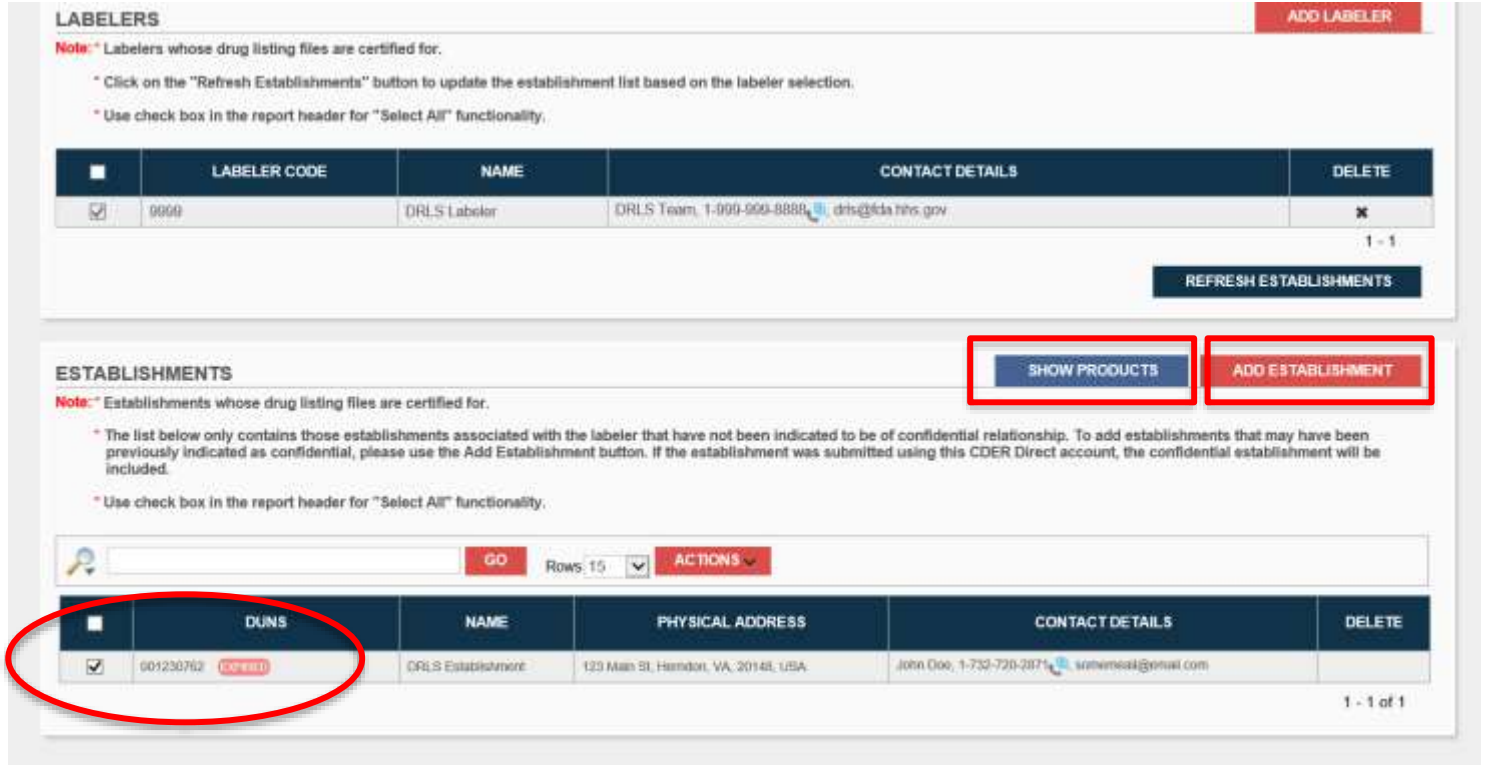


Because this is a single submission every year, you can use the auto generated SET ID and Root ID.

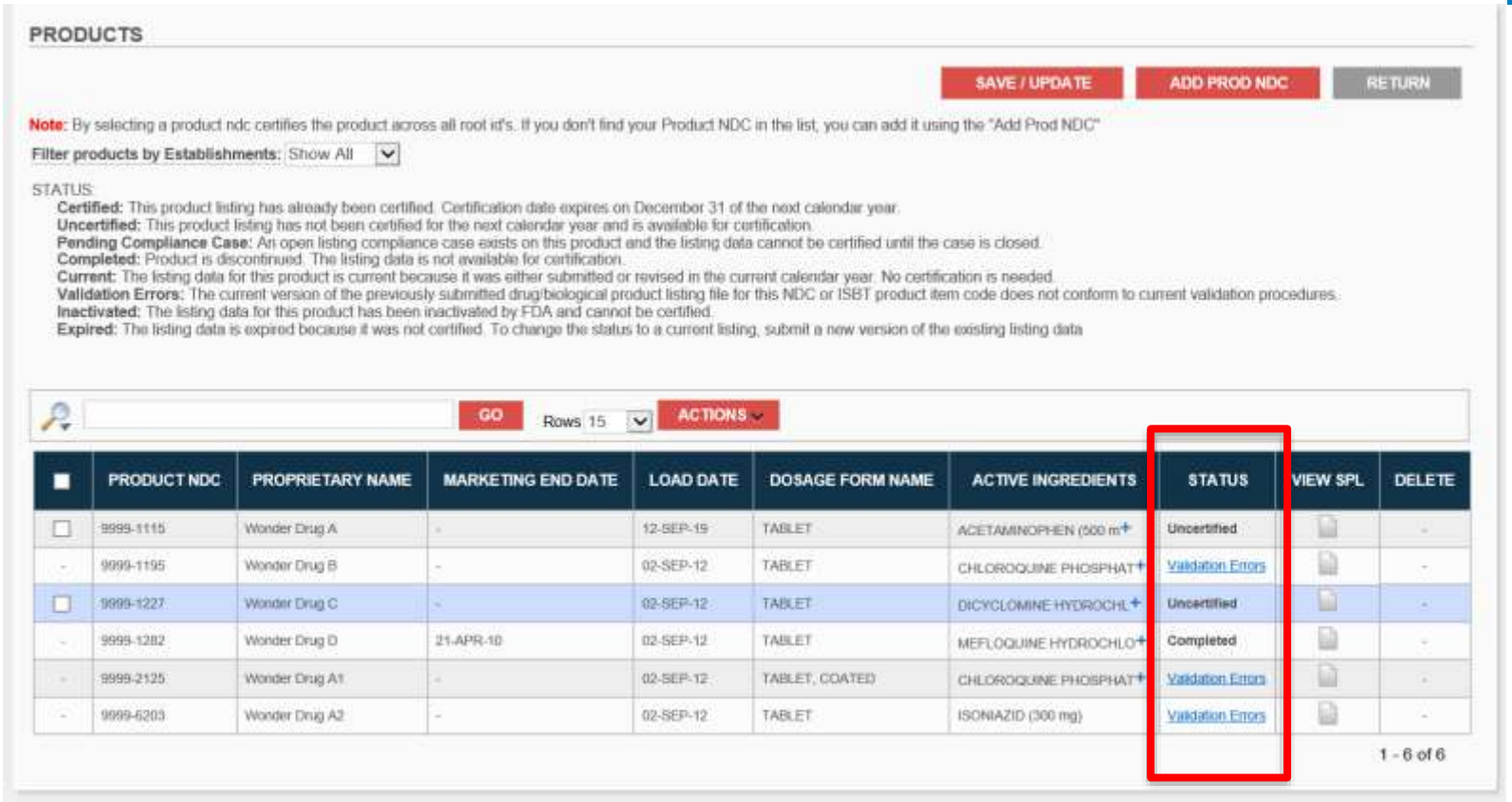
Step 6: Authorized Agent is generally the same as CDER Direct account owner

Click on **"Add Labeler"** button and enter the labeler code of the product(s) you wish to certify. Once you have all the labelers identified, click on **"Refresh Establishments"** to find all the establishments that are involved with the Labeler(s). products.

How to Certify?



Understanding Product Status



PRODUCTS

SAVE / UPDATE | ADD PROD NDC | RETURN

Note: By selecting a product ndc certifies the product across all root id's. If you don't find your Product NDC in the list, you can add it using the "Add Prod NDC"

Filter products by Establishments: Show All

STATUS:

Certified: This product listing has already been certified. Certification date expires on December 31 of the next calendar year.
Uncertified: This product listing has not been certified for the next calendar year and is available for certification.
Pending Compliance Case: An open listing compliance case exists on this product and the listing data cannot be certified until the case is closed.
Completed: Product is discontinued. The listing data is not available for certification.
Current: The listing data for this product is current because it was either submitted or revised in the current calendar year. No certification is needed.
Validation Errors: The current version of the previously submitted drug/biological product listing file for this NDC or ISBT product item code does not conform to current validation procedures.
Inactivated: The listing data for this product has been inactivated by FDA and cannot be certified.
Expired: The listing data is expired because it was not certified. To change the status to a current listing, submit a new version of the existing listing data

GO | Rows 15 | ACTIONS

	PRODUCT NDC	PROPRIETARY NAME	MARKETING END DATE	LOAD DATE	DOSAGE FORM NAME	ACTIVE INGREDIENTS	STATUS	VIEW SPL	DELETE
☐	9999-1115	Wonder Drug A	-	12-SEP-19	TABLET	ACETAMINOPHEN (500 m+	Uncertified		-
-	9999-1195	Wonder Drug B	-	02-SEP-12	TABLET	CHLOROQUINE PHOSPHAT+	Validation Errors		-
☐	9999-1227	Wonder Drug C	-	02-SEP-12	TABLET	DICYCLOMINE HYDROCHL+	Uncertified		-
-	9999-1282	Wonder Drug D	21-APR-10	02-SEP-12	TABLET	MEFLOQUINE HYDROCHLO+	Completed		-
-	9999-2125	Wonder Drug A1	-	02-SEP-12	TABLET, COATED	CHLOROQUINE PHOSPHAT+	Validation Errors		-
-	9999-6203	Wonder Drug A2	-	02-SEP-12	TABLET	ISONIAZID (300 mg)	Validation Errors		-

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Understanding Product Status

Certified: This product listing has already been certified. Certification date expires on December 31 of the next calendar year.

Uncertified: This product listing has not been certified for the next calendar year and is available for certification, if it remains in the market with no change to previous data.

Pending Compliance Case: An open listing compliance case exists on this product and the listing data cannot be certified until the case is closed.

Understanding Product Status

Completed: Product is discontinued.

Current: The listing data for this product was either submitted or revised in the current calendar year.

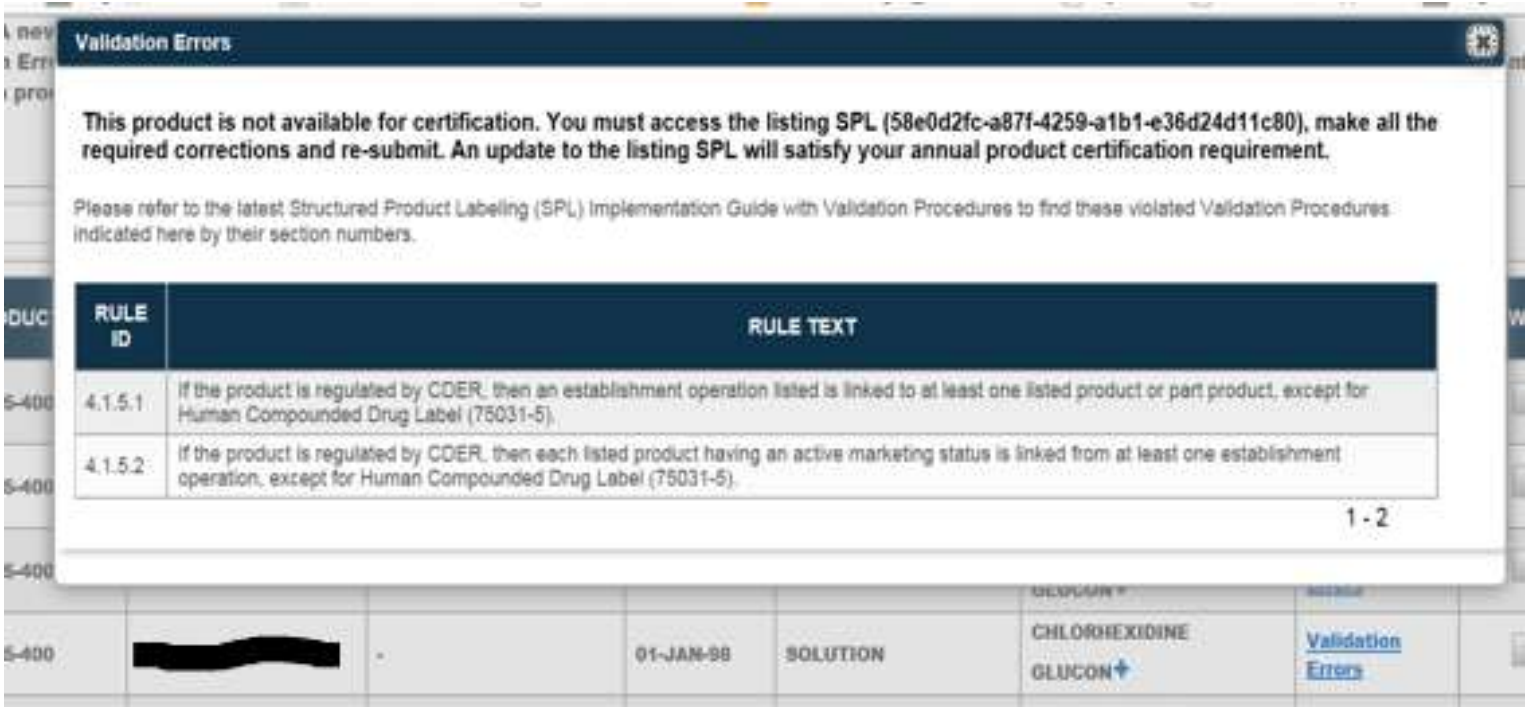
Validation Errors: The current version of the previously submitted product listing file does not conform to current validation procedures.

Understanding Product Status

Inactivated: The listing data for this product has been inactivated by FDA.

Expired: The listing data is expired because it was not certified to be current.

Validation Errors Identified



Certifying Product NDC

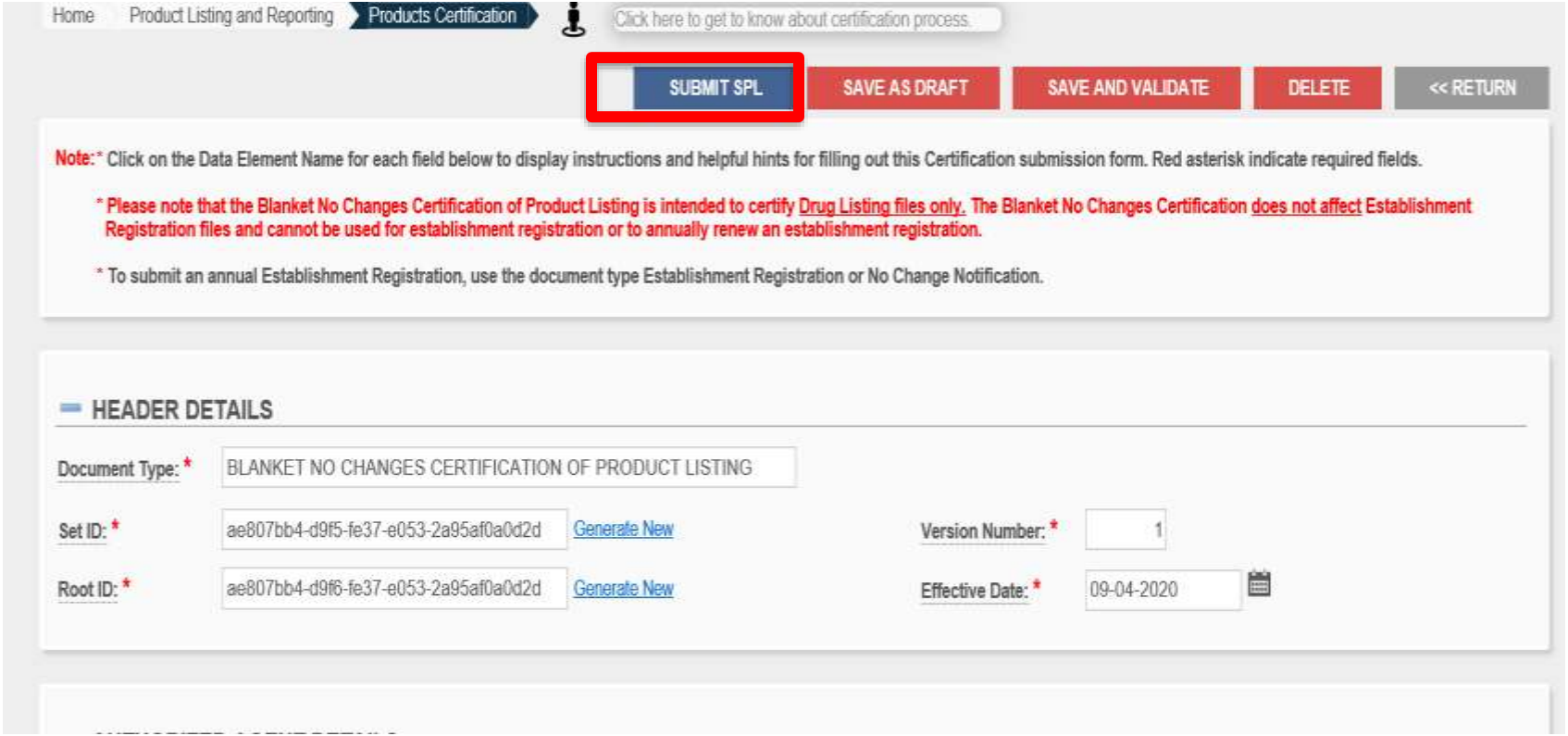
SAVE / UPDATE

GO Rows 15 ACTIONS

	PRODUCT NDC	PROPRIETARY NAME	MARKETING END DATE	LOAD DATE	DOSAGE FORM NAME	ACTIVE INGREDIENTS	STATUS	VIEW SPL	DELETE
☑	9999-1115	Wonder Drug A	-	12-SEP-19	TABLET	ACETAMINOPHEN (500 m+	Uncertified		-
-	9999-1195	Wonder Drug B	-	02-SEP-12	TABLET	CHLOROQUINE PHOSPHAT+	Validation Errors		-
☑	9999-1227	Wonder Drug C	-	02-SEP-12	TABLET	DICYCLOMINE HYDROCHL+	Uncertified		-
-	9999-1282	Wonder Drug D	21-APR-10	02-SEP-12	TABLET	MEFLOQUINE HYDROCHLO+	Completed		-
-	9999-2125	Wonder Drug A1	-	02-SEP-12	TABLET, COATED	CHLOROQUINE PHOSPHAT+	Validation Errors		-
-	9999-6203	Wonder Drug A2	-	02-SEP-12	TABLET	ISONIAZID (300 mg)	Validation Errors		-

1 - 6 of 6

Submit SPL: BLANKET NO CHANGES CERTIFICATION OF PRODUCT LISTING



Frequently Asked Questions

- **Should I use the same SET ID to update a blanket no changes certification?**
  - If you choose to update a blanket no changes certification with the same SET ID, remember to include all NDCs from the previous version or else they will be replaced by the new version. However, you may add new NDCs to be certified with a new SET ID.

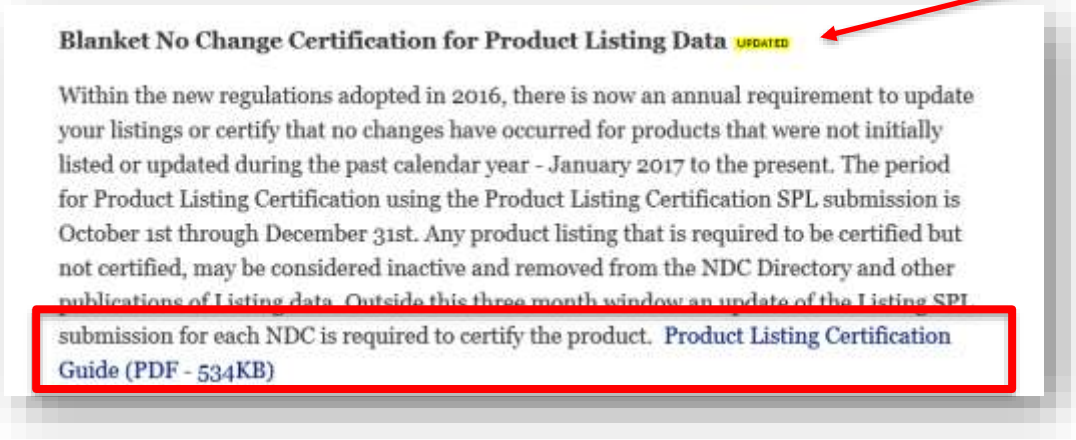
Frequently Asked Questions

- **Does this blanket no changes certification renew my establishment registration status?**
  - No, these are two separate renewals. The blanket no changes certification SPL is to certify drug listings only.

Frequently Asked Questions

- **What if my product has an end marketing date and completed status, does it need to be certified?**
- **Do I need to certify my product if it has a future marketing date?**
- **These questions and more are answered on the eDRLS website**

https://www.fda.gov/edrls



Challenge Question 1

Blanket No Changes Certification SPL must be submitted

1. June and December
2. Anytime
3. As soon as there's any change.
4. October 1 – December 31

Challenge Questions

- If I listed or updated a product in the current calendar year, do I need to ensure that I certify that product between Oct. 1 - Dec. 31?
  - Yes
  - No

Summary

- **Every active listing on file** with the FDA that has not been updated within the current calendar year must be certified that no changes have occurred in order to remain active for the coming year.
- Certification SPLs are only submitted during the annual listing certification period October 1 – December 31
- Products that are not certified will be considered expired and removed from publication on January 1 of the following year.
- Products that are expired, delisted, or have a listing deficiency or "validation errors" cannot be certified and must be updated with a full product listing SPL
- Products under the category of "Unapproved Drug for use in Drug Shortage" cannot be certified

Thank You for Keeping Your Drug Listings Up-to-Date!